

**Nurse Initiated and Managed Anti-Retroviral Treatment:
An ethical and legal analysis in South Africa.**

Pelisa Ford

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DECLARATION OF OWN WORK:

I, **Pelisa Ford**, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine (Bioethics and Health Law) in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

2nd day of May, 2013

A handwritten signature in black ink, appearing to read 'Pelisa Ford', with a large, sweeping flourish extending to the left.

Dedication:

In humble gratitude to my husband,
Vusikaya Mancapa

Abstract

This research investigated the ethical and legal issues that impact on the urgent implementation of Nurse Initiated and Managed Anti-Retroviral Treatment (NIMART) in South Africa, which is part of the task-shifting strategy recommended by the World Health Organization (WHO) to deal with the human resource shortage that has negatively impacted access to Anti-Retroviral Treatment (ART) in developing countries (WHO;2006). The objectives were to review and analyse the existing legal framework and provisions for NIMART in South Africa; and to identify ethical issues and implications of NIMART within the current legal framework. It analysed the legal issues that impact on the implementation of NIMART within the public health service in South Africa, as well as the ethical basis and implications of NIMART on the practice of nurses in the scale-up of Anti-Retroviral Treatment in Primary Health Care (PHC). A comparative analysis was done with case studies of task-shifting in other developing countries and evidence-based recommendations for an enabling and long-term sustainable ethico-legal approach to task-shifting were established. The research concluded that despite the existing legal framework for NIMART in South Africa being firmly founded in the Constitution and further enabled by health policy, challenges exist in implementation of certain critical aspects of the enabling legislation relating to nurse training and accreditation required for full authorization to practice NIMART and that these technical challenges if not attended to could threaten the long-term sustainability of NIMART.

Table of Contents

DECLARATION OF OWN WORK:	ii
Dedication:.....	iii
Abstract	iv
List of Figures	vi
List of Tables.....	vii
List of Appendices.....	viii
Acknowledgements:.....	ix
List of Acronyms.....	x
Definitions of Terms:.....	xii
1.0 Introduction	2
1.1 Statement of the Problem	2
1.2 Rationale for the study.....	6
1.3 Literature Review	8
1.4 Aim and Objectives	14
2.0 Materials and Methods.....	14
3.0 South Africa in the global context of HIV/AIDS	16
3.1 The HIV/AIDS epidemic in South Africa	16
3.2 Universal access to ART and the South African context.....	18
4.0 NIMART and the legal framework in South Africa.....	22
4.1 NIMART and its implications for service delivery.....	22
4.2 The South African legal framework and its provisions and implications for NIMART ...	27
5.0 Ethico-legal Analysis of NIMART	32
5.1 Ethical Implications of NIMART in the South African legal framework	32
5.2 Country Case Scenarios and the lessons learned.....	34
6.0 Discussion, Recommendations and Conclusion.....	45
6.1 Discussion	45
6.2 Recommendations.....	47
6.3 CONCLUSION.....	52
REFERENCES	54
Legal References.....	59

List of Figures

Figure:	Page
1: Models by which nurses may be involved in prescribing	7
2: Standard, Expanded, and Proposed RN Scope of Care in HIV/AIDS	22
3: WHO Delegation of ART-related Tasks to Nurses (Illustrative)	23

List of Tables

Table:	Page
1: WHO Delegation of ART-related Tasks to Nurses (Illustrative)	24

List of Appendices

Appendix:	Page
A: South African Pharmacy Council Legal Services Statement	58
B: Waiver of Ethics Approval	59
C: Table of Review of Studies/Reports on Task-shifting	60

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List of Acronyms

AIDS: Acquired Immuno-Deficiency Syndrome

ART: Anti-Retroviral Treatment

ARVs: Anti-Retroviral drugs

ECSA: East, Central and Southern African region

FHI: Family Health International

GMC: General Medical Council (British)

HAART: Highly Active Anti-Retroviral Treatment

HIV: Human Immuno-deficiency Virus

HRH: Human Resources for Health

HPCSA: Health Professions Council of South Africa

ICN: International Council of Nurses

IOM: Institute of Medicine

NGO: Non-Governmental Organisation

NHS: National Health Service (British)

NICE: National Institute for Clinical Excellence

NIMART: Nurse Initiated and Managed Anti-Retroviral Treatment

NPC: Non Physician Clinician

MOH: Ministry of Health

PEPFAR: United States President's Emergency Plan for AIDS Relief

PHC: Primary Health Care

PMTCT: Prevention of Mother to Child Transmission

TB/HIV: Tuberculosis and HIV Co-infection

TMs: TécnicosdeMedicina

SANC: South African Nursing Council

STI: Sexually Transmitted Infection

WHO: World Health Organisation

OHCHR: Office of the High Commissioner for Human Rights

UNAIDS: Joint United Nations Programme on HIV/AIDS

Definitions of Terms:

Clinician: A health professional, such as a physician, psychiatrist, psychologist, or nurse, involved in clinical practice, as distinguished from one specializing in research.

Physician: A person licensed to practice medicine; a medical doctor(International/American). In the South African context this term is reserved for a medical practitioner with specialization in internal medicine. For the purposes of this research report physician is used as in the first meaning where reference is made to international literature.

Clinical officer: A clinical officer (CO) is a mid-level practitioner of medicine in East Africa and parts of Southern Africa who is qualified and licensed to perform general medical duties such as diagnosis and treatment of disease and injury, ordering and interpreting medical tests, performing routine medical and surgical procedures, and referring patients to other practitioners. A clinical officer is not from a nursing background and provides routine medical care in general medicine or within a medical specialty such as anesthesia and carries out treatment that is out of the nurses' scope. To practice medicine as a clinical officer, one must complete at least four years of full-time medical training, supervised clinical practice and internship at an accredited medical training institution and hospitals and register with the relevant medical board in their country.

Clinical associates: are a category of healthcare providers found in South Africa. They assess patients, make diagnoses, prescribe treatment and perform minor surgery under the supervision of a medical doctor. The clinical associate is regulated by the Health Professions Council of South Africa (HPCSA) and may only work under the direct or indirect supervision of a medical practitioner. The education and training of the clinical associate is currently prepares this category of health care worker to work only in district hospitals. Registration with the HPCSA requires a Bachelor of Clinical Medical Practice degree - a three-year program offered at the Walter Sisulu University since January 2008and now also offered at the University of Witwatersrand, University of Pretoria and the University of Limpopo (Medunsa Campus).

Registered Nurse: one who (a) has successfully completed a programme of education approved by the nursing board/council of the specific country, (b) has passed the examination established by the nursing board/council (if appropriate), and (c) continues to meet the standards of the nursing board. The terms licensed, professional or qualified nurse are used in a similar sense.

1. Introduction

1.1 Statement of the Problem

Section 27(1) of the Constitution of South Africa provides that everyone has the right to have access to healthcare services, including reproductive healthcare. Thus this places a duty on the government of South Africa, both from an administrative as well as an implementation point of view, through its employees, to provide health care services to its citizens.

It is in the provision of these services that healthcare workers need to be guided by ethical principles to ensure that services are provided in a timely, safe and efficient manner to those deserving. The four basic principles of health care are critical in gauging the ethical merits of any health service, and thus form the basis of my discussion on Nurse-Initiated and Managed Anti-Retroviral Treatment (NIMART).

Firstly, Autonomy requires that the patient have autonomy of thought, intention, and action (Beauchamp and Childress, 2001) when making decisions regarding health care procedures. Therefore, the decision-making process must be free of coercion or coaxing. In order for a patient to make a fully informed decision, she/he must understand all risks and benefits of the treatment and the likelihood of success. Secondly, Beneficence requires that the treatment be provided with the intent of doing good for the patient involved. It therefore demands that health care providers develop and maintain appropriate skills and knowledge, continually update training, consider individual circumstances of all patients, and strive for net benefit.

Thirdly, Non-maleficence requires that a treatment does not harm the patient involved or others in society and that even in the most challenging circumstances, efforts be taken to at least minimise harm by pursuing the greater good. Lastly, Justice requires that treatment services uphold the spirit of existing laws and are fair to all players involved. The health care provider must consider four main areas when evaluating justice: fair distribution of scarce resources, competing needs, rights and obligations, and potential conflicts with established legislation.

Of course it cannot be denied that a duty of care includes a duty of minimising harm produced by that care, hence the importance of beneficence and non-maleficence in healthcare ethics. The specific aspect of healthcare provision that NIMART is concerned with is nursing care, which is defined by the International Council of Nurses (ICN) (2009; 6) as follows:

'Nursing encompasses autonomous and collaborative care of individuals of all

ages, families, groups and communities, sick or well and in all settings. Nursing includes the promotion of health, prevention of illness, and the care of ill, disabled and dying people. Advocacy, promotion of a safe environment, research, education, and participation in shaping health policy and in patient and health systems management, are also key nursing roles.'

Ethics is an integral part of the foundation of nursing (American Nurses Association, 2001). Nursing has a distinguished history of concern for the welfare of the sick, injured, and vulnerable and for social justice. This concern is embodied in the provision of nursing care to individuals and the community.

It cannot be denied that all four principles are important when considering the challenges of health care provision, but the principle of justice takes on an important fundamental theme in the discussion on NIMART because the very course of arriving at NIMART is borne out of a struggle between scarce resources, competing needs, rights and obligations, and challenges with existing legislation.

In as far as scarce resources are concerned, the human resources for health (HRH) crisis in the East, Central and Southern African (ECSA) region is attributed to a number of factors, including high disease burden, high demands due to HIV/AIDS, and low capacity for the production of health professionals in most of the ECSA countries (Dambisya&Matinhure; 2012). This in the face of an ever burgeoning AIDS epidemic poses further challenges as in South Africa in 2007 the situation was such that of the 5,5 million people who were infected with HIV, about a million were in need of ART (WHO; 2007). Standard antiretroviral treatment (ART) consists of the combination of at least three antiretroviral (ARV) drugs to maximally suppress the HIV virus and stop the progression of HIV disease. According to the World Health Organisation (WHO) (UNAIDS; 2003) huge reductions have been seen in rates of death and suffering when use is made of a potent ARV regimen, particularly in early stages of the disease. Furthermore, expanded access to ART can also reduce the HIV transmission at population level, impact orphanhood and preserve families.

By the end of 2008, five years after the public sector antiretroviral treatment (ART) program was launched, an estimated 700,500 people were accessing ART in South Africa, with the number infected expected to have increased to 5,9 million by 2011 (WHO; 2007). Add to this shifting target the ambitious targets of the committee of health ministers of the Southern Africa Development Community (SADC) which endorsed the HIV prevention strategy of the Southern Africa Development Community aiming to reduce the number of people newly infected with HIV by 50% by 2015 and to virtually eliminate the transmission of HIV from mother to child (SADC; 2009). Even in the Western Cape, the best performing province in

South Africa with regard to HIV/AIDS treatment roll-out, the number of doctors per 100 000 uninsured persons in 2005 was 55 (Breier et al; 2010), a far cry from the requirements of such an audacious plan.

Despite this obvious deficiency, the role of nurses in expanding access to ART remained relatively limited due to limitations of existing legislation, mainly focused on prevention and testing. However, Section 27(2) of the Constitution of the Republic of South Africa (1996) provides that “the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights”, and access to health care being one of these rights. It therefore became a matter of urgency that the country’s laws be revised in order for solutions to the HIV/AIDS epidemic within a human resources shortage crisis to be implemented. With the South African president’s announcement (Zuma;2009) on December 1st , 2009, came the expectation that any citizen, no matter how far flung in rural South Africa, could henceforth get almost immediate access to ART as necessary.

The announcement by the President (Zuma; 2009) signified the adoption of certain strategic policy changes regarding increased testing and wider eligibility criteria for ART. Key to these strategies would be the implementation of NIMART, which was hoped, would accelerate the country’s achievement of the targets of the HIV&AIDS and STI National Strategic Plan (NSP 2007-2011). The primary aims of the HIV&AIDS and STI National Strategic Plan 2007-2011 were to reduce the number of new HIV infections by 50% and expand access to treatment, care and support to 80% of all people diagnosed with HIV (NSP, 2006). In the year 2009, it was estimated that around 200,000 people were started on ART each year in South Africa (WHO, 2010). According to the targets of the HIV&AIDS and STI National Strategic Plan (NSP 2007-2011), this number should have been 285,000 (NSP 2006, 78). This number would need to double, to 420,000 each year, if the goal of 80% coverage was to be reached by 2011.

Key to meeting these targets amongst other priorities would be strengthening of the health system so as to better manage the dual epidemics of HIV/AIDS and TB. Acknowledging the unavailability of skilled personnel whilst simultaneously rejecting the misuse of human resource shortages as justification for paralysis, the NSP had identified task-shifting as a priority. NIMART is one aspect of a broader strategy commonly referred to as task-shifting. According to the WHO (2008:7), task shifting refers to a process of delegation whereby tasks are moved, where appropriate, to less specialized health workers so that by reorganizing the workforce in this way, task shifting can make more efficient use of the human resources currently available. Task-shifting is widely promoted, not only by countries who have

themselves implemented various aspects of it, but it is endorsed by the WHO as the solution to expanding Anti-Retroviral Treatment (ART) access.

NIMART is a strategy that forms part of a wider policy around task-shifting in South Africa. As a strategy, NIMART seeks to help the scale up of HIV services by enabling nurses, to perform a wider scope of HIV-related services within a regulated framework and thereby make more efficient use of doctors and nurses in the Primary Health Care (PHC) sector. The specific category of nurse NIMART pertains to is the registered nurse category. The ICN (2009; 6) defines a registered nurse as:

'..one who (a) has successfully completed a programme of education approved by the nursing board/council of the specific country, (b) has passed the examination established by the nursing board/council (if appropriate), and (c) continues to meet the standards of the nursing board. The terms licensed, professional or qualified nurse are used in a similar sense.'

For the purpose of this document nurse is used to denote this category of nursing personnel. This wider scope includes initiation of ART by nurses, which previously was limited to doctors only, with nurses only allowed to re-prescribe for patients already on treatment. Prescription of ART is not an isolated task, therefore in terms of NIMART, nurses may be allowed to diagnose, treat and manage patients with HIV/AIDS once the necessary training, mentoring and competency has been attained.

According to Colvin *et. al.* (2010: 210), the 900 000 people started on ART in the first 6 years of the South Africa's ART program, as well as the targeted additional 1.2 million to be started over the next 2-3 years, raises concerns about the practicality of the governments objective of providing this life-saving treatment to all who need it, given the limited capacity of the public health sector. In fact these authors argue that the legal requirements for NIMART are simple and comprise only of aligning nurse prescription with the Medicines and Related Substances Control Act of 1965 (as amended), which has already been done. They advance the argument that the real concern about NIMART should be whether it will provide the solution to expanding access to ART, and whether it will be effective and sustainable.

In summary therefore, it would seem that the constitution of South Africa asserts the right to health for all citizens, and that the government of the land has made significant efforts to deliver through the promulgation of enabling laws and policies. Pertaining to the specific issue of HIV/AIDS, recognizing the crippling disease burden and human resource shortages as serious challenges, task-shifting in the form of NIMART has been advanced as one of the strategies through which the government and citizens of South Africa can make quick gains in reversing the devastating effects of this pandemic.

1.2 Rationale for the study

Sharing of roles and responsibilities is understandably not a new concept in the provision of healthcare, where realignment of roles and responsibilities has been a long-standing response to changing healthcare needs, particularly in emergency situations or underserved areas. The HIV/AIDS crisis has resulted in the re-emergence of the concept of task-shifting, notably with increased urgency. It is this urgency that may prove to be a challenge to its sustainability.

This sentiment is cautiously articulated in the IOM report entitled "Preparing for the Future of HIV/AIDS in Africa: A Shared Responsibility" wherein the authors distinguish between "task-shifting" and "task-sharing" (2010: 5-8). WHO defines task shifting as the process whereby specific tasks are transferred, when appropriate, to health workers with less training and fewer qualifications (2008:7). The proposed argument for this distinction is that "although task-sharing does not adequately encompass the concepts of realignment and recognition of appropriate responsibility, it does capture a narrower and sometimes temporary arrangement to meet emergency needs" (IOM; 2010: 5-8). Thus the WHO suggests that shifting specific tasks enables more efficient use of existing human resources and eases bottlenecks in service delivery.

WHO also notes that when additional human resources are needed, task shifting may also involve the delegation of some clearly delineated tasks to newly created cadres of health workers who receive specific competency-based training (2008: 7). This delegation of the health care responsibilities of the various health professionals to others, including community health workers, has been shown, through the numerous studies now available, to be effective in addressing the severe human resource shortages in many African countries (Zachariah *et. al.*, 2009). Callaghan *et. al.* (2010: 7) conclude that "task shifting is a viable and rapid response to sub-Saharan Africa's human resources crisis in HIV care". The IOM report notes with concern though, that because these responsibilities require not only skills but also relevant knowledge, this delegation goes beyond the mere performance of specific tasks, and thus elects to focus on task-sharing instead.

The basis for this concern is very real when one considers that in South Africa it takes four years to train a nursing or midwife student; two years to train pupil nurses; and one year for pupil nursing auxiliaries (Sudebar, 2005). In contrast, medical school courses consist of five years followed by two years of internship and one year of community service; for a total of eight years in order to become a practicing physician. It is not surprising therefore, that task sharing may not be readily accepted by various professions, as some doctors and pharmacists have objected to the delegation of their tasks to what they perceive as

professionals with less specialized training (Zachariah *et. al.*, 2009: 554). On the other hand too, nurses have resisted taking on doctors' roles without adequate training and commensurate salary increases. Thus policies to enable task sharing, such as remuneration packages and clear job descriptions and strategic plans with delineations of professional boundaries and responsibilities, have been identified as prerequisites by policy analysts (Zachariah *et. al.*, 2009).

The question still remains then, whether there is any real difference between task-shifting and task-sharing with regard to the ethico-legal requirements and long-term sustainability. It would seem, according to the IOM report (2010: 5-9) that task-sharing may be a safer option in the current situation where urgency sacrifices proper planning for adequate training, skills transfer as well as commensurate remuneration. However, Zachariah *et. al.*(2009) argue that policy analysts conclude that these very same issues need to be addressed just as adequately for task-sharing to be successful. Thus, regardless of the theoretical and practical differences between task-shifting and task-sharing, the implications for staff and patients in the long-term are similar and therefore both need a secure ethico-legal framework for successful implementation.

