
from the

Global Meeting on Surveillance for

Vaccine Preventable Invasive Bacterial Diseases (VP-IBD)

and Rotavirus

22-24 September 2010

with WHO internal meeting on 21 September 2010

Geneva, Switzerland
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Executive Summary

WHO and surveillance partners have progressed significantly during the past few years in strengthening and expanding the WHO coordinated global surveillance networks for rotavirus and vaccine preventable invasive bacterial diseases (VP-IBD). Some of the main accomplishments have included transition of different rotavirus and VP-IBD surveillance sites into one WHO coordinated global surveillance network, agreement to standardize surveillance data and to use selected surveillance performance indicators to monitor and improve the networks, as well as establishment of a reporting and feedback mechanism between Ministry of Health (MoH) sentinel sites and WHO. In addition, rotavirus and VP-IBD laboratory networks have been established globally and work is under-way to define methods to synergize these surveillance networks with other programmes.

To further enhance the rotavirus and VP-IBD surveillance networks, particular activities are required to determine:
1. How to best improve data quality by further streamlining the WHO data management system;
2. How to best improve VP-IBD epidemiologic and laboratory data quality;
3. How to maximize the information available from Tier 3, population-based sites, both those participating and not participating in these surveillance networks;
4. How to best enhance rotavirus surveillance to ensure lessons learned in implementing surveillance activities are made available globally;
5. How to enhance national MoH ownership of the surveillance networks, and how to best integrate these networks with other national activities; and
6. How to most effectively improve the VP-IBD and rotavirus laboratory networks.

Meeting Objectives:

This surveillance meeting was convened to review and discuss data generated by the global rotavirus and VP-IBD surveillance networks, and to discuss the above six priority challenge issues for advancing the networks. For each identified key challenge, the meeting objective was to agree on three (3) achievable priority actions to be implemented at global and regional levels within the next 12 month period to further strengthen these surveillance networks globally.

Meeting Structure

From 21-24 September 2010, staff from WHO HQ and Regional Offices with responsibility for new vaccine surveillance, along with invited expert immunization

partners, met in Geneva to review progress made, and to discuss the six identified challenge issues for both rotavirus and VP-IBD surveillance networks. All meeting participants received the meeting agenda in advance, and also received background and draft documents for discussion. The meeting structure included an introductory plenary session, followed by several concurrent epidemiology and laboratory workgroups in which discussions over the six selected challenge issues took place. During a final plenary session, workgroups provided feedback to all participants to agree jointly on achievable milestones to be completed at global and regional levels within a 12 month timescale.

Main Conclusions and Recommendations

A recurrent theme emphasized during various workgroup sessions was the management and support of these surveillance networks should be further strengthened by increased involvement and subsequent ownership by the Ministries of Health (MoH). Several workgroups also highlighted the importance of adhering to standardized case definitions and protocols, to ensure not only comparability within the system but the attainment of high-quality data. Overall, it was also apparent that the rotavirus surveillance network was more robust than the VP-IBD network. This is in part due to inherent diagnostic difficulties in isolating and identifying the bacteria as well as due to delays in processing samples. It was also emphasized that rotavirus surveillance benefited from building upon the well established poliomyelitis and measles virology networks. In contrast, VP-IBD surveillance was unable to build upon the strengths of an already existing global bacterial laboratory network. Since VP-IBD surveillance is relatively new, it will require significant support and mentoring until the system matures and data quality improves. However, meeting participants identified numerous activities to enhance VP-IBD quality; in particular, discussions in both epidemiology and laboratory related workshops emphasized the importance of visiting and assessing the individual sentinel sites. Meeting participants also agreed that it would be useful to identify a ‘champion’ for the vaccine preventable disease surveillance networks that might be able to provide higher profile to seek support for surveillance both globally and also within countries.

This meeting provided the first opportunity for the global rotavirus and VP-IBD laboratory networks to meet. Hence, much of the discussion centred around management issues related to the networks, such as agreeing on roles and responsibilities of the global reference laboratory (GRL), regional reference laboratories (RRLs), national laboratories (NL), and sentinel hospital laboratories. The VP-IBD laboratory meeting also discussed in detail how to further improve quality of the data.

For each identified challenge issue, workgroups provided prioritized recommendations for activities to be accomplished at global and regional levels during the next 12 months. WHO and partners will seek to implement these activities to further enhance these surveillance networks.
Background and overview of the current WHO coordinated global VP-IBD and rotavirus surveillance networks

A global surveillance network for rotavirus and invasive bacterial disease based on sentinel surveillance has been established in the past several years and has been recently transitioned into WHO funding and coordination. It is expected that these networks generate data which will allow disease burden estimation, support evidence-based decision making on vaccine introduction, monitoring of circulation of specific serotypes/genotypes and changes in serotype/genotype distribution and antimicrobial resistance, and evaluation of vaccine impact after vaccine introduction. Additionally, these networks can also contribute to the early detection of outbreaks or epidemics.

In 2008, the foundations for this global surveillance network were laid out, considering the Global Framework on Immunization Monitoring and Surveillance (GFIMS), and included the following premises:

- Move from time-limited surveillance projects to sustainable networks;
- Integration with existing networks;
- Collect & report standardized data to facilitate regional and global monitoring;
- Country-ownership;
- Hospital-based sentinel surveillance;
- WHO regional offices coordination; and
- Technical support from WHO and partners.

During the transition period from 2008 to 2010, with the support of GAVI funding, the global rotavirus and VP-IBD surveillance networks were strengthened and expanded, mainly in GAVI eligible countries. Coordination mechanisms between WHO regional offices and Ministries of Health (MoH) were improved with technical support provided by WHO and partners to all requesting countries. In addition, global rotavirus and VP-IBD laboratory networks were established.

Currently, 55 countries globally are participating in the WHO coordinated rotavirus surveillance network, and 47 countries are participating in the VP-IBD global surveillance network. A "layered approach" to the surveillance network structure has been promoted, while strengthening and expanding sentinel based surveillance for rotavirus and VP-IBD surveillance. This follows a tiered structure, described below:

- **Tier One**: “Core” sites have focused on conducting country-level surveillance for rotavirus diarrhoea and meningitis. These sites require technical expertise to identify suspect cases and laboratory capacity to perform a minimum of diagnostic tests to identify probable bacterial meningitis cases where *Haemophilus influenzae* type b (Hib), *Streptococcus pneumoniae*, or *Neisseria meningitidis* are the causative pathogens. Based on data reported via the Global VP-IBD and Rotavirus Information and Surveillance Bulletins in 2010, a total of 25,440 children...
enrolled in sentinel sites conducting VP-IBD surveillance, and 50,412 children were identified globally during 2009 in sentinel sites conducting rotavirus surveillance, respectively\(^2\).

- **Tier Two VP-IBD Sites**: Selected VP-IBD sites have conducted invasive bacterial disease (meningitis, pneumonia, or sepsis) surveillance. In addition to performing Tier One meningitis surveillance, these "enhanced" sites will collect blood cultures which allow the identification of pathogens in other invasive bacterial disease including bacteremic pneumonia and sepsis. Information provided by these sites will complement data generated by the "core" sites. During 2009, 17,811 children were detected in Tier Two sentinel sites conducting VP-IBD surveillance, globally.

- **Tier Three Sites**: At least one site per region or sub-region will also perform population-based surveillance for rotavirus and VP-IBD, some using a demographic health surveillance system (DHSS). These sites include more sophisticated centres of excellence with capacity in place for conducting population-based surveillance for hospitalized cases. Currently two population-based sites, one each in AFR and WPR, are reporting to the global surveillance networks. To a limited extent, hospital-based disease rates and case fatality ratios can be applied to national data to generate national disease burden figures in countries or sites with adequate access to care. However, high quality incidence rates derived from population-based denominators are needed to provide additional useful information, especially for evaluating vaccine impact and safety.

I. **Six Identified Challenge-I ssues for the WHO Coordinated Rotavirus and VP-IBD Surveillance Networks**

Six challenge-issues have been identified as important to the advancement of the VP-IBD and rotavirus surveillance networks globally, as follows:

1. How to best improve data quality by further streamlining the WHO data management system;
2. How to best improve VP-IBD epidemiologic and laboratory data quality;
3. How to maximize the information available from Tier 3, population-based sites, both those participating and not participating in these surveillance networks;
4. How to best enhance rotavirus surveillance to ensure lessons learned in implementing surveillance activities are made available globally;
5. How to enhance national MoH ownership of the surveillance networks, and how to best integrate these networks with other national activities; and
6. How to most effectively improve the VP-IBD and rotavirus laboratory networks.

This surveillance meeting was convened to bring together global experts to discuss these challenge issues and to prioritize specific action items that can be achieved at the global and regional levels to make progress in each of the challenge-issue areas identified above. (Agenda, Annex 1).

II. Meeting Structure, Objectives, and Participants

The meeting was convened to review current progress achieved in strengthening global surveillance networks for rotavirus and VP-IBD, and the data collected at sentinel sites and shared through WHO Regional Offices. Furthermore, the advice and inputs of the participants were sought around the identified challenge-issues. For each identified challenge issue, the main meeting objective was to agree on three (3) achievable priority actions to be implemented at global and regional levels within the next 12 month period to further strengthen these surveillance networks globally.

Meeting participants represented the following:
- Ministries of Health;
- WHO Headquarters, and WHO Regional offices staff responsible for new vaccines surveillance and data management activities;
- WHO Lyon/meningitis/influenza/child health colleagues;
- Global and Regional Reference laboratories participating at the Rotavirus and VPD Laboratory Networks; and
- Partner institutions including the US Centers for Disease Control and Prevention (CDC), GAVI, the Bill & Melinda Gates Foundation (BMGF), among others (Annex 2). Representatives of vaccine manufacturers also attended the meeting as observers.

III. Surveillance Meeting Issues and Workgroups: Objectives, Summaries and Recommendations

CHALLENGE ISSUE 1: Improving Data Quality: Enhancing Data Management

Solving problems that limit conduct of high-quality VP-IBD and rotavirus surveillance (WHO Closed Session on Data Management)

Workgroup Objectives:
Review current WHO data collection, analysis, and management processes to identify areas for further refinement and improvement

Workgroup Summary:
WHO Regional Office and headquarters surveillance staff (epidemiology, laboratory and data management) discussed current data management
processes in place at the sentinel sites, Regional Offices and Headquarters. Additionally, the case definitions currently being used were discussed in detail and an agreement was made to implement and ensure strict adherence to standardized case definitions (Annex 3).

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. **Ensure adherence to standardized case definitions.** (Note: The transition to the agreed case definitions will take time to allow for the revision of existing protocols and case report forms at the various sentinel sites. An update on progress to achieving global use of the standardized case definitions will occur during the 2011 global new vaccines surveillance meeting.)

2. **Regional Offices will transition to transmitting data files to headquarters on a monthly basis using an agreed data exchange format with the currently used spreadsheets being phased out.** (Note: the previous month's data may be simply resent if there are no new reports or updates.) Headquarters will propose both case-base (preferred) and aggregate formats for the data with pre-calculated indicator values. Additional discussions will need to be held regarding the feasibility and efficiency of conducting case-based versus aggregated data sharing.

3. **Headquarters will transition to providing internal feedback to Regional Offices on a monthly basis.** Feedback will include standardized tables, graphs, and maps of global and region-specific data summarizing the rotavirus and VP-IBD surveillance networks. The twice yearly analysis and publication of global data via Global VP-IBD and Rotavirus Surveillance and Information Bulletins to be shared with MoH and external partners will continue. These bulletins will also use a format of standardized presentation of information via agreed tables and figures, which may be periodically updated as required.

