Scope of Practice Laws Affecting ART Initiation and Maintenance in Tanzania

AIDS LAW BRIEF
BACKGROUND PAPER
SEPTEMBER 2015

I. Introduction

This AIDS Law Brief Background Paper assesses the legal environment in Tanzania[1] regarding scope of practice laws affecting the initiation and maintenance of antiretroviral therapy. This Background Paper compares the existing legal framework with the World Health Organization's (WHO) *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach*, which "strongly recommend" that non-physician clinicians, nurses, and midwives initiate and maintain (i.e., prescribe) antiretroviral therapy (ART) and that trained and supervised community health workers dispense ART between clinic visits.[2]

This AIDS Law Brief Background Paper was prepared by the University of Washington and the Tanzania Women Lawyers Association and provides support for an AIDS Law Brief on Scope of Practice Laws Affecting ART Initiation and Maintenance in Tanzania. This Background Paper does not constitute legal advice and should not be relied on for the purposes of complying with Tanzanian law.

II. Summary

- Tanzanian statutory law established councils to regulate physicians, nurses, midwives and pharmacists, but these statutory laws do not define their scopes of practice
- In 2014 the Nursing and Midwifery Council adopted a Scope of Practice for Nurses and Midwives that authorized nurses to initiate ART
- Tanzania has two cadres of non-physician clinicians (assistant medical officers and clinical officers), but neither cadre's scope of practice is established by statutory law
- Community health workers are not recognized or regulated by Tanzanian statutory law

III. Background

1. HIV/AIDS and the health worker shortage in Tanzania

UNAIDS estimates that approximately 1.4 million people in Tanzania are living with HIV and 5.3% of people between the ages of 15 and 49 are HIV positive.[3] Current estimated ART coverage in Tanzania is only 52 percent.[4]

Tanzania also has an acute shortage of health workers. The Tanzania Ministry of Health and Social Welfare ("MOHSW") estimated in 2008 that Tanzania had only 35% of needed health workers.[5] Other studies have found that Tanzania has 20% of needed clinical staff and 15% of needed nurses.[6] Tanzania has the lowest physician to population ratio in the world.[7]

"Task shifting" or "task sharing," such as nurse initiated and managed anti-retroviral therapy (NIMART), is used in many African countries to mitigate the impact of the health worker shortages. For example, Zuber et al. found that NIMART was being practiced in 11 out of 15 sampled African countries, but not in

Tanzania.[8] While NIMART is not being practiced widely in Tanzania, at least one recent study found that task shifting for other types of medical conditions "has been in practice for many years in Tanzania."[9]

2. WHO task shifting recommendations

The WHO has recommended task shifting to address health care worker shortages generally, and in Africa specifically.[10,11] The WHO task shifting framework identifies 4 classes of health workers: (1) medical doctors, (2) non-physician clinicians, (3) nurses, and (4) community health workers. The WHO has recognized that non-physician clinicians, nurses, and community health workers are capable of undertaking a number of tasks that may be outside of their traditional scope of practice.[12] The WHO also recognizes that a number of different task shifting practices are effective and that countries should "elect to adopt, adapt, or to extend, those models that are best suited to the specific country situation."[13] The WHO emphasizes that regardless of the task shifting model chosen, the three pre-requisites for effective task shifting are (1) appropriate training, (2) regular supportive supervision, and (3) well-functioning referral systems.[14] These pre-requisites can be supported by simple, standardized protocols for both treatment and monitoring and evaluation.[15]

The WHO global recommendations and guidelines on task shifting[16] include recommendations for creating and enabling the regulatory environment for implementation of task shifting.[17] The WHO has recognized that in the absence of a formal and enabling regulatory framework "government support and the necessary resources for task shifting will be lacking and the approach is unlikely to be sustainable."[18] The WHO has also found that a formal regulatory framework for task shifting is essential to the protection of both patients and health workers.[19]

The WHO task shifting guidelines recommend the use of existing legal frameworks when implementing the regulatory environment for task shifting, as "adapting the regulatory framework to accommodate task shifting need not necessarily involve extensive changes in policy and legislation."[20] To that end, the WHO recommends adopting a "fast-track strategy to produce essential revisions to … regulatory approaches (laws and proclamations, rules and regulations, policies and guidelines) where necessary."[21]

