STRATEGIC FRAMEWORK FOR RESEARCH ON IMMUNIZATION IN THE WHO AFRICAN REGION

IMMUNIZATION AND VACCINE DEVELOPMENT

World Health Organization
REGIONAL OFFICE FOR Africa
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<tr>
<td>AFP</td>
<td>Acute Flaccid Paralysis</td>
</tr>
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<td>AFR</td>
<td>African Region</td>
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<td>AMRH</td>
<td>African Medicines Regulatory Harmonization Initiative</td>
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<td>AVAREF</td>
<td>African Vaccine Regulatory Forum</td>
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<td>BMGF</td>
<td>Bill &amp; Melinda Gates Foundation</td>
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<td>CDC</td>
<td>Center for Disease Control &amp; Prevention</td>
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<td>cMYP</td>
<td>Country Multi-Year Plan</td>
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<td>DoV</td>
<td>Decade of Vaccines</td>
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<tr>
<td>DTP</td>
<td>Diphtheria, Tetanus &amp; Pertussis</td>
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<tr>
<td>EC</td>
<td>Ethical Committee</td>
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<tr>
<td>EDCTP</td>
<td>European and Developing Countries Clinical Trials Partnership</td>
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<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>GIFT</td>
<td>Global Information Full Text</td>
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<td>GIVS</td>
<td>Global Immunization Vision and Strategy</td>
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<td>GVAP</td>
<td>Global Vaccine Action Plan</td>
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<tr>
<td>HIV/AIDS</td>
<td>Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome</td>
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<td>HPV</td>
<td>Human Papillomavirus Vaccine</td>
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<tr>
<td>IND</td>
<td>Investigation of New Drug</td>
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<td>IPV</td>
<td>Inactivated Polio Vaccine</td>
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<td>IR</td>
<td>Implementation Research</td>
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<tr>
<td>IVD</td>
<td>Immunization and Vaccine Development</td>
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<td>M&amp;E</td>
<td>Monitoring &amp; Evaluation</td>
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<td>MCIA</td>
<td>Ministerial Conference on Immunization in Africa</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>NIAID/NIH</td>
<td>National Institute of Allergy and Infectious Diseases/National Institute for Health</td>
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<tr>
<td>NGO</td>
<td>Non-Governmental Organization</td>
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<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
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<td>NMRA</td>
<td>National Medicines Regulatory Authority</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>NTD</td>
<td>Neglected Tropical Diseases</td>
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<td>NRA</td>
<td>National Regulatory Authorities</td>
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<td>OPV</td>
<td>Oral Polio Vaccine</td>
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<tr>
<td>OVI</td>
<td>Objectively Verifiable Indicator</td>
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<tr>
<td>PEI</td>
<td>Polio Eradication Initiative</td>
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<tr>
<td>PIE</td>
<td>Post Introduction Evaluation</td>
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<tr>
<td>R&amp;D</td>
<td>Research &amp; Development</td>
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<tr>
<td>RITAG</td>
<td>Regional Immunization Technical Advisory Group</td>
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<td>RSPI</td>
<td>Regional Strategic Plan for Immunization</td>
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<td>SDG</td>
<td>Sustainable Development Goal</td>
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<td>SFRI</td>
<td>Strategic Framework for Research on Immunization</td>
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<td>SIA</td>
<td>Supplementary Immunization Activities</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<td>TFI</td>
<td>Taskforce on Immunization</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>USA</td>
<td>United States of America</td>
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<tr>
<td>VPD</td>
<td>Vaccine Preventable Diseases</td>
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<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO/AFRO</td>
<td>World Health Organization Regional Office for Africa</td>
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EXECUTIVE SUMMARY

Progress has been made towards achieving global and regional immunization targets in the African Region. The introduction of new vaccines in Africa has been a major success, gathering pace with Gavi support. Introduction of multiple new vaccines, such as pneumococcal conjugate and rotavirus vaccines, have taken place in several countries simultaneously.

Despite these achievements critical diseases, including measles and maternal and neonatal tetanus—which have been eliminated or are near elimination in other regions of the world—remain endemic in Africa. Fewer than half of African countries met the Global Vaccine Action Plan (GVAP) target to increase coverage with three doses of diphtheria, pertussis and tetanus containing vaccines (DTP3) coverage nationally above 90% in 2016, and regional DTP3 coverage has stagnated below 80% in the last six years. Seven African countries have an estimated DTP3 coverage of less than 50%.

Reaching GVAP targets requires better implementation of current immunization strategies, as well as identification of new approaches to overcome bottlenecks to improving coverage with existing vaccines. GVAP calls for immunization research across the spectrum of discovery, development, and delivery of vaccines, including operational research on maximizing vaccine delivery effectiveness; accelerated development, licensing and uptake of vaccines; development of bio-processing, formulation, manufacturing, and delivery technologies for new and improved vaccines; and establishment of disease-burden and cost-effectiveness data for in-country decision-making.

The Strategic Framework for Research on Immunization in the African Region (SFRI) provides immunization stakeholders with guidance to facilitate scientifically rigorous, coordinated research that addresses African country priorities. It identified research areas grouped under three thematic areas, namely assessment of disease burden and potential public health and economic impact of vaccines; vaccine and immunization technology development; and implementation research. These are designed to aid the goal of reducing vaccine preventable morbidity and mortality in the African Region through research on vaccines and immunization. It also provides principles for immunization research in line with global best practices and suggested some research financing and coordination mechanisms to promote the conduct of immunization research in the African Region.
ABOUT THE STRATEGIC FRAMEWORK FOR RESEARCH ON IMMUNIZATION IN AFRICA

This resource document provides a strategic framework for immunization stakeholders to stimulate and facilitate Africa-driven, coordinated, and robust vaccine and immunization research. The SFRI identifies research guiding principles, offers three broad immunization research themes in the African context, and outlines basic steps in the research planning process. It targets current and potential immunization researchers in the African community, National Immunization Technical Advisory Groups that can gain from using research findings for decision-making, national policy makers and programme implementers who can use research data to define programme targets and implementation strategies, donors and partners.

