

REPORT



Second Laboratory Directors' Meeting and Workshop on Enhancing the Laboratory Expertise through Quality Management Systems in SAARC Countries

12-13 March 2013, Colombo, Sri Lanka



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Acronyms and abbreviations

AGPT	Agar Gel Precipitation Test
AAHL	Australian Animal Health Laboratory
BLRI	Bangladesh Livestock Research Institute
BSL	Biosafety Level
BSO/ABSO	Biosafety Officer/Assistant Biosafety Officer
ECTAD	Emergency Centre for Transboundary Animal Disease
ELISA	Enzyme Linked Immunosorbent Assay
EMPRES	Emergency Prevention System for Transboundary Animal, Plant Pests and Diseases
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FMD	Foot and Mouth Disease
HI	Haemagglutination Inhibition
HPAI	Highly Pathogenic Avian Influenza
HPEDs	Highly Pathogenic and Emerging Diseases
HSADL	High Security Animal Disease Laboratory
IQC	Internal Quality Control
LPB-ELISA	Liquid Phase Blocking ELISA
ND	Newcastle Disease
NRLPD	National Reference Laboratory for Poultry Diseases
OIE	World Organization for Animal Health (Office International des Epizooties)
PCR	Polymerase Chain Reaction
PD-FMD	Project Directorate on Foot and Mouth Disease
PPR	Peste des Petits Ruminants
PT	Proficiency Testing
QA	Quality Assurance
QM	Quality Management
RAP	FAO Regional Office for Asia and Pacific
RLDL	Regional Leading Diagnostic Laboratory
RSU	Regional Support Unit
SAARC	South Asian Association for Regional Cooperation
SOPs	Standard Operating Procedures
TADs	Transboundary Animal Diseases

Summary

The Regional Support Unit, based in the FAO's Sub-regional ECTAD Unit in Kathmandu, organized "Second Laboratory Directors' meeting and workshop on enhancing the laboratory expertise through quality management systems in SAARC countries" from 12-13 March 2013 in Colombo, Sri Lanka with support from the European Union. The main objective of this meeting was to keep the Directors of RLDLs and key national laboratories updated on the ongoing activities related to laboratory capacity building and laboratory networking in South Asia. The ultimate goal of this meeting was to provide a platform to discuss problems and issues related to the national veterinary diagnostic laboratories and the laboratory networks within the member states in the SAARC region. The meeting and workshop was attended by 23 participants from the SAARC countries including Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka with technical support from the Australian Animal Health Laboratory (AAHL), World Health Organization (WHO) and FAO ECTAD, Kathmandu, Nepal.

On the first day, presentations were made by the officials of the RSU, FAO, Kathmandu, Nepal, WHO officials and AAHL on behalf of ECTAD-RAP. These presentations included the background information on the meeting focusing on the recommendations of the First Laboratory Directors' meeting, update on the regional network activities, cross-sectoral collaboration to develop harmonized laboratory procedures and protocols on zoonotic diseases and regional strategic frame work for laboratory capacity building and networking in South East Asia. This was followed by the presentations by the laboratory directors of the RLDLs and OIE Reference Laboratory on avian influenza who gave an overview of the activities including the current QA system in place at their laboratories, constraints and challenges in implementation of quality standards.

The second day was entirely devoted to "Workshop on Enhancing the Laboratory Expertise through Quality Management Systems" which was facilitated by an expert from AAHL, Geelong, Australia. The workshop ended with drawing the conclusions and recommendations.

Based on the deliberations of the Second laboratory directors' meeting and workshop on quality management systems, the following main recommendations were drawn;

Recognizing that the:

1. National animal disease diagnostic laboratories are responsible for disease surveillance programmes; which enable the countries to detect HPED outbreaks early and respond in a timely manner in their respective countries.
2. Regional laboratory networks have a role as a coordinating platform for the national laboratories to enhance their laboratory capacity for the diagnosis of various infectious diseases, assure quality of diagnostic findings and promote sharing of reagents, biological materials and information at the national and regional levels.

3. The laboratory directors' meeting can provide a platform to discuss regionally relevant problems of mutual interest and issues among national and leading laboratories of SAARC Region.

The Laboratory Directors' meeting recommends:

1. To institutionalise the SAARC Laboratory Directors' Forum with commitment to organise annual meetings with participation from the National laboratories and RLDLs.
2. The Laboratory Directors' Forum to constitute a technical advisory group (TAG) to guide and monitor the laboratory activities in the region.
3. The RLDLs should take initiative to ensure full ownership of the network and support capacity building and laboratory networking activities on a long term sustainable basis.
4. The RLDLs should develop linkages with public health laboratories to foster collaboration for one health activities.
5. Develop a road map for regional laboratory quality assurance (QA) scheme to garner institutional and political support and commitment.
6. Based on the laboratory assessments; guidelines and programmes may be developed to address the deficiencies and shortfalls in implementing QA, quality management (QM), biosafety and trainings as priority activity to overcome these shortcomings.
7. The RLDLs in collaboration with Regional FAO/OIE Reference Centres/Laboratories should conduct annual proficiency testing and manage trainings for production of regional internal quality controls (IQC) for its subsequent sharing with national labs.
8. The RLDLs/Regional FAO/OIE Reference Centres/Laboratories should provide technical assistance for development and validation of diagnostic kits.
9. The RLDLs/Regional FAO/OIE Reference Centres/Laboratories should make efforts to get their laboratory accredited as per ISO guidelines (ISO 9001/ ISO/IEC 17025).
10. Efforts should be made to undertake joint research activities to address the priority HPEDs in SAARC region.
11. The RLDLs/Regional FAO/OIE Reference Centres/Laboratories should create a database including gene sequences of the causative agents for SAARC priority diseases for reference and sharing.

Background

The Food and Agriculture Organization of the United Nations (FAO) is implementing an European Union (EU) funded regional project entitled "Regional Cooperation Programme on Highly Pathogenic and Emerging Diseases (HPED) in South Asia" under the umbrella of the South Asian Association for Regional Cooperation (SAARC) at FAO Sub-regional ECTAD Unit in Kathmandu, Nepal. The overall objective of the project is to strengthen and empower SAARC countries in their ability to prevent, control and eradicate HPED, including HPAI, through improved veterinary and public health services and inter-sectoral collaboration on a regional basis.

To fulfil the mandate of the project, SAARC Regional Leading Diagnostic Laboratories (RLDLs) have been established in Bangladesh (PPR), India (FMD) and Pakistan (HPAI) as agreed by the member countries. These laboratories are co-coordinating and leading a network of national diagnostic laboratories, primarily focusing to maintain uniform diagnostic standards, support training of laboratory scientists/technicians from the member states, and backstop regional surveillance and epidemiological studies. The activities are also being supported by the international OIE and FAO reference laboratories like Australian Animal Health Laboratory (AAHL), Geelong, Australia and High Security Animal Disease Laboratory (HSADL), Bhopal, India.

The RLDLs implemented a number of laboratory activities including trainings in laboratory diagnostic protocols for regional priority diseases and implementation of proficiency testing (PT) programmes in the region. The PT of National FMD laboratories is ongoing since September 2012 in Bangladesh, Bhutan, Nepal and Sri Lanka with support from RLDL-FMD. The RLDLs also supported the standardization of diagnostic technologies and instrumentation besides setting up FMD virus typing facilities in Bhutan and hands-on PCR training on HPAI diagnosis in Bangladesh.

The laboratory networking was initiated in March 2011 followed by the First Laboratory Directors' meeting and workshop on laboratory networking and proficiency testing for priority HPEDs in SAARC Countries in January 2012 in Dhaka, Bangladesh. Some of the recommendations of the First Meeting relevant to this follow up meeting include: Regional quality assurance (QA) scheme must be a priority and be supported to include institutional commitment to carry out PT and sharing of results among network laboratories.

- (i) The Laboratory Directors' Forum is institutionalized and the meeting be held annually with participation from the National and Regional Leading Laboratories.
- (ii) The Laboratory Director/s Forum could provide guidelines for all laboratories in a number of areas like biosafety, quality assurance (QA), testing requirements for test validation, equipment calibration (e.g. BSL II cabinets, PCR machines) etc.
- (iii) The quality assurance system needs to be implemented and supported and National laboratories should seek accreditation from their own country.

To take forward these recommendations, it is essential that these laboratories are engaged in quality assurance (QA) programmes and participate successfully in PT schemes. Additionally, a laboratory should implement a quality management (QM) programme that is appropriate for its mandate, clients', needs and goals and that can be shown to be effective in meeting quality objectives. Many factors affect the quality management programme, the OIE standards on this subject is a useful guideline for laboratories seeking accreditation for ISO/IEC 17025.

The Regional Support Unit based in the FAO's Sub-regional ECTAD Unit in Kathmandu, organized "Second Laboratory Directors' Meeting and Workshop on Enhancing the Laboratory Expertise through Quality Management Systems in SAARC Countries" from 12 to 13 March 2013 in Colombo, Sri Lanka with support from the EU and AAHL.

