The Research Council of Norway

Work programme 2012–2020

2017 – second revision

Programme

Global Health and Vaccination Research – GLOBVAC

The Research Council of Norway

Work programme 2012-2020

(2017 - second revision)

Global Health and Vaccination Research
(GLOBVAC)

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Summary

Marginalised populations in low- and middle-income countries contribute disproportionately highly to the global burden of disease. A wide range of poverty-related health problems remain prevalent, including respiratory and diarrhoeal diseases, malnutrition, HIV/AIDS, tuberculosis, malaria, and maternal and perinatal health problems.

Norway has had a long-standing commitment to global health, particularly through the UN Millennium Development Goals (2000–2015) (MDGs), and, more recently, through its commitment to Agenda 2030/the Sustainable Development Goals (SDGs). Investing in global health research in Norway has a threefold perspective that also reflects the needs for research: i) the development perspective: research and research funding are limited to addressing the health problems of marginalised populations in LLMICs; ii) the health security perspective: the world has become more interconnected and potentially dangerous new or re-emerging infectious diseases might pose a challenge to the Norwegian health system and the global community; iii) the health diplomacy and political awareness perspective: global health research generates results, knowledge and competence that can support Norwegian interests in global health policy and participation in global health initiatives. Norway invests in a number of international, multilateral health initiatives. It is also in Norway's best interests to contribute to the global knowledge pool and to have a solid national knowledge base.

The primary objective of the Programme for Global Health and Vaccination Research – GLOBVAC is *to support high-quality research with a potential for high impact that can contribute to sustainable improvements in health and health equity for people in low- and lower-middle-income countries (LLMICs).*The secondary objectives are: 1) Strengthen internationally competitive and sustainable research groups and institutions in Norway; 2) Strengthen national and international research collaboration and partnerships; 3) Strengthen the capacity of research groups and institutions in LLMICs by supporting collaborative research and training, and 4) Increase awareness of the need for global health research among policymakers, researchers and the general public.

The programme has a wide scope, but will give highest priority to projects in the following thematic areas:

1) Prevention and treatment of, and diagnostics for, communicable diseases, particularly vaccine and vaccination research;
2) Family planning, reproductive, maternal, neonatal, child and adolescent health;
3) Health systems and health policy research;
4) Innovation in technology and methods development.

Research and innovation along the whole R&D value chain, and interdisciplinary research that addresses the greatest global health challenges is particularly encouraged. This investment in global health and vaccination research in Norway provides an opportunity to strengthen Norwegian research expertise in these areas that is timely and in line with international efforts. The sustainability of investments in this research field should be prioritised.

1 Background and challenges

The Programme for Global Health and Vaccination Research – GLOBVAC covers the period from 2011 to 2020. It is a continuation and expansion of the previous programme with the same name (2006–2011). The latter was part of Norway's commitment to the three Millennium Development Goals (MDGs) for health. Global health as understood by the GLOBVAC programme is:

'…an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide. Global health emphasises transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences and promotes interdisciplinary collaboration; and is a synthesis of population-based prevention with individual-level clinical care'.[1]

1.1 Global health challenges

Marginalised populations in low- and middle-income countries contribute disproportionately highly to the global burden of disease[2] and experience excessive morbidity, disability and mortality due to a range of communicable and non-communicable diseases. Annually, more than six million children below the age of five years die from diseases that are largely preventable and are due to causes that are relatively minor health problems in high-income countries. A wide range of poverty-related health problems remain prevalent, such as respiratory and diarrhoeal diseases, malnutrition, HIV/AIDS, tuberculosis, malaria, and maternal and perinatal health problems.[3] A number of diseases are neglected since they are largely absent in high-income countries. In addition, the burden of non-communicable diseases in these countries is increasing.[4]

Despite an impressive global effort to improve health outcomes for the poorest and most vulnerable segments of society through the MDGs, a wide range of poverty-related health problems remain prevalent. The goals of the health MDGs that have not yet been fully accomplished (the unfinished agenda) remain research priorities in GLOBVAC.

1.2 The need to invest in global health research

Norwegian investments in global health research have a threefold perspective:

I. The development perspective: health problems and inequitable health service delivery in LLMICs contribute substantially to the global burden of disease. The need for research and research funding to address them is substantial, but research funds in the LLMICs themselves are limited;
II. The health security perspective: the world has become more interconnected, and potentially dangerous new or re-emerging infectious diseases present new challenges to global health;

[1] Koplan, JP, Bond, C.P., Merson, M.H, Reddy, S., Rodriguez, M.H, Sewankambo, N.K.: *Towards a common definition of global health,* The Lancet, Volume 373, Issue 9679, 6–12 June 2009, Pages 1993-1995
[2] OECD: http://www.oecd.org/dac/stats/daclistofodarecipients.htm
[3] WHO: Global burden of disease project, http://www.who.int/healthinfo/bod/en/index.html
[4] Global action plan 2013-2020: Prevention and control of non-communicable diseases http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf

III. The health diplomacy and political awareness perspective: Norway invests in a number of international, multilateral health initiatives. It is also in Norway's best interest to contribute to the global knowledge pool and to have a solid national knowledge base that can support Norwegian interests in international health policy and participation in international health initiatives.

Norwegian investments in global health through GLOBVAC have increased during its two phases (Phase 1 2006–2011, Phase 2 2012–2020)[5], but they have recently been reduced despite calls for increased investment in research and development in SDG 3 – *Good Health and Well-being – ensuring healthy lives and promoting well-being for all at all ages*. There is a need for further commitment to global health research, both as a response to Agenda 2030 and in order to fully achieve the goals of the GLOBVAC programme.

The 2016 midterm evaluation of the GLOBVAC programme points out that GLOBVAC fills an important gap in the Norwegian funding landscape.[ibid.] It has been particularly successful in boosting national capacity for global health and vaccination research. The number of research groups and institutions that are involved in the field has increased significantly. There is a much greater degree of collaboration, both nationally and internationally, with a clear emphasis on North-South cooperation. The latter has contributed to essential capacity development in the South. The programme has already achieved some remarkable scientific successes that will have an important impact on the health of target populations. The scientific quality and relevance of the project portfolio are found to be good overall, with numerous projects achieving recognition at the international level.

