Progress in public health depends on innovation. Some of the greatest strides forward for health have followed the development and introduction of new medicines and vaccines.

Dr Margaret Chan, Director-General of the World Health Organization
Conference on Intellectual Property and Public Policy Issues,
Geneva, 14 July 2009
IVR’s vision is a world in which vaccines and related technologies are developed and effectively used to protect all people at risk against infectious diseases of public health importance, particularly in developing countries.

IVR’s mission is to accelerate the development and optimal use of safe and effective vaccines and related technologies.
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<tr>
<td>AAVP</td>
<td>African AIDS Vaccine Programme</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>GIVS</td>
<td>Global Immunization Vision and Strategy</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>human immunodeficiency virus/acquired immunodeficiency syndrome</td>
</tr>
<tr>
<td>HPV</td>
<td>human papillomavirus</td>
</tr>
<tr>
<td>IVAC</td>
<td>IVR Vaccine Advisory Committee</td>
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<tr>
<td>IVB</td>
<td>WHO Department of Immunization, Vaccines and Biologicals</td>
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<tr>
<td>IVR</td>
<td>Initiative for Vaccine Research</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
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<tr>
<td>PDP</td>
<td>product development partnership</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
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<tr>
<td>SAGE</td>
<td>WHO Strategic Advisory Group of Experts on immunization</td>
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<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TDR</td>
<td>UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases</td>
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<tr>
<td>TPP</td>
<td>target product profile</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<tr>
<td>UNDP</td>
<td>United Nations Development Programme</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Vaccines are one of the most effective public health tools and protect millions of lives each year from infectious diseases. As such, they are also critical to reach the Millennium Development Goals (MDGs), particularly the goals to reduce infant and child mortality (MDG4) and to combat HIV/AIDS, malaria and other diseases (MDG6). Progress over the last decades to increase the potential of vaccines and save more lives, from both current and emerging diseases, has been encouraging. Yet an estimated four million people still die each year from diseases for which vaccines are available, and millions more die or suffer while waiting for vaccines to become available, such as against malaria and dengue. In addition, the potential of vaccination could be enhanced considerably if expanded beyond paediatric populations.

Hence, continued efforts are needed to develop new and improved vaccines and to assure their safe and effective implementation. However, the introduction of a new vaccine faces many hurdles and, increasingly, depends on post-licensure research, comparative assessments and tools to inform policy-makers. Developing countries suffer not only from a lack of research carried out on diseases that afflict primarily their populations; in addition, vaccines produced for developed country markets may have characteristics making them less suitable for the developing world. Slow, but steady progress is being made to address these issues, as well as to improve implementation research capacity, notably through new public–private partnerships that focus directly on developing country needs.

The WHO Initiative for Vaccine Research (IVR) was established in 1999 as the Organization’s unified entity for vaccine research, and has been successful in driving many major projects forward. Since its inception, the global vaccine research and development (R&D) environment has significantly evolved. With the injection of new funding, primarily from philanthropic organizations, several new, largely disease-focused initiatives have emerged that aim to develop and accelerate access to affordable vaccines for all those who need them.

THE ADDED VALUE OF IVR IN 2010–2020

Building on a decade of experience, IVR has formulated a long-term Strategic Plan that takes account of the evolving vaccine R&D landscape, and of the strong leadership role it can play as the WHO integrated vaccine research arm. The much welcomed new players in the vaccine R&D pipeline accentuate the need for increased global coordination and normative and technical support to countries, roles that are at the heart of IVR’s mandate.

The Strategic Plan 2010–2020 has a matrix approach that uses four strategic functions and a set of priority areas to address public health priorities, and it is here that IVR has most significantly evolved since the previous strategy. The matrix is directly aligned with WHO’s corporate strategy and policies to stimulate innovation in health research, as well as with the global immunization agenda of the Organization. This
harmonization will further strengthen synergies between research- and disease-focused programmes.

**STRATEGIC FUNCTIONS**

The four strategic functions that will guide the core work of IVR over the next 10 years are:

i) identification of vaccine and vaccination research priorities;

ii) the development of research standards and guidelines;

iii) the strengthening of research and product development capacity;

iv) the translation of research results into policy and practice.

**Identification of vaccine and vaccination research priorities.** As the number of donors and technical actors supporting the development and use of vaccines increases, so does the demand for an independent evaluation of needs, an assessment of priorities, and coordination of efforts to optimize efficiency and alignment of activities. IVR’s role in these activities will be to identify research gaps of particular relevance to low- and middle-income countries; establish technical agendas to address these gaps; stimulate the implementation of the technical agendas; and synergize its portfolio of activities with those of its partners.

**Development of research standards and guidelines.** The second IVR strategic function is to develop and support standards and guidelines for research into vaccines and vaccination. These activities inform the establishment of new regulatory standards, harmonized methods, and tools that permit a comparison of research results. This is particularly relevant for new vaccine candidates as their mechanisms of action are more complex than those of existing vaccines, and often target diseases with multiple clinical manifestations. In addition, IVR will continue to develop practice guidelines for the appropriate and ethical conduct of research in developing countries, thereby encouraging public confidence and participation in research.

**Strengthening research and product development capacity.** As a minimum, all countries should be able to assess their immunization needs, assess or carry out vaccine evaluations and decide whether to introduce a new vaccine into their immunization programmes. In addition, an increasing number of countries are interested in establishing the technology base to develop and produce vaccines of assured quality. To meet these needs, IVR will strengthen capacity in developing countries as an integral part of its projects. Examples of this support are providing guidance on good clinical practice; facilitating technology transfer to vaccine manufacturers for product development; and supporting the development of technology hubs and research networks.

**Translation of research results into policy and practice.** At the global level, IVR will generate and/or analyse the scientific data to enable the overarching WHO advisory body on vaccines and immunization – the Strategic Advisory Group of Experts on immunization (SAGE) – to make evidence-based recommendations. IVR will help develop the knowledge base for local deployment of vaccines, and vaccination strategies and schedules. Attention will be given to the development and validation of tools to inform vaccination policy by gathering, where relevant, country representative epidemiological, social or economic data and demonstrating their use in decision-making at country level.

**PRIORITY AREAS AND LEAD PROJECTS**

Applying the strategic functions described above, IVR will initially focus on the following three priority areas
each with a lead project – that can have a major impact on public health:

i) vaccination as an element of health security;

ii) vaccination strategies for all age groups;

iii) vaccines against poverty-related diseases.