This is stated most clearly in the conclusion by Callaghan *et. al.* (2010: 7) that firstly, task shifting alone will not solve human resources problems in HIV services or in health care more generally, in areas with substantial staff shortages and failing health systems. South Africa is a case in point, particularly the more rural areas. Secondly they caution that task shifting should not be considered simply as a means of saving money, as indeed it should be a means of extending access to quality care to a greater number of people, thus requiring strong government leadership to ensure an enabling regulatory framework, adequate training and financing.

As nurses are expected more and more, to provide health care services at the interface between nursing and medicine, presumably an inevitable consequence of resource constraints coupled with an overwhelming demand for health services in the presence of an ever expanding HIV/AIDS epidemic, what are the ethical and legal issues inherent in the implementation of the NIMART strategy? What is the critical balance of these ethico-legal issues that will ensure sustainability of this policy?

It was anticipated that the study would fill part of a gap in the literature on NIMART, which has largely concentrated on proving the effectiveness of task-shifting. As the implementation of NIMART kicks off and in the absence of a substantial body of evidence for its effectiveness on a national level, it is important to evaluate whether the ethico-legal framework that supports this strategy adequately favours its successful implementation and

sustainability. Some of the factors that are expected to influence this balance are presence of realistic, achievable and implementable policy and legislation; access to adequate training and objective proof of competence of nurses as proxies of quality of care; presence of an enabling work environment in the form of mentoring, referral policies and ongoing clinical support; and an acceptable ethical framework for the professional ownership and implementation of the NIMART strategy within the context of the South African healthcare system.

1.3 Literature Review

To the end of proving effectiveness of NIMART, there is a growing body of research which unanimously confirms that nurse provided ART services can be as good as doctor provided ART services in resource-limited countries such as Malawi, Uganda, Swaziland and even South Africa (Zachariah *et. al.* ,2007;Humphreys *et. al.*, 2010;Bedelu *et. al.*, 2007). However, what is often down-played is that most such studies have been based in relatively well-resourced centres, with access to NGO support or tertiary level health faculty. This is not the norm even in the resource-limited countries where the research has taken place.

Miles *et. al.* (2006: 290) acknowledge that in order to meet community healthcare need, nurses often perform roles, including prescribing medication, for which they may or may not have had adequate training, often in the absence of legislation and regulation. To complicate matters further, many of these nurses work in rural areas where there is limited or no access to medical personnel and allied health professionals, and inadequate infrastructures to support their practice and continuing professional development. Thus, nurses are left in the vulnerable position of either providing care to the best of their ability that will enhance the health of the populations they serve, or providing inadequate care that may be harmful.

In their concluding remarks, Price and Binagwaho (2010; 102) concede that recognising that physician centred AIDS care and treatment policies unduly deny treatment to patients in need provides an ethical rationale for changing these policies. Other benefits besides increasing access to AIDS treatment, they argue are:

Firstly, that the adoption of a task-shifting policy legitimises the informal task-shifting practices already adopted by some nurses out of necessity, thus safe-guarding the health and lives of the public at large. The assumed components of such task-shifting policy that would work to improve the quality of life of patients include a formal training program, support mechanisms and referral procedures.

Their second argument for task-shifting is that it will free up physicians from the mundane task of initiating ART in stable, adult patients thus allowing them to focus on the complex

cases, paediatric patients, clinical-mentoring and quality assurance.

Lastly, they propose that by providing more AIDS treatment, greater gains will be realised in the prevention battle through suppressed viral load and positive prevention, ultimately averting new infections and thus reducing the strain on healthcare systems in the immediate and in the long term.

Central to the provision of health care is the provision of medication for the treatment of disease, and thus the legal framework becomes very critical as it determines what drug classes or specific drugs or for what specific conditions nurses may prescribe and whether this is determined by scope of practice or speciality or place of work (Miles *et. al.*; 2006: 291). Due to these differences in approach between the various countries, which are largely determined by the differing needs of healthcare services, which of course vary greatly between countries; the respective disease burden, income status and governing infrastructure of individual countries; the International Council of Nurses (ICN) has defined four models by which nurses may be involved in drug-prescribing (Miles *et. al.*; 2006: 291), as tabulated below:

1. Initial/independent/autonomous/substitutive prescribing

Practitioner accountable for assessing client, making a differential diagnosis and determining the appropriate medication, treatment or appliance required to manage the client, and issue the prescription accordingly.

2. Dependent/collaborative/semi-autonomous/complementary/supplementary prescribing

Practitioner may prescribe as a 'dependent' prescriber in collaboration with an independent prescriber, usually a medical practitioner, but without the need for direct supervision by the independent prescriber. The dependent prescriber not usually responsible for the assessment and diagnosis of the client. Useful for issuing ongoing prescriptions after the initial prescription has been issued by the independent prescriber.

3. Group protocols/patient-group directions

Practitioner may supply and/or administer a named medicine in an identified clinical situation directly to groups of patients who may not be individually identified before presentation for

treatment. It is not a form of prescribing.

4. Time and dose prescribing

Involves practitioner working within patient-specific protocols. It allows nurses to alter the time and dosage of particular medications. Again not strictly regarded as prescribing in definition

Figure 1: Models by which nurses may be involved in prescribing (information adapted from ICN 2004)

In the South African context, NIMART entails a shift from level 2 to level 1 according to the table above, which essentially confers prerequisite clinical knowledge, insight, and skills as well as individual professional responsibility and accountability for clinical decisions and actions. A significant recognition by Miles *et. al.* (2006: 291) is that in developed-world nations, the need for nurses to take on prescribing roles has generally gone hand in hand with the innovation of new advanced roles for nurses in response to clinical factors, influenced amongst others by medical and technological advances, changing health needs, changing public expectations, an ageing population, an increase in chronic illness and an emphasis towards the promotion of health and the prevention of illness. However, in nations with fewer resources, the drive for nurses to prescribe medicines appears to have arisen predominantly from the shortage of medical staff to cope with the vast curative and preventative healthcare needs of the respective populations (Miles *et. al.*; 2006: 291).

This observation is echoed yet again, by Gray and Strasser(1999: 3), that in South Africa, progress towards legislating nurse prescribing stemmed from the recognition that there were not enough prescribers to deal with community health need, and to address the blurring of boundaries that had existed for some time at the interface of medicine and nursing. The original right of nurses to prescribe was dealt within Section 38A of the Nursing Act No 50 of 1978. This Act stated that registered nurses could, after consultation with the South African Pharmacy Council, be authorized by a responsible medical officer to prescribe certain medicines. However, it transpired that this legislation was intended to be used as an exceptional situation, only to be resorted to when a medical officer was not available. This Act conflicted with the Medicines and Related Substances Control Act of 1965, which did not include nurses among those as recognized prescribers.

In 1996, national drug policy began to change, introducing the idea that prescribing would be based on competency and not on occupation (Gray and Strasser, 1999: 6). The Medicines and Related Substances Control Act was amended in 1997 to include nurses in the definition

of authorized prescribers. In late 1998, a new South African Medicines and Medical Devices Regulatory Authority Act repealed certain sections of the Medicines and Related Substances Control Act to make broader provision for nurse prescribing. Although the new legislation was seen as progress, Gray and Strasser (1999:5) outlined the constraints that still existed with regard to nurse prescribing and dispensing, such as training, monitoring and evaluation. Later, further amendments to the Medicines and Related Substances Control Act came into operation, stipulating that nurses wishing to prescribe medicines must complete a competency-based course as outlined by the Pharmacy Council of South Africa. The Pharmacy Council would then issue a special license on successful completion of the course.

This latest amendment the Medicines and Related Substances Control Act came into operation in June 2003 and makes provision for nurses to prescribe from all schedules 1–6 from an Essential Drugs List compiled by the South African government. This has made a significant impact on the practice of nurses in PHC, where previously patients would have had to wait for a doctor's prescription to have common conditions such as sexually transmitted infections treated. Health facilities in rural and peri-urban areas also have the added restraint of having no resident pharmacist or pharmacist assistant, therefore relying completely on the nurse to perform all the functions from clinical assessment to dispensing of medication.

Colvin *et al.* (2010: 211) suggest that proponents of a rapid, national rollout of NIMART argue that the needs of the country demand a drastic response, that a rare political space for decisive action in the health system has finally opened up, and that phasing in NIMART or offering nurses clear criteria for referral of complex cases will only serve to create bottlenecks and reduce access. This, they accept, is a compelling argument, both from a moral point of view and in terms of the universal tendency of state bureaucracies to avoid change, promote inefficiencies and maintain entrenched habits and hierarchies. They argue further however, that the available evidence points to NIMART being a potentially effective, sustainable and acceptable approach, but one that also entails significant stresses and realignments in the health system.

An ongoing trial being conducted in the Free State, the Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) trial, has been lauded as a landmark study as it attempts to address some of the gaps in the evidence for task-shifting by evaluating the effect of NIMART on ART access and on quality of ART care (Colvin et al., 2010). It does this by comparing mortality among patients eligible for treatment, and by comparing viral load suppression rates in those receiving ART respectively. Its strongest point, a departure from

the usually unrealistic setting of funded studies is that it is a pragmatic trial that is being implemented within all the usual constraints of the public health system, including ART supplies procurement difficulties such as occurred during late 2008 and 2009. As is often the case with currently available research in task-shifting, the areas assessed are clinical outcomes and economic factors, and in this regard STRETCH uses ART initiation guidelines tailored specifically to nurses which provide clear clinical criteria for referral of complex cases to a doctor.

So far the researchers are confident that their research confirms that NIMART is highly acceptable among nurses, patients and doctors, and that managers and nurses express confidence in their ability to apply the guidelines and deliver ART successfully, however, this confidence developed slowly through a phased and well-supported approach that guided nurses through training, re-prescription and initiation. The researchers also strongly believe that the key to building and sustaining that confidence depended firstly, on ongoing clinical support from a range of sources including doctors, district ARV co-ordinators, STRETCH trainers, and experienced fellow nurses, and secondly, on clear criteria for the referral of more complex cases.

The STRETCH qualitative research findings are cited, along with the wider international literature on scaling up, as pointing to the potential dangers of a too-rapid roll-out that does not build incrementally the capacity, confidence, co-ordination and support needed to implement NIMART at scale. Thus, Colvin et al. conclude that there is a risk that if these factors are not given adequate attention, nurses will be left to shoulder the ongoing burden of rapid expansion without adequate training or support, which could have grave outcomes for both patients and nurses within a health system already under considerable strain.

The Medicines and Related Substances Act of, 1965 (as amended) which governs all manufacturing, control and use of medication in the country, recognises the nurse and midwife as prescribing practitioners provided that they are authorised by the South African Nursing Council (SANC) to do so. It makes provision for prescribing practitioners to have access to all schedules of medication provided that regulations are developed to indicate which drugs in each schedule nurses and midwives can have access to. The Act further determines that prescribing practitioners also have to:

Obtain a S 22A (15) permit to acquire, keep, use and supply medication. Such a permit will indicate which medication the practitioner has access to. Nurses and midwives are not allowed to keep an open shop or sell scheduled medication.

Obtain a S 22C dispensing license if the practitioner is expected to dispense medication. This license is applied for after successful completion of a dispensing course accredited by

the Pharmacy Council of South Africa.

The Nursing Act (Act 33 of 2005) determines, in S56(1), that nurses and midwives who become prescribing practitioners must complete a prescribed training program followed by registration with the SANC to assess, diagnose, prescribe treatment, keep and supply medication for prescribed illnesses and health related conditions. This registration will be valid for three years after which the practitioner has to re-apply. The practitioner must be an employee of the state services at national, provincial or local (municipal) level where there is no doctor or pharmacist available. Another option for authorisation is provided in the Nursing Act in S56 (6) in terms of which the Director General of Health can authorise nurses and midwives to prescribe treatment without necessarily complying with the provisions of S56(1) (Geyer; 2010: 15).

Geyer (2010: 15) believes that there are many challenges to increasing the number of nurses and midwives trained in NIMART, citing amongst others the slow pace of development of regulations required for implementation of the relevant sections in the Nursing Act. She highlights the fact that even though one such regulation has been developed already, 2 years later and it has yet to be promulgated. This includes the regulations to the Medicines and Related Substances Act prescribing the medication that nurses and midwives could have access to which still has to be drafted.

According to Geyer (2010: 15) another concern has been expressed about the ability of the current system to produce a sufficient number of NIMART trained nurses and midwives in a short period of time to address the need for ART in the country. The overnight switch from no nurse initiation to NIMART and the limited time available for training has further raised concerns around the competence and confidence of practitioners to perform NIMART. From a labour point of view and worker protection, the concern is that when a mistake is made, the nurse or midwife is accountable and will stand alone.

In light of the already existing legislation permitting and regulating nurse drug-prescription detailed above, NIMART changes the playing fields where previously, the policy of the country indicated that nurses and midwives would not be involved in the initiation of antiretroviral treatment (ART). As far back as 2007 when the HIV&AIDS and STI National Strategic Plan 2007 - 2011 was approved, policymakers and nursing regulators were aware of its contents which clearly indicates that nurses and midwives would be expected to assist with the initiation of ART for adults. In fact, the indicators provided in the National Plan states that the proportion of adults started on ART and managed by nurses/midwives must increase by 80% by 2011. However, the country policies on treatment for HIV and AIDS states that only registered health professionals, in line with the relevant legislation and regulations, are

allowed to prescribe ART according to the protocols provided.

1.4 Aim and Objectives

The aim of this study was to conduct an ethico-legal analysis of NIMART in South Africa to identify challenges for its implementation. The study objectives were:

To review and analyse the existing legal framework and provisions for NIMART in South Africa; and

To identify ethical issues and implications of NIMART within the current legal framework.

2. Materials and Methods

A literature search was conducted through electronic as well as physical searches of library textbooks and journals at the University of Witwatersrand (WITS) Library and the University of Cape Town (UCT) Library. Search terms and phrases included the following:

- “task-shifting”
- “task-shifting in South Africa”
- “NIMART”
- “ethics in health care”
- “health policy change”
- “ethics in HIV/AIDS”
- “HIV/AIDS policy”

Search engines used included Google, LexisNexis and ExLibris. Data bases searched included Cochrane Library, EBSCO, Elsevier, Google Scholar, JSTOR, Medline, Medscape, Mendeley, PubMed, ScienceDirect, SpringerLink and Wiley Online Library.

Literature from South Africa as well as international authors was obtained and careful selection was made of material that is relevant to the subject at hand. The majority of material on task-shifting was located in journal articles as this is a fairly new policy change in the developing world. As such, studies reported from the developing countries are largely pilots and often lacked the necessary legislative framework themselves, thus making a comprehensive comparison between these countries and South Africa difficult. The selected country case scenarios where “task-shifting” has been piloted or implemented were chosen based on the fact that these countries have similar epidemiological and healthcare systems

challenges as South Africa, i.e.:

1. Developing country or Resource-Limited country.
2. Significant to severe shortage of doctors.
3. HIV/AIDS epidemic putting a significant strain on health care services.

The one similarity therefore was that all are grappling with the issues of human resource shortages and generally poor access to health care in the face of a devastating HIV/AIDS epidemic. Only studies pertaining to task-shifting from doctors to nurses were considered for the purpose of this study. It was thus necessary, for comparisons in the legal framework, to utilize materials from developed countries, where task-shifting has occurred as a progressive process in the development of nursing, and has thus been duly considered in the accommodating legislation.

As the study does not involve human subjects or information related to human subjects, waiver of ethics approval (Appendix B) was sought and obtained from the Witwatersrand University Health Research Ethics Committee.

Method:

In order to achieve the objectives set out, in section 3, a background of South Africa's position in the global HIV/AIDS epidemic is given, and linkages are made between this scenario and the urgency for implementation of strategies to accelerate universal access to HIV care and treatment. One of these strategies has already been identified as task-shifting, which forms the basis for the NIMART. This is followed by an analysis of the ethical arguments for the global promotion of universal access to ART. Parallels between these ethical arguments and the South African context of health care delivery are explored.

In section 4, I present a brief synopsis of NIMART and its implications for the South African public and health care delivery platform, with particular attention to its impact on nursing practice. Due to the fact that NIMART is a fairly new strategy, literature on this subject in the South African context is lacking. Available literature of task-shifting in South Africa was reviewed and the issues identified by the papers were extracted. This is then followed by an analysis of the South African legal framework with particular focus on its provisions for the implementation of NIMART and gaps therein are identified.

In section 5, I identify ethical issues related to NIMART within the current legal framework in South Africa and explore their implications for nurses and the implementation of NIMART itself. Selected relevant country case scenarios based on the criteria detailed above are then reviewed and the issues identified by the studies are extracted. For ease of reference, the

literature reviewed is presented in the form of a table in Appendix C. The table reflects the authors and year of publication; the country and context in which the study was conducted; the type of study and the methods used to gather the data; the outcomes of the study and most importantly the issues raised by the study. Due to the variability in the type of studies as well as the paucity in number of studies, the focus in extracting the data was placed on the qualitative data rather than the quantitative data so as to facilitate the process of extracting lessons and trends. For each country the selected studies are reviewed, the parallels drawn and the broad categories of issues identified are extracted. Due to the advanced nature of task-shifting in the United Kingdom, no studies on task-shifting at the level that is relevant to NIMART in South Africa are available. Therefore, literature that analyses the course and impact of task-shifting on the nursing profession in that country is reviewed in an attempt to find possible solutions to the challenges identified in the ethico-legal framework for NIMART in South Africa.

Section 6 presents a discussion of the legal and ethical issues related to NIMART in South Africa as identified in the previous chapters. The conflicts of individual rights and professional ethics as opposed to public good and policy in the face of resource constraints is explored. Finally, in the conclusion, an attempt is made to crystallise the critical challenges for NIMART implementation and concrete recommendations on legislation and policy review are made.

