Draft Report

Global Meeting of the
WHO-Coordinated Global IB-VPD and Rotavirus
Sentinel Hospital Surveillance Networks

Executive Summary and
Full Meeting Report

27th-28th October 2014

Geneva, Switzerland
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Section I: Executive Summary

Background and Meeting Objectives: During 2013, a global strategic review was conducted of the invasive bacterial vaccine preventable diseases (IB-VPD) and rotavirus sentinel hospital surveillance networks. During that meeting, 50 recommendations were made to advance the status of both networks. The objectives of the 2014 global meeting were to:

1) Review progress in implementation of the 50 strategic review recommendations:
2) Review the most recent data from 2013 to better understand data quality and identify systematic problems;
3) Identify criteria to select higher performing sites for analysis of disease epidemiology and time trends; and
4) Agree on prioritized recommendations to improve both networks over the next 12 months.

Meeting Structure: Representatives from WHO (HQ and regional offices), the informal Technical Advisory Group, global and Regional Reference Laboratories (RRL) as well as partners met in Geneva, Switzerland during 27-28 October 2014. The meeting included global and regional updates, an assessment of progress on a web-based data management tool, discussion on developing criteria to select higher performing sites and a closing session to agree on prioritized recommendations to be implemented during 2015. A WHO closed session was held 31 October to develop action points for improving data management and analyses.

Findings:

Management: A Performance Management Framework was successfully used to track the progress and the implementation of last year’s 50 recommendations. By end 2014, 31 (62%) recommendations were completed, and 16 (32%) were in progress including implementation of zero reporting, use of unique identification numbers to link clinical and laboratory data, transition to case-based reporting, site assessments, and exploration of in-country funding. Three (6%) recommendations were deferred due to lack of funding.

Data Management and the Web-Based Data Management Tool: Standardized case-based variables were developed and sites in 5 regions and RRLs in 4 regions have transitioned to case-based reporting. The lack of zero reporting resulted in the inability to differentiate absence of reporting from lack of enrolment of cases. A web-based data management tool was developed that included standardized data entry processes with automated data cleaning and the potential for automated analysis. The tool was piloted in 3 Member States with lessons learned including the critical need for integration and interface with existing in-country systems.

Laboratory EQA/QC Programmes: The successful global external quality assessment (EQA) program and quality control (QC) programmes continue to provide critical information needed to target technical support.

IB-VPD Surveillance: In 2012, 150 sites reported data including 105 (70%) sites in Gavi-eligible countries. Among those 105 hospitals, 71 (68%) hospitals comprising 66 sentinel sites in 40 Member States were targeted for financial and technical support through 2015. All the 66 targeted sites perform Tier 1 surveillance for meningitis, 14 sites perform Tier 2 surveillance for meningitis, pneumonia, and sepsis and 2 sites conduct Tier 3 population-based surveillance. By the time of this global meeting, 79% of targeted sites were located in the 30 (75%) Member States that have introduced PCV.

During 2013, clinical data was linked with RRL data for 708 (26%) of the 2,723 enrolled cases by use of unique identification numbers. Overall, <30% of historical polymerase chain reaction (PCR) data was linked into the clinical database. Despite only 10-50% of specimens from children with suspect meningitis having been tested by PCR, PCR doubled diagnostic yield in some regions. When compared directly to culture, PCR yielded over a 3-fold detection for all three pathogens. Assessment of sites that reported 2013 data identified 35 sites that consistently reported data and enrolled the targeted number of cases in the pre-PCV baseline year.

1 Implementation status has been updated to end 2014 rather than at the time of the global meeting
**Rotavirus Surveillance:** The 117 sites that reported 2013 data were categorized as an ‘inclusion site’ if data was reported for the full 12 months and at least 100 stool specimens were tested within the 12 month period. Among the 97 sites in Gavi-eligible countries, 63 (65%) met inclusion criteria while only 20 (27%) of 73 sites in non-Gavi-eligible countries met criteria. At the time of the meeting, 23 (53%) of 43 Member States with an inclusion site had introduced rotavirus vaccine. Assessment of the 100 stool specimen target suggested a downward revision in vaccine using countries as fewer children may be anticipated with acute gastroenteritis.

**Conclusions:** Since the global strategic review meeting was held in September 2013, significant progress has been made to further improve the IB-VPD and rotavirus sentinel hospital surveillance networks. Network management has been strengthened with the use of a Performance Management Framework to track implementation status of annual global recommendations. A major achievement was the transition to standardized, case-based reporting with quarterly data sharing plus feedback of standard process and performance indicators to sites. Data management processes continue to be improved toward having a more systematic approach in reporting, cleaning, analysing and interpreting data. The reference laboratories are appropriately supporting sites and network laboratory performance has been successfully monitored by the global external quality assessment (EQA) program as well as quality control (QC) programmes. Sentinel site and laboratory assessments have been prioritized but have not been able to include all priority sites.

The most recent 2013 data available for the meeting may underestimate data quality because none of the actions taken after the 2013 strategic review are yet reflected. IB-VPD data analysis focused on assessing laboratory testing performance of culture and PCR, and found <30% of PCR results were linked into the clinical database as well as a 3-fold improved detection of pathogen by PCR over culture alone. Beginning in 2014, RRLs will only process specimens with a unique identification number and it is thus anticipated that a larger percent of cases will have clinical data that can be linked with RRL data.

Network data has contributed to vaccine introduction decisions and the surveillance networks have been used as platforms for vaccine impact evaluations. Moving forward, the rapid introduction of PCV and rotavirus vaccines by Member States now requires the surveillance networks to focus on improving baseline data for sites in non-vaccine using Member States and to ensure consistent surveillance practices for sites meeting inclusion criteria in vaccine using Member States. The web-based data management tool has great potential to improve data quality and may be expanded to other vaccine preventable diseases in due course.