Unlike the United Kingdom and the United States, Norway does not have a long-standing tradition of global health and vaccination research. Although the Norwegian government has long been an important funder of health and development programmes in LLMICs and a contributor to international health efforts, the amount of research conducted in Norway prior to the first GLOBVAC period (2006-2011) was relatively small and confined to a small number of institutions. One of the main goals of the programme is to strengthen this knowledge base by making dedicated funding available.

In Norway, there is broad political agreement that the official development assistance (ODA) budget should amount to at least one per cent of GDP. Research is an important and integral part of development aid, underpinning both development policy and development projects in LLMICs. White paper to the Storting 24 states that Norway supports knowledge production and international research collaboration, that Norway has a responsibility to contribute to global knowledge development and that research is an important basis for a knowledge-based development policy.[6]

1.3 Norwegian commitments

Agenda2030, also known as the *Sustainable Development Goals (SDGs),* was agreed upon in September 2015 by all UN member states, including Norway. A universal, integrated and transformative 2030 Agenda for Sustainable Development was adopted, along with a set of 17 Sustainable Development Goals and 169 associated targets. SDG 3 – *Good Health and Well-being –*

[5] Mid-term evaluation of the second Programme for Global Health and Vaccination Research (GLOBVAC2). Technopolis Group, 2016.

[6] White paper to the Storting no 24 (2016-2017) St.meld.24 Felles Ansvar for felles fremtid, Bærekraftsmålene og norsk utviklingspolitikk

ensuring healthy lives and promoting well-being for all at all ages – is highly relevant to GLOBVAC. It incorporates the unfinished agenda of the MDGs for health, but is much broader. SDG3 encompasses reproductive, maternal and child health; communicable, non-communicable and environmental diseases; universal health coverage; and access for all to safe, effective, high-quality and affordable medicines and vaccines. SDG 3 also calls for more research and development, health systems financing, and strengthened capacity in all countries for health risk reduction and management.[7] Norway is committed to Agenda2030, and it was one of the first UN member states to deliver a national review of the implementation process.

Norway was strongly committed to the objectives of the UN Secretary-General's *Global Strategy for Women's and Children's Health* (2010-2015). The strategy highlighted the inequities suffered by women and children around the world and set an agenda to save 16 million lives by 2015. It has been a key focus to increase access to life-saving commodities to secure the Continuum of Care[8] and to identify key interrelated barriers that prevent access to and use of essential medicines, medical devices and health supplies, with particular importance being attached to family planning, maternal and child health.[9] An updated Global Strategy was developed with strong Norwegian support. It was aligned with the new SDGs and launched in 2016. The strategy has widened its scope from only mortality reduction i.e. 'survival', to a broader perspective of 'thrive' and 'transform'. The updated strategy also includes a focus on adolescents. It has strengthened the focus on service quality and rights, placing clear emphasis on leaving no one behind.[10]

Norway is strongly committed to following up the London Summit on Family Planning 2020[11] to ensure that 120 million additional women and girls have access to effective family planning information and services by the year 2020. Priorities include barriers to the use of family planning services, the impact of interventions on family planning use, cost-effective strategies for mainstreaming integrated family planning services and novel financing mechanisms.[12]

Norway also supports a number of international health initiatives, such as the *Global Alliance for Vaccines and Immunization* (GAVI), the *Global Financing Facility* (GFF), the *Global Fund to Fight AIDS, Tuberculosis and Malaria* (The Global Fund) and *UNITAID*.

More recently, the Norwegian government has expanded its efforts into health security through commitments to the *Coalition for Epidemic Preparedness Innovations* (CEPI) and *Global Research Collaboration for Infectious Disease Preparedness* (GloPID-R). CEPI is a partnership between public, private and humanitarian organisations that will stimulate, coordinate and fund the development of vaccines against diseases with epidemic potential, particularly where development does not occur through market incentives. GloPID-R is a network of research funding organisations in the field of infectious disease preparedness research. Its goal is to facilitate an effective research response

[7] Read the entire goal here: https://sustainabledevelopment.un.org/sdg3

[8] The *Continuum of Care* for reproductive, maternal, newborn and child health (RMNCH) includes integrated service delivery for mothers and children from pre-pregnancy to delivery, the immediate postnatal period and childhood. Such care is provided by families and communities, through outpatient services, clinics and other health facilities (WHO, The Partnership for Maternal, Newborn and Child Health, 2013)

[9] Report: UN commission on Life Saving Commodities for Women and Children. 2012 http://www.everywomaneverychild.org/images/UN_Commission_Report_September_2012_Final.pdf

[10] Global Strategy for Women's, Children's and Adolescents' Health (2016-2030) – Survive, thrive, transform *http://www.who.int/pmnch/media/events/2015/gs_2016_30.pdf?ua=1*

[11] http://www.familyplanning2020.org/ and Summaries of Commitments after the London Summit 2012

[12] Examples of identified research gaps according to http://www.popcouncil.org/pdfs/2013RH_FP2020RRPolicyBrief.pdf

within 48 hours of a significant outbreak of a new or re-emerging infectious disease with pandemic potential.[13]

1.4 Programme challenges and priorities

GLOBVAC has managed to boost national research capacity during the period 2006–2015, but many of the research groups are not yet self-sustainable. Research projects on health systems and policy, implementation and innovation are underrepresented in the portfolio,[14] and many groups have not yet matured to the level where they can compete in the international arena.

In order to build on the impact made to date, the programme will maintain a clear focus on a limited number of thematic areas, but allow for flexible interpretation of them. The programme generally supports projects at the downstream end of the R&D value chain – where the visible impact is most immediate – but GLOBVAC is also an important funder of upstream basic research. It is challenging to strike an appropriate balance between the two, and to provide opportunities for researchers to move their projects forward along the value chain.

