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SCHOOL OF CLINICAL MEDICINE

STEVE BIKO CENTRE FOR BIOETHICS

Ethical and Legal Issues Related to Health Surveillance Assistants' Job Description in Malawi

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A Research Report submitted to Faculty of Health Sciences, University of Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Masters of Science in Medicine in Bioethics and Health Law

JOHANNESBURG, 25th SEPTEMBER 2017

DECLARATION

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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ABSTRACT

The study critically analyzes the ethical and legal issues related to Health Surveillance Assistants (HSAs) job description in Malawi. HSAs are community health workers employed by the Ministry of Health and comprise 30% of the health workforce. Historically, the HSAs cadre evolved from Smallpox Vaccinators in 1960s, to Cholera Assistants in 1973 and HSAs in 1995.

Due to the shortage of qualified health workers, the Ministry of Health delegated clinical tasks to HSAs to provide curative care in rural areas in addition to their traditional basic environmental health roles to improve health care access. However, the delegation of clinical tasks to HSAs attracts ethical and legal issues which are the basis of this research.

I argue that the benefits of using HSAs include reducing disparity and inequality in accessing quality health care between urban and rural population. However, I claim that HSAs clinical practice exposes patients to risks of harm and conflicts with ethical and legal principles. I recommend that HSAs upon completion of accredited training should be regulated using the Reservation of the Title Only and Grandfathering for experienced HSAs by a health regulatory body. Furthermore, I recommend that the Ministry of Health, regulatory bodies and stakeholders should review the policy frameworks which will guide on supervision, liability standards, and training of HSAs.

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LIST OF ABBREVIATIONS

ACSD – Accelerated Child Survival and Development

ARI- Acute Respiratory Infections

CEDAW – Convention on the Elimination of all forms of Discrimination against Women

CHW- Community Health Workers

DBS - Dry Blood Samples

DPMA – Depot Medroxyprogesterone Acetate

EID - Early Infant Diagnosis

HCAs- Health Care Assistants

HSAs - Health Surveillance Assistants

ICCM – Integrated Community Case Management

ICESCR – International Covenant on Economic, Social and Cultural Rights

NGO – Non –Governmental Organization

NTDs - Neglected Tropical Diseases

PMTCT- Prevention of Mother to Child HIV Transmission

SADC- Southern African Development Committee

STI - Sexually Transmitted Infections

TTV – Tetanus Toxoid Vaccine

UDHR – Universal Declaration of Human Rights

UNICEF – United Nations Children's Fund

WHO – World Health Organization

DEFINITIONS OF TERMS/NOMENCLATURE

1. **Task sharing** is "the process by which tasks are delegated to less specialized workers in order to use human resources more efficiently and increase capacity and health care coverage within a constraint budget." (Padmanathan, 2013)
2. **Task shifting**: is the "rational redistribution of tasks from highly qualified health workers to lower cadre health workers for efficient use of human resources, from specialist doctors, non–physicians, nurses, community health workers." (World Health Organization, 2008)
3. **Case Managers** are community health workers "who are involved in the diagnosis, treatment of core ICCM diseases such as pneumonia, diarrhea, and malaria, including malnutrition and neonatal care and they, may supervise other CHWs cadres that have less disease-related activities, for example, health promoters." (Kumar, 2014)
4. The **health post** is "the basic level of service delivery provided by HSAs supported by Village Health Committees and members of the community based on Essential Health Care package" (MOH, 2009)
5. A **health centre** is "defined as the health facility that provides primary health care including preventive, curative and promotional care, EPI, antenatal care, usually has 13 beds and supported by limited laboratory services." (MOH, 2009)
6. **District Hospital** complements as a referral point hospital from the Health Centre, providing more advanced curative care, plus internal medicine supported by a well - equipped laboratory, x-ray, pediatrics, obstetrics and gynecology and general surgery. It also provides primary health care. (MOH, 2009)

7. **A Central Hospital** is a hospital clinically run by the medical doctors, clinical officers, medical assistants, dental therapists, laboratory technicians and laboratory technologists, radiography technicians and radiographers, environmental health officers, assistant environmental health officers, nutritionists, nurses and pharmacists.
8. **A Community Hospital** is a facility that has bed capacity ranging from 50-200 and is cut between a health centre and a district hospital. (MOH, 2009).
9. **Certification** means "that someone is certified that he/she is qualified to perform a defined job and also means that others can rely on this proof of your qualifications." (Rush, 2012)
10. **Licensing** means that "what the licensed person does is illegal to do without the license. For example, in a clinical occupation such as medicine the licensed individual is expected to be accountable for producing clinical outcomes with individual patients or clients." (Rush, 2012)
11. **Registration** is "similar to licensing, in that for some occupations, it is a requirement to practice some activities, for example, a Registered Nurse as the most familiar example of registration as a form credentialing." (Rush, 2012)
12. **Grandfathering** is defined as "any policy or rule that exempts a group of individuals, organizations, drugs from meeting new standards or regulations. For example, when a new subspecialty board in internal medicine is created, the physicians practicing in that area may be grandfathered into that subspecialty and not required to meet residency or other educational requirements." (Seden Medical Dictionary, 2012)
13. **The Medical Practitioner** in this document shall mean medical doctors, clinical officers and medical assistants.

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CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND LITERATURE ANALYSIS AND CRITIQUE

1.1.1 Historical Background of Health Surveillance Assistants

Historically, Malawi has had a problem of shortage of health workers. "According to 2012 World Health Organization Report (WHO) on the health situation analysis of the African Region, Malawi compared on the country level with other countries in the Southern African Development Community region (SADC), scores poorly, for example: the physician-to-population ratio per 100,000 stands at 0.2 as compared to 1.2 for Uganda, 3.4 for Botswana, 3.7 for Namibia while the ratio for nursing and midwifery per 100,000 stands at 2.8 as compared to 13.1 for Uganda, 27.8 for Namibia and 28.3 for Botswana." (Ministry of Health, 2014)

Additionally, according to the WHO report on Density of skilled health professionals in East, Central and Southern Africa, Malawi has the least density of skilled health professionals of doctors, nurses and midwives/100,000 population and compared to other African countries "Malawi has 0.362, Mozambique 0.452, Tanzania 0.462, Zambia 0.957, Zimbabwe 1.418 and South Africa 5.890." (ECSA Health Community, 2016) Furthermore, to the shortage of health workforce, Malawi has both a high disease burden and high fertility rate as shown in the following indicators: "total fertility rate 4.4 children per woman, infant mortality rate 42 per 1000 live children, child mortality rate 23 per 1000 live births and under-five rate 64 per 1000 live births." (National Statistical Office, 2016)

Since 1964 to the early 1990's, there was no medical school to train doctors and Malawi relied on the delegation of duties from highly qualified cadres to other lower health cadres such as from doctors to non-physicians and to community health workers. Thus, in 2008, Malawi adopted the principle of Task Shifting set by the World Health Organization (WHO) which guides countries on proper delegation of clinical tasks among health workers. (Ministry of Health, 2014) Based on this principle, the organization set up guidelines such as Recommendations 5 and 8 which "provide for countries to consider assessing and using their current regulatory frameworks (laws and proclamations, rules and regulations, policies and guidelines) in order to allow health workers to practice per the expanded scope of practice. (World Health Organization, 2008)

In Malawi, Health Surveillance Assistants (HSAs) are community health workers employed by the Government of Malawi under the Ministry of Health. (Phuka, 2014) A Community Health Worker is defined as "a community member who works almost exclusively in community settings and who serves as connectors between health care consumers and providers to promote health among groups that have traditionally lacked access to adequate health care." (Miller, 2014)

In 1960s, HSAs were called Smallpox Vaccinators. (Phuka, 2014) Following the cholera outbreak in 1973, Malawi created the community health worker cadre known as Cholera Assistants who were responsible for conducting mass cholera vaccinations, tracing and follow-up of the cholera patients, collecting data, chlorination of drinking water, and conducting health education. At the end of the outbreak, the demand for community health workers increased. Hence in 1995, the Ministry of Health created a cadre of Health Surveillance Assistants (HSAs), whose main purpose was preventive and health promotion. (Ministry of Health, 2014)

Accordingly, Health Surveillance Assistants are defined as “salaried community health workers responsible for preventive health and for several curative roles.” (Kok, 2013) In 2009, there were 10 507 HSAs constituting the largest health workforce in all districts in Malawi and they are under the Environmental Health Department within the Ministry of Health in Malawi. (Kok, 2013) In addition, it is reported that “HSAs comprise of 30% of the total health workforce in Malawi and often serve rural communities at a targeted ratio of 1:1000.” (Smith, 2014). Furthermore, they also provide immunizations for children at the Central Hospitals, District Hospitals and Community Hospitals.

Comparatively within Africa, Kumar et al found that “there were 37 CHW cadres in East, Central and Southern Africa and were classified as Case Manager, Community Liaison, Health Promoters and Traditional Birth Attendants. Case Managers are involved in diagnosis, treatment of core Integrated Community Case Management (ICCM) diseases such as pneumonia, diarrhea, and malaria, including malnutrition and neonatal care and supervision of lower CHWs” (Kumar, 2014) Hence, HSAs fall within the group of Case Managers since these activities are consistent with their current job description.

The Environmental Health Department hierarchy consists of different levels within the Ministry of Health from Environmental Health Officers, Assistant Environmental Health Officers at supervisory and program levels and the Health Surveillance Assistants in the community.

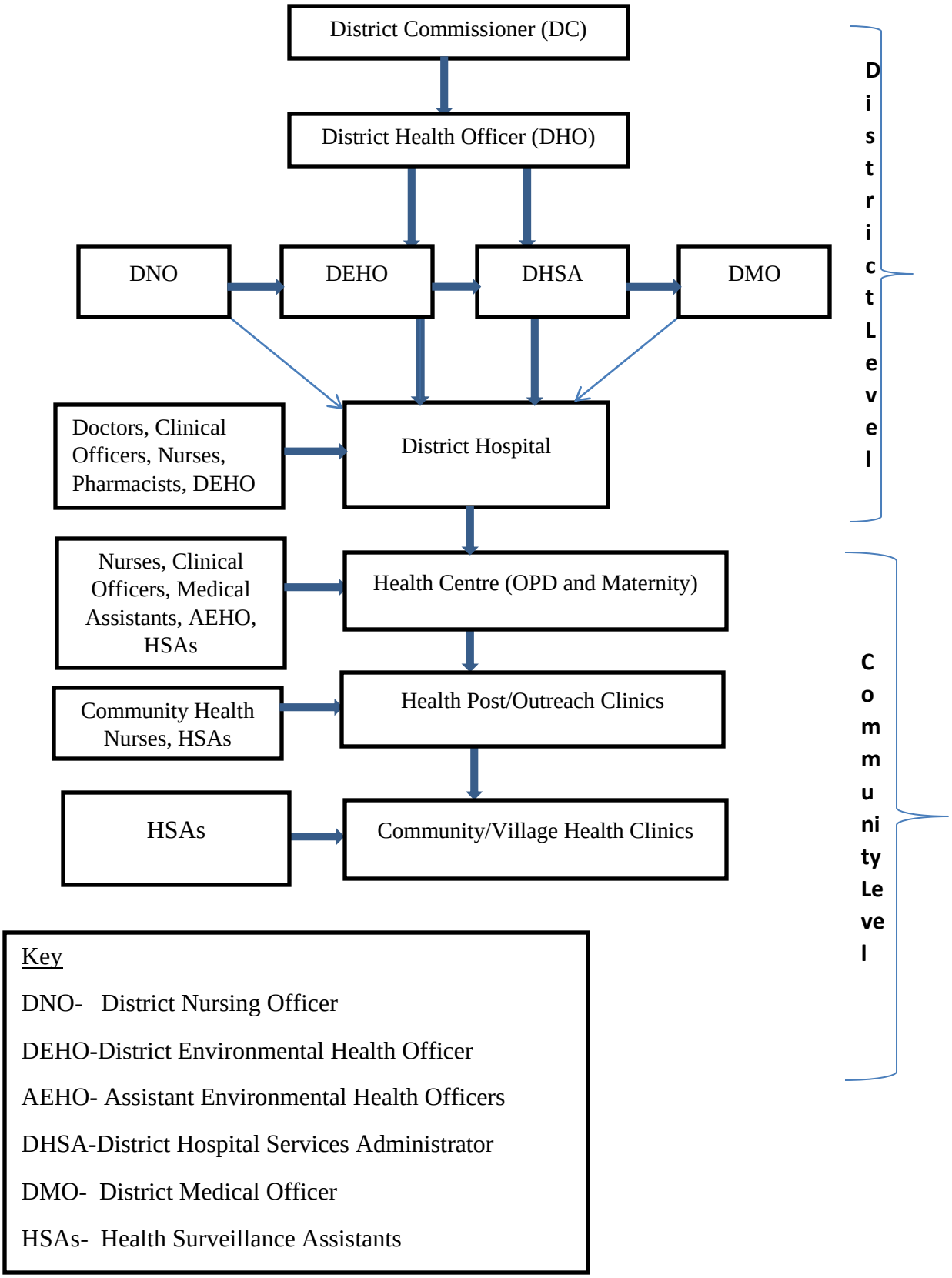


Fig 1: ORGANOGRAM FOR HSAs WITHIN THE DISTRICT HEALTH SYSTEM

Figure 1: Adapted from the Research Report on "Impact of the expansion of the Health Surveillance Assistants Programme in Nkhatabay District of North Malawi" by W. S. Ntopi: University of the Western Cape 2010.