**Key Agreed Recommendations for 2015 (refer to page 13 for the full list of recommendations):**

**Programme Management:**
- Strengthen involvement of Ministry of Health and national EPI programmes;
- By end-April 2015, IB-VPD specimen sharing agreements should be established between all 71 IB-VPD target hospitals and RRLs to further increase access to PCR’s improved diagnostic yield;
- All IB-VPD cerebrospinal fluid specimens should be tested by PCR at an RRL;
- Further focus efforts and define a subset of sites where PCV and/or RV vaccine impact evaluations may be feasible due to sufficient pre- and post-vaccine introduction data;

**Improve data management and analysis:**
- Link clinical and laboratory data by use of unique identification numbers. Prospective data linking should be established by 31 December 2014, and sites should be prioritized for retrospective linking;
- Zero reporting should be implemented at all sites by 31 December 2014;
- Identify a subset of core data variables for vaccine impact assessments;
- Draft guidelines for rotavirus data analysis/interpretation and assess probable bacterial meningitis data;
- Finalize the web-based data management tool;
- Revise site inclusion criteria: for rotavirus: reduce the number of annual stool specimens tested in vaccine using countries; for IB-VPD, include consistently performing sites that enrol fewer meningitis cases.
Section II

Day 1: Monday 27 October 2014

Session One: Introductions & Global Overview:

Presenters: Dr Mary Agocs, Dr Fatima Serhan, WHO Sentinel Hospital Surveillance Networks

Significant progress was made to implement the 50 global strategic review recommendations made last year. Of the 30 recommendations due for completion by Q3 2014, 26 (87%) were completed and 4 (13%) are in progress as of October 2014. In 2012, a total of 150 sites reported data to the WHO-coordinated IB-VPD surveillance network including 105 (70%) sites in Gavi-eligible countries. Among those 105 hospitals, 71 (68%) hospitals comprising 66 sentinel sites in 40 Member States were selected to be targeted for financial and technical support through 2015. In 2014, 79% of the targeted sites were located in Member States that introduced pneumococcal vaccine (PCV), with 30 (75%) of the 40 Member States with a targeted site having introduced PCV. In the RV surveillance network, 48 (72%) of Member States that reported 2013 data were Gavi-eligible countries. Overall, 65% of the 97 sites in Gavi-eligible countries met inclusion criteria for further analysis in comparison to 27% of the 73 sites in non-Gavi-eligible countries. RV vaccine was introduced in 23 (53%) of 43 Member States with a site that met the inclusion criteria.

One of the major achievements of the past year included transition to case-based reporting for both networks. In 2013, 6 out of 9 RRLs reported case-based data for IB-VPD while 7 out of 9 RRLs and 4 national laboratories reported case-based data for RV. Sites in 4 regions have begun sharing case-based data with progress underway in the other regions to start case-based data sharing. Sentinel site data has been shared on a quarterly basis and standard process and performance indicators calculated and provided back to sites. Another achievement of 2014 has been the implementation of the EQA global programs to assess laboratory performance for both RV and IB-VPD. The IB-VPD survey was completed, but there were challenges in delivering proficiency testing panels to 11 countries (21 laboratories) due to shipment and customs clearance issues. Guidelines were developed to improve specimen referral systems for both IB-VPD and RV surveillance. One of the initial objectives of the network has been to provide documentation of the burden of disease in countries which have not yet introduced PCV and the RV vaccine. As the countries have progressed to introduce these vaccines, there has been a shift in the surveillance network to emphasize on providing evidence of vaccine impact. To maximize the potential for vaccine impact evaluation, there is a need to retrospectively enter and link data for countries with consistent surveillance data collection, laboratory testing, and sufficient cases identified to potentially monitor impact and to prospectively improve data quality across all regions by linking the clinical and laboratory data.

Discussion

1. The importance of linking RRL and national laboratory testing results with clinical data: Improvement has been seen over the last 12 months, but because the meeting focused on 2013 data, this data does not yet reflect improvements and changes made following the 2013 strategic review. Sentinel sites should be prioritized for retrospective RRL data linkage and guidelines for RV and IB-VPD data analysis would be useful.
2. Only case-based clinical and laboratory data will be accepted.
3. The selection of targeted IB-VPD sites was based on consistent reporting, enrolling minimal numbers of cases, and individual discussions with the regions. Laboratory performance was not considered.
4. Sites and regions must report more systematically, including use of zero reporting.
Section III

Session Two: Status of the Regional IB-VPD and RV Networks

WPR Regional Update: Presented by Dr Kimberly Fox

In WPR, several countries have already introduced PCV or are in the process of introduction. In Fiji, PCV was introduced in October 2012 while Papua New Guinea just introduced during the fourth quarter of 2013. PCV was introduced in one area in the Philippines in 2013 and use will be expanded during 2015-16. Mongolia plans to introduce the vaccine in 2016. Within the IB-VPD surveillance network, there are 6 hospitals that represent one sentinel site for Mongolia, 1 sentinel site for Papua New Guinea, and 3 sentinel sites for Viet Nam. The RV vaccine has not been implemented yet in WPR except for two areas in the Philippines in 2012. The RV surveillance network includes 1 sentinel site each in Cambodia, Fiji, Papua New Guinea, and Laos while there are 4 sites in the Philippines, 4 sites in Viet Nam, 2 sites in Mongolia, and several sites that are expanding in China. To better target support, IB-VPD sentinel sites were reduced and Cambodia will withdraw from the network after December 2014 although the country remains willing to share data generated by a partnership with Oxford University/Welcome Trust. Papua New Guinea reduced sites from eight to one. Progress has also been made to standardize data entry methodology by developing a web-based RV database and recording RRL results into the case-based database through existing unique ID numbers. Yet, one of the biggest challenges remaining in WPR is to fit a systematic data entry management system in each Member State while maintaining integrity of national ownership of its surveillance system.