In recent years, there have been constraints on the development aid budget for research on global health as defined by the programme. While much progress has been made, there is broad consensus that the investments made to date are just beginning to have an impact and that more needs to be done to strengthen national research capacity in the field of global health.

2 Objectives of the programme

GLOBVAC is a targeted research programme that provides funding for public and private research groups in Norway within the field of global health and vaccination research.

2.1 Primary objective

The primary objective of GLOBVAC is to support high-quality research with a potential for high impact that can contribute to sustainable improvements in health and health equity for people in low- and lower-middle-income countries (LLMICs).

2.2 Secondary objectives

The secondary objectives are:

1. Strengthen internationally competitive and sustainable research groups and institutions in Norway;
2. Strengthen national and international research collaboration and partnerships;

[13] Other global funds and initiatives supported by Norway are: research programmes through the World Health Organization (WHO), the World Bank, the United Nations Development Programme (UNDP), the United Nations Children's Fund (UNICEF), the United Nations' Global Strategy for Women's and Children's Health, the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) and various product development partnerships (PDPs). Norway contributed to vaccination research through the International AIDS Vaccine Initiative (IAVI) from 2001 until 2015. Finally, an Indo-Norwegian collaboration on vaccine research was initiated in 2006 between the Research Council of Norway and the Department of Biotechnology (DBT), India. It included both human and fish/veterinary vaccines.

[14] Midterm evaluation of the second Programme for Global Health and Vaccination Research (GLOBVAC2). Technopolis Group, 2015. The recommendations from the midterm evaluation have been discussed and included in the programme plan.

3. Strengthen capacity of research groups and institutions in LLMICs by supporting collaborative research and training;
4. Increase awareness of the need for global health research among policy makers, researchers and the general public.

3 Thematic and scientific priority areas

Research is important to improve prevention, treatment and diagnostics of diseases that are major health problems in LLMICs. Evidence-based advice that is grounded in research is considered crucial in order to ensure the best possible focus on national and international priorities in global health.

In order to safeguard the principle of health equity, priority will be given to research that benefits the most vulnerable populations and/or those in poorly resourced settings. They can be defined as populations and groups that are characterised by poverty, lagging health outcomes relative to the rest of the host country, or by having the least access to treatment/prevention/adequate health services.

Multidisciplinary and interdisciplinary research approaches are of great importance. Research that cuts across two or more of the four thematic areas below can thus be of high relevance. Implementation research is key to the effective deployment and scaling-up of efficacious health interventions. Projects involving research into cultural and social dimensions of the given thematic areas are encouraged. Although the programme has a wide scope, priority is given to projects within one or more of the thematic areas.

The four thematic areas in GLOBVAC are chosen on the basis of several important factors. Vaccines are considered to be among the most cost-effective interventions. Research to improve reproductive, maternal, newborn, child and adolescent health is one of the remaining global challenges after the MDGs. Health systems and health policy research are recognized as key to making sustainable improvements in health. Innovation and the development of affordable and appropriate technologies for resource-constrained settings will make important contributions to solving some of the health problems in these areas.

3.1 Prevention and treatment of, and diagnostics for, communicable diseases, particularly vaccine and vaccination research

This thematic area includes all aspects of epidemiology, diagnostics, discovery/design of therapeutics and vaccines, development, evaluation/testing of medicines and vaccines, and delivery/implementation of vaccination/treatment strategies, including cultural perspectives on vaccination. Vaccine and vaccination research are given high priority since vaccines are considered to be among the most cost-effective interventions. Research that can lead from pre-clinical to clinical testing and participation in international product development, with the focus on diseases/pathogens that are a major global health burden, is particularly encouraged.

3.2 Family planning, reproductive, maternal, neonatal, child and adolescent health

Research aimed at improving reproductive, maternal, newborn, child and adolescent health, including child growth and development, contraceptive methods to delay and plan pregnancies, and safe abortion, is an important objective as these areas are considered key to improving health and survival among these groups in LLMICs.

This thematic area includes the production and application of knowledge to meet the need for an improved continuum of care for reproductive,[15] maternal, newborn, child and adolescent health. It encompasses all relevant health issues and health research (relating to both communicable and non-communicable diseases) and extends the maternal and child survival agenda to also include addressing health issues relating to the rights of women, adolescents and children, family planning, promoting child growth and development and an increased focus on adolescents. The research can involve a variety of disciplines, e.g. clinical medicine, epidemiology, economics, psychology, psychiatry, nutrition, sociology, anthropology, political science, philosophy/ethics, cultural studies and law. Research and innovation in accordance with Family Planning 2020 and the Global Strategy for Women's, Children's and Adolescents' Health 2016-2030 are considered to be particularly relevant.

3.3 Health systems and health policy research

This thematic area includes the production and application of knowledge to improve how societies organise themselves in order to achieve health goals. It encompasses how societies plan, manage and finance health services, as well as investigating the role and interests of different actors in the health system. It includes research on how health systems function in relation to human resources, health services, health information systems and supply chain management systems. Implementation research is also included in the thematic area of health systems and health policy research. It draws upon a variety of disciplines, including economics, sociology, anthropology, political science, law and epidemiology. Research can include cultural and social dimensions that influence health systems, and what can be considered to constitute resilient health systems. Local, national and international research approaches and foci can be applied.

3.4 Innovation in technology and methods development

Innovation and the development of affordable and appropriate technologies for resource-constrained settings will make important contributions to solving some of the health problems in LLMICs.

[15] 'Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are the right of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law, and the right of access to appropriate health-care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant. In line with the above definition of reproductive health, reproductive health care is defined as the constellation of methods, techniques and services that contribute to reproductive health and well-being through preventing and solving reproductive health problems. It also includes sexual health, the purpose of which is the enhancement of life and personal relations, and not merely counselling and care related to reproduction and sexually transmitted diseases.' - Final Plan of Action, United Nations International Conference on Population and Development (ICPD), Cairo, 1994

This thematic area includes research and innovation for the development of technology and methods that can help to meet the needs of patients and health personnel where appropriate technologies are either not available or do not exist. This includes developing high-quality products for prevention, diagnosis and treatment that are appropriate, accessible and affordable in resource-constrained conditions.