3. South Africa in the global context of HIV/AIDS

3.1 The HIV/AIDS epidemic in South Africa

The WHO Global Report 2011 (WHO, 2011) reports that the number of people living with HIV worldwide continues to grow, reaching an estimated 33.3 million people in 2009 – 23% higher than in 1999 (WHO, 2011:7). In the same year, 2009, there were an estimated 2.6 million new infections and 1.8 million HIV/AIDS-related deaths according to this report, and this despite the widely accepted observation that the overall growth of the global epidemic appears to have stabilized, with the annual number of estimated new HIV infections steadily declining (WHO, 2011:7). This contradiction is borne out by the fact that in 2009, the estimated number of new HIV infections was 19% lower than in 1999. Therefore, the increasing number of people living with HIV reflects in part the life-prolonging effects of ART (WHO, 2011).

According to the WHO Global Report 2010, an estimated 11.3 million people were living with HIV in southern Africa in 2009, nearly one third (31%) more than the 8.6 million people living with HIV in the region a decade earlier (WHO, 2010: 28). The prevalence of HIV among adults aged 15–49 years in the Sub-Saharan region was 17.3%, whilst the total African region prevalence was 4.7%, as opposed to the American average of 0.5% and a European average of 0.4%.

Mirroring the global trend, the HIV incidence (number of people newly infected with HIV) appeared to have peaked in the mid-1990s, and there was evidence of declines in incidence in several countries in sub-Saharan Africa, with an estimated 22 countries in this region seeing a decline of more than 25% between 2001 and 2009 (WHO,2010). But despite this, with an estimated 5.6 million people living with HIV in 2009, South Africa's epidemic remained the largest in the world at the time.

As of December 2009, the WHO estimated that ART was available to 5 million people in low-income and middle-income countries, and a further 700,000 people in high-income countries, bringing the global average to around 6 million at the time. Yet, despite such global progress, treatment-coverage rates were said to remain low in low-income and middle-income countries (36% overall) with significant variation at regional level (WHO,2011).

Specifically, the African region had achieved an average coverage rate of 37% in this period, while the Americas had the highest coverage at 50%. Antiretroviral therapy coverage among people with advanced HIV infection was 37% for the African region in this period, with South Africa just managing this average at 37%, whilst other fellow Sub-Saharan countries seemed to be well on top of things with Rwanda 88%; Botswana 83%; Namibia 76%; Zambia 64%; and Swaziland at 59%. Even poorer countries in this sub region, such as Lesotho (48%) and Malawi (46%) achieved better coverage than South Africa at this time.

So the question of why South Africa was failing so dismally despite the observation that since the adoption in 2000 by the United Nations, the Millennium Development Goals(MDGs) set for 2015 had become a part of the policy agenda of all of the member states was concerning (Sante, 2009). Three of the eight objectives of the MDGs deal with health issues and specifically, the sixth MDG "Combat HIV/AIDS, malaria and other diseases" was evidently not yet in full implementation by 2009. The Bulletin of the World Health Organisation had reported in 2003 that at a special session of the United Nations General Assembly in New York on 22 September, WHO together with UNAIDS and the Global Fund to Fight AIDS, Tuberculosis & Malaria had declared the failure to expand access to antiretroviral treatment in the developing world a global health emergency (WHO,

2003). The global target was to provide antiretroviral medicines to three million people by the end of 2005, however, using existing programs at the time, fewer than one million people who needed treatment would receive it by the close of 2005 (WHO, 2003).

Achieving the target, otherwise known as “3 by 5,” needed an immediate emergency response but also a change in long-term thinking, as aptly summed up by Dr LEE Jong-wook, Director-General of WHO at the time:

“To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act. Business as usual means watching thousands of people die every single day.” (WHO, 2003)

This was a chilling reminder to the world and humanity at large, of the carnage that was rapidly wearing away human dignity. Yet already in 1998, the Office of the High Commissioner for Human Rights (OHCHR) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued the International Guidelines on HIV/AIDS and Human Rights (UNAIDS, 2003). The Guidelines built on expert advice to integrate the principles and standards of international human rights law into the HIV/AIDS response, and later revisions attempted to reflect new standards in HIV treatment and evolving international law on the right to health. The Commission on Human Rights in 2001 and again in 2002 confirmed that access to AIDS medication is a key component of the right to the highest attainable standard of health, enshrined in the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights and the Convention on the Rights of the Child (UNAIDS, 2003).

This urgency in the global call to action was again echoed at the June 2006 General Assembly High-Level Meeting on HIV/AIDS, where United Nations Member States agreed to work towards the goal of “universal access to comprehensive prevention programs, treatment, care and support” by 2010 (UNAIDS, 2006). Prevention, treatment, care and support were seen as mutually reinforcing elements, forming a continuum of an effective response to HIV/AIDS. Still today, even more than ever before, these elements must be integrated into a comprehensive approach, which requires a multifaceted response. Based on human rights principles, universal access requires that the goods, services and information that this HIV/AIDS comprehensive approach entails, not only be available, acceptable and of good quality, but also within physical reach and affordable for all.

3.2 Universal access to ART and the South African context

The discussion about equal opportunity and the importance of health care by Daniels et al (1996; 21) is particularly helpful when attempting to understand the ethical basis for NIMART

because it reinforces the basic pillars on which the South African Constitution is built. Daniels and his co-authors (1996; 21) asserts that in different ways, all forms of health care function to prevent or treat disease and disability in order to keep us functioning as close to normal as possible. This, they consider, the key function to keep in mind when considering justice in the delivery of health care (1996; 21). The moral importance of the protection of normal functioning through the provision of health care services, they argue, is based on the tenet that disease or dysfunction restricts an individual's access to life's opportunities. It is indeed a fact that HIV/AIDS shortens lives and impairs individuals' ability to function, including through pain and suffering, as suggested by Daniels et al.

It is however useful to retract a little so as to fully appreciate the basis of this argument. In laying the foundation for their argument, Daniels et al. rely on Rawls' theory on the notions of equality of opportunity. Rawls' argument for the primacy of justice distinguishes between two notions of equality of opportunity, namely *formal* equality of opportunity and *fair* equality of opportunity (Rawls, 1999). The former refers to the insistence that factors such as race, gender, age or disability should not play a role in determining our opportunities, and thus they conclude, imposes only a negative obligation on the State to abstain from human rights violations. The latter notion of fair equality of opportunity on the other hand, imposes a positive obligation to eliminate residual unfairness in the distribution of capabilities, and thus denotes the State's obligation to engage in an activity to secure the effective enjoyment of a fundamental right, in this case, the right to health.

This sentiment forms the foundation of the assertion by the International Guidelines on HIV/AIDS and Human Rights as revised by the Third International Consultation on HIV/AIDS and Human Rights in 2003. This Commission recognized that universal access to HIV/AIDS prevention, treatment, care and support is necessary to respect, protect and fulfill human rights related to health, including the right to enjoy the highest attainable standard of health (UNAIDS, 2003). The Commission further acknowledged that universal access will be achieved progressively over time, however, States had an immediate obligation to take steps, and to move as quickly and effectively as possible, towards realizing access for all to HIV/AIDS prevention, treatment, care and support at both the domestic and global levels (UNAIDS, 2003: 13).

These assertions could not have more relevance than in the South African context where stark contrasts exist between public and private, tertiary and primary and urban and rural health care settings and services. Thus, without the necessity of going into a structured and logical argument about these two notions of equality of opportunity, one can simply dismiss the former as a basic assumption of the Constitution of South Africa, as espoused in Section

9. Section 9 assures all citizens equality before the law, which entails a right to equal protection and benefit of the law, and includes the full and equal enjoyment of all rights and freedoms. Thus Rawls' fair equality of opportunity offers a useful basis for the urgency and non-negotiability of the call for universal access to ART, not only with reference to affordability of drugs, but also to accessibility. Access to health care services as detailed in Section 27 of the South African Constitution thus places a positive obligation on the State to act with regard to the provision of ART.

Further in their argument, Daniels et al arrive at a conclusion that the right to health care deserves a special case of rights to equality of opportunity, albeit with restrictions in scope. It is from this premise that they assert that there are social obligations to design a health care system that protects opportunity through an appropriate set of services. In the South African context such services includes a basic package of PHC services which is inclusive of ART. Indeed, Section 27(2) further qualifies this positive obligation of the State to provide health care services, by stating that "The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights". This recognizes the fact that the State may not be in a position to provide all health care services to all citizens, but requires that the State demonstrate an effort to realize such rights.

If the basic tier of health services in a country torn by an HIV/AIDS epidemic of the proportions present in South Africa fails to include access to ART, the rights of millions of South Africans are arguably violated. It is therefore a necessity rather than a privilege that all citizens are assured access to life saving treatment, including ART. Dr Arthur J. Ammann, President of Global Strategies for HIV Prevention and Professor of Pediatrics at the University of California San Francisco asserts that based on current scientific evidence, all HIV-infected individuals must be treated with effective ART if the HIV contagion is to be brought under control (WHO,2010), and to do otherwise would serve only to sustain a costly and prolonged epidemic. Failure to provide ART means that millions of men, women, and children will be infected, become sick, and advance to AIDS, and children will be orphaned because of treatment delays.

Fortunately, the battle for availability of ART in South Africa was long won by its citizens, albeit at a very high cost to human life. The question that remains then is how to ensure that all citizens get timely access to treatment, as recognized earlier that universal access requires that the goods, services and information that an HIV/AIDS comprehensive approach entails, not only be available, acceptable and of good quality, but also within physical reach and affordable for all. Ruderman et al. posit that health care professionals are bound by an

ethic of care, and that therefore, obligations to patients' well-being should be primary (Ruderman et al.; 2006). The ethical foundations of the duty to provide care are grounded in several longstanding ethical principles, most significant of which is the principle of beneficence, which according to them, recognizes and defines the special moral obligation on the part of health care professionals to further the welfare of patients and to advance patients' well-being.

Even though their paper attempted to address the issue of the duty to care during pandemics, and more specifically, the SARS pandemic, their arguments are relevant to the HIV pandemic despite it not being quite an acute infectious disease emergency as SARS. Ruderman et al. argue that in modern health care, it is commonly understood and generally accepted that the principle of beneficence constitutes a foundational principle of the patient-provider relationship and that the medical profession is legitimated by social contract. Thus it is their assertion that in publicly-funded health care systems there is a strong claim for a social contract between the health care professional and society, making it a reasonable and legitimate expectation by the public that health care professionals will respond in an infectious disease emergency.

This contract hinges on society having granted and permitted professions to be self-regulating on the understanding that they would reciprocate by placing society's needs as a priority in situations of emergency. Self-regulating professions characteristically have well established standards of practice, which are articulated in professional codes of ethics. These codes of ethics are developed on the basis of the fundamental principles and values of the particular profession, as is the case in medicine and nursing, thus providing guidance to their members. It is therefore assumed that by joining a particular profession, individuals subscribe to the ideals of that profession, as borne out by the testimony of two physicians who worked in the frontline of the SARS epidemic in Taiwan (Dwyer & Tsai, 2006). Having had to contend with lack of cooperation from colleagues at referral hospitals, death of patients due to discriminatory attitudes, long working hours and even separation from families due to quarantine regulations, the two physicians expressed a yearning for the SARS experience because it made them feel like real doctors.

Thus it is their observation that these doctors were trying to realize certain ideals of care, which depends largely on social cooperation, organisation, and conditions. They conclude that society should not think of social support merely as goods that are owed health care workers for the role they assume during epidemics, but rather also as a means to help healthcare workers realise goods, ideals, and meanings that are internal to the practice of healthcare. This, however, does not suggest that healthcare workers must be taken

advantage of, and made to perform duties beyond their call of duty, or under conditions that are clearly uncondusive to the delivery of ethical healthcare services. It, however, highlights that the rewards for health care professionals must be considered in their entirety.

This section has contextualized the South African HIV/AIDS epidemic within the greater global and regional epidemic, using statistics and analysis thereof to demonstrate the trends that informed global strategies in the fight against the epidemic over the last two decades or so. The global call to action is traced to principles and standards of international human rights law, thus allowing for the universality of the global strategy against HIV/AIDS. The right to health care is explored through Rawls' theory on the notions of equality of opportunity and effectively linked to the Constitution of South Africa and urgent universal access to HIV prevention, treatment, care and support services. The ethical foundations of the duty to care which are relevant at a professional and individual level can effectively translate the global and national strategy into action. Grounded on these ethical principles, and given the necessary support and resources, healthcare professionals and workers are often able to realize goods, ideals and meanings beyond monetary reward, even in crisis situations.

4.0 NIMART and the legal framework in South Africa

4.1 NIMART and its implications for service delivery

NIMART is not an altogether new phenomenon, however the novelty of the concept is in the formalization and legislation of the practice, largely propelled by the WHO endorsement of task-shifting (WHO; 2008). The essential difference between the practice prior to task-shifting being officially recognized and the current is that where previously nurses took on some of the clinical roles of doctors out of necessity, now the practice has been endorsed through policy in South Africa. On World AIDS Day, 1st December 2009, President Jacob Zuma announced that the country had adopted certain strategic policy changes regarding increased testing and wider eligibility criteria for ART (Zuma, 2009). These changes would build on the successes already gained and help further to curb the rising incidence of HIV/AIDS in the country. In order to meet the need for testing and treatment, the government would ensure that all the health institutions in the country were ready to receive and assist patients and any citizen would be able to go into any health centre and ask for counseling, testing and even treatment if needed.

In the year 2009, it was estimated that around 200,000 people were started on ART each

year in South Africa (WHO, 2010). According to the targets of the HIV&AIDS and STI National Strategic Plan (NSP 2007-2011), this number should have been 285,000 (NSP 2006, 78). This number would need to double, to 420,000 each year, if the goal of 80% coverage was to be reached by 2011. The primary aims of the HIV&AIDS and STI National Strategic Plan 2007-2011 were to reduce the number of new HIV infections by 50% and to reduce the impact of HIV and AIDS on individuals, families, communities and society by expanding access to an appropriate package of treatment, care and support to 80% of all people diagnosed with HIV (NSP, 2006). Linked to these aims were, amongst other tasks, increasing the proportion of adults started on ART based outside the hospital setting to 70%, and increasing the proportion of adults started on ART by nurses to 80% by the end of 2011.

Key to meeting these targets amongst other priorities was strengthening of the health system so as to create the conditions for universal access to a comprehensive package of treatment for HIV, including antiretroviral therapy, and the integration of HIV and TB care (NSP 2006, 64). Furthermore, the NSP identified the unavailability of skilled personnel as a major threat to the implementation of these interventions. It rejected however, the misuse of human resource shortages as justification for paralysis, citing that South Africa had by this time already found innovative ways to mobilise local communities for the provision of services. Some of these strategies included defining clear responsibilities for the use of community development workers, community care givers and lay counselors in health facilities, which had been successful in promoting greater access to services.

The NSP therefore recommended task shifting, which it defined as a systems level strategy involving the delegation of activities to less qualified cadres. The following examples were offered as suggestions: training of primary health care nurses (rather than doctors) to initiate antiretroviral treatment; lay counselors (rather than nurses) "pricking" patients for rapid HIV tests; lay counselors (instead of social workers) for orphan support activities. Finally, in this regard, the NSP recommended that regulatory and policy barriers to task shifting be identified; nursing scopes of practice be amended and that processes be set in motion to provide the necessary training to healthcare workers.

Another condition necessitating a strengthened health system, and perhaps one not so well recognized at the time, was that as the number of people on ART increases, a greater number of patients requiring regular long-term care are retained in care, resulting in an ever increasing load of patients on the system. To illustrate this demand on the health system it is necessary to review, briefly, the roles of nurses through the rapidly evolving HIV/AIDS epidemic up to and including the endorsement of NIMART.

To achieve this in a brief yet comprehensive manner, reference is made to the Family Health

International (FHI) document titled “Guidance for Nurse Prescription and Management of Antiretroviral Treatment”, published in 2008 (FHI, 2008). This document describes a generic process intended to help HIV program implementers consider the need for nurse-prescribed and managed ART in resource-limited countries. Figure 2 tabulates quite effectively the changes in the scope of care of registered nurses (RN) through the years starting with a standard scope from presumably before the availability of ART to the expanded scope in the era of doctor-led ART care and finally to the proposed scope for NIMART.

Of relevance to the discussion at hand is the transition from the expanded scope of care to the NIMART scope of care, with particular attention to two roles that were previously solely performed by doctors. Of course, no role is more important than the other as the nurse cannot neglect any aspect of patient care if a comprehensive HIV/AIDS care service is to be provided. These roles are, firstly, the prescription of first-line ARV regimens for adult treatment-naïve patients and secondly, the management of uncomplicated opportunistic infections and drug toxicities. These may seem like two simple additional roles, thus begging an explanation for the extensive discussions and negative sentiment amongst some regarding these changes. In order to achieve the first role, i.e. prescription of first-line ARV regimens for adult treatment-naïve patients, the WHO illustrates this succinctly through Figure 3.

