

REPORT



First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency Testing for Highly Pathogenic Emerging Diseases (HPED) in SAARC Countries

23-24 January 2012, Dhaka, Bangladesh





Dr Khan Shahidul Huque, Director General, BLRI, Bangladesh addressing inaugural session. Ms Libuse Soukupova (third from left), representative of EU Ambassador in Bangladesh, among others in the dais.



Group work in progress

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Acronyms and abbreviations

AAHL	Australian Animal Health Laboratory
BLRI	Bangladesh Livestock Research Institute
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer
DIVA	Differentiation of Infected and Vaccinated Animals
ECTAD	Emergency Centre for Transboundary Animal Diseases
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
HPAI	Highly Pathogenic Avian Influenza
HPED	Highly Pathogenic Emerging Diseases
IQC	Internal Quality Control
LAMP	Loop Mediated Isothermal Amplification
LPB-ELISA	Liquid Phase Blocking ELISA
NRLPD	National Reference Laboratory for Poultry Diseases
OIE	World Organisation for Animal Health (Office International des Epizooties)
PD-FMD	Project Directorate on Foot and Mouth Disease
PCR	Polymerase Chain Reaction
PPR	<i>Peste des Petits Ruminants</i>
PRRS	Porcine Reproductive and Respiratory Syndrome
PT	Proficiency Testing
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
QA	Quality Assurance

Summary

The Food and Agriculture Organization of the United Nations (FAO) is implementing an European Union (EU) funded regional project (OSRO/RAS/901/EC) 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 HPEDs, including highly pathogenic avian influenza (HPAI), through improved veterinary and public health services and inter-sectoral collaboration on a regional basis.

Since the identification of the Regional Leading Diagnostic Laboratories (RLDLs) for the three priority diseases viz. foot and mouth disease (FMD), *peste des petits ruminants* (PPR) and highly pathogenic avian influenza (HPAI), a number of laboratory activities of the project have been implemented. Importantly, a consultative workshop for establishing a network of Regional Leading Diagnostic Laboratories in South Asia was held from 2 to 4 March 2011 in Kathmandu, Nepal. The main recommendations of the workshop included conducting regional laboratory assessment for diagnostic capacity and trainings, developing strategy to conduct regional proficiency testing, provide support to enhance diagnostic capacity in the region, developing regional and international sample sharing/referral system, RLDLs to produce reagents to develop regional diagnostic capacity, considering leading laboratories and other laboratories with salient resources for engaging in capacity building, organising 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 Laboratories.

Keeping in view the recommendations of the above consultative workshop, the Regional Support Unit (RSU), based in the FAO's Sub-regional ECTAD Unit in Kathmandu, organised "The First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency Testing for Priority HPEDs in SAARC Countries" from 23-24 January 2012 in Dhaka, Bangladesh. The main purpose of this meeting was to keep the Directors' of the 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. Further, this meeting was expected to act as a coordinating platform for the national veterinary diagnostic laboratories of the region to promote harmonisation of protocols and to enhance laboratory capacity and standards for the diagnosis of transboundary animal diseases (TADs) and emerging/re-emerging HPEDs. The main objectives of this workshop were:

- To update the Laboratory Directors' on the progress of and get advice to improve the following issues:

- ▶ Regional framework for animal health laboratory capacity building and networking in SAARC region.
- ▶ Roles and responsibilities of regional leading laboratories for FMD, PPR and HPAI.
- ▶ Regional guiding principles for diagnosis of priority diseases: FMD, PPR and HPAI.
- Establish modalities of Proficiency Testing on the diagnosis of priority TADs (FMD, PPR and HPAI).

The meeting and workshop were attended by 27 participants from the SAARC countries including Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, Sri Lanka with technical support from the Australian Animal Health Laboratory (AAHL), World Organisation for Animal Health (OIE), FAO Regional Office for Asia and the Pacific (RAP) and FAO ECTAD, Kathmandu, Nepal.

The Laboratory Directors made presentations on the mandate and facilities available in their laboratories. The Directors' Forum agreed upon the roles and responsibilities of the Regional Leading Diagnostic Laboratories (RLDLs) for HPAI [National Research Laboratory for Poultry Disease (NRLPD) Pakistan], FMD [Project Directorate on Foot and Mouth Disease (PD-FMD), India] and PPR [Bangladesh Livestock Research Institute (BLRI), Bangladesh] to support quality assurance scheme including proficiency testing. The First Laboratory Directors' meeting came out with a set of recommendations which included:

- i. Laboratory capacity building and networking activities be coordinated by RLDLs in South Asia.
- ii. The regional guiding principles for the priority diseases (FMD, PPR and HPAI) be prepared including collection and shipment of samples to the RLDLs and OIE Reference Laboratories.
- iii. Regional quality assurance scheme must be a priority and be supported to include institutional commitment to carry out proficiency testing and sharing of results among network laboratories.
- iv. Guidelines for sample collection, transportation, submission, interpretation of diagnostic result are developed, and awareness be created among all stakeholders accordingly.
- v. The Laboratory Directors' Forum be institutionalised and the meeting be held annually with participation from the National and Regional Leading Laboratories.
- vi. The Laboratory Director/s Forum could provide guidelines for all laboratories in a number of areas e.g. biosafety, quality assurance (QA), testing requirements for laboratories at each level in region and country, for test validation, regional resources for equipment calibration (e.g. BSL II cabinets, PCR machines) etc.

