Report from the Extraordinary SAGE Meeting

16-17 February 2012

Decade of Vaccines

The extraordinary meeting of SAGE on the Decade of Vaccines was opened by the WHO Director-General requesting SAGE to review version 3 of the revised draft Global Vaccine Action Plan (GVAP) and assess whether it adequately captured input received through the consultative process.

Draft 3 of the GVAP reflects an extensive consultation process with SAGE[1], regions, countries, international organizations, civil society organizations (CSOs), vaccine manufacturers and other stakeholders. This consultation provided a number of key themes, namely country ownership (implying not just governments), civil society and community engagement and capacity building, the need to proactively address vaccine hesitancy, to view vaccines as part of comprehensive disease prevention and control, a discussion on coordination rather than full integration of immunization into other health programmes as well the need for a fully developed accountability framework.

In January 2012, the WHO Executive Board had reviewed an earlier draft. At the Board meeting 16 countries (including on behalf of all EU countries and African countries) and 2 CSOs who spoke on behalf of over 200 non-governmental organizations had provided detailed feedback, overall welcoming the momentum towards morbidity and mortality reduction and the opportunities for boosting immunization coverage. Concerns were raised regarding anti-vaccination groups and there was a call for a clear leadership role of WHO in the endorsement of the plan through Member States at the World Health Assembly (WHA), in the monitoring the GVAP implementation, in setting norms and immunization policies, in providing guidance and technical assistance to countries when implementing the plan, and in actively coordinating research on new vaccine development. It was stated that sufficient resources would need to be made available to UN agencies for these to be able to support the GVAP at all levels.

SAGE endorsed the vision encapsulated in the document, noting the impressive consultation work that had taken place over a short period of time with countries and CSOs and still to be completed, but stated that in its present format the GVAP does not qualify as an action plan but more as a global vision, and that its name should capture this more clearly. SAGE called for country-specific 10-year plans to be developed with modified and adapted goals and priorities. Responsibility for the operationalization of the plan was to be with regions and countries and any top-down approaches should be avoided. In order to assist countries in this adaptation, the document would need to be followed by a roadmap with a series of companion tools and documents to operationalize the vision for each outcome. It also noted that the full development of the plans at country level may take up to two additional years.

SAGE clarified that the focus of the plan was primarily on low and middle income countries and that countries (not just governments) would need to endorse the final document. Care should be taken not to duplicate or reinvent existing disease control interventions but rather to build on regional goals and existing structures and initiatives (e.g. Global Polio Eradication, Measles Elimination , Global Vaccine

[1] Meeting of the Strategic Advisory Group of Experts on Immunization, November 2011 – conclusions and recommendations Weekly epidemiological report 2012;87: 1-16.

Safety Blueprint, Health Systems Strengthening, Primary Health care re-engineering), thus avoiding the creation of any new structures. SAGE insisted that the GVAP build on the mandates of international organizations and called for a clearer definition of the roles and responsibilities of WHO, UNICEF and GAVI in the further development and implementation of the plan and requested that this should be clarified before presentation to the WHA. SAGE insisted on firm WHO leadership and coordination at global, regional and country levels. SAGE suggested the enhancement of the content of the plan with further focus on equity between and within countries, to emphasize the life-course approach to immunization, to include vaccine safety issues including vaccine manufacturing quality assurance, and to reflect the key objectives of the Global Vaccine Safety blueprint to enhance confidence in vaccines. Noting the potential global impact of vaccine hesitancy, bolder statements to address this concern must be included. Strengthening of health systems was to be emphasized with a focus on human resources capacity building and improved management of the ever increasing immunization work load. Furthermore, stronger content and more resources were needed in the area of monitoring and evaluation with emphasis on vaccine-preventable diseases surveillance, which includes appropriate laboratory services. A stronger statement should be made about private sector integration and the role of NGOs in vaccine provision, with the balance between necessary coordination versus actual integration carefully adjusted.

SAGE provided the following comments and recommendations with respect to specific elements of the GVAP:

With respect to the DoV principles: Immunization as a right to be made more prominent; equity focus (lessening the gap between top and bottom income quintiles); and individual responsibility to be highlighted.

With respect to the Goals:

Goal 1. Polio: Need to expand language to better align to the polio eradication goal and reflect the further strengthening of the commitment to polio eradication by declaring it a global emergency.

Goal 2. Neonatal tetanus to be mentioned in conjunction with maternal immunization, keeping in mind that other interventions are also relevant for achieving neonatal tetanus elimination but that strengthening maternal immunization would also decrease the impact of other diseases (e.g. influenza).

Goals 3./4. Measles and Rubella to be combined in one goal, taking note of the recommendations in the recent WHO Rubella Position Paper.

Goal 5. Separate out immunization system coverage increases and new vaccines introduction into two goals. Emphasize routine immunization programmes, look at communities versus districts and emphasize priority given to the poorest SES quintile.