3. WHO's Task Shifting Guidelines for HIV Programs

The WHO has also issued strong recommendations regarding task shifting to scale up ART access. Specifically, the WHO's *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach* makes a "strong recommendation" that non-physician clinicians, nurses, and midwives initiate and maintain ART[22] and that trained and supervised community health workers dispense ART between clinic visits.[23]

a. The potential role of nurses and midwives in HIV programs

The WHO recognizes that nurses and midwives can "safely and effectively undertake a range of HIV clinical services."[24] This includes testing and counseling and associated services, and a wide variety of preventative services, including all major services associated with prevention of mother-to-child transmission, post-exposure prophylaxis, and positive prevention.[25] Additionally, the WHO recognizes that nurses and midwives can provide services in the clinical setting, such as HIV clinical staging and the management of opportunistic infection.[26] The WHO has found that nurses are competent to provide services for preparation, eligibility, recommendation (in the case of first line ART for ART-naïve patients) and initiation of ART, although the WHO recommends that nurses not prescribe second line ART medications.[27]

b. The potential role of non-physician clinicians in HIV programs

The WHO defines non-physician clinicians as professional health workers who are "not trained as a physician[s] but [are] capable of many of the diagnostic and clinical functions of a medical doctor and [have] more clinical skills than a nurse."[28] As discussed below, Tanzania has two categories of non-physician clinicians: assistant medical officers and clinical officers. The WHO recognizes that appropriately trained non-physician clinicians are competent for all tasks for which nurses and midwives are competent, and may additionally make ART recommendations for ART-experienced patients.[29] Early and long-term follow-up to ART treatment, treatment of HIV positive children and neonates, and the management of tuberculosis confection are other services which adequately trained nurses are capable of providing.

c. The potential role of community health workers in HIV programs

The WHO recognizes that community health workers may also provide services such as prevention and education services and basic monitoring (e.g., taking of weight, vital signs, or determination of the functional status of the patient), as well as distribution of ARTs and compliance assistance between doctor visits.[30] The WHO defines a community health worker as one "who has received training that is outside the nursing and midwifery medical curricula but is, nevertheless, standardized and nationally endorsed. This category can include health workers with a range of different roles and competencies and those who are providing essential services in a health facility, or in the community as part of, or linked to, a health team at a facility."[31]

IV. Key Findings

1. Tanzanian statutory law establishes councils to regulate physicians, nurses, and pharmacists, but does not define scopes of practice for any of these cadres

Tanzania statutory law recognizes and establishes professional councils for physicians (known as "medical practitioners"), nurses, and pharmacists. However, Tanzanian statutory law does not define scopes of practice for any of these cadres.

a. Medical Practitioners and Dentists Act may restrict the ability of other cadres to engage in the practice of medicine

The Medical Practitioners and Dentists Act established the Tanganyika Medical Council and the registration process for physicians, who are referred to in the law as *medical practitioners*. The Medical Practitioners and Dentists Act defines the practice of medicine or surgery as "to give medical or surgical treatment or advice."[32] Section 40 of the act states:

> "Any person who…not being registered or licensed under the provisions of this Act as a medical practitioner practices or holds himself out whether directly or by implications as practicing or as being prepared to practice medicine or surgery…commits an offence and is liable upon conviction to a fine not exceeding ten thousand shillings or to imprisonment for a term not exceeding five years or to both."[33]

Nurses and non-physician clinicians could be concerned that, if they prescribe medications, they could be prosecuted for the unlicensed practice of medicine under Section 40 of the Medical Practitioners and Dentists Act. Notwithstanding this section, the Medical Practitioners and Dentists Act does provide that "[n]othing contained in this Act shall be deemed to prohibit or prevent…any person carrying out duties appropriate to a nurse under the supervision or pursuant to the instructions of a registered or licensed medical practitioner."[34]