The workshop on proficiency testing identified for regional proficiency testing programmes to be implemented in 2012. The following recommendations were agreed by the participants:

- i. The RLDLs should receive training on proficiency testing provider prior to the beginning of the proficiency testing round.
- ii. The RLDLs can supply small quantity of Internal Quality Control (IQC) to national laboratories upon request. After which the national laboratories can produce their own IQC from local strains.
- iii. Proficiency testing should be organised annually for the Real time PCR and HI for HPAI; ELISA for FMD and PCR for PPR.
- iv. The recipient laboratories should use both reagents supplied by RLDL and reagents available within their own laboratories for proficiency testing to identify if there is any problem with in-house reagents.
- v. The RLDLs will provide confirmation testing and carry out backstopping missions to other laboratories to address trouble shooting and provide in-house training.
- vi. Quality assurance system needs to be implemented and supported and National laboratories should seek accreditation from their own country.
- vii. The RLDLs will supply SOPs and regional guiding principles for diagnosis of FMD, HPAI and PPR.
- viii. The RLDLs should consider participating in recognised proficiency testing programme and be accredited as PT providers.
- ix. Create SAARC Working Groups for Priority Diseases.

Background

The Food and Agriculture Organization of the United Nations (FAO) is implementing an European Union (EU) funded regional project (OSRO/RAS/901/EC) 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 HPEDs, including HPAI, through improved veterinary and public health services and inter-sectoral collaboration on a regional basis.

To strengthen the disease diagnostic capacity of the Member States the following laboratories for the three priority diseases (FMD, PPR, HPAI) have been identified as Regional Leading Diagnostic Laboratories (RLDLs):

- Project Directorate on Foot and Mouth Disease (PD-FMD), Indian Veterinary Research Institute (IVRI) campus, Mukteswar-263138, Nainital (Uttarakhand), India for FMD,
- Virology Laboratory of Bangladesh Livestock Research Institute (BLRI), Savar, Dhaka, Bangladesh for PPR, and
- National Reference Laboratory for Poultry Diseases (NRLPD), Islamabad, Pakistan for HPAI

These Laboratories, in addition to providing confirmatory diagnostic facility, are expected to form and coordinate a network of national diagnostic laboratories. The network will facilitate sharing of virus isolates and disease information, maintain uniform diagnostic standards, support training of laboratory scientists/technicians from the member states and backstop regional surveillance and epidemiological studies. The networking activities that will also include proficiency testing programs will be supported by the international OIE and FAO reference laboratories like World Reference Laboratory, Pirbright, Australian Animal Health Laboratory, Geelong, Australia and High Security Animal Disease Laboratory, Bhopal, India.

Since the identification of these RLDLs, a number of laboratory activities of the project have been implemented. These are:

- a. A consultative workshop for establishing a network of Regional Leading Diagnostic Laboratories in South Asia was held from 2 to 4 March 2011 in Kathmandu, Nepal. Some of the main recommendations of the workshop include conducting regional laboratory assessment for diagnostic capacity and trainings, developing strategy to conduct regional proficiency testing, provide support to enhance diagnostic capacity in the region, developing regional and international sample sharing/referral system, leading laboratories to produce reagents to develop regional

diagnostic capacity, RLDLs and other labs with salient resources be engaged in capacity building, organising 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 Laboratories.

- b. A consultative workshop on Regional Epidemiology and Laboratory networking in the SAARC region was held from 27-29 July 2011 in Kathmandu, Nepal.
- c. Two rounds of Foot and Mouth Disease (FMD) Laboratory Training were carried out in May and June 2011 at RLDL (FMD), at Project Directorate on Foot and Mouth Disease, Mukteswar, India.
- d. Need assessment of the leading laboratories was initiated in May 2011 and completed in January 2012.
- e. The Central Disease Investigation Laboratory (CDIL) of Bangladesh was supported for standardising PCR technology by providing hands-on training to its staff on PCR and its instrumentation by RLDL on HPAI, Pakistan in October-November 2011.
- f. The National Veterinary Laboratory of Bhutan was supported to standardise and set up FMD virus typing facilities by RLDL on FMD, India in November 2011.
- g. A workshop on Laboratory Information Management System (LIMS) was held in December 2011.

Proficiency testing (PT) forms an important part of building regional epidemiology and laboratory networks. The PT has become an essential component of test result verification, method validation and harmonisation, laboratory approval by regulators, third party laboratory accreditation, and management of trade issues. The initiation of accreditation programmes for PT providers verifies the importance of the ability to demonstrate competence in this area by meeting required and relevant national and international standards. Participation in external PT programmes by a laboratory is strongly recommended to achieve ISO/IEC 17025 standard. Most laboratory accreditation bodies using this standard require that laboratories participate in such programmes to be accredited. These requirements emphasise the need for proficiency test providers to demonstrate their competence. Having imparted training for staff from laboratories of member states in the laboratory diagnosis of FMD and a planned training on diagnosis of PPR by RLDLs of the Regional Support Unit, 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.

The Regional Support Unit, based in the FAO's Sub-regional ECTAD Unit in Kathmandu, organised "The First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency Testing for Priority HPEDs in SAARC Countries" from 23-24 January 2012 in Dhaka, Bangladesh. The main objective of this meeting was to keep the Directors of 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. Further, this meeting was expected to act as a coordinating platform for the national veterinary diagnostic laboratories of the region to promote harmonisation of protocols and to enhance laboratory capacity and standards for the diagnosis of transboundary animal diseases (TADs) and emerging/re-emerging highly pathogenic infectious diseases (HPEDs).

