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HARMONIZATION OF HEALTH POLICIES AS A STRATEGY FOR REGIONAL INTEGRATION: A CASE STUDY OF THE EAST AFRICAN COMMUNITY

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DECLARATION

I hereby declare that this project is my original work that has solely been composed by me and that it has not been presented or submitted, in part or whole, in any previous application for a degree.

Signature……. Date……

ESTHER KARAPIO SOMOIRE

R51/82791/2015

Supervisor

This project has been supervised, submitted to me for examination with my approval as the University Supervisor.

Signature ……. Date ……..

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DEDICATION

I dedicate this project to my parents who meant and still continue to mean so much to me.Although they are no longer in this world, their memories and values they instilled me still regulates my life.

I also dedicate this project to my son and sibling for being there for me throughout this master's program. You is my support system and the best cheerleaders.

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God bless you all.

ABBREVIATIONS

AHS:	Africa Health Strategy
AIDS:	Acquired Immune Deficiency Syndrome
ARNS:	African Regional Nutrition Strategy
AU:	African Union
CRVS:	Civil Registration and Vital Statistics
EAC:	East African Community
EACJ:	East African Court of Justice
EALA:	East African Legislative Assembly
EU:	European Union
HIV:	Human Immunodeficiency Virus
IMF:	International Monetary Fund
MDG:	Millennium Development Goals
PMPA:	Pharmaceutical Manufacturing Plan for Africa
SPSS:	Statistical Package for Social Sciences
STIs:	Sexually Transmitted Infections
TB:	Tuberculosis
UNAIDS:	United Nations Programme on HIV/AIDS
WHO:	World Health Organization

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CHAPTER ONE

1.1 Introduction and background of the study

Regional integration involves arrangements, agreements and treaties between countries within the same geographical region to reduce, and ultimately do away with tariff and non –tariff restrictions that bar the free movement of products and other production resources[1]. Regional integration can be well understood by viewing it from the global ,continental and regional perspectives.

The international regional integration can be well articulated and exhibited when regions develop alliances or agreements with each other to undertake or fulfill given goals which neither of the regions would accomplish if they were to undertake it separately. These international regional integrations have been witnessed in the formation of the European Union, the North Atlantic Free Trade Area and the Association of Southeast Asia Nations.

A key cornerstone foundation for international regional integration, is to act as a catalyst for a more open and liberal trading ecosystem. However, health policies of the member states will one way or another affect regional integration. Earlier policies were founded on the basis that the development of the European Union health policy does not intrude on the rights of the member states to control their healthcare systems. One of the solutions developed by the European Union, as shown in the Maastricht Treaty of 1992, is to encourage cooperation between the European Union member states and to improve the support given to their activities as explained in public health (article 129(1)). However, while the European Union was given the mandate to provide finances to health projects found in the European countries, it was not allowed to pass legislations that would harmonize public health interventions in the member countries (article 129(4))[2]. The mandate of the EU when it came to coming up with health policy was reviewed and strengthened during the 1997 Amsterdam Treaty giving the union greater powers. The EU was given a mandate to make sure that attainment of quality protection

[1] Farrell, Mary. EU policy towards other regions: policy learning in the external promotion of regional integration. *Journal of European Public Policy* 6 no. 8 (2009): 1165-1184.

[2] Gerlinger, Thomas, and Hans-Jürgen Urban. "From Heterogeneity to Harmonization? Recent Trends in European Health Policy." *Public Health Books* 23 no. 2 (2007): 133–142.

of peoples health during the implementation of various undertakings and all policies. It was further mandated to work hand in hand with member states to improve public health, protect people from diseases and eliminate the causes of harm to citizen's health as stipulated in article 152(1)[3].

Before long after independence of most African countries, different leaders within the continent called for African integration, but it is only until the 1960's and 1980's the efforts of establishing integration were visible in all sub-regions. First, integration calls were motivated by the political vision of African Unity.[4] In the 1960s, African countries initiated a process of continental integration envisioned to ultimately provide critical ingredients for economic and social development as well as political stability for the continent. Several attempts, initiatives and policy decisions have been adopted and implemented to accelerate the African integration agenda, with the African Union as its principal executive body with its main aim been for Africa to fulfill its potential as a thriving, peaceful continent, poverty eradication and minimizing dependency, which engages fully with its international peers on the global stage.

The African Union in 2007 developed the first Africa Health Strategy 2007–2015 which was endorsed in 2008. In 2015, the African Union Specialized Technical Committee on Health, Population and Drug Control made a recommendation that a reviewed Africa Health Strategy to be formulated for the period ranging from 2016 to 2030 based on an analysis of the previous strategy and the relevant African Union health policy instruments.

The African Health Strategy 2016–2030 policy framework is based on various global and continental health policy instruments and commitments. Crucial policy instruments include Agenda 2063 as well as 2030 Agenda for Sustainable Development, including its Sustainable Development Goals. There are other policy frameworks from which Africa health strategy 2016–2030 is reinforced include the Sexual and Reproductive Health and Rights Continental Policy Framework as well as its revised Maputo Plan of Action 2016–2030. Other policy frameworks include the African Regional Nutrition Strategy 2015–2025

[3] European Health Management Association. *Impact of European Union internal market regulations on the health services of member states. (*Dublin, EHMA, 2001).

[4] Wanyama Leonard. The economic diplomacy of Kenya's regional interests. 2013, SAIIA Occasional Paper No 137.

(ARNS), Pharmaceutical Manufacturing Plan for Africa (PMPA), the African Union Abuja commitments meant to combat Malaria, Tuberculosis and AIDS in Africa, the Catalytic Framework aimed at ending TB, AIDS and Eliminating Malaria in Africa by 2030 and the Global Strategy for Women's, Children's and Adolescent's Health (2016–2030).

1.1.1 EAC integration

The East African Community (EAC) is an intergovernmental organization found in the Eastern Africa region covering five countries: Burundi, Rwanda, Sudan,Tanzania, Uganda and Kenya. The headquarters of the organization are in Arusha, Tanzania[5]. Its vision is to have a united, stable and competitive East Africa. Its core mission is to deepen and widen social, political, cultural and economic integration so as to ensure improvement in the living standards of the citizens of these countries by use of trade, investments, value-added products and higher competition.

Regional co-operation efforts within East Africa region can be traced back to 102 years whereby the initial Customs Union was formed by Uganda and Kenya in 1917 and thereafter joined by Tanganyika, currently referred to as Tanzania, in 1927. There was an original attempt in 1967 at instituting the East African Community by Kenya, Tanzania and Uganda but later botched in 1977, due to the lack of unanimity on key fundamental issues on both political and socio-economic fronts by the three states[6]. Later in March 1996, robust efforts of the East African co-operation commenced when the commission was started at EAC Arusha headquarters[7].

The community was initially part of the Permanent Tripartite Commission for East African Co-operation before it was handed over to the EAC. The organization is made up of partner nations from the onset of July 1st 2011. The republics of Rwanda and Burundi signed Treaties of Accession to the community in the year 2007 while the other three member

[5]Hazlewood, Arthur. The end of the East African Community: What are the lessons for regional integration schemes?. *JCMS: Journal of Common Market Studies*, 18 no. 1 (1979): 40-58.

[6] Mushega, Amanya. EALA 10th Anniversary symposium catalyzing the EAC integration process: a recipe for realization of the East African Political Federation. (2011). Retrieved from 25th June 2019 from http://repository.eac.int/123456789/235. Date: 30/06/2011.

[7] Oduor, Paul Aginnah. Role of Political Parties in Regional Integration: Case Study of East African Community (Eac). *Signature* 50 (2016): 88794.

states, Kenya, Uganda and Tanzania were the original members[8]. The East African Community was established with the goal of improving and strengthening unit among member states from the context encompassing historical ties and understanding. Thus member states have laid more emphasis co-operation in a variety priority sectors such as those of the health sector, transport sector, security, immigration, communication, trade, industry and the promotion of investments within the region[9].

1.1.2 EAC Policy Formulation

The frequent movements of the people across the borders of the six members of the EAC poses a great risk due to the danger of spread of illnesses from one state to the other. Since the East Africa regional trade has continued to grow, there is a higher risk for spread of diseases especially epidemics which are likely to affect all the member states. The responses to such eminent danger need strategy and also the involvement of international, regional and national organizations. There is need for information to be quickly and freely relied to prevent such occurrences. The re-establishment of the EAC in 1999 opened more room for partnership on the surveillance, control and prevention.

Article 118 of the EAC treaty indicates the harmonization areas in relation to health. The first area involves the promotion of health care through the health delivery systems' management as well as improved planning mechanisms to enhance efficiency of service delivery in the member states. The second area is the development of a common drug policy that would include the establishment of good procurement practices and quality control capacities. The third area is harmonization of drug registration procedures in an effort to ensure good pharmaceutical standards' control without obstructing or impeding the movement of pharmaceutical products across the different states. The other important area is harmonizing of health regulations and policies and encouraging the exchange of information data across the nations to enable quality health standards among the different member state and the EA community as a whole. Other areas focused on include cooperation in the development of specialized health research, the

[8] Ciganikova, Martina. *Of Mustard Seeds and Democracy". Assessing the Impact of "Movementocracy on Uganda's Contemporary Modes of Governance*. Retrieved from 25th June 2019 from https://www.africabib.org/rec.php?RID=325658412

[9] Mwapachu, Juma. Rethinking Africa: Interview with Juma V. Mwapachu. *Development* 55, no. 4 (2012): 441-448.

pharmaceutical products, health training, preventive medicine and reproductive health; Promotion of the use of quality nutrition regulations and population of the eating of indigenous foods; and the use of common standards when it came to providing awareness to the people and the police on issues to do with control, trafficking and misuse of illicit and banned drug products.

Article 118 that touched on the development of EAC and the treaty between the five states led to the development of five groups that were mandated with being in charge of health matters including: Child, Reproductive, Adolescent Health and Nutrition; HIV and AIDS, Control and Prevention of Sexually Transmitted Infections (STIs); Health Research, Policy Medicines and Food Safety; and Health Systems Development; and Control and Prevention of Communicable and Non-Communicable Diseases.

The Health Department in the East Africa Community secretariat has developed various instruments and frameworks in response to different regional health challenges as well as priority interventions. These include: Draft EAC Regional Food Safety and Quality Policy; draft EAC Regional Pharmaceutical Policy; Rights in East Africa and the Regional Strategic Plan on Sexual and Reproductive Health (2008-2013); Regional Reproductive Health Strategic Plan, the EAC Biennial Work Plan on Disease Prevention and Control; EAC Regional Pharmaceutical Manufacturing Plan of Action (2012-2016); and The EAC HIV and AIDS Multi-Sectoral Strategic Plan (2008-2013).

However, the provisions, as per the Article 118, require pro-active efforts by individual Partner States to improve health situations to their citizens within their localities. That means the Partner States should ensure adequate access & attainable healthcare to their citizens, health services without classes, improved health infrastructures, contend against imposition of substandard or outdated consuming products which may cause health problems to users, time to time vaccinations to protect people against a particular strain of diseases and provide trainings on certain health areas.

1.2 Problem Statement

Africa's health systems are essential if the continent is to achieve sustainability and inclusivity. Despite the ever increasing population in Africa, there is a growing demand for health services

which is becoming difficult for the continent to handle due to lack of well-established foundations for long-term inclusive healthy society development. In EAC, despite the formation of the first commission of the East Africa cooperation in 1967, the integration and harmonization process of the health policies have been a major challenge. Up to today 2019, member states have not been able to establish proper and mutual integration structure despite the numerous strategy documents put across in actualizing article 5 of the EAC treaty.

The translation of these strategies, policies and commitments to provision of resources in the health sector is not going as expected as there is the prioritizing of other issues that seem more important than the provision of quality health care to the people of EAC. Many member countries in the EAC bloc are characterized by high rates of maternal and child mortality rates, disease outbreaks, malnutrition, epidemics and the increase in lifestyle diseases. These problems require for more commitment and quicker progress in the harmonization of health systems which will allow every person to receive quality healthcare which is affordable and without restrictions.

EAC member states have great diversities and capacities. Most are facing common challenges that can be addressed collectively. Communicable and non-communicable diseases have been integrated as goals in their national health strategies. Therefore, stronger regional integration can mitigate these challenges since it enhances collective responsibility. Harmonization of the health policies within the region will ensure that national dialogue among states is promoted thereby creating more access to the information pertaining health. In addition, harmonization of the health policy can vividly enhance interdependence in the region. It is not only possible but essential for healthy political and economic growth.

1.3 Research Questions

i. What are the prospects for harmonization of health policy framework in the EAC integration process?
ii. What are the impacts of the health care integration on the EAC member countries?
iii. What are the key challenges affecting the harmonization of the health policies in the EAC integration process?

1.4 Study Objectives

The general objective of the study is to assess the harmonization as a strategy for regional integration in EAC and its impact on enhancing the EAC integration agenda.

1.4.1 Specific Objectives

i. To examine the prospect for harmonization of health policy framework as a strategy for East African Community integration process.

ii. To establish the impact of health care integration on EAC member countries.

iii. To investigate the key challenges affecting the harmonization of health policy in the East African Community Integration processes.

1.5 Literature Review

There has been a wide range of literature discussing regional integration in the EAC region through harmonization of various policies as one of the strategies. The harmonization of the health policy in the EAC region has evolved overtime. This study employs both theoretical and empirical literature review. Theoretical review covers two theories namely functionalist and neo-functionalist theories and examines key debates by scholars. On the other hand the empirical literature reviews is done as per the objectives; prospect for harmonization of health policy framework as a strategy for East African Community integration process; impact of health care integration on EAC member countries; and key challenges affecting the harmonization of health policy in the East African Community Integration processes. This is then followed by identification of research gaps.

1.5.1 Theoretical Literature

1.5.1 Functionalism and Neo-functionalism

There is increased involvement of governments in the global integration process. The expanding number of international and regional blocs is arguably clear signal that integration is very important in promoting agendas that protects the interests of nation states. Because of

globalization there is greater interconnectivity occasioned by technological advances and need for development, hence cooperation has become essential for survival of the nation states and has expanded to include non-state actors and social movements[10].

The functionalists believe that the nations maximize their interests due to the help offered by international organizations that use functional rather than territorial considerations. Mitrany[11] observes that peace can be achieved due to socioeconomic welfare since people think rationally. According to Mitrany, there should be the development of federation. Unfortunately, many countries see this view as too ambitious and in its place they have embraced economic integration as the essential initial step to encourage mutual connectivity amongst states thereafter political union that will promotes peace and stability in the regional bloc[12].

Neo-functionalism on the other hand emphasize that there is need for a federal organization. Posada posits that integration found in the social and economic sectors should be based on the political will of the partners. For more integration, neo-functionalism points out that that is need for the development of institutions.

Neo-functionalism explains that the functionalist principles should be used to develop regional institutions. According to functionalists point of view integration cannot be avoided as it results from development which tasks the state with more responsibilities that push the state to partner with state international institutions. According to neo-functionalists institutions make integration move further although this was the intended aim during their creation. The end results of integration between the neo-functionalists and the functionalists are also said to be different. As the latter explains that the outcome of integration is the rise of different institutions that perform different duties. The neo-functionalist, according to Haas[13] all the functions are done by one center due to the creation of a single political community.

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[10] Giulianotti Richard Charles, Robertson Roland. Recovering the social: globalization, football and transnationalism. *Global Networks*, 7 no. 2 (2007): 166-186.

[11] Mitrany David. The functional approach in historical perspective. *International Affairs (Royal Institute of International Affairs*), 47 no. 3 (1971): 532-543

[12] Mitrany David. The functional approach in historical perspective. *International Affairs (Royal Institute of International Affairs*), 47 no. 3 (1971): 532-543.

[13] Haas Ernst Bernard. '*Introduction: Institutionalisation or Constructivism?' in The Uniting of Europe: Political, Social and Economic Forces 1950-1957*, 3rd edition, (Notre Dame: University of Notre Dame Press, 2004)

Increased integration among European nations resulted to more peace and harmony in the region[14]. Neo-functionalism point out that nationalism and national state will no longer be important once the a central supranational sate rises. Neo-functionalism is viewed as a driver of the positive impacts brought about by integration such as technocratic automaticity and domestic partnerships. Despite these driving forces, varied national interests of the nation states to achieve different objectives have made harmonization processes to be cumbersome[15].

Because of the minimal strengths of both functionalism and neo functionalism approaches, intergovernmentalism approach is essential in this study as it have better avenues for harmonizing state values. The approach illustrates that state capability should match national interests. Hoffmann[16] further notes that the orientation and velocity of regional integration is a trait of the quality of interaction among the member nations. Integration success or failure is determined on the interests and power brought to the table in different issues by the member nations. It is the sovereign nation states that have the moral authority to make policies that address issues of common interests.

1.5.2 Inter-governmentalism Theory

The intergovernmentalism theory will aid in understanding regional integration among the African countries with emphasis on the EAC integration and how it impacts member states. The theory was first explored to explain the European Union integration process[17]. In this context of intergovernmentalism is characterized by state centrism. It views intergovernmentalism as a game where the winner is given all the winnings while the topic only touches on policies and not on other issues that are of national importance. According to Hix, integration among the European member states is due to their actions and interests in different issues affecting the region[18].

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[14] Barry Andrew. The European Community and European government: harmonization, mobility and space. *Economy and Society,* 22 no. 3 (1993): 314-326.
[15] Nye, J. S. Comparing common markets: a revised neo-functionalist model. *International Organization,* 24 no. 4 (1970): 796-835.
[16] Hoffmann Stanley. Obstinate or Obsolete? The Fate of the Nation-State and the Case of Western Europe. *Daedalus,* 95 no. 3 (1966): 862–915.
[17] Moravcsik Andrew & Schimmelfennig Frank. Liberal intergovernmentalism. *European integration theory*, 2 (2009): 67-87.
[18] Hix Simon. The *political system of the European Union*. (New York, Macmillan International Higher Education, 1999).

Intergovernmentalism lays focus on the concept of the roles of nation states in the integration process. It argues that the national governments of member states are the primary actors in any integration process and become strengthened by the same[19]. This is as a result of some policy areas; it is in the member states' interest to pool sovereignty. A theoretical account on the intricacies of regionalism around Africa has been limited with so much having been published on regional integration. In the case of the EAC, Liberal Intergovernmentalism can apply; a theoretical concept used in the 1990's as a model for European Integration.

The liberal intergovernmentalism theory operates on a three-stage continuum. In the first stage, the nations present their preferences to the negotiation table – deemed necessarily achievable through the regional integration arrangement. The important question here is what informs a state's national preferences. In EAC integration, each of the five countries has to bring on board their preferences in terms of health policies. By implication, if these preferences are not met, which means that a state's national interest will not be accommodated, then there is likelihood that the said member state's commitment to integration could be in doubt[20]. In the EAC during the initial stages of a customs union, preferences of prominent business groups in the three original member states; Kenya, Tanzania and Uganda, influence the governments' policy position as regards integration. In addition, in the EAC case, there is a decentralized decision making model that allows the council of ministers to make recommendation on the important policies which are later taken to the Summit of the heads of state for approval. However, the decision making process only occurs if there is a binding element that makes the political union lasting.

The second stage concerns interstate negotiations, which member states undertake during the integration process. Each member state seeks to ensure maximum incorporation of its respective national preferences, referred to as "grand bargaining". In addition, member states' adherence to regional health regulations are likely to depend on the degree to which each member perceived that their national preferences were incorporated at the regional level to their principal national actors' benefit and satisfaction. The different member states perform serious lobbying and seek audience with the different governments in a bid to have their preferences included in the state

[19] Pentland Charles. *International theory and European integration.* (London, Faber & Faber, 1973).
[20] Schimmelfennig Frank. Liberal intergovernmentalism and the euro area crisis. *Journal of European Public Policy*, 22 no. 2 (2015), 177-195.

policy of integration. As well, the outcomes of interstate bargaining activity and the institutional choice echoed the wishes of the three member-states of ensuring that integration would maximize their welfare[21].

The delegation of decision-making powers to international institutions refers to the extent member states are ready to allow a regional institution to determine crucial elements of the integration process without interference from those member states. In the case of the EAC II, the test of whether delegation exists is best applied by determining how strongly each member state abides by decisions reached at the regional level, including by the community's technical organs. In particular, this refers to the roles and perceptions, at the national level, of decisions reached in the context of the Secretariat, East African Court of Justice (EACJ) or the EastAfrican Legislative Assembly (EALA).

While the outcomes of "grand bargaining" remain crucial to forecasting the importance principal actors and groups in respective national settings place on a regional institution, Moravcsik cautions that any efforts by the member states to negotiate "package deals" in order to achieve concessions that would enable them to reach set regional goals will likely create "domestic losers." As a result, states are likely to "limit the use of package deals" when negotiating initiatives aimed to achieve integration goals. Consequently, whichever principal national actors influence the process of integration for a particular member state, they are bound to impact the attainment of regional integration goals from the standpoint of the state concerned. The third and final stage, known as "institutional choice," seeks to explain the rationale by which, after "grand bargaining"; member states decide either to "pool" their sovereignty or to "delegate" their decision-making powers to the international institutions they create.

It is important to find out whether people centeredness remains central to the EAC II's integration as emphasized in the treaty and what means of popular participation are being employed to implement it. Furthermore, understanding who plays the predominant roles in determining integration is likely to shed light on whether the EAC II will truly attain its ultimate objective, that of a political federation, which is expected to be attained more quickly when the community is people centered. Furthermore, by incorporating the role of domestic actors, liberal

[21] Moravcsik Andrew & Schimmelfennig Frank. Liberal intergovernmentalism. *European integration theory*, no. 2 (2009): 67-87.

intergovernmentalism theory is likely to provide a useful guide for the analysis of people centeredness.

A nation that is unhealthy physically is also unhealthy politically. In case the larger population in a country is sick the economy and governance is also affected. In recent times there has been increased emphasis on infectious illnesses which often affect security, development and the health of others negatively.

Considering health security rubric, there is a view that the health of any nations citizens is vital to the ability of the country to do well globally hence head of states are forced to work together to aid addressing common concerns that might have spillover effects in their regions[22]. When the citizens cannot access quality care this translates to human insecurities. If the insecurities are not taken care of the wellbeing of the citizens will be at risk. Further, they negatively affect the dignity and freedom of the people. Health is a vital human need and if it is not available, there is bound to be discontent and conflict among the affected people. Moreover, it can lead to the spread of life-threatening diseases which can lead to loss of lives. There is proof of this as diseases such as HIV/AIDS have led to the death of high number of people with the number being higher than people who died in national disasters such as wars. The burden of such diseases is very high for the political, economic and social structures of nations not forgetting the negative effect they have on those affected[23].

Liberal Intergovernmentalism approach is very essential in this study since the member countries are the major actors in the integration[24]. The integration of the EA nations is aimed to advance the member nations interests by use of common organizations that will help the member states use harmonized structures rather than act on their own. The states benefit from integration as it opens a door to overcome sub-optimal collective outcomes and achieve cooperation for mutual benefit through reducing transaction costs. Liberal intergovernmentalism is relevant since it is the state that leads in giving its people quality health services. Therefore governments will be

[22] Hartzenberg Trudi. *Regional integration in Africa*. 2011. Retrieved on Retrieved from 25th June 2019 from https://ssrn.com/abstract=1941742

[23] Adogamhe Paul. Pan-Africanism revisited: Vision and reality of African unity and development. *African Review of Integration*, 2 no. 2 (2008): 1-34.

[24] Moravcsik Andrew & Schimmelfennig Frank. Liberal intergovernmentalism. *European integration theory*, no 2 (2009), 67-87.

engaged in the harmonization of health matters since states have a part to play in providing health security despite having varied national interests[25].

1.5.2 Empirical Literature Review

This section covers literature review based on the three research questions: What are the prospects for harmonization of health policy framework in the EAC integration process? What are the impacts of the health care integration on the EAC member countries? What are the key challenges affecting the harmonization of the health policies in the EAC integration process?