4 Priorities for structuring the research effort

In order to achieve its primary objective of contributing to sustainable improvements in health and health equity for target populations in LLMICs, the programme will provide substantial support for internationally competitive research projects of the highest quality and with a potential for high impact. Research is key to improving knowledge-based determination of national and international priorities. In addition to the importance of project quality and the potential for impact, multidisciplinary and interdisciplinary research approaches are needed to meet many global health challenges. There is also a need to strengthen capacity in certain research areas in order to build a stronger foundation for future global health research, both in Norway and in LLMICs.

4.1 Types of support

The programme has various types of support available that are used by the Research Council of Norway. The different types of support will be adapted to the needs of the programme to ensure that they meet its objectives. To the extent possible within the programme framework, GLOBVAC aims to be innovative in its use of different support mechanisms to strengthen research capacity in Norway and in LLMICs. Some of the programme's thematic areas have a weaker researcher base than others. The programme will need to develop and implement special measures to promote higher quality. Dedicated competitive arenas for areas with special needs, networking calls and/or calls for outline pre-proposals for projects may be relevant options. Examples of types of support that can be used by the programme are:

- Researcher Project
- Young Research Talents
- Personal Doctoral Research Fellowship with mandatory stay in LLMICs
- Innovation Project for the Industrial Sector
- Outline pre-proposals for projects
- Personal Overseas Research Grant
- Support for Events
- Support for Researcher Networks
- Support for Researcher Schools

4.2 Types of research

Research and innovation along the whole R&D value chain can be funded, and interdisciplinary research that addresses the biggest global health challenges is particularly encouraged. The programme is broad, but the types of research that are particularly relevant to each thematic area are described above.

Multidisciplinary and interdisciplinary research approaches are of great importance. Research that cuts across two or more of the four thematic areas above can thus be highly relevant. Projects that

involve research on cultural and social conditions of relevance to the thematic areas are encouraged. Implementation research should also be emphasised as highly relevant to all the thematic areas.

Implementation research is key to the effective deployment and scaling-up of efficacious health interventions. This includes research to promote the uptake of research findings in public health programmes, and to expand knowledge about strategies for implementation and wider scaling-up of effective health interventions and health services.[16] Research must be based on, and linked to, health implementation activities in LLMICs.

4.3 Norwegian capacity-building and national collaborations

The programme's investments in global health and vaccination research in Norway provide an opportunity to build Norwegian research expertise in this field that is timely and in line with international efforts. The programme will support public and private Norwegian research groups and institutions. Norway has a number of research groups working on infectious diseases, maternal and child health, and health systems research.

Strengthening research capacity at Norwegian institutions, including research training at PhD and postdoc level, should be an integral part of all projects. National collaborations should be strengthened, taking advantage of complementary competence. This includes:

- Recruiting new researchers in Norway, e.g. by providing support for training and career development;
- Recruiting new research groups with expertise that is relevant to global health;
- Encouraging long-term commitments by Norwegian research institutions, for example providing positions and ensuring the continuation of activities beyond the duration of the projects and the programme;
- Alignment and potential coordination with other relevant and related Norwegian actors/funders/investments, including other funding mechanisms used by the Research Council, Norad (the NORHED programme), the Norwegian Forum for Global Health Research, foundations, charities, philanthropic sources and others;
- Stimulating contributions from the private sector to public-private partnerships in global health and vaccination research.

The programme already supports the Norwegian Research School of Global Health[17] and the Norwegian Forum for Global Health Research,[18] which has also been important in the work on establishing Global Health Norway[19].

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[16] There are several definitions of implementation research and science. The joint Framework for Operations and Implementation Research in Health and Disease Control Programs developed through a collaborative effort between the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the Special Program for Research and Training in Tropical Diseases (TDR) and an inter-agency technical working group guide GLOBVAC's activities in this area, http://www.who.int/hiv/pub/operational/framework/en/index.html . More information is also available through the Implementation Research Platform managed by the Alliance for Health Policy and Systems Research http://www.who.int/alliance-hpsr/en/

[17] https://www.ntnu.edu/nrsgh

[18] http://www.globalhealth.no/

[19] Global Health Norway consist of four regional health authorities, four universities and one representative from the Norwegian Institute of Public Health. The aim of the network is to strengthen cooperation, coordination and development between Norwegian institutions working in the field of global health, research, education and competence building. It is a virtual network, and was officially launched on December 6th 2017.

Social science institutes at Norwegian universities and several independent Norwegian research institutes have extensive experience of research based in low- and lower-middle-income countries and of good collaborations in LLMICs, e.g. research on conflict studies, human rights and gender. Several of these institutions already carry out health-related research and can be encouraged to target their research even more towards global health issues.

4.4 Internationalisation

The GLOBVAC programme is, by its nature, internationally focused. Internationalisation should be strengthened through collaboration and partnerships between Norwegian research environments and highly qualified international research groups and institutions in order to produce high-quality research that is relevant to health improvements and health equity in LLMICs. Funding from the programme should primarily go to Norwegian research groups and partners, and activities in LLMICs.

Research partnerships should be encouraged and facilitated, both where international research groups and institutions can become partners in proposals to the programme from Norwegian institutions, and where Norwegian research groups can become partners in international research projects. The programme should assist and guide Norwegian researchers to apply for funding through Horizon 2020, and particularly through *The European & Developing Countries Clinical Trials Partnership (EDCTP)*. Collaboration between Norwegian and high-quality Nordic research institutions in global health will also be encouraged in order to take advantage of and add value to similar research infrastructures and political priorities in global health.