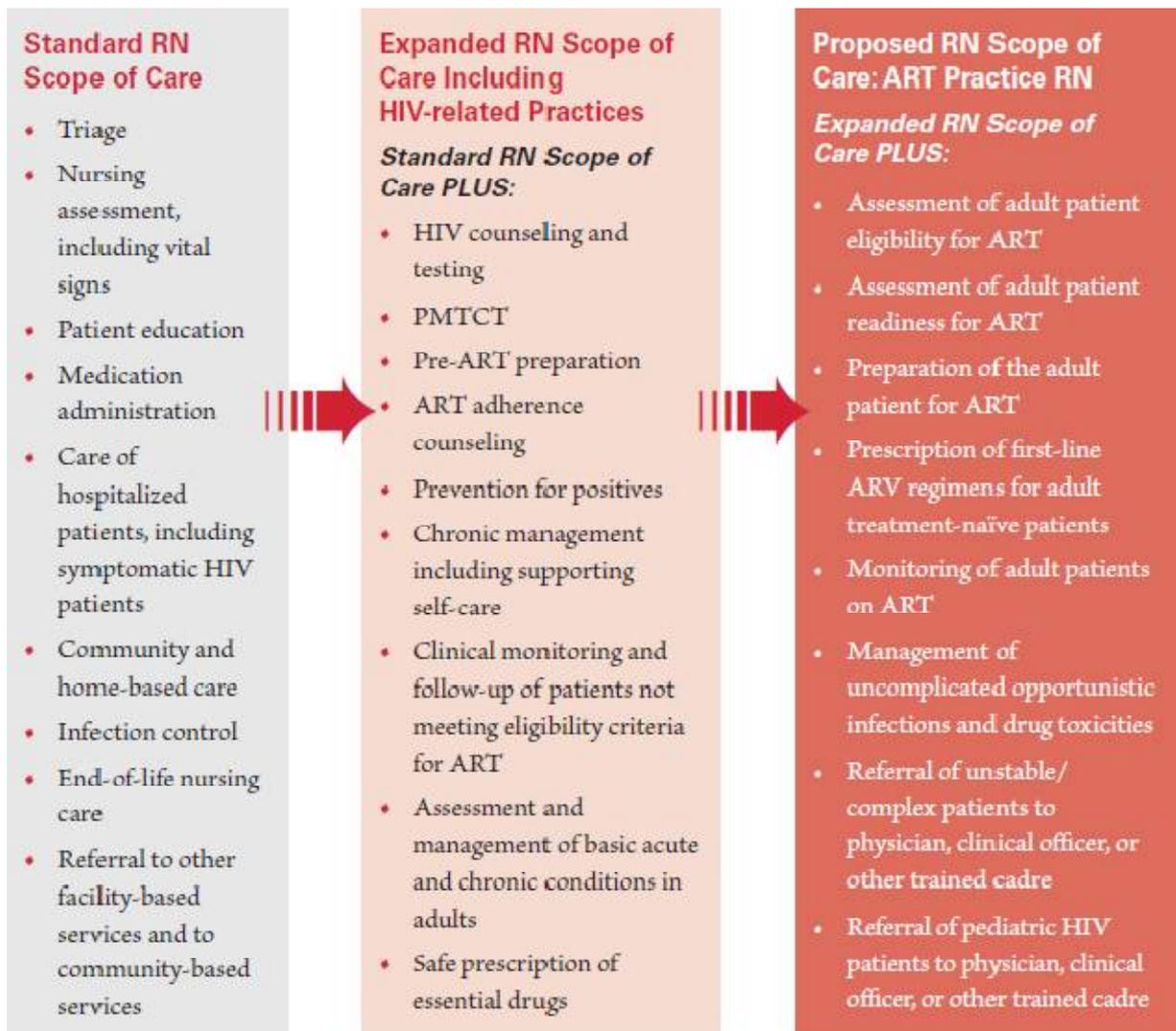


Figure 2: Standard, Expanded, and Proposed RN Scope of Care in HIV/AIDS

Source: Family Health International, December 2008

Table 1: WHO Delegation of ART-related Tasks to Nurses (Illustrative)

Establish medical eligibility for ART in a naïve patient.

Recommend first-line ARV regimen for ART-naïve patient, patient with TB co-infection, and pregnant women.

Decide when to start ART in eligible patients who have an active opportunistic infection.

Prescribe first-line ART.

Conduct clinical monitoring of naïve patient on first-line ARV regimen.

Recognize/manage self-limiting ARV drug side effects.

Recognize treatment failure from clinical symptoms.

Source: WHO PEPFAR, UNAIDS. Task shifting: Global recommendations and guidelines. Geneva. 2008.

Prescription and management of ARV drugs involves all the steps in the WHO illustrative table above, and effectively demonstrates the complexities of achieving this seemingly simple task. These complexities are not limited to knowledge and skills alone as may initially seem, but the attendant issues of time, staffing, training and clinical support begin to emerge. Implementation of a strategy of such proportions would require major investments of resources in order to achieve any measure of success.

The expansion of access to ART would cut across all health institutions, from tertiary hospitals to rural primary health care clinics. The scenario of the lone nurse in a rural clinic without the services of a doctor whatsoever was a common one, and in such circumstances, nurses had, out of necessity, prescribed and dispensed authorised medicines to patients themselves for years. The tertiary and secondary level hospitals, which were originally earmarked by the Operational Plan for the Comprehensive Management, Care and Treatment of HIV/AIDS in South Africa of 2003 (The Operational Plan for HIV/AIDS) had most often been ideally staffed with a minimum of one doctor and a pharmacist (DOH, 2003; 106). This would mean that they would have been less affected by the previous restrictions on nurse prescription of ART. However, for rural clinics access to a doctor or pharmacist may be such a challenge that without alternative mechanisms, patients in these settings would never get access to ARVs.

The Operational Plan for HIV/AIDS further classifies patient visits into short and long visits, dependant on the services to be provided and thus impacting on the requirement for the different cadres of professionals (2003,106). The availability of a doctor is also dependent on

the type of clinic, its location and the type of health service provided. According to the Re-engineering Primary Health Care in South Africa Discussion Document of November 2010, (NDOH;38), the full time equivalent (FTE) requirement for PHC clinics for doctors is 0.1 per clinic, as compared to that of professional nurses which is currently at 3. This poses serious challenges to NIMART as doctors are required for clinical care as well as mentoring and supervisory functions according to the task-shifting strategy (WHO; 2007).

Without trivializing the importance of the additional resources highlighted above, i.e. time, training, human resources, and clinical support, the NSP recommendation that regulatory and policy barriers to task shifting be identified still holds. Of paramount concern for the achievement of the objectives of this paper is that a deeper analysis of the supporting legal framework for NIMART, as well as its implications for all parties affected by it, with special focus on nurses be conducted.

4.2 The South African legal framework and its provisions and implications for NIMART

The intention of this section is by no means to give an in depth historical perspective of South African Law, It is simply to analyse the legal framework of South Africa currently, as it pertains to NIMART as presented previously, given the background of the HIV/AIDS epidemic already presented in the preceding sections. Thus the questions it attempts to answer are:

Under what laws, policies and regulations is NIMART mandated?

Are these legislative provisions adequate to ensure the successful implementation of NIMART?

Are there any reparative provisions required to ensure the successful implementation of NIMART?

Previously the ethical basis for the right to healthcare was examined. The right to health care was explored through Rawls' theory on the notions of equality of opportunity and effectively linked to the Constitution of South Africa. The urgent call for universal access to HIV prevention, treatment, care and support services was traced to an ethical and international human rights framework, thus providing a global framework for NIMART. How then, is this global human rights framework for NIMART translated into the South African legal framework?

In reviewing the link between human rights and law, Hassim et al (2007, 7) note that in 1948, the recognition of health as a human right took a great step forward when the newly formed

United Nations adopted the *Universal Declaration of Human Rights (UDHR)*. Article 25 of the UDHR states that everyone:

“has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.”

These authors note further that in 1966, nearly 20 years after the adoption of the UDHR, the responsibility of governments in respect of the right to health was made even more specific in the *International Covenant on Economic, Social and Cultural Rights (ICESCR)* (Hassim et al., 2007). Article 12 of the ICESCR mandated governments to undertake, amongst other steps, the prevention, treatment and control of epidemic, endemic, occupational and other diseases as well as the creation of conditions which would assure to all medical service and medical attention in the event of sickness. These were some of the steps member states had to take in order to achieve full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

According to Hassim et al. (2007:8), in many countries human rights are not recognised in laws and are therefore not enforceable by courts. Section 27(1)(a) of the Constitution of the Republic of South Africa, 1996 provides that “everyone has the right to have access to ... health care services, including reproductive health care”. Section 27(2) requires the state to “take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of” the right. Therefore the South African Constitution’s Bill of Rights specifically enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom. The rights that are listed in the Bill of Rights give courts the privilege to exercise judicial authority in disputes concerning them, and thus means they are legally enforceable if there is a dispute. The Constitution being the highest law in South Africa, is binding to all citizens and all levels of government itself, and thus ensures that human rights that are set out in the Constitution must guide every law in South Africa. A legal framework that tries to respect, protect, promote and fulfill people’s human right of access to healthcare services is developed mainly through policies and the laws that try to implement these policies (Hassim et al., 2007).

Hence, policies such as the *White Paper on the Transformation of the Health System in South Africa (1997)*, which sets out a detailed framework for health care delivery, also identified how government intended to transform South Africa’s healthcare system. It states that government’s overall objective is to develop a unified health system capable of delivering quality health care to all, guided by the strategic approach of providing comprehensive primary health care (PHC). It also speaks about decentralising the management of health services and sets out the position and objectives of government in

areas such as human resources, health information, HIV/AIDS and STIs. With regard to HIV/AIDS and STIs, a further policy in the form of the NSP (first NSP 2007-2011, and currently NSP 2011-2016) provides a national framework for South Africa's national response to HIV/AIDS. Although it is true that policy is not law (Hassim et al., 2007), it is important that policies respect the constitutional right of access to health care because policies guide the conduct of government. In fact, in a general sense, policies can be understood as political, management, financial, and administrative mechanisms arranged to reach explicit goals.

The National Health Act (NHA), No 61 of 2003 gives legislative effect to the 1997 White Paper. It is the most important law setting out the legislative framework for health care delivery in the country and works in combination with other pieces of legislation which relate to other areas of the healthcare system such as the development, registration, regulation and access to medicines. Of particular interest to this discussion, is the legislation that relates to the dispensing of medicines, as this is one of the key implications of NIMART. In South Africa, anti-retroviral drugs are governed by the Medicines and Related Substances Act, 1965 (Act 101 of 1965), which provides for the registration and control of medicines and related substances intended for human or animal use. In terms of section 22 (c) of the Medicines and Related Substances Act, a person who wishes to handle drugs in the various ways stipulated by the Act, must obtain the necessary dispensing license and complete a supplementary course prescribed under the Pharmacy Act, 1974 (Act 53 of 1974).

Although it is unclear what the contents of the required training should/does entail, neither the Medicines and Related Substances Act nor the Pharmacy Act give insight as to the contents of the prescribed course. It can be presumed to be equivalent to the Dispensing Course which both doctors and nurses must acquire in order to dispense medications in South Africa. According to the Medicines and Related Substances Control Act, (Act 101 of 1965) as amended, any healthcare professional that intends to dispense medicine must complete a supplementary course in dispensing and subsequently be licensed by the Director-General of Health in order to dispense medicine.

According to Mc-Quoid-Mason and Dada (2011; 107), while the Medicine and Related Substances Act makes provision for the inclusion of nurses as prescribing practitioners, they have to be authorized to do so in terms of the Nursing Act, 2005 (Act 33 of 2005). In terms of section 56 (1) of the Nursing Act, the South African Nursing Council (SANC) "*may register a person who is registered in terms of section 31(l)(u), (b) or (c) to assess, diagnose, prescribe treatment, keep and supply medication for prescribed illnesses and health related conditions, if such person-*

- (a) provides proof of completion of prescribed qualification and training;*
- (b) pays the prescribed registration fee; and*
- (c) complies with subsection 6*

Thus in order to dispense medication as part of their work, nurses must not only be registered with the SANC, but must also obtain the prescribed qualification and training, pay the prescribed registration fee and comply with the provision of section 56(6) of the Nursing Act. Section 56(6) reads, “*Despite the provisions of this Act, the said Medicines and Related Substances Act, the Pharmacy Act, 1974 (Act 53 of 1974), and the Health Professions Act, 1974 (Act 56 of 1974), a nurse who is in the service of-*

- (a) the national department;*
- (b) a provincial department of health;*
- (c) a municipality; or*
- (d) an organization performing any health service designated by the Director-General after consultation with the South African Pharmacy Council referred to in section 2 of the Pharmacy Act, 1974,*

and who has been authorized by the Director-General, the head of such provincial department of health, the medical officer of health of such municipality or the medical practitioner in charge of such organisation, as the case may be, may in the course of such service perform with reference to-

- (i) the physical examination of any person;*
- (ii) the diagnosing of any physical defect, illness or deficiency in any person; or*
- (iii) the keeping of prescribed medicines and their supply, administering or prescribing on the prescribed conditions;*

any act which the said Director-General, head of provincial department of health, medical officer of health or medical practitioner, as the case may be, may, after consultation with the Council, determine in general or in a particular case or in cases of a particular nature, if the services of a medical practitioner or pharmacist, as the circumstances may require, are not available”.

The Presidential announcement of 1st December 2009 essentially invoked this section of the Nursing Act. However, in order for this piece of legislation to be fully promulgated, it is important that the provisions of other legislation referred to also be fully promulgated. The roles of the South African Pharmacy Council (SAPC) referred to in section 2 of the Pharmacy

Act, 1974, referred to above are those pertaining to the recognition of pharmacy-related qualifications and the requirement that any person or institution registered in terms of this Act, or involved in pharmacy practice or offering pharmaceutical education or training, to furnish the council with the information the council requires. In the case of NIMART, the SAPC issued the following statement on 12 May 2010 (SAPC, 2010), through its legal services (see Appendix A):

“We confirm that ART medicines are Schedule 4 and therefore in terms of Section 22A of the Medicines and Related Substances Act, (No 101 of 1965) may only be dispensed by a pharmacist on a valid prescription by a medical practitioner or an authorized prescriber.

We confirm that currently the South African Pharmacy Council is unaware of any nurses being identified/licensed as authorized prescribers in terms of the nurse initiated ART role out.”

Section 29(3) of the Pharmacy Act provides four instances when non-pharmacists may perform the functions of a pharmacist, namely to keep and supply medicines. The Act allows for:

(1) the keeping of medicines or the supply of medicines to his or her own patients by any medical practitioner, dentist, practitioner or nurse in accordance with the provisions of the Medicine and Related Substances Act, 1965.

(2) the handling of medicines or the supply of medicines to members of the armed forces, under the supervision of a medical practitioner or pharmacist, by members of the medical service of the armed forces provided such members of the said medical service have undergone training therein;

(3e) the keeping of medicines and its supply to patients in hospitals or other institutions for the treatment of sick persons, under the direction of a medical practitioner and in accordance with the provisions of the Medicines and Related Substances Control Act, 1965, by any person registered or enrolled under the Nursing Act, 1957 (Act 69 of 1957);

(4f) the keeping of medicine and its supply by any person or organization performing a health service and authorized in writing by the Director-General acting after consultation with the council, to acquire medicines for the performance of such service.

It is clear therefore that the Pharmacy Act itself does not prohibit the supply of medicines by a nurse, but in addition to it first approving and recognizing the qualification of the said nurse, it requires that the medicines to be prescribed by the nurse be in accordance with the provisions of the Medicine and Related Substances Act, 1965. The fact that ART medicines are Schedule 4 drugs does not in itself prohibit their prescription and dispensing by nurses,

but rather it is the provisions for other authorized prescribers, in this case nurses, that remain elusive. This boils down to the failure of the responsible parties to furnish the SAPC with the necessary documentation of the training and qualification of nurses who will then, under the provisions of section 56(6) of the Nursing Act, be fully legally enabled to implement NIMART. The responsible parties should in the least include the Director-General of the DOH, who is the authorizing figure for health services; the training authority whether in the form of a government body or designated agency, which is the body responsible for the development, provision and accreditation of the training which should be provided to nurses for the fulfillment of the competency criteria; and lastly the SANC, which is the ultimate regulatory body for nursing practice.

5. Ethico-legal Analysis of NIMART

5.1 Ethical Implications of NIMART in the South African legal framework

It would seem, from the review of the legislation enabling NIMART above that all angles have been taken care of and therefore NIMART should be easily implemented across the country. This is of course, provided that the issue of the training and qualifications of nurses can be easily resolved with the SAPC.

As discussed previously, Nursing Act, 2005 (Act 33 of 2005) Section 56(6) permits the performance of the physical examination of any person; the diagnosing of any physical defect, illness or deficiency in any person; or the keeping of prescribed medicines and their supply, administering or prescribing on the prescribed conditions by nurses, if the services of a medical practitioner or pharmacist, as the circumstances may require, are not available. As a result, nurses practicing in rural clinics and other PHC clinics without the regular services of a doctor have over the years been legally enabled to perform the above functions, which would ordinarily fall in the scope of medical practice. This provision also limits nurses to prescribing drugs within their scope of practice according to the Medicines and Related Substances Control Act, 1965.

Based on the SAPC statement, the issue of ART medicines being Schedule 4 drugs becomes problematic in these very circumstances where NIMART is most needed, if nurses have as yet not been fully legally accredited according to the Pharmacy Act as discussed previously. In its statement of 12 May 2010, the SAPC explicitly confirmed that nurses who are registered in terms of Section 38A (old Nursing Act) / Section 56 (new Nursing Act) are permitted to dispense medicines they have prescribed, i.e. nurse initiated treatment in terms

of prescribed regulations. The old Nursing Act is relevant because it has not been fully repealed, and Section 38A still applies to some PHC nurses and Occupational Nurses who qualified as nurse clinicians and prescribers through the acquisition of a supplementary training accredited by the SAPC in accordance with the Pharmacy Act. However, the nurses authorized under Section 56 subsequent to the Presidential pronouncement on NIMART (Zuma; 2009), would have at that stage still been without the necessary accredited training and qualification required by the Pharmacy Act.

It is debatable whether the legal implications for nurses implementing NIMART under these circumstances would clearly be unfavourable, given that they would be acting on an urgent government mandate. Of course if the SAPC chose to pursue the case in the interest of protecting professional territory, it would seem that only government and its officials would suffer embarrassment for lack of foresight, and possibly be accused of dereliction of duty and responsibility. However, the ethical implications of harm to patients brought by nurses implementing NIMART under these circumstances might be inexcusable because on a personal and professional level, nurses should be guided by their professional and ethical code of conduct.