The SFRI was developed at the request of the Taskforce on Immunization (now the Regional Immunization Technical Advisory Group (RITAG)) in December 2013 in response to the recognition of the potential contributions of research to optimally use vaccines and immunization services as a foundation for health and socioeconomic development in the African Region. The SFRI was developed in the context of global and regional policy documents that reflect the power of research to improve health, including: Strategic Directions for WHO work in the African Region 2010-2015; Regional Immunization Strategic Plan 2014-2020; and the Global Vaccine Action Plan and Sustainable Development Goal number 3. It complements the Guide for Implementation Research for EPI Managers, which was developed to sensitize EPI managers on the need for immunization implementation research. The SFRI provides strategic outline and structure for a broad range of immunization research including implementation research.
INTRODUCTION

Context of the SFRI
Despite the proven impact of immunization in reducing vaccine preventable disease-related morbidity and mortality,4 countries in the African Region face challenges in optimizing the use of available vaccines. Some countries are yet to introduce licensed vaccines, while others are unable to maintain the high vaccination coverage required to achieve impact. Immunization coverage, as measured using the third dose of diphtheria, pertussis and tetanus (DTP3) containing vaccine, has failed to reach the GVAP target of 90% at national level and at least 80% in every district in many countries.5–7

Figure 1: Factors affecting immunization programmes in the African Region8
In addition to improving implementation of strategies that have proven effective in achieving and maintaining high immunization rates, immunization research can help identify and find innovative solutions to programme challenges. However, research can only meet its purpose if it is part of a national immunization agenda. Research must be country-driven to meet country needs, and be coordinated, rigorously planned, well-resourced, and meticulously executed following the highest ethical and regulatory standards. Immunization research is a multi-stakeholder process that requires a commitment to translating findings into practice with the aim of reducing vaccine preventable morbidity and mortality. In addition, literature on available data in African region on immunization research revealed that factors which affect the immunization programmes could be summarized as factors located within the health system environment itself. These derive from multiple aspects operating within and around the health system environment, touching on the service delivery, human resources, medicines and technologies as well as leadership and governance. There were also issues of the people’s belief and perception and attitude health workers. See Figure 1.

As a leading global public health institution, WHO has a mandate to set the norms and standards and to establish a framework of research that meets international standards. It is consistent with this role that the Strategic Framework for Research on Immunization in Africa (SFRI) was developed under the auspices of the WHO Regional Office for Africa.

**Goal and Objectives of the SFRI**

*Goal*

To reduce morbidity and mortality in the African Region from vaccine preventable diseases by guiding and implementing high-quality research on vaccines and immunization

*Objectives*

General: To provide countries and immunization stakeholders with guidance and support to facilitate Africa-driven, coordinated, and robust vaccine and immunization research. The specific objectives are to:

- Identify and periodically update priority areas for immunization research in the African Region;
- Describes the principles for immunization research consistent with international best practices.

**Guiding principles of the SFRI**

*Country ownership and commitment*

Consistent with declarations and commitments made by Member States of the WHO African Region in Ouagadougou and Algiers, it is the responsibility of Member States to ensure that research that addresses priority needs of immunization in the Region receive adequate resources.
Shared responsibilities, partnerships and collaboration
Research involves multiple stakeholders, including investigators, ethics committees, regulatory authorities, sponsors, product developers, communities, and health care providers. Immunization programmes should enhance partnerships and collaborations across these stakeholders to ensure priority products and strategies, which fit into their programmes and meet their needs, are identified for development, evaluation, and implementation.

Demand-driven
Research should be responsive to priority immunization and vaccine-related questions in the Region, tackling the most critical priorities in immunization.

Respect for legal, ethical, regulatory and human rights
The dignity and rights of all research participants including vulnerable populations must be promoted and protected as enshrined in the bioethics principles, national policies, regulations and guidelines in tandem with international laws and principles guiding research that involve human participants.

Peer review
Collaborative review should involve subject matter experts and relevant stakeholders throughout the research process, from inception through implementation and results dissemination to enhance the quality and impact of research.

Networking, public and private partnerships and collaboration
Collaborative and strategic partnerships with the public and private sectors should be promoted.

Multi-disciplinarity and complementarity
Research studies that are multidisciplinary or complementary in nature should be promoted to build capacity, optimally use resources, and translate research findings into policy and practice.

Sensitivity to gender issues and needs of vulnerable populations
Promote more gender sensitivity/equity in research leadership and ensure fair participation of both sexes and vulnerable populations in research, taking into account their special needs, should be encouraged to reduce immunization inequities. In this regard, it is necessary to ensure that participating communities are given primary attention as beneficiaries of the research when products or intentions are ready for use, and that policies emanating from research favour deprived populations who lack access to immunization services.
SFRI DEVELOPMENT METHODS

A working group to develop the SFRI was constituted with colleagues at the WHO Regional Office, the Bill and Melinda Gates Foundation, the Medical Research Council, Gambia, Ministries of Health in Ghana, Mozambique, Malawi and Kenya, South African Medical Research Council, the US Centers for Disease Control and Prevention, WHO’s Strategic Advisory Group of Experts on Immunization, and WHO’s RITAG.

In developing the SFRI, a situational analysis was conducted using primary and secondary sources of information. The primary sources of information were interactions with immunization experts, including WHO staff at the Headquarters, the African Regional Office, inter-county support teams (ISTs), WHO country offices and country EPI staff, and researchers and health systems experts. The secondary sources of information were peer-reviewed publications, reports of various global and regional technical advisory groups, recommendations of the RITAG, and global and regional immunization goals.

Consultations with immunization experts
Two interactive workshops were held in May and August 2014 for immunization staff to identify factors affecting country immunization programmes. Immunization and research staff from Ministries of Health and WHO country offices of 11 countries participated. Workshop participants came from Angola, Cameroon, Central Africa Republic, Congo, Democratic Republic of Congo, Ethiopia, Kenya, Niger, Nigeria, and Uganda.

Literature review
A review of immunization research conducted between 2013 and 2016 was undertaken. In identifying which publications to include in the review, particular attention was paid to the following: 1) types of study, 2) countries where the studies were conducted, 3) the population size studied, 4) the subject of the research, and 5) publication status (published or unpublished).

The search for published literature was limited to materials obtained from the AFRO literature search system using the Global Information Full Text (GIFT). The keywords used were “study or research”, “immunization” and “vaccination coverage”. We excluded publications and reports that merely discussed personal opinions of the authors, not written in English, and research conducted more than three decades earlier.

A total of 3211 publications were found. However, 79 remained for review after exclusion of those that did not meet the inclusion criteria. Twenty-eight of these publications (35.4%) were conducted in Member States of the African Region. Almost half of these (13) were in grey literature and unpublished. Studies were of varying scale and sizes with sample/response sizes ranging from 13 to 24,147 respondents.