4.5 Strengthen the capacity of research groups and institutions in LLMICs by supporting collaborative research and training

Norwegian institutions with activities in LLMICs should enter into partnerships with local institutions and contribute to strengthening research capacity in the context of the project. Projects should also emphasise the co-production of knowledge with relevant users and stakeholders, both in Norway and in LLMICs, when designing and implementing research and research results. By their nature, research funding programmes are not optimally suited to sustainable and systematic capacity development in LLMICs, because the funding is tied to specific projects that usually have a duration of around three to five years. However, strengthening capacity through research collaboration remains one of the pillars of GLOBVAC. GLOBVAC will provide support for equal partnerships and to increase the pool of highly competent researchers in LLMICs, thus *strengthening* existing research capacity.

LLMICs' ownership of the research agenda is important, and, although the funding conditions require a Norwegian institution to be the project owner, LLMIC co-investigators are encouraged to have a leading role in project proposals. GLOBVAC will allow researchers from LLMICs to be PIs in research and Young Researcher Talent projects. Collaboration with LLMICs is understood to mean collaboration in all phases of a project, from the development of a research proposal to the publication of results and dissemination to policymakers. This includes having partners from these countries contribute to researcher training (PhD, post doc.) and leadership development (e.g. Principal Investigators), support for research activities in these countries, ensuring open access publications, support for research equipment and support for training, e.g. in research methods or academic writing.

The programme should build on and collaborate with other capacity-building programmes to secure support for junior faculty and for researchers to return to or establish research groups in their home countries. Capacity strengthening in LLMICs will be facilitated by establishing stronger connections and better alignment and coordination with other Norwegian investments.

4.6 User involvement, benefit and identification of needs

To achieve relevant research and good implementation strategies for providers of health services/ treatments/vaccinations in LLMICs, it is necessary to incorporate the experiences and views of users, e.g. as regards the language used, demonstration techniques or dissemination processes.

User involvement. Users are to be involved in all phases of the research process that they and the researchers find relevant. User involvement will help to better define priorities, devise more relevant research questions and enhance the benefit to society of the research. Users in GLOBVAC-funded research are participants in studies (clients/patients) and the communities in which they live, next-of-kin/family members of participants, international organisations working on global health, companies, governments and policymakers in LLMICs, and members of the public in LLMICs who are likely to eventually use the research results.

Benefit. The research will form the basis for new knowledge that is relevant to a knowledge-based healthcare policy. The knowledge acquired is considered beneficial if it is applicable and can be used in practice. This can take the form of designing new measures that can be implemented at the national level in LLMICs to improve public health and whose impact is subsequently evaluated. Research related to the prevalence and causes of ill health and good health must be viewed in the context of its benefit to the population.

Identification of needs. The programme will endeavour to generate new knowledge based on documented knowledge gaps and knowledge needs identified by users and other relevant actors. This will help to increase the benefit of the research to the population and the public authorities. The identification of needs entails systematic preparatory work prior to selecting the research questions to be addressed. Research activities should build on and supplement previous research and must therefore be based on systematic overviews of previous research, when relevant.

4.7 Gender balance and gender perspectives

GLOBVAC follows the Research Council of Norway's policy for 'Gender balance and gender perspectives in research and innovation, 2013–2017'. The policy states that the RCN will work more systematically to promote gender balance within projects funded by the RCN. GLOBVAC will strive to achieve one of the main goals of the strategy, namely to increase the proportion of female project managers and women in senior academic positions.

A gender perspective in research implies that biological and social gender is reflected in research content. A growing number of studies show that diversity, including gender balance and gender perspectives, helps to enhance the scientific quality and social relevance of research. Gender perspectives will be integrated in all research activity funded by the Research Council. Gender

perspectives in research are especially relevant to GLOBVAC. The programme's main objective concerns health and health outcomes for marginalised populations in LLMICs. A majority of them are women and some of the most pressing health challenges are related to women, e.g. improving maternal health.

4.8 Ethical perspectives in research

All research and innovation must conform to basic ethical principles and comply with the Health Research Act.[20] Research in the medical and health sciences is closely regulated in national and international laws, regulations and conventions. Research projects designed to produce new knowledge about health and disease and that involve human subjects must be assessed and approved by the Regional Committees for Medical and Health Research Ethics (REC). The projects must also be ethically approved in the countries where they are implemented, and sometimes in the countries of project partners. These approvals must be obtained to ensure that scientific and medical progress is not achieved at the expense of the rights and integrity of the individual, and to regulate the obligations of researchers.

4.9 Social dialogue and meeting places

The programme's results should have an impact on and be important to policymakers in Norway and in LLMICs, and to health and service providers, patients, family members/next-of-kin, business and industry, and society at large. Diverse communication and dissemination activities are required in order to reach the intended target groups. The programme aims for high visibility, and communication and dissemination activities should contribute to:

- Attracting excellent research groups as applicants to the programme;
- Demonstrating results from the programme to the research community, to stakeholders and users in LLMICs and Norway, to international organisations working on global health and to the general public;
- Informing policy debate and increasing awareness of health as a public good and fundamental right.

4.9.1 Communication activities by the Research Council

GLOBVAC will establish a variety of meeting places for researchers and stakeholders. The communication activities will be designed so that they support the main goals of the programme. A separate communication plan will specify communication and dissemination goals and activities. It will be updated annually.

The main meeting place organised by the programme is the bi-annual GLOBVAC conference. It is a meeting place for Norwegian and international researchers, students, health professionals, policymakers, representatives of the biotech industry, and others with an interest in global health. It is an arena for presentations and discussions on topical subjects relating to research for improved health in LLMICs and of relevance to Norwegian research environments. The conference is the main platform and meeting place for all GLOBVAC-supported research projects within all the thematic areas of the programme.

[20] ACT 2008-06-20 no. 44: Act on medical and health research (the Health Research Act) https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=Helseforskningsloven

The programme website is the main source of updated information about the programme, including calls for proposals, information about annual conferences and key documents. The Research Council of Norway maintains a database of all funded projects, Prosjektbanken, which contains key information about all projects funded by the RCN, including GLOBVAC.[21] GLOBVAC has an electronic newsletter service that is available to subscribers who are interested in information about programme activities.