**CHALLENGE ISSUE 2: Improving VP-IBD Surveillance Quality**

1. **Defining problems that limit conduct of high quality VP-IBD surveillance (Workgroup 3a)**

**Workgroup Objectives:**
Describe factors that account for heterogeneity in surveillance data across and within sites and define solutions to better define and adjust for these factors, in terms of case ascertainment and laboratory methods.

**Workgroup Summary:**
The global VP-IBD surveillance data was presented. It was agreed that there is significant data heterogeneity between and within countries/sites and that overall bacterial isolation rates were quite low. Factors potentially contributing to
heterogeneity include variations in healthcare seeking behaviour and practice; inconsistency of surveillance population; use of antibiotics prior to specimen collection; inconsistency in application of patient screening criteria (suspect meningitis, pneumonia and sepsis) and case definitions; incompleteness of case ascertainment; lack of standardized collection processes, inappropriate specimen transfer and processing; laboratory issues related to isolation and identification of pathogens from CSF and blood cultures, and variable data (epi, clinical, lab) collection, management, and analysis practices. Trends over time are yet difficult to assess, primarily due to the impact of data quality variations and lack of full standardization of surveillance methods but also because data is only available from the sites that were transitioned to WHO in 2008.

Focus and Scope of VP-IBD Surveillance: All meeting participants acknowledged that VP-IBD surveillance is expensive, time consuming, and complicated. To work correctly all parts of the system have to be functional – clinical, specimen transport, laboratory, data management and communication. Hence, sites will require close monitoring and adequate technical support. The point that poor surveillance data can be misleading was made several times and quality of data was stressed over both quantity and representativeness. Focus should be on improving quality of existing sites before adding new sites.

Adherence to Case Definition and to Transport and Lab Processing Procedures: Following review of the data from different sites, many questions were asked about the adherence of the sites to the case definition. In particular, it appears that the point of recruitment to the surveillance in some sites was the laboratory, following a positive CSF result and not the clinical assessment made by the health care provider. Also, there was greater than expected variation between sites on frequency of specimen collection and percent of bacterial isolation and identification.

Communication, Advocacy and Ownership: Much discussion focused on the necessity for MoH ownership. Decision making is a country-based activity and is influenced by country-based data. However, many sites indicate that the MoH currently has limited involvement in their site. To ensure ethical practice and maintain positive feedback cycles between the lab and clinical staff, surveillance results available at the sentinel hospital should be channelled to clinicians as soon as feasible. The two parties should use the obtained data to benefit the individual (treatment and empiric prescribing patterns) and the population, in terms of vaccine use decisions. The whole process needs a champion or advocate that can operate at different scales – locally, nationally, regionally – to bring the various parties together and animate new vaccines surveillance.

Diagnostics: The point was made repeatedly that surveillance for VP-IBD would be considerably easier if there were better diagnostics for major vaccine preventable bacterial diseases such as *H. influenzae* type b and the pneumococcus. The rapid improvements in molecular techniques can help
increase sensitivity of testing, particularly in the diagnosis of bacterial meningitis. Some delegates noted that the same sentiments have been expressed since 1980, and that a sensitive and specific diagnostic test still does not exist for pneumococcal disease. In the meantime, however, improvement and ensuring full standardization of appropriate bacterial culture techniques are critical.

**Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels***:

1. **Audit/assess sites** systematically by using a standardized tool to determine their practices with the following goals: (a) in the short term, to assess continued inclusion in the network, and (b) to maintain standardized working practices over the duration of surveillance. This process should fully involve and potentially be led by the MoH, and should promote the MoH's role in ongoing supportive supervision of site activities. These visits should include subject matter experts, and ideally be coordinated with the GRL and RRLs. Following a careful evaluation process with adequate time for correction and improvement, sites that are continuously underperforming should be dropped from the surveillance network.

2. WHO should further define an additional limited number of key performance indicators to help evaluate adherence, potentially including:
   - % of CSF samples logged into the laboratory within 2 hours of the lumbar puncture (LP) draw
   - Contamination rates of blood cultures, which is a good indicator of overall laboratory performance
   - % of blood cultures for which the minimum required volumes of blood is obtained, as determined by weight.
   Refer to Annex 4 for additional details.

3. WHO Headquarters should actively seek a Champion for the network who can operate at local, national, regional and global level to inject enthusiasm and resources into the process as a civic partner to the WHO and Ministry efforts. An organization such as Rotary International would be a suitable example.

*Refer to Annex 6 for additional recommendations.

2. **Solving problems that limit conduct of high-quality VP-IBD surveillance (Workgroup 5b)**

**Workgroup Objectives:**
Identify potential performance indicators and a system to monitor sentinel site performance and develop criteria for when to intervene to improve or exclude a reporting site
Workgroup Summary:
Current surveillance data were reviewed; the main barriers to obtaining high quality surveillance data and development of potential new performance indicators were discussed. The purposes of performance indicators are to diagnose data problems, identify and characterize differences in practice, measure country commitment to surveillance and monitor performance for defining future directions of surveillance. Identified barriers to VP-IBD surveillance data and suggestions for improvement to be implemented in the site level were provided:

<table>
<thead>
<tr>
<th>Identified Problem/Area of Concern</th>
<th>Potential Solutions</th>
</tr>
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| Use of antibiotics prior to sample collection decreases yield of pathogen or results in culture negative results | • Query cases/care-givers for use of antibiotics prior to hospitalization  
• Collect clinical samples before antibiotics are administered at the hospital  
• Use polymerase chain reaction (PCR) to test some sub-sets of clinical samples, such as purulent cerebrospinal fluid (CSF) samples, to detect presence of DNA of any of the 3 pathogens |
| Incompleteness of case ascertainment | • Ensure understanding and consistency of surveillance methods  
• Establish increasing, routine MoH supportive supervision and feedback to sites |
| Inappropriate CSF and blood specimen collection, including contamination and inadequate blood volume | • Encourage 24/7 CSF collection in sentinel sites performing VP-IBD surveillance (and 24/7 blood culture collection in Tier Two sites)  
• Sites without 24/7 laboratory and collection processing in place should use TI media to improve yield from specimens kept overnight  
• Periodic assessment of LP and blood culturing techniques  
• Monitor volume of blood and CSF collected |
| Lack of appropriate specimen transfer and processing, including delay in placing blood cultures in incubator, delay in blood culture subculture, use of human blood in blood agar plates, lack of growth factors (X, V) in chocolate agar (for Hi), among others. | • Training of laboratory staff in standardized methodologies, thus reinforcing laboratory capacity  
• Ensure strict adherence to lab quality assurance/quality control (QA/QC) for appropriate specimen transfer and processing  
• Establish new performance indicators for contamination  
• Monthly review of blood & CSF culture results |
| Data (epi, clinical, lab) collection, management, | • Periodic site visits by MoH, RRL, etc  
• Clearly defined time periods for reporting, to |
Increased feedback to clinicians, laboratorians, and epidemiologists at sentinel site hospitals thus strengthening communication within sites

• Regular refresher training for physicians and others involved in surveillance

• Timely feedback to physicians to obtain more buy-in for surveillance activities

In addition, the following issues and proposed approaches to improve data quality were highlighted:

• **Use of a consistent case definition:** It was agreed that the definition stated in WHO surveillance standards should be implemented in all sites for consistency and better data quality. However, an exclusion criterion should be included in the suspect meningitis definition (e.g., “altered consciousness” to be modified to “altered consciousness with no other alternative diagnosis”) to improve specificity of the screening definition and reduce unnecessary work.

• **Ensure consistency in the age group under surveillance:** Overall, the target population should be children 0-59 months of age. Some sites are currently beginning to enrol children who are either >1 month or >2 months of age. For the purposes of the surveillance network, which has the longer term vision of enhancing VPD surveillance in general, the target population should be all children 0-59 months of age. Data analysis of case based VP-IBD data should be restricted to children >1 month of age.

• **Update the surveillance performance indicators:** The number of indicators should be kept to a minimum; however, several new indicators may markedly increase data quality and should be added. Additionally, process and outcome indicators should be separated, and an SOP of reporting on indicators should be developed by WHO. Additional indicators to be considered are included in Annex 4.

• **Improve blood culturing practices for Tier Two sites.**

• **Standardize and automate data output** (for ease and reduction of errors)

• **Increase frequency of data reporting** (monthly updates to allow trend monitoring)

• Develop a plan of action to increase MoH buy-in of surveillance

• **Visit and assess hospital sentinel sites** and laboratories (including site, NL, and RRL)

• **Encourage development of rapid diagnostic tools** for VP-IBD pathogens

**Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels***:

Note: This workgroup also included the recommendations from the previous session related to defining the problems that limit high-quality VP-IBD
surveillance on assessing sites, adhering to standard case definitions, and modifying indicators.

1. Update/standardize the case report forms being used to ensure that all critical variables are collected in a uniform way and that the data needed to calculate indicators are included.
2. Ensure that a global laboratory external quality assurance process is developed and implemented
3. Improved rapid diagnostics could play a valuable role in improving data quality, and the WHO surveillance team should further pursue this matter, particularly with funders such as the BMGF who are interested in this area.
*Refer to Annex 6 for additional recommendations.

**CHALLENGE ISSUE 3: Maximizing Tier 3 Population-Based Data**

Population based Sites and Centres of Excellence (Workgroup 3b)

**Workgroup Objectives:**
Identify how to strengthen partnerships with population based sites / centres of excellence and consider further integration and collaboration with the WHO VP-IBD and rotavirus surveillance networks

**Workgroup Summary:**
High quality population-based surveillance data is needed to calculate disease incidence rates and quantify potential shifts in bacterial strain distributions following vaccine introduction, among other objectives. This type of surveillance is resource intensive, and thus should be limited to a few sites. However, the potential value of the interaction between VP-IBD and rotavirus surveillance and population based studies was highlighted in the presentations. Information gathered from such sites would assist in assessing vaccine impact and safety and specifically include:
- incidence estimates;
- population descriptions that make it possible to generalize to similar populations; and
- research on access to care, which is essential to adjust hospital based incidence estimates.

There are a variety of existing sites that could be considered in this regard:
(i) INDEPTH – a network of demographic surveillance sites coordinated from a central office in Accra, Ghana. They have good inter-site communications and a proven record in working together. Their focus is on demography and population specifics; few sites have existing bacteriological surveillance capacity but they would be willing to partner with WHO to overcome this.

(ii) CDC IEIP (International Emerging Infections Programme). Currently established in Bangladesh, China, Egypt, Guatemala, India, Kenya, and being...
established elsewhere, this global programme focuses on population-based surveillance for new infectious symptoms linked to CDC supported laboratories for pathogen detection. The focus has been primarily on establishing surveillance for respiratory (viral and bacterial) and diarrhoeal diseases (http://www.cdc.gov/ieip/).

(iii) Academic/research centres/institutions. The WHO surveillance networks already include some centres such as Chaka Sishu Hospital in Bangladesh, MRC The Gambia and the KEMRI Wellcome Trust Research Programme in Kilifi, Kenya. Other potential contributors are the International Vaccine Institute in Seoul, and other Wellcome Trust funded research centres in SE Asia, including Ho Chi Minh City, Hanoi, Bangkok, Vientiane. The Institute Pasteur also has a chain of laboratories across both SE Asia and West Africa.

Centres of microbiological excellence could be incorporated into the laboratory network to provide academic and charity funded expertise to the WHO IBD surveillance. Since many of the regional reference laboratories are already in this class, these laboratories should be able to provide important training and support.