Consultation meetings with Member States and reviews of immunization literature verified well-known factors that impact immunization programme performance (Annexes 1 and 2).
Review of the health research infrastructure and capacities in Africa

Results of a 2014 questionnaire-based study to review of health research infrastructure and capacities in Africa identified 2,899 health research institutions in the Region. The number of institutions per country ranged from one in Equatorial Guinea to 382 in Nigeria (Figure 2), with most of these centers at universities, medical schools and teaching hospitals. However, gaps in research capacity were identified, and each country needs an assessment to address specific research capacity needs.\(^{14}\)

Building immunization research capacity will entail institutional and regulatory frameworks, infrastructure, investment, and sufficiently skilled people to conduct and publish research findings, and to translate research into action through sharing results with national and subnational stakeholders\(^{15,13}\). This has been summarized as a process which ensures clear definition of the institutional systems needed to support research, enumeration of existing and missing resources, and improvement of research support by addressing the identified gaps\(^{16}\).

**Review Workshop**

A two-day workshop was held in June 2017 to review and incorporate views of immunization partners and researchers in the Framework. Participants were drawn from WHO/AFRO, the
three WHO/ISTs in the African Region, and WHO/headquarters. Other participants included key vaccine and immunization researchers from Ghana, Kenya, Malawi and Mozambique, where recent immunization research was conducted, and representatives from the Bill & Melinda Gates Foundation (BMGF) and the U.S. Centers for Disease Control and Prevention (CDC). A draft framework was developed and circulated to the RITAG in December 2017.
THEMATIC AREAS OF RESEARCH PRIORITIES

Identified priority research areas were grouped under three thematic areas designed to aid the realization of the goals and targets of the Regional Strategic Plan for Immunization 2014-2020 and contribute to achieving GVAP strategic targets. Within each of the thematic priority areas, research sub-themes and ideas were identified broadly to allow research discretion and flexibility. Specific research questions in the three thematic areas should emerge directly from country priorities. A few such examples of country-driven research are included in Annex 3.

Thematic Area 1: Assessment of disease burden and public health and economic impact of vaccines

Examples:
(a) Research on disease trends and disease models for priority diseases for which there are no vaccines or second-generation vaccines are needed.
(b) Research on dynamics of vaccine preventable diseases (VPDs) to evaluate impact of vaccines and to identify any shift in disease trends or evolution of pathogens due to vaccine pressure.
(c) Research on priority epidemic prone diseases, risk mapping and disease modelling to inform public health preparedness (e.g. Ebola, Marburg, Rift Valley Fever, Zika, Influenza).
(d) Research on population immunity and susceptibility (e.g. polio seroprevalence surveys in high-risk areas).
(e) Research on cost effectiveness of vaccines.

Thematic Area 2: Vaccine and immunization technology development

Examples:
(a) Pre-clinical studies.
(b) Clinical trials of new vaccines against priority diseases.
(c) Clinical trials of vaccine efficacy (e.g., fractional intradermal IPV immunogenicity and schedule trials).
(d) Clinical evaluations of existing vaccines for new indications, schedules, and age groups.
(e) Clinical trials and evaluation of delivery systems (e.g., thermostable vaccines, micro-needles patches, aerosols).
Thematic Area 3: Implementation research

Examples:
(a) Research to generate evidence to prioritize new vaccines or use of existing vaccines.
(b) Research on immunization knowledge, attitudes and beliefs to inform vaccine demand creation.
(c) Research to identify operational barriers that prevent delivery of immunization services.
(d) Research to optimize immunization strategies and efficiency of health systems.
(e) Research to monitor vaccine effectiveness and safety.
(f) Research and surveillance for adverse events and for disease epidemiology.
(g) Research on development of tools to improve data availability and quality.
RESEARCH IMPLEMENTATION PROCESS

The research implementation process includes four key areas: (a) selection, analysis and definition of the problem; (b) protocol elaboration; (c) field implementation (collection and analysis of data to generate results for interpretation; and (d) dissemination and policy recommendations as shown in Figure 3.

Definition of the problem
National research plans should reflect national priorities. Research funding should be part of costed multi-year plans (cMYPs) for immunisation as well as national health sector strategic plans.

Figure 3: Flow chat of steps to be taken during the immunization research emphasizing the collaboration between investigators and EPI programme staff
Research priority setting should involve all relevant stakeholders.

The preliminary list of research questions should be contextualised and the feasibility of addressing questions assessed. Immunization research requires the consideration of:

(a) the relationship of immunization programmes to national health research objectives;
(b) the nature of programmes whether based on immunization commodities, diseases, regions, factors or disciplines;
(c) the process of allocating resources among immunization activities, based on opportunities for success and potential impact;
(d) the activities within immunization programmes from among the many alternatives possible, bearing in mind the importance of human resource capability, immunization programme resources, complementarity with other health programmes and likelihood of result which justify the investment.

**Protocol elaboration**

Development of an impactful scientific proposal is a technical process that requires formulation of scientific ideas by individual researchers. This process needs to be guided and aligned with the priority areas of immunization research.

**Logic framework**

A logic framework for conceptualizing immunization research called the logic framework is shown below (Table 1). The logic framework is simply a tool which provides a structure for specifying the components of an immunization research activity and the logical linkage between a set of means and a set of ends.17

**Table 1: Logic Framework**

<table>
<thead>
<tr>
<th>Narrative Summary</th>
<th>Objectively Verifiable Indicator</th>
<th>Means of Verification</th>
<th>Important Assumption</th>
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<tbody>
<tr>
<td>Inputs</td>
<td>Nature and level of resources</td>
<td>Sources of information</td>
<td>Initial assumptions about the activity</td>
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<td></td>
<td>Necessary cost</td>
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<td></td>
<td>Planned starting date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outputs</td>
<td>Magnitude of outputs</td>
<td>Sources of information</td>
<td>Assumptions affecting the inputs-outputs linkage</td>
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<td></td>
<td>Planned completion date</td>
<td>Methods used</td>
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<tr>
<td>Purpose</td>
<td>End of project status</td>
<td>Sources of information</td>
<td>Assumptions affecting the outputs-purpose linkage</td>
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<tr>
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<td>Methods used</td>
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</tr>
<tr>
<td>Goal</td>
<td>Measures of goal achievement</td>
<td>Sources of information</td>
<td>Assumptions affecting the purpose-goal linkage</td>
</tr>
<tr>
<td></td>
<td>Methods used</td>
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</table>

Each logical intervention is assigned an indicator of success, means of verification and set of assumptions. Objectives will have to be set for each principle, results and specific activities. Indicators of success will then be assigned to each means of verification and assumptions.
The immunization research logical framework serves as a useful tool for defining inputs, timeframes, and assumptions for success, outputs, and indicators for monitoring and evaluating performance. See Table 2 for details.