b. Nursing and Midwifery Council has authorized nurses to initiate ART

Nursing and midwifery in Tanzania are regulated by the Tanzania Nursing and Midwifery Council, established by the Nursing and Midwifery Act.[35] The Nursing and Midwifery Council is charged with the general regulation of the nursing profession, including the "standards of conduct, performance and ethics expected from nurses and midwives and prospective nurses and midwives" and with making policy recommendations to the MOHSW.[36] The Nursing and Midwifery Act grants the Minister of Health and Social Welfare (MOHSW) broad powers to make rules and regulations regarding nursing and midwifery practice on advice of the Nursing and Midwifery Council.[37] The Nursing and Midwifery Act does not prescribe scope of practice for nursing or midwifery. The Tanzania Nursing and Midwifery Council and the MOHSW, whether alone or on the advice of the Council, have authority under the Nursing and Midwifery Act to define those duties appropriate to a nurse, including duties relating to prescribing medications, including ART.[38]

In 2014, the Tanzania Nursing and Midwifery Council exercised its regulatory authority by issuing guidance titled *Scope of Practice for Nurses and Midwives in Tanzania*.[39] The guidance divides Tanzanian nurses and midwives into six categories: (1) Certificate in Nursing/Midwifery (also referred to as an enrolled nurse/midwife); (2) Diploma in Nursing/Midwifery (also referred to as a registered nurse/midwife); (3)

Advanced Diploma in Nursing/Midwifery; (4) Bachelor's Degree in Nursing Midwifery Sciences; (5) Master's Degree in Nursing/Midwifery; and (6) Doctorate Degree or PhD in Nursing Midwifery. The Nursing Scope of Practice guidance provides general scopes of practice for the above categories and specific scopes of practice for: public health nurses, paediatric nurses, nurses participating in Integrated Management of Childhood Illnesses programs, infectious diseases (including HIV/AIDS), non-communicable diseases, mental health and psychiatric nurses, operating theatre nurses, nurse anesthetist, ophthalmic nurses, and nurse tutors/lecturers.

The nursing and midwife scope of practice for HIV/AIDS addresses a range of activities central to ART initiation and maintenance, including counseling and testing, care coordination and supervision, reviewing and updating quality standards, and ART initiation and management. With respect to ART initiation for HIV/AIDS, the specific scope of practice for infectious diseases states that certificate level nurses, also known as enrolled nurses, may "Initiate ART including [Post-Exposure Prophylaxis]" and prevention of mother-to-child treatment (PMTCT).[40] Nurses with a diploma or advanced diploma level may "Prescribe and initiate ART (including [Post-Exposure Prophylaxis]) as per protocol – and supervise the practice."[41] Based on this scope of practice guidance, it appears clear that diploma level/registered nurses may prescribe ART in Tanzania. It is less clear, however, whether an enrolled nurse's authority to "initiate" ART means that an enrolled nurse can prescribe ART or if a certificate/enrolled nurse may only dispense ART on the orders of a diploma/registered-level or higher nurse.

c. The Pharmacy Act allows the MOHSW to authorize the Pharmacy Council to allow community health workers to dispense ART and other medicines

Pharmacists in Tanzania are regulated by the Pharmacy Council, which was established by the Pharmacy Act.[42] The Pharmacy Council is charged with the general regulation of pharmacists, pharmaceutical technicians, and pharmaceutical assistants, including the regulation of pharmacy standards and practices, and with advising the Minister on pharmacy matters.[43]

The Pharmacy Act provides that where "public interest require and upon advice of the Council, the [MOHSW] may…by order published in the *Gazette*, allow any persons or group of person to be permitted by the Council to dispense such medicines as may be specified."[44] The same section states that the special permit allowed by the Minister may require the applicant for such a permit to possess specified qualifications or training.[45]

The Council may itself also "issue a dispensing certificate to a practicing medical practitioner."[46] The Pharmacy Act defines *medical practitioner* as someone who is registered under the Medical Practitioners and Dentists Act, which is generally only possible for medical doctors.[47]

2. Tanzanian statutory law does not establish scopes of practice for non-physician clinicians (i.e., "assistant medical officers" and "clinical officers"), medical attendants, or community health workers

Tanzanian statutory law does not establish the scopes of practice for the two cadres of non-physician clinicians in Tanzania (known as "assistant medical officers" and "clinical officers"), medical attendants, or community health workers.

