Kingdom of Swaziland

NATIONAL HEALTH RESEARCH POLICY (2014 - 2023)

Ministry of Health

23 August 2013

World Health Organization

FOREWORD

The Ministry of Health takes pride in presenting the 2014-2023 National Health Research Policy. This achievement is viewed to be a milestone particularly considering that health research in the country has been functioning without national guiding instruments for many years. By issuing this policy, the ministry hopes to improve availability and accessibility of data, health research practice as well as related products.

The policy was developed through a consultative process which included Ministry of Health officials, development partners, Non-Governmental organizations (NGO) and stakeholders. The ministry believes that such a process has motivated all partners to own the policy and to commit to its full implementation. Over and above enhancement of capacity to generate quality health research products, the ministry also hopes that implementation of the policy will improve financing and coordination of research in the country as well as partnership among research stakeholders.

Research has always been an essential element of the Swaziland health service. It provides critical information and guidance to policy formulation, planning, resource allocation and intervention development. This it does by providing empirical evidence in response to questions that challenge program managers and policy makers in their quest to improve service delivery and by extension health outcomes.

It is against this background that I present this National Health Research Policy whose aim is to create an opportunity for bridging a gap between researchers, program managers, policy makers and consumers of health services. On behalf of His Majesty's Government, I therefore call upon all health service providers, policy makers, development partners and relevant stakeholders to support the health sector in the implementation of this policy with the intention to ensure ethical and scientific conduct of research in the country.

The Honorable Minister of Health
Mrs Sibongile-Ndlela Simelane
Senator

ACKNOWLEGDEMENTS

Development of the National Health Research Policy could not have been possible without the generous contribution of many individuals and organizations. The Ministry is indebted to WHO Country Representative Dr. Owen. Kaluwa and the WHO Regional Office for the financial and technical support as well as for advice provided by Dr. M. Ota the regional advisor on health research.

The ministry is also grateful for the commitment and dedication of a WHO supported independent consultant, health research stakeholders, Technical Working Group and writing team members namely: Ms. Zelda Nhlabatsi; Mr. Masitsela Mhlanga; Mr. Sonic Dlamini; Ms. Victoria Masuku; Ms. Harriet Nuwagaba-Biribonwoha; Dr. Samson Haumba; Mr. Rudolph Maziya; Ms. Khosi Mthethwa; Ms. Sibongile Mndzebele and Ms. Babazile Shongwe; who invested time and efforts in the finalization of the policy document.

Dr Simon Zwane
Principal Secretary

ABBREVIATION AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
CDR	Crude Death Rate
CSO	Central Statistic Office
IMR	Infant Mortality Rate
MICS	Mixed Indicator Cluster survey
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
MMR	Maternal Mortality Rate
MOH	Ministry of Health
MOHSW	Ministry of Health and Social Welfare
MOU	Memorandum of Understanding
NHRD	National Health Research Department
NGO	Nongovernmental Organization
NHRA	National Health Research Agenda
NHSSP	National Health Sector Strategic Plan
PPCU	Public Policy Coordination Unit
SDHS	Swaziland Demographic and Health Survey
SEC	Scientific and Ethics Committee
SID	Strategic Information Department
TB	Tuberculosis
TWG	Technical Working Group
WHO	World Health Organization

TABLE OF CONTENTS

Foreword i
Acknowledgment ii
Abbreviations and Acronyms iii
Summary vi
Policy History vi
Applies to vi
Version vi
Policy Statement vi

Chapter 1 1
1.1 Introduction 1
1.2 Context 1
1.3 Profile of Health Research in the country 3
1.4 Process for Developing the Policy 3
1.5 Policy Rationale 4
1.6 Key Policy Issues 4

Chapter 2 6
2.1 Vision 6
2.2 Mission 6
2.3 Objectives 6
2.4 Scope 6
2.5 Guiding principles 6