1.2 HSAs Job Description, functions and their performance

1.2.1 Implementation of delegation of tasks through Task Shifting/ Task sharing policy

Due to a persistent shortage of healthcare personnel, Ministry of Health delegated clinical tasks by expanding HSAs job description beyond the preventive health approaches (see Appendix 1 and 2 for details of the expansion). This is consistent with a report that "HSAs primary role is to provide promotive, preventive and curative care, promote community participation in health care activities and to provide disease surveillance at the community level." (Smith, 2014)

Based on the HSAs Job description of 2014 (refer to Appendix 2), HSAs perform the following clinical tasks which amount to clinical practice usually performed by qualified and registered health professionals:

Firstly, on Tuberculosis, HSAs perform TB microscopy, smear and active TB case detection, treatment of TB with Isoniazid therapy for under-five year-old children, TB patients and Directly Observed Therapy for Multi -Drug Resistant TB patients.

On HIV/AIDS and STI treatment services includes: collection of Dry Blood Samples (DBS) for Early Infants Diagnosis (EID), follow-up of patients with opportunistic infections, screening of STI -syphilis, Intermittent Preventive Therapy (IPT) refill for pre-ART and ART patients on

monthly basis, Polymerase Chain Reactions(PCR), viral load blood draws, Cluster Differentiation 4 (CD4) blood draws, Cotrimoxazole Prophylaxis Therapy (CPT).

On Neglected Tropical Diseases (NTDs) –- HSAs conduct mass treatment campaigns for bilharzia and Filariasis and administering the anti-rabies vaccine.

On Integrated Community Case Management (ICCM) through Village Health Clinics, HSAs manage Acute Respiratory Infections (ARI), diarrhea, malaria in children, malaria rapid test and microscopy, administering of rectal artesunate as a pre-referral treatment, and malnutrition without medical complications. On family planning, HSAs provides oral contraceptives and Depot Medroxyprogesterone Acetate (DMPA).

On Maternal, Neonatal and Child Health: HSAs conduct Monitoring Antenatal Care (ANC), assess newborn babies, follow up on HIV-exposed infants, create community awareness on use of Misoprostol, treatment for neonatal sepsis, conjunctivitis, trachoma, skin diseases and referral of mental health problems, treatment and referral of convulsing and unconscious children. (Ministry of Health, 2014)

In addition, the deployment of HSAs to provide curative care in the rural areas is aimed at decreasing high mortality rates in children from preventable diseases such as “malaria (13%), HIV/AIDS (13%), pneumonia (11%), diarrhea (7%), and other conditions (17%).” (National Statistical Office, 2010)

Following the expanded job description, “HSAs were deployed to offer clinical services in rural areas to reduce inadequate access to quality health services.” (Malawi Child Health Strategy, 2013) This was in line with the Malawi Health Sector Strategic Plan 2011-2016 vision which is

to “achieve a state of health for all the people of Malawi that would enable them to lead a quality and productive life” (Malawi Health Sector Strategic Plan, 2011)

Furthermore, as a result of poor health indicators in children, the Ministry of Health established Integrated Community Case Management (ICCM) in which HSAs were trained, deployed and supported to run village health clinics in hard to reach areas which are usually more than 8 kilometers from the nearest health centre, to manage uncomplicated malaria, pneumonia, diarrhea, malnutrition, red eyes and refer complicated cases. (Gilroy, 2012)

Therefore, the roles of Health Surveillance Assistants have well been recognized in the “Malawi Health Strategic Plan (2011-2016) as an essential component in the health system in Malawi for scaling up activities within a comprehensive Primary Health Concept (PHC) approach.” (Malawi Health Sector Strategic Plan, 2011) HSAs are the main change agents on health issues in the community. In addition, the assessment report by Gilroy et al, (2012) showed that HSAs brought child care closer to communities in hard to reach areas. The positive results include: “providing correct treatment to children with anti-malarial 79%, diarrhea 69%, 52% were treated correctly with first line antibiotics and assessed correctly 37% of the danger signs.” (Gilroy, 2012) Therefore, the Ministry of Health recommended that “HSAs should be empowered to provide preventive services and perform simple and safe basic curative case on the important cause of morbidity.” (Malawi Child Health Strategy, 2013)

Similarly, another report on the outcomes of the community health workers in the USA, observed that they are important as they “improve health outcomes, reduce health care costs through the reduction of the effects of chronic illnesses, improved medication adherence, more patient involvement and a better community health.” (Miller, 2014) The core competencies of Community Health Workers in some states in the USA range from conducting outreach services,

individual and community assessment, health education for behavior change, application for public health concepts and approaches, advocacy and community capacity building, professional skills and conduct. In Ohio, in addition, certification is needed for CHWs to perform tasks delegated by the nurse and the Board of Nursing approves their training. (Miller, 2014) Despite these positive findings, the expanded job description of HSAs presents ethical and legal challenges as discussed below.

1.3 Challenges associated with delegating clinical functions to HSAs

According to Ministry of Health Guidelines on Task Shifting, HSAs run a high risk of neglecting quality health care especially if they are not supervised, trained, and aligned with broader health systems strengthening and have no legal indemnity cover in case of litigation. In addition, the Ministry of Health observed that if task shifting is uncontrolled; issues of competencies are often ignored because it is being portrayed as a quick fix approach to mitigate the shortage of trained health workforce. (Ministry of Health, 2014)

The HSAs delegation and sharing of clinical tasks have led to concerns over the safety and quality of health services compounded by poor supportive supervision. This is consistent with the observation that "the job description of HSAs has expanded enormously to include a range of tasks that have been, and continue to be shifted and stakeholders decide on their own what tasks to shift to this cadre." (Phuka, 2014) Furthermore, the current training period of 12 weeks that HSAs undergo is not adequate to cover knowledge and skills required to offer the services prescribed in their job description. (Smith, 2014) Similarly, the training of CHW as Case Managers in Madagascar, Mozambique, Zimbabwe Rwanda, Tanzania, Uganda is also shortened. This is contrary to community health worker training approach in Zambia and

Ethiopia where the pre-service training of covers 12 months on promotive, preventive and curative services, including a component on Integrated Community Case Management - ICCM. (Kumar, 2014). Despite the differences in training among Case Managers in different countries, their scope of work is similar which range from providing preventive services, to providing ICCM, which mainly involves diagnosis and treatment of diarrhea, pneumonia, malaria, detection and treatment of non-communicable diseases, malnutrition, and neonatal care and reproductive and family

Finally, it was observed that HSAs frequently abandon their community work and prefer working at the health centers where they feel recognized and respected by the community. Their dissatisfaction is due to "lack of recognition, lack of community support and uncoordinated supervision." (Phuka, 2014) (Kok, 2013) (Smith, 2014) For example, it is claimed that some of HSAs were not able to state their job description.

Similar findings by "Institute of Medicine (IOM) in 2002 identified several barriers to the effective use of community health workers in multidisciplinary health care teams which included inconsistent scopes of practice, training and lack of recognition by other health professionals." (CDC, 2013) Another report found that "community health workers were not recognized as legitimate health care professionals and were in the process of defining their knowledge base and scope of practice." (O' Brien, 2011).

The other assessment studies on HSAs performance found that:

1. The proportion of children receiving the correct first dose of treatments for acute respiratory infections, pneumonia, malaria, and diarrhea from HSAs at Village Health Clinics was quite low (31%). (Gilroy, 2012)
2. Poor recognition of danger signs for the sick children such as fast breathing (tachypnea), poor physical examination skills thereby putting the lives of very sick children at risk through wrong diagnosis and treatment. (Institute for International Programs, 2010)
3. The six- day training course for ICCM was inadequate to impart clinical knowledge and skills and inadequate supervision as only 58% were supervised Integrated Management Childhood Illness Coordinator (trained health practitioner such as a Clinical Officer or a Nurse) the previous three months. (Gilroy, 2012)
4. The discontent by HSAs demonstrated by demanding more training to manage convulsions and unconsciousness and requests for inpatient practical sessions in hospitals to master skills. (Gilroy, 2012)
5. The training period for Depot Medroxyprogesterone Acetate (DMPA) was short as such HSAs were incompetent to rule out pregnancy and DMPA side effects. (Katz, 2010)
6. Increased workload for HSAs to run DPMA program, village health clinics in addition to their public health interventions. (Katz, 2010)
7. HSAs were not happy operating village health clinics since they were not trained as doctors and acknowledged that it was a difficult task. (Smith, 2014)
8. Women were not comfortable to be consulted by male HSAs in their practices as culturally, it is not acceptable. (Kok, 2013) Similarly in India acceptability of CHWs

depended on their personality, educational background, experience, and gender. (Padmanathan, 2013)

In light of the benefits and challenges brought about by HSAs, it is important to answer the research question of this report: **Is it morally and legally justified for Health Surveillance Assistants to practice clinical medicine in Malawi?**

In order to answer the above question, it will be helpful to compare the institution of HSAs to similar health workers in other countries.

Therefore, this report draws upon similar experiences in other countries such as Canada, where unregulated health cadre of Health Care Assistants were providing health skills, "Health Care Assistants are the front-line providers who provide personal care assistance and services in a variety of health care settings (acute hospitals, assisted living, group homes, residential care and community care)." (British Columbia, 2014) Like HSAs, historically HCAs had community health roles only but later took more responsibilities and carried out more procedures like venipuncture, catheterization of patients, undertaking cervical smear screening, Electrocardiogram (ECGs) and phlebotomy but they were not regulated and had no defined scope of practice. In addition, professional bodies like the Canadian Nurses Association observed that "globally, there was an increasing trend towards using unregulated health workers due to a shortage of nurses and cost containment particularly in community-based or home care settings hence in conflict with health regulatory requirements." (Canadian Nurses Association, 2008) Thus, the government of British Columbia developed strategies to retrain and regulate them, and to improve the quality of care.

In the United Kingdom, there was a similar problem with nursing assistants, where "the commission of inquiry observed that it was unacceptable that staff whose competence is not regulated or monitored are caring for vulnerable citizens, and that it was immoral for Registered Nurses to supervise colleagues on whose competency they cannot rely." (Collins, 2012)

Similarly, the Australian Nursing Federation observed that "the risks posed to the recipients/consumers of the health care provided by unlicensed health workers should be considered in the same way risks are considered in relation to the nursing care provided by the nurses." (Adrian, 2009)

As a result of similar problems, different states in the USA "developed credentialing systems for community health workers through certification and legislation as a way of addressing the barriers to the integration into the broader system and to achieve greater respect for them among other healthcare professions, increased working conditions, and increased job stability despite the objections that credentialing will create barriers to entry for some individuals." (Rush, 2012)

Hence, it was recommended that "in order to set the national community health workers programs, "it is necessary to develop regulatory frameworks to protect the patients and the health workers themselves." (Herman, 2009)

Against this background, it is ethically and legally wrong to allow HSAs to provide clinical care without proper training and without statutory regulation.

1.4 Rationale

As outlined in the historical background, HSAs have been tasked with clinical services which are usually provided by qualified and registered health practitioners. Their multiple roles have led to

slippery slope arguments as some are operating illegal medical clinics, selling free medications, involved in providing poor treatment to the patients, and drug pilferages.

HSAs lack regulatory oversight and accountability functions as they practice limited clinical medicine without the code of conduct, registration, and proper clinical training hence consumers have no protection or recourse if anything goes wrong. This means it is essential to assess the morality and legality of allowing the HSAs to practice medicine to maintain the standards of the medical profession in Malawi.

1.5 Thesis Statement

I will argue that allowing Health Surveillance Assistants to provide clinically related services to the public when they are not registered with appropriate health regulatory bodies is unethical and legally wrong.

1.6 Study Aim

To assess normative ethical and legal arguments for and against the provision of clinical services by HSAs

1.6.1 Objectives

In fulfilling this aim, I addressed the following research objectives:

1. To provide a normative analysis of the HSAs Terms of Reference against their current practices.
2. To argue that HSAs act beyond their job description in providing clinical services.

3. To propose recommendations in keeping with ethical and legal frameworks through necessary reforms for Health Surveillance Assistants including restrictions on scope, and extension of their training.

1.7 Research Design

I will use normative, argumentation and contextual analysis of the ethical and legal issues emanating from the HSAs job description hence addressing them through reviews and comparing them to the current minimum acceptable standards, guidelines, regulations of local and international legal instruments.

1.8 Research Methods

1.8.1 Argumentative Strategy

In -order to address the question on morality and legality for HSAs to practice clinical medicine, I will argue that Malawi needs HSAs to provide community health services using public health approaches until they are clinically well trained to increase treatment coverage through task sharing, which is defined as "the process of enabling lay and mid-level health care professionals to provide clinical tasks and procedures safely." (Schaefer, 2015) In Chapter 1, I will provide the historical perspectives of HSAs, on how they have evolved from smallpox vaccinators to HSAs providing preventive and curative services.

In Chapter 2, I will use Beauchamp and Childress's Principlism and the theory of Utilitarianism to argue against the HSAs clinical practice hence limiting their scope of work or job description in Malawi. Firstly, I draw on the "principle of beneficence which asserts practitioners to act in the best interest of the patient and requires that benefits and drawbacks be balanced." (Beauchamp, 2001, pp 166) I will argue that the benefits of providing quality clinical services in approved settings and using well trained and registered HSAs outweigh the benefits of using unregistered HSAs. Secondly, I will use the principle of non-maleficence which calls for health care practitioners not to inflict harm on the patients or the public.