The Norwegian Forum for Global Health Research is an important partner for GLOBVAC with regard to communication and dissemination activities. The Forum's website contains comprehensive information about external conferences and funding opportunities, and a searchable database of all Norwegian global health research projects. The Forum also organises a national conference on global health that is partly funded by GLOBVAC, and is held between the biennial GLOBVAC conferences.

4.9.2 Communication and dissemination by GLOBVAC-funded projects

In order for the GLOBVAC programme to achieve its intended outcome and impact, it is essential that findings from research activities are disseminated so that they can be translated into relevant technologies and interventions.

Projects funded by GLOBVAC are expected to communicate and disseminate through different channels, depending on the intended audience:

- Academic publishing in national and international journals
- Co-publications with LLMIC-based researchers
- Presentations at the biennial GLOBVAC conferences
- Popular science dissemination, including in social media
- Dialogue and meeting places to facilitate knowledge transfer between researchers, stakeholders and users in LLMICs and Norway, including the business sector, international organisations working on global health and the general public.

5 Cooperation with related instruments

5.1 Programmes in the Research Council

GLOBVAC is one of four health research programmes at the Research Council of Norway. The goal of the programmes is to provide funding for research that can address the major health and societal challenges and add value to the developing Norwegian health research and innovation sector. The three other health research programmes are:

- Better Health and Quality of Life (BEDREHELSE), which is aimed at promoting research and research-based innovation of high quality and benefit to society that can help to improve public health, enhance quality of life and reduce social inequalities in health.
- High-quality and Reliable Diagnostics, Treatment and Rehabilitation (BEHANDLING), which is aimed at supporting clinical research activities to help to ensure that patients receive high-quality and reliable diagnostics, treatment and rehabilitation throughout their disease trajectory.

[21] GLOBVAC projects in Prosjektbanken

- Health, care and welfare services research (HELSEVEL), which is aimed at promoting research and innovation that enhances quality, competence and efficiency in health, care and welfare services.

The four programmes will prioritise their respective research areas in a comprehensive way in order to find synergies and cross-sector areas for collaboration. Possibilities for joint calls for funding will be explored.

Norway Global Partner (NORGLOBAL2) aims to develop research-based knowledge of high quality on poverty reduction and sustainable development, in support of global efforts towards achieving the SDGs. Its priorities are global education, humanitarian efforts, conflict, security and fragile states, business development and job creation, the environment, climate and renewable energy. Health research is not among the primary research areas for NORGLOBAL2. However, social science research on health that includes aspects relating to the priority areas of the programme might be relevant.

Other potential programmes for innovation and technology development at the Research Council that may be suitable for collaboration are User-driven Research-based Innovation (BIA), ICT and digital innovation (IKT Pluss) and Commercializing R&D results (FORNY2020).

The VISJON2030 activity was initiated by the Ministry of Education and Research, the Ministry of Health and Care Services and the Ministry of Foreign Affairs in 2014. It is a joint initiative between Norad Innovation Norway and the RCN. VISJON2030 funds innovation projects in education and health to combat poverty, and possible mutual interests and synergies with this funding mechanism will be explored.

5.2 International funding schemes

The GLOBVAC programme should collaborate with international funding schemes where clear benefits/leverage can be anticipated and in accordance with available programme funding. International collaboration should be strengthened through measures such as:

- Sustaining established productive collaborations;
- Building on activities that are linked to existing Norwegian investments abroad, in particular to the EU Framework Programme for Research and Innovation (Horizon 2020) and other strategic Norwegian investments in global health, nationally and internationally;
- Developing strategic partnerships with key international actors, such as the World Health Organization (WHO), the US National Institutes of Health (NIH),[22] funders of international research (e.g. trust funds), research institutions, product development partnerships (PDPs).
- Encouraging the establishment of consortia of leading research groups with co-funding from other agencies.

Horizon 2020 is the world's largest research and innovation programme, with an overall budget of EUR 70–80 billion over a seven-year period. The framework programme is also an important source of funding for Norwegian institutions. Project collaboration and co-publication with European colleagues have increased significantly over the years. However, compared with the other Nordic

[22] A letter of intent was signed between the US National Institutes of Health (NIH) and the Research Council of Norway in April 2010 to foster collaborative biomedical and health research of excellent standard.

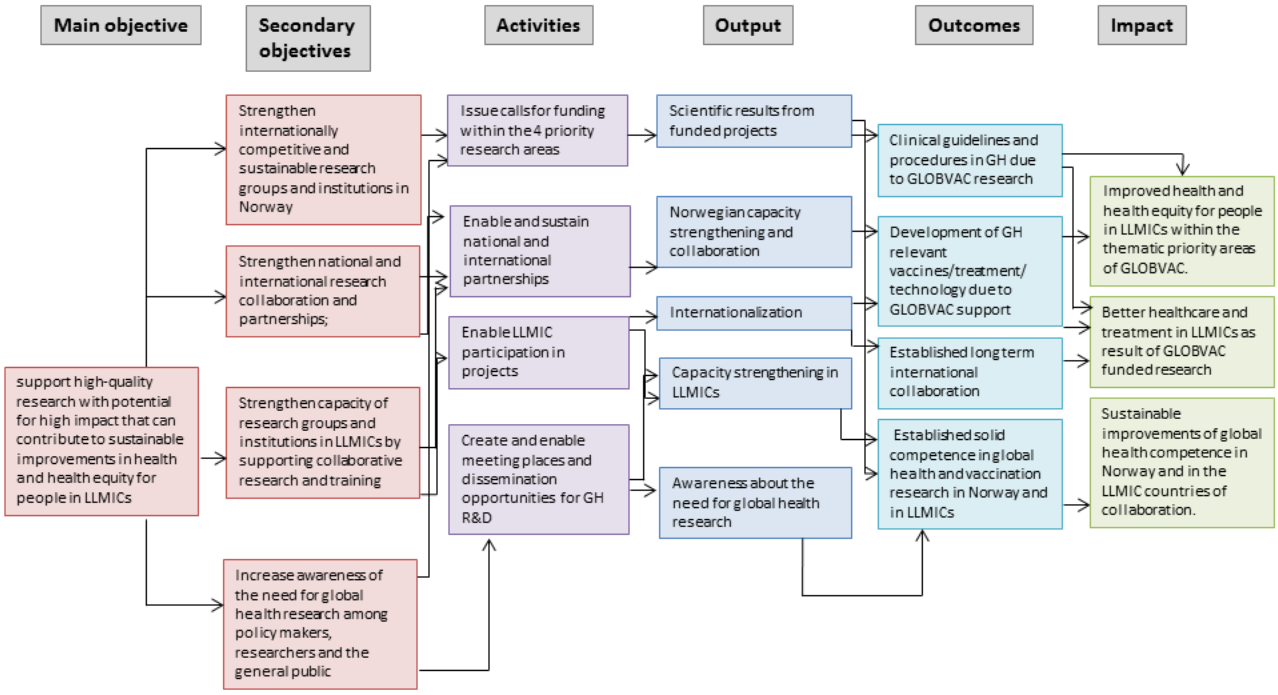
countries, Norway has considerable room for improvement as regards applying for funding from the EU, and this issue is a priority for the RCN.

