

Republic of Rwanda

Ministry of Health



Health Sector Research Policy

February 2012

List of Abbreviations

CHUK – Centre Hospitalier Universitaire de Kigali (University Teaching Hospital of Kigali)

CNLS – Commission Nationale de Lutte contre le SIDA (National AIDS Control Commission)

EDPRS – Economic Development and Poverty Reduction Strategy

GOR – Government of Rwanda

HSP – Health Sector Policy

HSRP – Health Sector Research Policy

HSSP II – Health Sector Strategic Plan II

IRB – Institutional Review Board

M&E – Monitoring and Evaluation

MDGs – Millennium Development Goals

MoH – Ministry of Health

NGO – Non-Governmental Organization

PI – Principal Investigator

RBC – Rwanda Biomedical Centre

RNEC – Rwanda National Ethics Committee

TWG – Technical Working Group

WHO – World Health Organization

Table of Contents

I.	Introduction	5
II.	Context of Health Sector Research in Rwanda	6
III.	Rationale for the HSRP	7
IV.	Definition of Research in the Health Sector.....	7
V.	Vision, Mission, and Goals of the HSRP document.....	8
VI.	Guiding Principles of Health Sector Research.....	9
1.	Country Ownership and Leadership	9
2.	Capacity-Building	10
3.	Financing	10
4.	Multi-disciplinary and Interdisciplinary Work.....	11
5.	Review and Coordination of Health Research	12
6.	Quality.....	12
7.	Research on Vulnerable Subjects.....	13
8.	Availability and Use of Data	13
9.	Monitoring and Evaluation	14
10.	Research Agenda.....	15
VII.	Conclusion.....	15

Foreword

I am pleased to present the Rwandan Health Sector Research Policy (HSRP). This policy defines the scope of research in our health sector and presents the strategic principles to ensure that the research done in Rwandan health sector will be conducted in a more coordinated manner, promoting research for equity and social justice and to benefit the Rwandan community as well as the global community in general.

Research is among key elements for the development of nations as it plays a crucial role in evidence based planning and decision making. The information generated by research serves as a light across the development pathway by providing solutions to problems and challenges.

The 2005 Health sector policy provides that health research capacity and specialised training will be reinforced according to national priorities. The Health sector strategic planning considered research as a programme and the 2009-2012 strategy highlighted the lack of research policy and coordination mechanisms as well as limited capacity.

This health sector research policy provides solutions to the challenges which have been identified in health research. It will support and improve Rwanda's health research environment, and create a space and framework in which health research will grow and support improved health outcomes in Rwanda. It will give also a clear orientation for dissemination and use of results.

For sustainability of health research in Rwanda, foreign researchers are called upon to collaborate with Rwandans with clear capacity building plans since this has been singled out as a big challenge.

In conclusion, I call upon all researchers, both foreign and Rwandans who are interested in health research in Rwanda to embrace this policy. I call upon all GoR's institutions and development partners to help towards its implementation.




Dr. Agnès BINAGWAHO
Minister of Health

I. Introduction

Research plays a crucial role in the success of a nation. Research capacity is often a reflection of development capacity. The World Health Organization (WHO) stated in 2008 at its Bamako Ministerial Forum Call to Action that “research and innovation have been and will be increasingly essential to find solutions to health problems, address predictable and unpredictable threats to human security, alleviate poverty, and accelerate development,” an acknowledgement of the broad benefits of strong research.

Around the world, the pace of research has been increasing. Advances in information technology have allowed for more complex research questions to be studied faster. The internet has enabled researchers separated by thousands of kilometers to communicate in real time and share their knowledge and research findings, augmenting the body of global knowledge. Inter-sectoral communication and collaboration has also increased, allowing for greater understanding in research areas that are cross-cutting.