The main objectives of the workshop were:

- To update the laboratory directors on the progress of and get advice to improve the following issues:
 - ▶ Regional framework for animal health laboratory capacity building and networking in SAARC region;
 - ▶ Roles and responsibilities of regional leading laboratories for FMD, PPR and HPAI; and
 - ▶ Regional guiding principles for diagnosis of priority diseases: FMD, PPR and HPAI.
- Establish modalities of Proficiency Testing on the diagnosis of priority transboundary animal diseases (FMD, PPR and HPAI).

The expected outcomes were substantive recommendations to improve the regional framework for capacity building and networks of leading laboratories and regional guiding principles as well as the way forward to gain political support from national and regional levels.

This is the report of First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency Testing for Priority HPEDs in SAARC Countries held as per the agenda attached at Annex I. The meeting was attended by 27 officials from various SAARC countries. Delegates from seven SAARC countries viz. Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka participated in the meeting. The meeting was also attended by representatives from FAO, OIE and Australian Animal Health Laboratory (AAHL). The list of participants is attached at Annex II.

DAY ONE

Inaugural session

The inaugural session started with opening remarks by Mr Dominique Burgeon, FAO Representative in Bangladesh. He introduced the project and its mandate. While stressing the importance of HPEDs, he commented that only few donors remained on board for supporting HPAI activities. He emphasised the importance of One Health (OH) to tackle the emerging diseases approach and more important issue for this approach would be laboratory strengthening.

Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal provided a background on the meeting and workshop. The main purpose of the meeting was to enhance the laboratory diagnostic capacity of the Member States in the SAARC region. While briefing, he explained on the identification of three priority diseases viz. FMD, PPR and HPAI and three RLDLs, respectively in the Member States. The mandate of the RLDLs is to form and manage laboratory networks, support training activities in the diagnosis of priority diseases in the region etc. He discussed the importance of laboratory networking and proficiency testing and stated that the networking activity was re-started in the region during March 2011.

Ms Libuše Soukupova, representative of EU Ambassador in Bangladesh welcomed the delegates from the SAARC countries. She recapitulated about her personal involvement during the course of development of negotiations of the EU-HPED project. She mentioned that the EU is involved in HPAI activities since 2005. Importance of pandemic influenza regarding human-animal interface was stressed. EU also realised the importance of OH approach in tackling HPEDs and started funding priority HPEDs using OH perspective and hence decided to fund other diseases to support for OH.

Dr Musaddique Hossain, Chief Veterinary Officer (CVO), Bangladesh while welcoming the delegates promised to extend maximum cooperation from the Government of Bangladesh for the activities outlined in the project. He explained the Bangladesh government's approach for compartmentalisation of disease free areas.

Dr Khan Shahidul Huque, Director General, BLRI highlighted the importance and the necessity of this kind of interaction/meetings for addressing HPEDs in this region effectively. He urged that the capacity to maintain the equipment should be built into the project.

Mr Mosharraf Hossain, Joint Secretary of the Ministry of Fisheries and Livestock, Government of Bangladesh requested to provide and upgrade diagnostic facilities to strengthen surveillance activities. He stressed the need for establishment of good laboratory network in the region.

Finally at the end of the inaugural session Dr Mohinder Oberoi thanked all the governments for nominating high level officials for this consultation and the delegates for attending the consultation meeting.

Technical Session 1: Laboratory capacity building and networking in SAARC

This session was chaired by Dr Khan Shahidul Huque, Director General of BLRI. Dr Venkatasubbarao Mandava, Laboratory Coordinator, Regional Support Unit/Sub Regional ECTAD, FAO, Nepal presented a 'Review of assessment of Regional Leading Diagnostic Laboratories'. He explained the general factors considered in the assessment of the laboratories in the SAARC region with a view to establish a standard outline of operations. A total of nine laboratories including three RLDLs and six national laboratories were assessed based on eighteen criteria. He discussed the weakness, similarities and differences among these laboratories in details. The activities undertaken by the RLDLs in capacity building were highlighted. The review of the laboratory assessment in the SAARC region is summarised in Annex III.

Dr Pawin Padungtod, Regional Laboratory Network Coordinator from FAO-RAP presented 'Experiences of ASEAN Regional Laboratory-Epidemiology Networks'. The main components of laboratory as well as epidemiology networking were discussed. The Regional Guiding Principles for animal influenza surveillance and diagnosis, and the roles and responsibilities of Regional Leading Diagnostic Laboratories were elaborated. He stressed on importance of coordination and collaboration among projects and international partners in maximising outputs and outcomes. He expressed that efficient networking can be maintained through a channel of personal contacts. The existing regional networks for epidemiology and laboratory can provide platforms for future emerging diseases for the region. The ASEAN model can be better utilised for SAARC countries also.

Dr Andrew Davis, Programme Coordinator, OIE Sub-Regional Representation for South East Asia, Bangkok, Thailand presented on 'OIE laboratory engagement and support: the South East Asia perspective'. He informed that, the network is made up of over 220 OIE Reference Laboratories and OIE Collaborating Centres, located in 41 countries. Each of these centres provides international support. He discussed the OIE mandate and its responsibilities of transparency for global animal disease information system. Three aims of OIE laboratory twinning and five key activities in 2012 for OIE laboratory capacity building were elaborated. A general observation was made that OIE should have its presence in South Asia in addition to Europe and North America.

Technical Session 2: Roles and responsibilities of Regional Leading Diagnostic Laboratories

Dr B Pattnaik, Project Director, PD-FMD and RLDL (FMD), Mukteswar, India presented a detailed account of the importance of FMD research in India and laboratory competency and its strengths. Efficient networking of national laboratories and the success of FMD Control Programme in India was highlighted. The gradual reduction in the FMD outbreaks and progressive build up of herd immunity

in vaccinated areas in India after launching the control programme was stressed. He also discussed the role and responsibilities of RLDL on FMD. These include providing training on FMD diagnosis, training on FMD epidemiology, proficiency testing, supply of diagnostic kits, setting of FMD laboratory and referral diagnostic services.