The main objective of this meeting was to keep the Directors' of RLDLs and key national laboratories updated on the ongoing activities related to laboratory capacity building and laboratory networking in South Asia. The ultimate goal of this meeting is to provide a platform to discuss problems and issues related to the national veterinary diagnostic laboratories and the laboratory networks within the member states in the SAARC region.

This is the report of "Second Laboratory Directors' meeting and workshop on enhancing the laboratory expertise through quality management systems in SAARC countries" held as per the agenda attached at Annex I. The meeting was attended by 23 officials from various SAARC countries. Delegates from six SAARC countries viz. Bangladesh, Bhutan, India, Maldives, Pakistan, and Sri Lanka participated in the meeting. The meeting was also attended by representatives from FAO, WHO, and Australian Animal Health Laboratory (AAHL). The list of participants is attached at Annex II.

DAY ONE

Inaugural session

Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal welcomed the participants and gave a brief on the purpose of the workshop and expected outputs. He informed that the Regional Cooperation Programme on Highly Pathogenic Emerging Diseases (HPEDs) in South Asia was funded by European Union with the help of SAARC Secretariat and implemented by FAO. He highlighted that Indo-Gangetic Plains is a global hotspot for emergence of new diseases including avian influenza. He informed that although the main focus of the activities under HPED programme is on priority diseases viz., FMD, PPR and HPAI, the activities will also be focused on other emerging diseases including zoonotic diseases as part of FAO's policy on One Health. He emphasized that leading laboratories have to take the role to continue the laboratory network activity.

Dr Seekkuge Susil Priyantha Silva, Deputy Director (Veterinary Research), Veterinary Research

Institute, Department of Animal Production and Health, Sri Lanka gave opening remarks on behalf of Dr K M T Kederagama, Secretary, Ministry of Livestock and Rural Community Development, Sri Lanka. He welcomed the delegates from SAARC countries to Sri Lanka. He informed that VRI has participated in the FMD PT programme and keen to support networking programme.

Dr Khan Shahidul Huque, Director General, Bangladesh Livestock Research Institute, Savar, Dhaka thanked the initiators of the HPED programme in the region. He informed that BLRI has initiated work on TADs and zoonotic diseases as these affect food security in terms of the demand of animal protein in Bangladesh. He informed that the country is growing at the rate of 20 percent but outbreaks of avian influenza is causing concern due to major economic losses affecting the food security of the population. A thermostable PPR vaccine has been developed and private sector will take up PPR vaccine production. However laboratory quality assurance and availability of quality manpower is a great concern.

Dr Iftikhar Ahmad, Chairman, Pakistan Agricultural Research Council, Islamabad informed that the Pakistan council is going through the mandate of work as in past it was mostly concentrated on crop production and at present 75 percent of GDP is from livestock sector. He stressed that proper surveillance system and quality assurance should be in place for effective control of animal diseases. He informed that Pakistan is free from HPAI since 2008 and FMD programme has been strengthened by the government. He emphasized that a proper mechanism has to be in place to handle TADs.

After the opening session, Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal provided a background of the meeting and workshop. He presented the key recommendations of the First Laboratory Directors' meeting 2012. He narrated key mandates of Laboratory Coordination and expectations from Regional Laboratory Network. He stressed the need to strengthen the in-country / national laboratory networks in addition to regional laboratory networks. He also discussed about the expected outcomes of present meeting where there is a need to prepare and agree on Regional Framework for laboratory capacity building and networking in South Asia.

Technical Session 1: Organize Laboratory Networks on Sharing of information

Dr Venkatasubbarao Mandava, Laboratory Coordinator, Regional Support Unit/Sub Regional ECTAD, FAO, Nepal presented an 'Update of Regional network activities and enhancing the laboratory expertise in SAARC Region'. He explained that building a well-organized diagnostic laboratory network can be the basis for the successful surveillance of HPEDs and their control. He informed that for the establishment of SAARC regional laboratory network, RLDLs were identified for priority diseases. As a part of the network activity, comprehensive hands-on trainings were organized by all the RLDLs and the participants returned with the knowledge of diagnosis and validated kits (FMD) to implement appropriate assays in their own laboratories. RLDLs provide a

comprehensive service for diagnosis (virus typing and surveillance) and supply of kits for the national laboratories in the network. Further, he informed that the network activities included organizing PT of FMD laboratories in the region. After briefing on the objectives of FAO laboratory mapping tool (LMT) and the purpose of laboratory mapping, he informed that a total of 13 Laboratories (including OIE Reference Laboratory, Bhopal, India, three RLDLs and nine national laboratories) in the SAARC region were assessed using LMT. The review of the laboratory assessments in the SAARC region is summarised in the Annex III. He discussed the weaknesses, similarities and differences among the laboratories in detail.

Dr Navaratnasingam Janakan, Focal Point Communicable Diseases, WHO Sri Lanka made a presentation on Cross-sectoral collaboration to develop harmonized laboratory procedures and protocols for zoonotic diseases. He discussed about the importance of laboratories, standards and guidance, international legal frameworks, capacity building strategy, cross-sectoral collaboration (FAO/OIE/WHO), WHO activities for strengthening laboratory capacity and influenza at the human-animal interface. He informed about the newly emerging disease threats in South East Asia that includes Pandemic influenza (H1N1) 2009, avian influenza A (H5N1), Nipah virus encephalitis and Crimean-Congo Haemorrhagic Fever. He discussed about the Asia Pacific Strategy for Emerging Diseases to build sustainable national and regional capacities and partnerships to ensure public health security through preparedness planning, prevention, early detection and rapid response to emerging diseases and other public health emergencies.

Dr Chris Morrissy, Diagnostic Virologist from AAHL made a presentation on behalf of Dr Sanipa Suradhat, Regional Laboratory Coordinator, FAO RAP on "Regional strategic framework for laboratory capacity building and networking in South East Asia". He discussed the technical scope of regional laboratory networking (RLN) capacity building, strengthening multi-sectoral collaboration and communication across network of laboratories, and gave an update on the ASEAN Regional Strategic Framework. He also discussed the ASEAN Animal Health Mechanisms and described the Laboratory Strategic Framework and its components and goals and implementation mechanism of the Regional Strategic Framework for laboratory capacity building and networking in ASEAN. The components of the laboratory strategic frame work include Laboratory Director's Forum concerning the policy, regional reference and leading laboratories and resource persons for technical support and implementation and laboratory technical advisory group (TAG) providing advisory and support implementation. In a short-term, the implementation of the Framework will be coordinated by the ASEAN Secretariat, with assistance from the ASEAN Regional Support Unit, in close consultation with Regional Laboratory Advisory Group. In a mid-and long-term, the Member States will implement their national laboratory capacity building programmes and the regional coordination will be responsible by the Laboratory Network Coordination Unit under the ASEAN Coordination Centre for Animal Health and Zoonoses (ACCAHZ). In the end the way forward for ASEAN Regional Laboratory Framework was discussed which includes supporting implementation of the framework and institutionalization of regional laboratory network within ASEAN mechanism through the regional framework and ACCAHZ in which Laboratory Directors' Forum plays a key role.

Technical Session 2: Overview of activities of SAARC laboratory Network Members in 2012

Dr B Pattnaik, Project Director, PD-FMD and RLDL (FMD), Mukteswar, India detailed the FMD RLDL activities in his presentation. He informed that PD-FMD organized a "Regional Training on Proficiency Testing for Veterinary Diagnostic Laboratories in SAARC countries". A total of 20 persons from six countries participated in the programme. Dr Chris Morrissy from AAHL, Geelong, Victoria facilitated the training programme. RLDL FMD also conducted training on vaccine matching to build capacity for selecting most appropriate vaccine strains to be used in the country and also in monitoring the appropriateness of in-use vaccine strains used commercially. A total of 14 laboratory staff of national laboratories from six SAARC Member countries participated in the training. He stated that RLDL FMD at Mukteswar is supplying all the diagnostic kits to member countries. The RLDL FMD has also played the role of PT provider and provided PT panels to four national laboratories in the region and provided technical back up for the participation of these laboratories in PT.

Dr Jahangir Alam, Senior Scientific Officer (Virology) from RLDL PPR, Bangladesh Livestock Research Institute, Dhaka, Bangladesh presented the existing in-country networks of laboratories, temporal distribution of PPR and activities undertaken at national and regional level. He informed that the laboratory is involved in diagnosis, isolation and characterization of virus. The RLDL also conducted a regional training on PPR diagnosis for the staff of national laboratories of the SAARC Member States. He also highlighted the workplan for 2013 at national and regional level.