Discussion

1. Negotiate and determine the minimum level of surveillance and data quality needed from non-funded, non-targeted countries willing to participate in the WHO network.
2. It is absolutely critical to have case-based data from all WPR countries but there must also be a reassessment on how the variables were collected at each site. Some of the critical variables were not entered into the database and the methodology taken for data collection was not done precisely. It is critical to compare cross-nationally and investigate the differences (or lack of differences) in data collection to provide information on vaccine impact.
3. The inclusion criteria for probable bacterial meningitis (PBM) is different from WHO’s guidelines. The WHO method for establishing denominators for tier 1 sites for meningitis has not been implemented. WHO methodology has been piloted in the Philippines but it was not sustainable and other countries do not see this as a priority issue.
4. There is tension between national ownership of data and following the WHO methodology for surveillance. However, just having data is insufficient to make decisions. Perhaps showing the countries what decisions need to be made can help demonstrate the importance of standardization.
5. Determine the best approach for testing among sentinel sites that receive a large number of samples due to high caseload. Among these, it is important to test and revisit the non-PBM cases in Vietnam given a high percentage test positive compared with non-PBM specimens. It would be useful to compare test positive rates in two groups among the non-PBM—those missing data to determine PBM category versus those with data to show the cases were not PBM

SEAR Regional Update: Presented by Dr Pushpa Ranjan Wijesinghe

In SEAR, the Hib vaccine was introduced in Bangladesh and Nepal in 2009 while it was introduced in Nepal in 2008. PCV is scheduled to be introduced in Bangladesh and Nepal during 2014 and in Myanmar in 2016. Additionally, a pilot project of RV immunization is ongoing in Thailand which is a Gavi-non-eligible Member State. While there are 10 sentinel sites within SEAR that perform RV surveillance, there are 6
sentinel sites that perform IB-VPD surveillance. There has yet to be case-based data reported from each of these sentinel sites. Although Bangladesh is in the process of reporting case-based data, many of the sites in other countries are compartmentalized and not fully linked with MOH. One of the reasons includes contractual issues related to yearly funding and late arrival of funds at the regional office. Countries in SEAR (Sri Lanka and Nepal) are interested in acquiring national capacity for PCR, and thus they are hesitant in sending cerebrospinal fluid (CSF) samples to the RRL for analysis. SEAR also has conflicting priorities such as polio, measles, and rubella, resulting in delayed progress in providing consistent support to Member States and sites. SEARO’s current goal is to transfer management and coordination to the WHO country offices while the regional office continues to provide technical support, data management, and monitoring and evaluation that will lead to more consistent data.

Discussion

1. All targeted sites within the IB-VPD network are held accountable for following the network standards. If laboratories are not able to perform at these standards, WHO should make a decision to cease providing Gavi funding.
2. SEAR will reinforce the role of the WHO country office and contract with sites through the country office.
3. A priority challenge in SEARO that must be addressed is contractual issues.
4. Countries, particularly Sri Lanka and Nepal, that want to acquire national capacity for PCR must still send CSF samples to the RRL for analysis, both to insure consistency of laboratory testing for the network as a whole, and also parallel testing could be useful as QA for country labs. There needs to be a better utilization of RRL to provide technical support for the sentinel site laboratories and to increase the diagnostic yield as bacterial isolation rates continue to be low. It is clear that network resources are limited; thus, funding to the laboratory network will first prioritize support to RRLs before any resources can be directed to support country-level PCR.
5. Take note of the heterogeneity of sites in terms of pre-existing relationships and surveillance systems. There may need to be a requirement to have samples tested at RRL or another hybrid approach - For example results obtained from an academic collaborator need to be shared with the network on the same time schedule as other sites -.

EUR Regional Update: Presented by Dr Annemarie Wasley

In EUR, among the five countries participating in IB-VPD surveillance, Azerbaijan is the only Member State that has introduced PCV which was implemented in December 2013. Two out of seven sentinel sites are currently on track in terms of progress monitored by IB-VPD performance indicators from 2013. For RV surveillance, seven countries have reported data and among these, all nine out of nine sentinel sites are on track as monitored by performance indicators from 2013. Comparatively, there is an issue of having only a small number of cases identified for meningitis, limiting the usefulness of IB-VPD surveillance. Logistics, such as shipment of samples, continue to be a problem for both IB-VPD and RV surveillance where challenging customs regulations and political conflict exist. Importing/exporting specimens and laboratory supplies remains difficult, and some laboratory items with short shelf lives expire soon after delivery due to customs delays. In addition, maintaining consistency and continuity for IB-VPD and RV surveillance can be challenging when there are high turnovers of hospital staff, many closing hospitals, and changing patterns of health care referral in some countries. There are also issues in data management that impact the quality of surveillance—the need for an updated IB-VPD software to accommodate necessary variables and implementing unique patient IDs to specimens will be crucial in prospective linkage of RRL and national data. As EUR expects further WHO assistance in site assessments in the future, the region will be reassessing its way to measure vaccine impact even with low case counts.
Discussion

1. In need of further assistance in site assessments.
2. Develop ways to assess vaccine impact with high quality laboratory performance and high rate of case enrolment but with low case counts (i.e. small number of meningitis cases). In this region it may be particularly important to look at the number of laboratory identified cases
3. Maintaining consistency and continuity for IB-VPD and RV surveillance where logistics is part of the issue, including maintaining sufficient supplies and overcoming delays in shipment due to political issues and customs regulations.

EMR Regional Update: Presented by Dr Hinda Ahmed

In EMR, a total of 23 sentinel sites reported data in 2013 for the IB-VPD network while 24 sentinel sites reported data in 2013 for the RV network. There are 14 Member States have already introduced PCV, 2 countries are planning to introduce PCV in 2015-16, 1 Member State has partially introduced PCV in 2009, and 5 Member States that do not have a target date that is specified for PCV introduction. There are 9 Member States that have introduced the RV vaccine, 13 Member States that have not yet introduced the vaccine, and 2 Member States that have applied to Gavi for the RV vaccine. EMR is encountering many challenges due to security conflicts that are rapidly growing in this region. The inability to send samples to RRLs on a timely basis as well as rapid diagnostic tests and PCR that are rarely performed affect the data quality and the potential for conducting local analysis of data. Despite the political conflicts, there has been much improvement in the laboratory-based sentinel surveillance network such as using appropriate packaging and shipment of samples, increasing the number of bacterial isolates, and utilization of sheep blood for cultures. Currently, EMR is organizing training workshops on PCR capacity building at two national laboratories, and follow-up visits, particularly at RV RRLs, will be planned to review surveillance methodology.

Discussion

1. If there are any countries that will be graduating soon and will take over financing themselves, have there been any cost-effective analyses done?
2. Important to note that EMR is the region that has the largest number of mixed RV infections and this needs to be followed up. It is unclear whether all of these samples have been sent to the global reference laboratory, but the RRL has sent 50 specimens to CDC including cases that have not been properly genotyped or classified as untypeable.
3. As more countries progress to introduce PCV and RV vaccines, there must be a transition from pre-introduction surveillance objectives to post-introduction objectives.