Given the difficulties of establishing and sustaining high-quality population-based surveillance in WHO VP-IBD and rotavirus networks – sites with much greater local expertise and with existing mechanisms of quality data assurance would be an economical and efficient way to expand the quantity and quality of observations, particularly of the VP-IBD network, in developing countries. However:

- These institutions have a moral obligation to contribute data to the host Governments and communities where they work, although the institutions may not receive a financial benefit for doing so;
- Academic and other centres of excellence have their own potentially conflicting agenda but areas of mutual interest can be explored; and
- Sites with established methods might not be willing to standardize data collection to that of the WHO system.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. Reach out to centres of excellence. It is unclear to what extent centres of excellence are able to contribute to the WHO surveillance network – though the potential is evident. One way to overcome this uncertainty is to reach out to the various groups proposed in the discussion and explore areas of common interest and science/public health overlap.

2. Define the utility. Both the CDC IEIP and INDEPTH programmes expressed interest in collaborating with WHO. However, there is need of a concept paper that would define the likely benefits in quantifiable terms before expending large
amounts of energy and resources building links. This concept paper should define the potential advantages of linking these sites to existing WHO surveillance exercises – defining the modelling approaches that were likely and the key assumptions underpinning such models. The paper should also explore the possibility of enhancing non-population-based sentinel site data by establishing links to national census data or by triangulating the surveillance data with other routine health statistics.

**CHALLENGE ISSUE 4: Using Surveillance Data**

**Uses of rotavirus surveillance to assess vaccine impact (Workgroup 5a)**

**Workgroup Objectives:**
Assess lessons learned for the need and use of surveillance data around vaccine introduction and use

**Workgroup Summary:**
Selected countries and regions presented experience on decision making for rotavirus vaccine introduction and uses of rotavirus surveillance and other studies to assess impact of rotavirus vaccine. The importance and use of surveillance - including sentinel and population based surveillance – secondary data, and special studies to assess rotavirus vaccination impact was discussed, as follows:

**Vaccine introduction decision making:** Experience from The Sudan and Americas has clearly demonstrated the value of local disease burden data as a driver for the decision to introduce vaccine. Many countries have chosen to have multiple sentinel sites so they could have truly local data for decision making. In settings where vaccine introduction is not imminent, countries may be reluctant to pursue surveillance for long periods. Additional value may be demonstrated by using surveillance data for other purposes such as assessing implementation of Integrated Management of Childhood Illnesses diarrhoea case management practices.

**Evaluating impact with sentinel surveillance and special studies:** Sentinel surveillance has been useful to help evaluate impact of rotavirus vaccination in early introducer countries in the Americas by monitoring trends in rotavirus detection rates. Special studies including studies of adverse events, cost-effectiveness, and vaccine effectiveness (built on existing surveillance platforms) have provided important complementary data. However, even in countries with well-established surveillance systems, there are challenges in staff turnover, specimen transport, etc. which require attention to maintain quality. Vaccination status information of case-children can be difficult to obtain via surveillance data and may only be collected in selected settings, such as special studies.

**Evaluating impact with secondary data sources:** Secondary data sources, such as national data on diarrhoea health care visits and mortality, have also been
useful to help assess declines in disease after vaccine introduction. This is especially well illustrated by a study in Mexico which used national data on diarrhoea deaths to document mortality declines, as impact on mortality is hard to assess in sentinel surveillance. Because rotavirus is an important overall contributor to severe diarrhoea and vaccines in the Americas have been highly effective in preventing rotavirus diarrhoea, even non-specific syndromic (e.g., diarrhoea hospitalizations) surveillance data have allowed monitoring of vaccine impact. However, syndrome data could be affected by trends in other pathogens (e.g., norovirus) so interpretation requires caution.

**Continued need to demonstrate impact:** As vaccine efficacy varies from country to country, surveillance and/or special studies will continue to be important to document the impact of vaccine introduction, especially in settings with high child mortality. While demonstration of vaccine impact has been rapid and relatively simple in the Americas, this will likely be challenging in low income settings where rotavirus vaccines perform less well, surveillance systems are less well developed, and evaluation is complicated by higher prevalence of other diarrhoeal pathogens and in some settings the lack of rotavirus seasonality.

**Population-based surveillance:** Population-based surveillance has unique strengths including the ability to: measure changes in disease rates and thus extrapolate to national level impact, provide data for additional age groups to better examine indirect effects, measure trends in cases presenting to outpatient settings including other levels of health care, and in some settings link cases to vaccine data and thus assess vaccine effectiveness.

**Rotavirus strain surveillance:** Current pre- and post-licensure data confirm that rotavirus vaccines provide good cross protection against a broad range of strains and there is no convincing evidence of strain changes attributable to vaccine pressure. However, such changes may occur after longer periods of vaccine use and so require continued monitoring.

**Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:**

In addition to continuing rotavirus sentinel surveillance to document trends in rotavirus detection rates and circulating strains before and after vaccine introduction, the following recommendations were made:

1. Summarize the experiences and lessons learned from vaccine effectiveness studies and impact assessments in early introducer countries in the Americas, Europe, and Australia, especially to capture messages that will assist other regions.
2. Summarize the excellent sentinel surveillance data generated over 2 years by the WHO networks for a WER/MMWR article so that the information can be widely available to decision makers and donors.
3. Assist countries planning to introduce rotavirus vaccines in the near future (several in EMR region especially The Sudan) to assess how ongoing surveillance could be enhanced to help assess vaccine performance and impact. The Sudan is the first GAVI country in Africa/Asia to introduce rotavirus vaccine so this is an important opportunity, especially given the somewhat lower performance of vaccine in trials in Africa and Asia.

*Refer to Annex 6 for additional recommendations.

**CHALLENGE ISSUE 5: Transitioning to Full Ministry of Health Ownership and Integrating Surveillance Activities**

**Transitioning to Full Ministry of Health Ownership (Workgroup 6a)**

**Workgroup Objectives:**
Determine the process of and the obstacles associated with fully integrating VP-IBD and rotavirus surveillance into the Ministry of Health.

**Workgroup Summary:**
Experiences from country and Regional level were presented and discussed, including a description of the current surveillance systems, review of the extent of involvement of the MoH regarding technical responsibility and financial contribution, and the possibility and potential impact of interruption of financial support. In various countries, particularly where surveillance was implemented in collaboration with MoH and through the WHO Regional Office, surveillance is coordinated by the MoHs. It was reinforced that National ownership means more than national funding.

Surveillance data was essential in decision making on new vaccines introduction in several countries. National Immunization Technical Advisory Groups (NITAG) and high level decision-makers still require local data in most countries to support decision making. Surveillance data will continue to be needed to study impact of the vaccine, specially for GAVI supported countries to:
- Ensure sustainability of co-financing;
- Maintain sustainability of the vaccination programme after graduation from GAVI support; and
- Allow policy makers to assess for disease trends and impact of the vaccine. Surveillance is perceived as extremely important at the technical level. However, it is not well perceived by some of the high level policy makers in some countries. It is unclear how much surveillance is deemed to be important by the various global immunization partners. Additionally, it is unclear if national policy makers are aware of the existence of complementary regional data and WHO disease burden estimates.

Funding for surveillance is provided both by MoH at the national level and also by partners. While the MoH provides some support in most countries, it was agreed that support from partners is essential for many countries. It has been indicated
that if partner's financial support is interrupted, current surveillance activities may
be maintained in selected countries (i.e. Albania and Bangladesh), whereas it
may be seriously affected in others (i.e. Africa, Mongolia and several in EMR and
WPR countries). In the latter, it is likely that surveillance would be interrupted or
its quality be seriously affected. Finally, as surveillance is just starting in several
countries in SEAR, long term commitment of support is important.

**Workgroup Prioritized Recommendations for Completion during the Next
12 Months at Global and Regional Levels**:  

1. Document the value of surveillance for decision-making on new vaccines
introduction and sustainability of the programme, and use this documentation
to advocate for allocating more funds for surveillance, both from the
government budget and from existing and new partners.

2. Include surveillance as part of the comprehensive multi-year plan (cMYP) and
update the costing tools to better reflect the surveillance costs in all countries
and to ensure that surveillance activities are budgeted in national plans. This
could then be used to secure either national funds or donor funds, including
support through GAVI Health Systems Strengthening funding.

3. Ensure that the strategy of preventing new vaccines-related diseases includes
a surveillance component. A step towards accomplishing this includes
packaging new vaccines introduction with a surveillance component in
applications and support of new vaccines introduction.

*Refer to Annex 6 for additional recommendations.

**Implementing Integrated Surveillance: Experiences from the Field
(Workgroup 6b)**

**Workgroup Objectives:**

Review lessons from the field for integrated surveillance activities, using the
Global Immunization Framework for Immunization Monitoring and Surveillance
(GFIMS) as a framework

**Workgroup Summary:**

Main discussion points of this session were: 1) What elements of VP-IBD and
rotavirus surveillance have been amenable to integrate and what has not worked,
2) What are the challenges that the countries face to improving/expanding to
integrated surveillance from country perspective, and 3) How do we strengthen
country capacity for estimating disease burden and monitoring impact on a timely
basis in preparation for introduction if new vaccines.
GFIMS was developed by global immunization partners and published in 2007, proposing, among others, further integration in surveillance activities, particularly encouraging combination and building on programmes already in place. Current experience indicates that full integration of the vaccine preventable disease (VPD) surveillance systems is not achievable. However, selected components of surveillance have successfully been integrated, particularly in pilot projects recently implemented and as described below.

The SURVAC project (Renforcement de la Surveillance en Afrique Central) has been implemented since 2009 in Central African Republic, Democratic Republic of Congo, and Cameroon by MoH with support from WHO (EPI and IHR/CDS groups), CDC Atlanta, CDC Foundation, and BMGF. The main project objectives are: capacity building for epidemiological surveillance and response including implementing field epidemiology and laboratory training programme courses, reinforcing laboratory capacity and networks, and strengthening communication channels. There has been strong political involvement and support of Ministers of Health. Coordination and operation bodies composed by the collaborating groups are functional. Case definitions, protocols, SOPs, and other tools and documents supporting surveillance activities have been standardized and the first public health Masters programme is being initiated in Cameroon. The main challenges are timeliness of implementation, effective collaboration between partners, maintaining high political commitment, and contributing to infant mortality reduction through an efficient surveillance and response project.

Costa Rican Pilot Project to integrate various VPD surveillances (All VPD surveillance) was launched with the support of AMR and CDC. This project considered the GFIMS as its backbone, and had as its main objective the integration of surveillance activities. The ultimate goals of surveillance integration are to reduce duplication, save time, use resources more efficiently, and build synergies by using existing systems. Components integrated included notification systems, outbreak responses, data management, and laboratory aspects. System implementation was initiated in 2007.

Integrating Surveillance for Japanese Encephalitis in the Western Pacific Region: Opportunities and Challenges. Sentinel surveillance for bacterial meningitis has been established in the Region, with a VP bacterial etiology identified in 13% of cases. Encephalitis surveillance has been integrated with meningitis surveillance in Cambodia, Philippines, and Viet Nam, with 10%-14% of combined meningitis-encephalitis cases in each country being JE. Opportunities in integration include clinical syndromes with significant overlap, surveillance for both syndromes targeting paediatric age ranges, the same CSF specimen can be tested for both JE and bacterial pathogens, and the same data collection and reporting system can be used. Challenges of integration include different target age groups, different geographical focuses, and different laboratory capacities. There are many options for integrating JE surveillance with other forms of surveillance. The best option depends on the country context, so a tailored approach is needed.
The design of JE surveillance should take into consideration the critical elements (geographic distribution, type of specimen available, need for vaccination data) and match with existing surveillance and health care infrastructure.

Global measles surveillance as coordinated through WHO has integrated coverage and surveillance data management. Data interpretation is done in a synergistic manner, through comparison of coverage and surveillance data. Epidemiologic characteristics of measles allow easy modelling of the disease, considering surveillance and coverage data by age. As such, the WHO Measles Strategic Planning tool was developed allowing simultaneous evaluation of surveillance and coverage data by age and generating useful information for planners and program managers to plan measles control activities.