1.5.2.1 The prospects for harmonization of the health policy Framework

In the past years, the World Health organization was tasked with developing global health policy. As pointed out by Brown[26] the representatives of the countries in the organization made their suggestions to the organization and countries that gained their independence recently were also giving a chance to air their views and be part of the formulation of the global health policy.

In different studies conducted by Abassi[27], Yamey[28] and Brown et al.[29] found out that during the late 1980s, the World Bank played a major role by bridging the financial deficit that existed and faced the increasingly ineffective and resource-limited WHO at the time[30]. IMF and World Bank also went further to exert influence over the making of health policies by different countries as they mobilized and gave funds to these nations that were used to bring changes in health policy, economic strategies and social and health sectors more so in developing countries which were characterized by the weak health policy and delivery strategy[31].

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[25] Moravcsik Andrew & Schimmelfennig Frank. Liberal intergovernmentalism. *European integration theory, no 2* (2009): 67-87.

[26] Brown Garret. Distributing who gets what and why: four normative approaches to global health Governance. *Globa Policy* 3 no. 3 (2012): 292–302.

[27] Abasi Kamran. The World Bank and World Health: Changing Sides. *British Medical Journal* 318 no. 7187(1999): 865–869.

[28] Yamey Garret. 'WHO in 2002: Why Does the World Still need WHO?', *British Medical Journal* 325 no. 7375 (2002): 1294–8

[29] Brown Theodore, Cueto Marcos and Fee Elizabeth. The World Health Organization and the Transition from "International" to "Global Health. *American Journal of Public Health* 96 no. 1 (2006): 62–72.

[30] Brown Garret. Distributing who gets what and why: four normative approaches to global health Governance. *Global Policy* 3 no. 3(2012): 292–302.

[30] Brown Garret. Distributing who gets what and why: four normative approaches to glo

[31] Brugha Ruairí, Bruen Carlos & Tangcharoensathien Viroj. Understanding global health policy. *The Handbook of Global Health Policy,* no. 21 (2014) 21, 45.

Brugha and Zwi[32] observed that the multifaceted funding agencies and other donors exerted undue influence on poorer developing countries to downscale the role which the state played of provision of basic services, creating a more profound role for private enterprises in provision of such services of health.

The World Bank introduced key radical changes to health policy by introducing user charges for provision of health services which initially was been offered by many governments especially developing countries for free to their population. These reforms introduced in 1987 were entailed in a wider set of market-based reforms[33]. This was followed by subsequent reforms at the tail end of the twentieth century. Studies undertaken by Buse and Walt[34] in 2002 revealed the internalization and shifting context of cooperation for, international health. This view of Buse and Walt were strengthened by a number of parallel developments that aided to ventilate this shifting perspective, they entailed: a changing meaning of the traditional legalities of the nation state; a radical incremental in other sectors who took part in global health matters and the improvement in the relationship existing between the state and non-state actors and shifting of power between the different actors found at the global, regional and national levels[35]. According to Lee and Goodman[36], globalization directly impacted the health policy of the state as there was improved interdependence and collaboration between the different countries.

The information age and efficiencies in modes and channels of communications have made it possible to learn from other state experiences when it came to health policy formulation and implementation, organizations and utilizing these ideas for differing situations, this process is known as policy transfer. According to Evans[37], revolution of digital communication had accelerated the intensity of policy transfer, thus enabling policy ideas to be shared, spread and

[32] [32] Brugha Ruairí, Bruen Carlos & Tangcharoensathien Viroj. Understanding global health policy. *The Handbook of Global Health Policy*, no. 21 (2014) 21, 45.

[33] Akin John, Birdsall Nancy, de Ferranti David. *Financing Health Service in Developing Countries: An Agenda for Reform. World Bank Policy Study*. (Washington, DC: World Bank, 1987).

[34] Buse Kelley and Walt Garret. 'Globalisation and Multilateral Public–Private Health Partnerships: Issues for Health Policy', in K. Lee, S. Fustukian and K. Buse (eds). *Health Policy in a Globalising World* (pp. 41–62). (Cambridge: Cambridge University Press, 2002).

[35] Buse Kelley and Walt Garret. 'Globalisation and Multilateral Public–Private Health Partnerships: Issues for Health Policy', in K. Lee, S. Fustukian and K. Buse (eds). *Health Policy in a Globalising World* (pp. 41–62). (Cambridge: Cambridge University Press, 2002).

[36] Lee K, Goodman H. Global policy networks: the propagation of health care financing reform since the 1980s. In Lee K, Buse K, Fustukian S (eds) Health Policy in a Globalizing World, pp. 97– 119. (Cambridge, Cambridge University Press, 2002).

[37] Evans Mark. Policy transfer in critical perspective. *Policy Studies*, 30 no. 3 (2009): 243-268.

domesticated within a new context. According to Walt, et al. communication technology played a crucial role in bringing regional, national and global actors together and it led to the creation of ample space through which incoming actors could be part of the international global health[38].

Utilization of modern day communication has played a key role in propelling global health policy in repressive regimes as they are out of reach of control of government. Activists and civil society groups have advocated through the emergence of non-state actors such as global health bodies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria[39].

According to Walt et al. policy actors are regarded as a cornerstone central to the examination of the methods used to formulate policies and implemented. International and national policy actors are made of individuals and institutions such as research institutions, civil society institutions, NGOs, program managers, health employees, community-based institutions and state organizations.

1.5.2.2 Impact of Healthcare integration on EAC member countries

In Comparison to the other continents, African countries are still worse off when it comes to health matters as the infant mortality rate, maternal mortality rate and the mobility and mortality from communicable diseases are still high. The burden from non-communicable, communicable, trauma and injury and the impact these have on the affected and the states has negatively affected the development of the African continent.

Nevertheless, the African continent has made some crucial steps when it comes to matters health as South of Sahara, Africa was the first region to meet the sub-targets of MDG 6 related to HIV&AIDS before the 2015 deadline.[40] HIV incidence, prevalence and deaths from AIDS have

[38] Walt Gill, Jeremy Shiffman, Helen Schneider, Susan F. Murray, Ruairi Brugha, Lucy Gilson. 'Doing' health policy analysis: Methodological and conceptual reflections and challenges. *Health Policy and Planning*, 23 no. 5 (2008): 308-317.

[39] Global Fund (Global Fund to Fight AIDs, Turberclosis and Malaria). 2012. *The Frame- work Document*. Geneva: Global Fund. Retrieved on 25th June 2019 from www.theglobalfund.org/documents/ . . . /framework/ Core GlobalFund Framework en/

[40] World Health Organization. *Millennium Development Goals (MDGs).* 2014 Retrieved on 25th June 2019 from https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs)

actually increased in some countries of North Africa[41]. In the years between 2000 and 2013, the ability to access HIV related drugs has increased by more than a 100% and more than 10 million patients in the continent have had access to the treatment. There has also been a decline in the deaths related to AIDS and in new HIV infections in African countries south of Sahara by 30% and 33% respectively[42].

Maternal mortality was reduced by 51% in North Africa[43]. The existing need for contraceptives between 2006 and 2013 is still high at an average of 26.2% while the prevalence rate of modern contraceptives has risen to 25.9% between the years 2006 and 2013 from 24.3% between 1990 and 2005[44].

The National Medicines Regulatory Authorities of the EAC member countries should consider that the harmonization of the health policy will enhance various impacts. For instance; patients and society members in the East Africa countries will be able to access effective, safe and quality treatment for their diseases, the market will also have ample medicines for different diseases, the countries will successfully achieve the health Sustainable Development goals due to the improved health of their citizens. In addition, through harmonization of the health policy governments and National Medicines Regulatory Authority will provide affordable medicines in a timely manner as it will have enhanced regulatory procedures and skilled workers to do the job. Further, with harmonization of the health policy there will be quality capacity and better and effective inspections done to rule out unregistered and counterfeit drugs. The pharmaceutical firms will also have simple and understandable regulatory procedures to follow and also to enable the approval of the services they offer. The various countries will be able to give lists of the medicines they need and the evaluation and provision times of these medicines will be shorter.

[41] UNAIDS. *Global HIV & AIDS statistics — 2018 fact sheet.* 2016. Retrieved on 25th June 2019 from https://www.unaids.org/en/resources/fact-sheet

[42]World Health Organization. *Millennium Development Goals (MDGs).* 2014 Retrieved on 25th June 2019 from https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs)

[43] WHO EMRO. *The work of WHO in the Eastern Mediterranean Region: Annual report of the Regional Director 1 January–31 December 2015*. 2015. Retrieved on 25th June 2019 from http://www.emro.who.int/annual-report/2015/index.html

[44] AUC/UNECA/UNDP. *Annual Report 2015 - United Nations Economic Commission for Africa*. 2015. Retrieved on 25th June 2019 from https://www.uneca.org/

Harmonization of the health policy will also enhance East Africa Disease Surveillance, where information is shared between countries so that each country gets to know of any epidemics happenings and take up the necessary measures to prevent and deal with these epidemics. The other vital network in the region is the East African Network for Monitoring Anti-malarial Treatment where malaria drug's effectiveness is monitored in the regions and where decision makers are informed.

The harmonization of the policies enhances networking among nation states. These networks must be strong in areas of border as diseases don't know border, so without control they can easily pass to the neighbor country without citizens knowing and so they die mercilessly. The most agreed diseases seems to be a threat include yellow fever, Ebola, rift valley fever, bird fever, HIV/AIDS and other communicable/non-communicable diseases. Previously we observed how easy rift valley fever spread all over East Africa countries and it started originally from Kenya and many animals left dead together with people who unknowingly consume the animals died of the disease. Also we saw how severely people died of the Ebola which often erupt in Uganda and led to a big number of deaths in Uganda and to people who live at the border of the neighbor countries like in Mwanza Tanzania, Siaya in Kenya etc. This reality would have commanded the Partner States to strategies improvement of health infrastructures by implanting health centers at border areas especially populated areas like Namanga(Kenya and Tanzania), Holili/Taveta (Kenya and Tanzania), Busiya/Malaba (Uganda and Kenya), Bukoba(Tanzania and Rwanda)[45].

1.5.2.3 Challenges towards harmonization of health policy

Harmonization of health policy as a strategy for regional integration has encountered challenges in the formulation and implementation process at the global level, continental level and regional level. One of the common underlying challenges is inward looking approach where different countries tend to prioritize their health policies nationally in a bid of self-interest thus negatively affecting the implementation process of common policies in their respective regions.

[45] Sanoiya Stanley. *Current status of Harmonization of Medicines Policies.* 2009. Retrieved on 25th June 2019 from https://www.uneca.org/oria/pages/harmonisation-sectoral-policies

The common explanation given why there is a crisis in health matters globally is that there is no more money to spend on issues of global health, politicians, donors and the general public has also been shown to lose interest in these matters. The financial crisis that occurred in 2008 led to decreased aid from North America and European donors. Since there are more budget cuts and tightening in the spending, the provision of development aid to African countries is the first one to be affected. There has been a shift in funding by international funding organizations such as World Bank to more sustainable projects which are not as specific as the global health projects[46].

The issue of lack of political will does not only lie with the issues that are shown to compete for politician's time. There is also a problem due to misgivings felt in regard to the perceived success of these projects. To secure the political will of leaders there is need to present some of the health issues as ones that need immediate attention or they will end up being a threat to the security of the public. Diseases like HIV&AIDS are no longer seen as a threat since there has been a decrease in the growth of the disease[47]. For instance, in the past the fight against malaria and tuberculosis has been met with positive political will but this trend has changed once there has been improvements and decline in those suffering from such diseases[48].

Although there has been increased financial resources provided to such health issues, the inclusion of various sectors in the health issues has led to division of power among the different actors where the popular NGOs and private players have gained more power when it comes to these issues and this has led to conflicts, unaccountability and misuse of participants[49]. State interests are still the dominating topics among the non-state actors and there have been issues observed such as voting problems in institutions such as Global Fund[50]. Therefore, the use of multi-sectorial approach led to dual issues of tokenistic inclusion of non-state organization while embracing the criticism of these organization by including these institutions into the policy making process. Thus, civil society organizations absorb criticism of the structures and

[46] World Bank (Africa Region). *Africa's Future and the World Bank's Support to It.* (Washington, DC, World Bank, 2011).
[47] UNAIDS. *Global HIV & AIDS statistics — 2018 fact sheet.* 2016. Retrieved on 25th June 2019 from https://www.unaids.org/en/resources/fact-sheet
[48] Harman, Sophie. *Global health governance*. (New York : Routledge, 2012).
[49] Harman Sophie. Innovation, multi-sectoral governance and the limits of rebranded privatization. *Globalizations* 15 no. 3 (2014) 362-376.
[50] Brown Garrett. Multisectoralism, participation and stakeholder effectiveness: increasing the role of non-state actors in the Global Fund to Fight AIDS, Tuberculosis and Malaria. *Global Governance* 15 no. 2 (2009): 169–77.

processes of global health policy-making by including them within the system. In effect, full multi-sectorial approach only exists at the implementation level with decision-making resting at the global level.

The provision of healthcare services by both public and private institutions has been there and a source of debate since global health reforms started in western countries in the late. The highest risk with these partnerships was that these partnerships could be a source of tensions or on the positive view could be a source of solutions. However, in the real sense the partnerships did not achieve neither, instead they were a source of a market-based approach to the issues of global health by the use of innovation, performance-oriented funding sand a move from the public and social health policy to the use of business plans and management strategies[51].

The mandate of WHO was challenged due to the increased participation of specialized health organizations such as UNAIDS, that collaborated in projects such as the Stop TB partnership, mission creep by the World Bank, the financial clout of the Bill and Melinda Gates Foundation, and the spending portfolio of the Global Fund. Although these agencies successfully collaborated with WHO, the later lacked the funding to be able to exert more power over these organizations[52].

Another challenge was the leadership challenges that occurred within the WHO leadership in the late 1990s which resulted to stagnation and lack of leadership at a time when the institution was at a crucial development stage[53]. Margaret Chan is a popular leader within and outside WHO circles. She knows the challenges that the organization faces. However, it is impossible for her to address these challenges without touching on the issue of provision of financial aid to global health issues[54]. Global health policy issues emphasize on repetitive, reactionary, results-oriented and the raising of financial resources.

In Africa, lack of consultation by partner state is one of the major problems facing harmonization of health policy. Each of the member states has been settings its own agendas on health issues by

[51] Harman Sophie. Innovation, multi-sectoral governance and the limits of rebranded privatization. *Globalizations* 15 no. 3 (2014) 362-376.
[52] UNITAID. *Innovative Financing to Shape Markets for HIV/AIDS, Malaria and Tuberculosis*. 2012. Retrieved on 25th June 2019 from http://www.unitaid.eu/en/about/innovative-financing-mainmenu-105.
[53] Lisk Franklyn. *Global Institutions and the HIV/AIDS Epidemic*. (Abingdon: Routledge, 2009).
[54] Lee Kelley. *The World Health Organization*. (Abingdon: Routledge, 2009).

considering domestic national areas of priorities without consulting neighbor States. The regional cooperation noted this as a challenge for the region as diseases easily spread over borders thus affecting the neighboring states and its people unnecessarily. Therefore, the community set up joint agendas where partner state can discuss common health priorities as a way to fight health problems jointly.

Sine there is no sufficient medicines and health facilities the quality of health care has declined and the health outcomes have been impacted negatively. The governing of the health sector is faced by various challenges such as accountability and transparency issues and the poor engagement of the different stakeholders in the development of plans, strategies and policies. Since the regulation for the private sector is weak, there has been an increase in the supply of counterfeit and substandard medicines. Health information systems are not commonly used in many African countries which is yet another challenge and fewer than two fifths of the African states use a civil registration and vital statistics (CRVS) systems[55].

Since the foundation of strategic information in most of the African countries is weak, there is poor use of data and evidence in the making of health related decisions such as policy development, national and regional planning, policy development and the management of health services. Climate change and other environmental challenges have aggravated the public health situation of the Africa continent. The impact of climate change on agriculture and food security directly impacts food availability and nutrition. Hence, there is need to come up with a balanced strategies which are long-term and forward looking.

1.5.3 Literature Gaps

There are numerous studies that have been undertaken both at the global arena by international bodies such as World Bank, IMF, WHO, AU, EU and state actors to determine the effectiveness of policy measures put in place in standardization of policies with the goal of improving collaboration among member state. Despite this numerous strategic health policies that have been in place since the formation of regional blocs, there have been varied outcomes and challenges in actualizing the intended objectives. The challenges analyzed in the literature shows

[55] Mikkelsen, L., Phillips, D. E., AbouZahr, C., Setel, P. W., De Savigny, D., Lozano, R., & Lopez, A. D. A global assessment of civil registration and vital statistics systems: monitoring data quality and progress. *The Lancet* 386 no. (10001): 1395-1406.

that there is room for examining the underlying bottlenecks to the harmonization of health policy in the regional integration, hence this study will look at the unique challenges facing the EAC region and propose tailored made solutions addressing the EAC member countries.

1.6 Hypothesis

This study has been guided by the following hypothesis

$H_{1:}$ The harmonization of health policy has a significant impact on the regional integration of East Africa community.

H_0: The harmonization of health policy has no significant impact on the regional integration of East Africa community.

1.7 Justification of the study

1.7.1 Policy Justification

EAC member states all have national health policies which articulate their different priority areas in the health sector. The study will look at common challenges affecting harmonizing of policies and standardizations on key areas. This will enable the EAC region to achieve mutual cooperation and regional integration through operationalization of health strategies articulated in article 118. It will enhance harmonization of health policy as a strategy of enhancing and supporting regional integration for the EAC region. This will be useful for the governments involved and policy makers to utilize the findings to enrich the pre-existing data and formulate more sound and evidence based interventions. The findings will also contribute to policy formulation on health interventions.

1.7.2 To the General Public

This study will enable the stakeholders involved identify the opportunity and challenges that jeopardize health integration and the possible ways and means of realizing mutual regional integration. This will propel the EAC initiatives in the right direction since a healthy people means a growing and developing region.

1.7.3 Academic justification

This study will be an addition to the academic sphere as it seeks to add knowledge to pre-existing knowledge and provide up to date factual and evidence based facts. The study will provide relevant information to scholars and it will as well bridge the gap that existed in the literature.

1.8 Research Methodology

This section covers the methodology that was applied for this study. It covers the research design and paradigm, target population, sampling techniques, data collection techniques, and data analysis to be utilized in study.

1.8.1 Research Design

Research design is an illustration of how an investigation should take place. It shows how data is to be collected, instruments for data collection as well as how the analysis is to be conducted[56]. The study will adopt descriptive and correlation designs respectively. During research, a given approach has to be adopted based on what is to be investigated. Descriptive research design was adopted in this case because it responds to questions such as who, what, where and how.

1.8.2 Research paradigm

The researcher used both qualitative and quantitative methods respectively. The two approaches aimed at building scientific knowledge about phenomenon. Mugenda and Mugenda[57] argues that quantitative and qualitative methods are distinguished on the basis of the views about reality, cause and effect relationship between the inquirer and the object and views about knowledge and truth.

The assumption of the quantitative methods helps the researcher to predict, describe, control and explain a phenomenon of interest. This therefore makes the study to be clear on the phenomenon to be investigated. It also enhances prediction by estimating a phenomenon, hence correlation

[56] Maxwell, Joseph A. Qualitative research design: An interactive approach. (New York, Sage publications, 2012).
[57] Mugenda, O. & Mugenda, A. *Research Methods: Qualitative and Quantitative Approaches.* (Nairobi, ACTS Press, 2003).

research. It enables control and manipulation of some parts of a variable in order to exert control over the other. Therefore, it gives accurate observation over a particular phenomenon.

1.8.3 Target Population

The target population for this research comprised of representatives in East Africa Legislative Assembly, Ministry of Health, EAC Secretariat Office staff and Ministry of East Africa Community staff.

1.8.4 Sample and Sampling Frame

Sample is defined as the selection representative parts of the total population under study[58]. The size of the sample size should provide enough data on the population which can be used to make inferences after being analyzed. The Slovi's Formulae helped deduce the sample size. This formula was used in line with the size of the population.

$$n = \frac{N}{1 + (NE^2)}$$

Where by:

n = no. of samples

N = total population

E = error margin / margin of error (0.05)

$$n = \frac{642}{1 + (642 * 0.05^2)}$$

$$n = 246$$

[58] Mugenda, O. & Mugenda, A. *Research Methods: Qualitative and Quantitative Approaches.* (Nairobi, ACTS Press, 2003).

1.8.5 Sampling Frame

Target group	Population	Sample size	Sampling technique
East Africa Legislative Assembly	233	89	Purposive sampling
EAC Secretariat Office	183	70	Purposive sampling
Ministry of East Africa Community	150	57	Purposive sampling
Ministry of Health	76	29	Purposive sampling
Total	**642**	**246**	

The sampling frame of this study comprised of representatives in East Africa Legislative Assembly, Ministry of Health, EAC Secretariat Office staff and Ministry of East Africa Community staff.

1.8.6 Sampling Techniques

The study employed purposive sampling technique, which allowed the researcher to select the samples that seem best according to the researcher's judgment and best answered the questions of the study while meeting the study objectives due to the fact that there are organs and representatives addressing EAC issues. The Purposive sampling was essential in this study in that it is a non-probability sampling that comes in handy when a researcher needs to look at a given domain with knowledgeable expert within. Purposive Sampling was very essential in this study because was used with both qualitative and quantitative research techniques. In addition, convenience sampling was used in the selection of individuals in East Africa Legislative Assembly, EAC Secretariat Office and Ministry of East Africa Community.

1.8.7 Data Collection Techniques

The researcher used both primary and secondary data to interpret the study. Primary data was obtained by the use of questionnaires and interview. The questionnaires and interview instrument for data collection were preferred as they help the respondents to be objective and more precise in responding to research questions. Semi-structured questionnaires was used to elicit information from the target populations. On the other hand, secondary data was obtained from document or sources such as books and academic journals, which were used by the researcher to refer and compare data findings in the past and present time. Interviews was conducted with the

key informants who include administrators in East Africa Legislative Assembly, head of EAC Secretariat Office and Minister of East Africa Community.

1.8.8 Data Analysis and presentation

The questionnaires generate quantitative data while the interview guides generate qualitative data. Both data sets were analyzed where thematic content assisted to analyze qualitative data and the findings given in prose. Inferential and descriptive statistics helped in the analysis of quantitative data and Statistical Package for Social Sciences (SPSS version 22) was used in this analysis. Descriptive statistics used include averages, standard deviation, frequencies and percentages. The outcomes is provided in graphs and tables and also in bar charts.

1.8.9 Ethical considerations

The respondents were made aware that they have a right to be part of the study or to refuse the offer. They were informed that participation is not forced on anyone nor is it compulsory and they have to give their consent in case they want to participate. The researcher also made the participants aware that the data they to give remained confidential and their identity would not be revealed or sought during the research. The researcher adhered to all the ethical procedures during the research. The researcher obtained a research permit from National Commission for Science, Technology and Innovation (NACOSTI).

1.9 Operationalization of key Terms

Harmonization: This refers to the adjustments of incontinences and differences among different health policies to make them mutually compatible and uniform.

Health policy framework: This refers to a group of policies to provide detailed descriptions of the objectives of health and social services and the ways that will be used to meet these objectives.

Health care integration: This refers to a global trend in the reforms of healthcare and arrangements made by the old and new actors in issues to do with healthcare in a bid to provide more coordinated and effective health care services.

Health policy: It refers to actions, plans and decisions made to meet healthcare objectives within different communities.

EAC integration: a processes through which countries agree to partner and collaborate to attain stability, peace and wealth.

1.10 Layout of the study

Chapter 1

This chapter comprises of the background of the study that covers EAC integration and EAC policy formulation. This is followed by problem statement, research questions and study objectives, which include both general objective and specific objectives. The chapter also presents literature review as per the specific objectives, which encompasses theoretical literature, empirical literature and literature gaps. Also, the chapter covers, hypothesis, justification of the study and research methodology that encompasses research design, research paradigm, target population, sampling frame, sampling techniques, data collection techniques, data analysis and presentation and ethical considerations.