a. Assistant medical officers can be authorized to practice medicine and surgery

Assistant medical officers are the cadre of non-physician clinicians in Tanzania with the most training.[48] Assistant medical officers receive an Advanced Diploma in Medicine after completing a two-year training program accredited by the Tanganyika Medical Training Board.[49] To be admitted to an assistant medical officer training program, applicants must have practiced as a clinical officer (see below) for at least three years.[50] After completing the assistant medical officer training program, the Medical Practitioners and Dentists Act permits assistant medical officers to be registered as a "medical practitioner" by the Tanganyika Medical Council.[51] If an assistant medial officer is registered with the Tanganyika Medical Council, he or she would be authorized to practice medicine, surgery and midwifery. However, to be registered as a medical practitioner, the Medical Council must be "satisfied that such person has sufficient qualifications, skill and experience in the practice of medicine, surgery, and midwifery."[52] An assistant medical officer has no appeal rights if his/her application to the Medical Council is denied.[53] The Medical Practitioners and Dentists Act does not define the scope of practice of assistant medical officers who are not registered as medical practitioners with the Medical Council.

b. Clinical officers are regulated by the Medical Council, but their licensed scope of practice is unclear

Clinical officers are an important cadre of non-physician clinicians in Tanzania and are primarily regulated by the Tanganyika Medical Council.[54] Clinical officers must complete a three year training program after completing at least grade 10.[55] The Tanganyika Medical Training Board accredits clinical officer training programs.[56] After completing the training program, a clinical officer can apply for a license from the Medical Council.[57] Clinical officers are generally authorized to manage common medical and reproductive health conditions and simple surgical problems.[58]

c. Medical attendants are the largest cadre of health workers, but are largely unregulated

Medical attendants, sometimes referred to as medical assistants, comprise the largest cadre of health workers in Tanzania.[59] Medical attendants have little, if any, formal training.[60] Little information is available on the regulation of medical attendants, but it appears that medical attendants are divided into at least four categories: laboratory, pharmacy, nursing, and mortuary.

d. Community health workers appear largely unregulated, and their legal authority to dispense ART between clinic visits may require a decree from the MOHSW

WHO ART Guidelines strongly recommend that trained community health workers dispense ART medications between clinic visits.[61] Community health workers have been used in a range of roles in Tanzania, including: home based care providers, community-based distributors/educators (family planning and HIV education), para-social workers for orphans and vulnerable children/most vulnerable children, peer HIV educators, peer counselors, community maternal, newborn and child health care providers, life skills trainers, and traditional birth attendants.[62] CHW training programs are not standardized and their content varies.[63] Community health workers do not appear to be registered, licensed, or certified by the Tanzanian government. The practice of dispensing medications, however, is regulated by the Pharmacy Act and the Pharmacy Council. For community health workers to be legally authorized to dispense medications, the MOHSW with the "advice of the Pharmacy Council" would likely need to issue a decree in the national *Gazette* or adopt a regulation permitting certain community health workers to dispense ART medications. [64] The decree could state that certain trained and recognized community health workers are authorized to dispense ART medications to persons between clinic visits who are otherwise under the care of a health worker authorized to prescribe ART.

V. Considerations

As described above, the Tanzanian scope of practice regulatory scheme is generally undefined and flexible. The Medical Council, Nursing Council, Pharmacy Council, and MOHSW have a great deal of delegated authority to clarify authority of various cadres of health workers to play significant roles in ART programs. This permits a framework with the responsiveness recommended by the WHO without requiring additional statutes or legislation. The *Scope of Practice for Nurses and Midwives in Tanzania* recently adopted by the Nursing and Midwifery Council provides helpful guidance to nurses and midwives regarding their permissible roles in ART initiation and maintenance. However, as noted above, the scopes of practice for non-physician clinicians and community health workers are generally undefined.

To align with WHO recommendations, Tanzania could consider adopting a formal, enabling task shifting policy and regulatory framework for clinical officers, medical attendants and community health workers. The respective regulatory councils have the authority to promulgate the necessary regulations for medical practitioners and midlevel health workers. The MOHSW also likely has the authority to promulgate the necessary regulation for all these cadres, although in the case of pharmacists this should be on the advice of the Pharmacy Council. The regulatory framework should be flexible and not unduly restrict the scope of any cadres. The recently adopted *Scope of Practice for Nurses and Midwives in Tanzania* could be used as a model for adopting similar scopes of practice guidance for clinical officers, medical attendants and community health workers. We learned that a broad MOHSW task-shifting enabling policy may be in draft form, but we were not able to obtain a copy of the draft policy.