### Table 2: Immunization Research Logic Framework:

<table>
<thead>
<tr>
<th>Narrative Summary</th>
<th>Objectively Verifiable Indicator</th>
<th>Means of Verification</th>
<th>Important Assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INPUT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research staff</td>
<td>Staff in place</td>
<td>Source of information and data collection tools clear</td>
<td>Research funds and staff approved and available</td>
</tr>
<tr>
<td>Research facilities and equipment</td>
<td>Functional facilities and equipment available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funds</td>
<td>Sufficient funds available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>Other favorable conditions in place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scientific leadership</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OUTPUT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preliminary research results</td>
<td>Data from surveys/experiment</td>
<td>Research reports</td>
<td>Scientific and ethical standards upheld</td>
</tr>
<tr>
<td>Completed research results</td>
<td>Recommendations by project staff and community</td>
<td>Statistical reports</td>
<td></td>
</tr>
<tr>
<td>Research capacity strengthened</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PURPOSE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generate new knowledge on immunization of interest and</td>
<td>Released ideas and/or technologies to advance immunization services</td>
<td>Programme records and immunization policies</td>
<td>New immunization ideas and technologies available at</td>
</tr>
<tr>
<td>relevance to policymakers</td>
<td></td>
<td></td>
<td>affordable prices</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GOAL</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New ideas/technologies contribute to enhancing the</td>
<td>Production of evidence on immunization to reduce barriers and enhance</td>
<td>Immunization access surveys</td>
<td>Policy continues to support immunization</td>
</tr>
<tr>
<td>impact of immunization programme</td>
<td>services</td>
<td>Input statistics</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Population studies</td>
<td></td>
</tr>
</tbody>
</table>

Input indicators for an immunization programme can include personnel, time, supplies used, training programmes or fund expended. The inputs at this stage are usually specified and can be measured or assessed. Verifying that implementation is proceeding as planned requires tracking actual inputs against proposed inputs within a specified timeframe.

When selecting indicators of the outputs level, it is helpful to think of the expected output and purpose of the activity in term of targets, answering the questions of what, how many, with which characteristics, when. If an expected output is 90% coverage with a new vaccine, then an appropriate indicator might be “coverage” with a particular antigen by end of the year. The means of verification in this case would be records from immunization programmes and coverage surveys.

At the input-output-purpose levels of inquiry, document & programme planning meetings, quarterly and annual research reports, research proposals, survey results, and scientific
publications can be used to evaluate immunization research implementation. In an ideal system, these reports would have been routinely gathered and monitored by researchers and programme management team to identify implementation problems.

With respect to assumptions, list those factors that are not controlled by the immunization programme, but which influence implementation success. Different community perceptions of vaccines are outside the control of the immunization programme but can affect the realization of the desired coverage rates. Assumptions at this level are often difficult to influence, but they should be defined in advance and monitored. The assumptions are meant to keep decision-makers realistic in their expectations. If a situation looks particularly hopeless, the programme managers should reorient their research programmes to consider this. Sometimes, where national policies are concerned, research and immunization programme managers can be successfully involved in policy dialogue to make assumptions. Assumptions are critical for research managers at the input and output levels, where the list of assumptions serves as a red flag to immunization managers that they must actively monitor and assure that the conditions listed are achieved.

Researchers often focus, primarily, on input-output, output and purpose level information. On the other hand, focusing the impact evaluation on the relationship of a research programme to larger development objectives makes the entire framework useful. The primary purpose for conducting any analysis at this level is to squarely understand the expectations placed upon the immunization programme research, the validity of these expectations, and whether the planned immunization research programme and how it is operating in the health system are logical responses to these health system expectations.

**Monitoring and Evaluation**

Monitoring and evaluation (M&E) is essential to maintain or improve the quality of research projects and to understand whether the planned goals are being achieved. M&E promote understanding and improve planning and decision-making. They have evolved as vital areas of work necessary for evidence-based justifications and targeted improvements of both funding and conduct of research and in unlocking the full potential of work in this area through reliance on the dynamic, interconnected and flexible yet collective and principled approach. It is an important source of evidence of the performance of the project, programme or policy, of the persons and institutions in charge of research implementation.

The first step in M&E is to develop a plan, which specifies how the project will measure its achievements. The M&E plan will document the stakeholders’ consensus on the project, thereby fostering transparency and accountability; serves as a record in the institutional memory; tracks progress against set plans; checks for compliance with established standards; identifies trends and patterns in the programme; and helps to adapt strategies and inform decisions for project management. Developing an M&E plan requires knowing what the project wants to change and how, what the specific objectives of the project are to achieve this change, what the major indicators (such as input, process, output and outcome indicators) are and how they will be measured, and how the data for M&E will be collected and analyzed.
The M&E plan is implemented in three stages, namely (a) checking and measuring progress, (b) analysing the situation, and (c) reacting to new events, opportunities and issues. Internal monitoring ensures adherence, timelines are respected and provides platform for future activities (lessons learned). External monitoring ensures adherence to international standards and norms. Key elements to be monitored should include the guiding principles. Indicators can be set against specific activities to address the guiding principles. This research framework proposes a logic framework approach to M&E.

**Field implementation**

Before embarking on field implementation, the research team needs to be assembled and logistic issues sort out. The project managers should allocate activities and tasks to research team members and establish research sites, as well to define the procedures for reporting on the progress, closing, and dissemination of the research findings. The project managers should train the data collectors, pre-test the data collection tools (making accommodation for data management processes including data back-up, protection, and sharing), and start the research implementation process with a launch function during which the entire team is presented to the community. The data analysis team is also trained on the relevant analytical tools. For some researches, particularly qualitative studies, analysis commences as soon as data collection has begun. Interpretation of findings is done at the programme level.

**Translation of immunization research into policy and practice**

*Dissemination*

Results from research need to be available to inform the decisions of policymakers and stakeholders. Dissemination must follow careful selection of strategies to address relevant audiences. At the highest level, providing research results to the WHO Strategic Advisory Group of Experts on Immunization (SAGE) is generally likely to maximize the impact of the research globally. Furthermore, as the vaccine research community on the continent continues to mature in the coming years such high-level impact should be expected to increase as the Region drives its own research agenda. Nonetheless, SAGE will not be the appropriate target for a large proportion of research which may either address local implementation needs or be more esoteric and without immediate global policy implications.