Thirdly, I will use the principle of justice which asserts that "inequality in accessing health care is a problem of distributive justice," (Beauchamp, 2001 pp 226) I will argue that the Ministry of Health action to use HSAs to provide clinical services is an attempt to solve the inequality in accessing health care between the urban and rural population. However, providing substandard clinical services to the public would be unjust.

Fourthly, I will argue against HSAs practice based on the principle of respect for autonomy: defined as "self- governance or self- determination." (Degrazia, 2010 pp. 41) In this regard, I will argue that self-determination in decision making among members of the rural population cannot be achieved as they lack information to determine whether the service provided is of good quality hence the need to protect them by regulating the HSAs. I will also argue that the Ministry of Health action towards introducing HSAs roles in clinical medicine is based on utilitarianism, in terms of which "all situations must lead to the greater happiness for the greatest number and the least amount of pain." (Crimmins, 2015) The Ministry of Health values the increase in access to health care than the rules governing the processes. On the contrary, I will argue against the practice using Kant's second formulation of the categorical imperative. This formulation holds

that it is unethical to use people as ends rather than as means. (Beauchamp, 2001 pp 57-225) Hence, I will argue that the Ministry of Health is using HSAs as a means, not an end to providing clinical care to the rural population.

In complementing these arguments, in Chapter 3, I will provide legal arguments using legal instruments such as the Medical Practitioners and Dentists Act No. 17 of 1987 which prohibits practicing as medical practitioner of one is not registered in terms of the Act. (Medical Practitioners and Dentists Act, 1987) I will also refer to relevant sections in the Constitution of Malawi, such as "Section 13c on the provision of health care, commensurate the health needs of Malawian society and international standards of health." (Constitution Malawi., 2006) Based on the common law, on delegation of duties, I will argue and HSAs are liable for tort acts for malpractice and vicariously the Ministry of Health is also liable for breach of duty based on contract law and for damages incurred to the body of the patient. Without registration with the regulatory body, HSAs risk consumers and patients not getting recourse if they are harmed.

I will argue against HSAs providing clinical services using the international legal instruments such as "Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides for the right of all enjoyment of the highest attainable standard of physical and mental health," (Zeldin, 2007) and "African Charter on the Rights and Welfare of Child, 1990, article 2 which provides for everyone's legal protection and particular care with regard to health, physical, mental, and social development." (Zeldin, 2007) Therefore, I will argue for statutory regulation of the HSAs in the provision of clinical services through licensing since it will increase benefits and reduce potential harms. Finally, drawing on experiences from other nations listed above, I will provide conclusions in Chapter 4 and recommendations for limitation of scope, increased training, regulatory and guidance in Chapter 5.

1.9 Ethics

The proposal was submitted for approval to Wits HREC (medical). No patients' records and related material was used throughout the process of this project. A letter requesting waiver was submitted for approval and the approval letter was issued (See Appendix 6).

1.10 Research Outcomes

In fulfilling the research objectives, I intend to achieve the following outcomes:

1. Recommendations for revised competency profile for HSAs
2. Recommendations for revised legislation/regulation framework of the new community HSA cadre that will provide clinical services based on the developed and accredited scope of practice.
3. A publication and conference presentation of the article

1.11 Limitations of the study

While I draw on the aforementioned similar experiences in Canada and the United Kingdom, the ethical and legal conclusions I reach may differ due to the differences in ethical-legal and healthcare environments.

1.12 Breakdown of Sections

Chapter 1: Background Information and Introduction

This chapter provides an account of HSAs historical background, the research aims and objectives, arguments for study and have used the research design to examine the research question.

Chapter 2: Ethical principles and theories arguments on HSAs roles

This chapter provides arguments against and for HSAs role in clinical medicine through the application of ethical principles and theories in discerning pros and cons for allowing HSAs to practice clinical medicine.

Chapter 3: Legal arguments on HSAs

This chapter argues on the HSAs roles by using the existing legal instruments such as Constitution, the statutory law, the common law, tort law and contract law. Finally, I present arguments based on the international legal instruments such as ICESCR article 12 on rights to health.

Chapter 4: Conclusion

This chapter provides the ethical and legal opinion and summarizes the discussion on issues related to HSAs job description in Malawi.

Chapter 5: Summary of Recommendations

This chapter provides the recommendations on how best to utilize HSAs in the provision of clinical care without exerting more harm and making HSAs legitimate to practice hence safeguard the health and safety of the public.

CHAPTER TWO:

ETHICAL PRINCIPLES AND THEORIES ARGUMENTS AGAINST THE HSAs CLINICAL PRACTICE

2.1 INTRODUCTION

In this Chapter, I will give an account of the ethical principles related to the HSAs job description or scope of work and provide arguments against using HSAs to provide clinical care to the rural population. Based on these principles as well as the theory of utilitarianism, I will argue that using less trained and unregistered HSAs with the extended job description is morally wrong. However, I will argue that using the proposed well trained and registered HSAs with the defined scope of practice to provide curative services in the community is morally right and justifiable. Finally, I will propose and defend my position of advocating for retraining, continuous supervision and registration of HSAs.

2.2 Beauchamp's and Childress Principlism

Firstly, I will provide and apply an account of Beauchamp and Childress Principlism. Principlism "is the approach to moral argumentation developed by Tom Beauchamp and James Childress and asserts that moral problems can best be approached by applying one or more of the four basic moral principles." (Moodley, 2011) The principles are: "respect for autonomy, non-maleficence, beneficence, and justice." (Moodley, 2011)

2.3 Respect for Autonomy

Respect for autonomy "refers to the right of every individual to make decisions for himself/herself and entails allowing an individual or patient to make the final decision regarding his/her treatment after being provided with the necessary and relevant information." (Moodley, 2011) In addition, autonomy is also defined as individuals "self- governance or self-determination." (Degrazia, 2010 pp. 41) In this regard, it would mean that the individuals in the community should make an independent decision whether to receive clinical care from HSAs after being informed of their clinical competences, and their status of non-registration with a health regulatory body. In addition, Autonomy implies that HSAs should be able to make independent decisions in diagnosing and treating the patients.

My argument against HSAs extended job description is grounded on the following premises: Firstly, members of the community have inadequate information on what defines quality health care due to information asymmetry and due to their vulnerability from poverty, limited literacy, geographical isolation, and childhood due to dependency. (Kaplan, 2013) It is, therefore, a violation of Kantian respect of persons and the Beauchamp's and Childress's principle of autonomy to provide curative services using HSAs based on their extended job description. Therefore, public health interventions and health policies should protect the vulnerable population by being provided with quality health care including their freedom of choice of care.

According to Pieterse, "the individual rights of autonomy and access to health care services are interrelated and mutually supportive, lack of autonomy can unconstitutionally hinder access to care, and consequently lack of access to care may in certain circumstances constitute an infringement of the right to bodily and psychological integrity." (Pieterse, 2014) I agree with the

author's opinion, as the information asymmetry between the providers and consumers act as a barrier to access quality health care. In this regard, I therefore, claim that the consumers are not aware of the scope of work of the Health Surveillance Assistants on clinical care services.

Secondly, HSAs are not adequately trained to provide clinical services such as 6-day training on ICCM to manage sick children in the rural population. In addition, it is claimed that for an individual to make autonomous decision, he/she should "fulfill the following conditions: It must be intentional, based on sufficient understanding, sufficiently free of external constraints and sufficiently free of internal conflicts." (Degrazia, 2010 pp. 41) Therefore, I claim that HSAs provide curative care is based on the insufficient understanding due to inadequate training hence inconsistent with the principle. (Gilroy, 2012) The call for regulation of HSAs is consistent with principles of the medical profession, which demands that practitioners have autonomous practice as reported by the "Virginia Board of Health Professions that the functions and responsibilities of the practitioner require independent judgment and the members of the occupation practice autonomously." (Johnson, 2010)

Therefore, I conclude that it ethically wrong for HSAs to provide clinical care to patients beyond their job description. I therefore, propose for HSAs retraining and/or registration/licensure in order to uphold independent decision making among themselves based on the principle of autonomy.

2.3.1. Liberty-Limiting Principles

These principles were developed by John Stuart Mill in his work "On liberty" 1869. I will use harm principle, paternalism, and social welfare principles to object to HSAs job description on

their ability to offer clinical services to the public through the Ministry of Health policy of providing care using HSAs. My arguments are reminiscent of public health ethics which asserts that "public health interventions are justified as long as they stay with certain pre-established parameters and when properly regulated and managed their existence is better than their absence for everyone." (Faden, 2015)

2.3.2 Harm Principle

The Harm Principle holds "that a person's liberty is justifiably restricted to prevent that person from harming others." (Degrazia, 2010 pp 46) In this case, HSAs demonstration of poor clinical skills in treatment, diagnosis, assessment of patients and indiscriminate use of antibiotics as reported by Gilroy et al (2012) exposes the patients to risks of harm such as complications and death resulting in physical and economic costs, hence calls for an intervention. Hence, the argument to regulate their practice is consistent with the harm principle to restrict them to practice within their scope of work. Therefore, I conclude that HSAs and the Ministry of Health will be accountable and liable for harm inflicted on the patients based on tort law.

2.3.3 Paternalism

Paternalism is defined as a "person's liberty being justifiably restricted to benefit that person." (Degrazia, 2010 pp 46) My argument is premised on the extended job description of HSAs which may result in detrimental effects on the patients and their dissatisfaction due to overload of tasks from task shifting by the Ministry of Health and NGOs, from failure to treat some patients due to inadequate training and incompetency in clinical care, lack of equipment and medical supplies, role ambiguity, lack of recognition and lack of remuneration accorded to their work. (Smith, 2014) (Kok, 2013) Therefore, against such findings, I claim that the appeal for

statutory regulation of HSAs through proper credentialing and registration is justifiable. HSAs should undergo an accredited training through vetted curriculum to boost their skill and knowledge acquisition.

2.3.4 Social Welfare Principle

Social Welfare Principle is defined as "the person's liberty being justifiably restricted to benefit others." (Degrazia, 2010 pp 46) My argument is premised on the HSAs liberty to provide clinical care will be restricted in a way that might be justified by appealing to the social welfare principle. HSAs clinical practice is inconsistent with the principle due to the reported risks of harm hence the need to restrict the practice through proper training and regulation. Therefore, to efficiently utilize HSAs in providing public health, clinical functions and enhance their capabilities, it is imperative that their competency profile is revised.

2.4 Beneficence

Beneficence "refers to doing good and the active promotion of goodness, kindness, and charity." (Moodley, 2011) In addition, the principle of beneficence "refers to the moral obligation to act for the benefit of others." (Beauchamp, 2001, pp 166) In this regard, doctors, other health practitioners, and stakeholders have the responsibility to provide beneficial treatment, favorable policies, and programs to the patients and the public. The principle requires practitioners to have rigorous and effective education and clinical competence to execute their clinical functions.

Therefore, based on the principle of beneficence I argue that HSAs work is consistent of its standards such as advocating for communities' best interests, strive to ensure equal access to health services, act as change agents for the rural communities in achieving health promotion. In

addition, the work of HSAs occurs within the caring relationships that are respectful and just. The implications are that institutions should have commitment that maximize the health of the communities that HSAs serve and to minimize harm. Institutions should support the health of HSAs themselves and ensure that education and training of HSAs should be adequate and accredited.

However, I claim that HSAs do not have the adequate clinical training to enable them to practice clinical medicine. Therefore, I argue that using unregistered HSAs to provide clinical care may result in negligence which can expose patients to risks of harm. Hence, it is right and proper to provide HSAs with right credentials through accredited training and registration for the public safety and their own benefits.

The claim is supported by Gilroy et al, (2012) who wrote that the proportion of children receiving the correct first dose of treatments for acute respiratory infections, pneumonia, malaria, and diarrhea from HSAs at Village Health Clinics was quite low (31%) and additionally, it was observed that HSAs demonstrated poor physical examination skills and failed to recognize the danger signs for the sick children such as fast breathing (tachypnea), put the lives of very sick children at risk of harm through wrong diagnosis and treatment. (Institute for International Programs, 2010) Hence, based on these findings, an obligation to protect the public by stakeholders is needed to prevent further harm to the vulnerable population.

For example, regulatory agencies like the "Food and Drug Administration (FDA) in the US and the Medicines Control Council (MCC) in South Africa will usually withdraw registration of a drug that has been found to cause more harm than good through monitoring and surveillance to protect the public" (Moodley, 2011) Similarly, the Medical Council of Malawi main goal is "to protect the patients and the general public and guide the medical profession." (Manyozo-Phiri,

2001) Therefore, through monitoring of health services, HSAs have been found and involved in malpractice and poor clinical practice such as over dosages of treatment of children, opening illegal private medical clinics have been discovered, reported and prosecuted. I claim therefore that the regulatory bodies' actions towards unregulated service are consistent with beneficence principle as it demands that agents ought to take positive steps to help others. (Beauchamp, 2001, pp 166) Against this background, I, therefore conclude that HSAs ought to be retrained, certified and registered to improve their competence to achieve the desired national goal of assuring quality health care services available in the interest of the public.