Chapter 2

This chapter covers prospect for harmonization of health policy framework as a strategy for East African Community integration process. The chapter covers a detailed account of the harmonization of the health policy frameworks that have been undertaken the East Africa Community since its onset to date. It will have a look at key priority health policies such 2017-2021 EAC HIV/AIDS Prevention and Management Act 2012 implemented, 2017-2021 EAC Health Policy, 2017-2021 EAC Health Sector Strategic Plan (2015-2020), 2017-2021, EAC HIV/AIDS, Sexually Transmitted Infections and Tuberculosis Plan (2015–2020), and 2017-2021 EAC Reproductive Maternal New- born Child and Adolescent Health among others policies.

Chapter 3

This chapter entails the impact of healthcare integration on East Africa Community (EAC) member countries. The chapter details how healthcare integration efforts affect the East Africa Community members in terms of health. This looks at how individual countries have been

impacted as result of joint efforts. A case by case impact analysis will be undertaken for the five countries namely Kenya, Tanzania, Uganda, Burundi and Rwanda.

Chapter 4

This chapter investigates the challenges been faced through the implementation of the actualization of policy harmonization by the member states of the East Africa Community. It brings out the bottlenecks experienced in the past, pre-existing and future that may or are already slowing or impeding the attainment of the desired projected harmonization of health policy in the regional integration.

Chapter Five

This chapter comprises of the finding of the entire study, conclusion, recommendations and optimal policy prescription for the actualization of health policy harmonization as a strategy of regional integration of East Africa.

CHAPTER TWO

PROSPECT FOR HARMONIZATION OF HEALTH POLICY FRAMEWORK AS A STRATEGY FOR EAST AFRICAN COMMUNITY INTEGRATION PROCESS

The aim of this chapter is to assess how the East Africa Community has harmonized policies so as to embark on joint action in the control and prevention of non-communicable and communicable vector-borne diseases which may endanger welfare and the health of residents of the community and cooperation in the facilitation of mass immunization as well as other health community campaigns is one of the main reasons for the harmonization of strategic plans and policies.

2.0 Introduction

The Rationale for the harmonization of health policies within the East Africa Community

The frequent movement of the population in East Africa across the borders of the six countries (Kenya, Rwanda, Burundi, Tanzania, Uganda and South Sudan) presents a great risk to the spread of diseases from one nation to another[59]. The respondents indicated that the development in trade among the different countries and travel, in the recent past, has led to an increase in the probability that cases of disease epidemics would occur in many nations. The solution to such health emergency is complicated and would require the collaboration of regional, national and global organizations. A quick and efficient information flow across the borders of EAC nations is therefore important in preventing cases and instances of cross border disease spread.

The re-establishment of the EAC in the year 1999 offers an opportunity for an improvement in collaboration in epidemic control, prevention of spread and disease surveillance. In an effort to ensure the goals were met in relation to corporation in key priority health initiatives in the EAC region as indicated the Article 118 of the treaty for the EAC establishment five technical working groups were formed to handle detailed health issues. These technical working groups include: Reproductive, Child, Adolescent Health and Nutrition; Control and Control and Prevention of STIs, HIV and AIDS; Prevention of Communicable and Non-Communicable

[59] Lisakafu, Jacob. "Interregionalism and Police Cooperation against Cross-Border Crime in East Africa: Challenges and Prospects." *South African Journal of International Affairs* 25, no. 4 (December 2018): 563–79

Diseases; Medicines and Food Safety; as well as Health Research, Policy and Health Systems Development. The technical groups have come up with policies such as EAC HIV AIDS Strategic Plan (2015 – 2020), EAC Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan (2016-2021), EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016) and EAC-RPMPOA (2017-2027).

2.1 Demographic Characteristics of the Respondents

The demographic traits of the participants includes their gender, age bracket and level of education. Out of the sample size of 246, the study obtained 147 responses, which gives a 59.75 percent. From the findings, 57.82 percent of the respondents were male while 42.18 percent were female, which implies that majority of the respondents in this study were male.

According to the findings, 33.33 percent of the respondents age were between 42 and 51 years, 31.29 percent were aged between 32 and 41 years, 25.85 percent were 52 years and above in age and 9.52 percent indicated that they were aged between 23 and 31 years. This implies that majority of the participants were aged between 42 and 51 years. In relation to the respondents' level of education, 53.74 percent of the respondents had master's degree, 30.61 percent indicated that they had undergraduate degree and 15.65 percent had PhD degrees. This implies that majority of the participants in this study had master's degree.

2.2 Harmonization of Social Health Protection in EAC

Social health protection involves the pooling of financial risks and prepayment that allows for the people to access quality care at a rate they can afford. The people contribute to the system based on their ability to pay and the benefits accrue to them based on their needs. This system also comes up with measures that solve the challenges associated with social distress, treatment cost, loss of wages and lack of productivity when a person is unable to work. The social health protection system aims at providing universal care to everyone and provides ways in which the people are protected from high health costs that can lower their living standards and make them poorer. The guiding principle of this system is to provide the people with quality health care that they can afford. The system is pegged on the equity principle where there is cross-subsidies in

the system. This means that the rich in the society subsidize the poor, they healthy subsidize for the sick while the productive subsidize for those who are not productive regardless of the reasons why the person is not productive[60].

In the East African Community, the use of the social health system is not new. The study observed that social protection has all through been used in the traditional African culture and it is one of the essential values based on solidarity, which dates back to the era of colonization. In the past, the social systems used were of help to the clans and extended families. Many African communities used the clan, families and communities to get health and social protection and they passed this concept to their descendants. In the context of East Africa, Holmes and Lwanga-Ntale[61] argues that the basis of social protection is in a community's social structure. Even though formal social security systems were not in existence, the society made use of the traditional family and kinship relationships to ensure the provision of social protection.

The study found that in strengthening social health protection in the East African Community region, the EAC Treaty highlighted the need for the harmonization of laws, systems, standards, policies and strategies in the Health Sector under Chapter 21 (Article 118) of the East African Community. The third EAC Development Strategy (2006-2010) and the November 2009 19th Ordinary Meeting of the EAC Council of Ministers that was organized after the 2nd meeting of EAC ministers which came up with Social Development (EAC/CM 19/Decision 58), made a recommendation for the a regional study on harmonization of policies. In September 2012 a conference was held in Kigali whose agenda was health protection and was attended by Ministers and experts of the six EAC member states. At the end of the conference, the Kigali Ministerial Statement on Universal Health Coverage and Long-Term Harmonization of Social Health Protection in the EAC was developed[62].

[60] Kasente Deborah & Asingwire Narathius. Social Security Systems in Uganda. *Journal of social development in Africa* 17 no. 2(2012): 23-45.

[61] Holmes Rebecca and Lwanga Ntale Charles. *Social protection in Africa: A review of social protection issues in research.* Retrieved on 20th July 2019 from http://www.pasgr.org/wp-content/uploads/2017/01/Social-protection-in-Africa_A-review-of-social-protection-issues-in-research.pdf

[62] Kasente Deborah & Asingwire Narathius. Social Security Systems in Uganda. *Journal of social development in Africa* 17 no. 2(2012): 23-45.

The study revealed that EAC members' states had over the years continued to ensure and strengthen integration and cooperation in the region whose aim is to come up with a common and functional market. The six member states aim to ensure continued provision of social protection and to ensure health services' portability that will be available even when the people of the different states move from one state to the other. Part of this endeavor saw the EAC start this research to have an assessment of the SHP strategies that were being used by all the member states before more could be done on harmonizing and refining the systems that were already in use. This move was as per the agreement between the partner states to enable easy access of health services across the region as was noted in Chapter 21 (Article 118) of the EAC Treaty that was reached upon during the development of the union[63].

It is essential that the EAC provide social health protection to its people in addition to giving them a common and functional market. As the 2005 World Health Assembly noted everyone should easily access affordable and quality health care services. Further, the EAC should also be a source of social protection other than just providing and implementing the free market and health protection if it is to achieve its development objectives.

According to the findings of the study, all the member states had started various initiatives to promote and enhance SHP. Some of the countries started projects that were based at the national levels, others had initiatives at the grassroots while others had comprehensive national initiatives[64]. These initiatives are all at different implementation and financing levels. Unfortunately, very few of the members had achieved the 15% health financing from the government expenditure as stipulated in the Abuja commitment. The members whose governments contributed the least to health among the state partners were Kenya and Uganda. Rwanda was the only state that had fulfilled the Abuja commitment while Burundi and Tanzania were making commendable strides towards achieving this commitment. The expenditure that the government allocates to health indicates its commitment to improve the health status of its

[63] Mwanyumba Robert Maganga. *Portability of Social Protection Benefits across the East African Community: A Case Study of Kenya, Tanzania and Uganda.* 2013. Retrieved on 20th July 2019 from https://pdfs.semanticscholar.org/4a0e/74e5b36680915b013b6ca19bb51151a98e56.pdf

[64] Buigut, Steven. "Trade Effects of the East African Community Customs Union: Hype Versus Reality." *South African Journal of Economics* 84, no. 3 (September 2016): 422–39.

people. Every one of the EAC member states should commit to provision of more financing to health issues if the SHP and UHC goals are to be achieved.

Another finding of the study was that each of the partner states was dealing with different challenges when it came to implementation of SHP. For, instance, Rwanda was at an advanced point as the country was looking at how its system can be enhanced to promote sustainability. On the other hand, Uganda was more than willing to start its first state SHP system. Uganda doesn't have a public health insurance scheme, but it can use the lessons from other member states in region to establish a system that uses the best practices from other member states systems initiated in the pats. There have been commendable efforts made by Tanzania, Burundi and Kenya to come up with health care systems that cater for the different population members in these countries[65]. Nevertheless, it was noted that there was no effective participation by all the involved stakeholders in the implementation and monitoring of these systems. The finding was that what was on paper was not what was on the ground. The countries claimed that free care was provided for all while in reality there was neither free nor effective care provided. In Burundi, Kenya and Tanzania together with Uganda which claims to provide free care to its police and military, the findings revealed that this system of free care resulted to poor health care services due to unmotivated works, lack of drugs and secret payments.

Another indicator of the government's progress on SHP and UHC in addition to the government spending is the population percentage under any SHP scheme. Rwanda is the country with the highest population percentage that is under a SHP scheme which comes at a high cost for the government since this country has the biggest budget allocation to health. The country has the returns to show for this investment since it has the lowest private expenditure spent on health, which resonates to a healthy nation that is able to focus on economic development[66]. Burundi also has a high budget allocation to health and it is the second best performer when it comes to the population percentage covered by a SHP scheme. However, the reality is that the country's

[65] Okello Julius. The role of Non-State Actors in the Implementation of Social Protection Policies and Programme in Uganda. *Research on Humanities and Social Sciences*, 5 no. 13 (2015), 32-44.

[66] East African Community. *Situational Analysis and Feasibility Study of Options for Harmonization of Social Health Protection Systems towards Universal Health Coverage in the East African Community Partner States.* Retrieved on 20th July 2019 from http://eacgermany.org/wp-content/uploads/2014/10/EAC%20SHP%20Study.pdf

facts on the grounds are different from the paper statistics as Burundi has the highest private expenditure on health services.

The results of the study indicated that among the six EAC member states, Uganda has the least budgetary allocation on health and it is also the country with the highest private expenditure on health. When the government contributes very little to the family's health expenditure, the family is forced to dig deeper in their pockets when one of their members is sick, which translates to increased poverty among the households. Fortunately due to other factors, Uganda is the country with the lowest population numbers that are under the poverty line. This is proof that the country has the potential to do more and enroll more of its citizens to a well-organized and working public insurance health scheme. Next in line were Kenya and Tanzania when it came to budgetary allocation and the population percentage of the population covered[67].

The provision of health services in most of the EAC countries is insufficient in regard to organization, infrastructure and human resource quantity and quality. In the rural areas, there are very minimal health care providers unlike in the urban areas[68]. Due to these challenges, the provision of trans-border SHP will need an improvement in human resources and infrastructure provision. The outputs of SHP can only be better if the inputs, which include financial and human resources are increased in the health sector. This is why the partner states need to review the amount of inputs they put in the health sector.

2.3 EAC Health Policy Frameworks

The health policy framework encompasses a set of policies and regulations that give direction to make sure that there is a significant improvement in overall status of the health sector. The health policy framework in the EAC generally demonstrates the commitment of the member states to the health sector to make sue that the region meets the best health standards in line with the needs of their population[69].

[67] Nalule, Caroline. "Defining the Scope of Free Movement of Citizens in the East African Community: The East African Court of Justice and Its Interpretive Approach." *Journal of African Law* 62, no. 1 (February 2018): 1–24.
[68] Oppong, Richard Frimpong. "The East African Court of Justice, Enforcement of Foreign Arbitration Awards and the East African Community Integration Process." *Journal of African Law* 63, no. 1 (February 2019): 1–23.
[69] Thomas, David. "Rwanda Preaches Community Spirit." *African Business*, no. 430 (May 2016): 44–46

The policy framework in the East Africa Community comprises of policies and strategic plan that include EAC HIV/AIDS Prevention and Management Act 2012; Multi-sectoral HIV and AIDS Strategic Plan (2008-2013); EAC Health Sector Strategic Plan (2015-2020); EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016); EAC Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan 2016-2021; Draft EAC Regional Pharmaceutical Policy; Regional Reproductive Health Strategic Plan, Draft EAC Regional Food Safety and Quality Policy; The EAC Biennial Work Plan on Disease Prevention and Control; EAC Regional Pharmaceutical Manufacturing Plan of Action (2012-2016); The Regional Strategic Plan on Sexual and Reproductive Health and Rights in East Africa (2008-2013).

The respondents indicated that while some of the policies were effective others were ineffective and needed more commitment from the member states in term of member states policies alignment and resources allocation. The most effective policies included the Multisectoral HIV and AIDS Strategic Plan (2008-2013) and EAC Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan 2016-2021. However, the EAC-RPMPOA: 2012-2016 required the members' states to show more commitment in terms of resources allocation and alignment with the member states drugs and medicines regulations.

2.3.1 EAC Health Sector Strategic Plan (2015-2020)

The study found that the East African Community Regional Health Sector Strategic Plan (2015-2020) articulates the East Africa Community's (EAC's) current strategic program direction in response to health challenges facing the Region. It provides an outlook of potential health risks and benefits that are likely to increase as a result of increased integration and free movement of people, trade, industry, livestock, medicines and food in the region. It identifies epidemiological trends from both communicable and non-communicable diseases for the foreseeable future[70]. The analysis provided by the strategic plan finds that there has been increased cross-border movement of people, animals, foods and medicines, as well as encroachment into wildlife habitat in EAC region. This has been caused by increased integration, relaxation of rules governing movement of people and trade, improvement of roads, flow of

[70] East African Community. *EAC Regional Health Sector Strategic Plan Final 240*315. 2018. Retrieved on 19th July 2019 from https://health.eac.int/index.php/publications/eac-regional-health-sector-strategic-plan-final-240315

traffic, population growth, and expansion of farming and industry into new areas. This trend is on the increase due to on-going deepening of integration of the Partner States. The trend has outpaced pre-existing capacities and mechanism for cross-border surveillance and control of health.

The study observed that the EAC Health Sector Strategic Plan elaborates EAC development strategy (2017 -2021) to respond to identified health situation in the region, with special emphasis on cross-border health challenges. The strategy is guided by EAC's mandate and functions as provided by the EAC development strategy (2017 -2021). The strategic plan recognizes that strategic partnerships and multi-sectoral collaboration, namely the One Health approach, is needed to achieve its objectives. The partnerships include implementation of the Strategic Plan's objectives principally through Partner State Governments, and their national stakeholders, EAC organs and institutions, autonomous commissions, civil society organizations (CSO), research and academic institutions, multi-lateral organizations and development partners, the private sector and other Regional Economic Communities (RECs)[71]. The respondents indicated that over the years, the partnership between various stakeholders has been clear with institutions including WHO, foundations and donors providing finding for various projects in the implementation of health policies. These projects include construction of laboratories, financing of HIV/AIDs awareness programmes.

The strategic plan is implemented through mainstreaming into the approved structures of the EAC[72]. Within the EAC secretariat, the strategic plan is implemented through inter-sectoral collaboration under the overall direction of the Secretary General of the East African Community. The health department of the EAC Secretariat is tasked with daily management and coordination of implementation of the strategic plan. Management of the funds follows the existing EAC Financial Rules and Regulations. The monitoring and evaluation of the EAC Health strategic plan highlights annual planning, quarterly monitoring and annual reporting. The reports are submitted to EAC Policy organs for approval and then shared with contributing

[71] Thomas, David. "Rwanda Preaches Community Spirit." *African Business*, no. 430 (May 2016): 44–46

[72] East African Community. *EAC Regional Health Sector Strategic Plan Final 240*315. 2018. Retrieved on 19th July 2019 from https://health.eac.int/index.php/publications/eac-regional-health-sector-strategic-plan-final-240315

partners and stakeholders. Indicators for monitoring the strategic plan's objectives and outputs have been developed and an overall cost[73].

2.3.2 Multisectoral HIV and AIDS Strategic Plan (2008-2013)

In article 118 of the EAC Treaty, the member states agreed to partner in sports, cultural, health and social welfare undertakings and also acknowledged that the six partners are affected by the same infectious diseases such as Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV and AIDS) and others. The development of the common market and the union among the partners increased the risk of the spread of HIV and other infectious diseases across the nations. The solution to this emergency health problem is complex and requires the nations to collaborate together with regional, national and global organizations and stakeholders. There is need for efficient flow of information across the countries and for the union to harmonize the responses to HIV spread in a bid to reduce the s[reading of the disease[74].

The research found out that in response to the HIV spread threat the community came up with a HIV and AIDS Strategic Plan (2008-2013) and the current EAC HIV AIDS Strategic Plan 2015 – 2020 and a framework that would be used to implement this plan. The community also sought financial support together with technical skills from the Norwegian and Swedish governments via the Swedish International Development Agency (SIDA) and also from the Republic of Ireland through Irish AID in November 2008. The EAC Secretariat came up with the 2008 HIV and AIDS Unit to implement the strategic plan. Since the implementation of the plan started in 2008, there have been many international, regional and national activities in the HIV and Aids space that has contributed greatly to the response taken up by the community to contain the spread of HIV and AIDS. A notable undertaking was the establishment and use of the 4th EAC Development Strategy (2012-2016) and also the June 2011 UN High Level Meeting

[73] East African Community. *EAC HIV/AIDS Prevention and Management Act 2012* 2018. Retrieved on 19th July 2019 from http://kelinkenya.org/wp-content/uploads/2010/10/QA_EALA_Bill_5July_Final1.pdf

[74] The East African Community. *The East African Community HIV and AIDS programme.* http://hdl.handle.net/11671/593

(HLM). Those undertakings and activities have seen the 2008-2013 strategic plan be realigned and revised[75].

The findings also provided that the HIV and AIDS related activities for this region were managed by the HIV and AIDS Unit (HAU) at the East African Secretariat. The unit that has four workers is meant to provide leadership, coordination and manage HIV and AIDs with the support of National AIDS Control Councils (NACs), the National AIDS Control Programmes (NACPs), and the ministries in the partner states that are in charge of health matters[76].

Since the EAC HIV and AIDs programme commenced in 2008, there have been notable achievements such as the investment in the EAC secretariat capacity to enable the implementation of the HIV and AIDs programme by providing human resource that has proper management and development skills for this programme ensuring it is sustainable in the long run. Further, the partner countries have partnered with the program coordinators to come up with management structures made up of STIs, HIV and AIDs and TB state programs that are constantly evaluated and monitored and that also help in the successful implementation of the HIV and AIDS program[77].

The results of the research also indicated that the secretariat came up with a workplace policy related to HIV and AIDs made up of guidelines provided by the unit. Moreover, the program collaborated with other EAC sectors such as tourism, security, peace and education and included HIV and AIDs programs in their operations. The program also came up with the 2012 Regional HIV and AIDS Prevention and Management Bill. The bill was passed by the East African Legislative Assembly (EALA), and it is awaiting assent by the partner countries. The bill was developed by the program which partnered with the 2012. The Bill, which is currently in the EAC Partner States for assent was developed in close collaboration with the

[75] Duby, Zoe, and Christopher Colvin. "Conceptualizations of Heterosexual Anal Sex and HIV Risk in six East African Communities." *Journal of Sex Research* 51, no. 8 (November 2014): 863–73.

[76] East African Community. *HIV & AIDS Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/hiv-aids

[77] Duby, Zoe, and Christopher Colvin. "Conceptualization of Heterosexual Anal Sex and HIV Risk in six East African Communities." *Journal of Sex Research* 51, no. 8 (November 2014): 863–73.

Eastern Africa National Networks of AIDS Service Organizations (EANNASO) and the regional Civil Society Organization[78].

The regional unit also came up with a HIV and AIDs program whose management was under the Lake Victoria Basin Commission (LVBC). The program targeted those living in the Lake Basin region including fishermen and women, farmers in the area and university students. This program has done studies related to HIV Sero-bevioural in the fishing community, farmers in the plantations and university students in Kenya, Uganda, Rwanda and Tanzania. There are also plans to do similar studies in Burundi. The findings of these studies have helped partner countries to come up with policies and programs that have helped in the fight against HIV and AIDS[79].

It was also noted that the EAC HIV and AIDS unit have come up with ways to harmonize the protocols followed by the partner countries in their prevention, treatment and care of STIs, HIV and AIDs, and TB, which results to simplified guidelines in the prevention, care and treatment of these conditions. The harmonization is also significant as it ensures any changes made related to cross border movements are harmonized and there is similar training offered to the partner state employees and the services provided are decentralized and the buying of drugs is done in bulk and done from the same supplier. The unit has engaged the partner countries to come up with the best way to harmonize the protocols and guidelines by having consultation in each of the partner states and trying to harmonize the protocols based on each country guidelines[80].

The unit also comes up with an annual report related to the EAC HIV AIDS Strategic Plan (2015 – 2020) implementation. The report provides reliable information on the current state of HIV and AIDs and the state of other epidemic diseases in this region and if the goals made in relation to these epidemics have been met. Further, the report provides information on whether there commitment from the political leaders and the actions that the countries have taken to respond to the disease epidemics. The report also gives data related to other issues related to HIV and AIDs

[78] East African Community. *EAC HIV/AIDS Prevention and Management Act 2012* 2018. Retrieved on 19th July 2019 from http://kelinkenya.org/wp-content/uploads/2010/10/QA_EALA_Bill_5July_Final1.pdf

[79] The East African Community. *The East African Community HIV and AIDS programme.* Retrieved on 20th July 2019 from http://hdl.handle.net/11671/593

[80] Muko Ochanda, Richard, Paul Kisolo Wakinya, and William Omondi Odipo. "Human Rights in the Context of Deepening Integration of East African Community (EAC)." *Postmodern Openings* 4, no. 2 (June 2013): 1–27.

and the programs started and integrated with the EAC AIDs program to address HIV and AIDS in the community[81].

The research also unearthed another achievement made by the regional AIDs unit as the program has been doing an analysis comparing the county members laws, strategies, policies and bills related to health and HIV. The research sought to determine any strategic challenges and gaps existing in the regulatory and legal frameworks found in the community states related to the community's HIV and AIDS Prevention and Management Bill. The community has in place a reform framework that is legal and which the community members will implement.

The community HIV and AIDs unit is also involved in the development of the community's 2nd HIV and AIDS, TB and STIs strategic plan (2015-2020). The community members have been active participants in coming up with this plan and the first draft is almost done. The unit has also been involved in coming up with the regional strategy to integrate HIV and health programs used in the border corridors in the EAC[82]. According to the community, the borderlines are very busy but don't have access to quality health care services which increases the risk of HIV infections. The community has also proposed the use of alternative means to access funds that could help finance the HIV and AIDs programs in the community. The community Secretariat aims to provide quality leadership to help implement quality and sustainable HIV and AIDs programs in the community.