In the same statement, the SAPC asserted further that it was and would at that stage continue to be the status quo that pharmacists could not dispense nurse initiated treatments unless such prescription has been authorized by a medical practitioner. This latter point refers to Section 29(3(e)) of the Pharmacy Act, which pertains to one of the four instances when non-pharmacists may perform the functions of a pharmacist, i.e.:

“the keeping of medicines and its supply to patients in hospitals or other institutions for the treatment of sick persons, under the direction of a medical practitioner and in accordance with the provisions of the Medicines and Related Substances Control Act, 1965, by any person registered or enrolled under the Nursing Act, 1957 (Act 69 of 1957);”

To adequately assess the validity of the SAPC assertion above, it is useful to review again the provisions of the laws referred to. According to the Medicines and Related Substances Control Act, (Act 101 of 1965) as amended, any healthcare professional that intends to dispense medicine must complete a supplementary course in dispensing and subsequently be licensed by the Director-General of Health in order to dispense medicine. The Nursing Act, 1957 (Act 69 of 1957) that is referred to in the excerpt above was completely repealed by Nursing Act, 1978 (Act 50 of 1978), and is thus no longer relevant in the current discussion. Nursing Act, 1978 (Act 50 of 1978) was itself, also repealed completely by Nursing Act, 2005 (Act 33 of 2005) , Therefore, the only laws relating to nurse prescribing that are relevant in current discussions are Nursing Act, 2005 (Act 33 of 2005) and Nursing

Act, 1978 (Act 50 of 1978) Section 38A . Therefore, it is erroneous of the SAPC to maintain that a pharmacist cannot dispense a nurse initiated script without the authorization of such a prescription by a doctor because this is without a legal basis. Most importantly, doing so may infringe on the right of citizens to access much needed health care.

5.2 Country Case Scenarios and the lessons learned

5.2.1 Botswana:

In 2004, the Ministry of Health (MOH) in Botswana expanded one Non-Governmental Organisation's (i.e. KITSO) didactic training for ART scale-up by incorporating additional training partners in the country through a preceptorship program (Bussmann, Ndwapi & Gaolathe; 2009). Under the supervision and mentoring of a preceptor, newly trained health-care workers gained valuable hands-on experience in the practical application of their didactic training. The motivation for taking this route was based on evidence from operational experience borne out by the field research, which strongly suggested that newly trained health-care workers require a period of close supervision and mentoring, whilst simultaneously gaining valuable hands-on experience in the practical application of their didactic training (Bussmann, et al.; 2009). As a result, mentorship has become the buzz word for HIV scale-up in the recent two years and going forward because it theoretically offers a balanced solution to the urgent need to train more health-care workers in good clinical HIV care practice, whilst also limiting the long periods often required for staff to attend training (Bussmann, et al.; 2009).

The challenge of non-uniform patient management protocols as a result of multiple trainers (Bussmann, et al.; 2009) thus necessitated that the responsibility for the regular updating of such curricula fall with the national authorities, hence the partnership. In Botswana's KITSO program, the curriculum was regularly updated by national and international experts to ensure that health-care professionals gain competency and confidence in the latest national standards of HIV care and treatment. As a result of its up-to-date relevance, the KITSO didactic training became the foundation and an important catalyst in the government's effort to create a comprehensive, integrated, and decentralised HIV/AIDS treatment program. This approach helped steer away from the traditional series of vertical programs which only address specific aspects of HIV care e.g. ART, PMTCT, TB/HIV, STI etc. It also focused interventions on a site level, thus incorporating teams rather than only a specific cadre.

By 2007, task shifting was already being implemented to mitigate the critical shortage of pharmacists, pharmacy technicians, and doctors/prescribers for the ART roll-out in Botswana. An important observation from this study by Bussmann, et al. was an ongoing

need at ART sites for continuing education, refresher courses, advanced training, and timely information regarding revisions and amendments made to national treatment protocols. Overall, the recommendation that the long-term need for ART in Botswana and elsewhere requires that adequate knowledge of HIV care and treatment be integrated into the pre-service training curricula for all health professionals needs to be taken seriously by all relevant parties. Adequate training is thus highlighted as a critical component for effective task-shifting, with the standardized and multi-phasic nature of this particular model ensuring steady, progressive acquisition of new skills and confidence.

In another study Miles, Clutterbuck, Seitio et al. (2007:501) propose that scaling up ART delivery will require tens of thousands of health-care workers with the experience and training needed to treat people with HIV, which is quite a complex health problem in itself. They argue for an urgent development of simple and sustainable models of delivering ART and its associated care by maximizing the potential of existing human resources in less-developed health-care delivery systems. This notion stems from the recognition that physician-based models of care adapted from industrialized countries will not suffice to treat the majority of patients in resource-constrained settings.

According to these authors (Miles, et al. 2007), task-shifting of components of ART care to nurses in Botswana arose when it became clear that the predicted long-term demand for ART services at rural primary hospitals was clearly going to exceed the availability of medical personnel in that country. After the medico-legal aspect was considered and local stakeholders were consulted, pilot work began in two centres in 2004, where nurses were trained to manage clinically stable patients who were being seen for follow-up. Criteria for these patients to be managed by a trained ART nurse, as opposed to a doctor, were agreed upon locally with medical and nursing directors. Clinical mentorship by ART preceptors ensured that national standards were met, that the nurses were clear about the limitations of their practice and that they knew when and how to refer patients to a doctor. This model apparently worked well and was communicated to interested stakeholders. However, Miles et al. (2007:557) note that timescales for addressing such issues may also present a barrier, particularly with the urgency of scaling up ART.

They conclude that the Botswana ART program has shown that better utilization of nurses has the potential to increase access to ART, reduce congestion at centralized ART centres, reduce unnecessary travel by patients and allow for localized provision of support for adherence and education. However, they note that their paper's limitations include a lack of operational outcomes demonstrating that in this context nurses could perform as safe, accountable and acceptable practitioners. In principle, therefore, NIMART is possible and

can be done in a manner that minimizes risk to the patient. The risk is associated with lack of knowledge, skills and access to referral channels for complicated clinical conditions, as would be expected of medical practitioners. This, really, is the crux of the debate about the risk to patients posed by NIMART. In contrast to South African nurses, nurses in Botswana are reportedly well-educated, have good access to ongoing continual professional development, and work within a strong framework of clinical governance (Miles, et al. 2007).

Unlike Botswana which has a standardized national curriculum for HIV management, South Africa has many NGO led in-service trainings for nurses, which poses a challenge when assessing the existing knowledge of practicing nurses in primary health clinics. There is no uniform standard against which to gauge nurses' clinical knowledge and skills as different cohorts in the various provinces are likely to have been trained and mentored by a minimum of two to three NGOs, and each NGO would have likely used its own curriculum. This is a legacy of the attempt by government to distribute equally across the country, the largely PEPFAR funded resources brought in to assist the roll-out of ART. This coupled with the many other competing tasks of nurses in PHC leads to understandable concern among public health experts about their capacity to appropriately initiate therapy and manage chronic HIV disease, but also about maintaining long-term treatment adherence and early identification of treatment failure. The latter could have implications for the development and proliferation of drug-resistant disease, with grave consequences for individual patients and the community at large.

Issues that require further investigation and attention arising from the Botswana experience of task-shifting fall into three broad categories. Firstly, leadership in the form of policy-makers need to have a clear understanding of task-shifting as well as the ability and influence to communicate the strategy as clearly as possible to all health workers so as to avoid misconceptions, and thus undermining of the strategy. Secondly, the implications of task-shifting for nursing as a profession need to be adequately interrogated so as to minimize the threat of taking on advanced clinical tasks, the attending medico-legal implications of nurses assuming an enhanced role and the wage implications, if any, of accepting the advanced tasks. Although successful implementation of task-shifting was demonstrated in Botswana, there was concern that the medico-legal position of nurses in enhanced roles was not formally recognised nor adequately clarified at the national level, thus legislation, policy and guidance needed review and modifying.

Lastly, training of staff posed serious logistical challenges, particularly in rural settings. Task-shifting requires standardized and expanded training efforts in order to reach far and wide, however this must be balanced against the need to regularly review and update content due

to continual advances in HIV care. Most studies which have looked at the feasibility and safety of nurse-initiated ART have been limited to assessing the ability of nurses to assess and prescribe ART, however, as treatment failure management will become critical in long-term ART management nurse training needs to anticipate these future trends. Threats to the successful implementation of task-shifting, as indeed seen in the long-term sustainability of HIV care, include the retention of trained staff as well as the evolving needs of the health sector.

5.2.2 Mozambique:

Brentlinger, Assan & Mudender (2010;1) report that in 2004, when the Mozambican Ministry of Health (MOH) first contemplated task-shifting, Mozambique estimated that the nationwide adult HIV sero-prevalence was 16.2%; 1.5 million citizens were infected with HIV, and the health workforce included only 662 physicians (0.35/ 10 000 population) and 2698 non-physician clinicians (1.43/10 000 population). Mozambique's strategic plan for 2004-2008 mandated expansion of ART from 17 to 129 health units, with the aim of increasing enrolled patients from 7 924 to 132 280 nationwide, and increasing ART availability in rural and peri-urban areas, which necessitated task-shifting and decentralization of care through the rapid training and deployment of non - physician clinicians known as 'técnicos de medicina' (TMs). Shortly after independence in 1974, the majority of physicians - mostly Portuguese nationals - departed from Mozambique, leaving fewer than 80 physicians to care for a population of 10.6 million. The government recruited mid-level workers such as nurses and midwives to be trained as TMs, similar to Western physician assistants. They characteristically undergo training for 30 months and are expected to provide the clinical and managerial tasks ordinarily carried out by doctors. TMs have since become the backbone of the PHC system in Mozambique.

In order to ensure adequate knowledge and skills in the TMs, and consequently provide high-quality clinical HIV/AIDS services, the Mozambique MOH developed a new in-service training course, which emphasized ART and co-trimoxazole prophylaxis, and lesser attention to clinical staging and opportunistic infections (Brentlinger et al.,2010). The authors specifically state that the TMs were intended as neither prescribers nor primary clinicians but only as care providers for stable, uncomplicated, ambulatory non-pregnant adults in WHO clinical stages I and II. Therefore they were also not expected to initiate ARVs, although they could then provide follow-up care for stable patients on first-line ARVs that had already been prescribed by the physician.

During the course of the implementation of the two-week in-service training for TMs,

developments arose leading to policy changes which then authorized them to prescribe first-line ART without physician consultation. This allowed the researchers to gain useful information regarding the performance of the TMs in the new extended role. Anecdotal reports pointed to deficiencies in quality of care, to which the MOH responded by conducting a survey to assess the situation. It was glaringly obvious that the two week training had been inadequate preparation of TMs to take over the highly skilled task of providing high-quality clinical HIV/AIDS services. As it were, they had literally overnight, been made to assume the responsibility of physicians and been expected to make highly sophisticated clinical decisions when faced with critically ill patients, with only an additional two weeks in-service training.

Although the same assumptions cannot be made between TMs and professional nurses, the findings of their report (Brentlinger et al.; 2010) are telling as the circumstances of the urgency of task-shifting are very similar in many other ways. Besides the course duration which was agreeably too short, the course content fell way short of what was required in order to adequately prepare the incumbents for the task ahead. Compromising patient safety for the sake of achieving targets is an unacceptable trade-off and is ethically indefensible under any moral framework. This study emphasizes the importance of innovative and visionary leadership which is participative and supportive at operational level.

5.2.3 Zambia:

In their landmark study, Stringer, Zulu & Levy et al. (2006; 788) reported on their initial clinical experience with the rapid scale-up of HIV care and treatment in the urban primary health care setting of Lusaka. They detailed survival, regimen failure rates, and CD4 cell response outcomes for more than 16 000 patients receiving ART through the health system in that district.

Findings such as in the case of Zambia (Stringer, Zulu, Levy et al; 2006) that the majority of patient deaths occur within the first three months of ART initiation due possibly to undiagnosed opportunistic infections and nutritional deficiencies amongst others, provide a powerful ethical mandate for the aggressive expansion of ART services. This finding poses a double edged challenge because not only does it suggest urgency in increasing access to ART, it also raises concerns about the feasibility of shifting ART prescription to nurses without ensuring comprehensive skills and knowledge transfer.

Stringer, Zulu & Levy et al. (2006:792) further noted that the more established Lusaka ART sites had begun to struggle with operational issues, such as patient overload and staff burnout, as well as difficult longer term AIDS clinical management issues, such as multiple

regimen failure, long-term adverse effects, and program attrition. This provides useful lessons for South Africa by highlighting the importance of a phased approach to task-shifting, as well as a comprehensive health system re-alignment so as to relieve nurses of some of their lesser skilled tasks, whilst also ensuring the availability of more skilled medical personnel, such as doctors, to deal with the more complex issues so as to allow nurses to concentrate on integrating the new tasks into their workflow.

Morris, Chapula, Chi et al.(2009) provide a descriptive report of the implementation of a task-shifting strategy in Zambia and provide an analysis of basic data to try to demonstrate feasibility of task-shifting. Aspects of the strategy that were analysed were provider roles in the task-shifting model, training, mentoring and continuous quality assurance. Access to trained personnel and central coordination of programs were highlighted as major barriers to task-shifting in a rural setting. Local government engagement was recognised as a pivotal determinant of success of the strategy. In an effort to circumvent the challenges associated with in-service training and mentoring of nurses, with all its implications on service delivery and patient care, the study suggests integration of task-shifting into formal nursing curricula. This would hopefully facilitate the recognition of expanded duties via certification, legal support, and professional regulation.

5.2.4 Rwanda:

Rwanda reportedly has a population of around 9 million inhabitants, with an overall HIV prevalence of 3% and more than 7% in urban areas (WHO; 2003). The national ART program, launched in 2003, was first established at the district level and was subsequently decentralized to Primary Health Centers (PHCs) so that by the end of 2007, 171 (39%) of the 434 health facilities provided ART services, most of these being PHCs (Shumbusho, van Griensven & Lowrance et al.; 2009).

The Rwandan case as reported by Shumbusho et al. (2009:2) offers a more relevant experience to the current challenge faced by South Africa, as prior to the intervention by Family Health International (FHI) in 2005, nurses in that country were not allowed to prescribe ART, despite their severe doctor shortage. The statistics reflected a physician ratio of 1: 50,000 inhabitants and a nurse ratio of 1: 3,900 inhabitants, with 80-90% of the population rural-based.

The authors reported evaluation results of the pilot intervention, using descriptive data extracted from patient records to assess (i) nurse performance vis-a'-vis compliance with national clinical guidelines for HIV care and treatment, and (ii) key patient outcomes, including retention, body weight, and CD4 cell count change after treatment initiation. The

initiative was funded as an intervention rather than as a research project, and limited resources precluded using a comparative study design, however, the power of this study, and indeed its relevance to this discussion, was the fact that the task-shifting initiative in Rwanda was carried out within a national framework with the explicit objective of evaluating its safety and potential for policy development.

A clear recommendation from this study therefore, is that task-shifting of doctors' roles to nurses should not be implemented in isolation but rather that regulatory frameworks integrating task shifting within national policy on human resources for health should be established. With specific reference to nurse task-shifting, high quality pre-service training with regular in-service updates focusing on both theory and clinical skills; adapted medical records, tools, and protocols; and tailored training curricula, are all highlighted as pivotal requirements for the long-term success of task-shifting. Such a comprehensive approach to task-shifting no doubt requires extensive collaboration between the various stakeholders, including the nursing profession itself under the auspices of its Nursing Council.

5.2.5 Uganda:

Task shifting in Uganda is, unsurprisingly, driven by shortages in human resources for health, and the high demand for healthcare services. While the country has no official policy or guidelines on task shifting, it is reportedly taking place on a wide scale and at various levels of care (Harrowing et al., 2010). Uganda has a long history of task shifting, dating as far back as 1918 when the Ugandan health service pioneered the use of a cadre of medical professionals originally referred to as licentiates, later medical assistants, and currently known as clinical officers (Mullan & Frehywot; 2007). They have also managed to implement this approach in pharmaceutical services where due to the lack of pharmacists, pharmaceutical technicians (or dispensers) staff most of the hospitals and render the full range of pharmaceutical services.

Harrowing et al.(2010; 723) describe the manifestation and impact of moral distress as it was experienced by Ugandan nurses who provided care to HIV-infected or –affected people, in their critical ethnography with 24 acute care and public health nurses at a large referral centre in Uganda. This was the first description of moral distress in sub-Saharan Africa. The authors define moral distress as the bio-psychosocial, cognitive and behavioural effects experienced by clinical personnel when their values are compromised by internal or external constraints as a result of an inability to provide the desired care to patients (Harrowing et al. 2010, 724).

Significant issues raised in the study were the finding that despite the passion and

commitment expressed by participants, moral distress at the perception that they were putting patients at risk due to lack of resources was a very real issue for them. The perception that the public blamed nurses for poor patient outcomes did not deter them from their determination to serve to the best of their abilities. The critical factor that they believed however, to hold the key to enabling them to function under these circumstances was access to education. It is laudable that even under such trying circumstances as described by the participants, their moral distress was focused on the impact for patients, communities and the nursing profession rather than on their own personal suffering.

A study by Vasan et al. (2009; 2) which set out to measure the agreement between doctors and non-doctor clinicians, clinical officers in this case, in starting ART in rural Uganda claims to offer preliminary evidence to support increased investment in task-shifting and training of non-doctor clinicians to deliver ART in rural primary care settings. Clinical officers are credentialed/licensed non-physician clinicians with post-secondary level of training of variable duration across countries and in some countries completion of undergraduate education is a prerequisite. In South Africa, they undergo university education of three or four years during which time diagnostic and clinical skills are developed, including drug prescription.

The study was conducted at 12 government ART sites in three regions of Uganda, all of which had staff trained in delivery of ART using the WHO Integrated Management of Adult and Adolescent Illness guidelines for chronic HIV care. Seven key variables were collected in order to measure patient assessment and the decision as to whether to start ART, the primary variable of interest being the Final Antiretroviral Therapy Recommendation. Patients saw either a clinical officer or nurse first, and then were screened identically by a blinded doctor during the same clinic visit. Agreement between the decisions of the non-doctor health workers and doctors in the ART assessment variables were measured using simple and weighted Kappa analysis.

The authors assert that their study offers compelling evidence in these results that non-doctor clinicians, i.e. clinical officers, should be allowed to initiate ART immediately, and can do so with a high level of agreement with physicians. However, the development of this particular cadre of health professional is still in its infancy in South Africa, and as such this study offers little immediate solutions, but rather gives a possible additional strategy for long-term expansion of access to ART as these competencies should ideally be incorporated into pre-service training of clinical officers.

