

Accelerated Development and Introduction Plans (ADIPs)
Management Committee Meeting
15-16 October 2003
Seattle, Washington
Bill & Melinda Gates Foundation

Report of Decisions and Action Points

1. ADIP Management Committee Membership and TORs

The Committee:

- 1.1. Accepted the terms of reference as included in the meeting folders.
- 1.2. Committed to act as the main communication vehicle between the ADIP teams and the GAVI Board in order to ensure consistency between ADIPs and overall GAVI strategic directions.
- 1.3. Agreed that its main management responsibilities are to:
 - 1.3.1. advise the Rotavirus and Pneumococcal ADIPs on priorities and operations; and
 - 1.3.2. make recommendations to the GAVI Board concerning ADIP management and funding.
- 1.4. Agreed that the GAVI Secretariat should facilitate the operations of the Committee

2. Definition of success

The Committee:

- 2.1. Decided that the main goal for the ADIPs should be to provide the GAVI Board and GAVI partners – including developing country governments, technical partners and the Vaccine Fund– the evidence base they need to evaluate the potential value of introducing pneumococcal and/or rotavirus vaccines.
- 2.2. Agreed that, from the perspective of the GAVI/VF Boards, the evidence base could point in one of three directions:
 - Evidence in favour of using VF funding to procure vaccine and accelerate introduction of vaccine in VF eligible countries
 - Evidence not in favour of using VF funding to procure vaccine and accelerate introduction of vaccine in VF eligible countries
 - Evidence in favour of introduction of vaccine in VF eligible countries, however, evidence indicate that GAVI and The Vaccine Fund resources do not have an added value role in accelerating this introduction.
- 2.3. Requested each ADIP to update the criteria for success, based on this discussion.

3. Framework for the investment case

The Committee:

- 3.1. Endorsed the following framework upon which to build an investment case for each ADIP:
 - Pricing, including a prediction of vaccine price reductions over time
 - Uptake strategy
 - Revenue and financing strategy over the course of a few years
 - Outcome measure (disease and deaths averted) relying on surrogate measures of disease burden and vaccine efficacy
- 3.2. Agreed that developing the investment case is the most important aspect of the ADIPs. The Committee will review and assess each of the ADIP investment cases at each meeting, and ADIP team leaders will be asked to revise their casework as necessary, based on these discussions.
- 3.3. Welcomed the proposal of the Vaccine Fund to suggest a system for consistent communication between the ADIPs and VF staff in order to synchronize fundraising activities with data emerging from the ADIPs.
- 3.4. Requested each ADIP team to provide a one-pager on their activities and goals, for use by the Vaccine Fund and the Secretariat in fundraising discussions and meetings.

4. Definition of 'late-stage' vaccine candidate

The Committee:

- 4.1. Defined the criteria for a 'late-stage' vaccine candidate as follows:
 - Vaccine candidate has positive safety and efficacy data from phase I and II trials; and
 - Vaccine candidate is produced by a producer¹ that has put candidate on a credible trajectory toward immediate phase III and introducing it in a market
- 4.2. Agreed that even if the above criteria are met with a certain vaccine candidate, the ADIP teams will need to evaluate and prioritize the opportunities and decided whether they have the human and other resources to pursue that vaccine candidate.

5. Segmentation of countries

The Committee:

- 5.1. Agreed that the ADIPs could choose to support a defined set of countries in their preparation toward early introduction of rotavirus and/or pneumococcal vaccines.
- 5.2. Decided that ADIP resources could be used for research (e.g., surveillance) and support activities in middle income countries, if those efforts are demonstrated to contribute to accelerating the introduction of new vaccines in all developing countries.
- 5.3. Requested that each GAVI-Vaccine Fund eligible country be sent an invitation to submit an 'Expression of Interest' in working with the ADIPs toward early introduction of rotavirus and/or pneumococcal vaccines. The GAVI Secretariat will help facilitate this. The invitation should also be distributed more widely through internet and other means.

¹ A 'producer' might be an emerging supplier that has licensed a candidate and would therefore need to re-conduct phase I and II clinical trials. However, funding for these early clinical trials would not be provided by the ADIPs.

- 5.4. Agreed that disease burden and cost effectiveness studies should be conducted in an appropriate mix of geographic settings. Furthermore, data resulting from these studies must be verified by independent experts.

6. Budgets for 2004

The Committee:

- 6.1. Reiterated the need for any potential agreement with an industry partner to be presented to, and approved by, the Committee before it is signed.
- 6.2. Endorsed the proposed 2004 budgets for the pneumococcal ADIP. However, in order to ensure that resources are available when needed, the team leader will re-examine his program budget to identify encumbrances that extend beyond 2004, so that these may be included in the 2004 budget. Once the revised 2004 pneumococcal ADIP budget is received, pending endorsement by the Chair, it will be forwarded to the full GAVI Board with a recommendation to approve.
- 6.3. Endorsed the proposed 2004 budgets for the rotavirus. However, in order to ensure that resources are available when needed, the team leader will re-examine his program budget to identify encumbrances that extend beyond 2004, so that these may be included in the 2004 budget. Once the revised 2004 rotavirus ADIP budget is received, pending endorsement by the Chair, it will be forwarded to the full GAVI Board with a recommendation to approve.
- 6.4. Agreed that it should receive the normal audited reports that are provided to the respective ADIP hosts. If the Committee feels these are not sufficient for adequate oversight, the ADIP teams will work with the Committee chair to develop appropriate reports.

7. GAVI-ADIP agreements

The Committee:

- 7.1. Expressed its concern about the slow progress in completing the memoranda of understanding between the ADIP teams and the UNICEF Vaccine Fund Trust Account, which is acting as trustee on behalf of the GAVI and Vaccine Fund Boards, and urged all partners to intensify activity to finalize the MOUs.
- 7.2. Decided that if the MOUs are not completed by the time of the next GAVI Board meeting on 9-10 December, the Committee would recommend to the Board that it may need to consider whether the Vaccine Fund, rather than UNICEF, should enter into agreement.

8. Other issues

The Committee:

- 8.1. Scheduled its next meeting for 9-10 June 2004. The location will be determined at a later date; Johns Hopkins School of Public Health has offered to host the meeting in

Baltimore.

8.2. Decided that the two ADIP team leaders should work with the Committee Chair to develop the presentation to the GAVI Board at its meeting in December. The presentations should include:

- Summary plans and progress reports
- Definitions of success

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