Chapter 3 7
3.1 Policy Directions 7
3.1.1 Policy and Legal Environment 7
3.1.2 Governance and Leadership 7
3.1.3 Capacity Development 7
3.1.4 National Health research Agenda 7
3.1.5 Conduct of Health Research 8
3.1.6 Health Research Financing 8
3.1.7 Information and Knowledge Management 8
3.1.8 Clinical Trials 8

Chapter 4 10
4.1 Policy Implementation 10
4.1.1 Institutional Arrangements 10
4.1.2 Implementation 10
4.1.3 Monitoring and Evaluation 10
4.14 Funding 10
4.1.5 Revision of Policy 10
4.2 Conclusion 11

References 12

Summary: The purpose of this policy is to provide guidance to Health Research in Swaziland; it outlines the responsibilities of health sector, and other stakeholders in relation to Health research. It also establishes health research standards as well as policy principles and directions.

Policy History: While the Health Research Unit was established in late 1990s, it operated without a policy framework. This is therefore the first written and dedicated health research policy for the country.

Applies to: This policy shall apply to all national and international agencies and researchers who will engage in research on human subjects in the country: More specifically, it will apply to funders, researchers, regulators and consumers of health research products

Policy Statement: The Ministry of Health Swaziland acknowledges that absence of an enabling policy and legal environment in support of health research has the potential of compromising funding as well as the quantity, quality, relevance, accessibility and utilization of health research in the country. The ministry also notes that health research is critical for evidence based decision making, practice and achievement of health outcomes. Consequently, the ministry undertakes to provide necessary support in order to ensure effective implementation of this policy.

CHAPTER 1

1.1 Introduction

Swaziland is a landlocked country with an estimated surface area of 17, 364 square kilometers and a population of 1, 018,449 which translates to a population density of 58.6 people per square kilometer. Population growth has decreased from 3.2% in 1986 to 0.9% in 2007. A majority (78.9%) of the population resides in rural area and children under the age of 15 years make up 39% of the total population (CSO, 2007). Life Expectancy at birth declined from 63 to 43 years among females and from 58 to 42 years among males in the period 1997 -2007 due to enhanced HIV related mortality. HIV prevalence among adults 15-49 years is high at 26% (SDHS, 2007).

Swaziland is a lower middle income country with 69% of the population reported to be living below the poverty line. Economic growth is relatively low at 0.2%. Unemployment is reported to be 27% and is more wide spread among young people and women. Literacy is relatively high in the country. It is however slightly higher among males (90.2%) than among females (88%). The health system is modest and benefits from a government investment of US$120 per capita per year and additional donor support to the tune of US$60 per capita on health per year. The Human Development Index was estimated to be 0.522 in 2012 placing the country at position 140 out of 180 countries.

1.2 Context

The current policy environment of Swaziland provides a framework for research. The National Health Policy promotes health research and its effective coordination in the country.

The Kingdom of Swaziland through the Ministry of Health has set up structures to promote and manage research in the country. The NHSSP (2009) identifies health research as a priority and has established a Research Unit under Strategic Information Department (SID) in the ministry to coordinate all research activities in the health sector. The unit is also responsible for the National Health Research Review Board (SEC) that is supported by a Technical Working Group

(TWG) to ensure that research conducted in the Kingdom is scientifically and ethically sound.

The country is experiencing an epidemiological transition in which both communicable and non-communicable diseases pose a major challenge for the country. According to Health Statistics Reports, upper respiratory conditions are by far the leading outpatient conditions. The burden of communicable diseases is similarly reflected in the leading causes of inpatient morbidity and mortality, with AIDS and TB together accounting for admissions and a third of deaths. Others are gastro-enteritis, colitis and pneumonia.

The most cited reasons for admission include pulmonary tuberculosis, malaria, gastro-enteritis, colitis and pneumonia. On the other hand diabetes mellitus, a non-communicable disease was reportedly among the top ten (10) leading cause of inpatient admission in 2009 (HMIS Report, 2009). Others that have added in the burden include cancers, cardio-vascular diseases, nutritional conditions and injuries or trauma (Essential Health Care Package, 2010).