AMR/PAHO Regional Update: Presented by Dr Lucia Oliveira

In AMR, 28 Member States and 7 territories have introduced PCV while 17 Member States and 1 territory have introduced the RV vaccine. A total of 38 sentinel hospitals among 11 Member States participate in the IB-VPD network while there is a total of 83 sentinel hospitals among 18 Member States that have implemented RV surveillance. AMR has not yet presented case-based data, and the majority of the challenge is rooted from the strong country ownership of data. This makes it difficult for each Member State to transition towards new surveillance indicators for regional and global purposes. The capacity of bacteriology is quite strong at most sentinel sites, and sites often have the capacity to serotype/serogroup the pathogen. However, in order to move towards a unified surveillance network within the region, AMR will be continuing to encourage each site to send CSF samples to a RRL for confirmatory testing. Another issue to note is the difficulty in reaching the target of 500 pneumonia samples and 100 meningitis samples per year. This target can be hard to reach in most sentinel sites in AMR as the disease burden starts to lessen with
vaccine introduction. Furthermore, this threshold must be revisited, particularly for well-performing sites that present with less than this target, so these sites can still be incorporated in the global surveillance network.

Discussion

1. Need to revisit threshold criteria for well-performing sites with <100 meningitis cases/year. Also need to consider appropriate thresholds in countries that have introduced vaccine.
2. There is a strong capacity of bacteriology in the laboratories at the national level, but effort is much needed to encourage sentinel sites to start sending CSF specimens to RRLs for confirmatory testing since so far, only isolates are being sent. The region that receives the largest number of isolates is PAHO, and even though bacteriology has been implemented at most sentinel sites, not all sites yet have the capacity to perform PCR, so the role of RRL has to be more reinforced.
3. A potential strategy was put forward to increase motivation in maintaining participation with the surveillance network: award sentinel sites for good performance.

AFR Regional Update: Presented by Dr Jason Mwenda

In AFR, 22 out of 32 countries received targeted support to conduct surveillance for IB-VPD and 29 countries for RV surveillance. Currently, all 47 countries in AFR have introduced the pentavalent vaccine, including Hib, and among these countries, 31 have introduced PCV and 21 have introduced the 2-dose or 3-dose RV vaccine. The current Ebola epidemic has adversely impacted the surveillance networks and has also delayed shipments of laboratory kits and reagents. Regardless of the logistical issues, AFR has been able to make an immense amount of progress to improve data quality and management. WHO workshops were held for data management in IB-VPD and RV surveillance networks. Several workshops were held throughout 2013-14 in AFR for both IB-VPD and RV networks where WHO regional officers, IST and data managers, surveillance officers, and the HQ data manager participated. The focus was on providing training on sample shipment to RRLs, assigning unique patient IDs to specimens, and linking of laboratory results in case-based data. Site assessments have also continued to be held in many countries, including Uganda, Ethiopia, Zambia, Zimbabwe, and Burkina Faso, with members from the RRL, WHO regional officers, and data managers. As a result, an effective referral system of specimens to RRLs has been implemented in AFR, and there is continued progress in improving this system.

Discussion

1. Input regarding how the technical working group determined the Ct value cut-off for target genes that were defined.
2. Among countries that only present a small number of cases or have insufficient data to make any conclusions about the disease burden and vaccine impact, should we instead rely on cross-country comparisons among similar countries or settings that have some homogeneity in data collection methods?
3. A future vision for WHO could be to build national capacities for PCR as referral of samples to RRLs continues to be a challenge.
4. The linking between the case-based data and laboratory data is still in progress for both historical and current data. For 2014, data from the Eastern and Southern countries should be fully linked, but West African countries remain a challenge due to the current Ebola outbreak.
5. Standardization is crucial when determining how to report inconclusive PCR results with negative detection of human DNA that is used as an internal control for PCR. WHO needs to determine how to distinguish PCR results that are indicated as “inconclusive” and “negative.”

Section IV
Session Three: Status of the Web-Based Data Management Tool

Presented by Dave Jackson, Nathanael Noblet, Claudia Ortiz, and Samir Saha

One of the 2013 Strategic Review recommendations was to develop a standardized web-based data management tool. The goals of the tool include having standardized case-based data collection across all the sentinel sites and linking in RRLs for more timely access to surveillance data, to ensure automated data quality checks, to facilitate linkage of surveillance and laboratory data, and to ease data analysis. The tool allows entry of unique IDs and also auto-assigns a single global unique case ID. Currently, work is in progress to coordinate with WHO regional offices to pilot the tool at RRLs. Linking the RRLs will ideally resolve the issue of having a mismatch between the clinical and RRL databases. Another focus of the tool is to work towards a system with real-time verification and analysis capacity, so the system will be dynamic and can be constantly managed by either the regional offices or the individual countries. This will allow them to export reports and validate data as it is entered into the system.

During this session, presentations summarized the lessons learned from pilots of the web-based data management tools in Nicaragua, El Salvador, and Bangladesh. All countries have strong ownership of their surveillance systems. Nicaragua uses a case-based system called SIVEflu that includes all Severe Acute Respiratory Infections including bacterial pneumonia. However, even though WHO offered funds to have the standardized WHO web-based tool implemented, Nicaragua did not see it to be sustainable and nor cost-effective. El Salvador has an existing web-based tool that is another good example of a solid surveillance system because it integrates the data from the national laboratory with the sentinel sites. During the pilot, data from the El Salvador system was successfully merged into the WHO data tool. In Bangladesh, the surveillance system has a network of 4 hospitals in urban and rural regions. With the usage of tablets by the community health workers, data can easily entered onto the online database which is then saved in the central database server. As a next step, Bangladesh will pilot the WHO web-based data management tool by uploading and sharing data from their existing surveillance system.

Discussion

1. Clarified points on how the WHO web-based data management tool functions in terms of data entry, data import/export, API, reporting methodologies, and HQ conversions.
2. Generated a discussion with various laboratory stakeholders on how the WHO web-based data management tool can be piloted by RRLs and how the WHO can apply the lessons learned from the pilots implemented by Nicaragua, El Salvador, and Bangladesh.
3. General agreement on the need for this web-based data management tool and agreement that implementation of the tool could facilitate data management at all levels-- most important functionalities are ability to export data from the national system, integration with RRL data systems, and data analytic tools.