**Vaccination as an element of health security.**

The potential of emerging diseases and pandemics to threaten world health on an unprecedented scale has led WHO to step up its efforts in global health security. IVR activities will include the development of simplified vaccine production and administration, computational modelling, and scenario development for vaccine deployment. The lead project under this priority area is to assist developing country manufacturers to produce influenza vaccine.

**Vaccination strategies for all age groups.**

Expansion of the age scope for vaccination beyond the traditional paediatric segment is critical to maximize the benefits of vaccination, and a prominent element of the WHO Global Immunization Vision and Strategy.Driven by changing epidemiological patterns and the availability of new vaccines, reaching older children and adolescents becomes a programmatic priority. In older age groups, infectious diseases cause significant morbidity and mortality, but existing vaccines are thought to have limited effectiveness. Defining the true burden of infectious diseases in the elderly, particularly in developing countries, and exploring strategies to increase the immune responsiveness of this age group to vaccines will be important activities of IVR’s lead project on vaccines for the elderly.

**Vaccines against poverty-related diseases.**

Three killer diseases – HIV/AIDS, tuberculosis and malaria – remain leading public health priorities for many low- and middle-income countries. IVR will advocate for the accelerated development of vaccines against these diseases in the context of existing preventive measures, and particularly through its lead project, the HIV Vaccine Initiative which it will continue to host. IVR will also coordinate activities related to the development and evaluation of vaccines against other diseases – especially neglected tropical diseases – that disproportionately affect poor and marginalized populations.

**IMPLEMENTING THE STRATEGIC PLAN**

IVR will continue to function as a small, highly skilled and experienced group collaborating with a wide range of partners to achieve its goals. Periodic monitoring, evaluation and risk assessments will examine the priority areas and lead projects for relevance, feasibility, progress and the impact that IVR can effect. The results of these reviews will inform decisions on the continuation of projects. However, it is underlined that whether or not priority areas or projects are modified to meet the needs of countries or to match scientific advances, the strategic functions will remain constant throughout the period of the Strategic Plan.
1. INTRODUCTION

Vaccination has proven to be among the most efficient and cost-effective ways of reducing mortality and morbidity from infectious diseases worldwide. Yet an estimated four million people die each year from a vaccine-preventable disease, and some 50% of all child deaths and an average 25% of adult deaths (15–59 years) are still attributed to infectious diseases. In fact, adult deaths from infectious diseases rise to a staggering 55% in the African region due to the toll of HIV/AIDS. Recognizing these challenges, the World Health Assembly endorsed an ambitious and comprehensive plan, the Global Immunization Vision and Strategy (GIVS) covering the period 2006–2015, to fight communicable diseases through immunization. Improving access to immunization is also critical to achieve the Millennium Development Goals (MDGs), and will particularly contribute to the MDG targets to reduce child deaths and to combat HIV/AIDS, malaria and other diseases.

1.1 REALIZING THE POTENTIAL OF VACCINES

With regard to the traditional EPI vaccines, one goal of the GIVS is that from 2010, at least 90% of children across the globe will be receiving their third dose of diphtheria-tetanus-pertussis vaccine. While this target has been met in several WHO regions, coverage varies significantly and in some cases remains below 70%. In fact, coverage gaps translate into more than 23 million children not, or only partially being vaccinated with basic EPI vaccines.

In parallel, the introduction of new vaccines promises to reduce significantly the burden of infectious diseases. Several new vaccines already recommended for introduction in developing countries could, together, save the lives of up to a million children a year, including pneumococcal vaccine, which prevents pneumonia and meningitis, and rotavirus vaccine against diarrhoeal disease. In addition, the human papillomavirus (HPV) vaccine has the potential to prevent most cervical cancers in women.

However, new vaccine introduction is complex and financial considerations are not the only constraint. The decision to introduce a new vaccine into a country needs to be based on a broad set of factors that often intertwine. Experience with the Haemophilus influenza type b vaccine, for example, showed a lag in introduction in low- and middle-income countries due to delayed translation of research findings into policy and practice, in particular in relation to the burden of disease, the cost of the vaccine and ineffective communication and advocacy efforts.

Learning from these lessons, implementation research is needed to provide critical information and tools, and to understand factors that influence coverage or slow uptake of vaccine. Analyses may include the study of gender issues hindering coverage, and research into predicting the impact of new vaccines. Increasingly, decisions will rely on comparative assessments to make choices between vaccines or alternative health interventions against a target disease or to combine them in a more effective manner. Tools and data
are required to assist country decision-makers in this process, as well as modern information technology to gather, transfer and manage data.

Other research priorities are to enhance immunization schedules and thereby improve vaccine delivery strategies and the impact of vaccination. Although WHO periodically revisits schedules of individual paediatric vaccines, a review is needed of the combined immunization schedules developed over three decades ago. IVR will carry out this comprehensive review to ensure that the delivery of traditional and new vaccines are appropriate to country disease epidemiology and health infrastructure. The delivery of new vaccines such as HPV to young girls provides an opportunity to develop schedules and delivery strategies beyond the child age group. There is also the potential to expand the integrated delivery of vaccines with non-immunization health services in order to improve child, adolescent and maternal health.

Looking to the future, several novel vaccines are in an advanced stage of development. In the next few years, for instance, vaccines against bacterial meningitis group A, malaria and dengue, along with improved vaccines against cholera, Japanese encephalitis and typhoid fever may become available for introduction into immunization programmes and protect a broad range of ages. On the other hand, diseases such as Enterotoxigenic Escherichia coli, shigellosis and streptococcus group A will probably lack an effective vaccine for some time.

Of the mortality caused by infectious diseases that yet lack an effective vaccine, 40% is caused by HIV, tuberculosis and malaria alone. While a first-generation malaria vaccine is likely to be available in the next few years, improved tuberculosis vaccines have several more years to go to licensure. HIV vaccine research is still facing major challenges, despite encouraging results from a prime-boost clinical trial that demonstrated for the first time some efficacy in preventing HIV infection.

The potential of existing and future vaccines in relation to the mortality caused by infectious diseases can be seen in Figure 1.

1.2 PRODUCING VACCINES AND TECHNOLOGIES THAT MEET DEVELOPING COUNTRY NEEDS

Typically, more than 10 years are required from concept to licensure of a vaccine, and up to a further 10 years to introduction and use of the vaccine in national immunization programmes. WHO actively facilitates each step along the pathway with the aim of accelerating the process (Figure 2). The cost of the research and process development for a single vaccine candidate is in the hundreds of millions of US dollars, and as the technological complexity of vaccine candidates and the ensuing regulatory requirements increase, so will the cost. The rate of attrition during the development process is high, and candidates may even fail at a late stage of clinical development. These costs need to be offset and thus significant capital, highly skilled labour and know-how are required to bring a vaccine to licensure.