The Regional Immunization Technical Advisory Group (RITAG) for Africa makes recommendations to the Regional Director on immunization and vaccine policies. Other groups with far reaching remit such as the WHO Polio Research Committee (PRC) or organizations that play key high-level roles in vaccine delivery, including Ministries of Health, UNICEF, PATH, MSF, NIH among others, may also be important stakeholders in some fields of vaccine research.
Research, which addresses questions of local or sub-regional relevance, should be reported to the National Immunization Technical Advisory Groups (NITAG), where they are functional, or directly to stakeholders in the Ministries of Health in the absence of an effective NITAG. NITAGs also take global or regional recommendations and adapt into local context, implementable nationally or sub-nationally.

Vaccination implementation challenges can have commonality across different settings. Even if research findings are context-specific, sharing methodology can help others facing similar challenges. Finally, providing results in an easily accessible and often digestible format to the wider health community and general public should always be considered. Some of the possible channels to results dissemination are also illustrated in Figure 4.

Traditional methods of dissemination including presentation of results at relevant scientific or public health conferences and publication in reputable, high quality, and peer-reviewed journals remain essential. Conference presentation ensures those with a high interest in the field have the results presented to them and provides an opportunity for further discussions.

Publication in reputable, peer-reviewed journals ensures the scientific integrity and value of the research has been confirmed. There is need to promote publication in open/free access to research journals for wider dissemination here. Providing synthesized findings to those experts developing global, regional or national policy documents is essential.

Figure 4: Target audience for immunization research data dissemination
To maximize the immediate impact of any research finding the development of tools for implementation to enhance the transition from research to practice may also assist in results dissemination. Feedback to the research participants (or their families) and to the wider local community is also a central element to closing the circle. The approach used will depend on the target audience (see Figure 5).

Finally, the opportunities provided by social media to disseminate results across the globe real time should not be missed. The media chosen (e.g. Twitter, Facebook etc.) to achieve maximum impact is likely to change and will, to some degree depend on media streams used by the agencies involved in the research. Such media may not directly target those who are responsible for policy decisions. However, the power of social media should not be underestimated and serves to ensure the widest audience possible is aware of the wide portfolio of research being undertaken across the Region. The social media also act as advocates for vaccination research and vaccination in general with funders, governmental and non-governmental organizations. As with all results dissemination, messages in this arena should be clear, honest and chosen with care to avoid feeding of those with an unwarranted anti-vaccine agenda.

Policy change process
The WHO is tasked to provide leadership in global health, to shape research agendas, to provide guidance and standards for public health practice, and to provide support to country programmes with global recommendations for vaccine use. The SAGE on Immunization is an independent advisory committee with a mandate to advise WHO on the development of policy related to vaccines and immunization. SAGE follows an established process leading to WHO recommendations on the use of vaccines described in the WHO Handbook for Guidelines Development [http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf?ua=1](http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf?ua=1).

SAGE meets biannually and reviews and critically appraises the evidence on immunization and vaccine-related topics and formulates recommendations that are then reflected in the WHO vaccine position papers. SAGE benefits from the inputs of the SAGE Working Groups, the relevant existing technical advisory committees and the Regional Technical Advisory Groups and from regional consultations.
The RITAG for Africa makes recommendations to the AFRO Regional Director regarding vaccine policy for the continent including, when appropriate, adapting SAGE recommendations for regional/local implementation. The RITAG can also identify relevant policy questions that need to be address and inform SAGE as appropriate.

When appropriate, research, which addresses questions of local or sub-regional relevance, are reported to the National Immunization Technical Advisory Groups (NITAG), or directed to the Ministries of Health in the absence of an effective NITAG. NITAGs are responsible for providing independent, evidence-informed advice to policy makers and programme managers on policy issues related to immunization and vaccines.

**Advocacy toolkits for policy makers**

Advocacy toolkits are also useful in shaping the perceptions of policy makers on immunization research and issues. Advocacy toolkits effectively contribute to the development and implementation of public policy on health issues or to challenge policies that undermine research to improve the delivery and uptake of immunization services. Effective advocacy toolkits should outline policy advocacy strategies that can be used to influence policy processes, especially those that are counter to the allocation of resources and use of results from immunization research.

Advocacy can be conducted at the global, national, regional or local levels, depending on where support is needed. In most cases, effective policy advocacy works through advocacy networks or alliances. These are groups of organizations and individuals working together to achieve policy changes with regards to delivery and utilization of immunization services. The mission, here is to create a policy environment that supports utilization of results from immunization research for change and development.

Policy advocacy follows a multi-layered approach in formulating policy for delivery of immunization services. To be effective, there will be need to engage with people and institutions that are key to the development of immunization policies, which in this case include government, civil society, the media, and community, among others. Each of these spheres informs the development of immunization policy.
CRITICAL ISSUES FOR RESEARCH ON IMMUNIZATION

Research Capacity strengthening
Research capacity is built over a long term and in a systematic way. It includes identifying talent very early, training and assembling multidisciplinary teams, identifying the right sites and populations, equipping the facilities with appropriate tools, establishing processes, standard operating procedures, building institutional capacity, ethics and regulatory systems and assembling partners, both local and international. Research capacity may be structured under individual, institutional, national, regional and global.

Individual and Institutional
The framework stresses the multidisciplinary approach. The WHO and partners have over the years supported capacity building for research covering various expertise including research ethics, regulatory capacity, Good Clinical Practice, among others. Appropriate infrastructure, such as laboratories, field sites and clinics, laboratory equipment, vehicles, etc. is fundamental to carrying out good research. Schools of public health provide opportunity for relatively inexpensive research, with students willing to carry out research in fulfilment of part of their requirements for graduation and in some cases with funding and looking for research questions. Institutional research capacity is also dependent on ethics and regulatory oversight.

National
Each country needs an assessment to address specific research capacity needs (vaccinology, behavioural science, immunology, health economics, health systems, epidemiological models, communication, etc.). Countries should make use of existing schools of public health, medicine, nursing and pharmacy, laboratories, public health institutes, professional associations, and NGOs to help address research. Opportunities exist for building sustainable research capacity in countries, from traditional funders such as WHO/TDR, the European and Developing Countries Clinical Trials Partnership (EDCTP), The National Institute of Allergy and Infectious Diseases/National Institute for Health (NIAID/NIH), the Welcome Trust, the BMGF, and several other foundations and institutions and trusts.