VI. Research Methods

This AIDS Law Brief Background Paper analyzes scope of practice laws in Tanzania for nurses, non-physician clinicians, and community health workers in Tanzania and the implications of these laws, or lack thereof, for scale up of NIMART in Tanzania. To assess the legal framework in Tanzania relating to scope of practice issues, we used a wide range of online legal and non-legal resources in the preparation of this Background Paper, including: LexisNexis, Westlaw, GlobalLex, WorldLII, and Brill Online. Legislative acts were accessed primarily through either the Tanzania legislature's website or the website of the Law Reform Commission of Tanzania. WHO, UNICEF, and UNAIDS resources were consulted for guidelines and best practices, as wells as HIV/AIDS data for Tanzania and East Africa. Non-legal databases included the Library of Congress, PubMed, EBSCO, and the University of Washington WorldCat service. Sections of the Laws of Tanzania (Revised Edition 2002) unavailable through online resources were obtained from the library at the UC Berkeley School of Law. Primary research limitations were the shortage of secondary research on the topic, the lack of an official edition of the 2002 revision of the Laws of Tanzania online, and the incomplete nature of online resources for Tanzanian case law.

Authors: Jeff Lane, Michael Windle, Sallie Sanford, Amy Hagopian, Tike Mwambipile and Aaron Katz.

This AIDS Law Brief Background Paper was prepared by the University of Washington and the Tanzania Women Lawyers Association and has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of Cooperative Agreement Number U48-DP001911. The findings and conclusions are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. This AIDS Law Brief does not constitute legal advice.

References:

[1] Unless otherwise specified, these findings apply only to mainland Tanzania. Zanzibar has a separate legislative and judicial system, and is independent from the rest of Tanzania in matters not designated as "Union Matters" in Schedule 1 of the Constitution of the United Republic of Tanzania.

[2] WHO, CONSOLIDATED GUIDELINES ON THE USE OF ANTIRETROVIRAL DRUGS FOR TREATING AND PREVENTING HIV INFECTION, 192 (2013).

[3] *United Republic of Tanzania: HIV and AIDS Estimates (2014)*, UNAIDS.ORG, http://www.unaids.org/en/regionscountries/countries/unitedrepublicoftanzania (last accessed September 13, 2015).

[4] UNAIDS, COUNTRY CASE STUDY: UNITED REPUBLIC OF TANZANIA, 2 (2012).

[5] MINISTRY OF HEALTH AND SOCIAL WELFARE, HEALTH SECTOR STRATEGIC PLAN III JULY 2009 – JUNE 2015, 11 (2009).

