

Rotavirus Vaccine Program

Annual Work Plan 2005

The Rotavirus Vaccine Program (RVP) was established in 2003. Its strategic goals are to: (1) provide information that enables national decision-makers, and the GAVI Board and its partners, to make an evidence-based decision regarding the use of rotavirus vaccines, and (2) accelerate the availability of new rotavirus vaccines appropriate for use in developing countries.

This work plan summarizes the key activities to be completed by the RVP team in 2005.

Surveillance and Disease Burden:

Addressing lack of disease burden data and information on the cost-benefit and cost-effectiveness of a rotavirus vaccine

2005 Budget: \$2,627,576

Objective I: Establish global, regional, and national estimates of rotavirus disease burden in selected countries.

Outcome A: Simple methods for establishing rotavirus disease burden, economic impact, laboratory surveillance, intussusception, and health utilization are available to all countries.

Activities (expected status by end of 2005):

1. Pilot test generic protocol to conduct intussusception surveillance in developing countries. *(Completed)*
2. Finalize and disseminate standard protocols for laboratory procedures for rotavirus surveillance. *(Completed)*
3. Ensure that all protocols are available via website and through mail. *(Completed)*
4. Revise generic protocol to estimate costs of rotavirus gastroenteritis in developing countries following pilot studies. *(Ongoing)*

Outcome B: Surveillance systems in Asia, Africa, Latin America, and Europe are established and are producing quality data and reporting regularly.

Activities (expected status by end of 2005):

1. Oversee surveillance studies in 14 countries in Asia. *(Ongoing)*
2. Initiate and oversee enhanced surveillance studies in Kenya, Malawi, South Africa, and Ghana. *(Ongoing)*
3. Initiate surveillance studies in selected countries in WHO's EMRO and EURO regions; oversee activities. *(Ongoing)*
4. Conduct health utilization study in South Africa. *(Completed)*
5. Facilitate and coordinate initiation of core surveillance in several African countries in collaboration with AFRO. *(Completed)*
6. Coordinate monthly reporting of African surveillance sites with AFRO coordinator. *(Ongoing)*
7. Oversee surveillance in currently-funded Latin American Countries. *(Ongoing)*

8. Initiate and oversee hospital-based surveillance in Bolivia. (*Ongoing*)
9. Produce and disseminate monthly reports of data from all countries conducting surveillance. (*Ongoing*)

Outcome C: Results from regional, multi-country surveillance networks have been disseminated.

Activities (expected status by end of 2005):

1. Convene surveillance network meetings in Africa, Latin America, and Asia as needed. (*Completed*)
2. Produce quarterly newsletters/reports of summary data from each surveillance network. (*Ongoing*)

Outcome D: Remaining gaps in disease burden and economic data have been addressed.

Activities (expected status by end of 2005):

1. Review existing data and identify remaining gaps. (*Completed*)
2. Design and initiate appropriate studies. (*Ongoing*)

Outcome E: Baseline data on disease and economic burden has been established for the Honduras partnership, and systems are in place to monitor impact of vaccination program.

Activities (expected status by end of 2005):

1. Initiate sentinel hospital-based surveillance in several cities in Honduras. (*Ongoing*)
2. Establish baseline mortality data and mechanism to detect and monitor rotavirus-associated mortality in Honduras. (*Completed*)
3. Establish baseline economic data prior to vaccine introduction. (*Completed*)
4. Establish pre-introduction rates of intussusception and establish a sensitive system to detect new cases. (*Completed*)
5. Establish pre-introduction rates of hospitalizations, clinic visits, and less severe outcomes; and system to monitor impact of vaccination program on these outcomes. (*Completed*)

Objective II: Determine and describe economic impact of rotavirus disease and cost-effectiveness of rotavirus vaccine programs.

Outcome A: Reliable estimates of costs and cost-effectiveness from the global and regional perspectives are established and provided to policy makers.

Activities (expected status by end of 2005):

1. Revise global cost-effectiveness model that incorporates data from country studies and other new data sources. (*Completed*)
2. Harmonize global cost effectiveness model with other relevant models (e.g. pneumococcal vaccine model). (*Completed*)
3. Conduct regional cost-effectiveness analyses in Asia and the Eastern Mediterranean region. (*Ongoing*)
4. Convene expert panel to review all relevant rotavirus cost studies conducted in past 3 years and derive consensus estimates and summary. (*Completed*)

Outcome B: Reliable estimates of costs and cost-effectiveness from country-level perspective are established in representative countries.