2.4.1 Cost -Benefit Analysis

Costs are defined as the "resources to bring about the benefit, as well as the negative effects of pursuing and realizing that benefit." (Beauchamp, 2001 pp 194) Despite the benefits realized from HSAs practice and the proposed HSAs registration such as career progression, the stability of employment, and recognition, there are costs associated with regulation of the new cadre such as HSAs. The costs imposed on the HSAs as requirements for registration and finally the costs associated with acting on complaints and issues. This is consistent with Solomon et al findings who wrote that "costs on managing complaints from the public usually will engender resources and could open up a range of high costs arising from litigation." (Solomon, 2015) I conclude that the cost of managing immediate and long-term effects of harms incurred by patients cared by HSAs would outweigh the benefits of credentialing and registration hence not ethical.

2.5 Non-maleficence

The principle is defined as “primum non nocere- first do no harm consistent with the Hippocratic Oath and the medical practice is firmly rooted in the principle of non-maleficence.” (Moodley, 2011) The principle provides that practitioners ought to avoid or minimize harm to patients as such requires thorough, sound and rigorous medical training. The principle sets the standards for practitioners such as “not to kill, not to cause pain or suffering to others, not incapacitate others, not to offend others, and to deprive others of the goods of life.” (Moodley, 2011)

In addition, the principle “asserts that harm is caused to patients as a result of a distortion in the risk-benefit analysis assessment and the fact is all interventions on healthcare carry an element of risk and the practitioners are obligated to warn patients of material risks.” (Moodley, 2011) The principle, therefore, demands that HSAs ought to be aware of the risks associated with the practice to reduce risks of harm to the patients or the public. However, I claim that based on their job description and training, HSAs has limited knowledge on clinical medicine and lack ethical training hence falls short of the standards of the principle of non-maleficence.

The arguments using non-maleficence will base on the risk-benefit analysis. I will argue that allowing HSAs to practice beyond their scope of work and without statutory registration is flawed and such unregulated clinical practice sets the ground for review of the policy and regulations.

2.5.1 Risk- Benefit Analysis

Firstly, I will give an account of the term risk-benefit analysis. “Risk is the probability and magnitude of negative outcomes following the evaluation of harms and Risk-Benefit Analysis

(RBA) is the evaluation of risk in relation to probable benefits." (Beauchamp, 2001 pp 199) In practice, it is essential to balance the principles of beneficence and non-maleficence to achieve net benefit for the patient.

The benefits of using HSAs to provide clinical care in rural populations includes: improvement of access to health care in hard to reach areas, the treatment of malaria was found to be over half correctly treated hence help reduce the mortality rate of children from malaria, and provision of family planning to women in addition to disease surveillance, prevention and health promotion.

The arguments on risks of harm from HSAs provision of care using extended job description is based on the following premises: The training of ICCM training is short for them to comprehend, conducted for six days to manage sick children including complicated cases of unconsciousness or convulsion. Even in DMPA program, the HSAs decried inadequate period of training which is usually detrimental to their practice motivation and to the patients/clients as they get substandard care, their inability to provide correct treatment (31%), misdiagnosis, and failure to recognize danger signs in children hence failure to refer them at appropriate time. (Gilroy, 2012) The risk interpretation is that majority of sick children (69%) risked developing severe complications and death due to incorrect treatment. In addition, using antibiotic wrongly increases the risk of harm from emerging resistant bacteria or super bugs hence exposing the public from developing diseases which are untreatable as Smith et al wrote that "the rate of antimicrobial resistance is accelerated by the use and misuse of antimicrobials due to over the counter availability without professional controls, counterfeiting, and availability of drugs from stalls or hawkers who have little knowledge on dosage regimens, indications and contraindications." (Smith, 2002 pp 126) In addition, HSAs are involved in unprofessional conduct such as selling medicines to patients meant to be provided free. (Kadzandira, 2001)

The findings were consistent with Australian Nursing Federation (ANF) findings which reported that “unlicensed health workers in Aged Care facilities gave wrong medications and incorrect dosages.” (Adrian, 2009)

The other risk of harms to both HSAs and patients is the unsafe environment where HSAs provide care to patients in the community such as in the patients’ homes and under the trees. (Kok, 2013) This violates the patients’ right to privacy and confidentiality. Such places expose patients from further contracting infections since infection prevention practice is compromised or non-available. Hence, I conclude that the response is to set policies that will review HSAs clinical practice that will enable them to provide quality clinical services in approved settings as the benefits of such interventions outweigh the benefits of using unregulated HSAs. The approved settings shall include renovated health posts, rural government dispensaries. In addition, the existence of such functioning rural clinics shall counter the “existence of illegal medical clinics which are operated by non-medical personnel in rural areas.” (Manyozo-Phiri, 2001)

2.6 Justice

Justice is defined as “fair treatment of patients in health care through the obligations of respect for morally acceptable laws – legal justice, respect for people’s rights – right based justice, fair distribution of limited resources” (Moodley, 2011) Similarly, it is asserted that “inequality in accessing health care is a problem of distributive justice,” (Beauchamp, 2001 pp 226)

Therefore, the Ministry of Health action to use HSAs to provide clinical services is an attempt to solve inequality and disparities in accessing health care between the urban and rural population.

The rural population is vulnerable due to "poverty, limited literacy, long distances between health facilities and childhood due to their dependence." (Kaplan, 2013) I agree with the author since these vulnerabilities are consistent with what the rural population face in Malawi. Therefore, deploying HSAs in rural population is a public health intervention to remedy the issues of poor access to health care. This is consistent with "Rawls view of justice which prioritizes the most vulnerable and worst off." (Kaplan, 2013)

However, I argue that providing substandard clinical services to the public would be unjust. The Principle of Justice asserts that "fair, equitable and appropriate treatment should be in light of what is due or owed to persons." (Beauchamp, 2001 pp 226) In addition, I argue that when patients are harmed while receiving health care and being attended to by the HSAs, a case of injustice has occurred. Such risks of harm can result from poor clinical judgment on the incorrect application of treatment, misdiagnosis, and failure to refer as exemplified by the HSAs in assessment reports already presented.

In addition, the patients may not find recourse for compensation if harmed as HSAs are not legally licensed to practice. HSAs cannot write medical reports which can be used as evidence in a court of law since they are not recognized to practice under the statutory law, even their supervisors could be at risk by writing the medical report based on the incorrect information provided by the HSAs hence both the HSAs and their supervisors could be liable for harm under tort law or common law. Finally, I claim that HSAs clinical practice is an act of injustice to them as they are overloaded with additional work, not recognized, not protected and have no legal indemnity. Therefore, if HSAs are involved in a malpractice which can result in harm to the patient, they would be liable under the common law and would not be protected due to their lack of scope of practice.

2.7 Utilitarianism

Firstly, I will give an account of utilitarianism based on "Jeremy Bentham (1748-1832) and John Stuart Mill (1806-1873) who provides the moral standard that an action is morally right if, when compared with possible alternatives its likely consequences are such to generate the greatest balance of good over evil everyone considered." (Degrazia, 2010 pp 8) Therefore, if the outcome of an action causes overall harm, it is deemed morally wrong. In addition, the theory "demonstrates that out of all actions in a given situation, the morally right action is that which will lead to the best consequences." (Degrazia, 2010 pp 7-62) Hence, I argue that revising HSAs competency profile to improve their practice will lead to self-esteem, improved knowledge, and skills to practice hence consistent with the theory of utilitarianism.

Therefore, the Ministry of Health action can be argued for based on the "utilitarian principle of utility of maximizing the goods for the greatest number." (Degrazia, 2010 pp. 41) As a country, Malawi needs HSAs as community health workers with clinical skills to improve health care access reminiscent of their "right to a decent minimum of health care, a positive right to goods and services grounded in a claim of justice." (Beauchamp, 2001 pp 244) Hence the Ministry's action is aimed at maximizing access to health care mainly curative care for a rural population which is composed of 85%. (Ministry of Health, 2009) The rural population is usually under-served in terms of provision of quality health care as health centers are located far apart from each other 8 kilometers or more which is a major geographical barrier against the WHO recommended distances of 6 kilometers.

However, an objection to the utilitarian approach of seeking the greatest good for the greatest number is that it poorly protects individual rights and hence I argue that using unregistered HSAs

to provide basic curative/clinical care does not produce the best outcome for the rural population as it overlooks issues of competence and quality of care provided by the HSAs. (Gilroy, 2012) Hence, the use of registered HSAs will have greater utility than the use of unregistered HSAs to provide curative/clinical services.

2.7.1 Rule Utilitarianism

The principle of Rule Utilitarianism asserts that "an action is right if it conforms to a rule of conduct that has been validated by the principle of utility applicable to the situation." (Degrazia, 2010 pp 14) The standard practice from this principle is that the right action is the use of well-trained and registered HSAs who can be accountable for their activities. The moral standard is that the HSAs are expected to practice according to the rule of conduct set by the medical profession which among other things demand that practitioners should be competent and registered to practice clinical medicine. Therefore, my arguments for proposing revising HSAs competence profile to meet registration requirements are consistent with rule utilitarianism. It is also consistent with the pluralist argument that "asserts the right action is expected to produce the greatest sum of intrinsic goods." (Beauchamp, 2001, pp 341) Hence, HSAs will be recognized and will have the self-confidence to practice.

However, despite existing ethical and legal principles which guide the practice of clinical medicine and prohibit practitioners without registration to offer curative services, the Ministry of Health informally continue to delegate certain clinical tasks to HSAs based on the utilitarian approach of providing clinical care to the largest number. This is consistent with a study in Germany which showed that "46 % of GPs were already delegating medical tasks to Physician

Assistants even before regulating the practice and hence the call to have the practice regulated." (Dini, 2011 pp 448)

Therefore, I conclude that delegating of clinical tasks to HSAs is inconsistent with the moral standard set by the Rule Utilitarianism. To remedy the situation, HSAs should be retrained and registered to justify the application of their job description and coupled with the benefits such as assurances for quality and safety during the practice, patients being able to get recourse when they are harmed, in addition HSAs will be able to seek employment, recognition and career progression.

2.8 Conclusion

In this Chapter, I have argued for and against HSAs practice through their job description. My arguments have been based on the Beauchamp and Childress Principlism on autonomy, beneficence, non-maleficence, and justice and used the ethical theory of Utilitarianism.

In my ethical evaluation, I have admitted the need for HSAs in rural population to make health services accessible and available. Despite the HSAs ability to generate positive results from their practice, there are times when their involvement can do more harm than good. Hence, I have faulted HSAs involvement in curative care because they are not well prepared to provide clinical care services, since they are not well trained in medical ethics hence risking the patients from harm. This is not to suggest that HSAs are bad or immoral, just that more regulation would better promote relevant ethical values. Therefore, I conclude that ethical rules prohibit unregistered

HSAs to provide curative services to the public until a reform to be regulated has been implemented.

CHAPTER THREE

LEGAL ARGUMENTS AGAINST THE HSAs CLINICAL PRACTICE

3.1 INTRODUCTION

Legal rules governing doctors and other health professionals demand that practitioners should practice medicine or nursing with proper credentials and should be in good standing with the common law and requirements of their health regulatory bodies. In this chapter, I will provide arguments against HSAs practice using the application of the "FIRAC formula which is explained as *F- Facts, I- Issues, R- Rule of law, A-Application, C – Conclusion and comment for problem-solving and legal analysis*." (Maisel, 2004 pp 101) I will provide the facts, issues, and the rules of law and the conclusion in this chapter.

Firstly, the facts have been provided in Chapter one grounded in the title: ethical and legal issues related to HSAs job description and the research question on whether it is ethical and legal for HSAs to practice clinical medicine based on the HSAs job description which empowers them to provide curative services.

Secondly, I will discuss the relevant issues related to HSAs job description which includes potential violation of patients' rights to health and to dignity, HSAs liability, HSAs supervision problems, HSAs eligibility to offer curative services, competence issues and HSAs eligibility to be regulated. These thematic areas will be guided by the following legal questions:

1. Does the HSAs clinical practice contribute to the realization of the right to health and right to access quality health care?
2. Does HSAs clinical practice provide for the patients' right to dignity and self - determination?
3. Are a HSAs clinical practice and task allocation consistent with medical liability standards?
4. Are HSAs current supervision policies consistent with the requirements of the common law and the guidelines on delegation/sharing of clinical tasks?
5. Are HSAs eligible to offer clinical care services to the public?
6. Are HSAs competent to offer clinical services to the public?
7. Does HSAs extended job description require statutory health regulation?
8. What regulatory option of health professionals can suitably be applied to HSAs practice?
9. Should the Ministry of Health stop delegating/sharing clinical care tasks to HSAs?

Thirdly, I will provide arguments based on international law, the Malawi Constitution and the common law, the Government Patient Charter and the Medical Practitioners and Dentists Act, No. 17 of 1987 applicable under each thematic area.

Fourthly, I will also discuss the application of regulation options used on unregulated health professions and will recommend one model suitable for statutory regulation of the HSAs and provide a brief conclusion.