The European & Developing Countries Clinical Trials Partnership (EDCTP) is part of Horizon 2020. Through European research integration and in partnership with sub-Saharan African countries, EDCTP intends to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria, as well as other poverty-related infectious diseases in sub-Saharan Africa, with the focus on phase II and III clinical trials. The RCN represents Norway in the second phase of EDCTP (EDCTP2), and co-funding opportunities will be investigated.

GLOBVAC will mobilise Norwegian researchers to develop project applications for the EU's Horizon 2020 and other international funding mechanisms, e.g. GloPID-R and CEPI. Possible mutual interests and synergies with these funding mechanisms will be explored.

6 Anticipated output, outcomes and impacts

GLOBVACs primary objective is to support high-quality research with a potential for high impact that can contribute to sustainable improvements in health and health equity for people in low- and lower-middle-income countries (LLMICs). To achieve this goal, a framework has been developed for measuring and assessing the output (results), outcomes and impacts of the programme. It is presented in the programme logic model below.



Programme logic model for GLOBVAC. Note that due to space limitations phrasing in the model might deviate from the text. Further explanation of the model is included in sub-chapters 6.1-6.3.

It is necessary to ensure that the programme develops in the intended direction through continuous monitoring and self-assessment. All activities in the programme, including new calls, are specified in the three-year action plan, which is updated annually. The programme will be monitored through portfolio analysis and annual programme reports, and the action plan will be adjusted accordingly.

The Health Research Classification System (HRCS) will be used in analyses of the portfolio. The HRCS is a tool developed in the UK[23] to analyse research activity of relevance to health and disease. The HRCS classifies all research in all fields and disciplines in the area of health along two dimensions: *Research Activity and Health Category.*

The programme will also actively incorporate the Health&Care21 monitor.[24] This monitor will compile knowledge about the resources, results and impact of research and innovation in the health and care field, and will include indicators for all the focus areas in the Health&Care21 strategy. The monitor will be an important management tool for the various actors in their efforts to follow up the Health&Care21 strategy.

The GLOBVAC programme was evaluated in 2015/2016. The recommendations from this evaluation have been taken into consideration in the present document and will be implemented in line with the present budget framework. A final evaluation of the present programme period is tentatively planned for 2019.

6.1 Output (results)

The anticipated output is here understood as the results from individual research projects or activities funded or supported by the programme. Output can typically be measured at the end of the individual research projects or shortly afterwards (normally within a three-year period):

6.1.1 Scientific output (results) and knowledge accumulation from GLOBVAC activities and funded projects

Projects funded by GLOBVAC are expected to make relevant and useful scientific findings. The number of high-level project proposals submitted to GLOBVAC calls is also expected to increase with time. Indicators measuring scientific output and knowledge accumulation during the programme period are:

- Number of scientific publications resulting from funded projects (also broken down by each thematic area);
- Number of scientific publications with authors from different disciplines and research fields, e.g. social science and medicine;
- Number of scientific publications in Open Access,
- Quality of the publications measured as citation frequency and impact factor;
- Number of patents resulting from funded projects;
- Number of prototypes resulting from funded projects.

[23] Visit http://www.hrcsonline.net/ for more on HRCS.
[24] Visit https://www.helseomsorg21monitor.no/ for more information.

6.1.2 Capacity strengthening and national collaboration between Norwegian global health researchers and groups

The programme will strengthen research capacity in global health and vaccination research in Norway. National collaboration across different institutions and disciplines should be strengthened in order to take advantage of complementary competence. Indicators measuring Norwegian capacity strengthening and national collaboration are:

- Number of project proposals submitted to GLOBVAC calls with the marks 5, 6 and 7;
- Number of project proposals submitted to GLOBVAC calls with user involvement and the marks 5, 6 and 7;
- Number of recruitment positions in GLOBVAC projects (doctoral degrees, postdoc positions and Young Researcher Talents) awarded to male/female applicants;
- Number of new senior researchers with GLOBVAC-funded projects (male/female);
- Number of GLOBVAC-funded consortia, including research groups from different Norwegian institutions;
- Number of private companies with projects in global health and vaccination research:
- Established/funded PhD schools and research centres dedicated to global health and vaccination research at Norwegian institutions.

6.1.3 Internationalisation

Internationalisation should be strengthened through collaboration and partnerships between Norwegian research environments and highly qualified international research groups and institutions. Output indicators for internationalisation are:

- Number of funded projects with partners from key international institutions or organisations;
- Number of funded projects with partners from Nordic institutions;
- Number of funded projects that have international co-funding;
- Number of Norwegian leads and co-applicants to Horizon 2020 within the field of global health and vaccination research;
- Number of scientific publications with co-authors from key Nordic institutions;
- Number of scientific publications with co-authors from other key international institutions.