Section V

Session Four: IB-VPD Sentinel Hospital Surveillance Network

Clinical and Laboratory Data Linkages

Presented by Ms Jillian Murray and Dr Fatima Serhan

Although each region has its own challenges, one of the issues highlighted among all the regions was the limited linkage between the clinical data and the RRL data. Among the 2013 IB-VPD data, 708 (26%) of the 2723 cases had exact matches between the two databases based on unique patient ID numbers. If unique patient ID numbers had been properly assigned to each case, the two databases could have been successfully linked and the RRL PCR and serotyping data known for the case. Due to the fact that the strategic review recommendation of linkage of the two databases was made just recently in 2013, less than 30% of historical data from 2013 has been linked. The percent of linkage will most likely increase with prospective data
because RRLs will no longer accept samples without a unique patient ID. The surveillance network needs to strategically select high priority sites for which retrospective linkage should be attempted based on local knowledge of how to link between local site and RRL specimen identifiers. This also further emphasizes the necessity of a standardized SOP for creating common unique IDs between the sentinel site and RRLs.

In addition to assessing the status of linking the RRL PCR data with the clinical data, evaluating the value of PCR for increasing diagnostic yield is important. Approximately only 10 to 50% of total specimens collected through surveillance at the RRLs were tested by PCR, but when compared to samples that were tested by culture or Rapid Diagnostic Tests, PCR doubled diagnostic yield in some regions. When tested specimens are directly compared to culture, PCR testing yielded over 3-fold increased detection for all three pathogens (Spn, Hi and Nm). Although PCR improves the diagnostic yield, it is crucial to have as much complete data as possible to make further conclusions and decisions from the IB-VPD surveillance network. When the number of PCR results from 2013 in the clinical and the RRL databases are compared, there is a discrepancy between what is reported in the clinical and the RRL databases. In AFR, for example, there is a large proportion of RRL results that are not being entered into the clinical database. In fact, particularly in AFR, most PCR results are not being entered into the clinical database, and there appears to be a bias towards entering positive results into the clinical database at some sentinel sites. On other hand in EUR and WPR, a greater number of PCR results exist in the clinical database since these two regions have national capacities in performing PCR. Additionally, EUR systematically updates RRL data before sending the data to WHO HQ. Although there are remaining issues that need to be improved, there has been a significant amount of progress since 2013 in making the linkage between the clinical and RRL databases possible.

Discussion

1. Although more PBM samples test positive for a VPD pathogen compared to non-PBM samples, further assessment of the accuracy of categorizing cases as PBM is warranted including reliability of results for WBC, glucose, and protein. Neither glucose nor protein testing is supported nor monitored by WHO. Additionally, proper adherence to case definitions should be ensured.
2. Because the data clearly showed the substantial increase in diagnostic yield with PCR, CSF specimens from all suspect meningitis should be tested by PCR. The network will need to assess the feasibility of implementing this recommendation.
3. Consider prioritization of sending specimens to RRLs from high-performing sentinel sites that conduct surveillance consistently and sites that have identified larger numbers of confirmed cases, so better quality data can be acquired from fewer sites.
4. Forty countries have a targeted IB-VPD site, and among these countries, 30 have already introduced PCV. Is it better to focus on acquiring specimens from the 10 countries that have not yet introduced PCV?
5. Ensure prospective linkage between clinical and RRL databases by use of unique case IDs and ensuring attention to this activity, particularly in select high priority countries. Sites should be prioritized for retrospective linkage.
6. Binax/latex data was not presented due to the incomplete data with small numbers.
7. Bacteriology is still considered the gold standard for IB-VPD diagnostics and laboratory tests must be prioritized in the network.
8. Consider decreasing the number of data variables collected to keep only the necessary ones for assessing vaccine impact.

Categorizing IB-VPD Sentinel Sites

Presented by Dr Annabelle de St. Maurice and Dr Mary Agocs

In 2013, 44 Member States reported IB-VPD data to WHO, including 38 Gavi-eligible Member States. Among Gavi-eligible Member States, 27 (71%) have already introduced PCV while one (17%) of the 6 non-Gavi-eligible Member States has introduced PCV. To select sites that may have a pre-vaccine introduction baseline, sites that reported 2013 IB-VPD data were evaluated based on three main criteria: Having enrolled cases for all 12 months in the year prior to PCV introduction, having enrolled at least 100 cases (Tier 1) or at
least 500 cases (Tier 2/3) in the year prior to PCV introduction, and if PCV was enrolled in the Member State prior to 2013, data should have been reported during the year following PCV introduction.

Among the 79 sites that reported 2013 data, 26 (33%) met the inclusion criteria. Among these sites, 37% were Gavi-funded and only 9% were non-Gavi-funded. Among the Gavi-eligible Member States that met the inclusion criteria during the baseline PCV year, 37% of sites (N=25 out of 68) met both criteria where sites enrolled cases for all 12 months and at least 100 cases during that year. There were 47% of sites (N=32 out of 68) that enrolled cases for all 12 months, and 51% of sites (N=35 out of 68) enrolled at least 100 cases during the baseline PCV year. Among the non-Gavi eligible Member States that met the inclusion criteria during the baseline PCV year, 9% of sites (N=1 out of 11) met both criteria, 45% (N=5 out of 11) of sites enrolled cases for all 12 months, and 9% (N=1 out of 11) of sites enrolled at least 100 cases during that year.

With further assessment of data from inclusion sites, WHO found variability in surveillance performance. One of the questions that must be explored further is the percent PCR positivity for Spn, Hi or Nm by the year of PCV introduction. This data may help evaluate disease trends over time particularly before and after vaccine introduction. However, as discussed previously, PCR data was incomplete and only 19% of all PCR data was entered into the clinical database. Specimen collection dates were not always entered consistently. These issues must be put right in order to analyse pre- and post-PCV introduction status data.