2.3.3 EAC HIV/AIDS Prevention and Management Act 2012

The proposal made by the community 2012 HIV & AIDS Prevention and Management Bill was that the countries should agree on an HIV legislation that would harmonize a HIV response strategy across the member states. This proposal was passed on April 202 by the East African Legislative Assembly (EALA). The community's Common Market Protocol, was developed in 2012 and its aim is to bring partnerships among the six countries and also ensure there is integrated guidelines followed to deal with challenges facing the member states including the HIV and AIDS challenge. The regional legislation would do away with existing

[81] East African Community. HIV & AIDS Unit. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/hiv-aids

[82] The East African Community. *The East African Community HIV and AIDS programme.* Retrieved on 20th July 2019 from http://hdl.handle.net/11671/593

gaps, inconsistencies and discrepancies in the current laws and regulatory practices existing in the region related to HIV and come up with globally recognized laws, standards and principles that are also consistent related to HIV and AIDs, protection of people's rights and for the provision of products and information.

The outcomes of the research also included that the harmonization of the legislation especially one related to the protection of human rights would help come up with guidelines on how the member countries could institute HIV programs and educate others on how to end stigma associated with HIV in the community. The law encourages the countries to jointly plan, advocate and account for their programs that address the common challenges and priorities within the member states. It also helps strengthen the responses used across the countries related to HIV and AIDs. The countries are also able to come up with effective, affordable and collaborative strategies related to HIV such as adherence to treatment. The legislation also provides the proper responses to HIV and AIDs to everyone affected by the epidemic even those who are hard to reach and also ensures that their rights are protected, there is no discrimination and there is equal access to treatment, prevention, support and care to all the member state citizens.

The research further indicated that the EAC HIV Bill was originally from the East Africa region and it was a response to an existence gap on proper guidelines and laws that could help deal with HIV in Africa. The bill was developed through a consultative process that took four years and different stakeholders were involved in the process including those from global partners, civil society and government. The legislation process started with an audit performed on the regional laws and policies related to HIV to come up with existing gaps, commonalities and problems in the countries responses to the epidemic. What followed was consultation among the country, regional and parliamentary stakeholders. There were initiatives instituted in the six countries to create awareness on the drafted legislation. The law was reviewed in 2012 by the East African Legislative Assembly (EALA) General Purpose committee and more input from the member countries was included in the Bill. The EALA looked into the completed bill which was passed in 2012 in the month of April. The bill came up with the proposal that a common response to

HIV and AIDs should be taken up by the member states to promote the universal access to HIV care, prevention, treatment and support[83].

The results indicate harmonization of this response helps protect the rights of those affected and also enables all the community population even those at high risk of HIV exposure access the proper education, data, communication related to HIV and also access prevention, voluntary testing, counseling, informed consent, care, support, treatment related to HIV. Further, it also ensures that there is ethical HIV research and protection of the rights of those affected by HIV and AIDs.

Nonetheless, the findings of the research indicated that the legislation did not include issues related to criminalization of offences to do with international transmission of HIV and advised that the EAC countries should use their existing laws to response to such cases. The bill pointed out that coming up with a HIV related offence was not practical and could not be enforced on the courts. It also stated that providing for such an offence would not be in the best interest for the prevention of HIV neonatal visits could also be negatively affected by the institutionalization of such an offence.

2.3.4 EAC Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan 2016-2021

The study provided that significant progress related to adolescent, child, maternal, newborn and reproductive health had been achieved by the EAC member states more so in the millennium and the partner states were committed to ensuring that they make even better progress past 2015. A notable health challenge common among the member countries was the inequities existing in access, coverage and outcomes of healthcare and its interventions. Progress in the region on women and adolescent girls health have been achieved due to the collaboration between the different government policies and frameworks and also due to the efforts of the EAC Sexual and Reproductive Health and Rights Strategy 2008-2013 and The Millennium Development Goals (MDG) framework. These efforts outcomes were enhanced further in the last five years due to the support from regional and global authorities such as the UN Commission on

[83] East African Community. *EAC HIV/AIDS Prevention and Management Act 2012* 2018. Retrieved on 19th July 2019 from http://kelinkenya.org/wp-content/uploads/2010/10/QA_EALA_Bill_5July_Final1.pdf

Information and Accountability; Global Strategy for Women and Children's health; Global Vaccine Action Plan (GVAP); the Commission on Life Saving Commodities for Women and Children's Health; directives of the EAC Sectorial Council of Ministers, EAC Regional Programmes and Initiatives including the Open Health Initiative whose aim is to ensure the government intervenes and supports health programs that support children and women health[84].

Further, another finding was that the 9th Sectorial Council on Health that was conducted in April 2014 gave the EAC a direction to make the SRHR Strategic Plan (2008-2013) scope bigger by including Reproductive Maternal, Newborn, Child and Adolescent Health (RMNCAH) - (EAC/SCM-9/Health/Decision 067). The EAC RMNCAH Strategic Plan 2016-2021 has its mandate from the EAC establishment treaty, article 118 that emphasis on regional collaboration in health issues among the members[85]. The mandate is also founded on the 4th EAC Development Strategy (2011/12 – 2015/16), that pinpoints health as one of the important pillars for improving integration and also on the 2015-2020 EAC Health Sector Strategic Plan 2015-2020. According to the community's Development Strategy, there should be growth and integration of adolescent health, sexual and reproductive health, maternal health, child health and the proper programs and polies to enable the provision of quality health in all the member states. The strategic plan is also aligned to existing regional and international initiatives and policies where EAC is in in partnership with international strategy related to newborn, women, children and adolescents 2016-2030 and the Sustainable Development Goals (SDGs).

2.3.5 EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016)

Other finding from the study was that the EAC countries had plans to grow their pharmaceutical industry in a bid to achieve the regions political and social integration goals. The countries agreed that there was need to promote the development of local pharmaceutical products to lower the cost of the medicine provided to the locals. This led to the development of the EAC

[84] Pike, Ivy L, Charles Hilton, Matthias Österle, and Owuor Olungah. "Low-Intensity Violence and the Social Determinants of Adolescent Health among Three East African Pastoralist Communities." *Social Science & Medicine (1982)* 202 (April 2018): 117–27.

[85] East African Community. *EAC RMNCAH Strategic Plan 2016-2021*. 2018. Retrieved on 19th July 2019 from https://health.eac.int/publications/eac-rmncah-strategic-plan-2016-2021

Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016) which was meant to provide guidance to the member's states on way to promote the development of effective and efficient pharmaceutical manufacturing firms in the region[86]. This plan implementation in addition to the development of other initiatives such as the EAC Medicines Registration Harmonization (MRH) and the EAC Industrialization Policy and Strategy related to the pharmaceutical sector has seen the sector grow due to the joint efforts from the sector partners. Implementation of the first phase of the EAC-RPMPOA: 2012-2016 was completed in 2016 and the members saw it fit to continue with the plan for further growth of the sector. A new plan EAC-RPMPOA: 2017- 2027 was instituted in 2017 which hopes to continue the great work of the first plan by building on the goals of the first plan, identifying the challenges and problems encountered in the first plan and coming up with challenges to deal with these challenges and also to continually improve the gains of the first plan. This new plan puts into account the Sustainable Development Goals (SDG) that relate to innovation, infrastructure, health and industrialization[87].

The results from this plan indicate the community pharmaceutical industry is growing at a high rate but most of the buyers get their drugs from oversees suppliers as the local companies do not have the skills and capabilities to manufacture advanced products fit enough for the market and many of the local firms are manufacturing drugs below their capacities. Although most of the diseases in the region are treated with locally produced drugs, the firms do not have the skills to come up with advanced drugs and the locally manufactured drugs only cater for 66% of the diseases in the region. The reason behind this is because there is a gap in skills related to drug formulation and production and the resources set aside for this industry are limited[88]. In spite there being challenges in this sector, there are numerous growth opportunities in this industry which spike the interest of investors. The population of the middle-class community in these countries is continually growing while infectious diseases and Non-Communicable Disease (NCD) continue to increase. Support can be given to the local drug manufacturers by improving

[86] East African Community. *2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027*. Retrieved from http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017–2027.pdf

[87] PATH. *Medicines Regulation in the East African Community*. 2018. Retrieved from https://path.azureedge.net/media/documents/APP_eac_reg_summary.pdf

[88] "WHO Support for Medicines Regulatory Harmonization in Africa: Focus on East African Community." *WHO Drug Information* 28, no. 1 (January 2014): 11–15.

the existing regulations, passing of more positive policies related to the sector, increasing the budgetary allocation to the sector and taking advantage of the economies of scale attributed to the integration in the EAC region.

2.4 EAC Reproductive, Child, Adolescents Health and Nutrition Unit

The study revealed that the Reproductive, Child, Adolescents Health and Nutrition unit aims to ensure the Regional Integrated Sexual, Reproductive Health andvRights initiatives and programmes are successfully implemented by seeking for their growth, adoption, harmonisation and the utilization of guidelines, quality standards and policies related to Sexual Reproductive Health and Rights (SRHR) issues that include gender health issues affecting the region. The unit has three units underway which are: International Planned Parenthood Federation - United Nations Population Fund Collaboration; Building Advocacy Capacity in East Africa; and the Open Health Initiative[89].

The building of advocacy capacity project was aimed at improving adolescent's capacity where the project was supported by the European commission which was also partnering with the Deutsche Stiftung Weltbevölkerung (DSW). The project aimed to improve the capacity of the young people and teenagers in the region and also to meet the MDGs 3, 5 and 6 goals while encouraging a holistic approach to SRHR based on the International Conference on Population and Development (ICPD) and the ICPD+5 Programme of Action principles. The SRHR project hopes to build the capacity and capabilities of the youth and the young people who are serving at existing Civil Society Organizations (CSOs) so that they can advocate for the growth and implementation of the SRHR policies, budgets and programs affecting the youth. The project points out that the needs of the young people are nit well understood and they are often not include in decision making processes. On the EAC, most of the young people are encouraged to volunteer in programs that affect them and those that grow their community such as in home-caregiving centers, health centers, heads of their households and also in providing care to those

[89] East African Community. *EAC Reproductive, Child, Adolescents Health and Nutrition Unit.* 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/reproductive-health-and-nutrition

affected by HIV and AIDs. However, many of these projects do not take into consideration the youths insights and they are not asked to participate in decision making of these issues[90].

The findings were that since the youths do not have the skills to communicate their issues and needs they are not able to contribute to the national and local civic processes. There is need to empower and acknowledge these adolescents if the SRHR is to work effectively. The aim of the project is to ensure that SRHR is accessible to everyone including the youths by encouraging the use of affordable interventions, political support that leads to action and the implementation of helpful policies and the provision of enough resources. The project points out that the youth and adolescents working in the CSOs have a comparative advantage and thus, aims to build their capacity and potential to ensure that the SRHR programs, policies and budget include the youth's needs. The project also hopes to improve the capacity of the youths as decision makers[91].

The research indicated that the initiatives started by the East African Community – International Planned Parenthood Federation - United Nations Population Fund Collaboration included: Strengthening of Human Resource capacity of EAC Health Department; advocacy with the EAC Regional Inter-Parliamentary Forum on Health, Population and Development (EALA and EAC Partners States National Parliaments); Review and implementation of SRHR Strategic plan; and the EAC Sectorial Council of Health and forum of Ministers responsible for Social Development.

The Reproductive Health Unit also has an ongoing third project referred to as the "Open Health Initiative" whose aim is to improve the child and maternal health and also help in achieving of the Millennium Development Goals (MDGs) 4 and 5 in the ERAC community members. The goals of the project include encouraging innovation and improving the access of data and information to improve the health outcomes and to provide enhanced oversight of resources and outcomes on resources related to children and women health both nationally and in the EAC

[90] Lisakafu, Jacob. "Interregionalism and Police Cooperation against Cross-Border Crime in East Africa: Challenges and Prospects." *South African Journal of International Affairs* 25, no. 4 (December 2018): 563–79

[91] "WHO Support for Medicines Regulatory Harmonization in Africa: Focus on East African Community." *WHO Drug Information* 28, no. 1 (January 2014): 11–15.

community[92]. The regional approach taken up by the program will go a long way in supporting the efforts taken by the individual countries in the region. For instance, the regional project improves value for money and encourages political support of the individual country programs. The 'Open Health Initiative', leverages on the support of the EAC Secretariat and that of the community members to come up with a working 'Open Health Initiative' Strategy and plans to implement this strategy. More emphasis focused on coming up with an e-health strategy in a bid to improve on the advances in technology made by countries such as Kenya and Rwanda. After consultation with the EAC community members, the Secretariat also provided a platform where all the countries could share on progress and challenges encountered during this process.

2.5 EAC Medicines and Food Safety Unit

The study determine that the goal of the Medicines and Food Safety Unit was to protect consumers and also to improve their confidence in the safety and quality of drugs, health products and foods provided to them. The unit main goal is to ensure the implementation of regional strategies, policies, standards and guidelines to improve safety, efficacy, quality and affordability of veterinary and human drugs and food products among the EAC community partners. The unit has taken notable steps in the implementation of the EAC Medicines Registration Harmonization (MRH) Project which was created as part of the larger African Medicines Registration Harmonization (AMRH) Programme that was developed to help the African nations have a proper response to the problems that come with registration of medicines. AMRH activities are in support of the integration of the EAC as it improves the community's health status by improving access to effective, quality, safe and affordable drugs by reducing the duration required for the registration of notable drugs used to treat priority illnesses.

The research determined that harmonization of medicines in the community was deemed necessary as most of the African nations have different drug regulations that result to duplication of governments efforts and wastage of resources and also negatively impact on the delivery of quality drugs. Therefore, the harmonization of regulations related to medicines in the various EAC countries will lead to improved access to essential and affordable drugs which will

[92] East African Community. *EAC Reproductive, Child, Adolescents Health and Nutrition Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/reproductive-health-and-nutrition

improve the quality of healthcare among the member states citizens; enhance the public health outcomes; improved control of drug use due to the use of harmonized drug regulations and similar authorities; the use of better procurement regulations for procurement of quality drugs; and the provision of affordable drugs by the governments to their citizens[93].

The findings further indicated that the EAC Medicines Registration Harmonization (MRH) Project is funded in part by World Bank and it is part of the global drug harmonization efforts. The benefits that EAC communities hope to achieve from the MRH project include; development of a harmonized dossier on technical requirements on this harmonization; improve the technical capacity of the health practitioners and ensure the efficient use of limited resources; more applications from drug manufacturers who want to register their drugs; increased savings on cost and improved access to affordable and quality drugs.

The EAC MRH was launched in 2012 and its aim was to assist the EAC countries develop and strengthen their drug regulatory systems through alignment and coordination of regional policies and regulations. Since the member countries had different regulations, the initiative also sought to strengthen the capacity of the partner states NRA. By assessing and approving of the drug registrations by all the member states, harmonization is hoped to reduce drug registration time, reduce the NRAs duplication of effort and improve the effective use of the available resources.

The results show that EAC implementation of the EAC MRH project led to the development of technical groups that are working on important regulatory activities such Information Rwanda led Management Systems (IMS); Uganda led Good Manufacturing Practice (GMP); Kenyan led Quality Management Systems (QMS); and Tanzania led Medicines Evaluation and Registration (MER). The technical groups have provided harmonized standards, requirements and guidelines for QMS, MER and GMP which gained approval from the Council of Ministers in 2014. The working groups are also preparing a draft for the development of a harmonized IMS. The groups

[93] Oppong, Richard Frimpong. "The East African Court of Justice, Enforcement of Foreign Arbitration Awards and the East African Community Integration Process." *Journal of African Law* 63, no. 1 (February 2019): 1–23.

also offer regulation support to the EAC members to ensure they come up with regulations that align to the global standards[94].

Further, other than coming up with harmonized technical documents, the EAC NRAs and the secretariat has partnered with WHO and the Swiss Agency for Therapeutic Products to produce a joint dossier assessment which began in 2015. There has been evaluation of eight medical product registration applications by the EAC. WHO has also collaborated with EAC technical experts to inspect the state of GMP compliance among medical facilities in Kenya and Uganda.

Although there was resolution made by a Council of ministers in 2000 requiring all the EAC member states to come up with autonomous NRAs only three countries that is Uganda, Kenya and Tanzania had come up with the NRAs. In Rwanda and Burundi, plans are underway to establish the NRAs although currently, the drug regulations are under their ministries of health. In Burundi, the health ministry and the fight against AIDS are in charge of coming up with health policies and also managing the Directorate of Pharmacy, Medicines, and Laboratories (DPML), which is the regulatory body in charge of regulation of medicines and drugs. The DPML is charged with the regulation of medicines but this mandate does not fall on the regulation of diagnostic, medical devices and vaccines. The body does not also have the mandate to provide oversight for clinical trials. The existing regulation gap is due to lack of technical, human and financial resources and also due to inadequate infrastructure and legal framework to aid regulation. Further, the DPML efforts are aided by the resources provided through the country's budgetary allocation which continues to decrease which results to limited resources being allocated to the EAC MRH project[95].

The findings also indicate that in Kenya there is a complex policy framework used to regulate medicines. The Kenyan Pharmacy and Poisons Board (PPB) is the regulatory authority charged with regulating pharmaceutical products, providing medicine registration and providing partial approval for clinical trials. The regulatory body provides the regulation of medical devices in partnership with the Kenya Bureau of Standards and the Kenya Radiation Board. The

[94] East African Community. *EAC Reproductive, Child, Adolescents Health and Nutrition Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/reproductive-health-and-nutrition

[95] Mwangi, John M. "Towards African Medicines Regulatory Harmonization: The Case of the East African Community." *Pharmaceuticals Policy & Law* 18, no. 1–4 (January 2016): 91–98.

National Commission for Science, Technology, and Innovation (NACOSTI) is charged with the regulation, oversight provision and quality assurance in the sector of science, technology, and innovation. The regulatory bodies charged with medicine regulation and other related products are many which lead to a complex and long regulatory process that discourage private sectors, research institutions and other investors and innovators from registering their health products and seeking clinical trials clearance. For instance, organizations that want to conduct preclinical trials have to seek clearance from six regulatory bodies. However, there is a drafted legislation that hopes to harmonize the countries policies that are related to the regulation of drugs and foods and there are also plans to create an independent authority in the country referred to as the Kenya Food and Drugs Authority (KFDA), whose mandate will be greater than that of PPB. Further, the PPB is at the fore front in supporting the EAC MRH technical working group on QMS that helps the countries develop standard health quality system requirements[96].

The findings also indicate that the Pharmaceutical Service Directorate (PSD), which is part of Rwanda's Ministry of Health, has the mandate to register medicines, develops medicine related policies and also oversees medicine production and procurement. However, it is not charged with regulation of vacancies, medical devices and diagnostics. The PSD is also in charge with aligning the nation's regulatory system with the EAC MRH project. Unfortunately, the regulatory environment in Rwanda is weak which has led in slow development of policies that support regional harmonization. The EAC MRH initiative has helped Rwanda move forward in the improved access to affordable and quality medicines. The POSD has supported the harmonization by providing leadership support of the IMS technical group. Although the initiative has helped the country make progress in provision of quality drugs, there is still a lot to be done as Rwanda has significant gaps in its human resources technical skills and numbers. Further, the Rwandan government has provided minimal political support to the EAC MRH initiative and many of the people who work outside the country's MOH are not aware of the harmonization initiatives[97].

[96] Dansie, Live Storehagen, Walter Denis Odoch, and Christine Årdal. "Industrial Perceptions of Medicines Regulatory Harmonization in the East African Community." *PLoS ONE* 14, no. 6 (June 19, 2019): 1–15.
[97] Mwangi, John M. "Towards African Medicines Regulatory Harmonization: The Case of the East African Community." *Pharmaceuticals Policy & Law* 18, no. 1–4 (January 2016): 91–98.

The study revealed that in Tanzania, the Tanzanian Food and Drug Authority (TFDA), regulates the registration and evaluation of medical products and ensures that the medical devices, drugs and medical products provided to the Tanzanian people are safe and of high-quality. The TFDA is also in charge of regulating the distribution and manufacture of health technologies and clinical trials regulation. The Directorate of Inspection and Surveillance which is part of the TFDA is charged with inspection of retailers, wholesalers, manufacturers and the sites of clinical trials. The manufacturing of medicines in Tanzania by local manufacturers has been on the rise. The local manufacturers provides a third of the country's medicines in 2009. The manufactures also came up with a working distribution system to supply drugs to even the rural parts of the country. In recent past, the country has been characterized by cheap export, human resources challenges, lack of technology upgrades and weak partnerships with global pharmaceutical companies. The government hopes to address these problems by developing incentives for the Tanzanian manufacturers such as restricting cheap imports, tax breaks for the locals and encouraging the manufacture of quality locally made drugs. According to stakeholders, the local manufactures are not well aware of the EAC MRH initiative and better engagement of these local manufactures in the initiative implementation could go a long way in its successful implementation. The stakeholders also argue that the local manufacturers should be part on the regional harmonization steering committee. There is fear among the manufacturers that the standards set by the initiative are too high. Although the TFDA has provided dossiers to encourage application through the EAC MRH initiative all the applications received were from foreign manufacturers. Some of the stakeholders proposed that there be a GMP road map like the one used in Kenya which would help to improve the capacity of the local manufactures and also level the playing field[98].

According to the study, the Ugandan government came up with a policy framework for the regulation of medicines and health R&D through the 2002 National Drug Policy 2002. The country's National Drug Authority (NDA) is in charge of ensuring efficient, quality and safety of medical products and also oversees their use, distribution, importation and production. The NDA is also in charge of licensing and manufacturing of the medicines and other related

[98] Rugera, Simon Peter, Ruth McNerney, Albert K. Poon, Gladys Akimana, Rehema Forgen Mariki, Henry Kajumbula, Elizabeth Kamau, et al. "Regulation of Medical Diagnostics and Medical Devices in the East African Community Partner States." *BMC Health Services Research* 14, no. 1 (November 2014): 588–601.

products. The NDA does not regulate medical devices and diagnostic as explained by the EAC employees interviewed for this study. The country has two research bodies; the Uganda National Council of Science and Technology (UNCST) that is in charge of coordination and oversight of research across the different players and sectors. The second research body is the Uganda National Health Research Organization (UNHRO) whose focus is on research in the health field. Any research done on human and animals and also those involving health products should get its approval from the NDA and UNCST[99].

The results indicate that the NDA is charged with implementation of EAC MRH initiative and it partners with UNCST and UNHRO to achieve this goal. Uganda is in charge of the GMP technical working group which came up with harmonized documents to guide the harmonization efforts of the NRAs and also to provide guidance on inspection and regulation of manufacturing of medical products. Harmonization activities in the region are also coordinated by the EAC employees but there has been minimal involvement of national stakeholders, citizens and experts in this process. This brings about the concern that there may be challenges in the implementation of the harmonization process and documents if those who are meant to use them are not part of their development process. Further, there is no clear plan on how harmonization will occur at the national levels. Countries such as Uganda are yet to provide budgetary allocation to the EAC MRH initiatives which leads to doubts on whether the harmonization process in Uganda will be sustainable without internal funding. Further, since NDA gets some funding from fees charged on medicine registration, there were concerns from stakeholders that this source of funding will be lost.

2.6 EAC Disease Prevention and Control Unit

The outcomes of the study revealed that the disease prevention and control unit is making key steps towards provision of quality healthcare. For instance, the unit has led to the establishment of the community's regional information exchange system for communicable and non-communicable diseases; it has developed a supranational regional public health laboratory for reference and that also support the strengthening of the country's public health laboratories;

[99] Dansie, Live Storehagen, Walter Denis Odoch, and Christine Årdal. "Industrial Perceptions of Medicines Regulatory Harmonization in the East African Community." *PLoS ONE* 14, no. 6 (June 19, 2019): 1–15.

strengthen rehabilitative, curative, preventive and promote health centers that provide services for non-communicable diseases; and strengthening the EAC partner states capacity to treat and diagnosis communicable and non-communicable diseases. To support these projects, the unit has established two projects namely: The East African Public Health Laboratory Networking Project (EAPHLNP) and the East African Integrated Disease Surveillance Network (EAIDSNet)[100].

