Importance of EQAS PATICIPATION IN PUBLIC HEALTH FACILITIES

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Public Health Core Sciences

What Is a Public Health Laboratory?

Video available at: http://vimeo.com/52548635

GUIDELINES ON INTEGRATED PUBLIC HEALTH LABORATORIES

Ministry of Health & Family Welfare
Government of India

NATIONAL QUALITY ASSURANCE STANDARDS
INTEGRATED PUBLIC HEALTH LABORATORIES
2024

Ministry of Health and Family Welfare
Government of India

Introduction

- India: high burden of emerging ID & prevalence NCD
- Mortality and disability: communicable diseases and emerging ID (COVID-19): human life and economic growth
- Effective healthcare solutions: control of existing diseases like HIV, TB, Malaria & detect, prevent, control, and manage emerging IDs and threats to human health.
- Cost-effective and efficient healthcare diagnosis and delivery mechanisms: Warranted

- **Critical: Cost-effective laboratory systems: rapid, reliable, and accurate test results for optimal impact on patient care and overall health outcomes.**
- **Network of IPHL at various levels of HCFs: diagnostics for disease-specific programmes and for integrating healthcare surveillance supported by quality assured laboratory data.**
- **Epicentre of such laboratories will be the district with defined upwards and downwards linkages.**
- **Establishing IPHL at District Hospitals.**

- **IPHL**
- **Lab providing comprehensive lab services: ID diagnostics along with other diagnostic services such as Haematology, Clinical Biochemistry, Microbiology, Virology, Pathology: Umbrella.**
- **Physical, functional and data integration of different sections of DH laboratories.**
- **Central sample collection facility in a patient-friendly location.**
- **Vertical program sections to operate as the coordinated limbs of a single body i.e. the district PHL: sharing space, manpower, equipment and thus, avoiding duplication and disconnect.**
- **Diagnostic facilities: communicable and NCD including tests: national programmes for TB, HIV, malaria, viral hepatitis etc., that require biosafety level 2 laboratories.**

Background

- Verticle disease programs have been successful in guiding the policy and field level operations to control many communicable diseases, this disease-specific fragmentation of laboratory systems : duplications of equipment and training programs and inefficient use of human resources under PHS
- Disease-specific approach: Not patient-centric or patient-friendly: multiple samples drawn from each pt: obscures correlation of results.
- Efficiency and effectiveness of laboratory services to support programmatic scale-up: establish integrated national laboratory systems.
- Optimise access to laboratory services, quality assurance efforts, cost-effectiveness and efficient use of human resources.

Vision Statement

- **“Reduction in mortality, morbidity and Out of Pocket Expenditure (OOPE) by effectively preventing and controlling the diseases through rapid and reliable screening, early detection and laboratory diagnosis of communicable, non-communicable and other emerging diseases”.**

Key functions of IPHL

Early detection of disease, surveillance, by monitoring of laboratory parameters including Haematology, Clinical Biochemistry, Clinical Pathology and some other tests (histopathology, etc) which are feasible at DH.

- **Provide laboratory support for communicable and non-communicable diseases by providing comprehensive laboratory services Microbiology, Haematology, Clinical Biochemistry, Clinical Pathology, Cytology, Molecular Biology.**
- **Carryout laboratory-based surveillance for ID and non-infectious diseases and also to support in outbreak investigation.**
- **Carryout water culture for coliforms and rapid diagnostic tests (RDTs) e.g. cholera RDT to support outbreak investigation**

- Act as a hub to provide technical support to Block PHL and other peripheral laboratories for sample collection, testing, referral as per GoI guidelines.
- Support the block and district surveillance units.
- Conduct training for peripheral laboratory staff as well as provide supervision and monitoring for implementation of Quality Management System.
- Function as a district laboratory for various PHP inc NACP, NTEP, NVBDCP, NVHCP, IDSP. It will support convergence/integrating of vertical programs at district level to optimally utilise resources without altering program strategies functions.
- Provide accurate and timely data for analysis, research, information, policy decisions to detect, prevent and respond to public health threats in real time.

Why focus on Lab Data?

Lab results are a component in 70% of clinical decisions.

The U.S. Bureau of Labor Statistics reports that roughly 10 billion lab tests are performed annually, and demand is expected to climb.

Laboratory Testing Impacts Nearly Everyone.