Research in health is pivotal to a strong, sustainable health system that utilizes evidence-based decision-making. Health research takes many forms, including clinical, operational, and health systems research, among others, each of which contributes in an important way to a functioning health system. Without research in health in all these areas, it is very difficult to establish best practices and policies that can lead to improved health outcomes for the population. Illustrating this point is that the WHO decided to focus its 2012 WHO World Report on health research, titling it “No Health Without Research.”

Health research has an effect that permeates beyond the health sector, and improves much more than just health outcomes. Improved health outcomes in turn lead to more productive citizens who are able to actively contribute to the economy. Increased research also increases job opportunities in many areas. These in turn improves socioeconomic development.

Rwanda aims to become a middle-income country by 2020, a goal that is outlined in Vision 2020. This goal is strategically addressed in Rwanda’s *Economic Development and Poverty Reduction Strategy 2008-2012 (EDPRS)*, which emphasizes the need for research in all sectors. The *Health Sector Strategic Plan II 2009-2011 (HSSPII)* is the plan specifically for

development of the health sector, and research plays a role in almost all of the ten programs addressed therein. Strong research will be key in the realization of the objectives of each strategy, and to the success of the nation as a whole. This policy will outline the position of Rwanda's health sector leadership on research in the health sector, and demonstrate commitment and support for its continued growth.

II. Context of Health Sector Research in Rwanda

Historically, many barriers have existed in Rwanda that have inhibited research in all sectors. For the health sector, some of these barriers are noted here. Capacity for research is one of the most important limiting factors. As Rwanda has limited numbers of qualified and experienced researchers, there is minimal capacity to train new researchers. There is also a lack of sufficient research infrastructure, including facilities and coordination mechanisms. Additionally, there is insufficient funding from a variety of sources to carry out all necessary and desirable research in Rwanda. There is a need for increasing publication in international peer-reviewed journals by Rwandan researchers. A research agenda for the nation has not been defined, resulting in insufficient established guidance on what issues are most pressing to improve the health of all people in Rwanda.

While there are large challenges for Rwanda in terms of research in its health sector, some great opportunities exist as well. A tremendous amount of high level political commitment for promotion of health research, coupled with a strong and stable government, will help move health research in Rwanda forward. Rwanda's leadership surrounding health research is based on a multi-stakeholder mechanism, with participation from the MoH, other ministries of the Government of Rwanda, academic institutions, and numerous international partners, among others.

Rwanda has validated the following policies and plans (among others) that outline goals for broad development, but that also address specifically goals for the health sector. These documents guide and govern the path for the health sector in Rwanda. The spirit of the *Vision2020* document captures the need for increased research in all sectors. The *2005 Health Sector Policy (HSP)* and the *Health Sector Strategic Plan II 2009-2012 (HSSPII)* both broadly address the need for improved research in the health sector in Rwanda, but leave

room for more specific and focused examinations of health research, which up to this point did not exist.

III. Rationale for the HSRP

This Health Sector Research Policy (HSRP) aims to fortify and expand upon the existing guiding documents of Rwanda and build upon the stated political commitment of the Government of Rwanda in terms of guiding research in the health sector in Rwanda. Given the crucial nature of strong health research to improving health outcomes and accelerating development, a policy that guides health research is required, and will greatly improve the research environment in Rwanda's health sector.

This HSRP aims to define a political will and commitment in the Ministry of Health (MoH) of Rwanda for advocacy, support and improvement of Rwanda's existing health research, and to create a space and framework in which health research can grow and support improved health outcomes in Rwanda. With this HSRP, research in Rwanda will continue to be developed, supported, and guided, resulting in an environment that is good for researchers, both national and foreign, and yielding positive results for Rwanda and the health of its people.

This HSRP shall provide an enabling framework for the conduct of research that contribute to improve human health and wellbeing in Rwanda. The HSRP aims to recognise the importance of knowledge, information and evidence where health research shall be linked and integrated into planning, policies and programs of health sector.