[6] Fatuma Manzi, et al., *Human resources for health care delivery in Tanzania: a multifaceted problem*, 10:3 HUM. RESOURCES FOR HEALTH 1, 1 (2012).
[7] Michael A. Munga and Ottar Mæstad, *Measuring inequalities in the distribution of health workers: the case of Tanzania,* 7:4 HUM. RESOURCES FOR HEALTH 1, 3 (2009).
[8] Alexandra Zuber et al., *A Survey of Nurse-Initiated and -Managed Antiretroviral Therapy (NIMART) in Practice, Education, Policy and Regulation in East, Central and Southern Africa*, 25:6 J. Ass'n Nurses in AIDS Care 520 (2014).
[9] Michael A. Munga, et al., *Experiences, opportunities and challenges of implementing task shifting in underserved remote settings: the case of Kongwa district*, 12:27 BMC INT. HEALTH AND HUM. RIGHTS 1, 1 (2012).
[10] WHO, TASK SHIFTING: RATIONAL REDISTRIBUTION OF TASKS AMONG HEALTH WORKFORCE TEAMS: GLOBAL RECOMMENDATIONS AND GUIDELINES, 3–5 (2008), *available at* http://www.who.int/healthsystems/TTR-TaskShifting.pdf.
[11] Brent D. Fulton, et al., *Health workforce skill mix and task shifting in low income countries: a review of recent evidence*, 9:1 HUM. RESOURCES FOR HEALTH 1 (2011).
[12] For complete recommendations, *see* TASK SHIFTING: GLOBAL RECOMMENDATIONS AND GUIDELINES, *supra* note 10, at 51–63 (Annex 1).
[13] *Id*. at 5, 38–40 (Recommendation 16).
[14] *Id*. at 18, 38 (Recommendation 16).
[15] *Id*. at 38 (Recommendation 16).
[16] TASK SHIFTING: GLOBAL RECOMMENDATIONS AND GUIDELINES, *supra* note 10.
[17] *Id.* at 20–23 (Recommendations 5–6).
[18] WHO, STRENGTHENING HEALTH SERVICES TO FIGHT AIDS, 7 (2007).
[19] TASK SHIFTING: GLOBAL RECOMMENDATIONS AND GUIDELINES, *supra* note 10, at 25 (Recommendation 7).
[20] *Id.* at 21 (Recommendation 5).
[21] *Id*. at 23 (Recommendation 6).
[22] CONSOLIDATED GUIDELINES, *supra* note 2, at 192.
[23] *Id.*
[24] *Id.* at 5, 43–45 (Recommendation 19).
[25] TASK SHIFTING: GLOBAL RECOMMENDATIONS AND GUIDELINES, *supra* note 10, at 54–55 (Annex 1).
[26] *Id.* at 55.
[27] *Id.* at 56–58 (Annex 1).
[28] *Id*. at 80 (Annex 6).
[29] *Id.* at 56–59 (Annex 1).
[30] *Id.*
[31] TASK SHIFTING: GLOBAL RECOMMENDATIONS AND GUIDELINES, *supra* note 10, 79 (Annex 6).
[32] Medical Practitioners and Dentists Act, 11/1959, § 2 (Tanz.).
[33] *Id.* § 40.
[34] *Id.* § 38(f).
[35] Nursing and Midwifery Act, 1/2010, §§ 4–8 (Tanz.).

[36] *Id.* §§ 6(b), 6(i).
[37] *Id.* §§ 48–49.
[38] *Id.* §§ 6, 48–49.
[39] TANZANIA NURSING AND MIDWIFERY COUNCIL, SCOPE OF PRACTICE FOR NURSES AND MIDWIVES IN TANZANIA (2014).
[40] *Id.* at 21.
[41] *Id.*
[42] Pharmacy Act, 1/2011, § 3 (Tanz.).
[43] *Id.* § 4.
[44] *Id.* § 40(1).
[45] *Id.* § 40(2).
[46] *Id.* § 42(1).
[47] *Id.* § 2.
[48] WHO, MID-LEVEL HEALTH WORKERS FOR DELIVERY OF ESSENTIAL HEALTH SERVICES: A GLOBAL SYSTEMATIC REVIEW AND COUNTRY EXPERIENCES, ANNEX 5: TANZANIA ,14 (2013).
[49] *Id.* at 15, 18.
[50] *Id.* at 14, 18.
[51] Medical Practitioner and Dentists Act, *supra* note 32, § 22.
[52] *Id.*
[53] MID-LEVEL HEALTH WORKERS, *supra* note 48, at 14.
[54] *Id.* at 15.
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.* at 14, 17.
[59] ANNEX 5, *supra* note 48, at 13; *see also* Delanyo Dovlo, *Using mid-level cadres as substitutes for internationally mobile health professionals in Africa: A desk review*, 2 HUM. RESOURCES FOR HEALTH 7, 11 (2004).
[60] *Measuring inequalities in the distribution of health workers*, *supra* note 7, at 3.
[61] CONSOLIDATED GUIDELINES, *supra* note 2, at 35, 192.
[62] Japhet Killewo, et al., *Community Health Workers' Training and Deployment in Tanzania: A review of PEPFAR funded programs*, 2 (2012), *available at* https://www.advancingpartners.org/sites/default/files/tanzania_community_health_workers_training_deployment.pdf.
[63] *Id.*
[64] *See* Pharmacy Act, *supra* note 42, § 40.