3.2 Right to Health

3.2.1 Rule of law related to the right to health

These are the laws relevant to the right to health and access to quality health care

3.2.2 International law

"Article 25 (1) of the Universal Declaration of Human Rights provides that everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing and medical care and necessary social services." (UDHR, 1948)

The "International Covenant on Economic, Social, and Cultural Rights (ICESCR) in Article 12 provides that states should recognize the right of everyone to the enjoyment of the highest attainable of physical and mental health." (Zeldin, 2007)

The "Convention on the Rights of the Child Article 24 (1) provides that states should recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States shall strive to ensure that no child is deprived of his/her right to access to such health care services." (UNICEF, 1990)

The "Convention on the Elimination of All forms of Discrimination Against Women Article 12 provides that states shall take all appropriate measures to eliminate discrimination against women in the field of healthcare in order to ensure on the basis of equality of men and women, access to health care service, including those related to family planning." (CEDAW, 2009)

3.2.3 Malawi Constitution

"Section 13 of the Constitution provides that the state shall actively promote the welfare and development of the people of Malawi by progressively adopting and implementing policies and legislation aimed at achieving the following goals: On Health: Section 13c asserts that the state shall provide health care, commensurate with the health needs of Malawian society and international standards of health." (Constitution Malawi., 2006)

Section 16 "provides that every person has the right to life and no person shall be arbitrarily deprived of her life" (Constitution Malawi., 2006)

Section 30 (3) of the Constitution "provides that the state shall take measures to introduce reforms aimed at eradication of social injustices and inequalities." (Constitution Malawi., 2006)

3.2.4 The Malawi Government Patient Charter

On rights and duties of health care providers, health professionals and health care consumers; the Ministry of Health of Malawi Government developed a "Charter on the rights and responsibilities of patients and health services providers and provides that a patient has the right to access to health care according to the patients need, right to be cared by a competent health worker, right to access medicines and vaccines." (Patients Charter, 2008)

3.2.5 Arguments and application of the rule of law relevant to the right of health

Firstly, I will provide an account of the scope of the right to health care in two forms; "the right to equal access to health care and the right to a decent minimum of health care." (Beauchamp, 2001 pp 244) The first right promotes "equal access to all bona fide health resources while the latter incorporates a weaker egalitarian point of view that entails access only to fundamental health care resources." (Beauchamp, 2001 pp 244) Malawi provides health care based on the decent minimum of health care using Essential Health Care Package (EHP) reminiscent of the notion that all patients have certain rights commensurate with their autonomy including to access quality health care. In order to provide EHP in rural areas, the Ministry deploys HSAs to offer health care including curative services to the rural population. In addition, HSAs job description has expanded disregarding issues of safety and quality. However, I claim that subjecting the patients to HSAs clinical care is a violation of the community rights to access quality care because of the flawed delegation of tasks hence it is observed that some "health policies, programs, and research can violate human rights." (Dhai, 2011)

In addition, "ICESCR Article 12 on the human right to health guarantees the creation of conditions which would assure to all medical service and medical attention in the event of sickness." (Zeldin, 2007) The "right to health care is a positive right as one is entitled to the provision of some good or service." (Beauchamp, 2001 pp 244) Hence, providing quality medical care is a positive right for the population while they have also negative right not to be provided with substandard clinical care. In this case, there is a moral urgency to achieve both rights to health as "to have a right is to have a valid claim." (Wenar, 2015) In addition, it is argued that "the fundamental right to health care does not exist but only exist where it has been

discovered or legislated as such." (Connor, 1990) Therefore, the provision of curative care to the public using the HSAs falls short of providing and achieving the right to access quality health care up until when the HSAs program in clinical care is properly regulated under statutory law. Hence, I claim that it is imperative that clinical care from HSAs should be improved and regulated to uphold the patients' right to health care.

Furthermore, the right to health is an economic, social, and cultural right and every human being is entitled to enjoy it and should promote a better environment to living a life in dignity. The right to health, therefore, is interpreted along with the determinants of health such as availability of food, clean and safe water, housing and quality health services. Therefore, a good health resulting from accessing medical care from qualified and registered HSAs will amount to a dignified life by the public. Likewise, the "Article 12.1 of ICESCR provides for the states' obligation to progressively fulfill the full realization of the rights under the covenant." (UDHR, 1948) Malawi acknowledges the right to health through the Government Patient Charter. Hence, it is obligatory for the health regulatory bodies, Ministry of Health and stakeholders to act as change agents to ensure that provision of curative services by HSAs complies with the good medical standards and appropriate for the rural population.

Additionally, the Charter sets the "core minimum obligations towards the realization of health such as the right to health services and its related goods, access to minimum essential food, shelter, housing and sanitation, and safe drinking water." (Malawi Law Commission, 2012) This is consistent with the Constitutional requirements in "Section 13 c which asserts for the provision of health needs of Malawian society and commensurate with international standards." (Constitution Malawi., 2006) However, the Malawi Law Commission on the Public Health Act

review observed that the Malawi Constitution does not enshrine the right to health directly. (Malawi Law Commission, 2012) The right is encompassed in the "right to life (Sec 16 of the Malawi Constitution) which is interpreted to provide for positive measures to reduce poor health indicators such as high infant mortality rate and increase life expectancy rather than ending of life only consistent with the international law." (Constitution Malawi., 2006) This is also consistent with the "The Convention on the Rights of the Child Article 24" (UNICEF, 1990) and "Article 12 of the Convention on the Elimination of All forms of Discrimination against Women." (CEDAW, 2009). In this regard, the HSAs have been applauded for work in programs that reduces child mortality through programs such as immunizations.

However, I claim that extending their job description to include clinical care functions without proper health regulation adjustments can derail or dent the progress of addressing disparities in accessing health care and expose the public to risks of harm due to compromised quality of care through misdiagnosis, poor recognition of danger signs in children. (Gilroy, 2012) Therefore, in order to further improve HSAs performance through operating village health clinics, which is an added clinical function to their job description, I propose for the redefinition of their competency profile through the revised curriculum, training, and proper supervision.

The right to health care is also expressed in "Section 30 of the Malawi Constitution which provides for the right to development as it recognizes that access to among other things, health services is one of the necessary measures for the realization of the right to development." (Constitution Malawi., 2006) Hence, based on the rights approach, which demands empowering people to know and claim their rights, providing services in a non-discriminatory and legally acceptable manner, I argue that the right to access health care goes beyond empowering HSAs to make health care and curative services available and accessible. In addition, the health care

should be acceptable and of good quality. The HSAs job description, therefore, needs proper credentialing and statutory regulation so that they are more capable of providing quality care in an acceptable environment.

3.3 Lack of appropriate Supervision

3.3.1 Rule of law

The relevant law related to supervision of HSAs is grounded from the common law and tort law

3.3.2 Argumentation and application of the law

I claim that supervision is one of the cornerstones in achieving maximum inputs from the community health workers such as HSAs, as another study observed that "the training and supervision helped community health workers to overcome difficulties and strengthened their capacity to meet participants' needs in India and South Africa." (Padmanathan, 2013) However, I argue that the HSAs supervision by the Environmental Health Officers, Nurses, Medical Assistants, Clinical Officers and Doctors is flawed based on the following premises: HSAs are supervised by Assistant Environmental Health Officers for their basic public health practices and the clinical team from the health center such as Medical Assistants and Nurse Midwife Technicians for clinical care services. Therefore, my objections and arguments to such arrangements are based on the following premises: The HSAs positions in the hierarchical structure of the Ministry of Health fall within the Environmental Health Department hence are required to report to the Assistant Environmental Health Officers. However, the approach creates role conflicts in terms of loyalty during supervision as Environmental Health Officers and

Assistant Environmental Health Officers have no expertise in clinical medicine hence subjecting HSAs to ambiguities in reporting structures since they are required to report to both the Environmental Health Officers and the clinicians. According to Smith et al, they observed that "Assistant Environmental Health Officers cannot supervise HSAs on clinical care since their expertise is on environmental health and are not oriented on curative services." (Smith, 2014)

In addition, I claim that it is unacceptable for the clinical team to supervise HSAs clinical practice on whose competency on curative services they cannot rely since they are not registered and have no scope of practice set by the health regulatory body which the supervisors can relate to, and based on the legal liability on delegation. HSAs do not have appropriate training for clinical medicine and hence, are vulnerable to committing negligence and providing substandard care. (Gilroy, 2012) When a patient is harmed or injured while under the HSA care, the clinician and the nurse charged with supervision may face legal liability from the injured patient based on vicarious responsibility. In addition, when the supervisor writes a wrong order, the HSA performs it; the supervisor will be liable for the injury directly. Therefore, either way, for Environmental Health Officers to supervise HSAs on curative services subject them to legal liability and for clinicians and nurses to supervise HSAs, expose them as well to the risk of legal liability. Therefore, I conclude that it is ethically and legally not plausible to allow HSAs to practice clinical medicine due to uncoordinated supervision.

3.4 Right to Human Dignity and Health Care Acceptability

Firstly, I will provide an account of human dignity and the account of health care acceptability. Human dignity is described by Immanuel Kant as "the inherent feature of persons and are entitled to be treated with respect by virtue of his or her humanity," (Degrazia, 2010 pp 18) It can be harmed by bad laws, policies and actions on individuals and the public. While as healthcare acceptability means "health facilities, goods, and services must be culturally appropriate and as well as sensitive to gender and life-cycle requirements." (WHO Fact Sheet, 2007) In this section, I will argue how HSAs clinical practice violates human dignity and fails to meet requirements on acceptability, quality issues, and professionalism.

3.4.1 The laws relevant to human dignity

3.4.2 International law

Article 3 provides that "everyone has the right to life, liberty, and security of person." (UDHR, 1948)

3.4.3 Malawi Constitution

Section 18 provides "that every person has the right to personal liberty and Section 19 (1) provides that the dignity of all persons shall be inviolable and (6) provides that every person shall have the right to free and security of person." (Constitution Malawi., 2006)

3.4.3.1 Argumentation

The statutory law demands that health care providers must respect individual dignity by following the medical ethics and protecting the patients' rights. HSAs do not have training in medical ethics and professionalism. Despite HSAs assumed superior knowledge of cultural practices and beliefs, I argue that HSAs fail to incorporate the ethical and legal requirements to their practice because of inadequate training, therefore are likely not to adhere to ethical issues such as privacy and confidentiality. For example, it is argued that "doctors have common law and statutory obligations to keep patient information confidential and any breach of this standard can be an act of malpractice." (Deubert, 2016 pp 105) This is consistent with the responsibilities enshrined in the Patient Charter which assert that "health workers should comply with the professional code of conduct." (Patients Charter, 2008) Hence, I claim that the use of HSAs to provide curative care is legally wrong since they are underqualified and unregistered and doing so is a violation of the right to human dignity. In addition, this is inconsistent with the Malawi Constitution, the Patient Right Charter and the international law which demand that states should use well qualified medical professionals to provide quality care and that the individuals' dignity must be protected and respected.

Furthermore, I claim that HSAs conduct of consulting in clients' houses and/or under the tree (Kok, 2013) instead of the accredited facility violates the patients' rights to privacy and confidentiality. Additionally, a study report showed that women were not comfortable with male

HSAs to consult in their house. (Kok, 2013) Therefore, I conclude that HSAs clinical practice violates the patients' rights to human dignity hence ethically and legally wrong.

3.5 Legitimacy, Training and Competency

3.5.1 Relevant laws related to HSAs training and competency

3.5.2 Medical Practitioners and Dentists Act No 17 of 1987

The relevant statutory law is enshrined in the Medical Practitioners and Dentists, Malawi.

"Section 59 provides that no unregistered persons should practice as medical practitioners:

a) For gain, practices or carries on business as a medical practitioner, whether or not purporting to be registered or performs or undertakes to perform any act especially pertaining to the practice of a medical practitioner.
b) Pretends or, by any means whatsoever, holds himself out to be a medical practitioner, whether or not purporting to be registered" (Medical Practitioners and Dentists Act, 1987)

3.5.3 Argumentation

In this section, I argue that HSAs are not allowed under statutory law to provide curative services to the population since they are not well trained using a vetted curriculum and are not registered with any health regulatory body. The law prohibits unregistered practitioners to practice

medicine. My arguments are based on the following premises: Firstly, I claim that there is significant inequality and disparity in healthcare access between the urban and rural population whereby the rural population is disadvantaged in receiving care from competent practitioners. Hence, to avert the situation, the Ministry of Health deployed the HSAs to provide curative services such as ICCM, DMPA programs in rural areas. However, HSAs do not have adequate key competencies relevant to clinical work consistent with the report that "HSAs are not competent or not happy to perform tasks for which they are not trained." (Smith, 2014) The implication is that the rural population is provided clinical care but of minimal standards. The Ministry of Health ought to provide education and training that promotes skills competency and professionalism of HSAs. This is consistent with "WHO recommendation NO. 5 and 8 on which advises countries to revise competency levels of existing cadres and new cadres being created to offer curative care." (World Health Organization, 2008)

Secondly, the law prohibits unregistered persons to offer curative/clinical services. This is provided in Section 59 of the Medical Act which restricts unregistered persons to practice medicine for gains or any other purposes. (Medical Practitioners and Dentists Act, 1987) I therefore, claim that HSAs are not registered to practice medicine. However, they offer curative services which is inconsistent with the Medical and Dentist Act and the International Law. The use of HSAs to provide clinical care without being well trained and not registered, risks the trust of the public and can erode the value of the medical profession and its role in improving health. Hence, it is legally wrong to allow HSAs to practice clinical care.

Thirdly, HSAs fail to get appropriate skills during their orientation training in 6-day ICCM training, among other conditions fail to manage a convulsing child. (Gilroy, 2012) Hence, HSAs

inadequate competences in clinical practice expose the vulnerable populations and the patients to the risk of harm. However, with proper training, I claim that HSAs will be valuable to manage childhood conditions including HIV/AIDS services in addition to providing prevention services.