Unfortunately, those who most need the vaccines are often the least able to afford or develop them. In addition, research efforts largely focus on diseases that affect industrialized country populations. Even if the same disease occurs in a developed and developing country, their characteristics are often different. For example, pneumococcal disease is caused by a different set of serotypes in Africa and Asia to those in North America and Western Europe, resulting in a vaccine targeted at industrialized countries having reduced effectiveness in many developing countries. A clear understanding of the burden of disease and targeted product development can help to address these differences.
A number of research partnerships and market incentive mechanisms have been created to address the needs of low- and middle-income countries. These efforts inject new funds into research and involve both the public sector, including WHO, and the private sector, particularly the vaccine industry. A few examples of public–private partnerships focusing on a specific disease are the International AIDS Vaccine Initiative, the Malaria Vaccine Initiative, the Pediatric Dengue Vaccine Initiative and the Aeras Global TB Vaccine Foundation. In addition, several non-profit initiatives are now being established to develop new vaccines for developing
countries against a broader range of diseases. The Merck-Wellcome Trust Hilleman Laboratories in India, established in 2009, is the latest of these.

 Nonetheless, many diseases, such as leishmaniasis, are currently unable to attract the resources and leadership to bring a vaccine to market. Recent analysis has shown that R&D funding streams still poorly match public health priorities.\(^5\) Mechanisms such as the Advance Market Commitment have been designed to create market incentives to push forward vaccine development for the poorest countries by committing funds for a specified target product profile. Their capacity to vitalize investment into earlier-stage candidates remains to be demonstrated.

Besides product development partnerships, research funding and market incentive mechanisms, a critical next step towards vaccine availability and affordability is to strengthen research and production capacity in countries or regions where the burden of disease is high. Typically, emerging suppliers have focused on traditional vaccines, often with limited margins, that they can produce in large volumes for middle- and/or low-income countries. In the last few years, some companies in these countries have acquired know-how and technologies allowing them to develop innovative products. Ensuring technology transfer, or connecting competency already available in target countries, combined with human and technological capacity strengthening for manufacturers within a solid regulatory framework, are essential to increase access to vaccines in developing countries and strengthen health security.

1. INTRODUCTION
IVR was formed in 1999 to facilitate the development of vaccines against infectious diseases of major public health importance, to improve vaccination technologies and to ensure that these advances are made available to those who need them most. Its three constituencies are the Special Programme for Research and Training in Tropical Diseases (TDR), the Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO. IVR acts as the focal point within WHO for vaccine R&D and is the interlocutor with external partners and organizations that work on the global vaccine pipeline. As of 2010, IVR comprises 25 staff.

2.1 IVR STRATEGIC PLAN 2006–2009

The Strategic Plan under which IVR operated from 2006 to 2009 used a three-tiered framework of research categories, namely: (i) knowledge management, guidance and advocacy to accelerate innovation for new and improved vaccines and technologies; (ii) support to research and product development for priority products; and (iii) implementation research and development of tools to support policies and strategies for optimal use of vaccines and technologies. This holistic approach was a deliberate effort to move beyond a largely product development perspective towards a broader vision of vaccination as a public health priority.

During this period, IVR’s leadership moved a number of projects forward, some of which are outlined in Table 1. These projects have been successful because IVR was able to identify a public health need and propose technology solutions, conceptualize and operate within partnerships that combine the strengths of its individual members, mobilize the best technical and scientific expertise, and build consensus on complex matters.

An external review conducted in 2008 reflected on IVR’s achievements and the hurdles it had faced, as well as the roles it should play within the global vaccine R&D arena over the next decade. The strong leadership of IVR and its neutral WHO hallmark were recognized as major assets. At the same time, the review emphasized that a periodic appraisal of programme priorities should highlight research areas that no longer justify IVR’s proactive involvement. The key recommendations of the external review were as follows:

- Focus on “landmark” projects that have a clear public health goal.
- Spotlight activities that build on IVR core competencies and the comparative advantages of WHO as a convener, facilitator, and interlocutor with developing countries.
- Increase the involvement of developing countries in product development partnerships, research, training and institutional capacity strengthening, both in vaccine clinical trials and implementation research.
- Build on WHO’s normative role to guide and facilitate vaccine development and evaluation.
- Develop a long-term strategic plan to provide a durable framework for interaction with partners and firmly position IVR in the evolving global vaccine research arena.
TABLE 1. HIGHLIGHTS OF IVR-DRIVEN VACCINE DEVELOPMENT PROJECTS

<table>
<thead>
<tr>
<th>Project description</th>
<th>Status at January 2010</th>
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<tbody>
<tr>
<td>The Meningitis Vaccine Project is a public–private partnership to develop a conjugate meningococcal A vaccine to eliminate epidemics in the sub-Saharan meningitis belt. IVR and PATH co-manage this development effort, including collaboration among the vaccine manufacturer, trial sites, laboratories and ministries of health; adherence to international standards; and capacity strengthening for vaccine trials and regulatory competence in African countries.</td>
<td>The vaccine is expected to be licensed and available to countries of the African meningitis belt in 2010.</td>
</tr>
<tr>
<td>The Measles Aerosol Vaccine Project, jointly overseen by WHO, the American Red Cross and the US Centers for Disease Control and Prevention, aims to develop an aerosolized measles vaccine in partnership with a major vaccine manufacturer and device companies. IVR manages the project with input from the best technical experts. The aerosolized vaccine will allow administration by non-medically trained personnel and avoid injection-related safety problems, especially in resource-poor settings and during vaccination campaigns.</td>
<td>The vaccine is expected to be registered as early as 2011.</td>
</tr>
<tr>
<td>The Pandemic Influenza Vaccine Production project seeks to increase influenza vaccine production capacity in low- and middle-income countries to bridge the considerable gap between current capacity and potential pandemic influenza demand. IVR has brought together significant funding, technical expertise and capable developing country vaccine manufacturers.</td>
<td>The domestic pandemic influenza vaccine production capacity of 11 developing country manufacturers is now being strengthened.</td>
</tr>
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2.2 HOW IS THE IVR STRATEGIC PLAN 2010–2020 DIFFERENT?