Dr Khalid Naeem, Senior Director, National Reference Laboratory for Poultry Diseases (NRLPD) and RLDL-HPAI, Islamabad, Pakistan gave an overview of activities at RLDL-HPAI Islamabad - Pakistan for the year under report. He mentioned that a large number of clinical and serum samples were tested under this project for virus isolation, surveillance and typing. He presented first isolation of AIV H4N6 from duck (*Anas platyrhynchos*) in live bird market of Pakistan in 2010. He stated that the laboratory organized national training workshop as well as "Regional training on differential diagnosis of avian influenza and Newcastle disease" for the participants from five SAARC countries.

Dr Jag Mohan Kataria, Joint Director, High Security Animal Disease Laboratory, OIE Reference Laboratory for Avian Influenza, Indian Veterinary Research Institute, Bhopal, India presented an overview of HPAI in India. He described the network of AI surveillance laboratories and the reporting system of the disease. He informed that the laboratory is involved in providing consultant expertise/technical advice to OIE or to OIE Members and production and distribution of diagnostic reagents of AI being used in the in-country laboratories. The laboratory is participating in the PT for international harmonisation and standardisation of methods for diagnostic testing and also providing scientific and technical training. The laboratory has made provision of diagnostic testing facilities to other OIE Members.

Dr Chris Morrissy, AAHL, Geelong, Australia presented a report on FAO mission to HSADL, Bhopal for "Biorisk Training for Laboratory and Engineering and Equipment Maintenance Training workshops". The observations and recommendations were given into six key areas that included laboratory biosafety and workflow, quality assurance, laboratory design, effluent treatment plant (ETP), maintenance of plant and equipment and electrical supply. He emphasized that the PCR workflow should follow international standards, more importantly separating clean and dirty steps of the PCR. He also presented a report on FAO mission on Regional training on 'Proficiency Testing for Veterinary Diagnostic Laboratories in SAARC countries'. The workshop included training in production of QA controls used in tests (IQC) and samples/controls used in PT programmes, analysis and reporting of PT results and in the use of statistics and general overview of the requirements of ISO 17025 for QA and biosafety for the laboratory. The workshop agreed that there was a need to have a harmonized approach to disease diagnosis and the implementation of QA in the laboratories.

Dr Aniket Sanyal, FAO National Consultant (Senior Scientific Officer), RLDL FMD, PD-FMD, Mukteswar, India presented the results of 'Proficiency Testing of FMD Laboratories conducted in South Asia'. Four national laboratories (Bangladesh, Bhutan, Nepal and Sri Lanka) participated in the PT programme of FMD. The preliminary results indicated that all laboratories produced results with variations within the normally accepted absolute score limit indication with acceptable reproducibility and repeatability for the analyzed PT samples.

Ms Fathimath Safoora, Scientific Officer, Maldives Food and Drug Authority, Ministry of Health, Republic of Maldives informed that the laboratory is ISO/IEC 17025 certified and all requirements are in place including competent staff, calibration and maintenance, testing environment, well established document control system, internal audits, management review, method validation, supplier evaluation etc. The laboratory does the QA that includes PT for almost all tests, inter-laboratory comparison and external assessment by the accreditation board.

Dr M D N Jayaweera, Deputy Director (Technical Services), Veterinary Research Institute, Department of Animal Production and Health, Sri Lanka presented the QA followed in National Veterinary Laboratory. He narrated the systems in place in national laboratory in Sri Lanka which includes sample acceptance and identification system, laboratory testing and SOPs followed, reporting system and laboratory waste treatment and disposal.

Dr Jambay Dorjee, Head Laboratory Services Unit, National Centre for Animal Health, Bhutan presented the QA system practiced in veterinary laboratories in the country. He explained the management restructure, management of laboratory reagents, chemicals and equipments, process control, documents and records system, information management and proficiency testing in Bhutan. He emphasized to create common forum to share information, communicate and discuss on issues related to laboratory activities.

Technical Session 3: Expectations of National Diagnostic Laboratories from the OIE Reference and Regional Leading Diagnostic laboratories

The participants were divided in three working groups to discuss. The groups came out with the following outputs.

- Constitution of FMD-Work Group for SAARC region for control under PCP-FMD with regular workshops (SAARC-FMD-COMMISION).
- Networking in SAARC region
- Continuity of scientific and technical manpower with backstopping scientist in the national laboratories
- Provision of diagnostic kits at affordable cost/free of charge to support FMD diagnosis and epidemiology
- Exchange of field virus materials and data for virus data base, and uniformity in vaccine components and companion diagnostics - SAARC FMDV Repository
- Upgrading laboratory facilities in national laboratories
- PT training at least once in a year to sustain competency
- Creation of SAARC FMD database for reference

DAY TWO

Session 4: Quality Management system: Why Quality Systems are essential for good laboratory practices

The proceedings of day two started with summarizing the outcomes of the Second SAARC laboratory Director' meeting by Dr Mohinder Oberoi.

Dr Chris Morrissy presented 'Background and overview of and components of quality system'. He narrated that every laboratory ensures that tests are preformed to a standard. He explained the key components of a QA system that includes QA management structure, SOPs and test records, IQC, PT etc.

This was followed by the presentations from RLDLs on challenges in implementation of quality standards. Dr B Pattnaik, Project Director, PD-FMD and RLDL-FMD, Mukteswar, India informed that remote location, less laboratory space, inadequate scientific and technical manpower, and lack of bar-coding facility are the challenges for RLDL-FMD.

Dr Khalid Naeem, Senior Director, National Reference Laboratory for Poultry Diseases (NRLPD), RLDL-HPAI, Islamabad, Pakistan informed that documentation in terms of quality of data received from the field, equipment calibration facilities for PCR and Real Time PCR, cost for

undertaking PT, reagents availability for IQC: cost vs. source vs. storage, poor control on sample quality received from peripheral laboratories/field and continuity of staff training are some of the challenges.

Dr Jahangir Alam, Senior Scientific Officer (Virology) from Bangladesh Livestock Research Institute, Dhaka, Bangladesh, RLDL-PPR listed poor national and regional laboratory linkages, poor quality and quantity of sample received, lack of equipment calibration, repair and maintenance, documentation and recognized record keeping format, QA, technical expertise up-gradation/training, reference materials, time and work load and lack of manpower as the main challenges.

Dr Jagmohan Kataria, Joint Director, High Security Animal Disease Laboratory, OIE Reference Laboratory for Avian Influenza, Indian Veterinary Research Institute (IVRI), Bhopal, India presented the challenges for the quality management in their laboratory as requirement of structural modification in the existing laboratory, lack of proper data for field samples, less manpower, lack of time for scientific staff for QA documentation, bar coding of all samples – due to huge inflow of samples, and time for equipment repairing.

This was followed by group discussion on roadmap for development of QMS in national laboratories to improve laboratory QA for tests and biosafety and biosecurity. Dr Chris Morrissy presented the roadmap of QA system that includes activities of gap analysis/audit of the laboratory for QA in the laboratory (external), QA management structure and training.

The participants were divided in three working groups to discuss the following issues:

- Review and discuss the quality systems suitable for veterinary diagnostic laboratories in SAARC region
- Biosafety and biosecurity as an important part of a QA system
- Development of laboratory quality systems within national laboratory plans,
 - What are the experiences and challenges of countries that have already made steps towards meeting the objectives
 - What are the important issues relevant to the development of quality systems on a national basis
 - What is preventing your laboratory implementing a QA system

The three groups came out with the following outputs:

Group 1:

- Constitution of QA committee at the level of national laboratory with QA manager. The committee will be comprised of Director, Chairman, Co-chairman, Quality Manager and Technical Managers and BSO/ABSO. The activities to be undertaken by the committee are:

- Development of SOPs
- Calibration and maintenance plans (both internal and external)
- Assessment of staff
- Set up of training requirement of staff
- Approve the validation of methods
- Internal Audit
- Participate in a recognized PT scheme
- They will work for ISO/IEC 17025 certification
- Decide on the tests to be used for accreditation

Group 2:

- National and Regional Expert Committee on QAS
- Policy needs with regard to QMS and QAS
- Assignment of duty, who will implement?
- Government in collaboration and cooperation with other organization and SAARC countries
- Matter to be implemented
- Technical matters
- Containment of pathogens
- Development of QA Manual
- Development of SOPs on all activities including entry into, working in and exit from the laboratory
- Reliability of test and acceptance by the end users
- Standards policy on testing (field workers- collection of sample, their storage and shipment)
- Secondary laboratory will conduct preliminary test like AGPT, HI, cELISA and other serological tests
- National laboratory- confirmatory test like virus isolation, RT-PCR, Gene sequencing, cartography, etc
- National laboratory should maintain tracking system and database
- National laboratory should have direct contact with RLDL
- Field laboratory will contact with RLDL in emergency situation

Group 3:

- To establish institutionalized SAARC mechanism for formulation of minimum biosafety/quality assurance standards for national laboratories depending on the individual country's requirements and resources
- Training on internal quality control production and conducting internal audits for QA of tests
- Need to formulate and harmonize the test records
- Need for a SAARC level mechanism for funding maintenance and validation of infrastructure and calibration of equipments for quality assurance
- Need to formulate SAARC specific information sharing network

All the three groups worked further to develop road map for development of QMS in RLDLs.