3.6 HSAs Legal Liability for Harm and Unprofessional Conduct

The laws relevant to HSAs liability are derived from the common law, tort law, statutory law, and international guidelines:

3.6.1 Medical Practitioners and Dentists Act No 17 of 1987

The relevant statutory law is enshrined in the Medical Practitioners and Dentists, Malawi.
Section 49 provides that "a registered person who has been convicted of an offence by a court of law within or outside Malawi, whether before, on or after the date of his registration, shall be liable to disciplinary inquiry by the Disciplinary Committee in accordance with the provisions of this part if the Disciplinary Committee is of the opinion that such offence constitutes: Improper or disgraceful conduct; or Conduct which, when regard to the profession or calling of that person, is improper or disgraceful." (Medical Practitioners and Dentists Act, 1987)

3.6.2 Argumentation

Under common law and statutory law, it is argued that "doctors have obligation to provide health care /clinical care according to the standard of care in their profession whether medical or nursing or they may be subjected to a malpractice claim." (Deubert, 2016 pp 105) This is

consistent with “Section 49 of the Medical Practitioners and Dentists Act, 1987 which provides that any practitioner that demonstrates improper and disgraceful conduct, criminal acts can be subjected to the disciplinary process.” (Medical Practitioners and Dentists Act, 1987) However, I argue that both HSAs and Ministry of Health are liable for the malpractice or harm inflicted on patients during their practice and criminal activities under tort law and could be subjected to the court process. “Tort law is defined as the body of rights, obligations, and remedies that are applied by the courts in civil proceedings to provide relief for persons who have suffered harm from the wrongful acts of others.” (Legal Dictionary, 2016)

Firstly, I claim that HSAs would be liable for the malpractice or harm caused on patients for performing delegated clinical tasks beyond their capacity, liable for follow-up care and abandonment, liable for exploitation of patients and have no indemnity cover. As delegated practitioners, HSAs are responsible for their actions on patients since they have a legal duty being employees of the Malawi Government. However, the medical treatment provided by HSAs may constitute a medical malpractice and they may have difficulties to prove that they acted within their scope of work since the clinical practice is not sanctioned by the health regulatory body such as the Medical Council of Malawi hence unacceptable.

Consequently, the Ministry of Health as the employer will also be liable for the breach of duty based on contract law and for damages incurred to the body of the patients by the HSAs through the doctrine of Respondeat Superior and vicarious responsibility. Under the “the principle of Agency which is part of contract law that embodies the concept of employer and employee, an employer is civilly liable for injuries to the person or property of third persons occasioned by tortuous negligence of an employee which occurred within the scope of employment.” (Kapp, 1983) The doctrine is referred to “as the Doctrine of Respondeat Superior and vicarious

responsibility which assert that an employer (Master) is civilly liable for injuries to the person or property of third persons occasioned by the tortious negligence of an employee (Servant) which occurred within the scope of employment." (Kapp, 1983) (Regan, 2002)

Furthermore, on delegation of clinical tasks to HSAs, I claim that the medical standard guidelines determine the liability standard. HSAs do not have defined clinical standards guidelines as exemplified by the uncoordinated delegation of tasks to HSAs job description by the Ministry of Health and NGOs. (Smith, 2014) Therefore, I conclude that delegation of clinical tasks to HSAs is flawed and the formulation of the guidelines can contribute to remedying of the legal uncertainty related to delegation or sharing of clinical tasks to HSAs since extending HSAs job description might require adapted liability standards. This can be achieved through proper credentialing and registration of HSAs.

Therefore, it is ethically and legally wrong to use HSAs to provide clinical care based on the job description and without statutory registration as they do not have scope of practice and cannot face disciplinary actions from a professional body as stipulated in "Section 55 of the Medical Practitioners and Dentists Act, No. 17 of 1987 which sets standards for the incompetent practitioner and with improper conduct to appear before disciplinary committee." (Medical Practitioners and Dentists Act, 1987)

3.7 Legal Justification of Statutory Regulation of HSAs

Having identified the flaws in how the HSAs program is implemented and managed and the need for the statutory regulation of their practice, I will provide and discuss the benefits of registration

based on the HSAs job description. In addition, argue that without registration, HSAs should stop practicing clinical medicine and concentrate on the public health or environmental health practice/interventions.

3.7.1 Medical Practitioners Act and Dentists Act, No 17 of 1987

Section 18 (2), provides that if the "Council establishes a register under subsection 1, it may by rule otherwise determine: the requirement to be established that includes experience to be acquired, the nature and duration of the training to be undertaken and the degree, diploma, or certificate to be held by medical practitioners or dentists before he can be registered on the register." (Medical Practitioners and Dentists Act, 1987)

"Section 42 provides that the Council shall have powers to approve of:

a. teaching hospitals
b. medical and dental schools
c. a basic medical curriculum
d. the basic medical qualification of persons to be registered as medical practitioners and dentists
e. And such other matters of training as may be within its competence under the Act or as may be expedient for the purpose and objects of the Act." (Medical Practitioners and Dentists Act, 1987)

In this regard, Medical Council of Malawi was not involved in the design and implementation of HSAs program, however Council has constantly advised the Ministry of Health to regularize HSAs program according to the statutory law.

3.7.2 Argumentation

Firstly, I provide the definition according to Johnson et al that, "registration is the process of legally recognizing practitioners' qualifications, experience, character, and fitness to practice and its purpose is to provide assurances of quality and safety, helping to overcome the information asymmetry between health professionals and the patients" (Johnson, 2010) Hence, I argue that the current clinical practice of HSAs is inconsistent with the law and put the lives of the patients at risk since they are not well trained hence prone to making errors and mistakes through misdiagnosis of patients, poor prescription practices and unable to examine patients. (Gilroy, 2012) Therefore, in order to allow HSAs to practice professionally as a remedy, they should be regulated and registered to be consistent with attributes of the medical profession and subsequently minimize harm towards the patients. A registered health care workforce provides consumers of health services with assurances to their competency skills and training. This is consistent with Health Care Assistants in Canada who were providing health care to the public despite being not regulated. Later, British Columbia set up regulations to register them. (British Columbia, 2014) Hence, I argue that HSAs should not be allowed to practice clinical medicine without statutory registration. In the absence of such regulation, they should pursue their core business of providing the basic environmental health interventions and prevention services for the benefit of the public.

Secondly, HSAs in Malawi are now performing duties supposedly done by qualified health care professionals. In addition, there is increased role of HSAs in community-based clinical care programs following reduced hospital admission stay. This is consistent with findings by "Korczyk 2004, who observed that that training home based care workers is more important as

medical advances permit more persons with complex needs to live in the community rather than in specialized hospitals." (Duffield, 2014)

The approach, however, attracts ethical and legal issues worldwide. Therefore, with respect to HSAs job description, there are issues of skills and competences, safety, professional integrity, cost, health rights issues and legal indemnity cover have come under scrutiny. It is against this background that internationally and nationally calls for regulation of unregulated health workers have been increasing.

In addition, it is argued that "ignoring the issue of new practitioner groups in regulatory schemes was unacceptable from a public health perspective and run against the key public protection of health practitioner regulation." (Lee Wardle, 2016) However, it is also observed that regulating a new group of health workers is not a simple task. According to "Royal College of Nursing, 2012, several factors must be considered including the model of regulation to employ, costs issues, and deciding which regulatory body is most suitable in overseeing this group of health workers." (Duffield, 2014) Therefore, I claim that regulating HSAs falls within Malawi's Constitutional requirements as enshrined in "Section 13 which promotes the welfare and development of the people in its quests to provide health care by progressively adopting and implementing policies and legislation aimed at achieving the health goals." (Constitution Malawi., 2006) Hence, to provide quality and safe care, the government must adopt appropriate legislation and policies on regulating HSAs and one such approach is to redefine their competences and skills and allow them to be registered as stipulated in Section 18 on the Medical Practitioners and Dentists Act, No. 17 of 1987 and consistent with WHO guidelines NO. 5, 8, and 10 which provides for the need for certification and regulations during delegation of clinical tasks to the lower cadre.

In addition, I claim that HSAs cannot write medical reports of the patients required by the police or court of law or for further treatment despite their practice since they are not registered. (Medical Practitioners and Dentists Act, 1987) The law demands that only registered medical practitioners are legally allowed to write medical reports for their patients. Furthermore, the uncoordinated expansion of HSAs job description can negatively impact team efficiency and patient care delivery through uncoordinated skills mix. Therefore, this is consistent with the observation that "the role ambiguity and role conflict for nurses toward support workers may negatively affect the functioning of the team." (Duffield, 2014)

Furthermore, HSAs lack organized professional associations where they can advance professionalism through continuous professional development and group needs.

Finally, I claim that through the promotion of the patient charter developed by the government; a lot of awareness has been carried out on the right to quality health care as enshrined in the charter. Health professionals no longer have patients who traditionally were treated as passive recipients of care

3.8 Regulation Options for Health Surveillance Assistants

Generally, health care services in Malawi are regulated by the Ministry of Health at different levels, namely the tertiary (involving referral, central or teaching hospitals) the secondary level (involving the district and community hospitals) and the primary level (involving the health centers, clinics, dispensaries, and health posts). (Malawi Law Commission, 2012) However, Ministry of Health falls short of statutory regulations as stipulated in the Medical and Dental Act,

Nursing and Midwifery Act and Pharmacy, Medicines and Poisons Act which belongs to the three health regulatory bodies in Malawi namely: Medical Council of Malawi, Nurses and Midwives Council of Malawi and Pharmacy, Medicines, and Poisons Board respectively. HSAs are not registered with either of the health regulatory body. In addition, my arguments are consistent with WHO Recommendation 5 which states that "Countries should assess and then consider using existing regulatory approaches (laws and proclamations, rules and regulations, policies and guidelines) where possible, or undertake revisions as necessary to enable cadres of health workers to practice according to an extended scope of practice and to allow creation of new cadres within the health workforce." (World Health Organization, 2008)

In order to remedy the problem created by HSAs job description status, I will discuss the regulation options that can possibly be used to remedy the HSAs job description by linking it to their proposed development of the scope of practice. The regulation options are adapted from the "Regulation of the health professions in Victoria (cited in Victoria Government Department of Human Services 2003 p.20) adopted by Australian Nursing Federation in 2009:" (Adrian, 2009) as they were applied to unregulated health professions.

3.8.1 Self- Regulation

This model suggests that “there is no occupational licensing or registration that requires members of the workforce to be registered with a statutory body, no government oversight functions of educational and work standards and there is no formal judicial process that makes up a disciplinary system for them.” (Adrian, 2009)

I claim that this type of regulation cannot be applicable to community health worker programs such as HSAs who are providing clinical care in addition to their basic public health practice, and does not protect the public from harm. The public cannot separate between members of self-regulating practitioners and those who are not members hence the patients informed choice may be compromised in choosing to be assisted by a qualified practitioner.

3.8.2 Licensing

This licensing option “requires that there are a normal classification and naming of the cadre/craft. The practitioners’ details are placed on a government oversight register of persons who are working in specific industries. The person must establish their credentials such as basic qualifications, being to abide by a code of conduct and/or ethics, and/or practice standards in order to be employed.” (Adrian, 2009)

This model can be recommended as it provides basic standards of education, practice, and conduct being set as a baseline but does not provide protection of the Title.

3.8.3 Negative Licensing

It describes that “any person is able to work in health and aged care institutions unless they are placed on a register of persons who are ineligible to practice. It does not establish barriers to entry to the workforce but allows those with poor practice records to be excluded from practicing without the need for a full registration system. This model, however, provides less protection to consumers and may be inappropriate where there is potential for serious harm.” (Adrian, 2009)

I argue therefore against the use of this model for HSAs clinical practice and job description as it does not adequately protect the community or set basic standards for education, practice or conduct.

3.8.4 Co-Regulation

Under this option, “regulatory responsibility is shared between government and the industry. For example, worker associations set membership requirements and administer a disciplinary scheme to ensure practice standards. The government monitors and accredits these organizations to ensure they act in a way that protects members of the public. However, workers who are not members of a co-regulated association are not legally prevented from practicing or using the titles of the profession.” (Adrian, 2009)

I argue that this model cannot be applied to HSAs clinical practice as it does not completely protect the community from unregistered practitioners hence is not feasible.

3.8.5 Reservation of Title Only

Under this option, “particular titles of the cadre can only legally be used by those who are licensed by the registration board. A statutory registration board establishes qualifications and character requirements for entry into the profession, develops standards of practice, and receives and investigates complaints of unprofessional conduct, poor health or performance and applies sanctions including deregistration. This form of regulation assures consumers that workers are qualified to provide services and their practice is subject to the scrutiny of a registration board.” (Adrian, 2009)

I will recommend for the use of this regulation model for HSAs limited clinical practice as it enhances transparency, competency, accountability, and professionalism. It is feasible for delegation and sharing of tasks.

3.8.6 Reservation of The Title and Core Practices

In this type of regulation option, “it describes that certain risky and intrusive acts or procedures within the defined scope of practice of a profession are restricted through legislation only to members of the registered worker group and others identified in the legislation. Unregistered and unauthorized workers are prohibited from using reserved titles and may be liable for prosecution for an offense if they carry out any of the reserved core practices. Exemptions are allowed for treatment provided in an emergency and where students perform core practices under the direction and supervision of an authorized and qualified member of the profession.” (Adrian, 2009) I would not support the application of the model of regulation despite that it fits well with principles of task sharing and task shifting where certain procedures are allowed to be performed

by the other cadre in times of emergencies and need. It is too strict in situations where a shortage of health workers is perennial.