In striving to achieve sustained, high-impact results, four strategic functions and a limited set of priority areas and projects described in the next Section will constitute IVR’s framework of operations for the next decade. While the areas of work and projects may need to be modified as scientific advances or new contexts dictate, the strategic functions will still be shaping IVR priorities in 2020.

IVR paid particular attention to the recommendations of the external review described above, as well as those of the IVR Vaccine Advisory Committee (IVAC) in the development of its Strategic Plan 2010–2020. IVR will strengthen its collaboration and synergies with the research-led programmes at WHO and with the global vaccine research community to ensure the long-term relevance and impact of its work and secure a productive interface with its partners.

Most importantly, the IVR Strategic Plan is directly aligned with the WHO/UNICEF Global Immunization Vision and Strategy,¹ and WHO’s policies and processes to stimulate research, innovation and access to intervention tools targeted at developing countries.
2.2.1 WHO/UNICEF GLOBAL IMMUNIZATION VISION AND STRATEGY

The Global Immunization Vision and Strategy 2006–2015 seeks to accelerate progress to reach global health and development goals through immunization. IVR focuses particularly on the GIVS Strategy 8 on vaccine R&D, whose concrete activities are to: generate and analyse country-contextual data; define research agendas; strengthen capacity in developing countries to carry out vaccine evaluations and clinical trials; foster innovation in vaccine R&D; and update evidence-based immunization schedules as new technologies become available.

2.2.2 WHO STRATEGY ON RESEARCH FOR HEALTH

The WHO strategy on research for health, endorsed by the Executive Board in January 2009, is a framework of strategic goals that harmonizes the research efforts of the Organization with its mandate and mission, and complements those of its partners. It seeks to improve and better communicate WHO’s role in supporting Member States to strengthen health research capacity, and to position the Organization as a strong leader and champion of health research within an increasingly complex global architecture of research initiatives. IVR’s strategic functions mirror the goals of the WHO strategy on research for health, illustrated in Figure 3, and provide a basis for more efficient collaboration among WHO research programmes.

FIG. 3. WHO STRATEGY ON RESEARCH FOR HEALTH

2.2.3 WHO GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

Recognizing the critical role that developing countries themselves should play in generating relevant research and innovation, the World Health Assembly adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in 2008 aiming to stimulate new thinking on access to health-care products. The plan of action – the fruit of an intergovernmental working group – sets out a framework of activities based on eight strategic elements that cover the development of research agendas; the promotion of health research, innovation and product R&D capacity in developing countries; the transfer of technology; intellectual property management; and activities that focus on translating research results into practice.
IVR goals and activities during 2010–2020 will contribute to each of the strategic elements of the Global Strategy and Plan of Action, and a series of projects will be implemented in conjunction with the plan. Moving beyond the traditional concept of bilateral collaboration between developed and developing countries, there is great potential for research networks within the developing world to consolidate competencies and develop vaccines adapted to regional needs.
3. THE IVR STRATEGIC PLAN MATRIX

IVR’s mission is to accelerate the development and optimal use of safe and effective vaccines and related technologies. The four strategic functions where IVR considers it has a strong comparative advantage, and which will therefore serve as an umbrella for IVR’s programme of work as from 2010, are:

- the identification of vaccine and vaccination research priorities;
- the development of research standards and guidelines;
- the strengthening of research and product development capacity; and
- the translation of research results into policy and practice.

Within this framework, IVR has selected three priority public health areas that require concerted global cooperation, and where IVR involvement can drive progress forward, namely vaccination as an element of health security; vaccination strategies for all age groups; and vaccines against poverty-related diseases. The matrix approach IVR will embrace is shown in Table 2.

### Table 2. IVR Strategic Plan Matrix

<table>
<thead>
<tr>
<th>STRATEGIC FUNCTIONS</th>
<th>Research priorities</th>
<th>Research standards</th>
<th>Capacity strengthening</th>
<th>Translation of research results</th>
</tr>
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<tr>
<td>PRIORITY AREAS</td>
<td>Vaccination for health security</td>
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<td></td>
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<tr>
<td></td>
<td>Vaccination for all ages</td>
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<tr>
<td></td>
<td>Vaccines for diseases of poverty</td>
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12
3.1 STRATEGIC FUNCTIONS

3.1.1 IDENTIFICATION OF VACCINE AND VACCINATION RESEARCH PRIORITIES

In an increasingly complex landscape of global health research, and a growing number of players in the field, it is important that actual public health needs are assessed through a transparent and inclusive process. The need to assess gaps in knowledge, and to analyse and identify R&D priorities for diseases of poverty has been recognized by WHO Member States, the outcome of which will be critically relevant for country research plans, major research funders and the private sector, and will ensure that new research actions will target where it is needed most.

IVR has extensive experience in identifying research gaps and a long-term record of advising the research community through its scientific and technical committees and expert groups. IVR also considers disease control efforts other than vaccines when conducting gap analyses and prioritization and, in this context, will continue to collaborate with programmes working in this area, such as TDR’s thematic and disease reference groups.

Of particular importance is the elaboration of technical agendas such as target product profiles (TPPs) to inform and guide the development of desirable new vaccines and related technologies adapted to developing country needs. Moreover, highly specific technical agendas have the potential to focus scarce resources on priority issues and thereby maximize impact. TPPs enable WHO to determine research and product needs through an evidence-based, transparent and consultative process and convey them to the global research community. This priority setting function builds on the neutral broker position of WHO and has been successful for the development of essential product characteristics of novel pneumococcal vaccines (Box 1). Such prioritization activities are assessed regularly to guarantee their relevance and validity. Irrespective of specific incentive mechanisms, TPPs are considered a suitable approach to shape and focus R&D efforts for other vaccines and related technologies, and will be developed by IVR for priority needs.

BOX 1. EXAMPLE OF A VACCINE RESEARCH PRIORITIZATION ACTIVITY: TARGET PRODUCT PROFILES

IVR developed the TPP for pneumococcal conjugate vaccines with the help of a dedicated advisory committee, extensive stakeholder consultations and special studies to develop criteria for maximum vaccine impact in target populations. Once a manufacturer supplies a product requested by developing countries that is judged to meet the TPP characteristics, funds pledged by donors to the Advance Market Commitment can be released to purchase the product at a pre-arranged price. Since the TPP is a formal eligibility criterion for funding, this mechanism stimulates industry investment in vaccines that are appropriate for developing countries. The official adoption by SAGE and the GAVI Alliance of this TPP is a powerful example of the public sector guiding private sector product development.