One critical objective of another study (Dambisya & Matinhure;2012) was to understand the policy and programmatic implications of task shifting in relation to the roles, responsibilities

and workload of health workers within the context of providing quality HIV and AIDS care and support services. What they found was that most of the task shifting was happening without enabling policy, regulations or legal protection for those who undertook delegated tasks, though there were successful examples of task shifting backed by institutional frameworks. The policy environment was supportive of task shifting, and the process was underway to develop a policy and guidelines for task shifting in Uganda. It was their argument however, that the HRH crisis in Uganda, and indeed anywhere else in Southern Africa, makes task shifting inevitable despite the many concerns from the health professionals regarding their protection should anything go wrong and fear for too much workload.

Their finding was that task shifting primarily takes place through internal institutional arrangements, a common characteristic in both developed and developing countries, and there is a general concern that nurses have taken on increasingly more clinical responsibilities that are beyond the scope of work of a traditional nurse. The counter argument has been that the situation is universal and thus requires drastic measures, provided it is understood that task shifting cannot be expected to make up for all the systemic short comings, a point well made by Phillips et al. (2008; 3). It is an already established fact that services such as HIV/AIDS care and support, anaesthetic services and psychiatric services rely heavily upon task shifting approaches, however, their conclusion that the future of task shifting in Uganda will depend on the extent to which concerns of health professionals are addressed going forward is one that all countries adopting this strategy should take heed of.

Issues for further consideration arising from the Ugandan experience of task-shifting can be broadly categorized into two groups. Firstly, human resource issues including reluctance to change; protection of professional turf; unclear professional boundaries and regulations; heavy workload and high disease burden; and the under-utilisation of unemployed health professionals. Variation in the level of training of nurses that participated in one study highlighted the plight of rural personnel in accessing quality training as too often NGO efforts are concentrated in urban and peri-urban areas. The ethical implications of these human resource challenges could be far-reaching on both an individual and societal level.

Secondly, strategic leadership as reflected in the identification of poor planning, lack of a task-shifting champion and lack of guidelines as barriers to implementation of task-shifting. Perhaps the sobering observation by Harrowing et al. (2010; 729) that constraints imposed by the inability to implement skills and knowledge to their fullest extent, as well as a lack of resources and infrastructure may result in the omission of care for patients by nurses should

serve as impetus for greater vigilance and action to minimize harm to patients.

5.2.6 United Kingdom

Developed countries that have progressed significantly in the development of nursing practice have useful lessons for developing countries that have had to make rapid adaptations to meet the challenges of human resource shortages and the AIDS epidemic. One such country worth looking closer at is the United Kingdom (UK), particularly with regard to how the legal framework has evolved with increasing clinical autonomy and accountability in nursing practice. In their book, *Law and Nursing*, John Tingle and Jean McHale (Tingle & McHale; 2007) give a detailed account of the context of the law and how the law impacts on nursing in the UK, however for the purpose of this discussion, focus will be placed on the legal implications of 'expanded' nursing roles. The expanded nursing role refers to the continually developing role of the nurse as changes in practice and training add new functions to the normal range of duties.

In chapter 4 the authors (Tingle & McHale; 2007) consider the area of legal aspects of the expanded role, clinical guidelines and protocols, as well as nurse prescribing. Attention is drawn to a report by Doyal et al.(1998) which looked in detail at the development of four new nursing posts in the UK, where each post involved nurses taking over some part of the work previously done by junior doctors. In exploring the views of the nurses involved it was evident that though most expressed excitement at the professional challenges they faced, some nurses reported that they received little support and that there was considerable confusion surrounding their new roles. Legal and accountability issues included lack of clarity about roles and accountability, as it was not clear who the nurses reported to i.e. the doctor or the nursing manager.

Another dimension of nurses' expanded roles that is highlighted is whether the nurses' services are fully understood and utilized in the health system. One study by Dowling et al (1996;) found that almost one in four (23%) of those who referred patients ($n = 428$) had had their referrals refused because they were a nurse rather than a doctor; and a third (33%) of the 315 respondents who ordered investigations had been refused on the same grounds. Both these negative factors could have disastrous consequences for the public and the nurses involved. The authors (Tingle & McHale; 2007) admonish that the resulting uncertainties about management of clinical roles evolving between the professions coupled with a public that is increasingly litigious puts nurses at risk for complaints, litigation and possible disciplinary hearing. Recommendations to reduce risk include making doctors and nurses equal partners in planning the new roles; informing patients in advance of the

changes in role and providing the relevant training to nurses; and ensuring that staff have access to legal advice and support.

The legal implications of unclear roles and accountability are far reaching as they are the responsibility of the employer ultimately, as the employer needs to ensure that a safe system of work is in operation for both staff and patients (Tingle & McHale; 2007). This responsibility arises from the common law duty on the employer to provide competent staff and the nurses in turn have a professional duty to act competently through the tort of negligence (Giliker & Beckwith 2004, cited in Tingle & McHale; 2001). Competence of staff can be gained through appropriate training and thereafter ensuring that the knowledge is sustained and updated. However, gaining of a new competence and additional tasks comes with additional professional responsibility and consequent accountability of individual practitioners, which ideally should be reflected in the scope of practice. The Queensland Nursing Council defines 'scope of nursing practice' very simply as:

"That which nurses are educated, competent, and authorised to perform."

Tingle & McHale (2007; 78) note that in the British legal system, where a nurse performs traditional nursing duties the standard of practice required is that of the ordinary skilled nurse in his/her speciality in the circumstances of the case – the *Bolam* principle. In seeking to establish the standard of care expected if performing an expanded role, he suggests that guidance can be taken from the case *Wilsher vs. Essex Area Health Authority* ([1986]). The key point to be taken from the *Wilsher* case is that a nurse is liable to be judged by the professional standard of the post that s/he is performing at that time. This means that if the nurse is performing an expanded role, s/he is expected to operate at the level of skill and competence outlined in the expanded role. Tingle finds support for this assertion in a statement by Kloss (1988) who argued that "*if a nurse undertakes a task for which she knows she has insufficient training, this in itself may constitute negligence, even if she is acting on the orders of a doctor. If a nurse takes on the doctor's role she will be judged by the standard of the reasonable doctor.*"

Faced with a charge of negligence, a nurse would thus not be in a position to use inexperience as an excuse. As reflected in many nursing codes (AMA; ICN), it is very important that nursing staff maintain professional knowledge and competence. One way of ensuring competence and uniform standards of care worldwide has increasingly involved the use of clinical protocols and guidelines. In the UK, the development of clinical guidelines is a government priority and an important aspect of its commitment to enhance the quality of patient care, and this is identified in the NHS National Plan (Department of Health 1999c, 2000b). A special health authority, the National Institute for Clinical Excellence (NICE) was

set up on 1 April 1999 to provide the NHS, patients and the public with authoritative, robust and reliable guidance on current 'best practice' (NICE; 1999).

However, despite the recognition that the drafting of clinical guidelines is a collaboration of experts in their respective professional fields, clinical guidelines are fundamentally regarded as only advisory (NICE; 1999). Clinical guidelines are based on a common-sense principle and should therefore not suspend clinical autonomy (NICE; 1999). Thus if nurses are by professional definition reflective and autonomous practitioners then it is a possibility that a patient's condition may clearly contraindicate the application of a clinical guideline. However, if a clinical guideline is not followed, a proper reason would be required as an explanation in a tort claim.

In 1972 the British Committee on Nursing (Briggs Report) concluded then that though there were no apparent legal objections to continuing the practice of dividing work between the professions, nurses should be required to undertake only those duties for which they had been educated and trained (BMA; 1977). Not much has changed legally since this caution was first given, but the advances on the clinical and technological front have no doubt introduced multiple complexities that blur the lines ever more out of focus. It is a chilling reminder by Tingle & McHale (2007; 80) that nurses practicing in the UK take note of the legal implications of taking on roles previously undertaken by a medical doctor as competence to perform that role is that of the level of the medical doctor. The authors also acknowledge that although clinical guidelines have the potential to reduce the level of complaints and litigation in health care by improving communication processes and the quality of care, they raise a number of important legal issues. In conclusion, Tingle & McHale (2007; 95) posit that enhanced prescribing powers in nursing are illustrative of the increasing autonomy given to nurses exercising an expanded role, however it does also provide another illustration of an area where, through expansion of responsibility, there is a risk of expansion of liability.

6. Discussion, Recommendations and Conclusion

6.1 Discussion

Task-shifting in the contexts of the global HIV/AIDS epidemic and ever worsening human resource shortages in health is a critical and viable strategy. Evidence for this is found in numerous sources of literature reviewed previously and is endorsed by significant organizations such as UNAIDS, PEPFAR, WHO and ICN. It was through the concerted efforts of these organizations and several other civil society groups that the call for

acceleration of universal access to ART came to the fore in the global strategy against HIV/AIDS. Recognising that the lack of trained health workers is a major barrier to scaling up AIDS services, particularly ART, policy change to support task-shifting was recommended as the strategy that would have the most immediate effect on increasing the number of health care workers. The moral rationale for task-shifting has been explored and found to be justifiable through Rawls' theory of justice, which is further expanded by Daniels et al in their thesis on the right to health care.

Through the review of the South African context of HIV and health service delivery platform, the report so far has established the importance of NIMART, given the additional discrepancies between rural and urban distribution of health workers and health services. The legal framework for the implementation of NIMART can be effectively traced from the Constitution of South Africa, through the *White Paper on the Transformation of the Health System in South Africa (1997)*, the National Health Act (No.61 of 2003), the old and current NSP for the Management of HIV, AIDS, TB and STIs. In light of these legal developments, the pronouncement by the State President on the 1st December 2009 regarding the policy change that would enable access to ART from every PHC clinic in South Africa gave NIMART political and social impetus.

Thus the legal framework for NIMART has been shown to have quite a concrete and justifiable foundation, however it seems as though the nuts and bolts of its implementation still requires much collaborative discussion. The gaps in the interpretation of the law regarding nurse prescribing in the absence or presence of a supporting doctor and the absence of an agreed curriculum/competency assessment are identified as treats to an otherwise viable strategy. Observations from other developing countries facing similar challenges as South Africa reveal a number of relevant lessons, which have been highlighted in the preceding section.

Lessons from the UK which is a developed country where expanded nurse roles began serious discussions between the medical and nursing professions more than three decades ago shed greater insight into the legal implications of NIMART. Although the legal framework of South Africa is different from that of the UK, and the context of NIMART somewhat different to that of advanced nursing practice, the essence of the discussion remains relevant. NIMART by definition involves the taking over of doctors' roles by nurses, and as such requires that nurses be adequately trained, competent and authorized prior to performance of those roles. Similarly, NIMART guidelines and protocols have been developed by NGOs and endorsed by the National Department of Health in an attempt to ensure competence and quality of care. The UK experience teaches us that the new roles

that nurses take on from medical doctors need to be incorporated into the scope of practice of nursing as this is the legal standard by which a nurse performing an expanded role should be held accountable, not that of a medical doctor. Nurses ought to be informed about the legal implications of accepting the additional roles of NIMART, and be better enabled to maintain their competence and skills through continuing professional development programs.

6.2 Recommendations

The report acknowledges that recommendations around mentoring and support, leadership and ethical implementation do not emerge consistently from the findings, however these have been found to be necessary elements for ensuring sustainability of NIMART in at least one study as well the literature relating to the United Kingdom experience.

Training and Continuing Professional Education

The training of nurses in NIMART in South Africa is non-standard despite a competency framework having been established (DOH, 2011). Different training organizations operating in various parts of the country have each developed their own materials based on this competency framework; however, implementation is largely determined by availability of resources. Another limitation is lack of compulsory continuing professional education for nurses as once in-service training is done; it needs to be maintained and updated through self-directed learning.

Provision of continuing education, refresher courses, advanced training, and timely information regarding revisions and amendments made to national treatment protocols for healthcare teams providing HIV care is critical to the successful implementation of national ART scale-up. Such training needs to be standardized by a national body, so that training received by nurses and other health workers is uniform.

A clear recommendation from this study therefore, is that task-shifting of doctors' roles to nurses should not be implemented in isolation but rather that regulatory frameworks integrating task shifting within national policy on human resources for health should be established. With specific reference to nurse task-shifting, high quality pre-service training with regular in-service updates focusing on both theory and clinical skills; adapted medical records, tools, and protocols; and tailored training curricula, are all highlighted as pivotal requirements for the long-term success of task-shifting. Such a comprehensive approach to task-shifting no doubt requires extensive collaboration between the various stakeholders, including the nursing profession itself under the auspices of the SA Nursing Council.

Mentoring and Support

It is a well established fact that didactic training is inadequate in changing the behaviour of healthcare professionals, and thus needs to be supplemented with one-on-one as well as healthcare team mentorship. Evidence presented previously shows that knowledge gained from didactic training does not necessarily translate to better decision making. As the skills being transferred are from doctors to nurses, the availability of doctors for mentorship of nurses is imperative; however this limitation threatens the very solution. Availability of doctors is not only critical for mentorship, but also for supporting nurses who may often have to consult either in person or telephonically when faced with challenging clinical conditions. Even the simple task of referring a patient from a Level 1 primary care clinic to a Level 2 community health centre requires the availability of a doctor at the receiving facility to assess and manage the patient further.

Innovative mechanisms must be employed to ensure support and mentorship of nurses in the implementation of NIMART so as to protect both nurses and the public at large. Not all facilities have access to the resources provided in research or pilot projects such as the Lusisiki project, on which the evidence for the effectiveness of task-shifting is often based. In real life situations, nurses in rural areas and high-volume peri-urban health facilities often do not have access to mentoring teams, regular doctor visits and efficient referral systems. On the other hand, it may not just be an issue of such resources not being made available, but may be related to scarcity of such expertise in that particular region. Therefore, all avenues that can contribute to an overall supportive environment should be explored, including various forms of communication and media e.g. Health Worker Hotline for clinical expert advice, Drug Safety Enquiry Service, Telephonic Counseling Services, Mobile Applications for on-hand reference etc.

Legislation

The contents and certification of the said prescribed qualification and training as stipulated in the Nursing Act, 2005 (Act 33 of 2005) (s56 (1)) must still be decided by the Pharmacy Council and the Nursing Council in South Africa, so as to finally settle the matter on the acceptance of nurses' competency to prescribe ART for the implementation of NIMART. The Pharmacy Council has been legally designated as the body that has the final say as to which other professionals other than pharmacists may perform the duties of a pharmacist, and which professionals' prescriptions they may dispense. The Nursing Council, being the regulatory body for the nursing profession, should have a participatory role in defining the prescribing and dispensing roles of nurses and necessary training required by nurses as well

as which categories of nurses are best suited for these. Most importantly, the Nursing Council needs to review and update the scope of practice of the various categories of nurses so as to factor in the changes brought on by HIV management over the past decade, as well as the coming changes as task-shifting slowly realizes full implementation.

The Nursing Act, 2005 (Act 33 of 2005) in Section 39, stipulates the conditions relating to the continuing professional development of nurses. The Nursing Council is the body that should determine conditions relating to continuing professional development to be undergone by practitioners, as well as the nature and extent of such development. Based on evidence from other countries and based on previous discussions regarding the rapid turnover of clinical evidence in HIV research, continuing professional development is a non-negotiable if high standards of patient care and safety are to be achieved and maintained.

The Nursing Council therefore, needs to implement compulsory continuing professional development for nurses, most especially for the provision of ART as this is such a dynamic field with a high turnover of information.

Long-term Strategy and Sustainability

Despite the pervasive acceptance of a general shortage of doctors worldwide (WHO, 2007) and in developing countries more especially, it remains to be tested whether this shortage is absolute or merely relative. In my argument for the ethical basis for expanded access to ART, a case was made for a strong moral imperative for nurses to provide ART based on a duty to care. If there is such a strong moral imperative for nurses to provide ART based on a duty to care, is the same moral imperative not applicable to doctors?

Save producing more doctors and nurses, which should be a crucial long-term goal of any country faced with shortages of health care professionals and an HIV/AIDS epidemic, it may be worthwhile reviewing the utilisation of the current workforce to further optimize service delivery. Task-shifting from one cadre to another must also necessarily include offloading of some tasks from the receiving cadre to the next level below and a review of the tasks of the offloaded cadre so as to maximize productivity and avoid the perception that some cadres will now have less work at the expense of others.

Task-shifting of doctors' roles to nurses should not be implemented in isolation but rather that regulatory frameworks integrating task shifting within the national policy on human resources for health should be established. Additional strategies for long-term expansion of access to ART should ideally be incorporated into pre-service training of nurses and clinical officers, so as to ensure standardized skills and knowledge, as well as to save on the costs of additional in-service trainings, which further compromise service delivery by removing

much needed personnel from the service delivery platform.

Clinical Officer training in South Africa is still in its infancy, whilst Community Health Worker training has supposedly resulted in an over saturation of these low-level health workers, whilst their maximal utilization has been hampered by delays in policy implementation. Mid-level and low-level health worker training and integration into the health system needs to take priority so as to ensure long-term sustainability of NIMART.

Ethical Implementation of NIMART

As the discussions in this report have demonstrated that the adoption of NIMART as a strategy is a moral and ethical imperative, so should the strategy employed in its implementation. What is meant by this is that, the same consideration given to the millions of South Africans who might be negatively impacted by the continued lack of access to ART should be given to those who might be negatively impacted by the abortive implementation of NIMART. Pertaining to the ethical issues that can be drawn from the foregoing discussions a careful balance between the interests of nurses on one hand and the interests of citizens on the other hand needs to be maintained. Applying the Universal Ethical Principles (Beauchamp and Childress, 2001), and considering the interests of the various parties directly affected by NIMART, the following issues need careful attention:

Autonomy:

In their quest to fulfill their duty to care, nurses must not be reduced to mere pawns in the global race to expand HIV treatment. Consultation with nurses is necessary to restore a sense of control of their personal and professional development so that NIMART is not seen as a threat, but rather that they buy into the strategy and champion it. If nurses are to act as autonomous clinical practitioners as is inferred by NIMART, they must take ownership of their continuing professional development to ensure accountability. This must be balanced by continued efforts to inform and educate communities about the ongoing changes in the healthcare delivery platform, in particular NIMART and how it will impact them so as to minimize negative perceptions. Citizens need to be continuously educated about their rights in general and their rights to health in particular, so that they can be agents of change where facilities and resources fall short of what is ethically acceptable.