IV. Definition of Research in the Health Sector

The Ministry of Health of the Republic of Rwanda defines health research as:

“Any activity intended to increase the stock of knowledge related to health that can be generalized and used to draw conclusions, devise new applications, and guide decision-making.”

This definition includes a) basic scientific research related to health, including investigation into fundamental scientific phenomena without a particular application in view; b)

applied/operational research, which is any generation of new knowledge with a specific practical aim; and c) experimental development, which is research intended to develop new or significantly alter and improve materials, products, systems and services. General-purpose data collection, including population- or facility-based surveys and censuses where health data are collected and the primary aim is studying health, are also considered research in the health sector.

Some activities are considered non-research in the health sector unless they are carried out for the purpose of assisting research and development. If not carried out for research-related purposes, these non-research activities do not fall under the jurisdiction of this HSRP. These activities include: standardization procedures, provision of specialized health care, program evaluations (excluding impact evaluations), outbreak investigation/surveillance, and routine software development.

V. Vision, Mission, and Goals of the HSRP document

Vision of the HSRP:

The overarching vision of the HSRP for Rwanda is *to have strong and vibrant research designed both a) to support evidence-based decision-making for an enhanced and sustainable health system in Rwanda, and b) to inform and improve health outcomes in Rwanda and around the world.*

Mission of the HSRP:

The mission of the HSRP for Rwanda is *to promote research which improves the availability of high quality information and its effective use in decision making at all in a manner that ultimately enables Rwanda to continuously improve the health status of its people.*

Goals of the HSRP:

The goals of the HSRP document are to:

- a. *Promote a culture of research in Rwanda;*
- b. *Ensure facilitation of health research in Rwanda;*

- c. *Reflect the guiding principles for health research in Rwanda.*
- d. *Coordinate research in health sector and protect the population*
- e. *Promote research education in health sector*

VI. Guiding Principles of Health Sector Research

1. Country Ownership and Leadership

As research improves and expands in Rwanda, is it important that Rwanda maintain country ownership and leadership of the direction of the work. Though many researchers will come from outside Rwanda, the research done in the country should have a significant impact on the country, and help to empower the country in its research capabilities, to inform policies and strategies formulation and improved health outcomes. The MoH should champion health research for equity and social justice. The Government of Rwanda is committed to using research findings to make evidence-based decisions that will improve health in Rwanda.

To that end, Rwandan people will lead the identification of a research agenda that does not succumb to external pressures to include priorities that are not relevant to Rwanda (see section VI.10). The HSRP does not seek to discourage researchers who bring funded, ethical, and scientifically sound research proposals, even if they are outside the scope of the defined research agenda. Investigators from outside of Rwanda are strongly encouraged to collaborate with a Rwandan investigator, and research projects will ideally involve genuine capacity-building for Rwanda (see Section VI.2). Finally, data collected from research in Rwanda will be co-owned by the Rwanda health sector and the home institution of the PI of the project, with the possibility of development of a memorandum of understanding for complicated cases. (see section VI.8).

Research commissioned and paid by a Rwandan institution is owned by that institution.

2. Capacity-Building

Building capacity for research in terms of both human resources and infrastructure is crucial to having vibrant research in Rwanda. Rwanda must have the people and the facilities in order to carry out effective research. There is high level political commitment in the Government of Rwanda for building capacity for research.

Improving human resource capacity requires attracting, training, and retaining researchers. Capacity for training new researchers will be important to continued and sustainable research, as students make up the next generation of principal investigators. Pre-service training should emphasize the importance of research to a quality health system and train students to carry out high-quality research.

In-service training on research should be similarly fortified, and foreign researchers can help with this by designing projects with Rwandan investigators that contain a component of formal research training. Finally, the problem of “brain drain” must be eliminated by making Rwanda an appealing place to do health research in terms of job requirements and possibility of career advancement, for all who do research in health – health professionals, economists, sociologists, etc.