The groups came out with the following outputs

Activities	Group 1: RLDLs represented by India and National Laboratories of Sri Lanka and Maldives	Group 2: RLDLs represented by Bangladesh, Pakistan, and National Laboratory of Sri Lanka	Group 3: RLDLs represented by Bangladesh, Bhutan, India, Pakistan, and National Laboratory of Sri Lanka
How to develop national laboratory policies and standards to support quality systems	<ul style="list-style-type: none"> • QMS has to be in place with Director as its chief and will be supported by scientists • Animal Ethics Committee and Institute Biosafety Committee to be in place • Availability of appropriate equipments and cold storage facilities and laboratory space to support GLP 	<ul style="list-style-type: none"> • Guiding and monitoring of QMS of national labs by RLDL • QA and Biosafety officer in place but need training on the subject matter 	<p>Assessment of national laboratories by the RLDLs for formulating/developing national laboratory policies and standards to support quality systems</p> <p>Periodical meeting of the planners of the SAARC member countries along with reference labs to advocate implementation of quality standards</p>

	<ul style="list-style-type: none"> Earmarking of appropriate funds and human resource by the Government to support QMS 		
EQA (External Quality Assurance) and development of monitoring tools	<ul style="list-style-type: none"> Regular EQA and PT to be conducted by RLDLs Providing test control panels from time to time to national labs to monitor performance / result accrued from time to time Creation of a website to link RLDL with national labs for exchange of data/information Continuity of manpower at the level of national labs to build up competency Provision for disease/ laboratory specific regional QMS manager Regional guidelines for important diseases to maintain uniformity 	<ul style="list-style-type: none"> Confirmation of RLDL findings by World Reference Laboratory Standardization of reagents to be used Establishment of pool of samples Development of PT scheme Monitoring of reagents and tools (techniques) to be used Monitoring of laboratory personnel for their proficiency, result interpretation, calibration of equipment, use of reagents Monitoring the quality of screening / confirmatory test, environment, temperature, cut points for positive and negative controls 	<ul style="list-style-type: none"> Upward and downward linkages for production and supply of internal and external quality controls <ul style="list-style-type: none"> Provision of standard diagnostic reagents Training for RLDL for production of standard reagents

<p>Advocacy for setting and implementing national quality standards</p>	<ul style="list-style-type: none"> • Setting and implementation of National Quality standards in the interest of the country for healthier livestock and human population and food security 	<ul style="list-style-type: none"> • Awareness of public and technical personnel on the realization of problem • Briefing of administration on the emergence, solution of the problem and strategic handling of the problem • Departmental head (DG/Director/institutional head) to be convinced on the gravity of situation • Secretary/relevant higher officials to be convinced for implementing required procedures and measures on quality standards of work at laboratory • Mobilization of media with right information through seminar, workshop etc. • Political will and provision of funds 	
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<p>Integrated approaches for quality programmes</p>	<p>• At the regional level</p> <p>it may be appropriate to have a QMS advisory group to help all member countries to achieve required laboratory standards as per ISO/IEC 17025</p> <ul style="list-style-type: none"> • Conduct of QMS training/awareness programs to sensitize national laboratory management • Commitment of scientists and supporting staff to follow GLP 	<ul style="list-style-type: none"> • Integration between education, research and extension workers • Technical and farmer level working group formation on QMS • Strategic implementation mechanism, legislation etc. 	<ul style="list-style-type: none"> • Formulation and sharing of quality manual by reference labs with national laboratories • Regional information sharing network developed by reference labs for integration with interested national laboratories
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Conclusions and recommendations

Based on the deliberations of the Second Laboratory Directors' Meeting and Workshop on Quality Management Systems, the following main recommendations were drawn;

Recognizing that the

1. National animal disease diagnostic laboratories are responsible for disease surveillance programmes; which enable the countries to detect highly pathogenic emerging diseases (HPEDs) outbreaks early and respond in a timely manner in their respective countries.
2. Regional laboratory networks have a role as a coordinating platform for the national laboratories to enhance their laboratory capacity for the diagnosis of various infectious diseases, assure quality of diagnostic findings and promote sharing of reagents, biological materials and information at the national and regional levels.
3. The laboratory directors' meeting can provide a platform to discuss regionally relevant problems of mutual interest and issues among national and leading laboratories of SAARC Region.

The Second Laboratory Directors' meeting recommends

1. To institutionalise the SAARC Laboratory Directors' Forum with commitment to organise annual meetings with participation from the National and Regional Leading Diagnostic Laboratories.
2. The laboratory directors' forum to constitute a laboratory technical advisory group to guide and monitor the laboratory activities in the region.
3. RLDLs should take initiative to ensure full ownership of the network and support capacity building and laboratory networking activities on a long term sustainable basis.
4. The RLDLs should develop linkages with public health laboratories to foster collaboration for one health activities.
5. Develop a road map for regional laboratory quality assurance (QA) scheme to garner institutional and political support and commitment.
6. Based on the laboratory assessments; guidelines and programmes may be developed to address the deficiencies and shortfalls in implementing QA, quality management (QM), biosafety and trainings as priority activity to overcome these shortcomings.
7. The RLDLs in collaboration with Regional FAO/OIE Reference Centres/Laboratories should conduct annual proficiency testing and manage trainings for production of regional internal quality controls (IQC) for its subsequent sharing with national labs.
8. The RLDLs/Regional FAO/OIE Reference Centres/Laboratories should provide technical assistance for development and validation of diagnostic kits.

9. The RLDLs/Regional FAO/OIE Reference Centres/Laboratories should make efforts to get their laboratory accredited as per ISO guidelines (ISO 9001, ISO/IEC 17025).
10. Efforts should be made to undertake joint research activities to address the priority HPEDs in SAARC region.
11. The RLDLs/Regional FAO/OIE Reference Centres/Laboratories should create a database including gene sequences of the causative agents for SAARC priority diseases for reference and sharing.

Closing remarks

Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal thanked SAARC member states for deputing delegates to the workshop. He emphasized the importance of information sharing, maintenance of quality standards in RLDLs and national laboratories and strengthening of in-country / national /regional laboratory networks.

Annex I

Agenda

Tuesday, 12 March 2013

Time	Topic	Facilitator
08.30 - 09.00	Registration	
	Inaugural session	
09.00 - 10.00	<p>Introduction to workshop and expected outputs</p> <p>Dr. Mohinder Oberoi, Sub Regional Manager – ECTAD, RSU Coordinator, FAO, Nepal</p> <p>Opening remarks</p> <p>European Union Representative</p> <p>Dr. Khan Shahidul Huque, Director General, BLRI, Bangladesh</p> <p>Dr. Iftikhar Ahmad, Chairman, PARC, Pakistan</p> <p>Address</p> <p>Dr. K.M.T. Kederagama, Secretary, Ministry of Livestock and Rural Community Development, Sri Lanka</p>	
	Photograph	
10.00 - 10.15	Tea Break	
10.15 - 10.25	Introduction of participants	
10.25 - 10.40	Background of the Laboratory Directors' meeting and key recommendations of the First Lab Directors meeting 2012 - Dr Mohinder Oberoi, FAO, Kathmandu Nepal	
	Session 1 Organize Laboratory Networks on Sharing of Information	
10.40 - 11.00	Update on Regional network activities and enhancing the laboratory expertise in SAARC Region - Dr. Venkatasubbarao Mandava, FAO, Kathmandu, Nepal	
11.00 - 11.20	Cross-sectoral collaboration to develop harmonized laboratory procedures and protocols for zoonotic diseases - Dr Navaratnasingam Janakan, WHO, Colombo, Sri Lanka	
11.20 - 11.35	Regional strategic framework for laboratory capacity building and net working in South East Asia - Dr Sanipa Suradhat, FAO-RAP (Presented by Dr Chris Morrissy, AAHL)	