Increasing trends have been observed in the country's Crude Death Rate (CDR), Infant Mortality Rate (IMR), Under-Five Mortality Rate (U5MR) and Maternal Mortality Rate (MMR). In fact, Crude death rate per 1 000 population increased from 13 in 1990 to 26.2 in 2005 (World Bank, 2006). According to the SDHS (2008) Infant Mortality (IMR) was 85/1000 live births while the under-five mortality was 120/1000 live births.

Maternal Mortality Rate is at 320/100,000 according to UN estimates despite high ANC attendance (97%) and skilled professional delivery (74%). The Maternal Death Review Audit Report 2008 - 2010 indicated that out of 16,898 live births that occurred between the three (3) years, there were 103 maternal deaths in four (4) regional hospitals. Less than 60% of these deaths were caused by indirect causes of maternal deaths.

Malnutrition is associated with high morbidity and mortality among children under five, with almost 31% of children in the country found to be stunted (Swaziland MICS 2010) and 5.1% severely underweight in 2004 (MOHSW & WHO, 2004).

TB and HIV and AIDS continue to be a challenge in Swaziland. In 2010, 11057 new confirmed TB cases were reported and the incidence has increased from 300 per 100,000 people in 1990 to 1,257 per 100,000 people in 2010. According to the National TB Program annual report (2010), 88% of TB patients have been tested for HIV and of these, 82% tested positive to HIV.

1.3 Profile of Health Research in Swaziland

In a quest to promote quality research in the country, the ministry of health established a health research unit in 1998 and charged it with a responsibility to coordinate health research in the sector: for some time due challenges with human resource availability, its activities were facilitated by the health statistics unit of the ministry. To-date, the ministry has a fully functional research unit and a Scientific and Ethics Committee whose responsibility is to review all research to be carried out in the country. Despite progress made so far, research still faces issues of inadequate coordination; underdeveloped institutional structures; limited technical capacity and resources. . In spite of the existence of the SEC some studies continue to be conducted without its approval. .

1.4 Process of developing the policy

The Ministry of Health initiated development of the policy in consultation with stakeholders through a request to the WHO. The development of the policy took a participatory process with respect to stakeholders' consultations on their expectations to implementation, current experience with health research in relation to improving policy and practice in the country.

Stakeholders were engaged at the various stages in the development of the policy to gain insight of the priorities and align the policy to on-going developments in health research in the country. The individual consultations were held with selected stakeholders to assess the current situation on the kind of research undertaken, priority areas, research products, management and dissemination of

results. In addition challenges pertaining to conduct, processing, dissemination and use of health research products were also assessed.

In order to enhance stakeholders' involvement and ownership of the policy, a two day retreat of public sectors, Non-Governmental Organizations (NGOs), Civil Society Organizations, development partners, was held to develop the preliminary draft of health research policy. Stakeholder consultations were preceded by review of official government documents, survey reports, local government plans, study reports and relevant publications to assess available evidence and best practices in health research. The development process was facilitated by a consultant.

1.5 Policy Rationale

Research is central to the overall human development because it generates critical evidence which provides a basis for policy and strategy development as well as decision making. Existence of this policy will provide an enabling environment for the development and regulation of health research practice in the country. It will consequently help address areas of weakness within research.

1.6 Key Policy Issues

This policy addresses several key issues including the policy and legal environment; governance and leadership; capacity development; national health research agenda; conduct of health research; health research financing; information and knowledge management; institutional arrangement; policy implementation; policy monitoring and evaluation. These issues were generated through a SWOT analysis whose details are presented in the table below;