3.8.7 Reservation of The Title and Whole Practice

It is the "most restrictive form of regulation and includes not only offenses for unregistered members to use the professional titles, but also a broad scope of practice definition of the profession. It is also an offense for unregistered persons to practice the profession." (Adrian, 2009) This model is not feasible for HSAs as community health workers because of its restrictiveness where a delegation of clinical tasks is based on task shifting and task sharing and the practice is usually supervised.

3.9 Implications

The implication of subjecting HSAs to registration is that only those who are registered and are in good standing will be allowed to practice restricting HSAs who are not qualified and are not in good standing to practice. Unregistered HSAs will be restricted to continue basic environmental health approaches such as the health promotion, disease surveillance, reporting outbreaks.

3.10 Conclusion

In this Chapter, I have provided arguments against and for HSAs clinical practice in their extended job description. On the Rights to Health, I have argued that HSAs provision of clinical care to the public is in contravention and violate human rights as issues of safety, competence,

and quality are compromised hence risking the vulnerable patients to risks of harm defeating its intended purpose of improving access to health care to the majority rural population.

On supervision, I have argued on the issues rising from the Environmental Health Officers supervising HSAs yet they do not have clinical expertise brings in reporting ambiguities on reporting boundaries and loyalty. Additionally, the supervision by the clinical team from the health center in the catchment area is flawed since they are mentoring and transferring clinical skills on the cadre who do not have the defined scope of practice. The approach exposes the practitioners, and the HSAs themselves to unnecessary risks of liability under the common law.

On liability issues, I have argued that HSAs scope of work exposes the HSAs and the Ministry of Health to liability issues through the principle of Agency and the Doctrine of Respondeat Superior and Vicarious Responsibility. The liability is defined by the medical standards liability of which HSAs are not registered to practice and have no scope of practice to refer to.

On the Right to Human Dignity, HSAs practice violates the patients' right to dignity since they are not trained in medical ethical codes, principles and basic legal issues hence cannot apply them when managing patients. For example, the patients' rights to privacy and confidentiality are violated as they are consulted in personal houses and under the trees.

Finally, I have argued that HSAs practice demands statutory regulations despite being regulated by the Ministry of Health as employees. I have provided the benefits of registration to HSAs, the patients, the community and the country. However, I have also argued that as a country, Malawi needs HSAs as community health workers competent in providing environmental health skills and basic clinical skills to improve access to quality health care services in pursuit to resolving the disparity in access between the majority rural population and urban population. The proposed

legal framework can provide practical regulations guidance not only for the HSAs but for the institutions with which they work.

CHAPTER FOUR: CONCLUSION

The aim of the research is to establish and discuss the ethical and legal implications of HSAs job description in Malawi, the problem perpetuated by the shortage of medical workforce in Malawi. Furthermore, O'Brien reported that "health workforce has replaced system financing as the most serious obstacle to realizing the right to health within countries and most health services cannot be assured in the absence of trained health workers." (O' Brien, 2011). However, I have argued that the current HSAs job description which enables them to provide curative care is both ethically and legally wrong. Hence, I have proposed the frameworks that will improve HSAs practice through proper credentialing and registration. The strategy of increasing medical doctors, clinical officers and nurses will not solve this problem alone.

HSAs have evolved from smallpox vaccinators, Cholera Assistants and HSAs who diagnose diseases in addition to their public health roles. Hence, continuing to ignore the issue to include HSAs in statutory regulations is detrimental from a public health perspective and is inconsistent with the key objective of "Medical Council of Malawi which is to protect the patients, the general public and guide the medical profession." (Manyozo-Phiri, 2001) Therefore, in- order to protect the public through the provision of quality health care, the development of the model for regulating HSAs is of paramount importance. The call for licensing of Health Surveillance Assistants in Malawi is consistent with the worldwide phenomenon such as the American and Canadian models on licensing community health workers who are involved in clinical care such as Health Care Assistants. (British Columbia, 2014) The models offer one strategy that could allow flexible medical delegation through task shifting and task sharing while expanding the role of regulatory bodies.

In this paper, I have argued that shortages in the professional health workforce compounded by the increasing demands of managing health care impacts the provision of health care in hard to reach areas. This has led to delegation of clinical tasks to community health workers like HSAs in Malawi through task shifting and recently task sharing. HSAs were initially tasked through their job description to do public health practice concentrating on basic primary health care. However, over the years due to shortages of professional staff to offer the clinical services to the rural population, the Ministry of Health expanded HSAs roles to offer clinical tasks beyond their job description or scope of work. For example, conducting sputum for TB, through microscopy and providing of treatment for children through Integrated Community Case Management (ICCM). This was consistent with practices comparatively from USA, Canada, Australia and UK where unlicensed community health workers were performing roles formerly done by qualified and registered health workers such as in nursing homes and in patients' care services.

Against this background, there have been calls internationally to regulate community health workers who are involved in providing clinical care to the public. Some States in the USA such as Texas and Alaska have set up regulations to license them for accountability, the safety of the public, and their own recognition and career progression. Similarly, in Malawi, there have been calls to regulate HSAs by Medical Council of Malawi and other stakeholders as the Ministry of Health continues to delegate clinical tasks with the aim of increasing access to health care services to the public.

Different studies have highlighted shortfalls of HSAs clinical practice such making the wrong diagnosis, providing wrong initial treatment, poor supervision, and inadequate training for the clinical care services. (Gilroy, 2012) Hence, I have argued that the practice has led to ethical and legal violations and have fallen short of medical profession standards and integrity requirements.

Despite the shortfalls, HSAs have proved to be a critical link between the community and the hospital; hence as a country, Malawi need HSAs to provide community health services and limited clinical practices to assist in improving access to clinical health care and social services among underserved populations in rural as well as urban places in the country. This can be achieved through revised competency profile, credentialing, defined scope of practice and registration. I therefore have argued for statutory regulation of HSAs as the current policy is both ethically and legally wrong based on the following ethical principles.

Beneficence: The state through its regulatory bodies such as Medical Council of Malawi ought to act in the best interest of the public by ensuring that quality health care services are provided, hence requires protecting the patients and the public from unscrupulous practitioners and unsafe practices. I have used the principles such as harm principle, paternalism and social welfare principle for restriction of HSAs practice until a formal review is done and scope of practice is developed. Finally, based on the Cost Benefit Analysis, I argued that the cost of managing the immediate and long term effects of using HSAs to provide clinical care outweigh the benefit of re-defining the HSAs competences on clinical care hence it is morally right to subject their practice to the statutory regulation, and if not the delegation of clinical care practice to HSAs by the Ministry of Health and health NGOs should cease.

Non-maleficence: The Ministry of Health action of expanding the job description through additional clinical tasks is subjecting the public to risks of harm for which they will have no recourse when they are harmed and the HSAs would not be subjected to disciplinary actions by a regulatory body as they are not regulated and registered. The state ought to prevent harm to the public through the regulatory authorities by allowing only qualified and registered health care personnel to practice clinical medicine. Based on the risk-benefit analysis, the risks of harm of

exposing the public to unregulated HSAs is inconsistent with the principle of non-maleficence hence ethically wrong.

Autonomy: The rural population decision to attend to such services is inconsistent with the right to self -determination since for an individual to make an independent decision on whether to access quality health care, requires one to have sufficient information. However, the rural population mainly children and women are vulnerable as they lack such information and their right to access quality health care does not exist as the right exists only when the health care services are legislated and regulated. It is in this context that allowing the HSAs to provide clinical care to the public based on the current job description is inconsistent with the principle of autonomy therefore ethically and legally wrong.

In addition, I have argued using "distributive justice which is defined by Beauchamp and Childress, as fair, equitable and appropriate distribution in society determined by justified norms that structure the terms of social cooperation." (Moodley, 2011) Based on this principle, I have argued that the Ministry of Health actions of using HSAs to provide clinical tasks is consistent with utilitarianism whose standard of justice depends on the principle of utility which "asserts to provide the greatest good for the greatest number." (Moodley, 2011) The Ministry of Health motivation is on improving access to health care and medicines to the public but ignores issues of quality of care and public safety. Therefore, providing unregulated health services based on the current HSAs job description to the public is unjust to the HSAs themselves and the patients. The HSAs are overloaded with delegated clinical tasks by different NGOs and the Ministry of Health and there are risks of harm to the patients associated with it. (Kok, 2013)(Gilroy, 2012)

I also argued that that the economic cost to the public of regulating HSAs are justified since the intent of regulation in the medical professions is to decrease the risk of harm to the public.

However, it is claimed that the "increased costs to the public are also considered harm and should be mitigated where possible." (Johnson, 2010) I also argued on the justification of HSAs registration in Chapter 3 that some mitigation will be to recommend the less restrictive form of regulation which would protect the public, increase the quality of care and including the consideration for grandfathering as a criterion for registration for experienced HSAs with the right qualifications.

I claim that legally: The Malawi Constitution, statutory law, Patients Right Charter and the international law call for everybody to access the highest standard of health care proportionate with the health needs of the population and international health standards to protect the public from harm. Hence, it is the Government responsibility to provide quality health care to the public. On this basis, the Ministry of Health use of unregistered HSAs in clinical medicine is in contravention of the law and infringe the rights of the public to access quality care and inconsistent with the WHO guidelines on Task Shifting hence ethically and legally wrong. In addition, I argued that allowing HSAs to practice medicine using the current job description and without registration means that they are not adequately held accountable for their actions regarding any adverse outcome. Finally, the HSAs, the Ministry of Health and the supervisors are exposed to liability issues under tort law based on the Principle of Agency and through the doctrine of Respondeat Superior and vicarious responsibility.

As detailed in the recommendations, the core implication is that only HSAs who are registered will be allowed to offer curative services in addition to environmental health roles.

CHAPTER 5: RECOMMENDATIONS

These recommendations are responses to the objections that HSAs clinical practice is both morally and legally wrong. Hence, in order to appropriately use the HSAs to provide community health services and clinical services to the public, the following recommendations should be met:

5.1 Stakeholders should develop a clear policy framework which will provide direction on training and supervision.

- HSAs shall undergo an accredited training and on the job training
- HSAs shall participate in continuous professional development
- Assistant Environmental Health Officers, Medical Assistants, Clinical Officers and Nurses shall form part of the supervisory team representing the District Health Officer.

5.2 HSAs should be regulated under the Reservation of the Title only model

Under this option, particular titles, such as Health Surveillance Assistants will legally be used by those who are licensed to practice by the registration board.

Medical Council of Malawi will establish qualifications and character requirements as requirements for registration, develop standards of practice, and receive and investigate complaints of unprofessional conduct, poor health or performance and apply sanctions including deregistration. This form of regulation will assure the patients that practitioners (HSAs) are qualified to provide services and that their practice is subject to the scrutiny of a registration

board. In addition, it is less restrictive form of regulation that can accommodate community health workers such as HSAs.

5.3 Medical Council of Malawi should set regulation framework for the HSAs cadre defining competences, scope of practice and liabilities

In response to the issues discussed and the set objective of proposing the ethical and legal framework, I have used the guide in appendix 4.

5.3.1 Medical Council of Malawi is appropriate health regulatory body to exercise responsibility for regulating HSAs

HSAs job description enables them to practice basic clinical medicine beyond their scope of training. Medical Council of Malawi's broad objective is to protect the public and guide the medical profession. The Medical Act in "Section 10 stipulates that it is the sole registering authority of all persons required under this Act" (Medical Practitioners and Dentists Act, 1987) In addition, HSAs are within the Environmental Health with the Ministry of Health hierarchy whose supervisors Environmental Health Officers and assistant Environmental Health Officers are registered. Finally, much of the delegated clinical tasks fall within the scopes of the medical profession.

5.3.2 The clinical activities performed by HSAs pose a significant risk of harm to the health and safety of the public

HSA training on clinical medicine is on workshops and is not included in core learning content with the normal twelve weeks, lack of professionalism and ethics training and coupled with poor skills in practice through wrong diagnosis and treatments. Hence, this inconsistent the Patients Right Charter that provides for the right to access quality care and to be treated by competent health professionals. (Patients Charter, 2008)

5.3.3 The existing regulatory or other mechanisms fail to address health and safety issues

The Medical Act provides for disciplinary action for those who are under their register and HSAs are not yet registered with any health regulatory board hence cannot provide oversight functions on safety and protection issues for the public despite the Ministry of Health having its own internal disciplinary processes.

5.3.4 It is feasible to implement statutory regulations for the occupation of HSAs cadre.

The feasibility of regulating HSAs is based on the following: They are salaried community health workers employed under Ministry of Health. The Ministry is willing to implement changes in one-year training among other things subjecting them to statutory regulations as stipulated in Task Shifting Guidelines. Finally, The Medical Practitioners and Dentists Act provides for the establishment of a new register for the new cadre whenever deemed necessary as enshrined in Section 18 (1) in addition.