Discussion

1. What are the best criteria for inclusion sites for vaccine impact? Reminder that having only one year of data post-PCV introduction is not ideal for measuring impact.
2. What are the best performance indicators for those sites and what are the key variables that are best for measuring PCV impact (CSF, PCR, WBC, etc.)? Reminder that we do not need as many variables that we have as of now; likely only 10-20 variables are necessary.
3. How do we prioritize linking clinical and RRL databases?
4. It is important to note that when looking at pathogen positive cases in non-PBM specimens, quality control systems are not in place for these tests to classify PBM (WCC, glucose, and protein) other than bacteriology.
5. In addition to looking at CSF appearance, WCC and glucose/protein tests, PCR data should be analysed with caution as well as availability of positive cases reported with serotype/serogroup results.
6. When analysing PBM vs. non-PBM samples, it should be determined how testing varies across sites and to compare non-PBM cases with cases with inadequate data to qualify as PBM. Thus, it may be better to analyse data from sites individually.

Section VI

Session Five: RV Sentinel Surveillance Network

Review of 2013 Rotavirus Surveillance Data

Presented by Dr Catherine Yen and Dr Mary Agocs

In 2013, case-based data was available from four regions and aggregated data from two regions as reported to HQ by July 31st, 2014. Data analyses from the RV surveillance network was based on two main sentinel site inclusion criteria: Reported data for all 12 months of 2013 (including zero reporting from two regions) and at least 100 stool specimens tested from enrolled cases for all RV by EIA. A total of 83 sentinel sites met the inclusion criteria for analyses, and among these sites, 76% (N=63) were Gavi-eligible Member States and 24% (N=20) were non-Gavi Member States. Of the 83 sites that met the inclusion criteria, 89% (N=74) were “on track,” 10% (N=8) were “at risk,” and 1% (N=1) was “off-track” with surveillance performance. A total of 23 out of 43 countries with inclusion sites had introduced the RV vaccine to date, and among these 23 countries, 14 are currently planning, conducting, or have conducted vaccine impact evaluations with additional support.
Analysis of Reporting and Testing Practices 2013 WHO Rotavirus Surveillance Data

Among the sentinel sites that reported at least 1 month of data to WHO across all 6 regions, a total of 97 sentinel sites were among Gavi-eligible Member States while a total of 73 sentinel sites were in non-Gavi eligible Member States. Among the Gavi-eligible sites that began reporting in January 2013 or earlier, case-based data from 3 regions were analysed and compared, including data received from AFR, AMR, and WPR. Sixty-eight percent of the sites in AFR (N=12 out of 34), 63% of the sites in AMR (N=12 out of 19), and 70% of the sites in SEAR (N=7 out of 10) tested at least 100 specimens in a year. Three out of 28 Member States in AFR and 14 out of 16 Member States in AMR had introduced the RV vaccine before 2013, and none out of the 4 Member States in SEAR have yet introduced the vaccine. In terms of specimen testing within the RV surveillance network, three regions including EMR, EUR, and WPR had at least 90% of sentinel sites that tested at least 100 specimens in 2013. At least 60% of the sentinel sites in AFR, AMR, and SEAR tested at least 100 specimens in 2013, which demonstrates that the majority of these regions were still meeting this criterion. In AFR, 40% of the total specimens were tested positive in Gavi-eligible sites that tested at least 100 specimens (N=23 sites) while 36% of the total specimens were tested positive in sites that tested 50-99 specimens (N=11 sites). In AMR, 27% of the total specimens were tested positive in Gavi-eligible sites that tested at least 100 specimens (N=12 sites) while 17% of the total specimens were tested EIA positive in sites that tested 50-99 specimens (N=7 sites). In SEAR, 36% of the total specimens were tested positive in Gavi-eligible sites that tested at least 100 specimens (N=7 sites) while 21% of the total specimens were tested positive in sites that tested 50-99 specimens (N=3 sites). This seems to indicate that the overall positivity in specimen results did not vary significantly regardless of the total number of specimens that were tested at each site.

Discussion:

1. No studies have been conducted that assess which sentinel site performs which surveillance better or worse—RV or IB-VPD or both. Are there any crossovers of the two surveillance systems?
2. Determine whether having a target of 100 stool specimens is appropriate as part of the inclusion criteria for site determination in RV vaccine using countries where a fewer number of children can be anticipated with acute gastroenteritis hospitalizations. Reassess necessary variables in case-based data and inclusion criteria.
3. For vaccine impact evaluations, keep mind the importance of capturing how many children were eligible to be included in the RV surveillance and among these children, how many were actually enrolled. The number of children eligible for enrolment may not be feasible to capture accurately from surveillance data.

Section VII

Session Six: Conclusions and Next Steps

Since the global strategic review meeting was held in September 2013, significant progress has been made to further improve the IB-VPD and rotavirus sentinel hospital surveillance networks. Network management has been strengthened with the use of a Performance Management Framework to track implementation status of annual global recommendations. A major achievement was transition to standardized, case-based reporting with quarterly data sharing plus feedback of standard process and performance indicators to sites. Data management processes continue to be improved toward having a more systematic approach in reporting, cleaning, analysing and interpreting data. The reference laboratories are appropriately supporting sites and network laboratory performance has been successfully monitored by the global external quality assessment (EQA) program as well as quality control (QC) programmes. Sentinel site and laboratory assessments have been prioritized but have not been able to include all priority sites.

The most recent 2013 data available for the meeting may underestimate data quality because none of the actions taken after the 2013 strategic review are yet reflected. IB-VPD data analysis focused on assessing laboratory testing performance of culture and PCR, and found <30% of PCR results were linked into the
clinical database as well as a 3-fold improved detection of pathogen by PCR over culture alone. Beginning in 2014, RRLs will only process specimens with a unique identification number and it is thus anticipated that a larger percent of cases will have clinical data that can be readily linked with RRL data.

Network data has contributed to vaccine introduction decisions and the surveillance networks have been used as platforms for vaccine impact evaluations. Moving forward, the rapid introduction of PCV and rotavirus vaccines by Member States now requires the surveillance networks to focus on improving baseline data for sites in non-vaccine using Member States and to ensure consistent surveillance practices for sites meeting inclusion criteria in vaccine using Member States. The web-based data management tool has great potential to improve data quality and may be expanded to other vaccine preventable diseases in due course.

Complete List of Meeting Recommendations Made to Advance the Network during 2015

IB-VPD Recommendations: Network Management

1. Determine how best to include Ministries of Health and Expanded Programmes on Immunization where linkages are not strong.

