

GAVI's PneumoADIP 2005 Workplan

Budget Narrative: Overview of the categories

The budget reports attached are broken down into 4 project areas that correspond to the main functional areas of the project: Vaccine Research/Surveillance; Communications; Vaccine Supply & Financing; and Project Administration. Within each functional area is a description of how funds are allocated by type of spending. The seven spending types and a description of the costs included in each are listed below:

Personnel. Includes the costs of salaries and fringe benefits for the PneumoADIP team, and costs related the recruitment and/or relocation of the individual team members.

Consultants. Includes the costs of sub-contracts to consultants who provide services to the PneumoADIP team.

Subagreements. This is the bulk of the money spent by PneumoADIP and it includes all the sub-contracts written to outside organizations in order to undertake the priority activities required to help attain PneumoADIP's strategic goals. In addition to the money transferred for each sub-agreement, the University charges a management fee equal to 20% of the first \$25,000 of the sub-agreement but not more than \$5,000 total.

Travel. Includes the costs of travel for the PneumoADIP team and for PneumoADIP sponsored-travel such as to bring key developing country researchers and/or country representatives to international meetings or to confer with PneumoADIP team.

Meetings and trainings. Includes the costs of PneumoADIP sponsored meetings and training fees for PneumoADIP team members and others who are sponsored by PneumoADIP.

Other project costs. Includes the equipment and supplies used by PneumoADIP team, telecommunications, and other miscellaneous expenses incurred in support of the project.

Costs to the host institution. This is the 20% charged by the University to the 'core team budget' as outlined in the original proposal. These charges provide for the facilities and support services provided by the School, including space, security, human resources, information technology services, research administration, and other basic services of the host institution.

GAVI's PneumoADIP Work Plan/Budget Narrative

2005 Proposed budget

GAVI's PneumoADIP at Johns Hopkins

- Created in 2003 with a \$30 million award from GAVI/Vaccine Fund.
- Mission: To improve child health and survival by accelerating evaluation of and access to new, life-saving pneumococcal vaccines for the world's children.
- Strategic goals:
 - To provide information that enables national decision-makers, and the GAVI Board and its partners, to make an evidence-based decision regarding the use of pneumococcal vaccines; and
 - To accelerate the availability of affordable, new pneumococcal vaccines appropriate for use in developing countries.
- Value goals:
 - Establish value: By 2007, provide core information on disease burden & vaccine impact to enable local decision-makers, GAVI, and its partners to prioritize pneumococcal vaccine introduction.
 - Communicate value: i) By 2007 have pneumococcal disease recognized as a serious & leading cause of childhood death and illness by governments and key opinion leaders in countries and key international donors. ii) By 2007 have governments in countries & donors indicate an increased interest in vaccines for prevention of pneumococcal disease.
 - Deliver value: By 2007 develop an actionable proposal for procuring an affordable, sustainable supply of pneumococcal vaccine sufficient to meet projected demand in the world's poorest countries.

The text below describes the activities that will be supported by PneumoADIP in 2005.

ESTABLISH VALUE

Disease Burden & Vaccine Research:

Value Goal: Establish global, regional, and national-level estimates of the burden of pneumococcal disease and the value of pneumococcal vaccination in developing countries.

Key milestones:

2004: Disease burden studies initiated in target countries

2005: Potential large scale vaccine evaluation sites in Asia selected

2006: Asian large scale vaccine trial [GO / NO GO / REDIRECT]

Core disease burden established in all target countries

2005 Budget (projected) = \$4,657,229

Activities include surveillance, vaccine research, cost-effectiveness, and other economic analyses. Specific activities to be covered by this budget area include:

Establishing local and regional evidence of pneumococcal disease burden including serotypes and antimicrobial resistance.

- Networks for surveillance of lab-confirmed pneumococcal disease:
 - netSPEAR [Ongoing]. Kenya, Uganda, Tanzania, Ethiopia, Rwanda, and AFRO involved.
 - Bangladesh [Ongoing]. ICDDR,B, 7 hospitals in national sentinel surveillance network and prospective cohort surveillance in one rural and one urban setting.
 - IBIS/SAPNA [Ongoing]. Sri Lanka and 2 sites in Nepal linked to ICMR supported IBIS network in India. Funded through IndiaCLEN.
 - Thailand [Ongoing]. Thai Ministry of Public Health/US CDC collaboration for population-based surveillance of pneumococcal disease and x-ray confirmed pneumonia in 2 provinces.
 - Viet Nam [Under negotiation]. IVI/VietNam MOPH collaboration for surveillance in one district.
 - EMRO [Anticipated]. We expect to include some or all of the following countries in a system for surveillance of lab-confirmed pneumococcal disease: Oman, Tunisia, Jordan, Iran, Qatar, Saudi Arabia, Morocco.
 - PAHO [Anticipated]. Country sites to be determined but expected to build on successful SIREVA network but with stronger clinical and epidemiologic methods.
 - AFRO [Anticipated]. Countries to be determined through discussions with AFRO.
 - Surveillance networks meeting [Anticipated]. In January 2005, with WHO/IVR, we are supporting a meeting of all the surveillance networks we support and ones that we don't support. The objective is to standardize case-definitions and reporting methods, to communicate data across networks, and to share best practices between developing country investigators. Approximately 60 participants are expected.
- Other pneumococcal disease surveillance or disease burden projects
 - Others targeted for surveillance support: Mongolia (Likely Early Adopter) [Anticipated].
 - Support for post-vaccine efficacy trial surveillance. Gambia, South Africa, Philippines [Anticipated].
 - Small Grants for limited surveillance/disease burden projects [Ongoing and anticipated]:
 - Pneumococcal disease: Benin, Burkina Faso, Congo (fmr Zaire), Fiji, Georgia, Mali, Nigeria, Pakistan, Togo
 - Serotype information: Indonesia
 - Disabilities following pneumococcal meningitis: Fiji
 - Development of software to allow electronic reporting of data from PneumoADIP-supported surveillance and to improve project management.