Accurate, reliable lab testing is essential to all aspects of health care.

Mission Differences

Clinical/Hospital Labs

- Diagnostic testing
- Some reference testing
- Medical management
- Focus = Individuals

Public Health Labs

- Some diagnostic testing
- Reference testing
- Surveillance, monitoring and outbreak response
- Focus = **Populations**

Providing data for decision making

Interdependent Network

Identification of Public Health Threats

Essential Capabilities of PHLs

- Identification – surveillance
  - Reference testing
  - Centralized repository for reportable or unusual conditions

HEALTH CARE	PUBLIC HEALTH
• Services focused on a patient	• Services aimed at a population
• Focus on a disease	• Focus on context of disease
• Specific diagnosis	• Unique case definitions
• Established tests	• New tests/methods
• Primary data based	• Secondary data required
• System defined within a plan (ACO)	• System defined nationally (e.g. CDC, DHS)

INTEGRATION OF PHL NETWORK WITHIN THE PUBLIC HEALTH SYSTEM

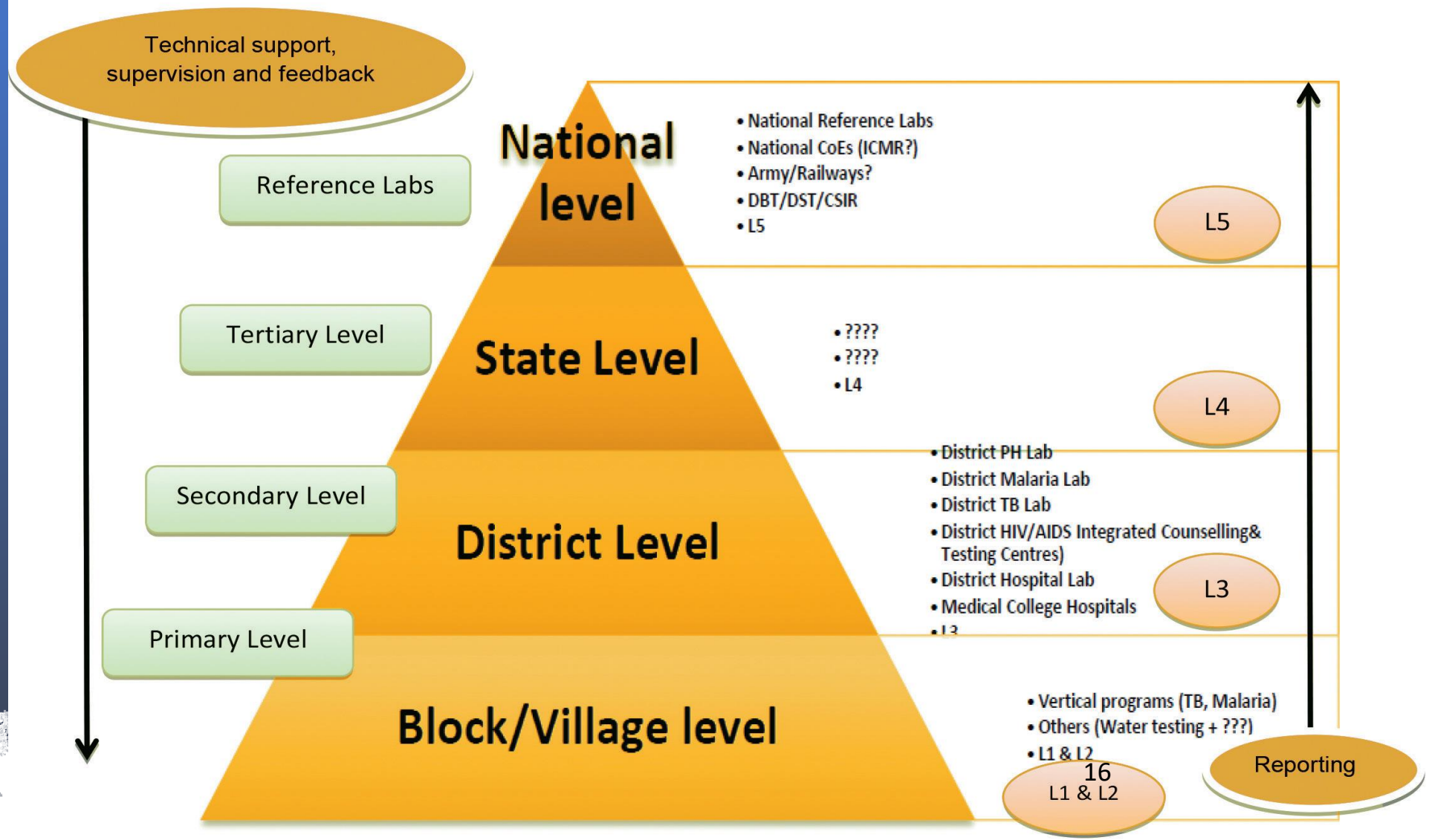
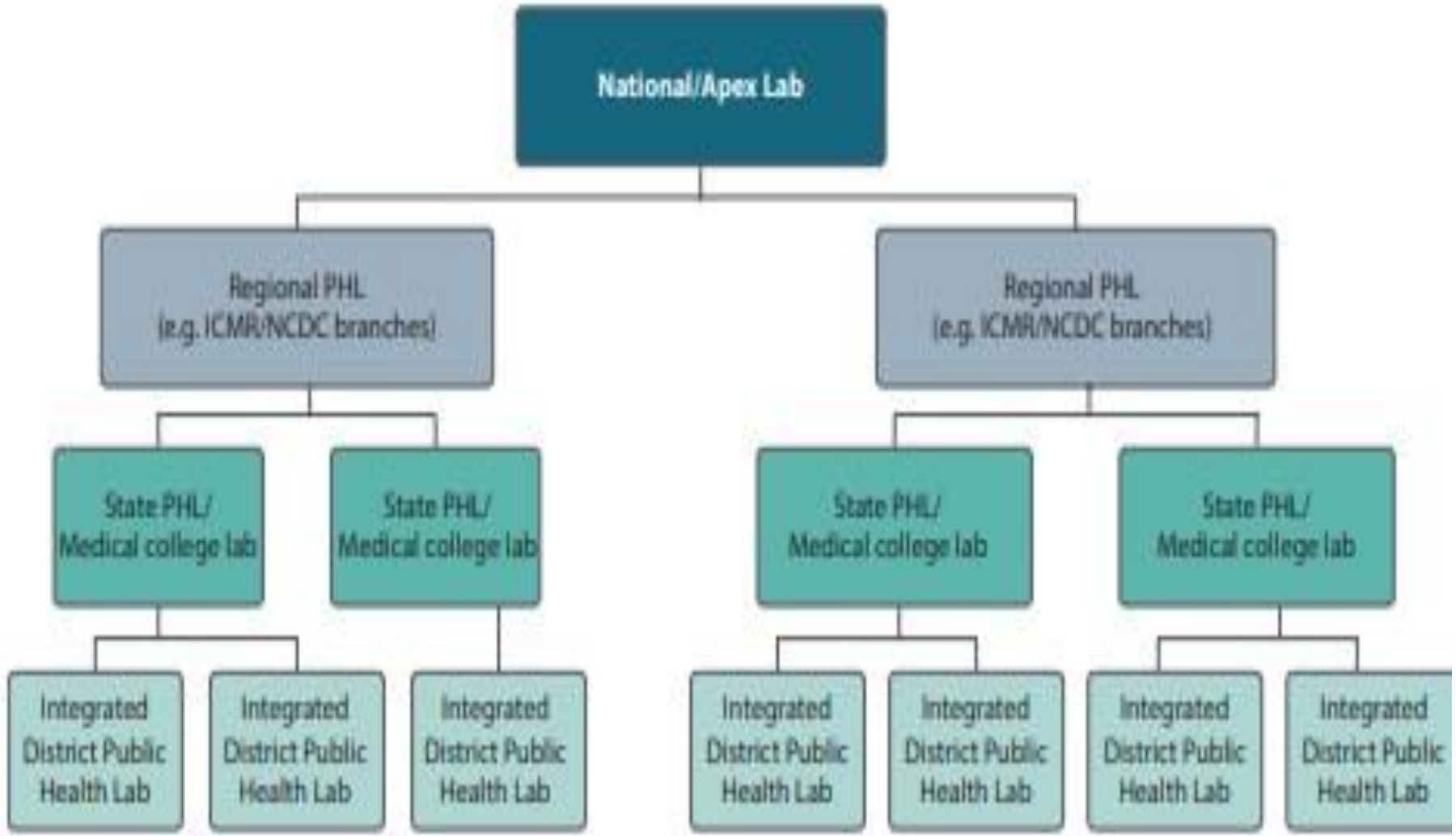