Activities (expected status by end of 2005):

1. Conduct country-level cost-effectiveness studies in Vietnam, Uzbekistan, Malawi, Ghana, and Honduras. *(Completed)*
2. Conduct cost studies in China and Indonesia. *(Ongoing)*

Objective III: Establish laboratory capacity to support regional networks and country activities.

Outcome: Regional reference laboratories are providing training and strain typing for surveillance activities in each region.

Activities (expected status by end of 2005):

1. Finalize and distribute laboratory manuals to public health and research laboratories involved in surveillance. *(Completed)*
2. Train visiting scientists at the CDC laboratory to utilize methods for rotavirus surveillance, including viral antigen detection and characterization. *(Ongoing)*
3. Collect regionally representative data on strain distribution and strain prevalence in all countries involved in surveillance. *(Ongoing)*

Vaccine Development:

Working with vaccine manufacturers to assess immunogenicity, safety, and efficacy of late-stage rotavirus vaccines in developing countries

2005 Budget: \$5,245,319

Objective I: Assess the efficacy and safety of live oral rotavirus vaccines in developing countries.

Outcome A: Phase III trials of Rotarix™ are underway in Bangladesh and South Africa.

Activities (expected status by end of 2005):

1. Participate in protocol development for Phase III trial in Bangladesh. *(Completed)*
2. Finalize and sign agreement with GSK and ICDDR,B. *(Completed)*
3. Finalize and sign agreement with GSK and Medunsa. *(Completed)*
4. Facilitate IRB review of protocols. *(Completed)*
5. Oversee implementation of the agreement. *(Ongoing)*

Outcome B: Phase III trials of RotaTeq™ are underway in at least two developing country sites.

Activities (expected status by end of 2005):

1. Review final data from 013 trial. *(Completed)*
2. Participate in site selection for Merck trials. *(Completed)*
3. Participate in protocol development for Phase III trials. *(Completed)*
4. Finalize and sign agreement with Merck and trial sites. *(Completed)*
5. Facilitate IRB review of protocols. *(Completed)*
6. Implement proactive project management. *(Ongoing)*
7. Oversee implementation of the agreement. *(Ongoing)*

Communication and Advocacy:*Addressing information needs of decision-makers at the global, regional, and country levels***2005 Budget: \$1,161,949*****Objective I: Conduct comprehensive audience research project to guide vaccine introduction communications at country, regional, and global levels.*****Outcome: Partial completion of Rotavirus Vaccine Communication Resource Kit.*****Activities (expected status by end of 2005):***

1. Conduct audience research to determine current audience perceptions, attitudes and knowledge about rotavirus, and, more broadly, diarrheal disease, its management, and prevention. *(Completed)*
2. Conduct message testing with key audiences. *(Completed)*
3. Build a collection of position papers on each of the components of the diarrheal disease management interventions (ORS, breast feeding/nutrition, clean water/sanitation), and their role in treating/preventing rotavirus. *(Ongoing)*
4. Package supportive data and information such as cost effectiveness, surveillance, and demand projections into materials that are understandable and obtainable by key audiences. *(Ongoing)*

Objective II: Raise awareness of rotavirus and the potential for rotavirus vaccines among key audiences.**Outcome: Demonstrated increases in levels of knowledge about rotavirus among key audiences leading to support and momentum for a global recommendation, and eventual country-level vaccine introduction.*****Activities (expected status by end of 2005):***

1. In collaboration with manufacturers and other partners, develop disease awareness campaigns in Asia, Africa, and Latin America, with particular focus on Thailand, Indonesia, India (Andhra Pradesh), Honduras, Ghana, and Malawi. *(Completed)*
2. In collaboration with Pneumo ADIP, host a donors conference about rotavirus. *(Completed)*
3. Conduct media outreach in key countries/regions. *(Ongoing)*
4. Conduct outreach through presentations and meetings with key groups and organizations involved with child survival and diarrheal disease. *(Ongoing)*
5. Document communication process and outcomes in key countries. *(Ongoing)*
6. Continue pursuing opportunities for presentations. On-going management of outreach activities (web site, newsletter, materials development). *(Ongoing)*

Objective III: Expanded advocacy for “new vaccines.”