2. Data from non-Gavi sites welcomed but must meet quality criteria for inclusion.

3. Within 6-months (by end April 2015), establish specimen sharing with RRL among all 71 target hospitals to continue in global network

4. Preliminary data analysis suggests all suspect meningitis specimens should be tested by PCR at RRL: suspend protocol to test only a sub-sample of cases at RRL until further analysis can be performed. Additional analyses also will include comparing PCR to BC, +/- Latex +/- Binax; utility of local RDT testing and appropriate policy for sites conducting PCR locally.

5. Refocus efforts to define a subset of sites where disease burden estimates may provide a platform for vaccine impact evaluation
   a) 10 countries which have not yet introduced PCV
   b) Countries already introduced PCV: identify those with two years credible baseline data (retrospective—PCR, linkage).
   c) Focus on both prospective and retrospective consistent quality over time periods consistent with SAGE guidance for impact evaluation

6. Discuss revisiting threshold criteria for inclusion sites; consider including smaller sites with quality data, especially substantial numbers of laboratory defined cases.

7. Consider alternative impact monitoring approaches in key strategic sites (e.g. hospitalized pediatric pneumonia databases).

8. Identify with partners other key objectives (eg ST epidemiol)

9. Given likely budget constraints, network resources should be focused on network strategic needs; other sources for support for countries such as Gavi HSS should be explored. Recognizing that reprogramming HSS funds for surveillance will depend on other critical country programmatic needs.
IB-VPD Recommendations: Surveillance Implementation

10. By December 31 2014, sites must implement linkage between clinical and laboratory data sources, including RRL, for prospective data.

11. Implement zero reporting in all sites by December 31, 2014.

12. Set timelines for linking data retrospectively; prioritize sites where impact assessments are possible.

13. Further analyze data to assess potential utility (or lack thereof) of PBM data (e.g. WBC, glucose, protein).

IB-VPD Recommendations: Data Use and Dissemination

14. Improve data sharing with MOH and NITAGS to strengthen local investment and policy decisions.

15. Priority consideration of strategic role of data management system—can it provide value added for RRL, data analytic capacity, or linkage?

16. Consider feasibility to create subset of core data elements and to prioritize critical data elements needs for vaccine impact assessments.

17. Provide positive reinforcement to well-performing sites through trainings, meetings, feedback, prizes and publications.

18. Analysis of latex and binax results should be prioritized to better understand PCR yield (ie compare site RDT with RRL PCR) and RDT specificity.

19. PBM analyses should develop a category for incomplete test results.

20. Surveillance cost studies may help strengthen in-country support of the network and improve sustainability.

Rotavirus Recommendations: Network Management

21. Determine how best to include MoH and EPI where linkages are not strong.

22. Define cut-off numbers for pre- and post-vaccine introduction countries and assess whether satellite hospital sites may be included.

23. Determine feasibility of establishing higher level testing (e.g. genotyping) at national laboratories.

24. Determine how to support non-Gavi countries that would like to contribute to the network.

25. Resolve issues related to sample transfer by discussion with country offices or early execution of MTAs.

Rotavirus Recommendations: Surveillance Implementation

26. Linkage of laboratory and clinical data

27. Reinforce zero reporting by all surveillance sites

28. Determine core elements to require of sites and laboratories for rotavirus surveillance for non-Gavi and Gavi-sites, which are monitored on a regular basis, ideally quarterly. Sites may require additional training to be able to provide these core elements.
29. For sites conducting vaccine impact evaluations, reinforce monitoring of total number of eligible cases (e.g., log book review, discharge data)

30. Revise, or draft where not available, standard definitions and protocols for surveillance implementation

31. Establish a standard system for performance monitoring and accountability at each level of the network where support is provided

32. Implement feedback systems and incentives (where not available) to encourage sites to improve and maintain surveillance

Rotavirus Recommendations: Data Use and Dissemination

33. Draft guidelines for data analysis and interpretation
   a. Provide guidance on analysis of data from countries where the amount of data are not sufficient
   b. Address limitations of data and how best to interpret the data analysis

34. Establish data dissemination plans
   c. Determine to whom (e.g. MoH, EPI, NITAGs, regional iTAGs, donors) and how information should be provided

Web-based Data Management Tool

35. Finalize the web-based tool particularly the data analysis component and begin to include RRLs

Section VIII

Closed Meeting Summary Notes from Oct 31, 2014

Summary on Data Management and Analysis:

One of the key points revisited during the closed meeting was what countries need from the data provided by the surveillance network. Due to data limitations and poor quality data in some sites, challenges are arising on how to interpret the data. Because of the many logistical challenges, particularly for IB-VPD surveillance, WHO should consider how best to provide countries with a flexible sentinel hospital surveillance system that can be easily adapted to monitor VPDs.

Although WHO’s objective is to provide assistance for countries in the network, WHO should consider whether capacity building should mainly focus on countries that have not yet introduced vaccine or all countries. Ensuring high-quality data is crucial for decision making as well as to secure future funding from Gavi. To improve data quality, WHO must ensure consistent surveillance practices over time to monitor trends over time and ensure linkage of clinical and RRL data with serotype/serogroup information.

Action Items for data management and analysis:

- Further data analysis is required for the sentinel sites in each region. A list of data analysis methods with core data variables should be provided with a description of the objective of the analysis.
- PAHO has an excellent, succinct site Excel tool used for hospital and laboratory assessment that should be translated from Spanish to be adapted for use in all other regions.
- Shorten the number of database variables and consider reducing the number of performance indicators.
- Phone conferences with regional offices (frequency of meeting TBD) and HQ should be scheduled to discuss data analysis results and further communicate on what is working and what is not working.

Summary on Web-Based Data Management Tool:

There was a consensus among all regions to try to adopt the web-based data management tool. WPR pointed out that there is already an effective web-based system in place in the Region for RV surveillance, so there is no compelling reason to adopt a new system for RV. However, the new system could be useful for IB-VPD surveillance. For SEAR, Bangladesh has already started piloting this system, and Sri Lanka can be the next possible site. The region recommends this system to be piloted at CMC in Vellore, India. For AMR, the region continues to work with countries to begin case-based reporting, and plans to continue to recommend the web-based tool. EUR, as well as EMR and AFR, are eager to first pilot the system at RRLs.