Dr Jahangir Alam, Senior Scientific Officer (Virology) from RLDL PPR, Bangladesh Livestock Research Institute, Dhaka, Bangladesh briefed on the several roles of the laboratory including confirmatory diagnostic facilities, training of laboratory people, supply of diagnostic reagents, sharing of PPR related information, strategic PPR control plan and participating/assisting in the proficiency testing.

Dr Khalid Naeem, Chief Scientific Officer, RLDL HPAI at NRLPD, Islamabad, Pakistan presented the role and responsibilities of RLDL on HPAI. National surveillance set up and AI in Pakistan and surveillance protocol was elaborated in his presentation. He detailed the roles and responsibilities of RLDL on HPAI. These roles and responsibilities include development of linkages with the National Laboratories in the region, develop standard AI surveillance procedures, extend staff training for national laboratories and harmonisation of testing protocols. Conducting annual proficiency testing, develop parameters for effective bio-safety practices, sharing of AI surveillance data and assisting in field investigations in member states were also emphasised. He mentioned that strategic vaccination along with culling and biosafety measures is followed in Pakistan. No outbreak of HPAI H5N1 was recorded in Pakistan since July 2008, he added. He mentioned that, vaccine produced using indigenous vaccine strain will have the closest match with field isolates.

Technical Session 3: Regional guiding principles for diagnosis of priority diseases

Dr B Pattnaik, Project Director, PD FMD and RLDL (FMD), Mukteswar, India, in his presentation stressed the importance of retrospective diagnosis using sero-surveillance. Various diagnostic methods available for FMD diagnosis were elaborated. Application of LAMP assay for rapid screening of FMD, DIVA and LPB-ELISA for sero- surveillance was of crucial importance in the control programme of FMD. The discussions were highlighted on step by step training of laboratory personnel. It was stressed that instead of just giving protocols, laboratory personnel should be educated about the aspects of the techniques and troubleshooting as well.

Dr Jahangir Alam, Senior Scientific Officer (Virology) from RLDL (PPR), Bangladesh Livestock Research Institute, Dhaka, Bangladesh pointed out that initial screening can be done at national laboratory and the samples can be forwarded to RLDL for further characterisation including virus isolation, molecular diagnosis and gene sequencing.

Dr Khalid Naeem, Chief Scientific Officer, RLDL (HPAI) at NRLPD, Islamabad, Pakistan presented on the regional guiding principles in the diagnosis of HPAI. Up-gradation of national laboratories for

diagnosis, provision of appropriate diagnostic tools at national laboratories, ensuring usage of harmonised diagnostic procedures, establishing early disease warning system in Member States, sharing information regarding new viral introductions among Member States and up-grading bio-safety standards at national laboratories, coordinated support between field and laboratory services were the major points put forward. Laboratory diagnostic techniques adopted by OIE should fit to all regions and can be transferred where as advanced diagnostic techniques can be reserved for national use. Issue of lack of trained man power and frequent transfer of trained personnel as a common hindrance for the functioning of diagnostic laboratories and necessity of in-house training of personnel was highlighted.

DAY TWO

The proceedings of day two started with summarising the outcome of the First SAARC Laboratory Directors' meeting by Dr Venkatasubbarao Mandava.

Technical Session 4: Proficiency testing (PT)

The second day of the workshop was exclusively devoted to proficiency testing for priority HPEDs. The sessions and group works were moderated by Dr Chris Morrissy, Diagnostic Virologist, CSIRO Australian Animal Health Laboratory, Geelong, Australia. He made a presentation on 'Role of the Quality Management System and Proficiency Testing (PT)' in ensuring that laboratories are producing accurate and correct results for tests carried out in the laboratory. While presenting the role of quality management system, he dwelled primarily on the following three areas:

- Quality Assurance (QA): Overview of requirements for ISO 9001 & ISO 17025
- Internal Quality Control (IQC) and External Quality Control (PT)
- Test optimisation, validation and verification

Dr Chris Morrissy made another presentation on 'Proficiency Testing (PT): Overview of requirements and benefits for the laboratory'. Various requirements under ISO 17043 and design of a PT panel, preparation of PT panel, steps required in establishing PT rounds and experiences in the region (HPAI, CSF and PRRS), analysis of PT results, and statistics and PT were discussed in detail.

Technical Session 5: Working groups

The participants were divided in two working groups to discuss the following issues.

Two groups viz. RLDL and National Laboratories worked on the same issues of

- Listing of priority diseases for which PT is required
- Achieving sustainability of PT programmes
 - ▶ Expectations of the users (National laboratories)
 - ▶ Expectations of the supplier (RLDL)
- Implementation of IQC and QA for diagnostic tests
- Partner discussion/listing of areas in which they could assist
- Linkage of needs and available support with specific activities

The groups came out with the following outputs:

Group 1: RLDLs represented by Bangladesh, India and Pakistan

Achieving sustainability of PT programmes	RLDL FMD	RLDL AI	RLDL PPR
Expectations of the users	Sandwich ELISA for FMD antigen detection and identification SP ELISA for antibody detection and titre measurement NSP ELISA (DIVA)	AGPT and HI for antigen detection and identification	Reverse transcription (RT) PCR for diagnosis
Expectations of the supplier	Suitable national laboratory to be identified for each country Some laboratories need to be appropriately equipped to undertake PT A panel of 3 master trainers should be identified Repeated training of master trainers at RLDL		
Problems in implementing PT/Testing of PT samples	Inadequate manpower Frequent transfer of trained manpower Lack of equipment in some laboratories Lack of National networks		
Do laboratories have tests in place for FMD / AI /PPR	Not in place in some laboratories		
Issues in implementation of IQC and QA for diagnostic procedures			
Can you start IQC in your laboratory	IQC in place		
What IQC do you use	Local controls		
Do you have QA system in place	QA in place		
Can you implement QA test SOPs, cover sheets	Yes		

Group 2: National laboratories represented by Bangladesh, Bhutan, Maldives, Nepal, and Sri Lanka

Priority Diseases identified: HPAI, FMD and PPR

Expectations

1. National Laboratory should be accredited
2. Training of the National laboratory staff is needed
3. Need technical support

4. Need adequate resources (reagents and kits)
5. Laboratory networking
6. Harmonised testing protocols

Problems

1. Inadequate laboratory infrastructures
2. Inadequate human resources
3. Inadequate bio-safety provisions
4. Frequent transfer of skilled manpower
5. Inadequate financial resources (budget)

Testing Capacity

1. FMD (all except Maldives)
2. AI (all except Maldives)
3. PPR (all except Bhutan, Sri Lanka and Maldives)

IQC for Testing: All countries follow IQC protocols

What IQC required for Testing: Reference Controls are to be supplied to the National Laboratories.

QA systems: Not existing

QA implementation and issues: Yes; there is a need for proper documentation

The second round of working groups discussed on the development of strategy for proficiency testing of a diagnostic test and priority HPEDs in SAARC (FMD, PPR and HPAI). The issues discussed were;

- Production of test, IQC and PT reagents
- Training, support and troubleshooting requirements
- PT rounds: timing, number of rounds and what tests
- Test optimisation, validation and verification
 - ▶ Who? How? Why?
 - ▶ Regional Guiding Principles
- Proficiency testing and IQC of FMD tests
- Proficiency testing and IQC of PPR tests
- Proficiency testing and IQC of HPAI tests

The participants were divided into two groups comprising of at least one representative from each country. The two groups worked on the above issues and came out with the following outputs:

Group 1:**Production of test, IQC and PT**

- RLDLs should harmonise their protocols with International Reference Laboratory, e.g. AAHL
- FMD-RLDL will provide test kit with SOPs, trouble-shooting, reagents for IQC (high +, low + and -) and PT (5 to 10 samples)
- HPAI-RLDL will provide HI reagents, testing protocols and primer sequences to detect H5 by real time PCR, reagents for IQC and PT
- PPR-RLDL can provide primer sequences for RT-PCR

Training, support and trouble-shooting

- RLDL-FMD will provide trainings, support for diagnosis, vaccine matching, sero-monitoring and support for trouble-shooting
- RLDL-HPAI will provide trainings, support for detection, diagnosis and support for trouble-shooting
- RLDL-PPR will provide trainings, diagnostic support by PCR and sero-monitoring and support trouble-shooting

PT rounds: Timings, number of rounds and what tests

- HPAI-Annually in September-November, HI and real time PCR
- FMD-Six monthly in March and October, antigen ELISA, LBP-ELISA and NSP-ELISA
- PPR-Annually in November, RT-PCR

Test optimisation, validation and verification

- RLDLs will optimise, validate and verify the results
- RLDLs will develop and provide regional guiding principles

Group 2: Development of strategy for proficiency testing of a diagnostic test and priority HPEDs in SAARC (FMD, PPR, HPAI)

Questions	FMD	PPR	HPAI	Remarks
Production of Test reagents, IQC and PT				
	For ELISA by RLDL-FMD 20x3 kits suitable for 50 test for PT purpose	RT-PCR, Not to be provided by RLDL-PPR	For AGPT, HI material Up to 200 tests each for PT purpose	For PPR primer sequence will be provided
Training, support and trouble-shooting				
	<ul style="list-style-type: none"> - Training of RLDL for conducting PT - One training per year for National Laboratories at the cost of project by RLDL 			
PT rounds, timing				
	twice a year,	once a year	once a year	
Test optimisation, validation and verification				
Test optimisation	National laboratories			
Validation				Selected tests don't need validation
Verification				Concerned RLDL will do it
Regional guiding principles				Tests validated/ verified by RLDL will only be used by national laboratories

Conclusions and recommendations

Based on the deliberations of the Laboratory Directors' and working groups, the following main recommendations were drawn;

Recognising that;

1. National Animal Disease Diagnostic Laboratories are responsible for disease surveillance programmes in their respective countries, which enable the countries to detect disease outbreaks early and respond in a timely manner.
2. Regional Laboratory Networks have a role as a coordinating platform for the national laboratories to enhance laboratory capacity for the diagnosis of various infectious diseases, assure quality of diagnostic result and promote sharing of reagents, biological materials and information.
3. The Laboratory Directors' Forum Meeting can provide a platform to discuss regionally relevant problems of mutual interest and issues among national and leading laboratories of SAARC Region.