Strength	Weaknesses
• Existence of a functional health research management structure • Existence of a functional Scientific and Ethics Committee (SEC) • Recognition of SEC by stakeholders and subjection of proposals for review by SEC • Existence of a functional Technical Working Group • Convening and hosting of a National Health Research Conference for dissemination of research products • Investments in Health Research Capacity building for human resource, financing and skills development • Existence of partnerships and collaboration with development partners	• Absence of a legal framework for research • Absence of a national health research policy and strategic plan • Inability of SEC to monitor the conduct, management and results or products of research projects • Absence of research agenda both at national level and within respective institutions • Inadequate resources • Limited research skills capacity • Poor information and knowledge management • Absence of a National Health Research Council
Opportunities	**Threats**
• Possibility for funding • Partnership and collaboration with international and local partners • Skills and technology transfer between different partners • Existence of databases and possibility for publications • Political will and commitment to development of the Health Research sub-sector • Efforts to revive the National Research Council (NRC)	• Over reliance on donor funding • Competing health priorities for financial resources • Failure to promote a strong culture of data use for evidence-based planning • Inability to retain Human Resource for health research

CHAPTER 2

2.1 Vision

By 2023, the country's health sector will be sufficiently capacitated to generate and utilize evidence for effective delivery of health services.

2.2 Mission

To guide and promote scientifically sound and ethical health research practice through a well-regulated resourced coordinated national research system.

2.3 Objectives

2.3.1 To create an enabling policy and legal environment for health research
2.3.2 To provide governance and leadership for health research
2.3.3 To provide a framework that will enhance and guide capacity building
2.3.5 To guide the conduct of health research
2.3.6 To provide a mechanism for resource mobilization for health research
2.3.7 To promote evidence-based decision making and practice

2.4 Scope

The policy shall provide guidance to all health research including traditional and alternative medicine conducted within the country to ensure adherence to scientific and ethical standards of health research.

2.5 Guiding Principles

All health research shall ensure adherence and compliance with fundamental Human rights; ethical practice; integrity and principles of inclusiveness; fairness and equity as well as timeliness and responsiveness of research to national health priority issues and emerging health challenges. Practice of health research shall always be conducted through a spirit of partnerships, collaboration and involvement of all interest groups.

CHAPTER 3

3.1 Policy Directions

3.1.1 Policy and Legal environment

Implementation of this policy shall be supported by dictates of public health and national research legislation and shall formalize existence of the National Health Research Department and the National Health Research Review Board. The National Health Research Department shall assume a status of an Institute of Health Research upon establishment of the National Research Council.

3.1.2 Governance and Leadership

Overall leadership and coordination of research on human subjects in the country shall be the responsibility of the Ministry of Health through actions of the National Health Research Department. The National Health Research Review Board shall be accorded a semi-autonomous status in order to ensure independence of its operations.

3.1.3 Capacity Development

The health sector through actions of National Health Research Department shall be responsible for facilitating capacity development in all spheres of health research across its four pillars based on a sector wide approach. Additional to national efforts to develop health research capacity, international agencies and individual researchers who seek to conduct research in the country shall contribute to capacity development of local researchers as a condition for protocol approval.

3.1.4 National Health Research Agenda

The National Health Research Department shall facilitate development of a national health research agenda, a guiding document which shall articulate priority health research issues based on burden of disease; bio-medical; clinical; health services and health systems; socio-cultural, environmental heath and special populations. All health research carried out in the country shall address National Research Agenda issues, except in cases of emerging and re-emerging issues.

3.1.5 Conduct of Health Research

Conduct of health research in the country shall adhere to high scientific and ethical standards as defined by international research guidelines. By consequence of this policy, all research on human subjects conducted in the country shall require prior approval of the National Health Research Review Board. Review of research protocols to be implemented in the country shall be carried out as the final review subsequent to reviews by institutional review boards whether national or international. Similarly, transfer of research databases and specimens shall require prior approval of the MOH, under facilitation of the health research department (NHRD). The National Health Research Department shall facilitate development and implementation of operational guidelines and tools to guide the practice of health research in the country. In approving research protocols, the National Health Research Review Board shall give consideration to the best interest of research participants (subjects) based on a risk/benefit analysis. Approval of clinical trials shall comply with Good Clinical Practice Guidelines as defined by the International conference on Harmonization (ICH) and Standard of Care requirements.