Summary on Zero Reporting Discussion:

One of the key issues of the RV and IB-VPD surveillance network must address is the lack of consistent zero reporting. In WPR, for instance, there are quite a few hospitals that do not admit any acute diarrheal cases, and among hospitals in small countries that have introduced the RV vaccine, the disease burden is continuing to decrease. Thus, it is crucial to have a uniformed zero reporting system to distinguish between lack or lag of data output (due to holiday season, staff turnover, other disease outbreak, etc.) and having actual zero cases.

Action Items for Zero Reporting:

- Starting with the next data collection period, regions should send a list of months of zero reporting for each site to HQ
- Discuss further during the regional office & HQ phone conference to decide on a methodology for zero reporting

iTAG Meeting Rapporteur Team

Team lead: Ms Tomoka Nakamura

Team members: Dr Laura Conklin, Dr Chris Van Beneden, and Dr Catherine Yen
**Section IX: Agenda**

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**Global IB-VPD and RV Sentinel Surveillance Meetings**  
**One Year After the Strategic Review: Progress, Challenges and Next Steps**  
Geneva, Switzerland; 27-31 October, 2014  
Hotel Royale, Rue de Lausanne 41, Geneva, CH-1201 (+41 22 906 1414)

### Monday 27 October 2014

**Session One: Introductions & Global Overview**  
**Chair:** Dr Thomas Cherian/WHO  
**Presenters**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenters</th>
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| 09:00 – 10:30 | • Welcome and Introductions  
  • Meeting overview  
  • WHO Performance Management Framework: Implementation  
  Status of Recommendations from the 2013 Strategic Review  
  • Structure of the Surveillance Networks: Countries & Sites, Laboratory Testing Algorithms, Flow of Data & Feedback Loops  
  • RV & IBVDP: global overviews  
  **Discussion** | T Cherian / C Broome  
  M Agócs / F Serhan |
| 10:30 – 11:00 | Coffee                                                                  |                             |

### Session Two: Status of the Regional IB-VPD and RV Networks

**Session Objective**  
**Chair:** Dr Cherian  
- For each Region, review the countries and sites in both networks, activities to implement the Performance Management Framework, data from the networks, and key challenges

**Session Outcomes**  
- Understanding of the status of the Regional networks, and identification of cross-cutting challenges  
- Short-list of actions identified to overcome key challenges in the Regions & the cross-cutting challenges

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<th>Time</th>
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<th>Presenters</th>
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| 11:00 – 12:30 | Regional Update: WPRO  
  • 20 minutes presentation with 25 minutes discussion  
  Regional Update: SEARO  
  • 20 minutes presentation with 25 minutes discussion | K Fox  
  P Winjesinghe |
| 12:30 – 13:30 | Lunch                                                                  |                             |

### Session Two Continued: Status of the Regional IB-VPD and RV Networks

**Chair:** Dr Gagandeep Kang / iTAG

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<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenters</th>
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| 13:30 – 15:00 | Regional Update: EURO  
  • 20 minutes presentation with 25 minutes discussion  
  Regional Update: EMRO  
  • 20 minutes presentation with 25 minutes discussion | A Wasley  
  H Ahmed |
| 15:00 – 15:30 | Coffee                                                                  |                             |
### Session Three: Status of the Web-based Data Management Tool

**Session Objective**
- Review the current status of the web-based data management tool and pilots including lessons learned

**Session Outcomes**
- Understanding of the web-based tool
- Short-list of actions to improve the tool and to ensure the tool can help overcome challenges identified during Session One

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<tr>
<td>09:00–</td>
<td>Status of the web-based data management tool (10 minutes presentation)</td>
<td>D Jackson</td>
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<td>10:30</td>
<td>and pilots (AMR &amp; Bangladesh, 10 minutes presentation each)</td>
<td>C Ortiz &amp; S Saha</td>
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<td>10:30–</td>
<td>Coffee</td>
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### Session Four: IB-VPD Sentinel Hospital Surveillance Network

**Chair:** Dr Broome

**Session Objective**
- Review the status of the laboratory processes
- Begin to characterize sentinel site performance

**Session Outcomes**
- Improve ability to screen site laboratories on a timely basis for technical assistance
- Improved ability to characterize sentinel site performance

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<th>Time</th>
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<tr>
<td>11:00–</td>
<td>IB-VPD Issues</td>
<td>F Serhan / J Murray</td>
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<td>12:30</td>
<td>Laboratory quality assurance</td>
<td>M Agócs / A de St. Maurice</td>
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<td><em>Discussion</em></td>
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<td>Categorizing sites: sites meeting inclusion criteria (sites enrolling</td>
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<td>cases every month and enrolling &gt; 100 meningitis cases or &gt; 500</td>
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<td>meningitis, pneumonia &amp; sepsis cases annually), surveillance</td>
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<td>performance indicators and next steps</td>
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<td><em>Discussion</em></td>
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<td>12:30–</td>
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### Session Five: RV Sentinel Surveillance Network

**Chair:** Dr Jason Mwenda / WHO

**Session Objective**
- Better understand the quality of data being produced by the sentinel sites

**Session Outcomes**
- Improved ability to characterize sentinel site performance (and therefore to intervene early to
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<td>13:30 – 15:00</td>
<td>RV Issues: Categorizing site performance</td>
<td>M Agócs</td>
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<td>• Data from inclusion sites (sites enrolling cases every month and</td>
<td>C Yen</td>
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<td>testing ≥ 100 stool specimens annually), surveillance performance</td>
<td>U Parashar</td>
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<td>indicators and next steps</td>
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<td>Discussion</td>
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<td>• Further assessing inclusion criteria: Analysis of reporting and</td>
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<td>testing data by site</td>
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<td>Discussion</td>
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<td>15:00 – 15:30</td>
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<td><strong>Session Six: Conclusions and Next Steps</strong></td>
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<td><strong>Chair:</strong> Dr Thomas Cherian / WHO</td>
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<tr>
<td>15:30 – 17:00</td>
<td>Summary of actions identified to improve the networks</td>
<td>iTAG &amp; WHO</td>
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<td>Discussion and agreement</td>
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<td><strong>Meeting conclusion</strong></td>
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