"PRIORITIES OF HEALTH ECONOMICS IN AFRICA"
Inaugural Conference of the African Health Economics and Policy Association (AfHEA)
10th – 12th March 2009 - Accra, Ghana

PT 05

Probabilistic methods for economic evaluation alongside a multi-country trial in sub-Saharan Africa: a case study from the clinical trial of GlaxoSmithKline Biologicals' RTS,S/ASO1 malaria vaccine candidate

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Introduction

Evidence from economic evaluations can assist policy-makers in identifying interventions representing the best value for money. Therefore, as the PATH Malaria Vaccine Initiative (MVI) and partners begin to prepare for Phase 3 clinical trials of RTS,S in seven sub-Saharan African countries, there is a need to plan for economic and financial data collection alongside these trials, which would enable economic evaluation as well as budget impact analysis of this vaccine candidate to be performed should it successfully reach the licensure stage.

Aim and objectives

The overall aim of the study is to develop a protocol to estimate the cost-efficacy as well as budget impact analysis of the RTS,S/ASO1 candidate malaria vaccine.

Methods used

The primary perspective of the analysis will be societal, but other key perspectives will include those that are most likely to interest national decision-makers, i.e. the healthcare system and patients and their families. The incremental vaccine costs will be estimated outside of the trials by using standard WHO guidelines. Data will be collected on direct medical costs, non-medical direct costs and indirect costs. Key features of the approach will include:

- Using a healthcare utilization survey to collect information on household costs associated with cases that do not seek formal care (i.e. traditional healers, pharmacies, or home care);
- Information on healthcare resource use (visits, medications, diagnostics) will be collected using a separate abstracting form based on clinical records. Information on costs associated with long-term consequences (nutritional deficits, impaired cognitive development) captured in a follow up questionnaire will also be considered;

- Unit costs associated with each input (medication, test, visit, hospital day) will be determined using standardized costing approaches;
- Total costs per case will be calculated using the caregiver information, healthcare resource use, and unit costs of those resources;
- Cost per child and national annual costs will be estimated by combining cost per case with epidemiological information on incidence in the different age groups.

Key findings

While external validity is an important consideration for economic evaluations, the key advantage of doing economic evaluation alongside the vaccine clinical trial is that it allows patient-level data related to the incremental costs and effects of the vaccine to be collected from the trial participants. Such patient-specific distributional data are attractive for reasons of high internal validity associated with the clinical trial design and also allows for statistical analysis of the uncertainty and variability around costs, effects and the interaction between them, including country-level effects.