3.1.6 Health Research Financing

Efforts to mobilize resources for health research shall be facilitated by the National Health Research Department with the support of ministry of health leadership. A proportion of financing for health research shall be provided by the national budget as part of health sector expenditure. Funding for health research shall prioritize dictates of the national research agenda in an effort to promote evidence-based planning and policy making.

3.1.7 Information and Knowledge Management

The National Health Research Department shall facilitate management and periodic dissemination of health research products.

3.1.8 Clinical Trials

1 . The Minister of Health , in consultation with the Principal Secretary together with Directorate, shall provide guidelines for the conduct of clinical trials in Swaziland.

2. The Principal Secretary may constitute a special expert review panel on matters of public interest, public policy or national security concerning the conduct of clinical trials.

3. The medicine to be used in a clinical trial shall be approved by the Swaziland Scientific and Ethics Committee and Swaziland Medicines and Regulatory Authority.

4. A clinical trial on human beings shall only be conducted:
   (a) In the prescribed manner according to guidelines of good clinical practice;

   (b) If the researcher is in possession of a letter of approval issued by the relevant research ethics committee;

   (c) If the researcher has a clinical trial certificate issued by the relevant Regulatory Authority;

   (d) Has ethical approval granted by the Board;

   (e) With proven evidence of being in possession of a no fault

   (f) Insurance for all research participants.

CHAPTER 4

4.1 Policy Implementation Framework

4.1.1 Institutional Arrangements

Implementation of this policy shall be the responsibility of the National Health Research Department. The NHRD shall constitute operational technical committees as required and shall collaborate with the national research council once established and all research stakeholders based on sector wide principles.

4.1.2 Implementation

This policy shall be translated into related legislation, a national health research strategic plan, and costed annual action plans as well as operational protocols and guidelines. The policy and related documents shall be communicated and disseminated to policy makers and stakeholders for purposes of sensitization and implementation.

4.1.3 Monitoring and Evaluation

Progress assessment in implementation of this policy and related instruments shall be based on a monitoring and evaluation framework which will be developed by the health research unit with assistance of the Monitoring and Evaluation unit of the Ministry of Health. The policy shall be subjected to mid and end of term reviews. Review findings shall be disseminated to all stakeholders.

4.1.4 Funding

The Health Research Unit shall develop budget estimates based on annual action plans as part of the national health sector budget and in line with sector wide principles.

4.1.5 Policy Revision

The Health Research Unit shall facilitate revision of this policy in consultation with the Public Policy Coordination Unit (PPCU) and stakeholders based on findings of policy reviews and emerging health research issues.

4.2 Conclusion

This policy is a reflection of the commitment of the Swaziland Government and the Ministry of Health to improve availability and accessibility of quality evidence as part of promoting effective heath sector planning and development.

REFERENCES

1. National Commission for protection of Human Subjects of Biomedical and behavioural research. (1979). Belmont Report, Ethical Principles and Guidelines for Protection of Human Subjects of research.
2. Council of International Organization of Medical Sciences (CIOMS) in collaboration with World Health Organization. (1993). International guidelines for biomedical research involving human subjects, Geneva, ISBN 92-9036-0560-9.
3. Central Statistics Office. (2007). Swaziland Census.
4. Kingdom of Swaziland. (2007). Swaziland Demographic and Health Survey (SDHS).
5. Ministry of Health. (2009), Health Management Information System (HMIS).
6. Ministry of Health. (2010). Essential Health Package.
7. Ministry of Health. (2010). Multiple Indicator Cluster Survey (MICS).
8. Ministry of Health (MOH) and World Health Organization (2004).
9. Kingdom of Swaziland. (2009). National Health Sector Strategic Plan (NHSSP).
10. World Bank, 2006
11. World Medical Association. (1964). Declaration of Helsinki.
12. Government of Swaziland. Ministry of Health Swaziland Annual Health Statistical Report; 2010

Notes

Notes