Time	Topic	Facilitator
Session 2	Overview of Activities of SAARC Laboratory Network Members in 2012	
11.35 - 11.50	FMD Regional Leading Laboratory - Dr B Pattnaik, FMD RLDL (India)	
11.50 - 12,05	PPR Regional Leading Laboratory - Dr Jahangir Alam, PPR RLDL (Bangladesh)	
12.05 - 12.20	HPAI Regional Leading Laboratory - Dr Khalid Naeem, HPAI RLDL (Pakistan)	
12.20 - 12.35	OIE Reference Laboratory on Avian Influenza - Dr Jagmohan Kataria, HSADL India	
12.35 - 13.15	Overall discussion on activities undertaken in 2012 by SAARC Laboratory Network members and progress made since the last meeting - Report on FAO mission to HSADL Bhopal for Biorisk Training for Laboratory and Engineering and Equipment Maintenance Training workshops, Dr Chris Morrissy, AAHL - Report on FAO mission on Regional Training on Proficiency testing for Veterinary Diagnostic Laboratories in SAARC countries, 21- 26 May 2012, Mukteswar, India, Dr Chris Morrissy, AAHL - Proficiency testing of FMD Laboratories conducted in the SAARC region, Dr Aniket Sanyal, FAO	
13.15 - 14.00	Lunch	
Session 3	Expectations of National Diagnostic Laboratories From the OIE Reference and Regional Leading Diagnostic Laboratories	
14.00 - 15.00	Group discussion	
15.00 - 15.30	Tea Break	
15.30 - 16.30	Outcome of the Second SAARC Laboratory Directors' meeting - Dr. Mohinder Oberoi, FAO	

Time	Topic	Facilitator
	Wednesday, 13 March 201	
Session 4	Quality Management Systems: Why Quality Systems Are Essential for Good Laboratory Practices	
09.00 - 09.30	Background and overview of and components of quality system - Dr Chris Morrissy	
09.30 - 10.30	Challenges in implementation of quality standards Speakers Dr B Pattnaik, RLDL - FMD Dr Khalid Naeem, RLDL - HPAI Dr Jahangir Alam, RLDL - PPR Dr Jagmohan Kataria, OIE Reference Laboratory for Avian influenza	
10.30 - 10.50	Tea Break	
10.50 - 12.30	Group discussion: Road map for development of QMS in National Laboratories to improve laboratory QA of tests and Biosafety and Biosecurity Participants in four working groups to discuss: Review and discuss the quality systems suitable for Veterinary Diagnostic laboratories in SAARC region <ul style="list-style-type: none"> • Biosafety and Biosecurity is an important part of a QA system: <ul style="list-style-type: none"> Review and Discuss Biosafety and Biosecurity • Development of laboratory quality systems within national laboratory plans <ul style="list-style-type: none"> - What are the experiences and challenges of countries that have already made steps towards meeting the objectives - What are the important issues relevant to the development of quality systems on a national basis - What is preventing your laboratory implementing a QA system 	Dr Chris Morrissy
12.30 - 13.00	Report on group work	
13.00 - 14.00	Lunch Break	
14.00 - 15.30	Group work: Road map for development of QMS in RLDLs Participants in four working groups to discuss: <ul style="list-style-type: none"> • how to develop national laboratory policies and standards to support quality systems • EQA (External Quality Assurance)/PT (Proficiency Testing) and development of monitoring tools • advocacy for setting and implementing national quality standards 	Dr Chris Morrissy

Time	Topic	Facilitator
	and • integrated approaches for quality programmes	
15.30 - 15.45	Tea Break	
15.45 - 16.30	Report on Group work	
16.30 - 17.30	Conclusions and recommendations	
	Concluding remarks – Dr Mohinder Oberoi, FAO	

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Annex III

Summary of Assessment of Veterinary Disease Diagnostic Laboratories in the SAARC Region

A 'Consultation for establishing a network of RLDLs in South Asia' was held in March 2011 at Kathmandu, Nepal that provided an opportunity to share information about the mandate of the leading laboratories, facilities available in these regional and national laboratories and discuss how the laboratories could be strengthened to assist in the progressive disease control pathways in South Asia to improve control of priority diseases that have significant socio-economic impacts. The meeting also considered ways of strengthening cooperation, through formation of regional laboratory networks (disease surveillance and diagnosis) and harmonization of laboratory protocols to control important TADs in SAARC member countries. One of the recommendations of this consultation was to conduct regional laboratory assessment for diagnostic capacity and trainings. It was also envisaged that the leading laboratories and other labs with salient resources should be engaged in capacity building. Deficiencies in the capacities and capabilities of laboratories may lead to inadequate responses to disease emergencies including prevention and control of infectious diseases.

During this consultation the regional and national laboratories were requested to make a self assessment for their capacity for which they are intended. For this purpose, the RSU sought information on 23 items which were primarily related to have a basic inventory of the facilities and infrastructure available with three disease specific laboratories (FMD, PPR and HPAI) in the region. The overall observation on the self assessment of these laboratories was that these laboratories are deficient in several respects and this led to the recommendation of the workshop to "Conduct regional laboratory assessment for diagnostic capacity and trainings".

As a follow up to these recommendations and as part of identifying gaps in laboratory functionality and define mechanisms and targets for capacity building, mapping of the laboratories was undertaken using FAO Laboratory Mapping Tool (LMT) to aid laboratory assessment in a systematic and semi-quantitative manner. Using this LMT, need assessment of the 3 RLDLs and 6 National laboratories of the member countries in the SAARC region was initiated in May 2011. This is an ongoing process and continued in the year 2012. The primary purpose of the assessment of the laboratories is to assess the diagnostic capacity and trainings, developing strategy to conduct regional proficiency testing (PT), provide support for diagnostic capacity in the region, developing regional and international sample sharing / referral system, capacity of the RLDLs to produce reagents to develop regional and diagnostic capacity. Also it is envisaged that the RLDLs and other laboratories with salient resources be engaged in capacity building, organizing technical / laboratory networks meetings, at least once a year to present and discuss scientific information and sharing of diagnostic specimens and results with international reference laboratory.

During 2012, the mapping was carried out for one OIE Reference Laboratory, three RLDs and nine National laboratories using the most recent (2012) FAO Laboratory Mapping Tool (LMT). This tool comprises of five modules: i) general laboratory profile; ii) infrastructure, equipment and supplies; iii) laboratory performance; iv) quality assurance and biosafety/biosecurity; and v) laboratory collaboration and networking. Within these five modules, 18 categories and 95 subcategories have been selected. The 18 categories used were geographic location, laboratory budget, basic supply, organization, linkage with satellite laboratories, communication, infrastructure, equipment, reagent supply, staff skills and availability, sample accession, available technology, training, quality assurance, biosafety/biosecurity, staff security/health, laboratory collaboration and use of databases/ platforms. For each subcategory, one of four options can be selected corresponding to scores from 0 to 3. A detailed questionnaire is used to collect data (95 scores of 0 to 3 each), and an overall score for the laboratory and summary scores for each of the categories are generated. The LMT allowed the generation of a laboratory profile to help RLDs to devise strategies for improving other laboratories within the network.

The general factors considered of importance to the valuation/assessment of the laboratories include the ability of the laboratory to perform diagnostic work and the available facilities. More specifically, to have a regional laboratory status, the laboratory needs to have a sustainable national budget, a well-structured management system in place, robust diagnostic protocols and techniques in use, and appropriate human resource (personnel), etc.

The following laboratories in the SAARC region were assessed:

1. OIE Reference Laboratory for avian influenza, High Security Animal Disease Laboratory (HSADL), Bhopal, India
2. Regional Leading Diagnostic Laboratories – SAARC
 - i. Project Directorate on FMD Mukteswar, India
 - ii. Virology Laboratory (PPR), BLRI, Savar, Dhaka, Bangladesh
 - iii. National Research Laboratory on Poultry diseases (HPAI) - Islamabad, Pakistan
3. Other National Laboratories in SAARC region
 - 3.1. Bangladesh
 - i. Central Disease Investigation Laboratory (CDIL), Dhaka, Bangladesh
 - ii. Virology Laboratory (HPAI), BLRI, Savar, Dhaka, Bangladesh
 - 3.2. Bhutan
 - i. National Centre for Animal Health (NCAH), Bhutan
 - 3.3. India:
 - i. Indian Veterinary Research Institute (IVRI) - PPR – Mukteswar, India
 - 3.4. Nepal:

- i. National FMD and TADs Laboratory, Kathmandu, Nepal
- ii. Central Veterinary Laboratory (CVL), Nepal

3.5. Pakistan:

- i. National Veterinary Laboratory (NVL) - FMD - Islamabad, Pakistan
- ii. National Veterinary Laboratory (NVL) - PPR - Islamabad, Pakistan

3.6. Sri Lanka:

- i. Veterinary Research Institute (VRI), Sri Lanka

The laboratory mapping was done through visits and discussions with the directors of the laboratories in the region. The results of this mapping carried out during 2011 are presented in the table 1 and for the year 2012 in table 2. It can be seen from the tables that there is only a marginal (in some cases about 4%) improvement in the overall score of the veterinary diagnostic laboratories between 2011 and 2012.