The Bill and Melinda Gates Foundation (BMGF) have supported various immunization related activities and projects and identified surveillance as a priority area approximately 3 years ago. BMGF conducted a landscape analysis by interviewing surveillance technical staff at different organizational levels and identified gaps in surveillance investments in selected Regions, of which the Central African Region was selected as a priority Region to be targeted by the SURVAC pilot project. Additional surveillance activities/projects funded by BMGF include:

- Global enteric Multicenter Study (GEMS) – multi centre case control study to quantify burden, etiology, and sequelae of diarrhoeal diseases including rotavirus in sub Saharan Africa and Asia
- Pneumonia etiology research (PERCH)
- Johns Hopkins University
  - Binax now and comparability with PCR
  - Role of older children and adults in pneumococcal transmission
- Mobile technology working group
- Diagnostics working group
  - Multiplex tools for enteric diseases point of care diagnosis
  - New saliva based assays
- Polio laboratory network and serosurveys

Lessons learned from the VPD surveillance integration experiences include:

- Integration is a long process and is not always feasible or desired.
- A tailored approach for surveillance integration needed.
- Integrated surveillance coordination bodies – at country level and intra and inter-institutionally -- are critical.
- Political commitment in country level is crucial for successful integration of surveillance.
- Care should be taken to review the existing health system structure which may prohibit integration due to jurisdictional issues.
- There may be a limited ability of participation of the private sector in surveillance activities, as the public sector may not have jurisdiction over the private sector.
Laboratory integration (structure, training, others) for VPD diseases of viral aetiologies has been successful, culminating in an integrated measles/rubella, JE, and yellow fever laboratory networks.

Surveillance objectives of selected VPD diseases impact the ability to integrate
- Monitor changes in disease epidemiology
- Support elimination and eradication efforts
- Detect outbreak or emerging threats

For specific diseases, surveillance and coverage data management and analysis can be integrated resulting in benefits, particularly for planning and programmatic purposes.

Sustainability of integration is still a challenge
- Important to conduct economic analysis of integrated surveillance
- It is important to include surveillance in the investment strategy for new vaccine introductions.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. WHO to support documenting and sharing of experiences of integrated surveillance projects (SURVAC, Costa Rica, others). Particular emphasis should be placed on how the various support systems for surveillance were coordinated (e.g. procurement of supplies, laboratory management, surveillance process management from the time a patient arrives until a laboratory result is available, monitoring).

2. Promote establishment of surveillance coordination bodies in country level (based on the experience of integration projects, i.e. SURVAC).

3. Finalize cost assessment of all VPD integrated surveillance in Costa Rica

CHALLENGE ISSUE 6: Strengthening the Rotavirus and VP-IBD Laboratory Networks

1. Lessons learned from the Measles-Rubella Laboratory Network (Workgroup 4)

Workgroup Objectives:
To learn from the Measles LabNet and share experiences regarding establishment of a LabNet, validation and standardization of procedures, building capacity, quality assurance and monitoring, accreditation systems, management of supplies and data, integration with other Lab Networks, and coordination

Workgroup Summary:
Members of the Measles-Rubella Network shared lessons learned around the establishment of a Laboratory Network, and were provided an overview of the
progress made to date with setting up rotavirus and VP-IBD laboratory networks. It was acknowledged that the VP-IBD Lab network is more complex than rotavirus as it involves processing of CSF, blood cultures and pleural fluids. The rotavirus laboratory network is more robust, although it still requires additional support, particularly for genotyping activities in Africa.

Lessons learned from the measles-rubella network include the need for:
- Clear case definitions and objectives;
- Strong links with surveillance colleagues;
- Standardized procedures;
- Reporting in a defined time period; and
- Capacity building in an integrated form.

It is also important to start small and build up the network progressively with a minimum number of laboratories per country and region.

Capacity building should include:
- **Trainings** that focus on follow up outcome of training and follow up training, and that ensure training is not a one-off but is a continuous process. Trainings should include laboratory capacity building, equipment and consumables (maintenance plan, UPS), QA –proficiency tests and confirmatory testing, and accreditation- certificates.
- **Meetings-regional and on-site** that: build up good communication channels between laboratories and WHO. Regular laboratory network meeting should be held at the Global/ Regional/Interregional levels. Additionally, annual or biannual meetings should be held at sub-national levels to determine if labs are adhering to the standard operating procedures (SOPs.) Regular questionnaires can be administered during these meetings to determine any changes.

Development of SOPs: There is an ongoing debate regarding having one standardized laboratory method or a variety of similar methods. At the higher level, it is less critical to have one method, however, conversely it is critical to have one method at the lower level in the network. Ongoing discussions regarding the best laboratory methods are an active feature of a healthy laboratory network.

Advocacy is crucial for sustainability of the networks and should include debriefing with MoH and WHO WR, and data sharing and dissemination through a Bulletin, among other activities.

Management of laboratory supplies should include:
- A basic list of standard kits, reagents, consumables and equipment;
- Regularly updating this list to account for changes in procedures, availability and cost;
- A template for annual supplies ordering, inventory management and cost
- Implementation of a schedule of cyclic ordering (1-2 x per year);
• Consolidation of procurement wherever possible to reduce costs but keeping in mind that some products have a short shelf life; and
• Ensuring supplies are available in the WHO supplies catalogue to streamline procurement through WHO.

Frequent problems with stock management include:
• Poor estimation of supplies required;
• Incomplete/incorrect specification;
• No consideration of installation and maintenance of equipment;
• Request for supplies not required for the project;
• Urgent orders;
WHO should also consider maintaining a reserve stock of critical supplies.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels*:

1. The VP-IBD and rotavirus networks need to have very clear objectives and case definitions.

2. Training of laboratory staff at all levels including data management is vital. There should be comprehensive SOPs for all aspects of the surveillance network including laboratory and epidemiological activities. As appropriate, SOPs should be translated into French.

3. There must be a sustainable source of supplies. Many of the supplies could be placed on the WHO supplies list to ease procurement. Requests for supplies should be reviewed by WHO country or regional office to ensure requests are reasonable and necessary for the MoH surveillance.

*Refer to Annex 6 for additional recommendations.

2. The Rotavirus Laboratory Network

2a. Management issues (part 1): Roles and responsibilities (Workgroup 10)

Workgroup Objectives:
• To review, discuss and agree on:
  o Roles and responsibilities of GRL, RRL, NLs, sentinel hospital laboratories;
  o Checklist for laboratory assessment; and
  o Performance indicators.

Workgroup Summary:

Roles and responsibilities
The draft document on roles and responsibilities was reviewed, discussed and agreed. Key roles of the different levels of laboratories include:
- **Sentinel hospital laboratory:**
  - collects stool samples, performs RV EIA antigen testing, refers stool samples to a laboratory performing genotyping, and reports to the NL according to an agreed frequency and format.

- **NL:**
  - performs antigen detection from faecal samples using standardized protocol and reagents; refers positive samples to RRL for strain characterization; if capacity exists, performs rotavirus characterization by genotyping and refers untypeable samples to the RRL; facilitates referral of stool samples from sentinel hospital laboratories; participates in a quality assurance programme developed by WHO including referral of a representative selection of positive and negative stool samples to the RRL for quality control; provides training for and oversight of sentinel hospital laboratories using standardized procedures; coordinates quality assurance for sentinel hospital laboratories including validation of positive and negative samples for quality control and managing RV antigen EIA proficiency testing; provides technical training and assistance in standardized methodologies; and coordinates with national EPI or RV surveillance coordinators, RRLs and WHO.

- **RRL:**
  - performs/confirms RV genotype identification from sentinel or NLs; provide genotype characterization of untypeable and unusual strains in the region using standardized methodology; participates in the WHO quality assurance program; coordinates quality assurance in the region by performing validation testing on + and - samples and managing the proficiency testing programme, provides training of laboratory personnel and assist with addressing laboratory problems that may arise; serves as a distribution center for reference reagents and materials; provides technical advice to WHO; participates in collaborative studies aimed at improving RV detection; collates and analyzes RV strain distribution in the region; and provides results of analysis to referring laboratories and WHO in a timely manner using an agreed format and frequency.

- **GRL:**
  - develops and distributes EQA proficiency test panels for RV EIA antigen detection and RT-PCR genotyping; assists network laboratories in the identification of untypeable strains; provides training to RRLs; provides technical advice to the WHO surveillance programme; conducts research aimed at improving diagnosis or characterization; provides standardized reagents including reference strains and primer kits; collates and analyzes strain distribution globally; and provides results to referring laboratories and WHO in a timely manner using an agreed format and frequency.
Once the current documents are finalized, additional efforts are warranted to develop a sampling mechanism to obtain an appropriate subset of samples to genotype from each country.

Checklist for laboratory assessment
The draft checklist was reviewed and discussed. The checklist includes the following components:
- Part I: laboratory performance in the previous 12 months
- Part II: laboratory profile
- Part III: laboratory operating procedures and work practices
- Part IV: summary of review criteria
The checklist for assessing NLs was agreed upon and should also be adopted for hospital sentinel sites.

Laboratory Performance Indicators were discussed and it was agreed to include the following additional indicators:
- Rotavirus antigen detection testing by enzyme immunoassay is performed
  - Minimum 100 specimens
- The accuracy of rotavirus antigen detection testing
  - Minimum 90%
- Internal quality control (QC) procedures are implemented
- The score of the most recent WHO proficiency test
  - Minimum 80%
- Timeliness of rotavirus testing completed within 1 month AND data reported to WHO monthly
  - Minimum 80%
- On-site review of laboratory operating procedures and practices are satisfactory

Refer to the Annex for additional details.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. Finalize and distribute the roles and responsibilities of GRL, RRL, NL and SHL based on the current drafts, and also develop roles and responsibilities in the rotavirus laboratory network for WHO.
2. Finalize the assessment checklist for NL (SHL should be assessed using the checklist developed for NL) and develop an assessment checklist for RRLs.
3. Assess the capacities of each RRL using the assessment checklist. As part of this process, the number of strains that the RRL can genotype should be determined.
2a. Management issues (part 2): Standardizing procedures at the sentinel laboratories (Workgroup 10)

Workgroup Objectives:
• Review the WHO rotavirus laboratory manual to determine if it covers current needs; and
• To discuss the validation of procedures and the need to have standard laboratory methods within the network.

Workgroup Summary:

The WHO rotavirus laboratory manual was reviewed and it was agreed that it met most of the current needs, particularly at sentinel hospitals. However, the manual does not describe in detail (or at all) sample collection, aliquoting, storage, extract preparation, shipping and data management. Model SOPs should be developed, and the currently used SOPs in AFR and EMR could be used as a model. Additionally, training modules should be standardized to fit the standardized methods, with AFR offering to share their training materials.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. SOPs around standardized laboratory procedures should be developed. SOPs are available from AFR and EMR to use as a starting point to develop model SOP’s for the network.

2. Training modules should be standardized to fit the standardized methods. The AFR training materials can be used as a model.

3. A forum should be organized to allow for regional and global information exchange information, e.g. meetings, website

2b. Supplies, procurement, and delivery (Workgroup 11)

Workgroup Objectives:
• Compile a list of standard supplies for rotavirus laboratories
• Address challenges of supplies procurement and how better can we improve or facilitate procurement by the regional and national labs

Workgroup Summary:

The pros and cons of having a laboratory supply list were discussed, as follows:
• Pros: facilitates standardization of laboratory protocols, allows for selection of appropriate reagents, supplies, and equipment; and potentially allows for price negotiation with vendors.
• Cons: It is not clear whether it is possible to standardize reagents and supplies globally, supply bottlenecks can occur, laboratories may have unique
preferences, regional availability will vary, and procurement as well as supply issues are potentially compounded.