In addition, IVR will conduct assessments to identify suitable technologies and methods to be applied to vaccine development, production and administration. Once promising technologies have been evaluated, IVR will analyse relevant intellectual property positions in
order to provide the best advice to developing country vaccine manufacturers.

In summary, IVR will:

- develop and apply rigorous scientific review processes, including systematic reviews and methodologies, and prioritize the research gaps identified;
- develop technical agendas such as target product profiles;
- conduct assessments to screen for promising and accessible vaccine technologies;
- convene ad hoc advisory committees at the request of Member States or WHO policy-forming bodies to inform research agendas and policies.

3.1.2 DEVELOPMENT OF RESEARCH STANDARDS AND GUIDELINES

Establishing norms, standards and guidelines for health are part of WHO’s core mandate. Applied to vaccine research, standards help to achieve a consistently high level of quality, ensure comparability of results, provide national authorities with guidance for the evaluation of products and, in the form of good practice guidelines, ensure that research is conducted efficiently and to the highest ethical principles. They also help to protect research participants and to maintain public confidence.

For regulatory standards, IVR identifies, initiates and coordinates pre-normative research, i.e. research that may lead to the establishment of regulatory standards for the evaluation and quality control of vaccines and biologicals by other teams at WHO. Ultimately, these regulatory standards are endorsed and published in the WHO Technical Report Series as standards for vaccine prequalification.

The pre-normative research typically emerges from vaccine research projects that require advanced methodologies to measure immunogenicity and safety, and usually requires evaluation of novel laboratory methods and technologies, their comparative assessment and the development of standard protocols for their further evaluation. Of particular importance are approaches and laboratory assays that may help to establish correlates of protection, as they greatly facilitate the prediction of vaccine impact and the evaluation and licensure of second generation vaccines.

IVR will continue to develop guidelines for the clinical evaluation of vaccines. For vaccines targeting diseases with complex pathologies and multiple clinical manifestations, IVR has initiated, coordinated and facilitated research and consensus-building activities that resulted in guidelines on basic trial design, and evaluation criteria such as clinical endpoints to assess the safety of candidate vaccines. Such guidelines, as have already been produced for malaria and dengue, provide valuable information for vaccine developers and national regulatory authorities, and facilitate the comparative evaluation of vaccine candidates (Box 2).

With regard to good practice guidelines for vaccine and vaccination research, IVR will particularly focus on the protection of vulnerable populations enrolled in clinical trials, and on research areas that largely lack
BOX 2. EXAMPLE OF A VACCINE RESEARCH STANDARDS ACTIVITY: 
CONSENSUS RECOMMENDATIONS FOR THE DESIGN AND EVALUATION OF MALARIA 
VACCINE CLINICAL TRIALS

With malaria vaccines entering pivotal phase 3 evaluation, the standardization of methods and reporting practices in controlled trials of preventive interventions became a high priority. IVR convened advisory groups to define measures of efficacy as consensus recommendations on the choice of endpoints, clinical case definitions, sample size, duration and nature of follow-up, as well as on key trial design and analysis issues. IVR will facilitate priority research into the statistical methods for estimating efficacy against the overall community burden of clinical malaria. In addition, IVR will synthesize the wealth of information on malaria vaccine performance as an aid to policy-makers and as a bridge between scientific proof-of-principle endpoints and the public health impact of malaria vaccines. Analogous approaches will be tailored to HIV, tuberculosis and dengue vaccines, among others, as they reach the pivotal phase 3 evaluation stage.

harmonized methods, such as health economics. IVR will also support the implementation of good practice guidelines through its training and capacity strengthening activities for improved efficiency and harmonized, quality research, in collaboration with TDR.

In summary, IVR will:

- identify and prioritize needs for research standards development, and conduct pre-normative research to identify and improve suitable methods and measurement technologies;
- conduct comparative studies to inform biological standards development;
- develop consensus and guidelines for the evaluation of complex vaccines and related technologies, based on broad consultations and special studies;
- develop good practice guidelines in areas where it is critical to protect research subjects, or to advance the relevance and comparability of research;
- develop, disseminate and implement good practice guidelines in conjunction with training and capacity strengthening efforts and with WHO collaborating centres.

3.1.3 STRENGTHENING OF RESEARCH AND PRODUCT DEVELOPMENT CAPACITY

Strengthening country capacity for contextual research serves as their scientific basis to inform health policy and assures that technical competency is developed. In addition, an increasing number of countries are interested in establishing the technology base to develop and produce vaccines of assured quality. The Mexico Ministerial Summit on Health Research called for all countries to invest systematically a small percentage of their health budget into research to address their most pressing public health needs. While some countries have made progress in developing research capacity – both in the public and private sectors – others are lagging considerably behind.

Some programmes, notably TDR, have a specific mandate for training, career development and institutional capacity strengthening for health research. IVR, in contrast, strengthens capacity as an integral
component of its research projects and clinical trials. Both programmes join forces for specific training activities such as on good clinical practices to ensure that clinical trials are conducted to the highest international standards. Similarly, IVR supports training and good practices in research ethics jointly with UNAIDS and the TDR-led Strategic Initiative for the Development of Capacity for Ethical Review, which are important opportunities to implement and disseminate good practice guidelines.

IVR will place specific emphasis on vaccine technology capacity development in line with the objectives of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. IVR will assess intellectual property and freedom to operate for critical vaccine technologies, identify appropriate manufacturing technologies and technology providers, and commission market analyses to facilitate technology transfer to developing countries. Technology networks will also be set up within and among developing countries to maximize the sharing of knowledge towards regional or country competency for vaccine development and production. The African Network for Drugs and Diagnostics Innovation is one such model, where a partnership of African institutions has formed to strengthen R&D capacity throughout the continent.10

Following the successful establishment of a technology transfer hub to support the acquisition and enhancement of influenza vaccine production capacity in low- or middle-income countries, the concept of technology hubs will be further developed. These hubs will serve as competency centres to advise developing country manufacturers on the selection and implementation of novel production technologies for other vaccines of high public health value.

IVR has identified limited knowledge on vaccine formulation and the lack of access to innovative adjuvants as major impediments to many vaccine R&D projects. A Global Adjuvant Development Initiative will enable the vaccine research community, and in particular developing countries, to access adjuvants, critical data on these products, and technical advice and training in relation to vaccine formulation (Box 3).