The legend for the tables and Fig. 1 is given in the box below:

Legend for the Table 1, 2 and Fig 1

- A. RLDL - FMD (Regional Leading Diagnostic Laboratory - foot and mouth disease, Project Directorate on Foot and Mouth Disease (PD-FMD) Indian Veterinary Research Institute (IVRI) campus, Mukteswar, Nainital (Uttarakhand), India)
- B. NFMD-TL (National foot and mouth disease and TAD Laboratory, Kathmandu, Nepal)
- C. CDIL-FMD (Central Disease Investigation Laboratory- foot and mouth disease, Dhaka, Bangladesh)
- D. NVL-FMD (National Veterinary Laboratory-foot and mouth disease, Islamabad, Pakistan)
- E. RLDL-PPR (Regional Leading Diagnostic Laboratory – PPR, Virology Laboratory, Bangladesh Livestock Research Institute (BLRI), Savar, Dhaka, Bangladesh)
- F. IVRI-PPR (Indian Veterinary Research Institute -PPR, Mukteswar, Nainital (Uttarakhand), India)
- G. NVL-PPR (National Veterinary Laboratory-PPR, Islamabad, Pakistan)
- H. RLDL-HPAI (Regional Leading Diagnostic Laboratory – HPAI, National Reference Laboratory for Poultry Diseases (NRLPD) Islamabad, Pakistan)
- I. BLRI-AI (National Reference Laboratory for avian influenza, Bangladesh Livestock Research Institute (BLRI), Savar, Dhaka, Bangladesh)
- J. CVL-KTM (Central Veterinary Laboratory, Kathmandu, Nepal)
- K. HSADL-BP (High Security Animal Disease Laboratory, Indian Veterinary Research Institute, Bhopal, India)
- L. NCAH-BT (National Centre for Animal Health, Thimpu, Bhutan)
- M. VRI (Veterinary Research Institute, Sri Lanka)

Table 1: Laboratory Mapping of Veterinary Diagnostic Laboratories in SAARC for the year 2011

Category	A	B	C	D	E	F	G	H	I
Geographic location	67	78	44	100	56	67	100	89	56
Laboratory Budget	89	44	44	67	67	67	67	67	89
Basic supply	100	89	89	78	67	89	78	89	89
Organization	100	100	100	100	67	100	100	100	67
Linkage with satellite labs	100	33	67	67	56	78	67	78	83
Communication	67	67	67	58	83	92	58	83	83
Infrastructure	67	50	42	75	54	67	75	67	63
Equipment	83	50	50	56	44	72	56	62	39
Reagent supply	87	50	38	67	42	75	67	67	50
Staff skills and availability	100	78	58	92	54	92	92	75	71
Sample accession	87	60	67	72	39	72	72	78	61
Available technology	67	70	22	52	37	63	52	89	48
Training	61	28	44	72	22	61	72	56	28
Quality Assurance	75	29	21	63	13	58	63	67	33
Biosafety/Biosecurity	67	50	33	67	40	27	67	80	67
Staff Security/Health	22	11	44	44	22	11	44	67	56
Laboratory collaboration	87	70	73	73	53	40	73	60	80
Use of databases/platforms	58	33	42	67	50	58	67	67	75
Grand Total	77	51	53	70	47	66	70	74	63

The figures in the cells denote percentage of scores obtained

Legend

90-100%	80-89%	70-79%	60-69%	50-59%	≤50
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Table 2: Laboratory Mapping of Veterinary Diagnostic Laboratories in SAARC for the year 2012

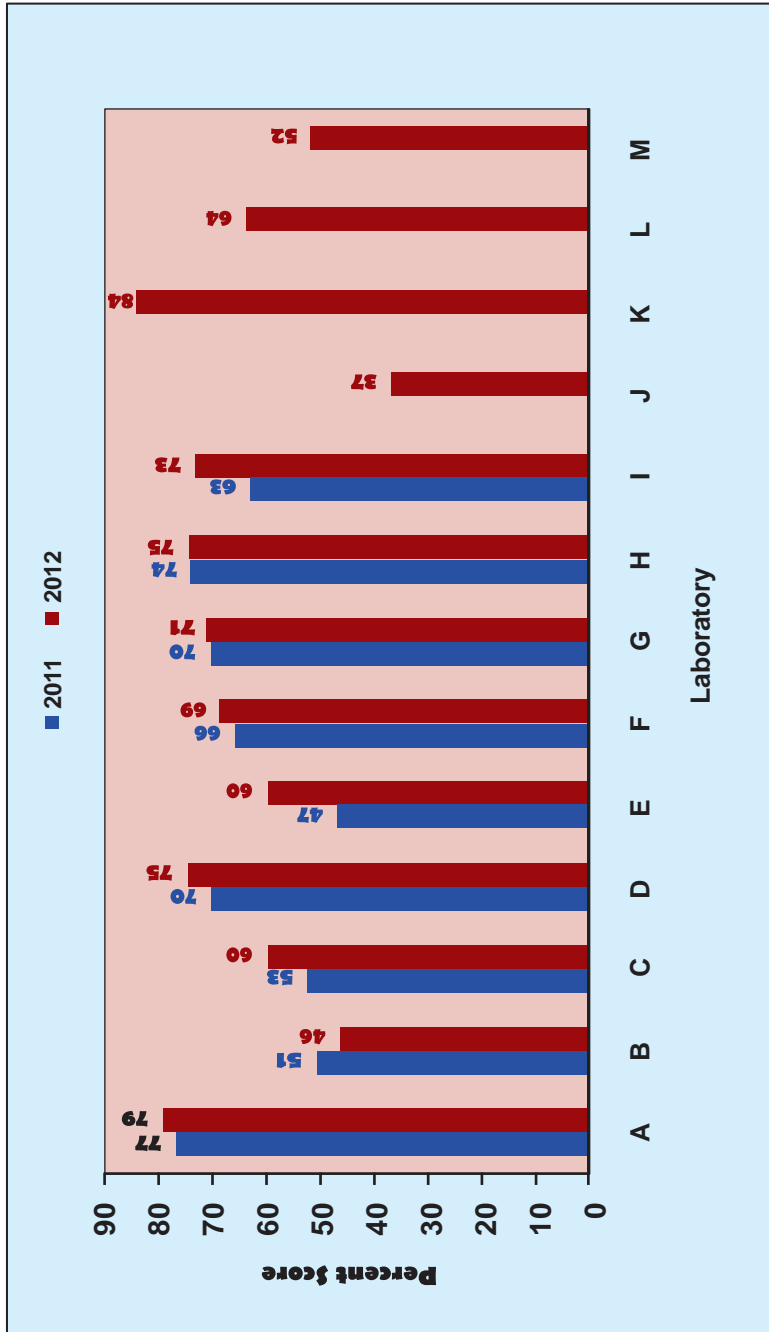
Category	A	B	C	D	E	F	G	H	I	J	K	L	M
Geographic location	67	56	44	89	78	67	100	89	78	22	100	44	56
Laboratory Budget	100	44	56	67	78	78	67	67	78	11	100	89	33
Basic supply	100	89	78	67	100	89	78	89	100	56	89	100	78
Organization	100	100	100	100	100	100	100	100	100	67	100	100	100
Linkage with satellite labs	100	33	56	67	67	89	67	78	67	67	78	78	56
Communication	83	58	58	67	92	92	58	83	92	50	92	92	50
Infrastructure	67	42	58	63	46	67	75	63	58	25	96	46	46
Equipment	56	33	56	72	44	78	56	61	44	56	73	80	61
Reagent supply	100	40	75	83	54	75	67	67	63	75	90	71	54
Staff skills and availability	100	61	54	100	79	92	92	79	92	54	92	67	63
Sample accession	83	28	72	83	33	78	72	67	78	56	83	67	50
Available technology	83	39	37	56	37	63	52	85	63	48	96	37	48
Training	52	24	33	71	38	33	62	67	52	0	62	14	19
Quality Assurance	92	42	50	71	25	54	63	79	42	21	79	50	58
Biosafety/Biosecurity	67	28	78	72	61	44	89	72	83	17	89	22	44
Staff Security/Health	17	17	56	67	22	33	44	56	78	0	78	33	22
Laboratory collaboration	87	67	67	93	73	53	73	67	87	40	60	80	40
Use of databases/platforms	75	33	50	58	50	58	67	75	67	0	58	83	58
Grand Total	79	46	60	75	60	69	71	75	73	37	84	64	52