6.1.4 Strengthen the capacity of research groups and institutions in LLMICs by supporting collaborative research and training

GLOBVAC encourages capacity strengthening in the context of the research project. Output indicators for capacity strengthening and training are:

- Number of recruitment positions in GLOBVAC projects (doctoral degrees, postdoc positions and Young Researcher Talents) awarded to researchers from LLMICs (male/female);
- North-South collaboration: Number of GLOBVAC-funded consortia including research groups from Norway and from one LLMIC;
- South-South collaboration: Number of GLOBVAC-funded consortia including research groups from several LLMICs;
- Number of PIs (co- and primary) from LLMICs in GLOBVAC-funded projects (male/female);
- Number of publications co-authored with researchers from LLMICs;
- Number of publications co-authored with researchers from LLMICs (in level 2 publications).

6.1.5 Increase awareness of the need for global health research among policymakers, researchers and the general public

GLOBVAC encourages increased awareness of global health research through communication and dissemination activities. Output indicators are:

- GLOBVAC conference organised by the RCN
- Other seminars organised by the RCN
- Support provided for conferences/seminars
- Support provided for networks

6.2 Outcomes

The outcomes show the implementation of project output/results. The outcome indicators demonstrate to what extent GLOBVAC has reached its objectives. The outcomes can typically be measured within four to six years.

6.2.1 Clinical guidelines and procedures in global health as a result of GLOBVAC-funded research

- Development or revision of clinical guidelines and protocols relevant to global health practices in LLMICs
- New or revised guidelines and/or protocols approved by WHO
- The use of new or revised guidelines and/or protocols in public health programmes in LLMICs or by international implementation/roll-out programmes.

6.2.2 Development of new vaccines/treatment or medical technology due to GLOBVAC support

- New or improved products that can lead to medicines, vaccines and diagnostic tools
- New or improved medicines, vaccines and diagnostic tools
- The use of/recruitment of new candidates for vaccines, diagnostic methods or medicines from GLOBVAC projects in international clinical trials
- The use of vaccines, diagnostic methods or medicines in public health programmes in LLMICs or by international implementation/roll-out programmes.

6.2.3 Established long-term international collaboration

- Duration of collaboration with specific groups in high-income countries
- Duration of collaboration with specific groups in LLMICs
- New collaborations with groups in LLMICs and in high-income countries

6.2.4 Established solid competence in global health and vaccination research in Norway and in LLMICs

- Established research groups actively engaged in global health research at different Norwegian institutions (measured through group output such as publications, ability to attract external funding, international funding, and international recognition);

- Established research groups actively engaged in global health research at different LLMIC institutions (measured through group outputs such as publications, ability to attract external funding, international funding, and international recognition);
- Established private Norwegian companies actively engaged in research and development for global health;
- Established new institutions in Norway dedicated to global health research with institutional long-term support for global health research (researcher schools, new faculties, centres of excellence or institutes).

6.3 Impact

The impact on society as a whole is here understood as to the extent to which the primary objective of the programme has been or can be expected to contribute to:

- Improved health and health equity for people in low- and lower-middle-income countries (LLMICs) within the thematic priority areas of GLOBVAC.
- Better healthcare and treatment in LLMICs as a result of GLOBVAC-funded research
- Sustainable improvements in global health competence in Norway and in the collaborating LLMIC countries.

7 Resources and budget

The main funders of the programme are the Ministry of Foreign Affairs (MFA) through Norad, and the Ministry of Health and Care Services. At present, the emphasis should be on the unfinished agenda of the health-related MDGs, and the thematic priorities indicated in Chapter 3. More funding must be secured to allow an expansion of the programme to fully encompass the complexity of SDG3, e.g. to include non-communicable diseases to a greater extent (beyond the present limitations, where they are only included when related to nutrition and maternal and child health), health security and environmental health. Both ministries should have a mutual interest in funding global health research to ensure Norwegian knowledge-based input to international policy debate and diplomacy, e.g. WHO processes.

Some of the projects GLOBVAC wants to fund are costly, e.g. multi-country clinical trials or large interdisciplinary studies. It is important that projects receive sufficient funds to cover all necessary costs in order to enable appropriate working conditions for research and thus optimise the potential for excellent results. Applicants to GLOBVAC are encouraged to contribute substantially through own or international funding. The total budget framework for the GLOBVAC programme will decide which activities can be started and thus indicate to what extent the programme will reach its goals. Action plans will be developed every third year. They will specify thematic and structural priorities for that period. The action plan will be revised annually.

The total budget for the remaining programme period is NOK 354.2 million, an average of NOK 78.8 million per year from Norad for the period 2017–2020 and NOK 9.8 million per year from the Ministry of Health and Care Services. The latter is earmarked for projects relevant to EDCTP. The MFA has announced that NOK 105 million will be available for new calls in 2018–2020.

Call for proposals 2017–2020 – Five-year budget

Calls for proposals	2017	2018	2019	2020	Comments
EDCTP2 joint call		Up to NOK 40 mill.			Clinical trials in Sub-Saharan Africa
Researcher projects		Up to NOK 60 mill.			

8 Governance and organisation

The Division for Society and Health has overall responsibility for the GLOBVAC programme. The programme is administered by a Programme Board that is nominated by, and acts on behalf of, the Division Board for Society and Health at the Research Council.

The programme board is organised under, and reports to, the division research board for Society and Health. The activities of the programme board must be in compliance with the framework set out for the programme, including the work programme, action plan, long-term budget and funding announcement plan. Activities must also be in compliance with the overall principles and guidelines for research programmes set out by the Research Council. The programme board is authorised to allocate funding to individual projects. The programme board acts on behalf of the Research Council within the framework set for the programme.

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