Countries should consider embedding research in health programmes. There are several initiatives aimed at strengthening research ethics and regulatory capacity in the African Region. Countries should explore these opportunities to ensure they have in place national ethics committees and national regulatory authorities (NRAs) to authorize clinical trials and to provide oversight.
Regional

Several collaborative consortia exist in the African Region. These networks of research facilities, universities and sites offer opportunity to leverage resource use and to minimize duplication of efforts. Member States are encouraged to make use of existing platforms and networks to support research. The African Vaccine Regulatory Forum (AVAREF) represents a unique capacity building effort supported by WHO, the BMGF and other partners to facilitate clinical trials for product development. WHO/AFRO regional office will support the member States and the research in the region in the following ways as listed below:

RITAG oversight and support for immunization research

The SFRI envisions that the RITAG regularly includes an item on immunization research on its agenda at a regular interval to offer advice on the set thematic priority immunization research areas and offer support/capacity building on scientific proposal development, data analysis, scientific publication and funding support

(a) Proposal development

Challenges in scientific expertise in immunization research in African region makes it difficult to achieve the high level scientific proposals. Development of an impactful scientific proposal is a technical process that requires formulation of scientific ideas by individual researchers. This thoughtful process need to be guided and aligned to the set priority areas of immunization research. The RITAG will guide this process and offer technical support. In this way, the committee will continually identify needs and where necessary organize workshops for capacity building for proposal development.

(b) Data analysis

Situational analysis on immunization research revealed that data management and analysis was one of the main challenges in most African countries (Annexes 1 and 2). Issues on data collection, quality assessment, analysis and interpretation are key for supporting scientific evidence. The Regional office should endeavour to build capacity through short and long-term trainings. This will ensure quality data collection, analysis and interpretation and this eventually will ensure data reliability.

(c) Scientific publication

Low number of scientific peer reviewed articles from the African Region on immunization indicates sub-optimal research portfolio and/or lack of skills in scientific writing. Since scientific writing is a technical peer reviewed process capacity building is of paramount importance. The envisaged co-ordination with the NITAGs should support this process through capacity building workshops and online trainings.
(d) Advocacy for funding support for key proposals

It will be the responsibility of WHO/AFRO together with other donor partners to advocate for fund to support research proposals that are considered of high merit and importance with an aim to minimize mortality and morbidity through immunization research.

Biennal immunization research conference

Lack of a platform for sharing scientific data may lead to duplication of research or even loss of otherwise important data. The SFRI recommends a biennial immunization research conference for the WHO/AFRO region, where researchers could share their findings and strengthen their technical skills. This could also be a way to take stock of the ongoing or finalized areas of immunization research in WHO/AFRO region. This conference has a number of advantages, including 1) celebrating immunization research in Africa; 2) exchanging ideas and research findings; 3) facilitating collaboration amongst researcher; and 4) getting potential donor excited about funding research. WHO/AFRO should mobilize partners to support and organize the biennial immunization research conference.

Global

Networks for capacity building in research exist on the continent. The European and Developing Countries Trials Partnership (EDCTP) have set up centres of excellence for clinical trials. In addition, the Malaria Clinical Trials Alliance brings together well-built centres for clinical trials of medicines and vaccines against malaria. International association of national public health institutes, other international academic institutions can serve as platforms for a regional approach to research. Most research is multi-country and therefore a regional approach will help to standardize procedures, processes, timelines and formats of protocols.

Research financing

“Financing is one of the three fundamental enablers of research and innovation for health. Research for health funding is a critical component underpinning national capacity to build strong research for health systems and promote research for health that responds to local needs”. Strategic and timely funding of research is critical for informed policy-making. From the perspective of investment theory, research has a number of attributes that make it different from ordinary investment and often less attractive for investors. In practice a good proportion of research spending is the wages and salaries of highly educated scientists and scholars. Their efforts create an intangible asset, from which profits in future years will be generated. This fact has often affected financing for research and the conduct of research in the African Region. However, with the realization of the critical role of research to development, the Members States in the Abuja, Algiers, and Bamako Declarations state that countries should dedicate 2% of their national health budgets to research. Countries should also explore other financing mechanisms for research, including the 2014 report on Sustainable Investment in Research for Health.

Strong partnerships are needed to address and fund research priorities. Immunization programme donors may see the advantages of providing seed money for priority research activities in Africa.
Research coordination

To support country-centric research, a key need is to identify the research questions pertinent to country immunization programmes and then make those questions known to potential domestic, regional, and global partners with expertise and ability to support the country research. Partners may be national research institutes, academic institutions (e.g., universities, medical schools, schools of public health, schools of nursing, etc.), private sector, nongovernmental organizations, bilateral or multilateral partners, donors, and others. Ideally, one would wish to routinely gather the key questions and challenges that are identified by immunization programme managers and policy makers. A solution may be to institute a standard practice at EPI managers’ meetings, NITAG meetings, and the RITAG of identifying key questions and challenges that require solutions and collating these in a periodically updated list made publicly available. As an example, at the Kigali RITAG, when the RITAG drafts its recommendations, it should also identify some key research questions (e.g., on typhoid, Ebola, polio transition, etc.) which need to be addressed so that it will be possible to make progress in deciding policy. Similarly, EPI program managers meeting reports should also highlight priority questions that need further implementation research. No one knows the country and field questions better than EPI program managers, NITAG members, and RITAG members. Having such experts highlight the priority research questions would be a step towards making it easier for researchers and donors to focus on country and regional research priorities.

A multi-country immunization research also provides an option to coordinating research on immunization in the Region. WHO has long experience in organizing multi-country and multi-site implementation or intervention research projects to address common problems among countries in a region or countries suffering similar health challenges. A prime example is the community directed intervention studies sponsored through the UNDP/World Bank/UNICEF/WHO Tropical Disease research programme that brought research teams together from onchocerciasis endemic countries in Africa to design and carry out interventions that involved the community in improving delivery of ivermectin. This research proved the feasibility of a community platform for drug delivery that was adopted by onchocerciasis endemic countries and later adapted to other essential health commodity distribution and ultimately the mass drug administration approach to the control and elimination of five neglected tropical diseases.