In summary, IVR will:

- enhance the competencies needed for IVR-sponsored research projects, and exploit opportunities offered by training schemes developed by partner programmes;
- use training efforts to disseminate and implement good practice guidelines;

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**BOX 3. EXAMPLE OF A CAPACITY STRENGTHENING ACTIVITY: TRANSFERRING KNOW-HOW ON ADJUVANTS**

The development of new vaccines will benefit from improved access to a range of novel technologies, especially adjuvants. IVR has initiated a number of activities, collectively referred to as the Global Adjuvant Development Initiative, that aim to facilitate the development of adjuvants and antigen delivery systems, and to supply these and know-how on their use to the public sector. It is envisioned that over the next 10 years the project will expand to include technology transfer to developing country research and manufacturing centres. Activities include: preparing, evaluating and supplying generic versions of known adjuvants; maintaining and making available databases of toxicology and clinical studies with adjuvants; training researchers in adjuvant formulation; and undertaking technology transfer to developing country vaccine manufacturers.
• seek suitable projects and strategies for technology transfer;
• encourage the set-up of research networks by and for developing countries;
• participate in research platforms that aim to establish research capacity at country level;
• further develop the concept of technology hubs as competency centres to assist with technology transfer to developing country vaccine manufactures and related public sector institutions.

3.1.4 TRANSLATION OF RESEARCH RESULTS INTO POLICY AND PRACTICE

Moving research findings more quickly into policy and practice has been recognized as a major avenue to harvest the benefits of innovation. This need was most recently highlighted in the Bamako Call to Action on Research for Health, which reiterated the value of research results to develop evidence-informed policies.

To address translational obstacles in immunization, IVR supports implementation research along several axes that aim to provide countries and the global community with relevant information for decision-making or policy development, such as for the optimization of immunization schedules. This research will be carried out in close alignment with teams at WHO that support national immunization programmes in developing countries, notably those of the Department of Immunization, Vaccines and Biologicals (IVB). The development and validation of tools to support vaccination policy will include an analysis of factors leading to effective vaccine implementation, with attention to gender and vulnerable populations where relevant; the gathering of country representative epidemiological, social or economic data; and demonstrating the use of these data in decision-making.

IVR will also review established vaccination practices and assess their potential for improvement. Of particular importance is to fully implement a comprehensive review of paediatric immunization schedules (Box 4),

**BOX 4. EXAMPLE OF A TRANSLATION RESEARCH ACTIVITY: OPTIMIZING IMMUNIZATION SCHEDULES**

The paediatric immunization schedule established by WHO more than 35 years ago still serves as the basis of most countries’ immunization programmes. While individual vaccine schedules have been updated, no combined review of all major paediatric vaccine schedules has been conducted. Yet the vaccines, epidemiological situations and immunization programmes have evolved. Some vaccines exert population effects that have not been considered sufficiently when designing vaccination schedules. The need to introduce an increasing number of new paediatric vaccines provides the opportunity for a comprehensive assessment of immunization schedules. The optimization of immunization schedules has therefore been identified as a landmark activity for IVR. The project will review the existing evidence, taking due consideration of epidemiological, economical and operational aspects. The project will also identify and prioritize areas for research to fill critical data needs in relation to vaccine scheduling. The final product will be an analytic framework to assist countries on optimal programmatic vaccine decision-making.
through the establishment of a transparent set of methods and decision-making approaches, a review of published and unpublished data, targeted research and demonstration projects.

IVR will support or assess projects that evaluate new products or interventions for their effectiveness and optimal use in field conditions. This research also assures that product and tool development meet the needs of the ultimate user and are tailored to real-life settings in developing countries.

Finally, serving as the research arm of the WHO Strategic Advisory Group of Experts on immunization, IVR reviews and analyses scientific evidence to inform global policy recommendations. For the purpose of assuring the highest standards in quantitative research, IVR will be assisted by the Advisory Committee on Quantitative Research in Immunization.

In summary, IVR will:

- develop tools for decision-making informed by country-relevant, contextual data;
- support studies that examine vaccine effectiveness and economic impact in relevant country scenarios;
- conduct a comprehensive review of immunization schedules;
- conduct systematic analyses of available evidence and synthesize the knowledge into guidance and technical advice to Member States and global partners;
- serve as the research arm for vaccines on the WHO Strategic Advisory Group of Experts on immunization;
- assure excellence and impartiality in quantitative research through the involvement of a dedicated advisory committee.

### 3.2 Priority Areas and Lead Projects

The implementation of IVR’s Strategic Plan, based on the four strategic functions described above, will focus on areas of global public health importance. Innovation will be at the centre of IVR’s activities and innovation potential a criterion for the selection of projects. It is within the Initiative’s mission to challenge the status quo and look at ways for vaccines to be developed and deployed differently – and better. Effectively fostering innovation requires looking beyond vaccine and vaccination research and examining other scientific disciplines and business areas for valuable input. IVR will conduct periodic screening for innovation potential to be applied from outside the field of immunization.

To launch the 10-year Strategic Plan, three priority areas have been identified, namely vaccination as an element of health security, vaccination strategies for all age groups and vaccines against poverty-related diseases. Within these major public health issues, lead projects that need urgent action or that hold particular potential for innovation will be pursued. These priority areas and lead projects, described below, were selected based on an analysis of IVR successes and comparative advantages, and following broad consultation with partners.

#### 3.2.1 Vaccination as an Element of Health Security

Emerging diseases, humanitarian emergencies, and health risks from the effects of climate change or environmental degradation are among the acute health threats that have become major public health priorities today. Framed by the international health regulations, global health security is the first line of defence against health catastrophes that can devastate people, societies and economies worldwide. Exemplified by the potential of influenza pandemics to cause harm at a global scale,
infectious disease outbreaks cannot be treated as purely national issues.

WHO has stepped up its operational capacity to identify and respond to disease outbreaks through the Global Outbreak Alert and Response Network\textsuperscript{13} and related efforts. In parallel, the Group of Eight (G8) has created a global health security initiative, with WHO as an advisor, which set out a series of global actions aimed at facilitating response capacity, such as research into vaccine formulations and regulatory frameworks for their development.

While many existing or pipeline vaccines such as the new vaccine against meningitis A could be considered as tools to support health security, special measures, e.g. specific clinical trial schemes and regulatory strategies, are needed to develop effective vaccines against future health threats. The development of simplified vaccine production technologies may also allow a more flexible supply infrastructure for sporadically-needed vaccines.

Based on experience gained with cholera and influenza vaccines, IVR will work with the research community to develop relevant computational modelling and socioeconomic research for vaccine deployment scenarios for prophylaxis or outbreak response.