Establishing global estimates of pneumococcal disease mortality

- With WHO/VAM we are supporting revision of the official WHO estimates of the global burden of pneumococcal mortality in children [Ongoing].

Establishing the value of vaccination for prevention of pneumococcal disease

- Research on the use of acute phase proteins (e.g., C-reactive protein, procalcitonin) as an alternative to x-ray confirmation for measuring the efficacy/effectiveness of pneumococcal vaccines for prevention of pneumonia. This includes support to the pneumococcal vaccine trials in South Africa, Gambia, and the Philippines [Ongoing].
- Selection and development of potential large-scale field sites in Asia to measure the public health impact of routine pneumococcal vaccination [Ongoing].
- Evaluation of fewer dose regimens as a way to reduce the cost of vaccination [Ongoing]. In collaboration with WHO/IVR, support for randomized controlled trials of Prevnar 7-valent vaccine in The Gambia and Philippines. With WHO/IVR, we have standardized study designs and methods in the two sites and worked with Wyeth to assure vaccine supply.

Development of a tool to estimate local burden of vaccine preventable pneumococcal disease

- Development of a PneumoBAT (Burden Assessment Tool) [Ongoing]. In collaboration with CDC and WHO/IVB, this tool will allow countries to collect and synthesize locally available data on pneumonia, meningitis, and sepsis and link it to regional data and clinical trial data.

Establishing the economic value of pneumococcal vaccination

- Analytic work on the cost-effectiveness of pneumococcal vaccination in developing countries and the value of accelerated introduction [Ongoing]. This work with Harvard University is expected to yield manuscripts and a Web-based tool in 2005.
- Assessing the macro-economic case for pneumococcal vaccine introduction [Anticipated]. In collaboration with David Bloom and David Canning at Harvard SPH, we anticipate building an analysis of the potential economic growth impact of infant pneumococcal conjugate vaccination. May be an opportunity for collaboration with RotaADIP.
- Projections of the impact of HIV on the global/regional burden of pneumococcal disease [Anticipated].

Vaccine Financing & Supply:

Value Goal: Develop an actionable proposal for procuring an affordable, sustainable supply of pneumococcal vaccine sufficient to meet projected demand in the world's poorest countries.

Key milestones:

2004: Target countries selected

2005: Initial demand forecast

2006: Potential price-volume agreements developed

2007: Investment case [GO / NO GO / REDIRECT]

2005 Budget (projected) = \$1,010,086

Specific activities to be covered in this area include:

Demand forecasting

- Develop a demand forecasting tool for dynamic, interactive construction of demand forecasts/roll-out plans [Ongoing].

Business case analyses

- Project the total potential global market for infant pneumococcal conjugate vaccination [Ongoing].
- Construct a net present value (NPV) model for development of an 11-valent pneumococcal conjugate vaccine that will assist us in strategic thinking about how to partner with industry in relation to investments in product development and pricing [Ongoing].
- Develop draft business cases for assuring affordable supply from various manufacturers [Anticipated].
- Partnership with industry to assure the development and commercialization of appropriate formulations for use in VF-eligible countries [Anticipated].

Regulatory pathways

- Develop potential alternative regulatory strategies for partnership with industry to assure licensure of appropriate pneumococcal vaccines for developing countries [Anticipated].
- Support for WHO Accelerated Vaccine Introduction personnel to support work with regional offices and evaluation of target product profile [Ongoing].

Communications:

Value Goals: i) By 2007 have pneumococcal disease recognized as a serious & leading cause of childhood death and illness by governments and key opinion leaders in countries and key international donors. ii) By 2007 have governments in countries & donors indicate an increased interest in vaccines for prevention of pneumococcal disease.

Key milestones:

2005: Communication plan launched in target countries

2006: Assessment of interest in vaccine by countries

2005 Budget (projected) = \$1,551,202

Audience research to assess current positions and evaluate impact of communications activities

- Audience research to assess baseline perceptions and attitudes of key decision-makers [Anticipated]. These baseline measures will be used as benchmarks for evaluating the impact of PneumoADIP-sponsored communications activities in the future.

Assuring information reaches decision makers

- Development of key messages and support with media communications and public relations [Ongoing].
- Development of Web-based tools for communicating disease burden and vaccine information to key opinion leaders and decision-makers at local, regional, and global levels [Ongoing].
- Development of printed materials in support of key messages [Anticipated].
- Sponsorship of international and regional meetings related to pneumococcal diseases and vaccines, including the Meningitis Research Foundation (UK) meeting and others [Anticipated].
- PneumoADIP sponsored and organized meetings, potentially including regional advisory boards designed to provide feedback on key issues to address for accelerating pneumococcal vaccine introduction [Anticipated].

Project Administration:

The aim of this area is to provide high quality support of the PneumoADIP team's mission and assure a high degree of integrity in the management and accounting of funds.

2005 Budget (projected) = \$534,393

Improving administrative systems

- Development of a PneumoADIP "portal" on the Internet to improve integration of team functions and project management [Ongoing].
- Development of a budget tracking/forecasting and contract management tools to allow timely reporting of actual and projected expenses according to GAVI formats and improve strategic forecasting [Ongoing].