Beneficence:

In order for nurses to provide a service that is ethically acceptable adequate training and mentoring must be provided for each individual nurse that is required to implement NIMART as part of the social contract of the ethic of care. Training is not an isolated provision for

NIMART and therefore attention should be given to the accompanying supportive resources for the successful implementation of NIMART i.e. referral authority, referral policies, enabling legal framework for medicine prescribing. A standardised and accredited NIMART curriculum in the context of an effective health care system will minimize harm to citizens.

Non-maleficence:

Concerns about the medico-legal implication of NIMART need to be investigated in the South African context and where necessary. legal and labour advice services should be provided to nurses so that they fully understand how NIMART impacts them professionally. Citizens also need to be protected from possible harmful consequences of NIMART as may result from unskilled and incompetent nurses providing NIMART without adequate supervision or support. A reciprocal action of good faith as part of the social contract of the duty to care must involve a comprehensively implemented task-shifting strategy so as to avoid overloading of nurses with additional tasks without relieving them of some of their less skilled tasks, thus placing them at risk for stress and its related complications. Citizens deserve a caring and therapeutic environment and thus efforts must be made to ensure that nurses and facilities are enabled to provide care without the additional stressors.

Justice:

Despite the general and immediate financial constraints, it is necessary for political leadership to consider long-term incentives and remuneration of nurses for the additional tasks shifted onto them. This should be done in line with the principle of fair compensation for services rendered. Whilst adequate staff and resources should be provided for all communities regardless of whether they are rural or urban, rural settings have been repeatedly shown to be at a disadvantage in regard to access to training, referral networks and advanced medical services. In fact, special efforts must be made to address the inefficiencies and challenges of rural health services in order to ensure the realisation of fair equality of opportunity of rural, and financial incentives are one possible solution to attracting health professionals to rural areas.

Leadership

Strong and visionary leadership in whatever strategy is adopted is crucial to the sustainability of the strategy, so that it matters not whether the strategy is expected to save costs in the short term, or if it will be costly initially. Forward planning and inclusive collaboration are important for developing a sustainable strategy.

Public health officials and national public service leadership must collaborate on providing

strategic leadership in the current phase of development as well as in planning ahead for the continuing human resources shortages in the face of the multiple epidemics concurrently snowballing and soon to explode in the very near future. Policy makers are often out of touch with reality on the ground, thus resulting in policy formulation that is out of sync with the needs of the population, whilst on-the-ground staff often pushes for the resolution of their immediate concerns without considering the wider context. It is therefore imperative that a two-way communication and planning system be developed so as to capitalize on the strengths of their different views and solutions to current and future health delivery challenges.

Future Research

In writing this report, some areas that raised pertinent questions and for which answers remained elusive include the following:

- a) What are the different training curricula for NIMART training for nurses and what is the status of their accreditation by the South African Pharmacy Council if any?
- b) What is the progress in NIMART implementation i.e. how many nurses are practicing NIMART and how many patients have been initiated by these nurses?
- c) What are the clinical outcomes of NIMART and do they meet quality and ethical standards?
- d) What are the challenges faced by nurses in the implementation of NIMART?
- e) What is the legal position of nurses who perform tasks that were previously performed by doctors in South Africa? What impact does the scope of practice have on this legal position?
- f) How did the Occupation Specific Dispensation (OSD) benefit nurses who had been actively involved in ART prior to NIMART and how have these “experienced” nurses been of benefit in the implementation of NIMART?
- g) What are the views, concerns and experience of other health professionals who are directly affected by NIMART i.e. doctors and pharmacists? How are they facilitating NIMART?
- h) What is the experience and perception in the community of NIMART?

6.3 CONCLUSION

The existing legal framework for NIMART in South Africa is firmly founded in our Constitution

and further enabled by health policy which identifies Primary Health Care as a priority in order to realize better health for all. Challenges exist in implementation of specific yet critical aspects of the enabling legislation relating to nurse training and accreditation required for full authorization to practice NIMART, and these technical challenges if not attended to could threaten the long-term sustainability of NIMART. The ethical and legal implications of NIMART for nurses are significant and could have disastrous consequences if the regulatory framework is not adjusted to accommodate the rapidly changing landscape of task-shifting.

REFERENCES

- 1) Address by President Jacob Zuma on the occasion of World AIDS Day, Pretoria Showgrounds Available: <http://www.info.gov.za/speeches/2009/09120112151001.htm> [Accessed: 23 April 2012]
- 2) Assefaa Y, Van Damme W and Hermann K. Human resource aspects of antiretroviral treatment delivery models: current practices and recommendations. *Current Opinion in HIV and AIDS* 2010,5:78–82. Available: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094207/>. [Accessed: 05 September 2011].
- 3) Beauchamp T L, Childress J F. Principles of Biomedical Ethics, 5th edition. Oxford University Press, 2001.
- 4) Bedelu M, Ford N, Hilderbrand K, and Reuter H. Implementing Antiretroviral Therapy in Rural Communities: The Lusikisiki Model of Decentralized HIV/AIDS Care. *The Journal of Infectious Diseases* 2007; 196:S464–8. Available: jid.oxfordjournals.org. [Accessed: 26 May 2011].
- 5) Brentlinger PE , Assan A, Mudender F et al. Task shifting in Mozambique: cross sectional evaluation of non-physician clinicians' performance in HIV/AIDS care. *Human Resources for Health* 2010 8:23. Available: <http://www.human-resources-health.com/content/8/1/23>. [Accessed: 11 February 2011].
- 6) Breier M, Wildschut A, Mqgqolozana T. Nursing in a New Era: The Profession and Education of Nurses in South Africa. Cape Town: Health Sciences Research Council; 2010 April.
- 7) Bulletin of the World Health Organization 2003, 81 (10)
- 8) Bussmann C, Ndwapi N, Gaolathe T et al. Supporting National ART Scale-Up in Botswana through Standardized, Multi-phased Training. In: Marlink RG, Teitelman ST, eds. *From the Ground Up: Building Comprehensive HIV/AIDS Care Programs in Resource-Limited Settings*. Washington, DC: Elizabeth Glaser Pediatric AIDS Foundation; 2009. Available: <http://ftguonline.org>.. [Accessed: 24 August 2011].
- 9) Clinical Mentorship Manual for Integrated Services. Department of Health, South Africa; 2011.
- 10) 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. Available: <http://www.human-resources-health.com/content/8/1/8> [Accessed 27 February 2011].

- 11) Colvin CJ, Fairall L, Lewin S et al. Expanding access to ART in South Africa: The role of nurse initiated treatment. *SAMJ* 2010, 100:4; 210-212.
- 12) Dambisya YM, Matinhure S. Policy and programmatic implications of task shifting in Uganda: a case study. *BMC Health Services Research* 2012, 12:61. Available: <http://www.biomedcentral.com/1472-6963/12/61>. [Accessed:22 March 2012].
- 13) Daniels N, Light DW, Caplan RL. Benchmarks of fairness for health care reform. New York: Oxford University Press, Inc., 1996.
- 14) Dowling S, Martin R, Skidmore P et al. Nurses taking on junior doctor's work: a confusion of accountability. *British Medical Journal* 1996; 312: 1211–1214
- 15) Doyal L, Dowling S, Cameron A. Challenging practice: an evaluation of four innovatory nursing posts in the south west. Policy Press, University of Bristol, 1998.
- 16) Dwyer J, Tsai D F-C. Developing the duty to treat: HIV, SARS, and the next epidemic. *J Med Ethics* 2008; 34:7–10. Available at: jme.bmj.com. [Accessed: on 1 May 2012].
- 17) East, Central, and Southern African Health Community (ECSA-HC). 2010. Task Shifting in Uganda: Case Study. Washington, DC: Futures Group, Health Policy Initiative, Task Order 1. Available: <http://www.healthpolicyinitiative.com/Publications/Documents>. [Accessed: 24 August 2011]
- 18) Epidemic update, 2010 Global Report. Available: http://www.unaids.org/documents/20101123_GlobalReport_Chap2_em.pdf
- 19) Family Health International. Guidance for Nurse Prescription and Management of Antiretroviral Therapy. 2008.
- 20) Giliker P, Beckwith S 2004 Tort, 2nd edition. Sweet & Maxwell, London
- 21) Gray A. Prescribing and dispensing by nurses neglected steps in the legislative process. *Southern African HIV Clinicians Society Nursing Magazine*, 2010; 1(2):28-31.
- 22) Gray A, Vawda Y, Jack C. Health Policy and Legislation. In: Padarath A, English R, editors. *South African Health Review* 2011. Durban: Health Systems Trust; 2011.
URL: <http://www.hst.org.za/publications/south-african-health-review-2011>
- 23) Geyer N., 2010. Prescribing by Nurses. *HIV Nursing Journal*, 1:1, 14-15.
- 24) Harrowing JN and Mill J. Moral distress among Ugandan nurses providing HIV care: A critical ethnography. *International Journal of Nursing Studies* 2010; 47:723–731.
- 25) Hassim A, Heywood M, and Berger J. Health and Democracy: A guide to human rights,

- health law and policy in post-apartheid South Africa. Siberlink, 2007.
- 26) HIV & AIDS and STI National Strategic Plan for South Africa (NSP 2007-2011). South Africa, 2006.
 - 27) Humphreys CP, Wright J, Walley J et al. Nurse led, primary care based antiretroviral treatment versus hospital care: a controlled prospective study in Swaziland. *BMC Health Services Research* 2010 10:229. Available: <http://www.biomedcentral.com/1472-6963/10/229>. [Accessed: 18 August 2011].
 - 28) Institute of Medicine (U.S.). Scaling up treatment for the global AIDS pandemic: challenges and opportunities. Board on Global Health; Curran J et al. editors. Washington: National Academies of Sciences, 2005.
 - 29) Ivers LC, Jerome J-G, Cullen KA, Lambert W, Celletti F, et al. Task-Shifting in HIV Care: A Case Study of Nurse-Centered Community-Based Care in Rural Haiti. *PLoS ONE* 2008; 6(5):e19276. doi:10.1371/journal.pone.0019276. [Accessed: 28 April 2011].
 - 30) Knebel E, Puttkammer N, Demes A, Devirois R and Prismo M. Developing a competency-based curriculum in HIV for nursing schools in Haiti. *Human Resources for Health* 2008,6:17. <http://www.human-resources-health.com/content/6/1/17>. [Accessed: 10 September 2011].
 - 31) Kober K, Van Damme W. Scaling up access to antiretroviral treatment in Southern Africa: who will do the job? *Lancet* 2004; 364: 103ess t
 - 32) Lehmann U, Van Damme W, Barten F and Sanders D. Task shifting: the answer to the human resources crisis in Africa? *Human Resources for Health* 2009; 7: Available: <http://www.human-resources-health.com/content/7/1/49>. [Accessed: 17 August 2011].
 - 33) Marchal B, De Brouwere V and Kegels G. HIV/AIDS and the health workforce crisis: What are the next steps? *Tropical Medicine and International Health*; 2005:10(4):300 Available: <http://www.ncbi.nlm.nih.gov/pubmed/15807792>. [Accessed: 10 September 2011].
 - 34) Maxwell B. Just compassion: implications for the ethics of the scarcity paradigm in clinical healthcare provision. *J Med Ethics* 2009; 35:219–223. Available: <http://jme.bmj.com>. [Accessed: 1 May 2012].
 - 35) McQuoid-Mason D, Dada M. *A-Z of Nursing Law*. Geyer N editor. 2nd ed. Cape Town: Juta & Co, 2011.
 - 36) Miles K, Clutterbuck DJ, Seitio O, Sebege, Riley MA. Antiretroviral treatment roll-out in

- a resource-constrained setting: capitalizing on nursing resources in Botswana. *Bulletin of the World Health Organization* 2007; 85(7):501-568. Available: <http://www.who.int/bulletin/volumes/85/7/06-033076/en/index>. [Accessed: 28 August 2011].
- 37) Morris MB, Chapula BT, Chi BH, et al. Use of task-shifting to rapidly scale-up HIV treatment services: experiences from Lusaka, Zambia. *BMC Health Services Research* 2009, 9:5 Available: <http://www.biomedcentral.com/1472-6963/9/5>. [Accessed: 17 November 2011].
 - 38) Mullan F, Frehywot S: Non-physician clinicians in 47 sub-Saharan African countries. *Lancet* 2007, 370:2158–63.
 - 39) Munjanja OK, Kibuka S and Dovlo D. The nursing workforce in sub-Saharan Africa. *International Council of Nurses*, Geneva (2005). Available: <http://www.icn.ch/>. [Accessed: 17 November 2011].
 - 40) National Strategic Plan on HIV, STIs and TB 2012-2016. SANAC 2011 Available:www.sanac.org.za
 - 41) Ogilvie L, Mill JE, Astle B, Fanning A and Opare M. The exodus of health professionals from sub-Saharan Africa: balancing human rights and societal needs in the twenty-first century. *Nursing Inquiry* 2007; 14:114. Available: <http://hrhforafrica.org.za>. [Accessed: 17 August 2011].
 - 42) Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa, 2003. Department of Health, 2003.
 - 43) Queensland Nursing Council. Scope of nursing practice: Decision making framework. Brisbane: Queensland Nursing Council, 1998.
 - 44) Re-engineering Primary Health Care in South Africa Discussion Document, November 2010. Department of Health, 2010.
 - 45) Pillay Y. Selected Health Professional Legislation. In: Vasuthevan S, Viljoen M, editors. *Educating for Better Health: A Handbook for Healthcare Professionals*. Cape Town: Juta & Co.Ltd. 2003: 35-44.
 - 46) Rawls, J. A theory of justice. Revised edition. Harvard University Press, Cambridge, 1999.
 - 47) Ruderman C, Tracy CS, Bensimon CM. On pandemics and the duty to care: whose duty? who cares? *BMC Medical Ethics* 2006, 7:5. Available: <http://www.biomedcentral.com/1472-6939/7/5>. [Accessed: 1 May 2012].

- 48) SADC HIV prevention meeting: achieving prevention targets, June 7–9 2009, Johannesburg, South Africa. Gaborone, Southern Africa Development Community, 2009. Available: http://www.unaidsrstea.org/sites/default/files/sadc_prevention_june2009.pdf. [Accessed 23 August 2011].
- 49) Salter B. *The Politics of Change in Health Service*. London: Macmillan Press Ltd., 1998.
- 50) Samb B, Celletti F, Holloway J, Van Damme W, De Cock KM, and Dybul M. Rapid Expansion of the Health Workforce in Response to the HIV Epidemic. *NEJM* 2007; 357(24). Available: www.nejm.org. [Accessed: 6 October 2011].
- 51) Sante. 2009 Jul-Sep; 19(3):121-32.
- 52) Shumbusho F, van Griensven J, Lowrance D, Turate I, Weaver MA, et al. Task Shifting for Scale-up of HIV Care: Evaluation of Nurse-Centered Antiretroviral Treatment at Rural Health Centers in Rwanda. *PLoS Med* 2009; 6(10): e1000163.doi:10.1371/journal.pmed.1000163. [Accessed: 20 October 2011].
- 53) Hoffmann, D. South African Pharmacy Council, D Hoffmann/nv/ag, 12 May 2010.
- 54) Stringer JSA, Zulu I, Levy J et al. Rapid Scale-up of Antiretroviral Therapy at Primary Care Sites in Zambia: Feasibility and Early Outcomes. *JAMA*. 2006; 296(7):782-793. Available: <http://jama.ama-assn.org/cgi/content/full/296/7/782>. [Accessed: 28 April 2011].
- 55) Subedar, H. Nursing profession: Production of nurses and proposed scope of practice. *South African Health Review, HST*, 2005, p.88-101.
- 56) Treat, Train, Retain: The AIDS and health workforce plan. Report on the consultation on AIDS and human resources for health, WHO, Geneva, 11-12 May, 2006. Geneva, World Health Organization available at <http://www.who.int/hiv/pub/meetingreports/ttr/en/index.html>. [Accessed: 28 August 2011].
- 57) UNAIDS/WHO AIDS epidemic update: December 2003. Available: http://data.unaids.org/publications/irc-pub06/jc943-epiupdate2003_en.pdf
- 58) Universal Declaration of Human Rights. Available: <http://www.un.org/en/documents/udhr/index.shtml>
- 59) Van Damme W, Kober K and Laga M. The real challenges for scaling up ART in Sub-Saharan Africa. *AIDS* 2006, 20:653. Available: <http://www.uneca.org>. [Accessed: 20

October 2011].

- 60) Van Niekerk A, Kopelman LM. Principles of global distributive justice and the HIV/AIDS pandemic: moving beyond Rawls and Buchanan. In: Fleming C ed. *Ethics and AIDS in Africa: The Challenge to Our Thinking*. Cape Town: New Africa Books, 2005: 84-110.
- 61) Vasan A, Kenya-Mugisha N, Seung KJ, Achieng M, and Banura P. Agreement between physicians and non-physician clinicians in starting antiretroviral therapy in rural Uganda. *Human Resources for Health* 2009; 7:75. Available: <http://www.human-resources-health.com/content/7/1/75>. [Accessed: 19 November 2011].
- 62) World Health Organization. Antiretroviral therapy for HIV infection in adults and adolescents. Recommendations for a public health approach, 2010 revision. Available: www.who.int/hiv/pub/arv/adult2010/en/index.html.
- 63) Zachariah R, Ford N, Philips M, *et al.*, 2009. Task shifting in HIV/AIDS: opportunities, challenges and proposed actions for sub-Saharan Africa. *Trans R Soc Trop Med Hyg*, 103: pg549-558. Available:<http://www.ncbi.nlm.nih.gov/pubmed/18992905>, [Accessed 7 March 2011].

Legal References

South Africa. Constitution, No. 108 of 1996

South Africa. National Health Act, No.61 of 2003

South Africa. Nursing Act, No.50 of 1978

South Africa. Nursing Amendment Act, No. 19 of 1997

South Africa. Nursing Act, No. 33 of 2005

South Africa. Medicines and Related Substances Control Act, No.101 of 1965

South Africa. Medicines and Related Substances Amendment Act, No. 59 of 2002

South Africa. Medicines and Related Substances Control Amendment Act, No.90 of 1997

South Africa. Medicines and Medical Devices Regulatory Authority Act, No.132 of 1998

South Africa. Pharmacy Act, No. 53 of 1974

South Africa. White Paper on the Transformation of the Health System in South Africa, 1997.