Simplifying vaccine administration could reduce the need for highly trained health-care workers and enable a faster and broader deployment of vaccines. This includes technologies such as skin patches, oral or sublingual wafers and nasal sprays. Other technologies such as thermostable formulations could reduce the need for the cold chain. IVR has already played a key role in this field through the continued screening of delivery devices, the evaluation of intradermal delivery of polio vaccine by needle-free injection and the development of an aerosolized measles vaccine delivery system.

As a lead project, IVR will continue to support pandemic influenza vaccine preparedness and production (Box 5). Involved in this activity since 2006, IVR supports the improvement of available vaccines, promotes and facilitates the scaling-up or acceleration of vital vaccine production and advises on the development of new formulations.

3.2.2 VACCINATION STRATEGIES FOR ALL AGE GROUPS

One goal of the Global Immunization Vision and Strategy\textsuperscript{1} is to protect more people through immunization, and a major strategy to achieve this entails the expansion of immunization beyond the traditional target group of children below the age of one. Indeed, over the past years, immunization needs as well as opportunities for older age groups have become apparent: vaccine boosters have been studied and recommendations issued, and new or underutilized vaccines are now available against diseases that cause burden beyond infancy. The most recent of these opportunities is the use of HPV vaccine in adolescent girls to prevent cervical cancer. Other vaccines that may be delivered outside the paediatric age segment
include typhoid and dengue. Developing strategies and policies to achieve broad coverage of these populations will require significant research.

Infectious diseases have huge public health implications in the elderly, even if direct mortality from infections is much less than from noncommunicable diseases: hospitalization rates for influenza and pneumonia are in the range of 500–2500 per 100 000 population above 65 years, which is similar to that for cardiovascular or ischemic heart disease.\textsuperscript{14}

The population older than 65 years is predicted to quadruple over the next few decades when it will exceed 25\% of the total population. As people grow older their immune system weakens (immune senescence) and they become increasingly susceptible to infections, in particular from influenza, pneumococci and respiratory syncytial virus, but also from opportunistic infections and the resurgence of chronic infections such as herpes zoster. Moreover, immune senescence diminishes the efficacy of vaccination in this population.

In developing countries, where the population is ageing rapidly without concomitant health care, the burden of infectious disease is likely to be much higher. So far, very few studies have documented the infectious disease burden in this group, and no studies have ever measured the immune function in the elderly in developing countries. Although the exact causes of immune senescence remain poorly understood, and as yet no treatment can reverse it, protective immunity might be induced in this population by developing and using special vaccines (e.g. those containing appropriate adjuvants or administered by alternative routes) and/or by immunizing adults prior to the onset of immune senescence.

IVR has thus identified vaccines for the ageing population as a lead project (Box 6). It will seek to
understand better the magnitude of the issue and the factors leading to immune senescence, such as the age at which onset occurs in different populations. This will be particularly important in respect to the effects of ageing on immune responses in developing country populations where frequent exposure to infectious agents may lead to different onset patterns.

3.2.3 VACCINES AGAINST POVERTY-RELATED DISEASES

Diseases of poverty are those that are more prevalent in poorer than in wealthier populations, or are more likely to drive affected people and their families into poverty. Socioeconomic factors can play a major role in aggravating certain diseases. The bulk of the disease burden of HIV, tuberculosis and malaria alone occurs in low- and middle-income countries, and control of these diseases remains the leading public health priority for many Member States. Recognizing the complex interactions between these diseases, their public health impact is increasingly considered together.

Poverty-related diseases such as pneumococcal and some diarrhoeal diseases are also important to mention, some of which have benefited from the development of powerful intervention tools. Others, often referred to as neglected tropical diseases, such as schistosomiasis, trachoma and leishmaniasis, figure among those against which no efficient preventive tools are yet available or being used.

For HIV, tuberculosis and malaria, IVR will support the development of vaccines through its guidelines on the evaluation and comparative assessment of candidate vaccines. Guidelines are also developed and widely disseminated on standards for vaccine efficacy and

**BOX 6. PRIORITY AREA LEAD PROJECT:**
**ASSESSING THE POTENTIAL OF VACCINES TO PREVENT INFECTIOUS DISEASES IN THE ELDERLY**

IVR will carry out the following activities in this area:

- Gather reliable, valid and comparable data on infectious disease burden in older adult populations in representative developing countries.

- Measure the immunogenicity and, where appropriate, efficacy of vaccines in the elderly in developing countries, and compare this to age-matched cohorts in industrialized countries. This will provide information on the effectiveness of existing and improved vaccines in developing country populations, whether they experience a comparable process of immune senescence, or whether this is modified by environmental factors.

- Promote an evaluation and understanding of how vaccination earlier in adulthood could impact the immune function in later life and delay hypo-responsiveness. The implementation of schedules beyond childhood is already taking shape in some developing countries and may provide preliminary data on immune functions and the challenges to reaching adult populations.

- Support the development of policies for the use of vaccines in adults and the elderly.
safety, and on ethical and social measures to accompany clinical trials.

IVR serves as the key facilitator for prioritization of the essential immunological measures for lead candidates entering efficacy trials and for enabling access to reagents, controls and consensus-harmonized standard operating procedures for the generation of clinical data. The outcome of these activities and ultimately the development of correlates of protection will be hallmarks for the accelerated evaluation of vaccines. Target product profiles may be developed for some vaccines in order to guide research towards products with the highest expected public health impact.

For neglected poverty-related diseases, where the utility of a vaccine has been clearly identified, IVR will develop research agendas and promote product development partnerships.

The lead project will be support to the WHO–UNAIDS HIV Vaccine Initiative (Box 7). The efforts of the lead project will follow three main avenues: (i) maintain a favourable global environment for HIV vaccine R&D through advocacy, promotion of effective collaboration and support to regional networks; (ii) develop and facilitate implementation of polices, norms and standards related to vaccine evaluation and access; and (iii) support sustainable capacity strengthening of clinical trial sites that are integrated into other prevention efforts, in particular for malaria and tuberculosis.

**BOX 7. PRIORITY AREA LEAD PROJECT:**
**STRATEGIC PLANNING, ETHICS AND COMMUNITY INVOLVEMENT IN VACCINE TRIALS**

There are significant logistic challenges in conducting HIV vaccine trials in less developed countries to acceptable scientific and ethical standards. To address this, IVR has supported these countries to develop National AIDS Vaccine Plans and to strengthen their clinical trial capacities. This includes political support, clearly defined legal, ethical and regulatory frameworks, media and community involvement, and scientific, human resource, epidemiological and clinical trial infrastructures. As of January 2010, 10 African countries had adopted National AIDS Vaccine Plans, some of which now have the capacity to carry out all stages of clinical trials. The next steps are to expand the strategy to clinical trials of other vaccines of public health importance, such as malaria and tuberculosis.