Items to include on a supply list include:

• EIA kits: ProSpecT rotavirus and Rotaclone
• RNA extraction kits and reagents: manual and automated
• Enzymes: reverse transcriptase, taq polymerase, RT-PCR kits (QIAGEN One Step)
• Other biochemicals: dNTPS, guanidinium isothiocyanate, PCR-grade water
• Gel electrophoresis supplies: agarose, running buffers, loading buffers, gel stains, and size markers
• Equipment: automated nucleic acid extractors, vortexers, thermal cyclers, centrifuges, pipetors, gel boxes, UV transilluminators, gel documentation units
• Plasticware: tubes, vials, pipette tips
• Oligonucleotides: different laboratories use different protocols and their corresponding RT-PCR primers, regional differences exist in primers utility due to different circulating genotypes (the WHO manual lists 50 genotyping primers)

Overall, the workgroup:

• reached agreement on standardization of reagents and supplies used globally for rotavirus surveillance
  o Agreed on kits, reagents, primers
  o Determined the need to develop/produce supplementary reagents to respond to changes in virus/genotypes
  o Noted the need to evaluate the various EIA kits commercially available
• Discussed challenges of supply procurement
  o The advantages and disadvantages of shipping either directly or through WHO procurement system were discussed. It was noted that local distribution is difficult.
• Discussed how to improve or facilitate procurement by regional and national laboratories
  o Noted the importance of creating standard items for the WHO catalogue
  o Recommended an annual list of needs as part of procurement plan
  o Advised WHO to facilitate procurement to overcome delays and differences in prices experienced by some labs
  o Suggested to use WHO procurement to obtain lowest prices
  o Urged to use experience from other labnets
  o Discussed local customs restrictions and controls and how WHO can mediate these issues
Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. WHO should develop a questionnaire (list) of standard supplies and a should work with RRLs and sentinel laboratories to facilitate procurement of these supplies

2. The GRL and RRLs should compare regional typing strategies.

3. The GRL and RRLs should finalize the validation of commercially available kits.

2c. External Quality Assurance and Quality Control (Workgroup 12)

Workgroup Objectives:
- To review and discuss the goals and importance of developing an External Quality Assurance programme in the network; and
- Discuss and agree on procedures for lab Quality control

Workgroup Summary:
The existing WHO EQA (proficiency testing) program organized by the South African VP-IBD RRL was reviewed. (Refer to the EQA section of the VP-IBD laboratory section of this meeting report for additional details on that programme.) The workgroup discussed the pros and cons of that system as a model for a rotavirus EQA programme.

Rotavirus proficiency testing panels
Part of the TOR of the GRL includes designing an external quality assessment protocol using test panels for rotavirus diagnosis by antigen EIA and genotyping by multiplex RT-PCR of well-characterized rotavirus strains that represent a standard range of important genotypes. The GRL should also analyse and report EQA test results to the individual labs within a month of completion of the proficiency challenges. Additionally, the GRL should analyse and prepare an annual summary of EQA results for RRLs and WHO headquarters/Regional Office laboratory coordinators.

Rotavirus proficiency testing panels are:
- important for the proficiency testing of laboratory staff in the performance of antigen detection and genotyping assays;
- prepared by diluting specific genotypes into an artificial stool matrix;
- include 8 samples, some positive and some negative samples;
- to represent 4 G-types and 3 P-types;
- prepared, quality tested, stored, and shipped by the GRL; and

It was proposed that a passing score would be 80%, hence one sample could be missed.
The GRL has started the first production of the proficiency panels, and plans an external QC. However, the distribution and shipping logistics need to be fully developed and are challenged by the requirement for dry ice.

The workgroup discussed in detail:

- Building an EQA strategy
  - PT panel preparation and distribution
  - Standard reporting forms with timeliness of reporting
  - Feedback to participating labs
  - Remedial action if non-compliance
  - Annual testing

- The role of GRL-RRL
  - Distribution and shipping of EQA
  - GRL to analyse and report to participating labs
  - Education and training

- Confirmatory testing (annual)
  - 10% or a minimum of 100 characterized positive samples for each sentinel site to be confirmed at RRL
  - 10% with a minimum of 50 negative samples

**Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:**

1. The current PT panel should be evaluated at RRLs, and the composition of next generation PT panels should be established to include regionally dominant representative strains (note: each strain should be a high titer, high volume stool so that it can be diluted extensively);

2. GRL, RRL, and WHO should refine distribution mechanisms and logistics; and

3. GRL and WHO should determine the appropriate sample size for quality control at each RRL.

3. The VP-IBD Laboratory Network

3a. Management Issues (Part 1): Roles and responsibilities(Workgroup 7)

**Workgroup Objectives:**

To review and discuss:

- The roles and responsibilities document which serves as a general and adaptable guideline for the functionality of the different levels of the IBD network laboratories: GRL, RRL, NL and Sentinel Hospitals laboratories.
Workgroup Summary:

The workgroup reviewed the draft documents which had been distributed in advance of the meeting. The following were discussed:

Roles and responsibilities of GRL, RRL, NL, and sentinel hospital laboratories

It was agreed that it is important to standardize roles and responsibilities for laboratories participating in the global laboratory network. Workgroup participants noted that the existing draft of the roles and responsibilities for each level of laboratory was useful, and that this document should be finalized by taking into account inputs from the GRL, RRL, and WHO. Additionally, when finalizing the draft roles and responsibilities, the following needs to be considered:

• Minimal performance criteria for sentinel sites in the network need to be defined including:
  • Proper sample transportation and receipt procedures;
  • Detection;
  • Isolation;
  • Identification;
  • Storage of viable isolates, CSF, and pleural fluid; and
  • Shipping to the RRL.

The workgroup also noted that additional work needs to be undertaken to define the needs of the laboratories in the network, especially sentinel site laboratories. Assessments of the sentinel laboratories are a very useful method to not only define capacity but to also determine needs for training, technical support and equipment. Additionally, these visits can provide a forum for on-site training. Such visits should fall within the responsibility of the RRLs. However, RRLs may initially require the support of the GRL, particularly to ensure adherence to a standardized assessment process. Hence, the GRL may be involved in the assessment of RRLs upon request from MoH and WHO Regional Offices.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. Finalize the roles and responsibilities document taking into consideration the inputs of the GRL and RRLs, as well as the laboratory capacities at the various levels.

2. RRLs in partnership with the GRL and WHO should assess laboratories, particularly sentinel site laboratories and provide feedback on suggestions for improvement. WHO and the laboratory network should consider establishment of an ongoing system for conducting such assessments. The MoH should be involved in these assessments, and the NL should be involved as appropriate. RRLs need to receive the financial support in order to undertake the travel required to provide this support.
3. The GRL and WHO should provide ongoing support to RRLs, as required, and ensure adequate capacity to implement site-visits, follow-up trainings, etc.


Workgroup Objectives:

To review and discuss:
- Review current draft of laboratory assessment questionnaire (part of the guidelines for IBD surveillance assessment) and discuss its uses, and any need for additional updates or review of the questionnaire; and
- Laboratory surveillance performance indicators: review existing ones, and evaluate the need for potential new indicators.

Workgroup Summary:

The workgroup's reviewed the draft documents which had been distributed in advance of the meeting. The following were discussed:

Laboratory assessment questionnaire
The draft laboratory assessment questionnaire was reviewed in detail and it was agreed that it is a useful tool for the assessment of laboratory performance. The questionnaire requires 2 hours to be administered, and additional 2-3 hours should be considered for report preparation. An experienced clinical bacteriologist should be responsible for administering the questionnaire. This questionnaire is to be used for assessment of laboratories which are conducting surveillance. It is not intended to identify new surveillance laboratories and sites, and it is not intended to serve for accreditation purposes.

It was recommended that:
- This assessment questionnaire be used to assess sentinel sites and NL
- Assessors should be experienced, clinical bacteriologists from the RRL who have been trained to use this assessment questionnaire.
- RRLs will assess the needs of having a shorter version of this assessment questionnaire that can be adapted to their regional context. RRLs agreed to share the shortened version with WHO before use.

Laboratory surveillance performance indicators
The workgroup reviewed the indicators that were agreed upon during the WHO new vaccines surveillance data standardization meeting in 2008. Additional time will be required to discuss the indicators in detail. However, it was noted that the targets for selected indicators still need to be determined, and discussions are warranted between the GRL and RRL to define these targets. Additionally, the following new indicators were suggested:
• Contamination rates of CSF <5 %, reported monthly
• Time between specimen collection and specimen reception and processing in the sentinel site lab (1 hour maximum)

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. The IBD laboratory assessment questionnaire should be used to assess sentinel hospital sites and national laboratories. The questionnaire should be administered by experienced clinical bacteriologists from the RRL, who have been trained on the use of the tool. Training requirements for use and administration of this questionnaire should be further defined considering regional specificities. RRLs will assess the needs of having a shorter version of the assessment questionnaire (i.e. a checklist), that could be adapted to specific regional contexts but which should be shared with WHO prior to use.

2. In addition to the assessment questionnaire, a complementary tool is needed for selecting new laboratory sentinel sites to be incorporated into the network. This new tool should assess whether the proposed site has a laboratory that has a bacteriology capacity, and this tool could be developed by modifying the existing IBD laboratory assessment questionnaire.

3. Core performance indicators, including both the existing and proposed new indicators, should be incorporated into the IBD laboratory assessment questionnaire. WHO, GRL, and RRLs should discuss and finalize the targets for these indicators.

3a. Management Issues (Part 3): Standardizing procedures, supplies and procurement (Workgroup 7)

Workgroup Objectives:

To review and discuss:
• The validation of possibly standardizing procedures for sentinel site laboratories; and
• The delineation of a basic list of selected supplies for each of the recommended methods to ensure good IBD laboratory surveillance quality.

Workgroup Summary:

Validation of standardized laboratory procedures and supplies

The workgroup discussed issues related to the advantages, disadvantages, and difficulties with standardizing procedures throughout the VP-IBD laboratory network.
Basic laboratory procedures are needed at the sentinel site level to ensure good laboratory quality data. As varying methods are used in the different regions, some standardization of laboratory methodology is needed. Protocols and SOPs are needed to cover the minimal requirement for the sentinel sites to be included in the network. The performance of these sites should be monitored.

Methodology should be fully standardized, as follows.

- Sentinel sites should monitor cases of invasive bacterial disease based on collection, culture and storage of samples (bacterial isolates, CSF, and pleural fluid)
- Gram stain and culture should be performed on all samples; latex will be used on probable bacterial meningitis CSF and pleural fluid as follows:
  - Turbid appearance; or
  - WBC >100 cells/mm$^3$ or
  - WBC 10-100 cells/mm$^3$ with either an elevated protein (>100 mg/dl) or decreased glucose (<40 mg/dl)
- Blood culture may be only included from laboratories already proficient in this work (WHO has to provide key supplies to support this activity in some regions)
- All CSFs have to be stored at -20°C or -70°C. Overall, 10% of CSF should be sent to RRLs for rechecking.
- Sentinel sites have to use the provided proper CSF collection tubes
- Laboratories should offer 24/7 services

WHO should maintain a list of key standard supplies to cover the validated procedures in GSM, to centralize the procurement as much as possible.

**Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:**

1. Standardized procedures should be developed for sentinel sites but these procedures must provide some flexibility for regional differences. Such procedures should include the performance of Gram stain and culture on all samples. Latex testing should be performed on probable bacterial meningitis CSF and pleural fluid as follows:
   - Turbid appearance; or
   - WBC >100 cells/mm$^3$ or
   - WBC 10-100 cells/mm$^3$ with either an elevated protein (>100 mg/dl) or decreased glucose (<40 mg/dl)
   Additional testing may be performed as appropriate both to the sample and to the regional context. The procedures should also delineate the proper storage and transport of samples/isolates.