The First Laboratory Directors' Forum Meeting recommends that;

1. The laboratory capacity building and laboratory networking activities be coordinated by Regional Leading Diagnostic Laboratories (RLDLs) in South Asia.
2. The roles and responsibilities of the leading laboratories should be in line with the international guidelines for foot and mouth disease (FMD), *peste des petits ruminants* (PPR) and highly pathogenic avian influenza (HPAI).
3. The Regional Guiding Principles for the priority diseases (FMD, PPR and HPAI) be prepared including collection and shipment of samples to the Regional Leading Diagnostic Laboratories and OIE Reference Laboratories.
4. Regional quality assurance scheme must be a priority and be supported to include institutional commitment to carry out proficiency testing and sharing of results among network laboratories.
5. The diagnostic laboratory and epidemiological networks be coordinated and supported through information sharing.
6. Develop guidelines for sample collection, transportation, submission, interpretation of diagnostic result and awareness be created among all stakeholders accordingly.

7. Institutionalise the Laboratory Directors' Forum and annually meeting be held with participation from the National and Regional Leading Diagnostic Laboratories.
8. The Laboratory Directors Forum could provide guidelines for all laboratories in a number of areas e.g. biosafety, quality assurance (QA), testing requirements for laboratories at each level in region and country, for test validation, and regional resources for equipment calibration (e.g. BSL-II cabinets, PCR machines) etc.

Conclusion and recommendation on Proficiency testing (PT)

1. The RLDLs should receive training on proficiency testing provider prior to the beginning of the proficiency testing round.
 - ▶ Production of reagents: internal quality controls (IQC) and PT samples
 - ▶ Preparation of proficiency testing panels
 - ▶ Analysis, interpretation and reporting of PT results
 - ▶ Trouble-shooting advise
2. The RLDLs can supply small quantity of IQC to national laboratories upon request, after which the national laboratories can produce their own IQC from local strains.
3. Proficiency testing should be organised annually for the following assay:
 - ▶ HPAI: Real time PCR, HI
 - ▶ FMD: ELISA
 - ▶ PPR: PCR
4. The recipient laboratories should use both reagents supplied by RLDL and reagents available within their own laboratories for proficiency testing to identify if there is any problem with in-house reagents.
5. RLDLs will provide confirmation testing and carry out backstopping missions to other laboratories to trouble-shooting and provide in-house training.
6. Quality assurance system needs to be implemented and supported. National laboratories should seek accreditation from their own country.

7. The RLDLs will supply standard operating procedures (SOPs) and regional guiding principles for diagnosis of FMD, HPAI and PPR.
8. The RLDLs should consider participating in recognised proficiency testing programme and be accredited as PT providers.
9. Create SAARC Working Groups for priority diseases.

Closing remarks

Dr Mohinder Oberoi, Sub-regional Manager, FAO ECTAD Unit, Kathmandu, Nepal thanked the SAARC Member States for deputing delegates to the workshop and hoped that once in their countries they would keep on engaged in these networks and help in furthering the objectives of the HPED project.

**First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency
Testing for Priority HPEDs in SAARC Countries
23-24 January 2012
Dhaka, Bangladesh**

Agenda

Monday, 23 January 2012

TIME	TOPIC	CHAIR/FACILITATOR
08:30-09:00	Registration	
09:00-09:40	Opening remarks Mr Dominique Burgeon, FAOR, Bangladesh Ms Libuse Soukupova, Delegation EU, Special Guest Dr Khan Shahidul Huque, Director General, BLRI Dr Musaddique Hossain, Chief Veterinary Officer Bangladesh Mr Mosharraf Hossain, Joint Secretary, Ministry of Fisheries and Livestock, Chief Guest	
09:40-09:50	Introduction of participants	
09:50-10:00	Background of the Laboratory Directors' meeting- Dr Mohinder Oberoi, FAO	
10:00-10:20	Tea Break	
Technical Session 1	Laboratory capacity building and networking in SAARC	
10:20-10:35	Review of Assessment of Regional Leading Diagnostic Laboratories- Dr Venkatasubbarao Mandava, FAO	Dr Khan Shahidul Huque, Director General, BLRI
10:35-10:50	Experiences of ASEAN Regional Laboratory Epidemiology Networks- Dr Pawin Padungtod, FAO	
10:50-11:10	OIE laboratory engagement and support: The Southeast Asia perspective- Dr Andrew Davis, OIE	
Technical Session 2	Roles and responsibilities of regional leading diagnostic laboratories	
11:10-11:30	FMD Regional Leading Diagnostic Laboratory - Dr B Pattnaik, FMD RLDL (India)	
11:30-11:50	PPR Regional Leading Diagnostic Laboratory - Dr Jahangir Alam, PPR RLDL (Bangladesh)	
11:50-12:10	HPAI Regional Leading Diagnostic Laboratory - Dr Khalid Naeem, HPAI RLDL (Pakistan)	
12:10-12:30	Discussion	
12:30-13:30	Lunch	

Technical Session 3	Regional guiding principles for diagnosis of priority diseases	
13:30-14:00	Regional Guiding Principles for Diagnosis of FMD- Dr B Pattnaik, FMD RLDL (India)	
14:00-14:30	Regional Guiding Principles for Diagnosis of PPR- Dr Jahangir Alam, PPR RLDL (Bangladesh)	
14:30-15:00	Regional Guiding Principles for Diagnosis of HPAI- Dr Khalid Naeem, HPAI RLDL (Pakistan)	
15:00-15:30	Tea Break	
15:30-16:30	Conclusion and recommendations	