Goal 6. Include part of goal 5 and use Global Immunization Vision and Strategy (GIVS) language to cover new vaccines introduction. Clarify how vaccine introductions are defined – this should cover both new and underutilized vaccines and should include expansion of their coverage.

Goal 7. Rewrite - this goal should also cover improvement of existing vaccines and technologies as well as the development of new vaccines against diseases for which vaccines are not yet available.

Goal 8. Remove – as it is already a well stated Millennium Development Goal (MDG) and does not cover other interventions which will be needed to achieve these MDGs.

New Goal. Consider including a new goal on timely and complete immunization of individuals in the target population. This goal would address the issue of vaccine hesitancy which is seen as a major issue requiring priority consideration in the next ten years.

Although SAGE debated the potential to add a goal covering vaccine safety as a critical component of increasing confidence in immunization and surveillance of adverse events following immunization (AEFI), it finally concluded that goals should be limited to actual output and that AEFI surveillance be better captured in the outcome indicators.

With respect to the Accountability Framework:

The framework contains indicators, stakeholder responsibilities/commitment and responsibilities for monitoring the progress of the GVAP. For the goal indicators, progress will be monitored against the set targets; for the outcome indicators, progress will be measured against a baseline which is still to be established. Indicators to monitor implementation of specific actions are yet to be defined.

SAGE stressed that as part of the accountability framework governments will need to be accountable to their constituencies using these indicators. SAGE reiterated the WHA call for UN agencies to oversee that the vision be translated into action and for WHO to play a global leadership and coordinating role. It suggested that in regular regional meetings, countries provide reports on implementation of the GVAP. SAGE's own role in monitoring GVAP's progress should be similar to its role in monitoring progress of the polio eradication initiative, including overview of health systems issues. A standing SAGE working group could be established, whose purpose would be to prepare for an annual review and report on progress of implementation to be presented to the WHA. Further discussions are warranted on whether sanctions or consequences for under-achievement should or could potentially be imposed, noting that international peer review at the WHA provides a level of international accountability. SAGE suggested that an additional outcome related to strong global, regional and national leadership be added. Accountability should be country specific. Along with country implementation plans, accountability indicators will need to be identified. Achieving success is dependent on all stakeholders, and all should be subjected to accountability including international agencies.

With respect to the indicators:

New indicators are to be developed for the revised goals and they should be better aligned with the outcomes. If possible, the number of indicators should be reduced and one should rely on existing indicators/and or already collected information in order to alleviate additional monitoring needs and related costs.

Outcome 1: Legislation to be kept as an outcome as it is one of the mechanisms to increase country-level accountability although it may be difficult to implement in some countries.

Outcome 2: Monitor vaccine refusals and stakeholder engagement. An AEFI surveillance indicator should be added. Reduction of vaccine hesitancy could be approximated by measuring the proportion of fully and timely immunized individuals. Look at new stakeholders' engagement at global, regional and national level.

Outcome 3: Socioeconomic status indicator (wealth quintiles) rather than districts; DTP should be replaced by DTP-containing vaccines. It would be appropriate to aim to capture the timeliness of immunization.

Outcome 4: Drop existing health system indicators and replace by one reflecting under 5 health care, such as management of pneumonia or diarrhoea and a second one reflecting functional AEFI monitoring and management. If there is a need to limit the number of indicators then second measles is more important than DPT and should be retained.

Outcome 5: Keep as is – potentially add a resource accountability indicator (total resources / immunization coverage achieved / cases of disease prevented).

Outcome 6: Include indicator for technology transfer and operational research and more short and mid-term R&D indicators. Look at strengthening social science and behavioral research in the text.

With respect to benefits, costs and funding:

SAGE had serious reservations about the model chosen to assess GVAP benefits and costs and was concerned that there were limitations in the assumptions within the model. SAGE was concerned that it had insufficient information to comment fairly on the Value of Statistical Life (VSL) approach used to assess health benefits but questions were raised about whether this was the best approach to use. SAGE commented that the analysis did not take into account the indirect benefits or impact of the interventions on morbidity and disability and reduction of resource needs for treatment services; that it did not include agency costs, costs for advocacy and civil society organizations, nor cost for scaling up and achieving equitable immunization coverage, or for surveillance or measles ramp-up – despite the inclusion of measles elimination as a main goal.

Furthermore, the analysis was limited to a subset of 94 countries, potentially too centered around GAVI eligible countries, and excluding China. Benefits of existing 6 vaccines of EPI including the proposed measles elimination programme have been overlooked. Most benefits are being ascribed to three vaccines: rotavirus, *Haemophilus influenza* type b, and pneumococcal conjugate. SAGE suggested that the aspirational goals of the GVAP should be better accounted for within the costing model, given that the present cost analysis was based primarily on existing country comprehensive multi-year plans and business as usual.