The WHO AFRO could bring countries together to plan and learn from each other in studying and generating new knowledge surrounding immunization implementation across the region. Regional meetings such as AU Health Ministers, the WHO Region Committee meeting in the African Region and RITAG can be used to generate research questions that cut across countries in the region. WHO AFRO can function like TDR and seek funding (e.g. Gates) to support the regional/multi-country studies as well as provide the TA to bring country research teams together to plan study protocols as well as develop team capacity.
CONCLUSION

This framework is a first step towards building a comprehensive regional approach towards quality immunization research that is driven by country priorities. It provides guidance on priority areas of research in immunization in the African Region as well as a description of the implementation process. The framework is aimed at reducing mortality and morbidity from vaccine preventable diseases through stimulation of research to identify and overcome barriers in achieving high immunization coverage.

The development of the SFRI took place through a wide range of consultations with a diverse group of immunization stakeholders and partners ensuring the representation of their views and opinions to the delivery of immunization services in the African Region. However, the implementation of the SFRI will be defined by the challenges and opportunities in each country. Overall, it is envisioned that the SFRI will undergo periodic review and assessment to maintain its relevance to ongoing priorities of disease control and prevention in the Region.
REFERENCES


12 University of Texas Medical Branch. Center to Eliminate Health Disparities. 2017.


ANNEXES

Annex 1: Problems of immunization as identified among the countries in African Region during the first consultation workshop in Brazzaville

Figure 6: Problems of immunization as identified among the countries in African Region during the first consultation workshop in Brazzaville
Annex 2: Problems of immunization as identified among countries in AFRO from the second consultation workshop

Figure 7: Problems of immunization as identified among the countries in the African Region during the second consultation workshop in Brazzaville
Annex 3: EPI Framework

**INPUTS**

- **External Environment**
  - Social
  - Political
  - Economic
  - Geographic
  - Epidemiologic

- **Health Sector**
  - Service delivery
    - Infrastructure
    - Integration
  - Health workforce
    - Availability
    - Development
    - Integration
  - Medicines
    - Regulation & Policy
  - Financing
    - SWAP
    - Sources
  - Leadership & Governance
    - ICC
    - Planning Cycle
    - Plans of Action

**PROCESS**

- **Immunization Operations**
  - Management
    - Planning CMYP
    - Partner support
    - Supervision
  - Financing
    - Funding sources
    - Disbursement mechanisms
    - Availability
  - Service Delivery
    - Delivery strategies
    - Management structure
    - Quality improvement strategies
  - Logistics
    - Cold chain
    - Waste Management
    - Supplies and equipment
  - Surveillance
    - SOP availability
    - Lab functions
    - Community involvement
  - Communications
    - Advocacy
    - Social mobilization
    - Community involvement
  - Vaccine Supply and Quality
    - Vaccine forecasting/management
    - Vaccine procurement
    - Vaccine regulation
  - Capacity Building
    - Training (RED)
    - Community empowerment
    - Tool availability
  - Monitoring & Evaluation
    - Data quality
    - Data use
    - Internal and external report mechanisms

**OUTPUTS**

- Improved process outputs
  - Good access
  - High safety
  - Good quality
  - High trust

**OUTCOME**

- High coverage
- High equity
- High timeliness
- Low morbidity from vaccine-preventable diseases

**IMPACT**

**Figure 8: Expanded programmes on immunization framework**

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20
Annex 4: Sample research questions and methods from WHO/AFRO guide for implementation research

<table>
<thead>
<tr>
<th>Title</th>
<th>Thematic Area</th>
<th>Brief justification and objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional survey of polio antibodies</td>
<td>Thematic Area 1: Epidemiology of diseases and impact of vaccines</td>
<td>The failure to interrupt endemic polio transmission or risk of re-introduction in polio-free countries is linked with low vaccination coverage or population vulnerability due to waning immunity. Given the issues associated with coverage data, a sero-survey would be a way of assessing population immunity as well as validating the coverage data. Therefore, a cross sectional sero-survey among children both under and above 5 years of age is proposed.</td>
</tr>
<tr>
<td>Safety of Vaccines Used for Routine Immunization</td>
<td>Thematic Area 1: Epidemiology of diseases and impact of vaccines</td>
<td>As the number of recommended immunizations has expanded across the population, so too have concerns about the safety of vaccines. Thus, vaccine safety is high on public health agenda. Evidence on the safety of vaccines recommended for routine immunization has thus become expedient. The study will conduct a comprehensive and systematic review of scientific evidence, describes potential associations between vaccines and adverse events [27]</td>
</tr>
<tr>
<td>Clinical evaluation of Ebola vaccine candidates during the large West Africa Epidemic</td>
<td>Thematic Area 2: Clinical trials (phases 1-IV)</td>
<td>This study will test the safety of an experimental vaccine developed to protect against Ebola virus infection and to determine if the vaccine induces an immune response to the virus. The vaccine used in this study is made from small parts of Ebola genetic material. It cannot cause Ebola hemorrhagic fever to develop in those who receive it [28].</td>
</tr>
<tr>
<td>The Power of Malaria Vaccine Trials Using Controlled Human Malaria Infection</td>
<td>Thematic Area 2: Clinical trials (phases 1-IV)</td>
<td>Controlled human malaria infection (CHMI) in healthy human volunteers is an important and powerful tool in clinical malaria vaccine development. To optimize power calculations for malaria vaccine trials, we developed a non-linear, Bayesian statistical model for parasite kinetics as measured by quantitative real-time polymerase chain reaction, using existing data from mosquito-based CHMI experiments. Using our model, we provide improved, robust power calculations for various hypothetical malaria vaccine trials, taking account of important sources of variation between and within individuals[29]</td>
</tr>
<tr>
<td>Title</td>
<td>Thematic Area</td>
<td>Brief justification and objective</td>
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<tr>
<td>Investigating awareness on acute flaccid paralysis (AFP) of health workers</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>Sensitive AFP surveillance is necessary to guide the interventions. A number of health workers especially in private hospitals are not aware of the AFP surveillance procedures. Given that a significant proportion of patients go to such clinics, the inability to detect, investigate or report AFP on time will be a major fault in PEI. This study aims to assess AFP awareness of health care workers in public and private hospitals on AFP reporting.</td>
</tr>
<tr>
<td>Impact of community reward/competition on immunization coverage</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>Community-based interventions such as immunization require community participation and committed health workers. Rewards of communities to raise coverage levels have been successful elsewhere. It is however not clear how this principle will work with immunization programme in a different setting.</td>
</tr>
<tr>
<td>Identification of incentives and disincentives of vaccinators during SIAs</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>Even though vaccinators have clearly defined areas to cover during SIAs, they do not reach a significant proportion of children. Understanding why vaccinators do not cover the entire area assigned to will be helpful in guiding vaccination practice. The reasons are likely to vary according to setting. The aim of this research is to interview vaccinators in areas with low vaccination coverage.</td>
</tr>
<tr>
<td>Mutual expectations of health care workers and the community for improved coverage</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>There has been a consistent blame game between health workers and users of their services regarding their expectations in improving immunization service delivery. A mutual understanding of these expectations will help to improve programmatic activities, attitudes of health care workers, community participation and ultimately immunization coverage. This study aims to evaluate the impact on immunization implementation of agreements on mutual expectations between health care workers and the communities on both routine and SIAs immunization services delivery.</td>
</tr>
<tr>
<td>Validation of routine immunization coverage data</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>Administrative data tend to be the primary source of estimates on national and global vaccination coverage and immunization systems performance for WHO and UNICEF. However, the validity of administrative data has been questioned repeatedly, particularly in the African Region. Therefore, this study aims to assess the validity of administrative-based immunization estimates compared with health facility records and household survey data.</td>
</tr>
<tr>
<td>Title</td>
<td>Thematic Area</td>
<td>Brief justification and objective</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Knowledge of parents on polio and other VPDs in good and poor immunization coverage areas</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>Some areas persistently have poor routine and supplementary immunization coverage. Ignorance of the etiology, transmission, pathogenesis and prevention of VPDs could be responsible for poor community motivation and demand for vaccines in such areas. The approach in such a community will not be to push more SIAs but to educate them on the causes of the common childhood diseases and the role of immunization in preventing them. This study aims to assess the knowledge of parents on polio and other VDPs in settings with low and high immunization coverage.</td>
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<tr>
<td>Risk factors for delays in age-appropriate vaccination</td>
<td>Thematic Area 3: Implementation research and community participation</td>
<td>Immunization coverage with the first dose of DTP3 is about 90% in the Region and that for the three doses has plateaued at about 70%. The reasons for children dropping out from the schedule or delaying in getting vaccines need to be identified and addressed to improve coverage. This research aims to study the degree of timeliness of routine immunization and the reasons associated with vaccination delay.</td>
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Annex 5: Country Models for Immunization Research Implementation