The figures in the cells denote percentage of scores obtained

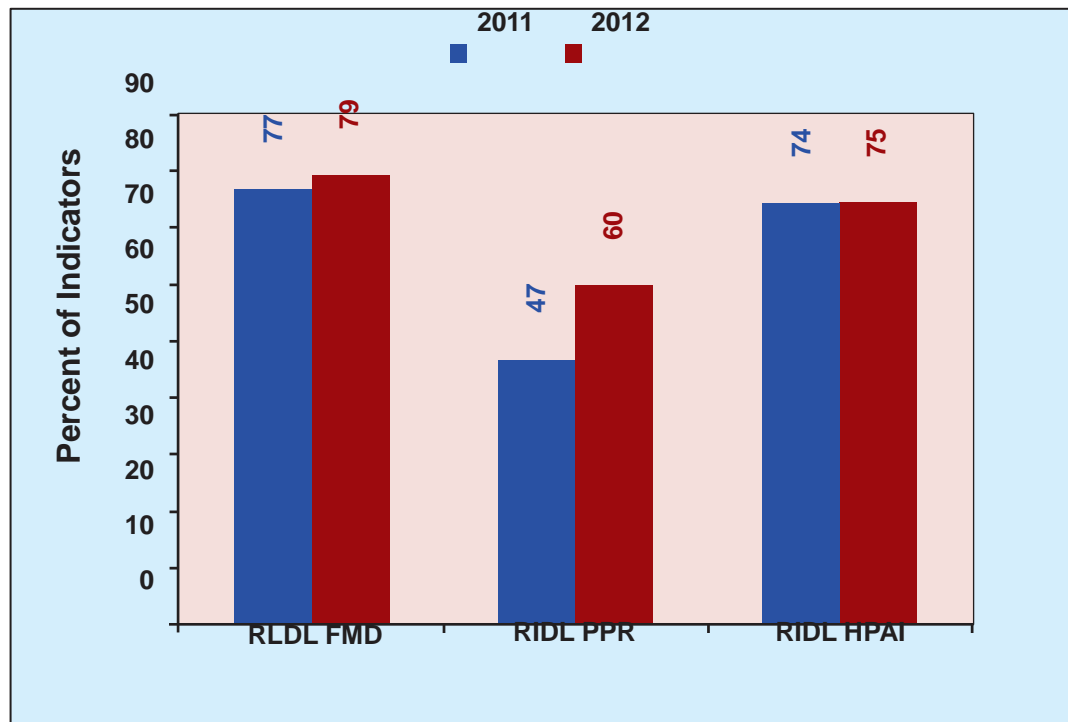
Legend

90-100%	80-89%	70-79%	60-69%	50-59%	≤50
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Fig 1: Assessment of Veterinary Diagnostic Laboratories in SAARC Region during 2011 and 2012



2: Assessment of SAARC Regional Leading Diagnostic Laboratories during 2011 and 2012



Observation:

The results of the mapping showed that there is a 13% improvement of scores from 2011 to 2012 with respect to the Regional Leading Diagnostic Laboratory on PPR at BLRI, Bangladesh. This is due to improvement in overall basic supplies, staff skills and provision of senior scientific officer from EU-HPED programme. However there is no further improvement or only a marginal improvement of scores with other two RLDLs.

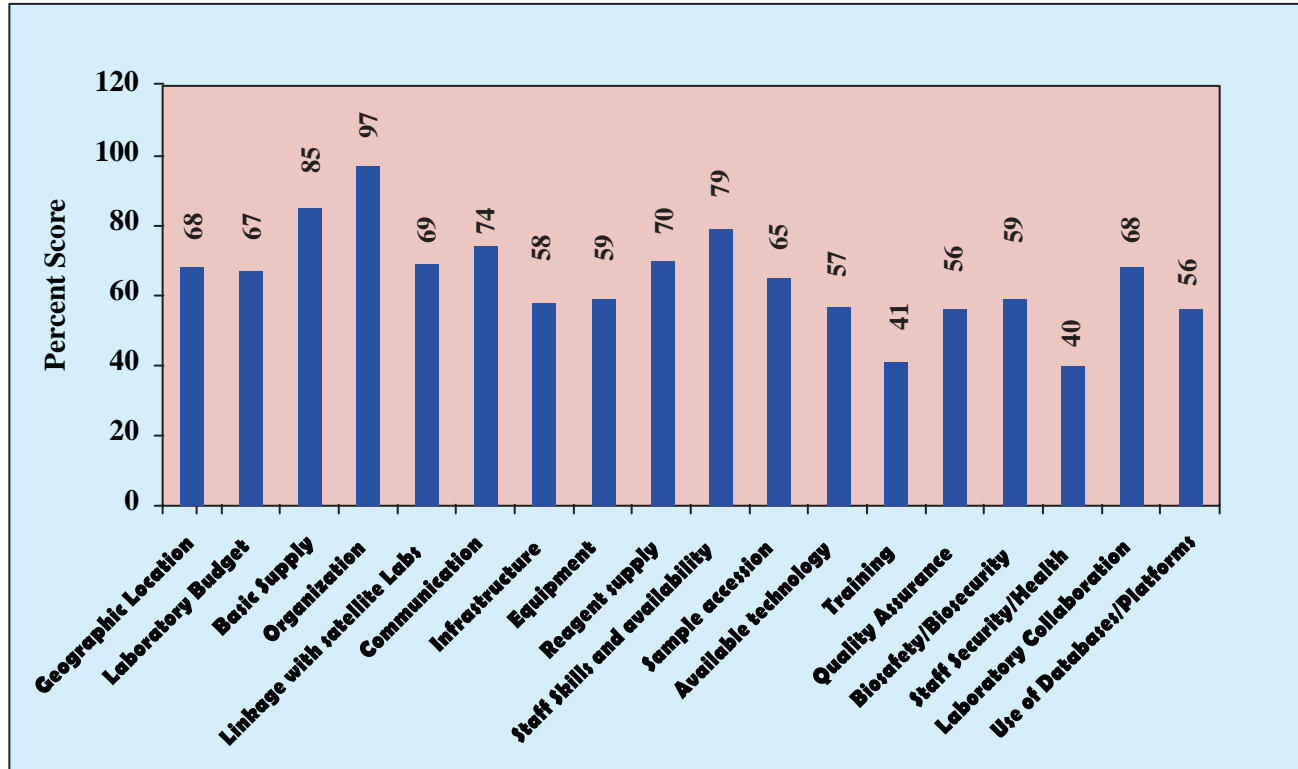
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- A. RLDL-FMD (Regional Leading Diagnostic Laboratory - foot and mouth disease, Project Directorate on Foot and Mouth Disease (PD-FMD) Indian Veterinary Research Institute (IVRI) campus, Mukteswar, Nainital (Uttarakhand), India)
- B. RLDL-PPR (Regional Leading Diagnostic Laboratory – PPR, Virology Laboratory, Bangladesh Livestock Research Institute (BLRI), Savar, Dhaka, Bangladesh)
- C. RLDL-HPAI (Regional Leading Diagnostic Laboratory – HPAI, National Reference Laboratory for Poultry Diseases (NRLPD) Islamabad, Pakistan)

Table 3: Mean LMT Results of SAARC Diagnostic Laboratories

Category	2011	2012
Geographic location	68	73
Laboratory Budget	67	67
Basic supply	85	85
Organization	97	93
Linkage with satellite labs	69	70
Communication	74	73
Infrastructure	58	62
Equipment	59	57
Reagent supply	70	60
Staff skills and availability	79	79
Sample accession	65	68
Available technology	57	56
Training	41	53
Quality Assurance	56	47
Biosafety/Biosecurity	59	55
Staff Security/Health	40	36
Laboratory collaboration	68	68
Use of databases/platforms	56	57

Fig. 3: Mean LMT Results of SAARC Diagnostic Laboratories for the year 2012



The overall observation of the mean LMT results is:

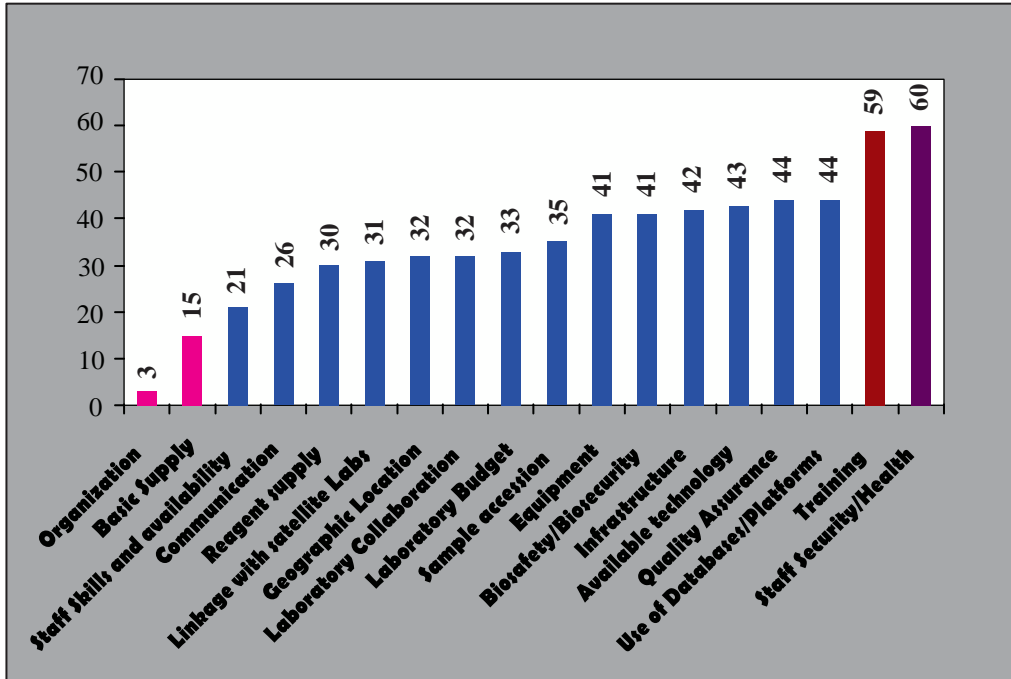
1. There is 10% improvement in the reagent supply in the region. This may be ascribed to the supply of reagents through the HPED project by RLDL-FMD, India and supply of PPR Diagnostic kits to RLDL-PPR, Bangladesh
2. There was about 12% improvement in the training for the region. This reflects the hands-on laboratory trainings on FMD, PPR, HPAI and Newcastle disease diagnosis provided by the three respective RLDLs through the HPED project
3. However there is 11% decrease in the quality assurance (QA). This is probably because of the change in the LMT tool which has clearer questions and options resulting in better evaluation of QA