The findings indicate that the EAPHLNP initiative is supported by World Bank in partnership with the World Health Organization, the EAC countries, the East African Community Secretariat, the US Centers for Disease Prevention and Control and the East Central and Southern Africa Health Community. The initiative aims to come up with an efficient, quality and easy to access network of laboratories that can help in the diagnosis and treatment of TB and other communicable diseases. Currently, the initiative oversees 25 public health laboratories in the EAC. These laboratories were chosen by the EAC countries due to where they are located close to the border points which are characterized by many vulnerable populations such as refugees and immigrants; predominantly close to indigenous communities; and most likely to have diseases outbreaks compared to other parts of the EAC. The initiative hopes to improve accessibility of treatment and diagnostic services to people who are at a higher risk of suffering from communicable diseases and ensure that such diseases don't spread to other areas of the EAC. The EAPHLNP program also aims to improve the public health facilities capacity such that they can better diagnosis of diseases and effectively monitor any drug resistance of diseases in the community and also improve the facilities ability to perform disease surveillance and be well prepared in case of emergencies. Further, the initiative hopes to provide vital laboratory data that can be an early warming of public health issues about to occur and also be a source of training and research on public health matters.

According to the study findings, the East African Integrated Disease Surveillance Network (EAIDSNet) is an initiative started in the EAC by the EAC countries ministries that are in charge of human and animal health. The ministries collaborate with the countries academic and health research institutions. The Rockeffer Foundation also provides support to this initiative. The

[100] East African Community. *Disease Prevention and Control Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/disease-prevention

project's main goals include to strengthen and improve collaboration between the countries and their institutions to ensure control and prevention of animal and health diseases under the One Health Initiative; provide proper information related to surveillance and control of integrated diseases; harmonize surveillance of integrated diseases in the community; strengthen the capacity of the EAC countries systems on surveillance and control of diseases; and ensure that there is constant exchange of best practices and expertise on disease surveillance and control. The EAIDSNET has made some notable achievements since the initiative was established including the development of disease control and surveillance systems in the EAC countries; identifying the key diseases that need surveillance and control in each of the member states; establish collaboration in decision making, policy making, control and research of diseases among the member states; ensure that each of the partners has disease testing and surveillance guidelines; ensure each of the partners has identified and implemented activities that would help in disease control and surveillance; and ensure that there is coordination in the EAIDSNET initiative[101].

Another finding from the study was that the EAC and its secretariat were determined to unite in the fight against infectious diseases in the region and this was declared as a health priority by the partner states. The EAC had started the project "Support to Pandemic Preparedness in the EAC Region" , which was being implemented by GIZ with the support of the government of Germany being assisted by the EAC Secretariat to ensure the member states were well prepared and had the right response mechanisms in place. The project also helps implement the community's contingency plan and also in the implementation of the regional risk and crisis communication strategy[102]. Those in charge of the initiative also act as an advisor on the sustainability of the One Health project. The project also seeks the help of society professionals that are stakeholders in public health and those involved in the prevention of infectious diseases outbreaks and also help control the outcomes of any outbreaks. Further, the project is a source of vital expertise and also improves the capacity of the EAC members in a bid to help them in improving how they prepare for epidemics. It uses a practical and participative approach to achieve these goals. The project is

[101] East African Community. *EAC Health Systems, Research and Policy Unit*.v2018. Retrieved on 19th July 2019 from https://www.eac.int/health/hiv-aids

[102] Mwangi, John M. "Towards African Medicines Regulatory Harmonization: The Case of the East African Community." *Pharmaceuticals Policy & Law* 18, no. 1–4 (January 2016): 91–98.

a vital resource when it comes to harmonization of pandemic preparedness approaches and ensuring the approaches taken are effective and balanced[103].

The results of the study further indicated that "Support to Pandemic Preparedness in the EAC Region" initiative looked into the Standard Operating Procedures SOPs used in pandemic preparedness. Such SOPs covered included the establishment of a regional pool of Rapidly Deployable Experts in the community, SOPs related to cross-border surveillance in the region, procedures followed in emergency reporting and ensuring the EAC Regional Emergency Response was working, managing the logistics of Regional Outbreak Preparedness, and having working Early Warning and Response mechanisms. SOPs on Risk and Crisis Communication focused on ways to develop response messages; how to share hazards information; how to seek the help of affected stakeholders; and how to gain approval to give press release.

2.7 East African Health Research Commission (EAHRC)

According to the study the provision of article 118 of the treaty that provides for the development of EAC, the EAC community agreed to partner and develop the East African Health Research Commission (EAHRC). The EAHRC is an institution that was established in 2008 by all the six EAC members and marked the development of a cooperation that dealt with health matters in the EAC community. The EAHRC was established to provide guidelines on health matters, research and outcomes which are important for generation of health data, technological growth, development of policies and also growth and development in the health field. The EAHRC is the main advisory institution to the EAC community on matters related to health development and research. The vision of the EAHRC is to develop quality research that can help improve the health statues of the people in the EAC[104]. Its mission is to do, promote and coordinate research in the EAC region and collect and distribute results of health related studies to ensure improved health practice and growth of policies. The EAHRC has led to the

[103] East African Community. *Disease Prevention and Control Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/disease-prevention

[104] Kibiki Gibson. *East African Health Research Commission (EAHRC) - an Institution of the East African Community (Kenya, Tanzania, Burundi, Rwanda, Uganda).* 2018. Retrieved on 19th July 2019 from https://www.eahealth.org/sites/www.eahealth.org/files/content/attachments/2019-02-21/EAST%20AFRICAN%20HEALTH%20RESEARCH%20COMMISSION%20%28EAHRC%29%20-%20Prof.%20Gibson%20Kibiki.pdf

establishment and growth of the EAC regional health research journal, The East African Science Journal (EASci) and the East African Health Research Journal (EAHRJ).

The study also found out that the EAHRC has made some notable achievements since it was operationalized in 2015 in the month of July. Some of these achievements include the establishment of the 2016-2021 EAHRC Strategic Plan with approval from EAC Council of Ministers, the establishment of the Digital Regional East African Community Health (Digital REACH) initiative which brings the different EAC region stakeholders and ensures they coordinate in community health matters and it also led to the partnering of other stakeholders beyond those in the EAC community so as to improve the outcome of health matters in the EAC. The institution has been of great benefit to the region especially when it comes to transformation and provision of ground breaking strategies related to health matters. It has led to the use of ICT in health matters as the use of Digital health technology is one of the priorities that the EAC member states approved to be used in the coming decade[105].

Further the commission led to the development of the Young East African Health Research Scientists' (YEARS') Forum an initiative aimed to empower the young health researchers in the EAC region. The commission also oversaw the development of the East African Health and Scientific Conference (EAHSC) which is a conference held every two years in the East African region although it is held in collaboration with the EAC partner states. The commission also established the One-Stop Center for Health Information in East Africa that is operated through the EAC official web portal that also has comprehensive health information in the EAC. Further, the initiative saw the publishing of EAHRC Scientific Journals, which are a great contribution to the global scientific knowledge on health and related matters.

2.7.1 Regional East African Community Health Policy Initiative (REACH)

The findings indicate that the initiative has resulted to the prioritizing of digital technology in the health undertakings and the east Africa health systems were included in the 20216-2021 EAHRC

[105] East African Community. East African Health Research Commission (EAHRC). 2017. Retrieved on 19th July 2019 from https://www.eahealth.org/sites/www.eahealth.org/files/content/attachments/2019-02-21/EAST%20AFRICAN%20HEALTH%20RESEARCH%20COMMISSION%20%28EAHRC%29%20-%20Prof.%20Gibson%20Kibiki.pdf

strategic plan. EAHRC with the support of USAID/Kenya and East Africa, countries, there was the development of a consultative process to come up with the Digital Regional East African Community Health (REACH) project that is detailed in a decade Digital REACH Initiative Roadmap[106].

the Digital REACH Initiative was shown to have a defined way of governance mandated with the coordination of action in the community, establishment of a support environment for the development of digital technology to support health issues in the region and support the use of digital health best practices to improve health outcomes in the region. The digital REACH initiative is aimed to meet certain objectives such as the support for public health education, the training and education of health workers, surveillance and response activities, treatment and diagnostic, the allocation and management of resources and management of supply and health products procurement[107].

The results indicate that the provided Roadmap is the first step that would help realize the Digital REACH Initiative. The roadmap has a detailed documentation of the initiative mission, goals and objectives. The roadmap also has the nine main activities of the initiative, the strategies used in these activities, their phasing and the roles of each of the EAC partners. The ten year roadmap provides the plan on how the EAC would create partnerships with other related partners, private state actors and related stakeholders to help accomplish the initiative objectives. Each of the activity work stream has the roles and responsibilities of the state partners laid out[108].

The findings also indicate that the various stakeholders have played a part in the development and growth of the Digital REACH Initiative Roadmap by way of interviews, workshops and conferences where the stakeholders and decision makers of the EAC were involved. The EAC and the EAHRC came up with this collaborative concept. The financial support for the initiative was given by the EAC and USAID. While the firms to be supported by the initiative were

[106] Hategeka, Celestin, Germaine Tuyisenge, Christian Bayingana, and Lisine Tuyisenge. "Effects of Scaling up Various Community-Level Interventions on Child Mortality in Burundi, Kenya, Rwanda, Uganda and Tanzania: A Modeling Study." *Global Health Research and Policy* 4 (May 29, 2019): 1. doi:10.1186/s41256-019-0106-2.

[107] Muko Ochanda, Richard, Paul Kisolo Wakinya, and William Omondi Odipo. "Human Rights in the Context of Deepening Integration of East African Community (EAC)." *Postmodern Openings* 4, no. 2 (June 2013): 1–27.

[108] East African Community. *Common Market.* Retrieved from on 19th July 2019. http://www.eac.int/integration-pillars/common-market.

provided from the Cross-Border Health Integrated Partnership Project (CB-HIPP) with the leadership of FHI 360 and the United States Agency for International Development (USAID) and Knowledge for Health (K4Health) Project provided the necessary technical support. Further, the Vital Wave, Inc came up when Roadmap document after incorporating the inputs and discussions made by the partners.

2.8 Summary of the Key Findings

In the past years, the EAC sought to ensure the harmonisation of the policies in the region. This would help them collaborate in the control and prevention efforts of communicable and non-communicable illnesses in the region, which can negatively affect the health and welfare of the citizens in the EAC member states. The major EAC policy ids the 2015-2020 East African Community Regional Health Sector Strategic Plan that provides for the EAC policy direction related to health issues facing the region. Part of the harmonization included the harmonization of social health protection policies. Responding to the HIV-AIDs epidemic in the region, the EAC came up with a 2008-2013 Multi-sectorial HIV and AIDS Strategic Plan and a framework for the plans implementation. For harmonization of maternal health policies, the 2016-2021 EAC Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan was established.

Further, the EAC also hopes to harmonize roles and policies related to their pharmaceutical industry in the region to enable the political and social integration of the EAC partner countries agenda. This led to the development of the 2012-2016 EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA), which is the roadmap that provides guidance on the growth of a working and efficient pharmaceutical manufacturing sector in the region. To improve the role of this plan of action the 2017-2027 EAC-RPMPOA was established. The EAC also came up with the 2016-2021the East African Health Research Commission (EAHRC) Strategic Plan to improve health research in the region. The EAC secretariat also developed different units to help in the policies harmonization process. Some of the units in the community include: Child, Adolescents Health and Nutrition Unit; the EAC Reproductive; the HIV and AIDS Unit (HAU); the EAC Disease Prevention and Control Unit; and the EAC Medicines and Food Safety Unit.

CHAPTER THREE
IMPACT OF HEALTHCARE INTEGRATION ON EAST AFRICA COMMUNITY (EAC) MEMBER COUNTRIES

3.1 Introduction

The chapter covers the impact of healthcare integration on East Africa Community (EAC) member countries. It encompasses improvement of social health protection and government expenditure on Health; implementation of HIV/AIDS programmes; adoption of information and communication technology in the health sector; ineffective and inefficient pharmaceutical manufacturing in member states; strengthened reproductive maternal new-born child and adolescent health; strengthened health systems; strengthened knowledge management; collaboration on regional responses to emerging pandemic threats; and provision of technical assistance for the EAC One Health Platform

3.2 Social Health Protection and Government Expenditure on Health

Social health protection is a system designed to alleviate the burden caused by ill health and reduce the indirect costs of disease and disability, such as lost years of income due to short and long-term disability, care of family members, lower productivity, and the impaired education and social development of children. An effective social health protection system provides universal access to needed health care that is affordable, available, of adequate quality and offers financial protection in times of illness, injury and maternity. Government expenditure the health spending measures the final consumption of health care goods and services (current health expenditure) including personal health care (curative care, rehabilitative care, long-term care, ancillary services and medical goods) and collective services (prevention and public health services as well as health administration), but excluding spending on investments.

The study found that the East Africa Community Secretariat in social health protection include creation of a commission, task force, or coordinating desk within EAC secretariat to guide and monitor SHP implementation; develop a regional policy towards social health protection; mobilize funds for support studies around social health protection (identifying the poor, defining minimum benefit package); and develop a legal framework to operationalize

health insurance within the EAC Partner States. Generally, the East Africa Community Secretariat sought to harmonize social health protection standards across Partner States; and define minimum package among others[109].

The study also found that different countries in the East Africa Community had adopted different initiatives to promote social health protection. While the EAC health policies are linked to Abuja health declaration where member states pledged to allocate 15 per cent of the total government expenditure to health, most of the countries in EAC community have not yet met this requirement. While some countries have been increasing government expenditure on health as a percent of the total expenditure every year, others have been reducing. For instance, the Kenyan and Ugandan governments have the lowest allocation to health, while Rwanda has the highest.

3.3 Implementation of HIV/AIDS Programmes

The study established that EAC health integration helps the member states to form a common ground in anti-Aids war. The leaders in EAC indicate the need for uniform HIV and Aids control policies in member countries to help in the fight against the disease. In a health integration effort to address the issue of HIV and AIDS, the East African Community developed a Multisectoral HIV and AIDS Strategic Plan (2008-2013). The technical and financial support was obtained from the Swedish and Norwegian Governments through the Swedish International Development Agency (SIDA) and from the Republic of Ireland through Irish AID in November 2008[110]. Other major activities that are currently being undertaken by the HIV and AIDS programme include the development of the 2nd EAC HIV and AIDS, TB and STIs strategic plan (2015-2020)[111]. The EAC HIV & AIDS Prevention and Management Bill 2012 proposed the adoption of a regional HIV law to regulate effective responses to HIV across all of the five countries of the East African Community (EAC). It was passed by the East African Legislative Assembly (EALA) on the 23rd April 2012. The EAC Common Market

[109] AUC/UNECA/UNDP. *Annual Report 2015 - United Nations Economic Commission for Africa*. 2015. Retrieved on 25th June 2019 from https://www.uneca.org/

[110] Duby, Zoe, and Christopher Colvin. "Conceptualizations of Heterosexual Anal Sex and HIV Risk in Five East African Communities." *Journal of Sex Research* 51, no. 8 (November 2014): 863–73.

[111] Muko Ochanda, Richard, Paul Kisolo Wakinya, and William Omondi Odipo. "Human Rights in the Context of Deepening Integration of East African Community (EAC)." *Postmodern Openings* 4, no. 2 (June 2013): 1–27.

Protocol, which came into effect in July 2010, fosters co-operative, integrated approaches to regional social and economic challenges such as HIV and AIDS[112].

The study revealed that in the implementation of the EAC HIV/AIDs policies, institutions in the member states have embarked on various interventions that include creating of awareness, male circumcision, and HIV Testing among Adults and Youth. Generally, male circumcision has been found to reduce HIV acquisition by 60%. Among the members states of EAC, Kenya has the highest percentage of male circumcision (85%), followed by Tanzania (72%), Burundi (33%), Uganda (26%) and Rwanda (13%). Generally, as a result of the awareness that has been created for the last one decade on the importance of male circumcision, the percentage of male circumcised has increased by 17%. In addition, the percentage of adults and youth tested in the EAC member states has increased for the last one decade. The percentage of adults and youth tested in Kenya increased by 32%, this was followed by 29% in Tanzania, 27% in Burundi, 32% in Rwanda and 21% in Uganda.

The study discovered that in a two day conference held in Kisumu the regional health workers and researchers sought to improve the effectiveness of the various HIV and Aids interventions through the harmonization of EAC Aids protocols, policies, plans, strategies and legislation[113]. However, despite the call for harmonization of policies related to HIV/AIDs, some member states have been having a challenge in adopting the new policies. For instance, the HIV law in Uganda is at odds with East African Community HIV/Aids Prevention and Management Act. In Uganda, the HIV/Aids Prevention and Control Act that was assented to law in 2014 criminalizes intentional transmission of HIV. This law requires mandatory testing for victims of sexual offences, pregnant women and their partners. It also criminalizes transmission of HIV, while medical workers are required to release results to sexual partners of HIV-positive persons. The law from EALA on the other hand says testing should never be mandatory, outlaws discrimination and guarantees rights to privacy. It is confusing to the implementers

[112] East African Community. *EAC HIV/AIDS Prevention and Management Act 2012*. 2018. Retrieved on 19th July 2019 from http://kelinkenya.org/wp-content/uploads/2010/10/QA_EALA_Bill_5July_Final1.pdf

[113] Otieno Kepher. *Find common ground in anti-Aids war, EAC tells member States*. 2017. Retrieved on 15th August 2019 from https://www.standardmedia.co.ke/

since one requires non-discrimination of people living with HIV/Aids while the other recommends the opposite[114].

The respondents indicated that in Kenya, the 2015 High Court's judgment on the constitutionality of the "Uhuru's HIV List" was a clear example of how the application of human rights principles could enhance the validity of laws and policies adopted in relation to health. In that case, a directive was issued by the President Uhuru Kenyatta to all County Commissioners to collect data on all school-going children living with HIV/AIDS. The Court found that the directive violated children's rights to privacy, which is a key part of the East African Community HIV/Aids Prevention and Management Act. The Court ruled that the directive and actions taken under its direction violated the Constitution, but refrained from mandating the government to adopt a certain policy or protocols that met specific criteria. Moreover, as the directive had begun to be implemented, there were already children who had been harmed, and for these children the court ruled that the government must de-identify the data in such a way so that it did not link a child to their HIV status.

The respondents also indicated that such harms can be avoided when the validity of legal frameworks are considered from the outset of policymaking. For example, the development of the East African Community HIV and AIDS Prevention and Management Act of 2015 provides an illustration of a legal framework that was developed using a Human Rights-Based Approach (HRBA) and which seeks to promote the rights of persons living with or affected by HIV, even overriding national laws that contain discriminatory clauses. The inclusive and democratic process for developing the law, which took 7 years of extensive consultations with stakeholders, including persons living with HIV, sex workers, men who have sex with men (MSM), drug users, health care workers, parliamentarians, civil society groups and religious leaders, not only exemplifies how HRBAs promote concern for and empower marginalized communities. From the perspective of health policy and governance, the process was critical to

[114] The East African. *Uganda's HIV law at odds with EAC Act.* 2014. Retrieved on 15th August 2019 from https: //www.theeastafrican.co.ke

both the law's legitimacy as well as that of the programs that were launched within its parameters[115].

3.4 Adoption of Information and Communication Technology in the Health Sector

The study found that the EAC Health Sector Strategic Plan (2015-2020) indicates that information and communication technology has played a major role in transforming the health sector service delivery in developed countries and it's hence expected to improve service delivery in the EAC partner states[116]. Articles 89, 99 and 103 of the EAC Treaty highlight the EAC quest to improve ICT to foster efforts towards economic development. The implementation of the telemedicine in East Africa will improve access to specialty care, reduce the cost associated with long distance travel for medical examination and treatment, increase access to continuing medical education and training, and reduce professional isolation among doctors and other health staff located in rural and remote areas[117].

The study also found that as a result, the East African Community (EAC) member countries have invested in digital technology to accelerate the implementation of the UN Sustainable Development Goals[118]. Tanzania has considerably embarked on digitizing its healthcare system through the Ministry of Health and several other agencies and this has helped in tracking medicine consignment from purchase point to delivery point and online reporting of the adverse effects of the use of medicine and cosmetics[119]. As such, the country has reported positive impact of the healthcare sector since it embarked on digitizing

[115] World Health Organization. *Millennium Development Goals (MDGs).* 2014 Retrieved on 25th June 2019 from https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs)

[116] East Africa Community. *Gaps in Health Care Provision for Key Populations Along East African Community (EAC) Transport Corridors*. 2015. Retrieved on 15th August 2019 from https://www.afidep.org/download/03.03.2016.PB.Mapping_CBHIPP%20final.pdf

[117] East Africa Community. *Gaps in Health Care Provision for Key Populations Along East African Community (EAC) Transport Corridors*. 2015. Retrieved on 15th August 2019 from https://www.afidep.org/download/03.03.2016.PB.Mapping_CBHIPP%20final.pdf

[118] Yamin, Alicia Ely, and Allan Maleche. Realizing Universal Health Coverage in East Africa: the relevance of human rights. *BMC international health and human rights* 17, no. 1 (August 2017): 13-29.

[119] TradeMark East Africa (2019). *Tanzania Urges East African Countries to Invest In Digital Health Technology*. Retrieved on 15th August 2019 from https://www.trademarkea.com/news/

its systems. Further, the rapid increase to mobile technology in Africa has fostered a conducive environment for the use of information and communication technology in health[120].

The findings of the study indicated that in Rwanda, telemedicine is used for medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology. After signing Head of Terms with RSSB and agreement to move to a full contract, babylon (a software developing country) has set-up a working center staffed with Rwandan nurses and doctors supported by an in-house call center launching what is Rwanda's first private digital healthcare service[121].

Majority of the respondents indicated that in the Ministry of Health (MoH) of Burundi initiated in 2014 the development of a national e-health enterprise architecture aiming to reclaim its leadership in this field and to better align existing and future ICT implementations in the health domain with the strategic options defined by the National Plan for Health Development (PNDS)[122]. However, despite the improvement in efficiency and quality in service delivery, the implementation faced challenges such as problems in internet connectivity, lack of standardization, data security risks, varying data quality, inadequate ICT infrastructures, an unregulated e-health sector and insufficient human capacity. Also, paper based instruments remained predominant in Burundi's health administration. In addressing these challenges the later architecture development effort resulted in the production and validation of a national e-health strategy for Burundi for the period 2015-2019 (PNDIS), which was also aligned with EAC Health Sector Strategic Plan (2015-2020) guidance of e-health management[123].

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[120] East Africa Community (2013). *EAC Youth Policy*. Retrieved on 15th August 2019 from http://meac.go.ke/wp-content/uploads/2017/03/EAC-Youth-Policy.pdf

[121] Rusatira, Jean Christophe. Enabling Access to Medical and Health Education in Rwanda Using Mobile Technology: Needs Assessment for the Development of Mobile Medical Educator Apps." *JMIR medical education* 2 no. 1 (June 2016): 7-13.

[122] Yamin, Alicia Ely, and Allan Maleche. Realizing Universal Health Coverage in East Africa: the relevance of human rights. *BMC international health and human rights* 17, no. 1 (August 2017): 13-29.

[123] East Africa Community. *EAC Youth Policy*. 2013. Retrieved on 15th August 2019 from http://meac.go.ke/wp-content/uploads/2017/03/EAC-Youth-Policy.pdf

The study also found that in Tanzania, the National eHealth Strategy 2012 – 2018 has considerably been used in the implementation of electronic health. The Ministry of Health and Social Welfare (MOHSW) indicates the potential of information and communication technology (ICT) in transforming healthcare delivery by enabling information access and supporting healthcare operations, management, and decision making. However, the Tanzanian health sector is characterized by a fragmented landscape of ICT pilot projects and numerous data and health information system (HIS) silos with significant barriers to the effective sharing of information between healthcare participants[124].