Various models for research exist in the African region. The two most common models are the health research departments with research centres under the ministry of health and the health research centre under the ministry of science and technology. The SFRI summarizes a few of these models, highlighting their strengths and weaknesses.

**Ghana Model**

The Ghana Health Service has three Health Research Centres. These centers conduct research in the country, in addition to collaborations with universities, medical schools, and other health research institutes such as the Noguchi memorial institute for medical research of the University of Ghana. The centres, the Navrongo Health Research Centre in the northern belt, the Kintampo Health Research Centre in the middle belt and the Dodowa Health Research Centre in the coastal belt represent the three ecological zones. These centres are financed through the health budget, including staffing. The centres are however expected to undertake competitive grant writing to secure funding for their research whose priorities are set through the ministry of health and with a broad range of other stakeholders, including the WHO.

The three research centres have undertaken background epidemiological studies on malaria, meningitis and diarrhoea for example. They have also conducted clinical trials for drugs and vaccines against national, regional and global priority diseases, such as malaria, meningitis, rotavirus diarrhoea, to name a few. They have also undertaken several KABP studies and EPI coverage surveys. Some of the clinical trials undertaken by the centres are for the malaria vaccine, RTSS, conjugate Meningitis A vaccine (MenAfriVac), the ACW polysaccharide vaccine, the Heptavalent vaccine (Penta + AC conjugate), and Rotavirus vaccine (RotaTeq) and HPV vaccine.

The KABP Studies are on New Vaccine Introduction (Pneumo and Rotavirus vaccine introduction, 2nd Measles and Men A conjugate vaccine in the second year of life), the results
of which have been fed into IEC campaigns for the introduction of these vaccines by the country. There is a national research agenda developed for 2015–2019, which includes components of immunization research. There is a capacity building programme for the conduct of research at all levels. An annual dissemination forum of research findings is conducted in the Health sector.

The Ghana model gives responsibility for health research, including immunization research to the ministry of health and career researchers are an integral part of staffing of the ministry from national to provincial and finally to district level. Although funding for all research is not guaranteed, minimum funding is made available for national priorities, including immunization. The concept of embedding researchers in programmes is a strong point of the model.

**Mozambique Model**

A national research agenda was developed with the involvement of many stakeholders, bilateral and multilateral and includes the WHO. The priorities are infectious diseases, chronic noncommunicable diseases, health systems, maternal health, clinical trials and pharmacovigilance, basic sciences, traditional medicine, social science and anthropology.

Research is publicly funded and the research centre is under the ministry of science and technology. The objective of the National Fund for Investigation (FNI) is to promote research in the country and to support financially research activities according to the government priorities. Most of the funding (47% and 23%) go to agriculture and health respectively with the rest evenly distributed among other sectors. Immunization research is covered within the health research budget.

The Manhinca Health Research Centre is collaboration between Spain and Mozambique and its work covers malaria, HIV/STDs, TB, respiratory infections, diarrhoeal and others. Under these are maternal health, epidemiology, clinical and molecular studies, immunology and pathophysiology, drug and vaccine studies, monitoring and evaluation and social science.
The centre carried out studies to validate immunization coverage in Mozambique, identify reasons for low coverage and provided recommendations for addressing the gaps. As a result, twenty-eight districts were selected as priority based on the highest number of unimmunized children, a plan to intensify activities in these areas was elaborated, specific resources (financial) where allocated for these areas to intensify immunization activities (outreach activities), regular supportive supervision to these districts is undertaken. Other key researches undertaken are impact of HIB and rotavirus vaccine on disease burden and studies on HPV vaccines. Studies on RTS,S began in 2004 and include the phase 3 study. The centre promotes transparency, inclusiveness, openness, leadership and a defined process.

Unlike the Ghana model research in Mozambique is under the Ministry of Science and Technology and health as one of the sectors being addressed. There is guaranteed funding, even though low for research and not just for staff salaries as in Ghana. Research is thus career pursuit in Mozambique and not necessarily in the health sector. The extent of collaboration with the ministry of health in setting the agenda and identifying priorities is however unclear.