5.3.5 It is practical to implement the regulation for the occupation of HSAs

Medical Council of Malawi is mandated to review and approve curriculums, teaching hospitals, medical and dental schools, and the basic medical qualifications of persons registered through its established committees such as Education and Training Committee as enshrined in the 'Section 42 of the Medical Practitioners and Dentist Act. In addition, Medical Council of Malawi already provides for registration of about 40 cadres in Malawi as shown in Appendix 3. On economic impact, the economic costs to the public for regulating the HSAs are justified, since HSAs will be trained using accredited curriculum, in accredited colleges, and will provide clinical care in approved settings such as renovated dispensaries and health posts

5.3.6 The benefits of regulation of HSAs to the public clearly outweigh its potential negative impact

The safety of the public and recognition of the HSAs will be improved following their statutory registration. Despite the strides achieved by HSAs in improving health indicators such as immunization programs, their involvement in clinical care have led to arguments such as poor clinical decision making, such as errors in treatment, and misdiagnosis that could subject patients to immediate and long term effects as reported by Gilroy et al. The regulation protects the public from getting health care from unscrupulous practitioners as only registered practitioners will be allowed to practice. Regulation is the catalyst for effective training and supervision programs which will improve their practice. In addition, the training will be the source of revenue for health training institutions and universities. This is consistent with findings by Solomon et al, who observed that registration of health practitioners "provides the necessary safeguards for

professionals and clients to ensure quality services are provided by people with the requisite skills and knowledge to practice provides standardization, credibility and professional identity." (Solomon, 2015)

Consumers will be able to lodge complaints against harm and unprofessional conduct. This is consistent with the Australian Parliamentary Committee Report that "registration process provides an important avenue of complaint and redress against the registered health professionals who fail to meet the standards required under the registration framework and enables meaningful responses to ensure public protection." (Health Practitioner Registration and Other Legislation Amendment Bill 2012, 2013)

5.4.0 HSAs should acquire proper credentials to qualify for registration with Medical Council of Malawi

In order to provide redefined competences which would result in desired knowledge, skills and attitudes, HSAs ought to achieve proper credentials that will be recognized. "Credentialing is a process of administrative procedures and documentation that one must meet to gain credentials that include the creation of a certificate showing completion of training and education, credentialing authority, and requires meeting eligibility." (Mayfield-Johnson, 2011)

A suggested credentialing system as adapted from Center for Health Law and Policy Innovation: Harvard Law School 2014 is detailed in Appendix 5. (Miller, 2014)

5. 4.1 HSAs will have desired definition and scope of practice

Health Surveillance Assistants are employed by the Ministry of Health and are front line workers that act as primary contacts to communities, families, act as a critical link to improving access to services and achieving many health care goals. (Ministry of Health, 2014) In Malawi, HSAs fit

in this definition. However, HSAs in addition performs clinical functions hence requires credentials for them to practice. Medical Council should set the scope of practice for HSAs to guide the profession and to limit unsanctioned delegation of tasks beyond their job description and scopes.

5.4.2 Credentialing will be linked to registration system in which only licensed HSAs will be permitted to perform tasks according to their scope of practice.

HSAs will undergo an accredited training and acquire a certificate and only licensed HSAs will be permitted to perform tasks according to their redefined scope of practice reminiscent of the statutory requirements of the Medical Practitioners and Dentists Act.

5.4.3 Medical Council of Malawi will accredit HSAs curriculum and training institutions.

Medical Council of Malawi is mandated through the Act to approve and accredit curriculums for Health professionals registered with it.

5.4.4 HSAs will need the credentials to practice and receive payment for their services

HSAs will have the defined scope of practice and will be able to claim for better incentives and get employment from private institutions because of their proper credentials. Hence, with the right credentials, HSAs will be recognized which is a great motivator. Credentialing will help mitigate the challenges faced by HSAs. For example, in other countries, credentialing programs of community health workers “improved career development, enhanced earning capacity that enable them to secure higher wages and improve job security, enhanced retention, improved

standards of care and health outcomes, the potential for enhanced recognition for their work and improved self-esteem and self -worth." (Kash, 2007 pp 32)

5.4.5 Malawi Government will establish training program and establish standards that private entities must meet to operate approved training programs

Generally, the Ministry of Health regulates health services in Malawi. However, per statutory regulations, the Ministry shall set up a curriculum which should be submitted to Council for accreditation. Similarly, universities and health training institutions willing to run the course will submit the curriculum for accreditation as enshrined in Section 42 of the Medical and Dentist Act that mandates Council to approve curriculums and health training institutions.

5.4.6 The HSAs will obtain a credential through completion of a training program, through qualifying work experience, or both

HSAs will obtain approved credentials from qualifications obtained at an accredited institution and training and through experience to register.

Medical Council of Malawi should set regulations through which HSAs with many years of experience can be considered for registration based on the Grandfathering. "Grandfathering is defined as any policy or rule that exempts a group of individuals, organizations, drugs from meeting new standards or regulations. For example, when a new subspecialty board in internal medicine is created, the physicians practicing in that area may be grandfathered into subspecialty

and not required to meet residency or other educational requirements." (Seden Medical Dictionary, 2012)

Under this clause, some HSAs will have to be subjected to limited training and examinations. Finally, newly employed HSAs must undergo a full training based on the approved and accredited curriculum by the Medical Council of Malawi.

5.4.7 Existing approved health training institutions, colleges, universities and health regulatory bodies and stakeholders will be involved in setting the credentialing systems for HSAs.

Approved Ministry of Health training institutions, public and private colleges and universities will have to apply for their willingness to run the program. Medical Council of Malawi usually should accredit both the institutions and their curriculums according to the set minimum requirements.

5.5.0 Additional General Recommendations

1. The Ministry of Health should revise the competency profile for Health Surveillance Assistants through revised job description.
2. Develop professional standards for HSAs that will define their role in the health care delivery system.
3. Medical Council of Malawi should develop a definition and scope of practice for HSAs in Malawi.
4. HSAs and other stakeholders must participate in the design and identification of skills and core competency requirements.

5. Medical Council of Malawi should accredit the training and certification standards that are flexible to accommodate those who are already practicing in the field, through work experience or grandfathering solutions.
6. Ministry of Health should link up with the already existing health training colleges to set modalities to train HSAs regarding approved curriculum.
7. The Ministry of Health and stakeholders should renovate and upgrade community dispensaries, under-five clinics and village health clinics where HSAs will offer services operating from the Health Centre.
8. There should be further studies to establish HSAs opinion on being subjected to statutory regulation.

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Appendix 1: Table 1: HSAs Job Description in 1997

Accessed from documentation in Government of Malawi, Human Resource Development, and Ministry of Health – Environmental Health section. 1997. (Kadzandira, 2001)

No.	Duties
1	Serves as a linkage between fixed district health services and the community
2	Works directly community leaders, volunteers, collaborates with Enrolled Community Health Nurses, Medical Assistants, and reports to Assistant Environment Health Officers.
3	Conducts community assessment
4	Conducts village inspections
5	Observes for and report disease outbreaks
6	Provides immunizations
7	Maintains equipment utilized on the job
8	Facilitates formation and training of Village Health Committees and volunteers
9	Chlorinating untreated water
10	Treats minor illnesses
11	Conducts growth monitoring
12	Refers patients and suspects to nearest health unit
13	Write monthly work plans and carries out any other duties as may be assigned to him/her by the immediate supervisor

Appendix 2: Table 2: Job Description of HSAs as adopted from Ministry of Health Guidelines for the Management of Task Shifting of HSAs in Malawi 2014

NO	ITEMS	DESCRIPTION
1	**Job Specification**	The Health Surveillance Assistant is a community-based health worker who will assist in the promotion of primary health care
2	**Relationships**	The HSAs work directly with village leaders, village health committees, and other community structures and work with other extension workers in providing promotive, preventive, and to a limited extent, curative and rehabilitative services in the assigned catchment area.
3	**Qualification**	Malawi School Certificate of Education or equivalent O-Levels
4	**Duties:**	a) Conduct community assessment within an assigned catchment area and facilities solving health and health related- problems b) Facilitates the promotion of hygiene and sanitation by conducting regular village inspection and health related problems c) Facilitates the formation and training of Village Health Committees d) Supervises Village Health Committees and other available community health support groups. e) Promotes information, education, and communication to individuals, families, and communities on health maintenance. f) Promotes and supports delivery of TB and HIV and AIDS services at community level. g) Promotes and participates in the delivery of Accelerated Child Survival and Development (ACSD) of under-five children as outlined: environmental hygiene practices, safe water supply, food hygiene practices, good nutrition practices, antenatal care

including Prevention of Mother to Child HIV Transmission (PMTCT), infant and young child feeding, vector and vermin control, family health, community home-based and palliative care, and priority health problems e.g. malaria, HIV and AIDS, anemia, diarrhea, STIs, malnutrition, and ARI).

h) Provides immunizations, vitamin A, deworming drugs, conducts growth monitoring of under-five children and give Tetanus Toxoid Vaccine (TTV) to women of child -bearing age.
i) Conducts disease surveillance and response to disease outbreaks
j) Facilitates provision of safe water supply, chlorination of water at the house- hold level, and monitors the quality of water.
k) Conducts village health clinics on specified days for the treatment of minor ailments and refers severe cases to the nearest health facilities.
l) Maintains equipment utilized on the job.
m) Records data in relevant registers and instruments e.g. Village Health Register and shares the information to relevant stakeholders within his/her catchment area
n) Conducts tracing, monitoring of treatment, and follow-up of patients and clients.
o) Inspects public facilities such as schools, markets, water sources, public toilets, health facilities, and restaurants.
p) Writes monthly work plans and reports.
q) Motivates communities about Reproductive Health (RH) and provides selected RH services
r) Promotes the control of vector and vermin at the household level.
s) Performs any other duties deemed reasonable for the post by the immediate supervisor.

Appendix 3: Table 3: Registered Practitioners as of July 2015

NO	CADRE	TOTAL NUMBERS
1	Medical Doctors	2080
2	Clinical Officers	1819
3	Medical Assistants	2481
4	Lab Technicians/	749
5	Lab Technologists	257
6	Dentists	131
7	Dental Therapists	224
8	Anaesthetic Clinical Therapists	143
9	Anaesthetic Nurse Therapists	19
10	Orthopedic Clinical Therapists	101
11	Orthopedic Clinical Officers	41
12	Clinical Nutritionists	8
13	Occupational Therapists	41
14	Physiotherapists	137
15	Clinical Psychologists	8
16	Clinical Counsellors	2
17	Opticians	26
18	Environmental Health Officers	307
19	Rehabilitation Technicians	77
20	Radiography Technicians	213
21	Orthopaedic Technologists	5
22	Psychiatric Clinical Officers	35
23	Radiographers	48
24	Radiography Assistant	3
25	Rehabilitation Assistant	77

26	Specialists Doctors	617
27	Speech Therapists	5
28	Dental Technologists	3
29	Community Oral Health Educators	4
30	Audiology Technicians	8
31	Audiologists	8
32	Assistant Environmental Health Officers	84
33	Optometrists Technicians	15
34	Optometrists	30
35	Orthopedic Technicians	14
36	Demarto-Venereology Officers	9
37	Dieticians	5
38	Ear, Nose & Throat Clinical Officers	13
39	Health Assistants	242
40	Laboratory Assistants	313
	TOTAL	**10,303**

Criteria for Assessing the Need for Statutory Regulation on Unregulated Health Occupations

To set the registration of the HSAs, I will use the following criteria as adapted from the Australian Health Ministers Advisory Council 1995. (Adrian, 2009)

Appendix 4: Table 4: Showing the criteria for assessing the need for statutory regulation on HSAs

Criteria	QUESTION
Criterion 1	Is it appropriate for Medical Council of Malawi to exercise responsibility for regulating the HSAs or does their occupation more appropriately fall within the domain of another health regulatory body?
Criterion 2	Do the activities of HSAs in practicing clinical medicine pose a significant risk of harm to the health and safety of the public?
Criterion 3	Do existing regulatory or other mechanisms fail to address health and safety issues
Criterion 4	Is regulation possible to implement for the occupation of HSAs in question?
Criterion 5	Is regulation practical to implement for the occupation of HSAs in question?
Criterion 6	Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

Appendix 5: Criteria for Community Health Worker Credentialing System

For Malawi to license and register HSAs for their clinical practice, I will use the community health worker credentialing system, as adapted from Center for Health Law and Policy Innovation: Harvard Law School: (Miller, 2014)

NO	CRITERIA
1	What will be the definition of Health Surveillance Assistants? What skills and core competencies will be required? Will the definition related to a candidate's relationship with the community to be served, which is central to many definitions of the community health worker?
2	Will the credentialing be a certification system, in which certified HSAs are designed as qualified to work in the field or a licensure system in which only licensed HSAs are permitted to perform tasks per their scope of practice?
3	Will the government create and manage the credentialing system? If so, which health regulatory body will handle these tasks?
4	Will HSAs need the credential to practice or need the credentials to receive payment for their services?
5	Will government through Ministry of Health establish a training program or establish standards that private entities must meet to operate approved training programs.
6	Will the HSAs be able to obtain a credential through completion of a training program, through qualifying work experience, or both?

7 Through what process will the credential and training system be designed? Who will be involved in the process?

Appendix 6: Copy of Ethics Waiver from Human Research Ethics Committee (Medical)

Human Research Ethics Committee (Medical)

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South African National Health Research Ethics Council registration: REC-250208-04
United States Office of Human Research Protections registration: FWA00000715 IRB00001223

Ref: W-CJ-160809-4 09/08/2016

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Richard M Ndovie (Student No 1379416)**

Project title: **Ethical and legal issues related to Health Surveillance Assistant's job description in Malawi.**

Reason: This study uses information in the public domain. There are no human participants.

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2016 -08- 09
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Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy – HREC (Medical) Secretariat: Zanele Ndlovu, Rhulani Mkansi.