3.3 SUMMARY OF THE IVR STRATEGIC PLAN MATRIX

The IVR Strategic Plan 2010–2020 matrix, showing the strategic functions as the four pillars of IVR’s work, along with cross-cutting priority areas and examples of projects, is represented in Table 3.
### TABLE 3. IVR STRATEGIC MATRIX WITH SELECTED PROJECTS*

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<tr>
<th>PRIORITY AREAS</th>
<th>STRATEGIC FUNCTIONS</th>
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<td></td>
<td>Research priorities</td>
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<td>Vaccination for health security</td>
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<tr>
<td>Vaccination for all ages</td>
<td>Vaccines for the elderly</td>
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<tr>
<td>Vaccines for diseases of poverty</td>
<td>Target product profiles</td>
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* * A comprehensive list of IVR projects will be established within the WHO core biennial workplan process.
4. IMPLEMENTING THE STRATEGIC PLAN

As of January 2010, IVR comprised 25 full-time employees. Over the course of the Strategic Plan 2010–2020, IVR will remain a small team working effectively with consultants and partners as needed to achieve its goals. To this end, IVR will continue to hold regular cutting-edge scientific conferences.

4.1 WORKING WITH PARTNERS

As a small programme, IVR’s success and the ultimate impact of its work will depend to a considerable extent on assuring constructive interfaces with global research efforts. IVR’s first 10 years of experience showed that collaboration with partners can be highly productive if built on the mutual strengths of each constituent. With its strategic functions clearly defined, IVR’s interaction with partners is expected to be even more transparent and its planning process more efficient.

Within WHO, IVR constitutes the unified entity for vaccine research and thus collaborates closely with a wide range of programmes at global and regional levels. For example, research on norms and standards for biologicals and on translational research is carried out with teams in the WHO Department of Immunization, Vaccines and Biologicals. IVR’s lead projects require strong alignment with disease control programmes and those that address health at different stages of the life course. IVR works particularly closely with other research-led programmes of WHO on the prioritization and coordination of research efforts, as well as on strengthening capacity in developing countries, notably with its constituents TDR and UNAIDS.

With regard to collaboration outside the Organization, IVR has privileged interaction as a WHO programme with governments and governmental institutions, particularly in developing countries. In this context, it can provide independent advice to Member States. This role also applies to its unique contacts with regulatory entities in the development of standards. It also allows IVR to function as broker or neutral participant in discussions of interested parties and stakeholders.

Product development partnerships (PDPs) have emerged over the last years as important players, and IVR is often represented on their advisory boards as a source of independent advice or as a collaborator for specific projects. IVR will encourage increasing developing country representation in the relevant PDPs.

IVR relies on the technical input and services from academia and WHO collaborating centres in support of its activities.

Finally, the vaccine industry is an important stakeholder for IVR. While mostly involved in projects with developing country vaccine manufacturers and the biotechnology industry to broaden the vaccine supply base, IVR also interacts with multinational manufacturers along well-defined projects that serve global public health needs. In this respect, IVR solicits technical advice and data from the vaccine industry as needed.

One major avenue for IVR interaction with the broader vaccine research community is the Global Vaccine Research Forum, convened by IVR every 18 months; another is through the IVR Vaccine Advisory Committee,
which provides overall strategic and technical advice to the Initiative. Its membership comprises a range of partners that represent the public and private sectors: national and international research institutions, donor and development agencies, United Nations sister organizations as well as the vaccine industry. Figure 4 summarizes the role and contribution of IVR with its diverse range of partners.

4.2 MONITORING AND EVALUATION

In compliance with WHO’s planning process, two-year workplans will be developed that set out specific activities, milestones and outcomes for IVR’s work. This process will also use the WHO results-based budgeting, management and monitoring approach. It should be noted that, while the IVR Strategic Plan 2010–2020 focuses on strategic functions, priority areas and lead projects, it is the WHO biennial workplans that will outline the full list and description of all IVR activities and related resources.

IVR’s priority areas, flagship projects and ongoing activities will be regularly monitored and evaluated to assess their continued relevance against the latest scientific developments and public health priorities. The process for the development of IVR products and services involves IVAC, SAGE and other independent evaluation mechanisms, and thus provides the quality assurance of IVR’s work. Assessments of both existing and potential projects will be based on criteria such as whether the project stands to contribute to improving public health, particularly in developing countries, and
whether the involvement of IVR will add significant value to the project’s objectives.

In addition, key performance indicators have been established to measure progress related to the strategic functions, examples of which are presented in Table 4.

As part of the monitoring and evaluation exercise, IVR will periodically carry out a risk management analysis to screen for three broad risks: (i) that one or more major projects fail; (ii) that IVR becomes redundant; and (iii) that funding becomes inadequate to sustain the programme of work. Regular portfolio reviews, discussions with IVAC and other stakeholders, and a focus on strategic functions should assure that IVR invests in areas of comparative advantage.

In addition, IVR will strive to raise the visibility on its role in vaccine research, particularly on the positive impact it can have on vaccination policies and vaccine availability in resource-poor countries.

IVR will solicit an external evaluation of its work at mid-term and at the end of this Strategic Plan.

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<tr>
<td>Research priorities</td>
<td>Number of target product profiles developed through an IVR-managed process</td>
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<td>1</td>
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<tr>
<td>Research standards</td>
<td>Number of regulatory standards developed based on IVR-sponsored research</td>
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<td>Capacity strengthening</td>
<td>Number of developing country vaccine products licensed following technology transfer facilitated by IVR</td>
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<td>3</td>
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<tr>
<td>Translation of research results</td>
<td>Number of SAGE policy recommendations informed by IVR-supported research</td>
<td>4</td>
<td>4</td>
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ENDNOTES


3. Information on WHO’s work on health-related Millennium Development Goals is available at www.who.int/topics/millennium_development_goals/en.


10. See http://andi.tropika.net/ for more information on the network.


13. Information on the Global Outbreak Alert and Response Network can be found at www.who.int/csr/outbreaknetwork/en/.

Progress in public health depends on innovation. Some of the greatest strides forward for health have followed the development and introduction of new medicines and vaccines.

Dr Margaret Chan, Director-General of the World Health Organization
Conference on Intellectual Property and Public Policy Issues,
Geneva, 14 July 2009