The study revealed that a Kenya National eHealth Strategy was developed in 2010, with an aim to harness information and communication technologies (ICT) for improved health care delivery by supporting informed policy, improving access to clinical evidence for care providers, fostering interoperability, and creating linkages between service providers and researchers. The strategy outlines 5 key areas: telemedicine, health information systems, information for citizens, mHealth, and e-learning. Kenya has also adopted, at a national level, the District Health Information Software Version 2 (DHIS2) for aggregating health data across different levels of the health system. The DHIS2 system was implemented as a response to challenges with the previous Microsoft Excel file-based system. These included an inability to fully analyze the data collected due to the way the data were aggregated, a lack of error-checking capabilities, incomplete data, and limited capacity in the use of information for decision making. KenyaEMR (Open Medical Record System; 2012-2013) is a tailored distribution of Open Medical Record System (OpenMRS), an open source EHR system that has been widely used in several African countries to support the management of HIV/AIDS patients (and more recently other diseases such as TB and noncommunicable diseases)[125].

The study established that in Uganda, the MOH developed a National eHealth Policy (2013), a National eHealth Strategy (2013), and subsequently a draft National eHealth Policy (2016) to guide the use of ICT in supporting health sector transformation. As part of these processes, the Ministry, through an eHealth Technical Working Group (eHealth TWG) supported by

[124] The United Republic of Tanzania. 2019. *Tanzania National eHealth Strategy 2012 – 2018.* https://www.who.int/goe/policies/countries/tza_ehealth.pdf

[125] Muinga, Naomi. Implementing an Open Source Electronic Health Record System in Kenyan Health Care Faci lities: Case Study. *JMIR medical informatics* 6 no. 2(April 2018): e22.

United Nations Children's Fund (UNICEF) and World Health Organization (WHO), conducted a series of national consultations that included health sector professionals, partners, faith-based organizations, Government, nongovernmental organizations (NGOs), and other stakeholders. In 2016, the Ministry, through technical and financial support from UNICEF and WHO under the stewardship of the eHealth TWG reviewed the draft eHealth Policy and strategy, seeking areas for improvement. The review process also followed a participatory approach driven by HSDP strategic objectives. The National eHealth Policy and Strategy provide an appropriate basis to guide the development of eHealth in Uganda[126].

3.5 Ineffective and Inefficient Pharmaceutical Manufacturing in Member States

The study observed that EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016) was developed to serve as a road map to guide the community towards evolving in to an efficient and effective regional pharmaceutical manufacturing industry[127]. The implementation of the plan along with other regional initiatives such as the EAC Medicines Registration Harmonization (MRH) and the EAC Industrialization Policy and Strategy (which prioritizes pharmaceutical sector) has contributed to the positive development of the sector and progress in harnessing joint economic potential. The implementation period for the first EAC-RPMPOA: 2012-2016 ended in 2016 and there was need for continuation and further improvement. The new plan (EAC-RPMPOA: 2017- 2027) builds on the achievements of the first plan, identifies gains and challenges encountered and; lays down strategic approaches for the EAC and the Partner States. The plan factors in the Sustainable Development Goals (SDG) especially with regard to good health (SDG 3) and industry, innovation and infrastructure (SDG 9)[128]. These policies and strategies have had different implications and impact on individual members states of the EAC.

[126] East Africa Community (2015). *Gaps in Health Care Provision for Key Populations Along East African Com munity (EAC) Transport Corridors*. Retrieved on 15th August 2019 from

[127] East African Community. *2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027*. Retrieved from http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017–2027.pdf

[128] PATH. *Medicines Regulation in the East African Community*. 2018. Retrieved from https://path.azureedge.net /media/documents/APP_eac_reg_summary.pdf

The study established that Tanzania requires all foods, drugs and cosmetics traded in Tanzania to be registered with TFDA. TFDA derives its mandate from section 5(1) of the Tanzania Food, Drugs, Cosmetics Act, 2003 (TFDCA). This provision confers upon TFDA the power to regulate the relevant products, including those from EAC Partner States. The purpose of registration is to control the importation, manufacture, labeling, marking or identification, storage, promotion, selling and distribution of food, drugs, cosmetics, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under the TFDCA. The registration requirement applies to all products regardless of their origin or whether they are certified in other EAC Partner States. Tanzania also requires retesting of all pharmaceutical and herbal drugs, poisons, cosmetics and food products. This is a compulsory requirement that importers must meet in order to be granted a registration permit that allows them to import their goods into Tanzania. Tanzania also requires relabeling when the labels on imported products do not meet TFDA's labeling standards as provided under the labeling guidelines for respective products.

Most of the respondents indicated that Tanzania's registration requirement has had a long history of reports in the EAC Non-Tariff Barrier monitoring framework with the EAC Regional Forum consistently recommending that Tanzania abolish this requirement with respect to EAC products. Presently, the NTB is reported as affecting all EAC Partner States. In Uganda, two companies, Mukwano Industries (U) Ltd and Samona Products (U) Ltd, reported this NTB for its effects, mainly on their cosmetics products.

Local manufacturers in Tanzania feel they have not been adequately engaged in the EAC MRH initiative and are not included in the regional steering committee on harmonization. Manufacturers fear that they cannot meet the high standards proposed by the initiative. Though the TFDA has assessed joint dossiers for medical product registration under the EAC MRH initiative, all applications came from foreign manufacturers. To level the playing field, some stakeholders proposed a GMP Road Map for Tanzania—similar to Kenya's—to provide a phased approach for increasing manufacturing capacity. Beyond dossier assessment, the TFDA has engaged with the EAC MRH initiative in various ways. The TFDA leads the technical working group on MER, which developed a compendium that outlines harmonized medicines registration procedures. This document aids partner

states' NRAs in managing applications for medicines registration and provides manufacturers with guidelines to follow when preparing a product dossier. There is no clear information, however, about what resources the TFDA invests in the EAC MRH initiative[129].

The study found that the government of Uganda developed a policy framework for medicines regulation and health R&D through the National Drug Policy (2002). The National Drug Authority (NDA) is mandated to ensure the quality, safety, and efficacy of medical products and regulate their production, importation, distribution, and use. The NDA also oversees manufacturing and licensing. In addition to the above licenses, firms must register their products in Uganda. To operate in Uganda and obtain the necessary licenses and registration, firms must comply with national standards, and/or WHO-issued standards as defined by NDA[130].

The study also revealed that Uganda also has two research bodies; the Uganda National Council of Science and Technology (UNCST) oversees and coordinates research across sectors, whereas the Uganda National Health Research Organization (UNHRO) focuses on health research specifically. Research involving animal and human health products must be approved by the NDA and UNCST. The NDA is responsible for implementing EAC MRH activities, in collaboration with UNCST and UNHRO. Uganda leads the technical working group on GMP, which developed a compendium of technical documents to guide NRAs in managing inspections of manufacturing facilities. Apart from this work, however, respondents revealed that all harmonization activities are being coordinated at the regional level by EAC staff—there has been very little involvement of national-level technical experts, citizens, and other stakeholders. This has led to concerns about how the harmonized documents will be implemented if those who use them are not consulted in the development process. More broadly, there is no clear mechanism or plan for how harmonized documents will be implemented at the national level. Uganda has not provided funding specifically for the EAC MRH initiative, which raised questions about harmonization's

[129] Rugera, Simon Peter, Ruth McNerney, Albert K. Poon, Gladys Akimana, Rehema Forgen Mariki, Henry Kaj umbula, Elizabeth Kamau. Regulation of Medical Diagnostics and Medical Devices in the East African Communi ty Partner States. *BMC Health Services Research* 14, no. 1 (November 2014): 588–601.

[130] USAID (2019). *EAC Common Market Implementation Impact of Technical Regulations on Intra-Regional Trade: The Experience of Ugandan Pharmaceutical Firms.* Retrieved from https://d3n8a8pro7vhmx.clo udfront.net/

sustainability—most funding has come from external sources. Moreover, because the NDA depends on medicines registration fees, some respondents were concerned about losing this source of funding[131].

The study unearthed that Ugandan firms exporting to Tanzania must also register with Tanzania Customs (Tanzania Revenue Authority) and, in compliance with the requirements of TFDA, register all their products in Tanzania. According to the pharmaceutical firms, the registration process takes a minimum of 12 months if all the necessary documentation and information is submitted and no queries are raised by TFDA. This is in conformity with the "Guidelines on Procedural Aspects for Applications for Market Authorization of Medicinal Products" in Tanzania. However, if TFDA requests additional information and documentation, the approval process could take up to 24 months. In accordance with the Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2015, the GMP inspection fee is USD 4,000. This fee is paid every three years. In addition to inspection fee, a registration fee of USD 2,000 must also be paid for each product to be registered. Finally a product retention fee of USD 300 is paid every year for each product in the market. These amounts are all more than three times what domestic manufacturers pay for the same services.

The study also found that Burundi's Ministry of Public Health and the Fight against AIDS develops health-related policy and oversees the Directorate of Pharmacy, Medicines, and Laboratories (DPML), which functions as the country's medicines regulatory authority. The DPML only regulates medicines— not vaccines, medical devices, or diagnostics—and does not have the capacity to provide oversight for clinical trials. This gap in regulation is largely due to chronic shortages of human, technical, and financial resources; a lack of infrastructure; and an inadequate legal regulatory framework. Moreover, the DPML relies on the budget allocated to the Ministry of Public Health, which continues to decline, leaving the DPML unable to allocate resources to the EAC MRH initiative.

The study found that Burundi has fast-tracked the enactment of a legal framework to recognize regulatory decisions made by NRAs of other partner states—but this does not yet happen in practice. Additionally, the Ministry of Public Health has not enacted a national health

[131] Dansie, Live Storehagen, Walter Denis Odoch, and Christine Årdal. Industrial Perceptions of Medicines Regu latory Harmonization in the East African Community. *PLoS ONE* 14, no. 6 (June 19, 2019): 1–15.

research policy, and coordination between entities involved in health research is lacking. The DPML has, however, engaged in the EAC MRH initiative through participation in technical working groups to develop regional documents. The government also plans to enact legislation that would establish a semi-autonomous NRA to regulate medicines, devices, diagnostics, and clinical trials[132].

The government of Kenya has created a complex policy framework for medicines regulation. The Pharmacy and Poisons Board (PPB) is Kenya's medicines regulatory authority and is responsible for the regulation of pharmaceutical products, registration of medicines, and some aspects of clinical trial approval. Medical device regulation, however, is divided between PPB, the Kenya Bureau of Standards, and the Kenya Radiation Board. The National Commission for Science, Technology, and Innovation (NACOSTI)—in its mandate to regulate and assure quality in the science, technology, and innovation sector—provides regulatory oversight[133].

The study observed that the number of government entities involved in regulation contributes to a long and complex regulatory pathway that research institutions, the private sector, and other innovators must navigate in order to register a health product or receive clinical trial clearance. Preclinical trials, for example, require research permits from six different regulatory agencies. A draft piece of legislation, however, aims to harmonize national policies related to food and drug regulation and create an independent national authority, known as the Kenya Food and Drugs Authority (KFDA), with a broader mandate than the PPB. A task force composed of government bodies and technical experts are currently developing the KFDA bill[134].

In addition to efforts to streamline the medicines regulatory framework, the PPB leads the EAC MRH initiative's technical working group on QMS, which developed a compendium to enable

[132] USAID. *EAC Common Market Implementation Impact of Technical Regulations on Intra-Regional Trade: The Experience of Ugandan Pharmaceutical Firms.* 2019. Retrieved from https://d3n8a8pro7vhmx.cloudfront.net/

[133] Mwangi, John M. Towards African Medicines Regulatory Harmonization: The Case of the East African Community. *Pharmaceuticals Policy & Law* 18, no. 1–4 (January 2016): 91–98.

[134] USAID. *EAC Common Market Implementation Impact of Technical Regulations on Intra-Regional Trade: The Experience of Ugandan Pharmaceutical Firms.* 2019. Retrieved from https://d3n8a8pro7vhmx.cloudfront.net/

partner states to adopt standard quality systems requirements. Despite this progress, there are concerns about varying regulatory capacity and resources across countries—and the potential for these disparities to delay harmonization. The need for regional legislation to be domesticated and adopted by each country is also likely to lead to delays. Other stakeholders were wary of harmonization because of potential revenue loss for member states in the form of application and registration fees. Finally, knowledge of the EAC MRH initiative varies widely—many stakeholders in the pharmaceutical industry, for example, have not been involved in regulatory harmonization discussions.

The study also found that the Pharmaceutical Service Directorate (PSD), a division of Rwanda's Ministry of Health, is responsible for medicine registration, oversight of medicines procurement and production, policy development, and pharmacovigilance. Diagnostics, vaccines, and medical devices, however, are not currently regulated. Though the PSD is also mandated to align the country's regulatory system with the EAC MRH initiative, Rwanda's relatively weak regulatory policy environment has resulted in slow progress in developing policies to facilitate regional harmonization. In 2013, the government of Rwanda passed a law that establishes the Rwanda Food and Medicines Authority and outlines its function—to regulate pharmaceutical products, medical devices, and other health commodities. It is unclear, however, to what extent this law has been implemented.

In Rwanda, the study revealed that the EAC MRH initiative is generally viewed as a positive step toward increasing access to high-quality, affordable medicines. The PSD has actively engaged in harmonization through its leadership of the IMS technical working group. Despite the initiative's capacity strengthening efforts, however, Rwanda continues to have significant gaps in human resources—both in numbers and technical skills. Additionally, there has been little technical or financial support from the Rwandan government toward the EAC MRH initiative, and outside of the MOH, many stakeholders had little knowledge about the harmonization process.

3.6 Strengthened Reproductive Maternal New-born Child and Adolescent Health

The 9th Sectoral Council on Health held in April 2014 directed the EAC Secretariat to expand the scope of the SRHR Strategic Plan (2008-2013) to include Reproductive

Maternal, Newborn, Child and Adolescent Health (RMNCAH) - (EAC/SCM-9/Health/Decision 067). The EAC RMNCAH Strategic Plan 2016-2021 derives its mandate from article 118 of the treaty for the establishment of the EAC, which calls for regional cooperation in Health among the Partner States[135]. It's also grounded on the 4th EAC Development Strategy (2011/12 – 2015/16), which recognizes health as a key pillar for deepening and accelerating integration and the EAC Health Sector Strategic Plan 2015-20208. The EAC Development Strategy identifies strengthening and integration of sexual and reproductive health, adolescent health, child health and maternal health and rights policies and programmes as one of the key areas of intervention.

The study found that the EAC Integrated Reproductive Maternal Newborn Child and Adolescent Health and HIV/AIDS Scorecard 2018 indicates that as a result of the implementation of the Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan 2016-2021 among other strategies and policies, reproduction maternal and productive health has increased considerably. In Burundi, maternal mortality ratio decreased to 334.0, under-five mortality decreased to 78.0, new-born mortality rate reduced to 56.0. However, contraceptive prevalence rate decreased to 29.0 while antenatal care (4 visits) decreased to 87.7. In addition facility delivery rate increased to 84.0, adolescence pregnancy rate decreased to 5.9, post natal care visits increased to 51.0. Further, the percentage of people with HIV/AIDs currently receiving ARV therapy increased to 86 percent[136].

In Kenya, the study established that the maternal mortality rate was at 362.0, under-five mortality rate was at 52.0, new-born mortality rate was at 26.0 while contraceptive prevalence rate remained at 58.0. In addition, antenatal care (4 visits) increased to 58.0, facility delivery ate increased to 62.0 adolescence pregnancy rate decreased to 9.6 and post natal care visits remained constant at 52.9. Also, the percentage of people with HIV/AIDS receiving ARV therapy increased to 83.0.

[135] East African Community. *EAC RMNCAH Strategic Plan 2016-2021*. 2018. Retrieved on 19th July 2019 from https://health.eac.int/publications/eac-rmncah-strategic-plan-2016-2021

[136] East Africa Community. *EAC Integrated Reproductive Maternal Newborn Child and Adolescent Health and HIV/AIDS Scorecard 2018.* 2018. Retrieved from https://health.eac.int/index.php/file-download/download/public/275

In the East Africa Community, Rwanda is considered to perform the best in terms of health indicators. In the EAC Integrated Reproductive Maternal Newborn Child and Adolescent Health and HIV/AIDS Scorecard 2018, maternal mortality rate in Rwanda was 210.0 (target achieved), under-five mortality was 50.0, new-born mortality was 20.0, under-five stunting was 38.0. In addition, contraceptive prevalence rate 53.2, antenatal care (4 visits) was 44.0, facility delivery rate increased to 91.0, adolescence pregnancy rate was at 7.3, post natal care rate was at 43.0 and the percentage of people with HIV/AIDS receiving ARV therapy increased to 91.0.

3.7 Strengthened Health Systems

The strengthening of health systems involves developing policies and regulations to address the health needs of mobile and other vulnerable cross-border populations. Strengthening health systems encompasses improving, human resource, adopting information technology, and ensuring adequate health financing. However, the general situation of human resources for health within the Community is characterized by: a severe shortage of health workers; inability to attract and retain health workers, especially in the public health sector; performance management issues; and unequal distribution of staff and diminishing productivity among the health workforce. However, the EAC Health Systems Unit has managed to co-ordinate the efforts of the EAC Partner States and to lobby them to invest in human resources in the provision of safe, quality, affordable and efficient health care services[137].

The study found that the East African Community heads resolved to expand access to specialized health care and cross border health services in the region to preserve the region's human capital base. The member states also agreed to strengthen the network of medical reference laboratories and the regional rapid response mechanism to protect the region from health security threats including pandemics, bio-terrorism and common agents. Also, in a joint communication, presented by the Secretary General of the East African Community (EAC), the leaders stressed the importance of strengthening health systems and preparedness to address both current and emerging challenges such as non-communicable disease like cancer and communicable diseases like HIV/ AIDS, malaria which pose significant challenges

[137] Ssali Godfrey. *East African countries to improve cross border health care.* 2018. Retrieved on 20th Septembe r 2019 from https://www.independent.co.ug/eac-improve-regional-health-care/

to regional development[138]. On infrastructure, the members states agreed to enhance capacity in health infrastructure projects coordination, preparation and development at the national and regional levels to accelerate the realization of prioritized health projects[139].

3.8 Strengthened knowledge management

Knowledge management is generally defined as the process of capturing, developing, sharing, and effectively using knowledge. Healthcare is a knowledge driven process and thus knowledge management and the tools to manage knowledge in healthcare sector are gaining attention. The aim of this systematic review is to investigate knowledge management implementation and knowledge management tools used in healthcare for informed decision making.

The dynamic nature of EAC regional health sector and the multifaceted challenges it comes with, poses hectic decision making demands. Further, these interventions present a major challenge for collection, synthesis and sharing of knowledge among Partner States and stakeholders. This not only creates a situation where Partner States and stakeholders face challenges in accessing necessary strategic information and knowledge for decision making but also the challenges of sharing tools and strategies, especially as it relates to providing access to services. Partner States Health Departments have realized the need to harness the opportunity provide by knowledge management (KM). Effective KM benefits the health sector by aiding good governance at the regional and national level and requires knowledge to infuse the practices and processes used to reach the decisions that impact the daily lives of citizens as well as the development direction of the region[140].

However, the absence of a harmonized approach to using health information systems and research findings within the region has been acting to weaken regional and individual Partner State programming, their advocacy agendas and requests for increased budgetary allocations for

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[138] Yamin, A. E., Maleche, A. Realizing Universal Health Coverage in East Africa: the relevance of human right s. *BMC Int Health Hum Rights*. 2017, 17(1):21.

[139] Kibiki Gibson. *East African Health Research Commission (EAHRC) - an Institution of the East African Community (Kenya, Tanzania, Burundi, Rwanda, Uganda).* 2018. Retrieved on 19th July 2019 from https://www.eahealth.org/sites/www.eahealth.org/files/content/attachments/2019-02-

[140] Ssali Godfrey. *East African countries to improve cross border health care.* 2018. Retrieved on 20th September 2019 from https://www.independent.co.ug/eac-improve-regional-health-care/

program implementation and service delivery. Furthermore, while various EAC Partner States have in place a number of health information and knowledge management systems at national and sub-national levels, these systems are largely fragmented, lacking in interconnectivity with the regional systems and are donor dependent. In response, the EAC establish the East African Health Research Commission to harmonize knowledge management in the region. The mission of East African Health Research Commission is to conduct, promote and coordinate health research in the EAC region and gather, source, and disseminate results from research studies for policy development and practice[141]. As part of knowledge management, the EAHRC led to the development of the EAC regional health research journal, the East African Health Research Journal (EAHRJ) and The East African Science Journal (EASci). In addition, the respondents indicated that through harmonization of policies in the EAC, a wealth web portal was created to share Knowledge from different regional Health Programmes of the Community.

At practice level, with advances in technology, many health professionals and decision- makers readily access the crucial information they need to make decisions. When health workers have easy access to and use the latest and most appropriate information, they provide the highest quality care, resulting in poor health outcomes. Knowledge is a resource - an input necessary to the success of any organization's activities. It is also a product—an outcome of experience that has value to others. In the field of health, knowledge is an asset most valuable when shared and used to guide decisions. To reach health goals, The EAC needs to continually identify knowledge needs, capture, synthesize and share knowledge among the various stakeholders, help them to use it, and help to collect and share the new knowledge generated by that experience.

3.9 Enabled Collaboration on Regional Responses to Emerging Pandemic Threats

The frequent population movement across the borders of the six countries poses a greater risk of spreading diseases from one country to another. The recent growth in regional trade and travel in East Africa has increased the likelihood that disease epidemics will involve more than one country. The response to such a regional epidemiological emergency is complex and involves national, regional and international agencies. An efficient and quick flow of information across the borders is therefore, crucial for averting such incidents of cross

[141] East African Community. *EAC Health Systems, Research and Policy Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/hiv-aids

border spread. The re-establishment of the East African Community (EAC) provides room for increased collaboration in the area of disease surveillance and epidemic control and prevention of spread[142].

Collaboration in health care is defined as health care professionals assuming complementary roles and cooperatively working together, sharing responsibility for problem-solving and making decisions to regarding emerging pandemic diseases. The study found that all partner states have put in place strategies that encourage timely sharing of information both formally and informally by technical officers in the cross-border districts and put in place policies and strategies that support community based disease surveillance incorporating human and animal diseases (one health). They have also provided a conducive and transparent environment (political & legal) and policy framework that enables PPP arrangements in disease prevention and control and strengthen laboratory systems in the Partner States to improve disease surveillance and clinical care.

The study found that through institution such as the East African Public Health Laboratory Networking Project (EAPHLNP) and The East African Integrated Disease Surveillance Network (EAIDSNet) the EAC members' states have enhanced disease surveillance, prevention and control[143]. The East African Integrated Disease Surveillance Network (EAIDSNet) is a regional collaborative initiative of the national ministries of the EAC Partner States responsible for human and animal health in collaboration with the national health research and academic institutions. In addition, the EAPHLNP is a project implemented by the EAC Partner States in collaboration with the East African Community Secretariat, the East Central and Southern Africa Health Community, the US Centres for Disease Prevention and Control and the World Health Organization. Using this project, the EAC has managed to establish and support 25 satellite laboratories in East Africa Community Member States for managing and responding to emerging pandemic threats.

[142] Muko Ochanda, Richard, Paul Kisolo Wakinya, and William Omondi Odipo. "Human Rights in the Context o f Deepening Integration of East African Community (EAC)." *Postmodern Openings* 4, no. 2 (June 2013): 1–27.
[143] East African Community. *Disease Prevention and Control Unit*. 2018. Retrieved on 19th July 2019 from https ://www.eac.int/health/disease-prevention

The study found that East Africa Community members states have in the past suffered from disease outbreaks like Ebola and cholera and both the EAPHLNP and EAIDSNet, played a major role in the prevention of the spread. The study also revealed that the EAC has developed regional communication strategies in response to specific disease threats, notably Highly Pathogenic Avian Influenza (HPAI) and Rift Valley Fever (RVF). The EAC regional communication strategy for HPAI underscores the coordination role of the Secretariat for all communication actions in collaboration with National Task Forces (NTF)[144].