2. A list of standardized supplies for sentinel sites should be developed that would be adaptable to each region's needs. In particular, sentinel sites should ensure use of the appropriate CSF collection and storage tubes.
3b. Rationalizing Diagnostic Testing (Workgroup 9)

Workgroup Objectives:

- To assess the advantages and benefits of using each of the laboratory diagnostics methods
- To discuss how to maximize yield in the most cost effective manner

Workgroup Summary:

Rapid diagnostic testing for *Streptococcus pneumoniae*

Existing rapid diagnosis tests were reviewed, as follows:

- **Gram stain for CSF and pleural fluid**: which assists with patient management, is rapid and is low in cost. However, the sensitivity and specificity are dependent on the quality of the reagents, microscopy, and presence of trained laboratory staff.

- **Antigen latex agglutination for purulent CSF and pleural fluid**: assists in patient management, is rapid, but is high in cost. The test has the advantage of being 'low-tech' but has a limited shelf life (3-9 months.) The sensitivity and specificity are dependent on the quality of reagents and presence of trained laboratory staff and strict adherence to methodology.

- **Binax NOW urinary antigen testing**: which detects pneumococcal C-polysaccharide in the urine by immunochromatography. In adults, sensitivity ranges from 77-88%, with specificity ranging from 67-100%. In children, sensitivity ranges from 82-92% and specificity ranges from 53-89%. False positives are due to nasopharyngeal colonization, the presence of pneumococcal antigen in the urine weeks after infection, and receipt of PCV.

- **Binax NOW immunochromatographic test (ICT) for CSF and pleural fluid**: has a 100% sensitivity and specificity for CSF/meningitis, and has been found to detect 30% more cases of pneumococcal meningitis than culture alone. However, the test has remained positive for at least 10 days after illness presentation. The advantages are that it is a simple assay procedure, results are available in 15 minutes, the test can be stored at room temperature, and has a shelf-life >1 year. The disadvantages are that it is expensive, only detects pneumococcus, is relatively insensitive (10^5 cfu/ml) compared to PCR, and serotyping cannot be performed.

- **Real time PCR detection and serogrouping/serotyping of Spn, HI, and NM**: has the advantages of increased sensitivity and specificity through use of gene-specific probes, low limit of detection, decreased risk of cross-contamination due to a closed system, and is faster than conventional PCR. Disadvantages include the need for trained laboratory personnel, special equipment, expensive reagents and equipment, high sensitivity/cross contamination during DNA extraction, and no information on antibiotic resistance.
• **Conventional Multiplex PCR for isolates, purulent CSF, and pleural fluid**: has the advantages of being able to confirm detection and serotype of the 40 most frequent serotypes, and is low in cost. Disadvantages include a longer time required for execution than real time PCR, relatively insensitive \(10^5\) cfu/ml, and has an increased risk of contamination.

**Rapid diagnostic testing for *Haemophilus influenzae type b***

As for Spn, the existing tests were outlined. Below, the unique issues for Hib are noted:

- **Gram stain**: assists with patient management, is rapid and low in cost. However, the sensitivity and specificity are dependent on the quality of the reagents, microscopy, and presence of trained laboratory staff. One of the more difficult organisms to detect is haemophilus with a sensitivity of only 25-65%.
- **Detection of antigen (latex agglutination test)**: has a sensitivity of 78-100% versus culture, but is often lower in laboratories with poor experience and in clinical settings as it only detects Hib and not NTHi or other capsulated Hi.
- **Real time PCR detection**: has advantages of being rapid (2-3 hours), having a high sensitivity (72-100%) and a 100% specificity, detecting <10 DNA copies, and having a sensitivity often higher than culture if antibiotic treatment has been started.
- **DNA micro-array**: detects capsule biosynthesis genes for each serotype, and has the potential to detect NTHI.

**Rapid diagnostic testing for *Neisseria meningitidis***

As for the other organisms, the existing tests were outlined. Below, the unique issues for NM are outlined:

- **Gram stain**: assists with patient management, is rapid and low in cost. However, the sensitivity and specificity are dependent on the quality of the reagents, microscopy, and presence of trained laboratory staff.
- **Latex agglutination**: has a sensitivity of 85-88% and a specificity of 93-97%. Various kits exist, but lack sensitivity for serogroups other than A, B, and C. Does not detect serogroup X.
- **Immunochromatography**: does not detect X, has a detection threshold of \(10^5\) cfu/ml CSF, and had a sensitivity in one study of 94-100% in CSF of Nigerian patients infected with A, W135, and Y.

**Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels**:

1. Gram stain should be used at all sentinel sites with the proper kits, microscope and training in place.
2. Latex agglutination should be used at all sentinel sites on probable bacterial meningitis CSF and pleural fluid, as noted earlier. Proper kits must be used and kits should be properly stored, and used within their shelf-life (3-9 months). Proper basic equipment including centrifuge, water bath and refrigerators should be available at all sentinel sites.

3. RT-PCR be used for detection of Spn, HI and NM, serotype/serogroup determination for NM and HI. However, conventional multiplex PCR should be used as the most cost-effective method for Spn serotyping.

3c. External Quality Assurance and Quality Control (Workgroup 8)

Workgroup Objectives:

- To review and discuss the goals and importance of developing an External Quality Assessment programme in the network; and
- To review and discuss internal quality control issues.

Workgroup Summary:

Proficiency Testing (PT)

The existing WHO EQA (proficiency testing) program organized by the South African VP-IBD RRL was reviewed. Challenges were particularly noted in maintaining an up-to-date list of participating laboratories. Currently, approximately 80,000 USD is needed annually to perform 3 assessments per year for 79 laboratories in 48 African countries. The program has also funded trainings according to needs identified annually.

To implement EQA for the WHO coordinated VP-IBD network, the number of sentinel laboratories must be determined. Some of the sentinel sites are quite advanced, while others do not have basic reagents. NLs exist in some countries, and should also be involved in the process. Overall, it is estimated that approximately 100 laboratories globally would need to participate in the EQA.

Issues related to the feasibility of extending the existing EQA programme managed by the South African VP-IBD RRL globally

- WHO should coordinate the EQA process, and both WHO HQ and ROs should receive results and recommendations in order to follow up on laboratory performance, and to facilitate training and visits to improve laboratory performance.
- The GRL agreed to decentralize PT panel preparation, distribution and analysis.
- The South African VP-IBD RRL is well poised to perform the analysis and feedback. Importantly, this RRL has a team dedicated to shipment of samples and evaluation of results.
- The global EQA programme should begin with meningeal pathogens only. Extension to other disciplines (enterics, tuberculosis, etc.) should be deferred.
- A main challenge is to locate new referee laboratories, as the CDC GRL cannot participate and act as a referee at the same time.
- Confidentiality of results must be maintained while at the same time ensuring that the RRL affiliated with the sentinel site needs to know the results in order to assist in implementing corrective actions.

Rechecking Processed CSF Samples
A percentage of samples will be sent to various laboratories for rechecking. However, further work is required to determine the specific percentage based on the number of samples processed at sentinel sites and the capacity of the NL, RRL, and GRL. A potential percentage might be:
- Sentinel/NL to RRL:
  - CSF: 10%:
  - Isolates: 10%
- RRL to GRL: 10%

Internal Quality Control
Additional efforts will be required to determine if it is realistic to use the same reference strains in all the VP-IBD laboratories. IQC must be implemented in all laboratories to ensure good laboratory practice. Issues to be considered include price, storage, supplier patent, etc. The GRL can be a source of strains not covered by copyright. The GRL is willing to send these strains to the RRLs for long-term storage. However, storage capacities are not developed enough in some sentinel sites. Also, it should be determined whether AST standardization is important for the VP-IBD laboratory network.

Workgroup Prioritized Recommendations for Completion during the Next 12 Months at Global and Regional Levels:

1. EQA proficiency panels should be developed and dispensed across the network from a central lab. WHO and the South African VP-IBD RRL should jointly explore the feasibility of expanding the excellent existing EQA programme globally to cover the WHO coordinated VP-IBD surveillance network. The specific logistical considerations such as dispensing control strains, shipping, and resources need to be clarified.

2. The global EQA programme that is developed should also include on site visits and trainings.

3. In order to implement EQA globally, the exact number of laboratories (sentinel, NL, RRL, referee) needs to be determined.
## Annex 1 - Agreed VP-IBD and Rotavirus Case Definitions

### Invasive Bacterial Diseases

<table>
<thead>
<tr>
<th>Case type</th>
<th>Definition</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suspected meningitis</strong></td>
<td>Any child aged 0-59 months admitted to a sentinel hospital conducting surveillance with sudden onset of fever (&gt; 38.5 °C rectal or 38.0 °C axillary) and one of the following signs: neck stiffness, altered consciousness with no other alternative diagnosis, or other meningeal sign.</td>
<td>WHO-recommended standards for surveillance of selected vaccine-preventable diseases, 2003</td>
</tr>
</tbody>
</table>
| **Probable bacterial meningitis**| A suspected meningitis case (as defined above) with CSF examination showing at least one of the following:  
- Turbid appearance;  
- Leukocytosis (> 100 cells/mm³);  
- Leukocytosis (10-100 cells/ mm³) AND either an elevated protein (>100 mg/dl) or decreased glucose (< 40 mg/dl)  
Note: if protein and glucose results are not available, diagnose using the first two conditions (i.e. turbid appearance or leukocytosis > 100 cells/mm³) | WHO-recommended standards for surveillance of selected vaccine-preventable diseases, 2003 |
| **Confirmed meningitis**         | A suspected meningitis case that is laboratory-confirmed by growing (i.e. culturing) or identifying (i.e. by Gram stain or antigen detection methods) a bacterial pathogen (Hib, pneumococcus or meningococcus) in the CSF or from the blood in a child with a clinical syndrome consistent with bacterial meningitis | WHO-recommended standards for surveillance of selected vaccine-preventable diseases, 2003 |
| **Pneumonia**                   | Any child aged 0-59 months admitted to a sentinel hospital conducting surveillance, demonstrating a cough or difficulty breathing and displaying fast breathing when calm (as defined by age):  
- Age 0 to <2 months: 60 breaths/minute or more  
- Age 2 to < 12 months: 50 breaths/minute or more  
- Age 12 to ≤59 months: 40 breaths/minute or more | WHO/UNICEF Integrated Management of Childhood Illness Chart Booklet - Standard, 2008 |
| **Severe pneumonia**            | Any child aged 0-59 months admitted to a sentinel hospital conducting surveillance, demonstrating a cough or difficulty breathing and displaying one or more of the following:  
- Inability to drink or breastfeed  
- Vomiting everything  
- Convulsions  
- Prostration/lethargy  
- Chest indrawing  
### Invasive Bacterial Diseases Continued

<table>
<thead>
<tr>
<th>Case type</th>
<th>Definition</th>
<th>Reference</th>
</tr>
</thead>
</table>
| Sepsis    | Any child aged 0-59 months admitted to a sentinel hospital conducting surveillance with the presence of **at least 2** of the following danger signs and without pneumonia clinical syndrome:  
  - Inability to drink or breastfeed  
  - Vomiting everything  
  - Convulsions *(except in malaria endemic areas)*  
  - Prostration/lethargy *(abnormally sleepy or difficult to wake)*  
  - Severe malnutrition  
  - Hypothermia *(≤36°C)*  

**NOTE:** this definition is proposed and will likely be revised pending additional input. | EMRO Surveillance for invasive Hib, Pneumococcal and Meningococcal Diseases. Standard Operating Procedures for Clinical and Laboratory Staff, 2007. |