Tuesday, 24 Jan 2012

TIME	TOPIC	CHAIR/FACILITATOR
09:00-09:15	Review of the first day output - Dr Venkatasubbarao Mandava, FAO	
09:15-09:45	Outcome of the First SAARC Laboratory Directors' meeting- Dr Mohinder Oberoi, FAO	
Technical Session 4	Proficiency testing	
09:45-10:15	Role of the Quality Management System and Proficiency Testing (PT) in ensuring laboratories are producing accurate and correct results for tests carried out in the laboratory <ul style="list-style-type: none"> • Quality Assurance (QA): Overview of requirements for ISO 9001 & ISO 17025 • Internal Quality Control (IQC) and External Quality Control (PT) • Test optimisation, validation and verification 	Dr Chris Morrissy, Australian Animal Health Laboratory
10:15-10:45	Proficiency Testing (PT): Overview of requirements and benefits for the laboratory <ul style="list-style-type: none"> • Requirements under ISO 17043 and design of a PT panel • Preparation of a PT panel • Proficiency Testing - steps required to establish rounds and experiences in the region (HPAI, CSF and PRRS) • Analysis of PT Results • Statistics and PT 	Dr Chris Morrissy, Australian Animal Health Laboratory
10:45-11:15	Tea Break	

Technical Session 5	Working groups on proficiency testing	
11:15-12:45	<p>Group work:</p> <ul style="list-style-type: none"> • Discussion/listing of priority diseases for which PT testing is required • Achieving sustainability of PT programmes <ul style="list-style-type: none"> ▸ Expectations of the users (National laboratories) ▸ Expectations of the supplier (RLDLs) • Implementation of IQC and QA for diagnostic tests • Partner discussion/listing of areas in which they could assist • Linkage of needs and available support with specific activities 	Dr Chris Morrissy, Australian Animal Health Laboratory
12:45-13:30	Lunch Break	
13:30-14:00	Report on Group work	
14:00-15:30	<p>Group work on development of strategy for proficiency testing of a Diagnostic Test and Priority HPEDs in SAARC (FMD, PPR, HPAI)</p> <ul style="list-style-type: none"> • Production of Test, IQC & PT reagents • Training, support and troubleshooting requirements • PT rounds: Timing, number, rounds and what tests • Test optimisation, validation and verification <ul style="list-style-type: none"> ▸ Who? How? Why? ▸ Regional Guiding Principles • Proficiency testing and IQC of FMD tests • Proficiency testing and IQC of PPR tests • Proficiency testing and IQC of HPAI test 	Dr Chris Morrissy, Australian Animal Health Laboratory
15:30-16:00	Tea Break	
16:00-16:30	Report on Group work	
16:30-17:00	Creation of SAARC working groups for Priority diseases (FMD/ PPR/ HPAI)	Dr Chris Morrissy, Australian Animal Health Laboratory
17:00-17:30	Conclusions and Recommendations	
	Concluding Remarks	Dr Mohinder Oberoi, FAO

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Summary of Assessment of Regional Leading Diagnostic Laboratories

The need assessment of the Regional Leading Diagnostic Laboratories (RLDLs) and National laboratories of some of the member countries in the SAARC region was initiated in May 2011 and is expected to be an ongoing process. The purpose of the assessment of the laboratories is primarily to assess the diagnostic capacity and trainings, developing strategy to conduct Regional Proficiency Testing, 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, organising 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.

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
 - a. Project Directorate on FMD Mukteswar, India
 - b. Virology Laboratory (PPR), BLRI, Savar, Dhaka, Bangladesh
 - c. National Reference Laboratory for Poultry Diseases (HPAI), Islamabad, Pakistan
3. Other National Laboratories in SAARC region
 - a. National FMD and TADs Laboratory, Kathmandu, Nepal

- b. Central Disease Investigation Laboratory, Dhaka, Bangladesh
- c. National Veterinary Laboratory - FMD, Islamabad, Pakistan
- d. National Veterinary Laboratory - PPR, Islamabad, Pakistan
- e. Indian Veterinary Research Institute - PPR, Mukteswar, India
- f. Virology Laboratory (HPAI), BLRI, Savar, Dhaka, Bangladesh

The assessment was carried out using FAO assessment tool comprising of 18 assessment criteria. The criteria used were geographic location, laboratory budget, basic supplies, organisation, linkage with satellite laboratories, communication, infrastructure, equipment availability, 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 (Table1, Fig.1 and Fig. 2).

Table 1: Assessment of Priority Disease Laboratories in SAARC region

Indicator	A	B	C	D	E	F	G	H	I
Geographic location	66.67	77.77	44.44	100.00	55.55	66.67	100.00	88.89	55.55
Laboratory Budget	88.89	44.44	44.44	66.67	66.67	66.67	66.67	66.67	88.89
Basic supply	100.00	88.89	88.89	77.77	66.67	88.89	77.77	88.89	88.89
Organization	100.00	100.00	100.00	100.00	66.67	100.00	100.00	100.00	66.67
Linkage with satellite labs	100.00	33.33	66.67	66.67	55.55	77.77	66.67	77.77	83.33
Communication	66.67	66.67	66.67	58.33	83.33	91.67	58.33	83.33	83.33
Infrastructure	66.67	50.00	41.66	75.00	54.17	66.67	75.00	66.67	62.5
Equipment	83.33	50.00	50.00	55.55	44.14	72.22	55.55	62.11	38.89
Reagent supply	86.67	50.00	37.50	66.67	41.67	75.00	66.67	66.67	50.00
Staff skills and availability	100.00	77.77	58.33	91.67	54.17	91.67	91.67	75.00	70.83
Sample accession	86.67	60.00	66.67	72.22	38.89	72.22	72.22	77.77	61.11
Available technology	66.67	70.00	22.22	51.85	37.04	62.92	51.85	88.89	48.15
Training	61.11	27.78	44.44	72.22	22.22	61.11	72.22	55.55	27.78
Quality Assurance	75.00	29.17	20.83	62.50	12.50	58.33	62.50	66.67	33.33
Biosafety/Biosecurity	66.67	50.00	33.33	66.67	40.00	26.67	66.67	80.00	66.67
Staff Security/Health	22.22	11.11	44.44	44.44	22.22	11.11	44.44	66.67	55.56
Laboratory collaboration	86.67	70.00	73.33	73.33	53.33	40.00	73.33	60.00	80.00
Use of databases/platforms	58.33	33.33	41.67	66.67	50.00	58.33	66.67	66.67	75.00
Grand Total	76.79	50.69	52.50	70.46	46.81	65.99	70.46	74.35	63.13