3.10 Provision of Technical Assistance for the EAC One Health Platform

The One Health approach is an innovative strategy to promote multi-sectoral and interdisciplinary application of knowledge and skills of medical, public health, veterinary and environmental experts by working together to address animal, human and environmental health challenges. The approach is recognized by the World Health Organization (WHO), Food and Agriculture Organization of the United Nations (FAO), World Organization for Animal Health (OIE) and the Global Health Security Agenda (GHSA) as a strategy for promoting the collaborative effort of multiple disciplines, working locally, nationally and globally, to attain optimal health for people, animals and the environment. Priority public health threats that can be addressed using the One Health Approach include, among others: emerging and re-emerging zoonotic and infectious diseases of epidemic and pandemic potential, antimicrobial resistance, pollutants and environmental contaminants, food safety and dietary health risks.

The harmonization of policies in the EAC strengthens collaboration across multiple sectors, including public health, livestock, wildlife, agriculture and environment. Using technical assistance from member states professionals such as medical doctors, veterinarians, environmental and agricultural experts as well as representatives from tourism and trade the EAC has been in a position to prevent and respond to outbreaks of infectious diseases in cross-sectoral, integrative epidemic management. In addition, the study found that the East African Integrated Disease Surveillance Network project offers technical expertise and capacity building with the overall aim of improving the EAC's support for the partner states in pandemic

[144] Kibiki Gibson. *East African Health Research Commission (EAHRC) - an Institution of the East African Community (Kenya, Tanzania, Burundi, Rwanda, Uganda).* 2018. Retrieved on 19th July 2019 from https://www.eahealth.org/sites/www.eahealth.org/files/content/attachments/2019-02-

preparedness. As such, this project contributes to a uniform, effective, responsible and balanced approach to pandemic preparedness at regional and national government level. Further, East African Integrated Disease Surveillance Network project facilitates collaboration between sectors relevant to the prevention of and response to outbreaks of infectious diseases of public health concern in the spirit of 'One Health'. In addition, it assists in the development of a post-graduate One Health curriculum on pandemic preparedness and its inclusion in syllabi of universities in the EAC region to ensure and improvement in technical expertise among the member states.

3.11 Summary of the Key Findings

Health integration has had some major impacts on social health protection and government expenditure on Health, HIV/AIDS programmes, information and communication technology adoption in the health sector, pharmaceutical manufacturing in member states, reproductive maternal new-born child and adolescent health as well as in disease prevention and control. However, while the EAC health policies are linked to Abuja health declaration where member states pledged to allocate 15 per cent of the total government expenditure to health, most of the EAC members have not yet met this requirement. Nonetheless, increase in social health protection was found to have a positive impact on health indicators such as under-five and maternal mortality rates, life expectancy. The study found that the EAC health integration through 2nd EAC HIV and AIDS, TB and STIs strategic plan (2015-2020) helps the member states to form a common ground in anti-Aids war. Specifically, the implementation of the EAC HIV/AIDs policies, institutions in the member states have embarked on various interventions that include creating of awareness, male circumcision, and HIV Testing among Adults and Youth. However, the implementation of the policies has not been without controversies and conflicting policies in the member states.

The EAC Health Sector Strategic Plan (2015-2020) highlights the EAC quest to improve ICT to foster efforts towards economic development. As such the member states have increasingly been adoption information and communication technology in the health sectors. The harmonization of Pharmaceutical Manufacturing policies in Member States guided by EAC-RPMPOA: 2017-2027 has different implications and impact on individual member states of the EAC. The requirements in each of the member states were different and each member state had different

number of institutions to approve the use of drugs. The maternal new-born child and adolescent health policies, which include SRHR Strategic Plan (2008-2013) and EAC RMNCAH Strategic Plan 2016-2021 have played a major role in improving sexual and reproductive health, adolescent health, child health and maternal health.

The study established that the East Africa Community health integration has strengthened health systems, policies and regulations to address the health needs of mobile and other vulnerable cross-border populations. In addition, it strengthened knowledge management, including sharing of regional research and best practices through East African Health Research Journal. Further, the study found that EAC health integration enabled collaboration on regional responses to emerging pandemic threats; and provided technical assistance for the EAC One Health Platform, which strengthens collaboration across multiple sectors, including public health, livestock, wildlife, agriculture and environment.

CHAPTER FOUR
CHALLENGES AFFECTING THE HARMONIZATION OF HEALTH POLICY IN THE EAC INTEGRATION PROCESSES

4.1 Introduction

Harmonization of health policy as a strategy for regional integration has encountered challenges in the formulation and implementation process at the global level, continental level and regional level. The EAC Secretariat and partner states have limited infrastructure and human resources to regulate all types of health technologies, and regulatory capacity varies widely from country to country. The implementation of harmonization efforts has also been slow, and funding is limited and largely donor dependent. While there is support for harmonization from donors, there is limited awareness among key stakeholders within partner states about ongoing harmonization activities. These challenges among others weaken EAC harmonization efforts and must be addressed to ensure that promising health technologies are developed, tested, and scaled up to improve health impact.

4.2 Inadequacy and Conflict of Policies in Member States

Some of the policies in the EAC have been conflicting with policies in the EAC member states. For instance, the HIV law in Uganda is at odds with East African Community HIV/Aids Prevention and Management Act. In Uganda, the HIV/Aids Prevention and Control Act that was assented to law in 2014 criminalizes intentional transmission of HIV. This law requires mandatory testing for victims of sexual offences, pregnant women and their partners. It also criminalizes transmission of HIV, while medical workers are required to release results to sexual partners of HIV-positive persons. The law from EALA, on the other hand, says testing should never be mandatory, outlaws discrimination and guarantees rights to privacy[145]. It is confusing to the implementers since one requires non-discrimination of people living with HIV/Aids while the other recommends the opposite[146].

[145] East African Community. *EAC HIV/AIDS Prevention and Management Act 2012* 2018. Retrieved on 19th July 2019 from http://kelinkenya.org/wp-content/uploads/2010/10/QA_EALA_Bill_5July_Final1.pdf

[146] The East African. *Uganda's HIV law at odds with EAC Act.* 2014. Retrieved on 15th August 2019 from https: //www.theeastafrican.co.ke

In Kenya, the 2015 High Court's judgment on the constitutionality of the "Uhuru's HIV List" was a clear example of how the application of human rights principles could enhance the validity of laws and policies adopted in relation to health. In that case, a directive was issued by the President Uhuru Kenyatta to all County Commissioners to collect data on all school-going children living with HIV/AIDS. The Court found that the directive violated children's rights to privacy, which is a key part of the East African Community HIV/Aids Prevention and Management Act. The Court ruled that the directive and actions taken under its direction violated the Constitution, but refrained from mandating the government to adopt a certain policy or protocols that met specific criteria.

In addition, the study found that national medicines policies exist within each Partner State as well as a legal frame work that provides for the existence of a National Medicines Regulatory Authorities (NMRAs). Currently only three Partner States within the EAC, namely Kenya, Uganda and Tanzania, have operational NMRAs, while Burundi and Rwanda carry out national medicines regulatory functions within the National Ministries of Health[147]. However, both countries are currently in the process of establishing NMRAs. Zanzibar has a separate NMRA, which relies heavily on the decisions made in mainland Tanzania. The regulatory regime in the region is characterized by a move towards the creation of semi-autonomous government agencies to spearhead the national regulatory affairs. However, only three drug quality control laboratories exist in EAC, one of which (Kenya) is pre-qualified by the WHO, while the Uganda and Tanzania are in the process of prequalification and accreditation to meet international standards.

The study also established that while the national drug registration systems exist, there were notable deficiencies, including the drug registration guidelines being incomplete. There is need to improve, and some of the actions required include the restructuring or establishment of NMRAs to enable them to undertake their regulatory activities more effectively, developing and implementing comprehensive guidelines and procedures for drug registration and strengthening human capacity at NMRAs in Partner States.

[147] PATH. *Medicines Regulation in the East African Community*. 2018. Retrieved from https://path.azureedge.net/media/documents/APP_eac_reg_summary.pdf

The study found that the EAC members recognize the local production of pharmaceutical products as one means to promote access to medicine and the key issues for policy coherence. Industrial policy aims at developing a competitive (viable and innovative) and responsible local industry, whereas, health policy aims at promoting access to quality, safe and effective medicine by all. Industrial policy alone is insufficient to leverage the potential benefits of local pharmaceutical manufacturing for key health policy goals. Equally, health policy alone is insufficient to incentivize local industry to provide competitive and reliable health products and services. Hence, there is a need for systemic intervention – covering key policies & all factors that influence the interaction between health and industry polices. Policies in trade, investment and intellectual property rights influence the way the objective of health and industrial polices interact and support each other. Direct and indirect government support to local pharmaceutical manufacturing, such as investment incentives, could target priorities in the access to medicine needs of a country. Tariff and fiscal concessions, government procurement and trade facilitation can ensure the viability and competitiveness of local pharmaceutical production[148]. In order to generate a functioning framework for local production of pharmaceuticals and access to medicine, the respondents stated that it is essential to have a focused pharmaceutical strategic plan sponsored by both the Ministry of Industry and Ministry of Health, with input from all stakeholders, supported by institutional mechanism for coordination and consultation.

Further, the study found that the EAC Common External Tariff (CET) covers all pharmaceutical products under its Chapter 30, among the eight tariff categories. All Pharmaceuticals attract 0% CET. According to the respondents, Pharmaceutical products featured both in the intra-regional trade and imports from outside the region. Kenya's imports in 2013 from India increased mainly on account of increased importation of pharmaceutical products, among others. In the same period its exports to EAC partner states including pharmaceutical products declined. Yet, pharmaceutical products remained one of the main imports of Tanzania and Rwanda from other EAC Partner States. Partner States have various policy documents and laws including on distribution system, health and

[148] USAID. *EAC Common Market Implementation Impact of Technical Regulations on Intra-Regional Trade: The Experience of Ugandan Pharmaceutical Firms.* 2019 Retrieved from https://d3n8a8pro7vhmx.cloudfront.net/

regulations that will affect the potential benefits of the CET for local pharmaceuticals manufacturing and intra-regional trade.

Although there is substantial progress on the harmonization of medicine regulations in the EAC region, currently there is no regional coordination mechanism on anti-counterfeiting measures and procurement of pharmaceutical products in EAC region. The EAC Anti-counterfeiting Bill was dropped by the EAC Council of Ministers during the meeting held in April 2015 and is replaced by draft provisions for the amendment of the Competition Act of 2006. The amendment applies anti-counterfeiting measures to protect trademarks and copyright. The EAC Competition Authority will have the power to harmonize the national legal framework on counterfeiting and piracy in the region. Partner states will be obliged to establish or designate an institution responsible for anti-counterfeit matters, and to enact laws prohibiting the manufacture or production, the possession or control in the course of trade, the sale, hire, barter or exchange, or the distribution of counterfeit goods for trade. They should also prohibit the importation into, the transit through, trans-shipment or export from a Partner State. As a safeguard for access to medicine, the amendment provides that its provisions shall not be construed as prohibiting the manufacture, importation, sale or dealing in medicinal products generally known as generic medicine provided such medicines are not counterfeit goods[149].

Further, the respondents indicated that despite improvements in the ease of doing business in the region, challenges persist. Infrastructure such as ports, roads and rail and their interconnectedness remains a weak point in the region. The cost of and access to reliable electricity remains a further challenge in the region. What is more, persistence of non-tariff barriers denies businesses across the region the full benefits of the Customs Union and the Common Market.

There are also some policy conflicts in pharmaceutical manufacturing in EAC. For instance, Tanzania requires all foods, drugs and cosmetics traded in Tanzania to be registered with TFDA. TFDA derives its mandate from section 5(1) of the Tanzania Food, Drugs, Cosmetics Act, 2003

[149] Rugera, Simon Peter, Ruth McNerney, Albert K. Poon, Gladys Akimana, Rehema Forgen Mariki, Henry Kaju mbula, Elizabeth Kamau. Regulation of Medical Diagnostics and Medical Devices in the East African Communit y Partner States. *BMC Health Services Research* 14, no. 1 (November 2014): 588–601.

(TFDCA). The registration requirement applies to all products regardless of their origin or whether they are certified in other EAC Partner States. Tanzania also requires retesting of all pharmaceutical and herbal drugs, poisons, cosmetics and food products. This is a compulsory requirement that importers must meet in order to be granted a registration permit that allows them to import their goods into Tanzania. Tanzania also requires relabeling when the labels on imported products do not meet TFDA's labeling standards as provided under the labeling guidelines for respective products. Tanzania's registration requirement has had a long history of reports in the EAC Non-Tariff Barrier monitoring framework with the EAC Regional Forum consistently recommending that Tanzania abolish this requirement with respect to EAC products.

In Uganda, pharmaceutical products are regulated by three bodies: Uganda National Council of Science and Technology (UNCST), Uganda National Health Research Organization (UNHRO) and the National Drug Authority (NDA). Specifically, the NDA oversees manufacturing and licensing. In Burundi the Directorate of Pharmacy, Medicines, and Laboratories (DPML) functions as the country's medicines regulatory authority. In Kenya, medicines regulation may fall under five institutions: Pharmacy and Poisons Board, Kenya Bureau of Standards, Kenya Food and Drugs Authority, Kenya Radiation Board and National Commission for Science, Technology, and Innovation. In Rwanda, only one institutions in mandated to regulate medicines and drugs, Pharmaceutical Service Directorate (PSD)[150].

4.3 Limited and Varied Capacity

The EAC Secretariat and many partner states have limited infrastructure and human resources to regulate health technologies, and regulatory authority capacity varies widely from country to country[151]. These asymmetries in capacity and resources have made harmonization difficult; whereas Kenya, Uganda, and Tanzania have operational and autonomous regulatory authorities, Burundi and Rwanda carry out medicines regulatory functions through their national MOHs. Moreover, some national regulatory bodies regulate clinical trials, medical devices, and diagnostics, whereas others lack the capacity or mandate to do so.

[150] Dansie, Live Storehagen, Walter Denis Odoch, and Christine Årdal. Industrial Perceptions of Medicines Regu latory Harmonization in the East African Community. *PLoS ONE* 14, no. 6 (June 19, 2019): 1–15.
[151] AUC/UNECA/UNDP. *Annual Report 2015 - United Nations Economic Commission for Africa*. 2015. Retrieved on 25th June 2019 from https://www.uneca.org/

The East African Community (EAC) partner states have a serious shortage of qualified medical specialists. According to the report, the regional bloc currently has less than 44.5 physicians, nurses and midwives per 10,000 people required to fast-track the attainment of health-related sustainable development goals (SDGs). Variances in skill, capacity, and resources complicate mutual recognition of regulatory decisions and joint registration. Recent advances in nursing and midwifery education in the East African Community have resulted in higher levels of specialization and education for nurses at the Masters and PhD levels. However, East African community partner states still have a high percentage (about 90%) of nurses and midwives educated at the certificate and diploma levels only. This percentage is below levels of other African Regions. Equally important to note is that currently, the admission requirements, duration of training, and outcome competencies of graduates for the same academic programs vary among academic institutions in the EAC states. This causes decreased labor mobility among nurses and midwives in the EAC partner states and emphasizes the need for harmonization and mutual recognition of programs. However, the harmonization of nursing and midwifery education and practice in the East African Community (EAC) partner states is in line with the relevant provisions of the Treaty on the establishment of the East African Community (Chapter 21, Article 118) (EAC, 2007). Under this provision, the East African Community partner states are required to harmonize and strengthen regional and national policies, laws, regulations, human resources, and institutional and infrastructure capacity in order to achieve quality health within the EAC, including the development of specialized health training, health research, preventive, curative and rehabilitative health services, and the provision of high quality nursing and midwifery services[152].

The EAC member states are also characterized by lack of or shortage of health facilities. The majority of the facilities in Rwanda, Tanzania and Burundi are government owned, 88.4 percent and 61.8 percent, respectively. Conversely, in Uganda and Kenya, more than three-quarters of the facilities are privately owned. Overall, most facilities mapped are both private-for-profit (51.9%). In terms of facility type, clinics comprised the largest proportion (44.9 percent), followed by health centers (26.7 percent). Hospitals comprise only 12 per cent of the

[152] Eannaso. *Status of health financing in East Africa.* 2018. Retrieved on 15th August 2019 from https://www.eannaso.org/resources/reports/33-eannaso-2015-eac-health-financing-profile/file

facilities mapped along major transport corridors in the EAC region. These results demonstrate substantial differences by country. For instance, in Uganda, clinics represented the most common type of health facility along the transport corridors (65.6%) followed by health centers (22.6%), while in Rwanda, health centers comprised 74.4 per cent of facilities, followed by both hospitals and dispensaries (11.6% each).

Ensuring a constant supply of essential medicines is also difficult due to inadequate local production of pharmaceuticals. Although countries like Kenya and Tanzania have a stronger manufacturing sector, it is often difficult for new manufacturers to be competitive, at least initially, without incentives or preferential procurement. Moreover, existing manufacturers are concerned about GMP requirements proposed by the EAC MRH initiative and whether they will have the capital to make required improvements up-front[153]. Though the EACRPMPoA envisions harmonization as necessary in facilitating local pharmaceutical production, there is concern among stakeholders that EAC MRH requirements might slow manufacturing growth. Additionally, there is an insufficient number of quality control laboratories for medicines in the EAC—only one laboratory in Kenya is prequalified by WHO.

4.4 Delayed implementation

Most respondents stated that the implementation of harmonization efforts has progressed slowly and is exacerbated by the need to establish NRAs in some partner states and strengthen weak authorities in others. Though the EAC treaty compels partner states to implement EAC regulations, directives, and decisions, the treaty is non-self- executing. Therefore, policies created at the EAC level require a change in the domestic legislation of all partner states—national parliaments have the ultimate decision-making authority. Respondents also pointed to the absence of a clear strategy for how different NRAs will work together. EAC legislation on medicines registration is very broad, and though it states that countries will harmonize medicines regulation, there is little detail about the required changes to domestic legislation or the timeline.

[153] Dansie, Live Storehagen, Walter Denis Odoch, and Christine Årdal. Industrial Perceptions of Medicines Regul atory Harmonization in the East African Community. *PLoS ONE* 14, no. 6 (June 19, 2019): 1–15.

Implementation of the EAHRC has also been slower than anticipated. The Protocol on the Establishment of the EAHRC was passed in 2008[154], but the EAC Secretariat has allocated limited financial and human resources to the EAHRC. Its capacity and resources need to be strengthened before it can fulfill its mandate of coordinating health related research in the region.

4.5 Resources Availability and Adequacy

The study found that there lacks political will among members' states in the EAC leading to failure to provide funds. The problem of political will, however, goes beyond competing claims on politicians' time in the international arena[155]. The Kigali Ministerial Statement on Universal Health Coverage and Long-Term Harmonization of Social Health Protection in the EAC was developed and was meant to ensure equity in the provision of health services across Africa. The basis of the heath sector in any country is financial resources. This is because financial resources a key in the provision of all the other types of resources including human capital, infrastructure, medical equipment and other facilities. Even through, all EAC Partner States have tried different initiatives to promote Social health protection, some have harmonized programs at the national level, some have fragmented initiatives and others have just initiated comprehensive national programs[156]. They are at different levels of policy-making implementation, and financing. In addition, most EAC Partner States have not yet met the Abuja commitment of allocating at least 15% of total Government expenditure on health. The Ugandan and Kenyan Governments are the lowest contributors to health, while Rwanda stands as the only country that has met the Abuja target. Tanzania and Burundi are approaching the Abuja commitment. Government expenditure on health is an indicator that shows how committed any government is towards improving the health status of its population. All EAC Partner States should strive to increase their spending on health to allow for the development of SHP mechanisms and meet UHC.

[154] PATH. *Medicines Regulation in the East African Community*. 2018. Retrieved from https://path.azureedge.net/media/documents/APP_eac_reg_summary.pdf
[155] UNAIDS. *Global HIV & AIDS statistics — 2018 fact sheet.* 2016. Retrieved on 25th June 2019 from https://www.unaids.org/en/resources/fact-sheet
[156] Buigut, Steven. "Trade Effects of the East African Community Customs Union: Hype Versus Reality." *South African Journal of Economics* 84, no. 3 (September 2016): 422–39.

The study found that the East African Community could sink deeper into the financial doldrums after unveiling a $111.4 million budget for the 2019/20 financial year, amid the failure by member states to honor their financial obligations. Some activities of the EAC organs and institutions are likely to stall or slow down due to member states delays in remitting their contributions for the 2018/19 budget, which stood at $99.7 million. Despite tabling of an ambitious budget anchored in transforming lives through industrialization and job creation for shared prosperity, dismal adherence by members to budgetary obligations continues to be a bane in the region's integration journey.

This has forced the Secretariat to look to development partners to finance key programmes and projects. Although donor contributions to the EAC budget have been declining — considering that in 2012 this support stood at $124 million — they remain the key financiers of the bloc's budget, contributing $43 million in the 2018/19 fiscal year.

While tabling the 2019/20 budgetary estimates before EALA, Tanzania's Deputy Minister for Foreign Affairs and East African Co-operation said the EAC expects to streamline and consolidate operational systems to achieve the desired level of efficiency, accountability and value for money. This year's budget is to include the continued and consolidated political support of the EAC integration and the availability of adequate financial resources and remittances. According to the estimates, EAC partner states are expected to finance the budget, with ministries of EAC Affairs contributing $49.7 million. Yet again the budget demonstrates the unprecedented rate at which EAC has become dependent on foreign financing considering that development partners are expected to support the Community to the tune of $54 million. It is a good budget, save for the reservation: EAC partner states have all along been delaying remitting their contributions to the bloc and, therefore, frustrating implementation of projects. Citing South Sudan, which joined the bloc over three years ago, but had never contributed a single cent, the respondents indicated that the trend did not only call into question the commitment of the partner states, but was also discouraging development partners whose contributions have been declining over the years.

Currently, the Community is going into a new financial year with a number of unfunded priorities occasioned by budgetary constraints. By March 2019 when the East African

Legislative Assembly approved a $12 million supplementary budget, Burundi and South Sudan had not remitted their full contributions for the 2018/19 financial year. In addition, Uganda had not provided funding specifically for the EAC MRH initiative, which raised questions about harmonization's sustainability—most funding has come from external sources. Moreover, because the NDA depends on medicines registration fees, some respondents were concerned about losing this source of funding[157].

The study found that although the EAC has a strong interest in regulatory harmonization, governments have not committed significant financial resources to harmonization efforts. Instead, the EAC MRH initiative is largely funded by donors, such as WHO, World Bank, and the Gates Foundation. These donors have been instrumental in initiating harmonization efforts, but a lack of partner state investment poses long-term challenges for sustainability.

The first Regional Economic Community (REC) to secure funding from the WHO trust fund was the East African Community (EAC). WHO became a sub-grantee to support the implementation of the AMRH initiative and signed a memorandum of understanding with the EAC to support the Medicines Registration Harmonization (MRH) project. In addition, the East Africa Public Health Laboratory Networking Project (EAPHLNP) is a World Bank-funded project that is being implemented by the EAC Partner States in collaboration with the East African Community Secretariat, the East Central and Southern Africa Health Community, the US Centres for Disease Prevention and Control and the World Health Organization[158].