### Rotavirus

<table>
<thead>
<tr>
<th>Case type</th>
<th>Definition</th>
<th>Reference</th>
</tr>
</thead>
</table>
WHO Summary Report on Meeting to standardize new vaccines surveillance data to be collected, shared and reported, 2008.  
WHO Summary Report on Meeting to standardize new vaccines surveillance data to be collected, shared and reported, 2008. |
Annex 2 - VP-IBD Surveillance Indicators: Current Indicators and Proposed Additional Indicators

### Tier 1 Meningitis Surveillance

<table>
<thead>
<tr>
<th>Current indicators (Based on Oct 2008 Standardization Meeting)</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of sites that report data according to agreed timeline for that site (at least quarterly)</td>
<td>No. of sites that report data according to agreed timeline</td>
<td>Total No. of sites reporting</td>
<td>80%</td>
</tr>
<tr>
<td>% of suspected meningitis cases that have a lumbar puncture performed</td>
<td>No. of suspected meningitis cases that had an LP performed</td>
<td>No. of suspected meningitis cases</td>
<td>90%</td>
</tr>
<tr>
<td>% of lumbar punctures performed that have a culture result recorded</td>
<td>No. of LPs performed that have a culture result recorded</td>
<td>No. of suspected meningitis cases that had an LP performed</td>
<td>90%</td>
</tr>
<tr>
<td>% of suspected meningitis cases with probable bacterial meningitis</td>
<td>No. of suspected meningitis cases with probable bacterial meningitis</td>
<td>No. of suspected meningitis cases</td>
<td>at least 20%</td>
</tr>
<tr>
<td>% of probable bacterial meningitis cases with a known outcome (e.g. died, improved) recorded</td>
<td>No. of probable bacterial meningitis cases with an outcome recorded</td>
<td>No. of suspected meningitis cases with probable bacterial meningitis</td>
<td>90%</td>
</tr>
</tbody>
</table>

#### Proposed additional indicators

<table>
<thead>
<tr>
<th>Proposed additional indicators</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of CSF samples logged into the laboratory within 1 hour of the lumbar puncture</td>
<td>No. of CSF samples logged into the lab within 1 hrs of the LP</td>
<td>No. of suspected meningitis cases that had an LP performed</td>
<td>75%</td>
</tr>
<tr>
<td>% of CSF contamination</td>
<td>No. of CSF samples contaminated</td>
<td>No. of suspected meningitis cases that had an LP performed</td>
<td>≤ 5%</td>
</tr>
</tbody>
</table>

---

3 2009 global VP-IBD median: 32%
4 To be further discussed by WHO, GRLs, and RRLs to determine if the target should be revised downwards to <1%
### Tier 2 Pneumonia and Sepsis Surveillance

#### Current indicators (Based on Oct 2008 Standardization Meeting)

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of sites that report according to the agreed timeline for that site (at least quarterly)</td>
<td>No. of sites that report data according to agreed timeline</td>
<td>Total No. of sites reporting</td>
<td>80%</td>
</tr>
<tr>
<td>% of pneumonia cases with a known outcome (e.g. died, improved) recorded</td>
<td>No. of pneumonia cases with an outcome (i.e. vital status) recorded</td>
<td>No. of children who met the pneumonia case definition</td>
<td>90%</td>
</tr>
<tr>
<td>% of sepsis cases with an outcome (e.g. died, improved) recorded</td>
<td>No. of sepsis cases with an outcome (i.e. vital status) recorded</td>
<td>No. of sepsis cases</td>
<td>90%</td>
</tr>
<tr>
<td>% of pneumonia cases with a blood culture performed</td>
<td>No. of pneumonia cases that have a blood culture performed</td>
<td>No. of children who met the pneumonia case definition</td>
<td>75%</td>
</tr>
<tr>
<td>% of pneumonia cases that have a blood culture performed</td>
<td>No. of children who met the pneumonia case definition</td>
<td>No. of children who met the pneumonia case definition</td>
<td>75%</td>
</tr>
<tr>
<td>% of pneumonia cases that have a blood culture performed</td>
<td>No. of children who met the pneumonia case definition</td>
<td>No. of children who met the pneumonia case definition</td>
<td>75%</td>
</tr>
<tr>
<td>% of sepsis cases that have a blood culture performed</td>
<td>No. of children who met the pneumonia case definition</td>
<td>No. of sepsis cases</td>
<td>90%</td>
</tr>
<tr>
<td>% of sepsis cases with a blood culture performed that have a culture result recorded</td>
<td>No. of sepsis cases that have a blood culture performed that have a culture result recorded</td>
<td>No. of pneumonia cases that have a blood culture performed</td>
<td>90%</td>
</tr>
<tr>
<td>% of pneumonia cases with a blood culture performed with HI identified by culture, latex or PCR</td>
<td>No. of pneumonia cases with a blood culture performed with HI identified by culture, latex or PCR</td>
<td>No. of pneumonia cases that have a blood culture performed</td>
<td>TBD by WHO, GRLs, RRLs</td>
</tr>
<tr>
<td>% of pneumonia cases with a blood culture performed with pneumococcus identified by culture, latex or PCR</td>
<td>No. of pneumonia cases with a blood culture performed with pneumococcus identified by culture, latex or PCR</td>
<td>No. of pneumonia cases that have a blood culture performed</td>
<td>TBD by WHO, GRLs, RRLs</td>
</tr>
<tr>
<td>% of sepsis cases with a blood culture performed with pneumococcus identified by culture, latex or PCR</td>
<td>No. of sepsis cases with a blood culture performed with HI identified by culture, latex or PCR</td>
<td>No. of sepsis cases that have a blood culture performed</td>
<td>TBD by WHO, GRLs, RRLs</td>
</tr>
<tr>
<td>% of sepsis cases with a blood culture performed with HI identified by culture, latex or PCR</td>
<td>No. of sepsis cases with a blood culture performed with pneumococcus identified by culture, latex or PCR</td>
<td>No. of sepsis cases that have a blood culture performed</td>
<td>TBD by WHO, GRLs, RRLs</td>
</tr>
</tbody>
</table>
## Tier 2 Pneumonia and Sepsis Surveillance Cont’d

<table>
<thead>
<tr>
<th>Proposed additional indicators/measures of quality</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of blood cultures contaminated</td>
<td>Total No. blood cultures contaminated</td>
<td>No. of sepsis cases that have a blood culture performed + No. of pneumonia cases that have a blood culture performed</td>
<td>≤5%</td>
</tr>
<tr>
<td>% of blood culture bottles placed in incubator within 2 hrs as evaluated during site visits</td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>% of blood agar plates made (commercially or locally) with sheep or horse blood as evaluated during site visits</td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>% of blood cultures collected and processed with results of non-BP-IBD pathogens documented and tabulated as evaluated during site visits</td>
<td></td>
<td></td>
<td>80%</td>
</tr>
</tbody>
</table>

**Indicators dropped:**
- Ratio between suspected meningitis and suspected pneumonia cases
### Annex 3 - Rotavirus Surveillance Indicators: Current Indicators and Proposed Additional Indicators

<table>
<thead>
<tr>
<th>Current indicators (Based on Oct 2008 Standardization Meeting)</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of children meeting the case definition that were enrolled with a case report form completed and specimen collected</td>
<td>No. of children meeting the case definition that were enrolled with a case report form completed and specimen collected</td>
<td>No. of acute diarrhoea hospitalizations in children &lt;5 years eligible for enrollment</td>
<td>80%</td>
</tr>
<tr>
<td>% eligible enrolled acute diarrhoea cases that tested positive for rotavirus among cases who had stool specimens tested</td>
<td>No. of eligible enrolled acute diarrhoea cases that tested positive for rotavirus among cases who had stool specimens tested</td>
<td>No. of total eligible enrolled (with CRF and specimen collected) acute diarrhoea cases that were tested</td>
<td>20%</td>
</tr>
<tr>
<td>% of cases with stool specimen collected within 2 days of admission</td>
<td>No. of cases with stool specimens collected within 2 days of admission</td>
<td>No. of children meeting the case definition that were enrolled with a case report form completed and specimen collected</td>
<td>90%</td>
</tr>
<tr>
<td>% of collected stool specimens that arrive at the laboratory for ELISA testing</td>
<td>No. of stool specimens that arrive at the laboratory for ELISA testing</td>
<td>No. of children meeting the case definition that were enrolled with a case report form completed and specimen collected</td>
<td>95%</td>
</tr>
<tr>
<td>% of received specimens that are tested in the site laboratory</td>
<td>No. of received specimens that are ELISA tested in the site laboratory</td>
<td>No. of stool specimens that arrive at the laboratory for ELISA testing</td>
<td>90%</td>
</tr>
<tr>
<td>% of rotavirus positive (ELISA confirmed) specimens sent to the RRL that are confirmed positive by the RRL</td>
<td></td>
<td></td>
<td>80%</td>
</tr>
<tr>
<td>% samples genotyped in the RRL with results available at the site/country level within 6 months of sending specimens</td>
<td></td>
<td></td>
<td>90% (to be further assessed and refined to take into account the total number of samples obtained)</td>
</tr>
<tr>
<td>% of sites that report according to the agreed timeline for that site (at least quarterly)</td>
<td>No. of sites that report data according to agreed timeline for that site (at least quarterly)</td>
<td>Total No. of reporting sites</td>
<td>80%</td>
</tr>
</tbody>
</table>
### Rotavirus Surveillance Cont'd

<table>
<thead>
<tr>
<th>Proposed additional indicators/Measures of quality</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of enzyme immunoassay tests performed</td>
<td></td>
<td></td>
<td>Minimum 100 specimens</td>
</tr>
<tr>
<td>Timeliness of rotavirus testing completed within 1 month AND data reported to WHO monthly</td>
<td></td>
<td></td>
<td>Minimum 80%</td>
</tr>
<tr>
<td>The accuracy of rotavirus antigen detection testing by external quality assurance testing</td>
<td></td>
<td></td>
<td>Minimum 90%</td>
</tr>
<tr>
<td>The score of the most recent WHO proficiency test as evaluated by on-site assessment</td>
<td></td>
<td></td>
<td>Minimum 80%</td>
</tr>
<tr>
<td>Internal quality control (QC) procedures are implemented as evaluated by on-site assessment</td>
<td></td>
<td>QC implemented</td>
<td></td>
</tr>
<tr>
<td>On-site review of laboratory operating procedures and practices are satisfactory as evaluated by on-site assessment</td>
<td></td>
<td></td>
<td>Review confirms procedures and practices are satisfactory</td>
</tr>
</tbody>
</table>
## Annex 3 - Additional Workgroup Recommendations