(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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Legend for Table 1 and Figure 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 (Virology Laboratory of 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 (National Reference Laboratory for Poultry Diseases (NRLPD), Islamabad, Pakistan for HPAI)
- I. BLRI-AI (Bangladesh Livestock Research Institute (BLRI), Savar, Dhaka, Bangladesh)

Fig. 1: Assessment of Priority Disease (FMD, PPR, HPAI) Laboratories in SAARC Region

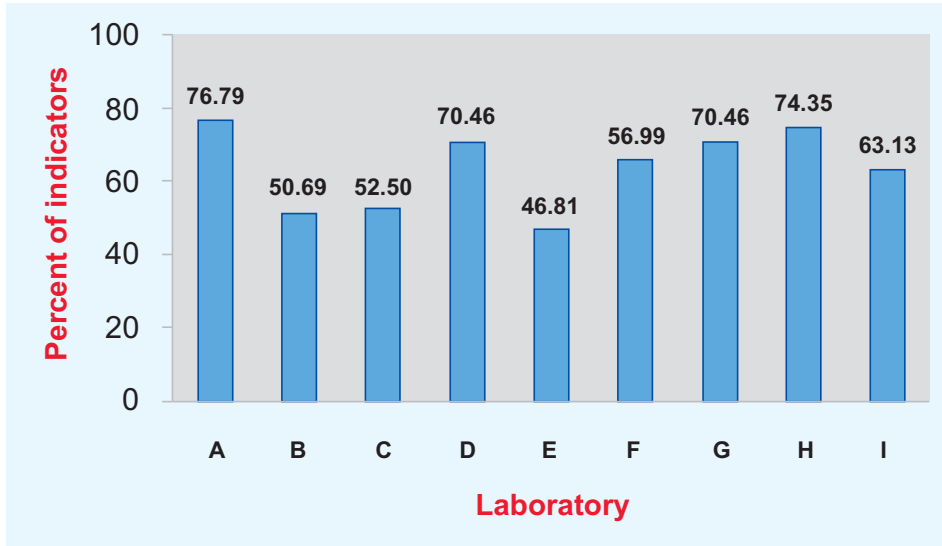
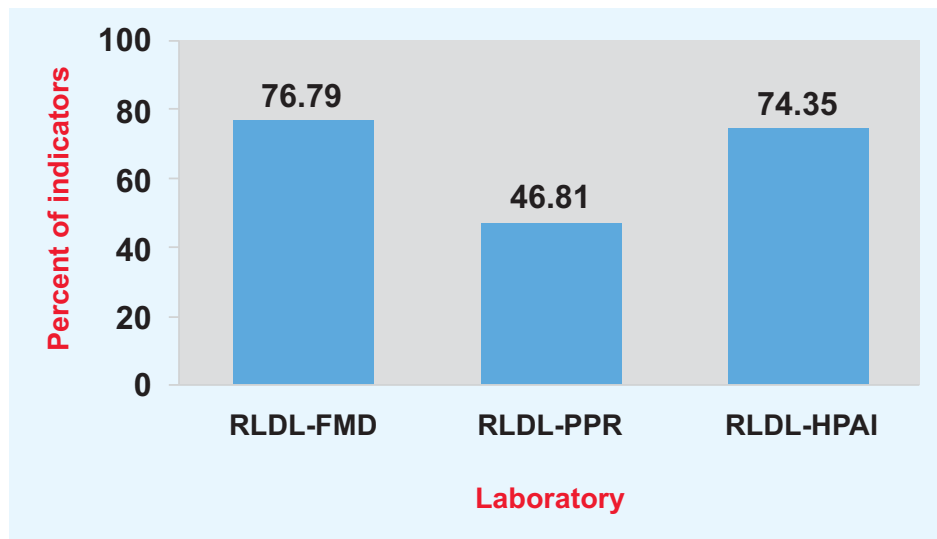


Fig. 2: Assessment of RLDLs for Priority Diseases



Legend

- | | |
|--------------|--|
| PD - FMD | Project Directorate on Foot and Mouth Disease - FMD |
| BLRI - PPR | Bangladesh Livestock Research Institute - PPR |
| NRLPD - HPAI | National Reference Laboratory on Poultry Diseases - HPAI |

On assessment of the priority disease (FMD, PPR and HPAI) laboratories in SAARC region, the following weaknesses were most often identified:

- 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 diagnosis activities for TADs
- Low number of samples submitted to the laboratories, etc
- Cramped space
- Electrical load shedding (power cut)
- Lack of logistical resources

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
- Quality and number of personnel
- Level of training for laboratory personnel

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Dr Bidhan Chandra Das (left), Principal Scientific Officer, Central Disease Investigation Laboratory and Dr Khalid Naeem (standing right), Chief Scientific Officer, RLDL- HPAI, Pakistan and Dr Venkatasubbarao Mandava (centre), Laboratory Coordinator of RSU having discussion



Representatives from OIE, FAO-RAP, AAHL and participants attending a technical session