Outcome: New thinking about the benefit of new vaccines, and the importance of investing in the distribution and subsidization of new vaccines to achieve MDG.

Activities (expected status by end of 2005):

1. Work with GAVI to develop messages. *(Completed)*
2. Utilize donor conference and meetings to communicate new messages. *(Completed)*

Objective IV: Enlist the involvement of RVP collaborators in broader advocacy and communication efforts.

Outcome: Demonstrated outreach and communications by RVP collaborators to key RVP audiences.

Activities (expected status by end of 2005):

1. Work with other RVP Team Leaders to identify opportunities for encouraging and training collaborators (e.g., Surveillance investigators) to reach key audiences in countries and regions. *(Ongoing)*
2. Provide collaborators with training, venues, materials, and support for outreach. *(Ongoing)*
3. Presentations and outreach to global vaccine and child survival groups (e.g., UNICEF). *(Ongoing)*

Vaccine Financing & Supply:

Addressing uncertain market demand, regulatory issues for new vaccines, vaccine financing, and other supply-related obstacles to vaccine introduction

2005 Budget: \$571,410

Objective I: Create demand forecast models for introduction and uptake of rotavirus vaccines.

Outcome: Estimates of developing country demand for rotavirus vaccine are available to assist with decision-making.

Activities (expected status by end of 2005):

1. Prepare “top-down” demand forecast for Vaccine Fund eligible countries using Delphi methodology. *(Completed)*.
2. Design and implement country-level data collection for demand forecast modeling. *(Ongoing)*
3. Update global demand forecast based on country-level information. *(Ongoing)*

Objective II: Develop rotavirus investment case for decision-making by GAVI.

Outcome: Rotavirus investment case is developed according to GAVI specifications.

Activities (expected status by end of 2005):

1. Follow status of investment case evolution. *(Ongoing)*
2. Prepare global rotavirus investment case, as requested. *(Ongoing)*
3. Follow evolution of GAVI’s financing policy; contribute input, as requested. *(Ongoing)*

Objective III: Optimize GAVI’s readiness to support decision-making, financing, and procurement related to rotavirus vaccines.

Outcome: Coordination between the various public sector organizations with which manufacturers will have contact during late-stage development and introduction.

Activity (expected status by end of 2005):

Chair ADIP Rotavirus Vaccine Working Group. *(Ongoing)*

Vaccine Introduction:*Assisting target countries to prepare for vaccine introduction***2005 Budget: \$1,165,068**

Objective I: Finalize RVP framework for implementing research to provide operational experience to enrich the vaccine introduction evidence base, and negotiate country agreements for participation in demonstration and research projects.

Outcome A: Final framework for country selection and research implementation.

Activity (expected status by end of 2005):

Incorporate any needed revisions to the country selection framework and disseminate.
(Completed)

Outcome B: List of demonstration and research projects finalized and work plans and budgets established for each.

Activities (expected status by end of 2005):

1. Develop short-list of demonstration and research projects in selected host countries.
(Completed)
2. Negotiate individual country and partner agency agreements to carry-out demonstration and research projects in accordance with RVP framework. (Ongoing)

Outcome C: A roll-out plan for introduction of rotavirus vaccines in Vaccine Fund eligible countries.

Activities (expected status by end of 2005):

1. Review data from demand forecasting and audience research programs. (Ongoing)
2. Develop preliminary roll-out plan. (Completed)

Objective II: Collect, compile, analyze, and document operational experience to contribute to the vaccine introduction evidence base.

Outcome: Documentation of theoretical estimates and/or practical experience regarding the impact of introduction of rotavirus vaccine on the following: (1) EPI management systems, e.g., transport and logistics & cold chain; (2) human resource requirements; (3) coverage monitoring systems; (4) medical waste disposal systems; and (5) stakeholder perceptions.

Activities (expected status by end of 2005):

1. Develop and implement study protocols with investigators in selected host countries.
(Completed)
2. Conduct demonstration or research projects to provide quantitative and/or qualitative data on additional requirement associated with rotavirus vaccine introduction. (Ongoing)

3. Compile demonstration and research findings in different settings, and document conclusions in an appropriate format for presentation to key country audiences. (*Ongoing*)
4. Document conclusions to contribute to the rotavirus Investment Case. (*Ongoing*)