<table>
<thead>
<tr>
<th>Workgroup Recommendations for Additional Activities to be Conducted at Global and Regional Levels during the Next 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workgroup</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
| Solving problems that limit conduct of high-quality VP-IBD and rotavirus surveillance (WHO Closed Session on Data Management) | Ensure indicator dates (year, month) are appropriately related to date of enrolment  
As needed, headquarters will provide technical and (limited) financial support to Regional Office focal points and regional data management staff to implement the above. |
|---|---|
| Defining problems that limit conduct of high quality VP-IBD surveillance (Workgroup 3a) | Further refine the ‘tiers’ of VP-IBD surveillance by seriously reconsidering the added value of Tier 2 sites (blood culture surveillance). If Tier Two surveillance is to be supported, this should only occur at a limited number of very high quality performance sites (e.g. 1-2 per region/sub-region). In selecting sites, consider those that have a 24 hour laboratory service.  
In addition to a recurrent (e.g. annual) site visit by external auditors, it would be useful for the MoH and WHO to ask sites to provide the following documentation:  
   - An annual internal review of practices  
   - A review of admission, specimen handling and laboratory log books  
Insist that for inclusion in the WHO IBD surveillance the point of contact for investigation of a surveillance case must be clinical (ward/clinic) not at the lab  
Because many sites do not realize the importance of proper filtering of patients and adherence to protocol in the collection, transporting and processing of specimens it would be useful for each site to identify a site-epidemiologist who would be responsible for internal reviews and preparation of annual reports to MoH and WHO.  
Each site should be able to define its reporting procedures (clinical and epidemiological), the impact that the results are likely to have and the appropriate responses from partners. These should serve as a benchmark for auditing communication failures  
The network needs to define a plan for the engagement of MoH. This should begin by asking the MOH what data they require, what they are likely to do with it and which decisions it is intended to influence. This should focus the data needs both in terms of scope and timeline – and the results should influence the surveillance exercise that has been established, ostensibly, to satisfy this need.  
The resolution of data reported back by the sites to both MOH and WHO should be greater, for example, giving precise ages of children, and precise days of admission, to allow more flexible regional and global analyses at line-level, taking account of major confounders. |
| Uses of rotavirus surveillance to assess vaccine impact (Workgroup 5a) | When countries conduct surveillance at a larger number of sentinel sites, this is likely a political decision rather than a scientific decision. It may be possible (and should be attempted) to decrease the number of sites once consistency of data is shown. (Note: The Sudan plans to reduce from 8 to 4-5 sites.)  
Surveillance post-introduction can be adapted to the country context, and it may be possible to rely primarily on data gathered from secondary data sources in some cases. |
| Transitioning to Full Ministry of Health Ownership (Workgroup 6a) | Approach more partners to identify other sources of funding to maintain the gains, categorizing countries for support according to situation and needs. |
| Lessons learned from the Measles-Rubella Laboratory Network (Workgroup 4) | • A single EQA panel should be prepared by one laboratory and distributed to all of the laboratories in the network (Sentinel site, national labs, regional labs GRL). EQA panels should be distributed at least annually.  
• In addition a comprehensive programme of IQC should be introduced into all laboratories in the network.  
• WHO should consider maintaining a stock of a few "critical" supplies in case of urgent requests. |
### Agenda Day 1: Wednesday, 22 September

#### 7:30 - 9:00 Registration

#### Plenary Session: CCV Salle A

**Session 1: Welcome, Introductions, and Opening of Meeting**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Chair</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>Opening remarks</td>
<td>J M Okwo-Bele</td>
</tr>
<tr>
<td>09:15</td>
<td>Overview and goals of meeting, introductions and administrative announcements</td>
<td>C. Mantel</td>
</tr>
</tbody>
</table>

#### Session 2: Global Updates, Key Challenges, and Charge to Meeting Attendees

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Chair</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:30</td>
<td>Strategic overview of Rota, Spn, and Hib vaccine use and planned introductions</td>
<td>C. Mantel</td>
</tr>
<tr>
<td>09:45</td>
<td>Discussion</td>
<td>M. Agócs</td>
</tr>
<tr>
<td>10:00</td>
<td>Overview of global IBD and RV surveillance: Past &amp; current networks, data, strengthens, areas for improvement</td>
<td></td>
</tr>
<tr>
<td>10:10</td>
<td><strong>Workgroup goals:</strong> Agreed &amp; prioritize 3 attainable global/regional actions to be completed during the coming 12 months to secure high-quality data under MoH ownership, improved data management/use practices, and an effective laboratory network.</td>
<td></td>
</tr>
<tr>
<td>10:30</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>10:45</td>
<td>Coffee</td>
<td></td>
</tr>
<tr>
<td>11:00</td>
<td>Global IBD and RV surveillance overview continued</td>
<td>F. Serhan</td>
</tr>
<tr>
<td>11:30</td>
<td>Overview of the global rotavirus and invasive bacterial diseases laboratory networks &amp; key challenges</td>
<td></td>
</tr>
<tr>
<td>11:45</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>12:00</td>
<td>Laboratory colleagues travel to WHO for lunch and sub-meeting (Contact: Ms. Erin Sparrow)</td>
<td>F. Serhan</td>
</tr>
</tbody>
</table>

#### Epidemiology Sub-Meeting: CCV Salle A

**Session 3: WHO Layered Approach to Surveillance**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Chair/ Rapporteur</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:30</td>
<td><strong>Workgroup 3a: Defining Problems that Limit Conduct of High Quality IBD Surveillance</strong></td>
<td>A. Scott/ J Mwenda</td>
</tr>
<tr>
<td>13:45</td>
<td>Identification of potential reasons that limit conduct of quality IBD surveillance</td>
<td></td>
</tr>
<tr>
<td>14:00</td>
<td>Coffee</td>
<td></td>
</tr>
<tr>
<td>15:30</td>
<td><strong>Workgroup 3b: Lessons Learned from the Measles-Rubella Laboratory Network</strong></td>
<td>D. Featherstone/ M. Slack</td>
</tr>
<tr>
<td>15:45</td>
<td>Presentations: C. Van Beneden, S. Gungaa, S. Saha</td>
<td></td>
</tr>
<tr>
<td>15:50</td>
<td>Coffee</td>
<td></td>
</tr>
</tbody>
</table>

#### Laboratory Sub-Meeting: WHO Salle B

**Session 4: Combined Meeting with Measles-Rubella Laboratory Network: Development of VPD LabNet**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Chair/ Rapporteur</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:00</td>
<td><strong>Lessons Learned from the Measles-Rubella Laboratory Network</strong></td>
<td>D. Featherstone/ M. Slack</td>
</tr>
<tr>
<td>14:15</td>
<td>Sharing of lessons learned around the establishment of a LabNet</td>
<td></td>
</tr>
<tr>
<td>14:30</td>
<td><strong>Refer to annotated agenda for details</strong></td>
<td></td>
</tr>
<tr>
<td>15:30</td>
<td><strong>Coffee</strong></td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>Event</td>
<td>Venue</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>16:00 - 17:30</td>
<td><strong>Workgroup 3b: Population Based Sites and Centres of Excellence</strong></td>
<td>M. Agócs, B. Coulibaly, R. Breiman, S. Khagayi, J. Mwenda</td>
</tr>
<tr>
<td>17:30</td>
<td>Adjourn</td>
<td></td>
</tr>
<tr>
<td>18:00</td>
<td>Reception at CCV</td>
<td></td>
</tr>
</tbody>
</table>
Day 2: Thursday, 23 September

**EPIDEMIOLOGY CONCURRENT SESSIONS:**

**Invasive Bacterial Diseases and Rotavirus**

### Session 5: Concurrent Workgroup Sessions: Using and Improving Data

|---|---|
| **Chair:** U. Parashar  
**Rapporteur:** K. Fox | **Chair:** T. Cherian  
**Rapporteur:** A. Wasley |
| **Presentations:**  
J. Tate  
J Sanwogou  
D. Pastor  
C. Kirkwood  
K. Lindblade  
A. Mostafa  
K. Fox | **Presentations:**  
A. Scott  
M. Agócs  
C. Van Beneden  
R. Hajjeh |
| **08:30 - 10:00** | **08:30 - 10:00** |
| Identifying key issues for post-licensure monitoring of rotavirus vaccine impact and how to approach them  
*Refer to annotated agenda for details* | Identifying additional indicators to monitor sentinel site performance and developing criteria for when to intervene to improve a reporting site  
*Refer to annotated agenda for details* |
| **10:30 - 11:00** Coffee | **10:30 - 11:00** Coffee |
| **11:00 - 12:30** Continued Session | **10:30 - 12:30** Continued Session |
| **12:30 - 14:00** Lunch | **12:30 - 14:00** Lunch |

### Session 6: Transitioning to Full Ministry of Health Ownership and Integrating Surveillance Activities

<table>
<thead>
<tr>
<th>Workgroup 6a: Transitioning to Full Ministry of Health Ownership: <strong>CCV Salle B</strong></th>
<th>Workgroup 6b: Implementing Integrated Surveillance: Experiences from the Field: <strong>CCV Salle A</strong></th>
</tr>
</thead>
</table>
| **Chair:** N. Teleb  
**Rapporteur:** A. Mostafa | **Chair:** T. Hyde  
**Rapporteur:** E. Simons |
| **Presentations:**  
A. Simaku  
S. Gungaa  
A. Mostafa  
SEARO  
GAVI | **Presentations:**  
T. Hyde  
G. Paluku  
J. Sanwogou  
K. Fox  
E. Simons  
L. Venczel |
| **14:00 - 15:30** | **14:00 - 15:30** |
| Determining the process of and the obstacles associated with fully integrating IBD and RV surveillance into the Ministry of Health  
*Refer to annotated agenda for details* | Exploring lessons from the field for integrated surveillance activities, using GFIMS as a framework  
*Refer to annotated agenda for details* |
| **15:30 - 16:00** Coffee | **15:30 - 16:00** Coffee |
| **16:00 - 17:30** Continued Session | **16:00 - 17:30** Continued Session |
| **17:30** Adjourn | **17:30** Adjourn |
## Agenda Day 3: Friday, 24 September

<table>
<thead>
<tr>
<th><strong>Session 13: Feedback</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chair:</strong> Dr. Okwo Bele</td>
</tr>
<tr>
<td><strong>Rapporteur:</strong> C. Toscano</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 - 9:00</td>
<td>Summary of epidemiology and data management action items with agreed milestones and timelines</td>
<td>M. Agócs</td>
</tr>
<tr>
<td>9:00 - 9:45</td>
<td>Discussion of epidemiology issues</td>
<td></td>
</tr>
<tr>
<td>9:45 - 10:15</td>
<td>Summary of RV and IBD laboratory action items with agreed milestones and timelines</td>
<td>F. Serhan</td>
</tr>
<tr>
<td>10:15 - 10:45</td>
<td><strong>Coffee</strong></td>
<td></td>
</tr>
<tr>
<td>10:45 - 11:30</td>
<td>Discussion of laboratory issues</td>
<td></td>
</tr>
<tr>
<td>11:30 - 12:15</td>
<td>Alignment of epidemiology, data, and laboratory action items to ensure consistency and timing</td>
<td></td>
</tr>
</tbody>
</table>

### Session 14: Surveillance Synergies

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:15 - 12:30</td>
<td>Meningitis surveillance</td>
<td>S. Hugonnet</td>
</tr>
<tr>
<td>12:30 - 12:45</td>
<td>HPV surveillance and vaccine impact monitoring</td>
<td>S. Wang</td>
</tr>
<tr>
<td>12:45 - 13:00</td>
<td>Closing</td>
<td>T. Cherian</td>
</tr>
<tr>
<td>13:00 - 14:00</td>
<td><strong>Lunch</strong></td>
<td></td>
</tr>
<tr>
<td>14:00 - 17:00</td>
<td><strong>Closed Session for Regional Office Colleagues:</strong> CCV Salle B</td>
<td></td>
</tr>
</tbody>
</table>

(Coffee 15:30 - 16:00)
Follow up of meeting outcomes (timelines and milestones for the next 12 months)
- SWOT analysis and setting priorities
- AOB

**Notes:**
Dr. C. Toscano will serve as the overall meeting rapporteur, and will coordinate input from the individual session rapporteurs.
## Annex 5 - List of Participants

**World Health Organization**  
**Department of Immunization, Vaccines and Biologicals**  
**Expanded Programme on Immunization**  

**GLOBAL MEETING ON SURVEILLANCE**  
**FOR INVASIVE BACTERIAL DISEASES (IBD) AND ROTAVIRUS**  
**22-24 September 2010**  

**Geneva, Switzerland**

### LIST OF PARTICIPANTS

### MINISTRY OF HEALTH

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Organization</th>
<th>Email</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

### REGIONAL REFERENCE LABORATORIES

<table>
<thead>
<tr>
<th>Organization</th>
<th>Name</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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<td></td>
</tr>
</tbody>
</table>
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<th>Email</th>
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<tbody>
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