The study also found that the East African Integrated Disease Surveillance Network (EAIDSNet) obtains financial support from the Rockefeller Foundation to develop and strengthen the communication channels necessary for integrated cross-border disease surveillance and control efforts[159]. In addition, the EAC requested and obtained financial

[157] East Africa Community. *Gaps in Health Care Provision for Key Populations Along East African Community (EAC) Transport Corridors*. 2015. Retrieved on 15th August 2019 from https://www.afidep.org/download/03.03.2016.PB.Mapping_CBHIPP%20final.pdf

[158] East African Community. *Disease Prevention and Control Unit*. 2018. Retrieved on 19th July 2019 from https://www.eac.int/health/disease-prevention

[159] Wamala Joseph Francis & Luwaga Liliane Christine. *South Sudan, Uganda, and Kenya strengthen implement ation of cross-*

and technical support from the Swedish and Norwegian Governments through the Swedish International Development Agency (SIDA) and from the Republic of Ireland through Irish AID in November 2008 to finance HIV and AIDS policies and plans such as Multisectroal HIV and AIDS Strategic Plan (2008-2013).

4.6 Weak Health Sector Governance

It's estimated that in Africa, more than $148 billion is lost annually to corruption and other graft-related vices, with perpetrators of corruption shipping the loot off to banks in the developed world. The study found that the health sector governance remains challenged by weak transparency and accountability mechanisms as well as by inadequate engagement of stakeholders in policies, strategies and plans development. The weak regulation of the private sector and the quality of medical product stocks has resulted to widespread availability of substandard and counterfeit medications. There are also major challenges in the health information system of most countries in EAC.

In Kenya, Corruption within the Health sector has been identified as a leading impediment in the implementation of the Universal Health Coverage (UHC) in the country. The EACC report findings indicate that the level of corruption in county health services stood at 37.4 percent. In addition, systemic weaknesses and opportunities exist in the procurement and dispensing stages of pharmaceutical and non- pharmaceutical supplies in the public sector. The issues on governance includes failure to maintain a national list of registered non-pharmaceutical supplies and a national list of accredited suppliers of which, EACC recommends maintenance of a national list for registered non-pharmaceuticals supplies and accredited suppliers among others recommendations[160]. The EACC is also recommending compliance with national specifications for medical and medical suppliers, disclosure of evaluation criteria in bid documents and capacity building in market survey to address noncompliance issues with national standard specifications for medical and medical suppliers in the acquisition stage. At dispensing stage the findings indicate that prescriptions of medicine are captured in the essential list without approval and is recommending enhanced monitoring to ensure compliance to the essential list during prescription approval.

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border disease surveillance and outbreak response in East Africa. 2018. Retrieved on 15th August 2019 from htt ps://www.afro.who.int/

[160] Harman, Sophie. *Global health governance*. (New York : Routledge, 2012).

In Uganda, Almost half of all people who made contact with the health sector in Uganda in 2017 paid a bribe. The sector is fraught with bribery and absenteeism, effectively undermining the population's health and realization of Universal Health Coverage and hence EAC health integration. Uganda's bribery prevalence rate in medical services is more than three times that of Kenya and almost twice that of Tanzania. Having a high rate of bribery introduces inefficiencies, unfairness, discrimination and unlawfulness in a critical component of the state's responsibility of providing services and care for its population.

In Tanzania, according to the Warioba Report, the health sectors was ranked third in the list of sectors with the highest incidence of corruption. This is also true to most developing countries and the reasons are clear that health is a service which is in great demand and touches the lives of most people, while on the other hand resources are scarce. Levels of corruption can be distinguished into two categories. There are those who engage in petty corruption, that is those who receive bribes as a supplement to their meager income. This is referred to as petty corruption and involves individuals being forced to pay small amounts of money in order to get the service that they deserve to get free or with a little payment. Majorities of the people who are forced to pay bribe are poor, and thus, the amount of money, which is involved, is a significant porting of their income. The impact to the poor is in most cases enormous. Further, despite the establishment of anti-corruption agencies, Burundi is facing a deepening corruption crisis that threatens to jeopardize health services delivery and EAC health care integration.

To achieve a successful regional integration and sustainable development, it is imperative for EAC partner states to develop regional standards and principles that they will abide by to sustain the fight against corruption. The five EAC partner States to entrench the culture of transparency among regional citizens, saying this will be a great tool in fighting graft. In order to attain a prosperous, competitive, secure, stable and politically united East Africa, issues of ethics, transparency and accountability have to be treated with utmost seriousness.

4.7 Lack of Consultation and Limited Involvement of Stakeholders

In Africa, lack of consultation by partner state is one of the challenges facing harmonization of health policy[161]. Each of the member states has been settings its own agendas on health issues by considering domestic national areas of priorities without consulting neighbor States. The regional cooperation noted this as a challenge for the region as diseases easily spread over borders thus affecting the neighboring states and its people unnecessarily. Therefore, the community set up joint agendas where partner state can discuss common health priorities as a way to fight health problems jointly.

The study also found that while there is extensive support for harmonization from donors, there is limited awareness among key stakeholders within partner states, including civil society, the private sector, and technical experts. Many respondents viewed harmonization as a top-down initiative, driven by external parties who may not adequately understand roadblocks to implementation. There was also a desire for increased consultation of regulatory staff who will be using common technical documents created by the EAC Secretariat and technical working groups.

In pharmaceutical manufacturing harmonization, Burundi has fast-tracked the enactment of a legal framework to recognize regulatory decisions made by NRAs of other partner states—but stakeholder interviews revealed that this does not yet happen in practice. Additionally, the Ministry of Public Health has not enacted a national health research policy, and coordination between entities involved in health research is lacking. The DPML has, however, engaged in the EAC MRH initiative through participation in technical working groups to develop regional documents.

The number of government entities involved in regulation contributes to a long and complex regulatory pathway that research institutions, the private sector, and other innovators must navigate in order to register a health product or receive clinical trial clearance. Preclinical trials, for example, require research permits from six different regulatory agencies. A draft piece of legislation, however, aims to harmonize national policies related to food and drug regulation and create an independent national authority, known as the Kenya Food and

[161] Otieno Kepher. *Find common ground in anti-Aids war, EAC tells member States*. 2017. Retrieved on 15th August 2019 from https://www.standardmedia.co.ke/

Drugs Authority (KFDA), with a broader mandate than the PPB[162]. A task force composed of government bodies and technical experts are currently developing the KFDA bill. In addition to efforts to streamline the medicines regulatory framework, the PPB leads the EAC MRH initiative's technical working group on QMS, which developed a compendium to enable partner states to adopt standard quality systems requirements. Despite this progress, an interviewee pointed to concerns about varying regulatory capacity and resources across countries—and the potential for these disparities to delay harmonization. The need for regional legislation to be domesticated and adopted by each country is also likely to lead to delays. Other stakeholders were wary of harmonization because of potential revenue loss for member states in the form of application and registration fees. Finally, interviews revealed that knowledge of the EAC MRH initiative varies widely—many stakeholders in the pharmaceutical industry, for example, have not been involved in regulatory harmonization discussions.

In Rwanda, the EAC MRH initiative is generally viewed as a positive step toward increasing access to high-quality, affordable medicines. The PSD has actively engaged in harmonization through its leadership of the IMS technical working group. Despite the initiative's capacity strengthening efforts, however, Rwanda continues to have significant gaps in human resources—both in numbers and technical skills. Additionally, there has been little technical or financial support from the Rwandan government toward the EAC MRH initiative, and outside of the MOH, many interviewees had little knowledge about the harmonization process.

Stakeholder interviews revealed that local manufacturers feel they have not been adequately engaged in the EAC MRH initiative and are not included in the regional steering committee on harmonization. Manufacturers fear that they cannot meet the high standards proposed by the initiative. Though the TFDA has assessed joint dossiers for medical product registration under the EAC MRH initiative, all applications came from foreign manufacturers. To level the playing field, some stakeholders proposed a GMP Road Map for Tanzania—similar to Kenya's—to provide a phased approach for increasing manufacturing capacity. Beyond dossier assessment, the TFDA has engaged with the EAC MRH initiative in various ways. The TFDA leads the technical working group on MER, which developed a compendium

[162] East African Community. *2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027.* Retrieved from http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017–2027.pdf

that outlines harmonized medicines registration procedures. This document aids partner states' NRAs in managing applications for medicines registration and provides manufacturers with guidelines to follow when preparing a product dossier. There is no clear information, however, about what resources the TFDA invests in the EAC MRH initiative.

The NDA is responsible for implementing EAC MRH activities, in collaboration with UNCST and UNHRO. Uganda leads the technical working group on GMP, which developed a compendium of technical documents to guide NRAs in managing inspections of manufacturing facilities[163]. Apart from this work, however, respondents revealed that all harmonization activities are being coordinated at the regional level by EAC staff—there has been very little involvement of national-level technical experts, citizens, and other stakeholders. This has led to concerns about how the harmonized documents will be implemented if those who use them are not consulted in the development process. More broadly, there is no clear mechanism or plan for how harmonized documents will be implemented at the national level. Uganda has not provided funding specifically for the EAC MRH initiative, according to interviewees, which raised questions about harmonization's sustainability—most funding has come from external sources. Moreover, because the NDA depends on medicines registration fees, some respondents were concerned about losing this source of funding.

4.8 Summary of the Key Findings

The study found that the East Africa Community is facing various challenges that affect the harmonization of health policy in the East African Community integration processes. First, the EAC is facing the challenge of inadequacy of regulating policies as well as conflict of policies in member states. Some of the EAC member states have policies that contradict the EAC in relation to the prevention and management of HIV/AIDS. In addition, different countries use different institutions to register and regulate pharmaceutical products. In addition, there exist deficiencies in the drug registration guidelines which are currently incomplete. In addition, health policy alone is insufficient to incentivize local industry to provide competitive and reliable health products and services. Therefore, industrial and trade polies should be considered too. The study

[163] East African Community. *EAC RMNCAH Strategic Plan 2016-2021*. 2018. Retrieved on 19th July 2019 from https://health.eac.int/publications/eac-rmncah-strategic-plan-2016-2021

also found that there is no regional coordination mechanism on anti-counterfeiting measures and procurement of pharmaceutical products in EAC region. Other challenges facing the pharmaceutical sector include poor infrastructure (rail, road networks and ports). The EAC countries are also characterized by limited and varied capacity in terms of serious qualified medical specialists, health facilities and inadequate local production of pharmaceuticals. The community has also experienced delays in the implementation of harmonization efforts. For instance, the implementation of the EAHRC has also been slower than anticipated.

The study found that there lacks political will among members' states in the EAC leading to failure to provide funds. The members' states had delayed to provide funds forcing the Secretariat to look to development partners to finance key programmes and projects. Therefore, although the EAC has a strong interest in regulatory harmonization, governments have not committed significant financial resources to harmonization efforts. Instead, the EAC MRH initiative is largely funded by donors, such as WHO, World Bank, and the Gates Foundation. Weak Health Sector Governance was another challenge facing the EAC. This is characterized by corruption in the health sectors of almost all EAC member states and lack of accountability and transparency. The other challenge to health policy integration in EAC is lack of consultation and limited involvement of stakeholders.

CHAPTER FIVE
SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the summary of the findings, conclusions and recommendations as per the objectives of the study. The purpose of the study was to assess the harmonization as a strategy for regional integration in EAC and its impact on enhancing the EAC integration agenda. The summary of the findings, conclusions and recommendations were done as per the specific objectives, which were to examine the prospect for harmonization of health policy framework as a strategy for East African Community integration process; establish the impact of health care integration on EAC member countries; and investigate the key challenges affecting the harmonization of health policy in the East African Community Integration processes.

5.2 Summary

Based on objective one of this study was to examine the prospect for harmonization of health policy framework as a strategy for East African Community integration process. Over the years, the health sector in the EAC has sought to harmonize its policies to embark on joint action in the control and prevention of non-communicable and communicable diseases which may endanger welfare and the health of residents of the community and cooperation. The main policy is the East African Community Regional Health Sector Strategic Plan (2015-2020) which articulates the East Africa Community's (EAC's) current strategic program direction in response to health challenges facing the Region. The study also found that the EAC was harmonizing policies related to social health protection. In response to the threat posed by HIV and AIDS, the East African Community developed a Multi-sectoral HIV and AIDS Strategic Plan (2008-2013) and an implementation framework to operationalize it. To harmonize reproductive health as well as maternal and child health policies, the EAC Sexual and Reproductive Health and Rights Strategy 2008-2013 and the EAC Reproductive Maternal New-born Child and Adolescent Health (RMNCAH) Strategic Plan 2016-2021 were developed.

The EAC Partner States aspire to develop their pharmaceutical industry as part of the regions', social and political integration agenda and hence an EAC Regional Pharmaceutical

Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016) was developed to serve as a road map to guide the community towards evolving in to an efficient and effective regional pharmaceutical manufacturing industry. To further improve the industry, the new plan (EAC-RPMPOA: 2017- 2027) was developed. To improve research in health, the East African Health Research Commission (EAHRC) 2016-2021 Strategic Plan was developed. Further, the EAC secretariat has various units that play a major role in the harmonization of policies. These units include: the EAC Reproductive, Child, Adolescents Health and Nutrition Unit; the EAC Medicines and Food Safety Unit; the EAC Disease Prevention and Control Unit; and the HIV and AIDS Unit (HAU).

The second objective of the study was to establish the impact of health care integration on EAC member countries. Health integration has had some major impacts on social health protection and government expenditure on Health, HIV/AIDS programmes, information and communication technology adoption in the health sector, pharmaceutical manufacturing in member states, reproductive maternal new-born child and adolescent health as well as in disease prevention and control. However, while the EAC health policies are linked to Abuja health declaration where member states pledged to allocate 15 per cent of the total government expenditure to health, most of the EAC members have not yet met this requirement. Nonetheless, increase in social health protection was found to have a positive impact on health indicators such as under-five and maternal mortality rates, life expectancy. The study found that the EAC health integration through 2nd EAC HIV and AIDS, TB and STIs strategic plan (2015-2020) helps the member states to form a common ground in anti-Aids war. Specifically, the implementation of the EAC HIV/AIDs policies, institutions in the member states have embarked on various interventions that include creating of awareness, male circumcision, and HIV Testing among Adults and Youth. However, the implementation of the policies has not been without controversies and conflicting policies in the member states.

The EAC Health Sector Strategic Plan (2015-2020) highlights the EAC quest to improve ICT to foster efforts towards economic development. As such the member states have increasingly been adoption information and communication technology in the health sectors. The harmonization of Pharmaceutical Manufacturing policies in Member States guided by EAC-RPMPOA: 2017- 2027 has different implications and impact on individual member states of the

EAC. The requirements in each of the member states were different and each member state had different number of institutions to approve the use of drugs. The maternal new-born child and adolescent health policies, which include SRHR Strategic Plan (2008-2013) and EAC RMNCAH Strategic Plan 2016-2021 have played a major role in improving sexual and reproductive health, adolescent health, child health and maternal health.

The study established that the East Africa Community health integration has strengthened health systems, policies and regulations to address the health needs of mobile and other vulnerable cross-border populations. In addition, it strengthened knowledge management, including sharing of regional research and best practices through East African Health Research Journal. Further, the study found that EAC health integration enabled collaboration on regional responses to emerging pandemic threats; and provided technical assistance for the EAC One Health Platform, which strengthens collaboration across multiple sectors, including public health, livestock, wildlife, agriculture and environment.

The third objective of the study was to investigate the key challenges affecting the harmonization of health policy in the East African Community Integration processes. The study found that the East Africa Community is facing various challenges that affect the harmonization of health policy in the East African Community integration processes. First, the EAC is facing the challenge of inadequacy of regulating policies as well as conflict of policies in member states. Some of the EAC member states have policies that contradict the EAC in relation to the prevention and management of HIV/AIDS. In addition, different countries use different institutions to register and regulate pharmaceutical products. In addition, there exist deficiencies in the drug registration guidelines which are currently incomplete. In addition, health policy alone is insufficient to incentivize local industry to provide competitive and reliable health products and services. Therefore, industrial and trade polies should be considered too. The study also found that there is no regional coordination mechanism on anti-counterfeiting measures and procurement of pharmaceutical products in EAC region. Other challenges facing the pharmaceutical sector include poor infrastructure (rail, road networks and ports). The EAC countries are also characterized by limited and varied capacity in terms of serious qualified medical specialists, health facilities and inadequate local production of pharmaceuticals. The

community has also experienced delays in the implementation of harmonization efforts. For instance, the implementation of the EAHRC has also been slower than anticipated.

The study found that there lacks political will among members' states in the EAC leading to failure to provide funds. The members' states had delayed to provide funds forcing the Secretariat to look to development partners to finance key programmes and projects. Therefore, although the EAC has a strong interest in regulatory harmonization, governments have not committed significant financial resources to harmonization efforts. Instead, the EAC MRH initiative is largely funded by donors, such as WHO, World Bank, and the Gates Foundation. Weak Health Sector Governance was another challenge facing the EAC. This is characterized by corruption in the health sectors of almost all EAC member states and lack of accountability and transparency. The other challenge to health policy integration in EAC is lack of consultation and limited involvement of stakeholders.

5.3 Conclusions

Based on objective one of this study was to examine the prospect for harmonization of health policy framework as a strategy for East African Community integration process. The study concludes that there has been harmonization of health policy framework in the East African Community as shown by development of common EAC health policies and strategic plans. The policies guiding health integration in the EAC include East African Community Regional Health Sector Strategic Plan (2015-2020), EAC HIV AIDS Strategic Plan (2015 – 2020), Reproductive Maternal New- born Child and Adolescent Health (RMNCAH) Strategic Plan (2016-2021), EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA) (2012-2016), EAC-RPMPOA (2017- 2027), East African Health Research Commission (EAHRC) 2016-2021 Strategic Plan.

The second objective of the study was to establish the impact of health care integration on EAC member countries. The study found that health care integration in the EAC has had negative and positive impacts on the EAC members' states. For instance, the EAC health integration has led to an improvement of social health protection and an increase in government expenditure on Health. In addition, it led to the implementation of HIV/AIDS programmes and adoption of information and communication technology in the health sector of the member states leading to

an improvement in healthcare service delivery. In addition, EAC health integration led to strengthened health systems, strengthened knowledge management and collaboration on regional responses to emerging pandemic threats. Also, the study found that EAC health integration led to the provision of technical assistance for the EAC One Health Platform. However, the integration of the healthcare in EACH has led to ineffectiveness and inefficiency in pharmaceutical manufacturing and importation in the member states or among the members states.

The third objective of the study was to investigate the key challenges affecting the harmonization of health policy in the East African Community Integration processes. The study found that the EAC was characterized by inadequacies of regulating policies as well as conflict of policies in member states, deficiencies in the drug registration guidelines, poor infrastructure (rail, road networks and ports). There were also limited and varied capacities in terms of human resource and facilities and slow implementation of common EAC health policies. Other challenges included lacks political will among members' states, inadequate and untimely release of funds (financial resources), weak health sector governance, lack of accountability and transparency as well as lack of consultation and limited involvement of stakeholders.

5.4 Recommendations

The pharmaceutical industry has been facing considerable challenges related to register and regulate pharmaceutical products. The study recommends that the East Africa Community should enhance the harmonization of policies related to medicines and drugs manufacturing and importation from member states. As such, each country should have one institution regulating the registration, manufacturing and importation of medicines and drugs. Many institutions regulating medicines and drugs in one country increase cost of production and bureaucracies leading to low production and ineffectiveness. Further, the EAC health polices on medicines and drugs should be integrated with trade and industrial polices to reduce bureaucracies.

The study found that the EAC is characterized by inadequate qualified medical specialists and inadequate health facilities. Therefore, EAC member states should invest more in the health sector by recruiting more health personnel to achieve the WHO recommended 250 health care workers (doctors, nurses and midwives) for a 100,000 population. The study also recommends an

increasing health facilities and adequate provision of medical supplies and equipment in the facilities.

The EAC member states have been showing lack of commitment and political will due to failure to provide funds on time. This study recommends that the EAC members' states should show their political will to the harmonization of health care policies by providing their obligation (funds) on time. In addition, there should be policies guiding the provision of policies as well as recommendations for late provision or failure to provide financial resources.

The study found that corruption was one of the main factors leading to weak health sector governance in the EAC. It is therefore recommended that EAC members' states should improve their policies on the accountability and transparency so as to reduce corruption. In addition, EAC should focus on developing and implementing a common Ethics and Anticorruption policy so as to prevent corruption cases in the EAC health sector.

The implementation of the harmonization of health policies as well as health policy integration in EAC has been without consultation and with limited involvement of stakeholders. The study recommends the involvement of all relevant stakeholders in the development and implementation of health policies in the EAC. For instance, the Medicines and Food Safety should involve importers, manufacturers and distributors of medicines and drugs in the development and implementation of health policies in the EAC.

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Appendix I: Questionnaire

HARMONIZATION OF HEALTH POLICY AS A STRATEGY OF REGIONAL INTEGRATION: A CASE STUDY OF THE EAST AFRICAN COMMUNITY

Section A: General Information

1. How important is regional integration of strategies in East Africa Community?

   ……..

   ……..

2. Are health policies harmonized in the EAC?

   ……..

   ……..

3. Which health policies have been harmonized in East Africa Community?

   ……..

   ……..

4. What is the implementation status of regional integration of strategies in East Africa Community?

   ……..

   ……..

Section B: The prospects for harmonization of the health policy Framework

1. What is the role of EAC in the harmonization of health policy?

   ……..

   ……..

2. What are the strategies for harmonization of health policy framework in the EAC integration process?

   ……..

   ……..

3. How have the following factors contribute to harmonization of health policy framework in the EAC integration process?

Factors	**Very strongly**	**Strongly**	**Moderate**	**Fair**
Support from international finance institutions (world bank and IMF)				
Support from health organizations (WHO)				
Effective communication				
Communication technology				
Advocacy by activists and civil society groups				
Support from international and national policy actors				

1. Which of the following joint health policies in EAC that have been implemented successfully

Joint health policies	
The EAC HIV and AIDS Multi-Sectoral Strategic Plan (2008-2013)	
Regional Reproductive Health Strategic Plan, EAC Regional Pharmaceutical Manufacturing Plan of Action (2012-2016)	
Draft EAC Regional Pharmaceutical Policy	
Draft EAC Regional Food Safety and Quality Policy	
The Regional Strategic Plan on Sexual and Reproductive Health And	

Rights in East Africa (2008-2013)	
The EAC Biennial Work Plan on Disease Prevention and Control	
The EAC HIV and AIDS Multi-Sectoral Strategic Plan (2008-2013)	

Section C: Impact of Healthcare integration on EAC member countries

2. Is the implementation of the harmonized health policy beneficial to the integration of member states of the EAC states?

3. ☐ Yes ☐ No Please explain

4. Do you believe harmonization of health policy will yield mutual benefits?

☐ Yes ☐ No Please explain

5. Which other joint health policies in EAC that have been implemented successfully?

……..

……..

6. What has been the impact of the above mentioned policies?

……..

……..

7. To what extent has the harmonization of healthy policy impacted on the following health sector measures in the EAC member states?

Health Outcomes	
Maternal mortality	
Infant mortality	
Communicable disease morbidity	
Communicable disease mortality	
Provision of quality services	
Accessibility to healthcare services	

Prevention of epidemics	
Reduction of counterfeit drugs	
Enhance East Africa Disease Surveillance	
Improvement of health communication	

8. What are the key impacts of the harmonization of healthy policy as a strategy of regional integration for EAC members?

   ……..

   ……..

Section D: Challenges towards harmonization of health policy

9. Which of the following challenges are experienced in the health harmonization of regional integration as an integration strategy?

Challenges	
Different countries prioritize their health policies	
Inadequate finances	
Lack of political will	
Lack of public support	
Weak transparency and accountability mechanisms	
Influence from other actors such as Bill and Melinda Gates and WHO	
Lack of public participation	
Lack of consultation by partner state	
Poor distribution of health facilities among member states	
Medical commodity shortages among member states	
Low quality of medical product stocks	
Widespread availability of substandard and counterfeit medications	
Climate change and other environmental challenges	

10. What other challenges are experienced in the health harmonization of regional integration as an integration strategy?

    ……..

    ……..

HARMONIZATION OF HEALTH POLICY AS A STRATEGY OF REGIONAL INTEGRATION: A CASE STUDY OF THE EAST AFRICAN COMMUNITY

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