Table 4: Gap analysis based on the identified Categories using FAO LMT for the year 2012

Category	Percent Gaps	Percent score
Organization	3	97
Basic supply	15	85
Staff skills and availability	21	79
Communication	26	74
Reagent supply	30	70
Linkage with satellite labs	31	69
Geographic location	32	68
Laboratory collaboration	32	68
Laboratory Budget	33	67
Sample accession	35	65
Equipment	41	59
Biosafety/Biosecurity	41	59
Infrastructure	42	58
Available technology	43	57
Quality Assurance	44	56
Use of databases/platforms	44	56
Training	59	41
Staff Security/Health	60	40

NB: The lowest gap is on the top and highest gap is in the bottom

Fig 4: Gaps identified in SAARC Veterinary Diagnostic Laboratories



Observation:

The results of gap analysis using the 18 categories of indicators of the Veterinary Diagnostic Laboratories in the SAARC region showed that there is an acute deficiency resulting in the lower level of functionality of the laboratories. The deficiency is uniformly high with more than 20 to 50 % gap as compared to the 100% requirement to be considered as a perfect laboratory. The gap with respect to trainings and staff health, security, quality assurance and biosafety, available technologies and infrastructure is about 40 to 60%

Legend



Overview of the Laboratory mapping in the SAARC Region

The laboratory mapping was carried out for OIE reference laboratory for avian influenza, RLDLs and the National laboratories in the SAARC region using the most recent (2012) FAO laboratory mapping tool for the year 2011 and 2012. From the overall results, it can be inferred that there is no improvement in the performance of the laboratories, there is improvement to the extent of 10 – 12 percent in the training and reagent supply.

Weakness observed:

- Lack of a reference handbook
- Lack/deficiency in QC and QA systems – absence or low level of observation of SOPs, GLPs, low biosecurity/biosafety level in many laboratories
- Low number of samples received for processing
- Lack of reference reagents

Several similarities exist between these laboratories specially on impeding factors for their operation:

- Limited investment for facilities or equipment
- Limited funding for diagnostic activities for TADs
- Low number of samples submitted to the labs, etc.
- Cramped space
- Electrical load shedding (power cut)
- Lack of logistical resources

Differences among the laboratories:

Some of the differences noted between individual laboratories with regard to certain resources:

- Level of equipment varies widely from one laboratory to another
- Availability of appropriate buildings and their geo-location
- Appropriately qualified and number of technical laboratory personnel
- Level of training for laboratory personnel

Conclusion and next steps

Application of the FAO Laboratory Mapping Tool in the SAARC region facilitated standardized assessments of a large number of laboratories and the evaluation of strengths and weaknesses at the national and regional levels. Results have served to measure progress and target needs for improvement, provide advocacy material, and to inform decision-makers, donors, national bodies, etc.

*Annex IV***Proficiency Testing of FMD Laboratories conducted in South Asia Region**

Proficiency testing (PT) forms an important part of building regional epidemiology and laboratory networks. Having imparted training for staff from laboratories of member states in the laboratory diagnosis of FMD, it is essential to take the capacity building to the next level by building the functional laboratory networks in the region for quality management of the laboratories. Consequent to the recommendations of the First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency Testing for Priority HPEDs in SAARC Countries held in Dhaka, Bangladesh in January 2012 a "Regional Training on Proficiency testing for Veterinary Diagnostic Laboratories in SAARC countries" was organized at the RLDL-FMD, India with the support of AAHL and Government of India during May 2012. This was intended for training of proficiency testing providers prior to the beginning of the proficiency testing round. As a follow up of these activities and part of QM of the national laboratories in the SAARC region, it was felt necessary to encourage and organize proficiency testing of the National FMD diagnostic laboratories in the region to achieve the goals of maintaining uniform diagnostic standards, support training of laboratory scientists/technicians and backstop regional surveillance and epidemiological studies with a broad objective of capacity development and QM of the laboratories.

In view of this, the RLDL-FMD conducted PT of four FMD laboratories in the region, the Central Disease Investigation Laboratory, Dhaka, Bangladesh; National Centre for Animal Health, Serbethang, Bhutan ; National FMD and TADs Laboratory, Kathmandu, Nepal; and Veterinary Research Institute, Peradeniya, Sri Lanka.

The RLDL-FMD provided the required reagents including test panels during the month of September 2012. The RLDL-FMD also backstopped the programme and provided required guidance for the purpose. Each Laboratory tested the PT Panel for 2-3 times under the guidance of RSU/RLDL laboratory expert. The results of the first round of PT are presented in table 1.

Table 1: FMD Serotype wise results obtained at different laboratories in the SAARC Region

Serum	Serotype O					Serotype A					Serotype Asia1					
	ID No.	Expected	Laboratory				Expected	Laboratory				Expected	Laboratory			
			A	B	C	D		A	B	C	D		A	B	C	D
S1	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20
S2	960	1920	960	960	960	240	480	240	240	240	>2560	>2560	>2560	>2560	>2560	
S3	960	960	960	960	960	240	240	240	240	120	1920	1920	1920	960	1920	
S4	960	960	480	480	960	120	240	120	120	120	1920	1920	>2560	1920	1920	
S5	960	960	480	480	480	120	240	240	120	120	960	960	960	960	960	
S6	480	480	240	240	240	120	120	120	120	60	320	480	480	320	480	
S7	240	240	60	240	240	60	60	30	45	20	120	240	120	120	240	
S8	480	480	320	480	480	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	
S9	20	30	30	20	60	120	240	240	120	120	<20	<20	<20	<20	<20	
S10	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	240	240	240	320	240	

NB: Numbers in the cells are 50% inhibition titers in serotyping ELSA

The preliminary analysis of the result revealed that the Z score value obtained by the laboratories for the samples of PT1 to PT 10 were between +3 to -3 Z-score range. Therefore, the results of the testing laboratory are satisfactory.

Table 2 provides an example of comparison between the RLDL and the Nepal laboratory.

Within laboratory results indicated that they have no significant variation from each groups. All groups were found to be within -3 to +3 z score range and ended up with satisfactory result (Table 2).

Table 2: Comparison of results between laboratories Z-score values between Expected Result and Laboratory A

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Lab	Transformed Results		Standardized		Between-Labs	Within-Lab
Code	RLDL, India	Nepal	Sum	Difference	Z-Score	Z-Score
PT1	20.00	20.00	28.2843	0.0000	-0.82	-0.21
PT2	960.00	1920.00	2036.4675	678.8225	2.10	2.87
PT3	960.00	960.00	1357.6450	0.0000	1.11	-0.21
PT4	480.00	960.00	1018.2338	339.4113	0.62	1.33
PT5	480.00	960.00	1018.2338	339.4113	0.62	1.33
PT6	240.00	480.00	509.1169	169.7056	-0.12	0.56
PT7	120.00	240.00	254.5584	84.8528	-0.49	0.18
PT8	480.00	480.00	678.8225	0.0000	0.12	-0.21
PT9	20.00	30.00	35.3553	7.0711	-0.81	-0.18
PT10	20.00	20.00	28.2843	0.0000	-0.82	-0.21

Overall Observations:

- All control positive and negative samples behaved as per expectation in all the laboratories.
- PT 1 was negative for all the three serotypes; all laboratories reported PT 1 as a negative.
- PT 10 was positive for serotype Asia1 and all the laboratories reported PT 10 as negative for Serotypes O and A, and positive for Asia1.
- For rest of the samples all the laboratory reported all samples within 1 dilution of the consensus median for serotypes O, A and Asia1 antigens used in testing of PT samples for antibodies against the corresponding FMD serotypes.

Conclusion:

Preliminary analysis revealed that the entire laboratory produced results for between laboratories and within laboratories varied within the normally accepted absolute score limits indication with acceptable reproducibility and repeatability for the analyzed PT samples.

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