Additionally, the capacities of research facilities need to be state of the art, so that researchers are not hindered by a lack of facilities or difficulty accessing those facilities. Resources other than facilities, including software and personnel with expertise, need to be more readily available and not limited. This in turn will help to make research positions more attractive, and in a circular manner support capacity-building of human resources in health research.

3. Financing

As capacity for research and the number of ongoing and upcoming health research projects grow, so too the financing will need to grow. There is a need for increased mobilization of funding, both internally and externally. The Ministry of Health will

strive to diversify sources of funding to protect research in Rwanda as a way to sustain its research agenda. This policy acknowledges that diversification of funding requires openness to funded projects that may be beyond the scope of the research agenda. The WHO recommends that ministries of health allot two percent (2%) of their annual budgets for funding health research. With that in mind, the Ministry of Health will advocate within the government to reach and maintain this level of financial contribution.

As important as the sources of funding are the ways in which research funds are managed. There is a need for transparent and responsible use of funds. Additionally, Rwanda should work to ensure, when it is possible, that funds are distributed equitably according to the country need vis a vis the burden of disease and based on equity and social justice. Around the world, 90% of research funds are spent studying diseases that make up only 10% of the disease burden. Rwanda aims to ensure that funds used for research in the country better reflects the need of the health sector according to the burden of disease so as to be more equitable and better improve the health of all in the country.

4. Multi-disciplinary and Interdisciplinary Work

Many disciplines contribute significantly to research in health, including biomedicine, public health, anthropology, sociology, economics, chemistry, political science, psychology, and many more. While not all health research undertaken in Rwanda will be interdisciplinary, the Ministry of Health will encourage multi-disciplinary and interdisciplinary collaboration that supports the health research agenda objectives. Collaboration across disciplines will allow investigators to utilize a variety of techniques, and expand the ways of addressing a research question beyond those approaches taken in just a single discipline. Disciplines can complement each other's strengths and weaknesses, resulting in overall improved research in health.

5. Review and Coordination of Health Research

There is a need to coordinate efforts in health research in Rwanda. Without coordination, research efforts in the health sector may be of varying quality, and may duplicate previous work, which wastes limited resources. Further, without coordination, it is also difficult to avoid duplication, to assure synergy and to design cross-cutting projects in research, which will be crucial to effective efforts to improve health in Rwanda.

Taking into account the existing structures for review of health research proposals, there is a need to expand the number of committees that are able to review research proposals for both scientific and ethical quality. This will reduce the burden on existing committees, and will help to build and expand capacity for research at a variety of institutions. Scientific review committees and ethical review committees are needed at all institutions which have health research in their mandate. It is important to coordinate all these committees centrally, so as to prevent duplication of research efforts and ensure that the committees are using identical standards and procedures. Additionally, after scientific and ethical review at the institutional level, all proposals will be submitted to the MoH for registration. The Ministry will keep a database of all ongoing and past research efforts (including proposals/protocols, datasets, and research reports) to prevent duplication of projects and to help researchers collaborate across disciplines and specialties.

6. Quality

Any research implemented in Rwanda should meet international scientific standards of quality in its design, implementation, analysis and dissemination of the results. Research projects carried out in Rwanda should conform scientifically to the most advanced standards of the scientific community, and should conform ethically to internationally accepted standards. Projects will also be appropriate to the context in Rwanda. This will ensure that research coming out of Rwanda is of the highest quality. The Ministry of Health and research institutions in charge of managing the Rwanda research agenda will provide the framework and the required insights to ensure this quality.

7. Research on Vulnerable Subjects

The Ministry of Health seeks to ensure the protection of vulnerable populations in the implementation of research programs in Rwanda. Five categories of vulnerability can be used to define vulnerable subjects: 1) cognitive/communicative vulnerability, which includes people with learning disabilities, people living with mental health problems, children, neonates, fetuses (pregnant women), and those with a language barrier; 2) institutional/deferential vulnerability, which includes prisoners, students, and employees; 3) medical vulnerability, which includes terminally ill patients; 4) economic vulnerability, which includes dependent and impoverished individuals; and 5) social vulnerability, which includes minorities.