Appendix A



EASTERN CAPE DEPARTMENT OF HEALTH
ASSISTANT MANAGER: PHARMACEUTICAL SERVICES
MR ADRIAAN LOUW
E-MAIL: Adriaan.Louw@impilo.ecprov.gov.za

Your Ref: Our Ref: Date:
D Hoffmann/nv/ag 12 May 2010

Dear Mr Louw

DISPENSING OF NURSE INITIATED ART PRESCRIPTIONS

We refer to the abovementioned matter and in particular your e-mail, the content of which pertains to the legality of dispensing of nurse initiated ART prescriptions by Pharmacists and any other implications/restraints regarding this matter.

We confirm that ART medicines are Schedule 4 and therefore in terms of Section 22A of the Medicines and Related Substances Act, 101 of 1965 may only be dispensed by a pharmacist on a valid prescription by a medical practitioner or an authorized prescriber.

We confirm that currently the South African Pharmacy Council is unaware of any nurses being identified/licensed as authorized prescribers in terms of the nurse initiated ART role out.

We further confirm that nurses who are registered in terms of Section 33A (old Nursing Act) / Section 56 (new Nursing Act) are permitted to dispense medicines they have prescribed, i.e. nurse initiated treatment in terms of prescribed regulations. However, it was and will at this stage continue to be the status quo that pharmacists can not dispense nurse initiated treatments unless such prescription has been authorized by a medical practitioner.

In conclusion we confirm that nurses (issued with a S38A/S56 registration) may dispense medicines on their own initiated treatments, and a pharmacist may only dispense on a valid prescription from an authorized prescriber.

We trust that this assists you in your enquiry herein.

Yours faithfully,
DEBBIE HOFFMANN
SENIOR MANAGER: LEGAL SERVICES & PROFESSIONAL CONDUCT

OBO MR TA MASANGO

ALL CORRESPONDENCE TO BE ADDRESSED TO THE REGISTRAR

**South
African
Pharmacy
Council**

Registered Office
SAPC Building
591 Belvedere Street
Arcadia, Pretoria 0083

Postal Address
Private Bag X40040
Arcadia 0007

Customer Care Line
0861 7272 00

Fax
(27)12-321 1492 /1479

E-mail
customercare@sapc.za.org

Website
www.sapc.za.org

Appendix B

University
of the Witwatersrand,
Johannesburg



Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical))

Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5709
Private Bag 3, Wits 2050, South Africa

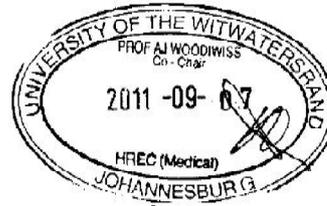
Ref: W-AJW-110906-2

06/09/2011

TO WHOM IT MAY CONCERN:

- Waiver:** This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).
- Investigator:** **Pelisa Ford (student number 456345)**
- Project title:** **A literature review and analysis covering the ethical and legal issues pertaining to the implementation of NIMART.**
- Reason:** This is a literature review of information in the public domain. No humans or patient records are involved.

Professor Angela Woodiwiss
Co-Chair: Human Research Ethics Committee (Medical)



copy: Anisa Keshav, Research Office, Senate House, Wits

Appendix C: Review of Studies/Reports on Task-shifting

Papers /Documents	Context and Objectives	Method	Findings	Issues identified
Bedelu, Ford, Hilderbrand & Reuter (2007)	South Africa, rural Lusikisiki district; Clinical Audit/Report of a decentralized HIV service delivery program to primary health care clinics, utilising task shifting (incl. nurse-initiated treatment), and community support.	Review of: Decentralization and task shifting. Training and mentoring through mobile teams. Creating new capacity.	Rapid scale-up of treatment with satisfactory outcomes achievable. 1-year outcomes comparable in the clinics and hospital. Greater proximity and acceptability of services led to faster enrollment into treatment and better retention (2% vs. 19% lost to follow-up). 95% coverage	-Nurse shortage a critical issue. -Creation of new capacity necessary for sustainability. -Lack of clear policy guidance and practice inconsistent with current policy. -Committed and innovative leadership necessary for sustainable financial support and ownership.
Colvin, Fairall, Lewin et al. (2010)	South Africa Preliminary review of evidence for NIMART using the Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) trial conducted in the Free State province. Training on the guidelines, nurse re-prescription, and finally, nurse initiation.	STRETCH is evaluating the effect of NIM-ART on ART access (by comparing mortality among patients eligible for treatment), and on quality of ART care (by comparing viral load suppression rates in those receiving ART)	-NIMART is highly acceptable among nurses, patients and doctors. -Managers and nurses confidence in their ability to apply the guidelines and deliver ART successfully -Nurse initiation increases access	-Ongoing clinical support -Clear criteria for the referral of complex cases - Knock-on effects e.g. training and support needs, workload and capacity constraints, logistical and infrastructural challenges, and shifts in the working and referral relationships between health staff. -Too-rapid roll-out that vs. incremental capacity, confidence, co-ordination and support building.
Brentlinger, Assan, Mudender et al. (2010)	Mozambique, rural; A nationwide evaluation of the quality of care delivered by non-physician clinicians (técnicos de medicina, or TMs), after a two-week in-service training course emphasizing ART.	44 randomly selected TMs directly observed by expert clinicians in their usual worksites. Observed clinical performance vs national norms as taught in the course.	Correct WHO stage-37.6%, Correct co-trimoxazole prophylaxis- 71.6% Correct ART- 75.5% Common errors: incl. assignment of WHO stage before patient evaluation, & initiation or continuation of co-trimoxazole or ART without indications or when contraindicated = lack of insight.	-The in-service ART training was suspended due to safety concerns. -Revision of policy : TMs' scope of work in HIV/AIDS care revised; new clinical guidelines defined, and a nationwide re-training and clinical mentoring program initiated.

Papers /Documents	Context and Objectives	Method	Findings	Issues identified
Bussmann, Ndwapi, Gaolathe et al.(2009)	Botswana, nationwide; Descriptive report of implementation of a MOH National training program with standardized training modules uniformly delivered to train a high volume of health staff ahead of the national ART roll-out.	-Phase 1- baseline assessments vs final examinations: Didactic Core Modules Advanced Modules (doctors & pharmacists) Satellite Modules Teaching Tools Distance Education -Phase 2- mentoring Clinical Master Trainer Program Laboratory Master Trainer Program	Marked improvement in knowledge - doctors and nurses. 85% active utilization of skills and knowledge gained. Knowledge retention below expectations. Training nurses in ARV prescribing and dispensing facilitated task shifting 63 - prescribing and dispensing course & 127 - dispensing course	-Treatment failure management will become critical in long-term ART. -Logistical approaches in training staff (urban vs rural). -Task-shifting requires standardized and expanded training efforts. -Retention of trained staff -Continual advances in HIV care and evolving needs of the health sector.
Dambisya & Matinhure (2012)	Uganda Objectives: 1. Reviews policy and programmatic implications of task shifting vs roles, responsibilities and workload of health workers for providing quality HIV care services. 2. Understand the policy & programmatic implications of task shifting in utilization of community based health workers and/or PLWHA 3. Assess attitudes & perceptions of health workers regarding task shifting	Qualitative, descriptive study through 34 key informant interviews, 8 focus group discussions, with participants from various levels of the health system.	Policy makers' vs front-line health workers' perception of task shifting incongruent. Absence of written policy /guidelines on task shifting. Factors in favour: -successful examples of task shifting, -proper referral channels, -the need for services, -scarcity of skills and -focused initiatives. Factors against: -seen as a quick fix for the poor, - threat to quality care and likely to compromise the health system.	Barriers: -reluctance to change, -protection of professional turf, -professional boundaries and regulations, -heavy workload & high disease burden, -poor planning, -lack of a task shifting champion, -lack of guidelines, -the name task shifting -unemployed health professionals.
Harrowing & Mill (2010)	Uganda; Describes the manifestation and impact of moral distress as it was experienced by Ugandan nurses who provided care to HIV-infected or -affected people. Critical ethnography was conducted with 24 acute care and public health nurses at a large referral centre in Uganda.	Data were collected through interviews, observation, and focus group discussions.	Nurses haunted by inability to ease suffering due to HIV. Impact of continuing education on capacity to transform attitudes and approaches in provision of nursing care. Concern about public's understanding of nursing role vs threat of disillusion due to inadequate resources, negative public perception, and staggering workloads.	-Constraints imposed by the inability to implement skills and knowledge to their fullest extent, as well as a lack of resources and infrastructure may result in the omission of care for patients.

Papers /Documents	Context and Objectives	Method	Findings	Issues identified
Vasan, Kenya- Mugisha, Seung, Achieng & Banura (2009)	Uganda A pilot study assessing agreement between non-physician clinicians (nurses and clinical officers, NPCs) and physicians in their decisions as to whether to start therapy. 12 government ART sites in three regions, all of which had staff trained in delivery of ART using the WHO Integrated Management of Adult and Adolescent Illness guidelines for chronic HIV care.	-Seven key variables to measure patient assessment and the decision to start ART; -Final ART Recommendation as primary variable of interest. -Patients saw a clinical officer or nurse first, then screened identically by a blinded physician in the same clinic visit. -Inter-rater agreement measured between NPCs and physicians in ART assessment variables.	-Nurses and clinical officers showed moderate to almost perfect agreement with physicians in their Final ART Recommendation. -Agreement was also substantial for nurses versus physicians for assigning WHO Clinical Stage but moderate for clinical officers versus physicians.	-Variation in the level of training of nurses depended on location and access to NGO support. -Clinical decision-making used as a proxy for quality of care and indication of clinical judgment that could be delivered by NPCs not ideal. -Ethical considerations in designing randomized trials that compare ART delivery and other HIV interventions delivered by non-physicians versus physicians i.e. safety must be proven first.
Humphreys , Wright, Walley et al. (2010)	Swaziland Evaluates the effectiveness of nurse led primary care based ART compared to usual hospital care in a typical rural setting. A prospective, controlled evaluation of planned service change.	Method: Clinically stable adults (CD4 count > 100; on ART +4 weeks at district hospital) assigned to either nurse led primary care based ART care or hospital care. Main outcome measures: clinic attendance and patient experience.	Primary care vs hospital -missed appointments better (RR 0.37, p <0.0001) -travel cost halved (p = 0.001) - satisfaction in staff management ability (RR 1.23, p = 0.003). Loss to follow up/other health outcomes equal.	-Drug toxicities, opportunistic infections or treatment failure not evaluated. -Ready access and appropriate referral to more specialised clinical care facilities for those receiving nurse led primary care based ART identified as critical.
Ivers, Jerome, Cullen, Lambert, Celletti et al. (2011)	Haiti, rural; A case study evaluating a health service delivery model of task-shifting in HIV care from doctors to nurses and community health workers. Data collected using mixed quantitative and qualitative methods at three clinics.	Distribution of tasks for HIV services delivery; Types of tasks performed by different cadres of healthcare workers; HIV program outcomes; Access to HIV care and Acceptability of the model to staff were measured.	Rapid scale-up achieved; Loss to follow-up < 5% at 24 months Staff satisfied with the model of care. Only 2% of HIV related tasks exclusive to doctors vs 64% in the traditional model of care.	-Need for ongoing training, supervision and adequate salaries for activities. -Role change not reduction i.e. additional duties. -A comprehensive, primary care approach to prevention, diagnosis and treatment of HIV, solid procurement system, collaboration with MOH and attention to socioeconomic needs critical for success.

Papers /Documents	Context and Objectives	Method	Findings	Issues identified
Knebel, Puttkammer, Demes, Devirois & Prismy (2008)	<p>Haiti.</p> <p>Ministry of Health and Population collaborated with the International Training and Education Center on HIV (ITECH) over a period of 12 months to create a competency-based HIV/AIDS curriculum to be integrated into the 4-year baccalaureate programme of the four national schools of nursing.</p>	<p>International health and education literature on HIV/AIDS competencies and models of curriculum development reviewed by Haiti-based curriculum committee. Expected HIV/AIDS competencies and related learning objectives drafted.</p> <p>Learning objectives mapped to current courses in the nursing curriculum and an 'HIV/AIDS Teaching Guide' for faculty on how to integrate and achieve these objectives within their current courses created.</p> <p>An 'HIV/AIDS Reference Manual' detailing the relevant HIV/AIDS content for each course also created.</p>	<p>-5 main HIV/AIDS competencies and 35 associated sub competencies finalised.</p> <p>-Over 350 learning objectives defined, with each sub-competency having multiple knowledge, skill and attitudinal learning objectives.</p> <p>-Up-to-date HIV/AIDS content factored into 'HIV/AIDS Reference Manual'</p> <p>-A 'HIV/AIDS Teaching Guide' organized by curriculum year and course approved for dissemination to the nursing schools.</p> <p>The final exam for nurses to obtain their license to practice also to be modified to reflect the new competencies.</p>	<p>-Identifying the right stakeholders for the coordinating committee and curriculum working groups.</p> <p>-A multidisciplinary approach enriched the collaborative process, garnered buy in, and improved the outcome.</p> <p>-Dedicated, passionate nurse leaders beneficial for curriculum development.</p> <p>-Collaboration between nursing schools provides a reproducible model for curriculum reform.</p> <p>-Stakeholders' experience, skills and motivation to strengthen other domains bolstered.</p> <p>-goals incorporated into Ministry of Health's strategic plan for 2005–10.</p> <p>-Flexible education must integrate into settings with varied types of HIV-related services and with varied staffing patterns.</p>
Miles, Clutterbuck, Seitio, Sebego & Riley (2007)	<p>Botswana;</p> <p>A concept paper which draws on experiences from the Botswana ART program.</p> <p>A clinical preceptorship program places senior international HIV clinicians in urban and rural hospitals and clinics for 3–6 months.</p>	<p>-Skills and confidence built through practical training and mentoring.</p> <p>-End 2004 numbers reached: 151 medical doctors 1701 nurses & counselors, 27 pharmacists 59 pharmacy technicians 22 preceptors involved 250 Family nurse practitioners est. in 1980s- equipped with advanced skills.</p>	<p>- Challenges:</p> <p>-Political and professional Barriers</p> <p>-Educational requirements and limitations of nursing practice</p> <p>-Clear referral pathways between medical and nursing personnel</p> <p>- Monitoring and supervision of practice.</p> <p>-Operational research to demonstrate safety, effectiveness and sustainability is lacking.</p>	<p>-Policy-makers and the public may perceive HIV care delivered by nurses is second-rate.</p> <p>- Taking on doctors' roles may feel threatening</p> <p>-New roles not factored into nurses' wages</p> <p>-Medico-legal position of nurses in enhanced role not formally recognized and clarified at the national level. Legislation, policy and guidance need review and modifying.</p>

Papers /Documents	Context and Objectives	Method	Findings	Issues identified
Morris, Chapula, Chi et al. (2009)	Zambia Descriptive report of a task-shifting strategy and provision of basic data demonstrating Feasibility.	Review and analysis of: <i>Provider roles in the task-shifting model</i> <i>Training</i> <i>Mentoring</i> <i>Continuous quality assurance</i>	-General improvements in several basic indicators despite significant increases in clinic volumes. -Strengths incl. focus on local capacity building and emphasis on clinical care quality rather than simple program indicators. -Criticism: intensive use of resources during the early years of scale-up.	-Trained personnel and central coordination lacking in rural settings. -Local government engagement a necessity. -Integration of task-shifting into formal nursing curricula - Recognition of expanded duties via certification, legal support, and professional regulation.
Stringer, Zulu & Levy et al. (2006)	Zambia, urban. The Ministry of Health had scaled-up HIV/AIDS care and treatment services at primary care clinics in Lusaka, using predominately non-physician clinicians. A report on the feasibility and early outcomes of the program. Main Outcome Measures: Survival, regimen failure rates, and CD4 cell response.	21 755 adults in HIV care, and 16 198 (75%) started ART. 1142 patients on ART died, 792 (71%) death 90 days of starting therapy (early mortality rate: 26 per 100 patient-years), 328 (29%) died after 90 days (post-90-day mortality rate: 5.0 per 100 patient-years). Of 11 714 patients at risk, 861 failed therapy by clinical criteria (rate, 13 per 100 patient-years)	-Massive, rapid scale-up of ART services with favourable clinical outcomes with NPOs. -Mortality highest at start of ART and in advanced HIV disease. Success factors: -Government leadership and political advocacy. - Use of standard care protocols by clinical officers and nurses circumvents the critical physician shortage. -Use of an electronic patient tracking and outcomes monitoring system. - Funded by PEPFAR	-Early mortality may be attributable to undiagnosed clinical conditions. -Limitation in ascertainment of new TB infections occurring while patients are receiving ART due to poor diagnostic methods.
Shumbusho, van Griensven, Lowrance, Turate, Weaver, et al. (2009)	Rwanda In September 2005, a pilot program of nurse-centered ART prescription was launched in three rural primary health centers. A retrospective evaluation of the feasibility and effectiveness of this task-shifting model using descriptive data.	Medical records of 1,076 patients (September 2005- March 2008) reviewed to assess: (i) compliance with national guidelines for ART eligibility, prescription, and patient monitoring (ii) key outcomes, such as retention, body weight, and CD4 cell count change at 6, 12, 18, and 24 mo after ART initiation.	-Nurses able to prescribe ART safely and effectively in a rural setting, given sufficient training, mentoring, and support. -Nurse-led prescribing of ART leads to rapid scale-up - Reduces burden of HIV care for doctors, freeing their time for other duties. - Rwandan Ministry of Health using study as basis for plans to adopt a task-shifting strategy for the national ART program.	-Pilot program for delivery of ART in rural areas vs a research project i.e. the most promising sites, nurses, and patients were selected for the pilot and careful monitoring may have been an additional motivation for the nurses and doctors taking part. -Task shifting as part of a wider investment in health systems, human resources, training, adapted medical records, tools & protocols.