SAGE felt uncomfortable with a potentially severely underfunded plan which may not achieve its goals during the decade and cautioned against publishing the present figures as currently presented. It also stated the need to present the current data only as high level cost with limitations and to clearly identify what was not taken into account.

SAGE recognized that the biggest costs were likely to be the core costs included to deliver and scale up the core immunization program. Further costing of the additional proposed initiatives was required.

Future publications would need to be accompanied by a detailed description of the assumptions and limitations and by plans for future work.

Polio eradication

SAGE received updates on the outline Emergency Action Plan for the Global Polio Eradication Initiative (GPEI), in the context of the Executive Board's resolution on polio as a programmatic emergency for global public health, the lessons learned from the success in India, the new tactics that are being intensified in priority countries, and potential innovations as discussed in an informal strategy review

meeting. In addition, SAGE received an update from the Chair of the SAGE Polio Working Group, on policy issues for the polio endgame that will be brought to SAGE formally in April 2012.

SAGE noted and applauded the multiple different types of interventions that have resulted in India having gone 12 months without detecting wild poliovirus. This is a major achievement and the removal of India as a global reservoir of wild poliovirus will have a significant impact on the potential for the spread of wild polio virus (WPV).

However, despite a decrease in cases globally between 2010 and 2011, the global initiative is still not on track to achieve eradication by the end of 2012. The major reason for this is the continuing extensive transmission in the endemic countries, Pakistan, Nigeria, and Afghanistan. SAGE noted the discussion at the Executive Board of WHO, and the resolution to regard polio eradication as a global public health emergency. This confirms the SAGE recommendations of November 2011[1] and SAGE urges that eradication be completed as rapidly as possible to avoid the very real possibility of failure of the entire eradication programme. Speed is also the essence to avert financial and programme fatigue. Further, SAGE noted that if eradication is further delayed, then significant funds will continue to be diverted away from other public health priorities. SAGE noted the key areas identified in the outline of GPEI Emergency Action Plan, which focus on actions to put the global initiative back on track, and that each of the priority countries (Pakistan, Nigeria, Afghanistan, Democratic Republic of Congo, and Chad) has developed or is in the process of developing a national emergency plan, specific to the issues being faced in those countries. SAGE recommended that for all three endemic countries particular attention should be given to strategies that address programmatic activities in the context of conflict, insurgency and insecurity.

SAGE was particularly concerned about Pakistan and Nigeria, where wild poliovirus transmission has significantly increased in 2011. Both countries have the potential to continue to spread WPV to polio free countries, and the ongoing transmission in these endemic countries is the major risk to achieving global eradication. In Nigeria the continued transmission of circulating vaccine derived type 2 virus threatens the unfolding of the endgame strategy for sequential removal of oral poliovirus vaccines, and this transmission must be stopped before the global strategy can be implemented. Nigeria must immediately tailor its emergency programme to address this problem. SAGE further commented that although Afghanistan is the third priority endemic country, no details about its country plans were outlined and this should be addressed at the April SAGE meeting. In view of these concerns, SAGE requests that the National Emergency Action Plans for Pakistan, Afghanistan and Nigeria be presented at the April 2012 meeting.

The funding gap for the global initiative remains a major concern. Unless this gap is filled, activities in infected countries and high risk countries planned for 2012 - 2013 will be significantly affected. The SAGE emphasizes that filling the funding gap is essential to the success of the initiative.

SAGE identified lessons learnt from the Indian programme which could be incorporated into country action plans. Noting all the updates received, SAGE made additional recommendations: including the need for:

1) An intensified and proactive communications strategy in each of the priority countries to address issues of community engagement and demand for polio immunization, as an integral part of the national emergency action plans.

2) A particular focus on the training, supervision, and motivation of immunization teams to ensure the highest possible quality of supplementary immunization activities.

3) The clear delineation of accountability as well as consequences for inadequate performance.
4) Continued efforts to integrate polio eradication activities with broader immunization and primary health care efforts.
5) Attention to maintaining, and expanding where necessary, the extensive partnership teams in key countries, and to maintaining in particular surveillance networks and activities in countries that have recently become polio-free or that remain at risk of importation and spread.
6) Piloting the use of IPV as a supplement to OPV campaigns in key infected areas; special attention would need to be paid to this pilot use to ensure that any potential negative impacts on eradication activities were identified and avoided. A specific communications strategy would need to be developed to avoid OPV being negatively impacted by such a pilot.
7) Maintaining a level of focus on recently infected and at-risk countries to ensure that all transmission is stopped and that the risk of further outbreaks is mitigated. Included in at risk countries are those experiencing financial constraints, sanctions, and those in conflict situations.

SAGE noted the update from the Polio Working Group, in particular that the Group has made significant progress in defining endgame strategies. Recognizing that the intradermal administration of IPV may be central to tOPV-bOPV switch, the SAGE Working Group highlighted the importance of the fast-tracking of regulatory review and approval of this route of administration. SAGE looks forward to a presentation of policy options at the April 2012 meeting.