Health research involving vulnerable populations must only be carried out when the research is directly relevant to the health needs of that population, and when it cannot reasonably be carried out on a less vulnerable group. Risk of harm must be minimal for participants. Informed consent must be carefully obtained, ensuring that consent is not given out of desperation or lack of other options. The MoH expects researchers to commit themselves to vigilant protection of vulnerable subjects, and all research performed in Rwanda must demonstrate that it does not exploit or take advantage of vulnerable populations.

8. Availability and Use of Data

It is of utmost importance that data generated through research in Rwanda be used to improve health in Rwanda while remaining in accordance with international intellectual property standards. Results of research are to be shared by the investigators with the stakeholders and communities in which the research was performed. Without this sharing of knowledge, the knowledge cannot be used to improve health outcomes.

Data will be co-owned by the National Institutions and the principal investigators (PIs) or the institution of the PI. In certain cases where this is problematic, an MOU

may be developed between the MoH and the research team. The MoH will assure investigators to publish the results of research in Rwanda, and will streamline the process where possible.

The MoH also commits itself to promotion of the use of existing data sources. This commitment will help to reduce waste of resources by collecting existing data for a second time. This will be facilitated by a central collection of research protocols, datasets (with data documentation), and research reports that are available to those interested in carrying out research or secondary analyses. It is also important to maintain data for later use in terms of validation of prior or future scientific research, or for audit. Data may also occasionally be needed by patients and clinicians after a study has concluded. The MoH will collect and preserve data for all these purposes.

Access to existing research and program databases are subject to the “law of access to information” issued by the Rwanda Parliament. Researchers desiring to use such data will need consent from the MoH to use them, and a separate consent to share the data with others, in order to protect the integrity of the datasets.

9. Monitoring and Evaluation

It will be important to monitor progress in development and continued improvement of research in the health sector of Rwanda. Without the ability to monitor and evaluate changes in research, Rwanda will not be able to change course and update its methods and plans as necessary. The specifics of monitoring and evaluation will be clarified in Ministry of Health and institutional strategic plans and other operational documents.

At the very highest level, success in improvement of research in the health sector will be reflected in improved evidence used in decision-making that results in policies and laws that improve health outcomes. However, research is a continuous

process, so it must be an ongoing process to contribute in a significant way to informed policy-making.

10. Research Agenda

There is a recognized need to identify and update research priorities on a regular basis in a clear research agenda for the Rwandan health sector in order to ensure that the research carried out in Rwanda is the one needed to improve health in Rwanda. Stakeholders at all levels should contribute to the identification of the priorities so that they truly reflect the pressing concerns in the health sector. Such an agenda will help both domestic and international investigators to guide design of new research proposals in a way that is aligned with the real research needs in the country. This research agenda should be dynamic and revised regularly. This will ensure that the agenda, and therefore ongoing and new research, will stay relevant to the health needs of the Rwandan people.

VII. Conclusion

The HSRP was created in alignment with high level Government of Rwanda commitment and in order to demonstrate Ministry of Health support for strengthening research in Rwanda, and to define an important place for research in Rwanda's health sector. However, this HSRP does not define the extent of MoH commitment, and it is not intended to be the only guiding force for research in Rwanda. Instead, it is the beginning of a permanent commitment to strong research in Rwanda, and should lead the way forward.

The HSRP is meant to guide creation of strategic plans, institutional research plans, and development of research projects in Rwanda. These documents and proposals will be what support and fulfill the vision outlined in the HSRP. It is the implementers and all stakeholders, guided by the HSRP, who will help research in the health sector in Rwanda reach its potential. Through this enhanced and strengthened research, Rwanda

will continue to make progress towards improved health for all in Rwanda and around the world, and will move ever closer to achieving its long-term goals of development, as well as the global development goals.