Figure 2: Upward Linkages of IPHL (Integrated Public Health Network) Network



GUIDELINES ON INTEGRATED PUBLIC HEALTH LABORATORIES

Laboratory Network and Linkages

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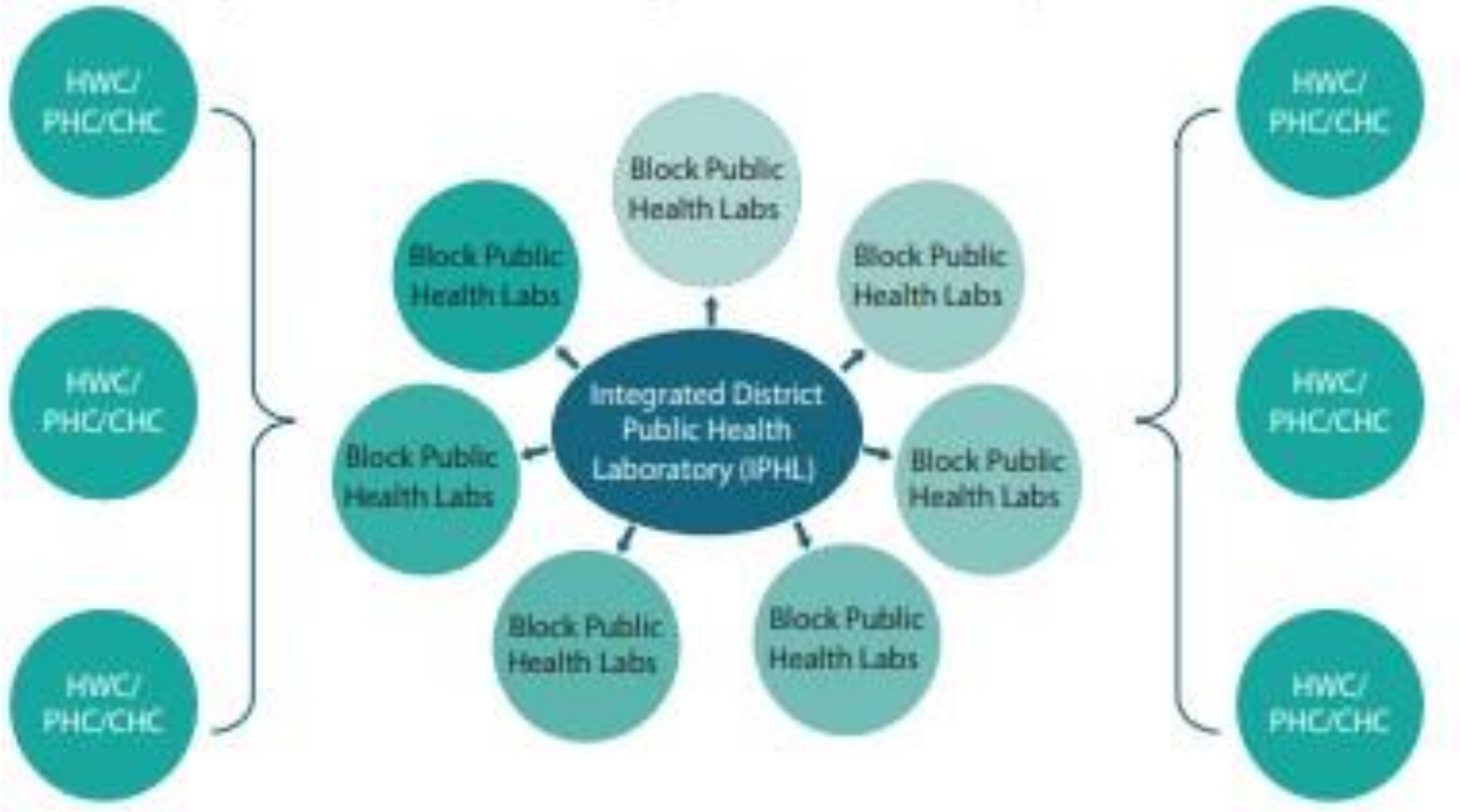
Figure 1: Downward Linkages of IPHL (Hub and Spoke Model)



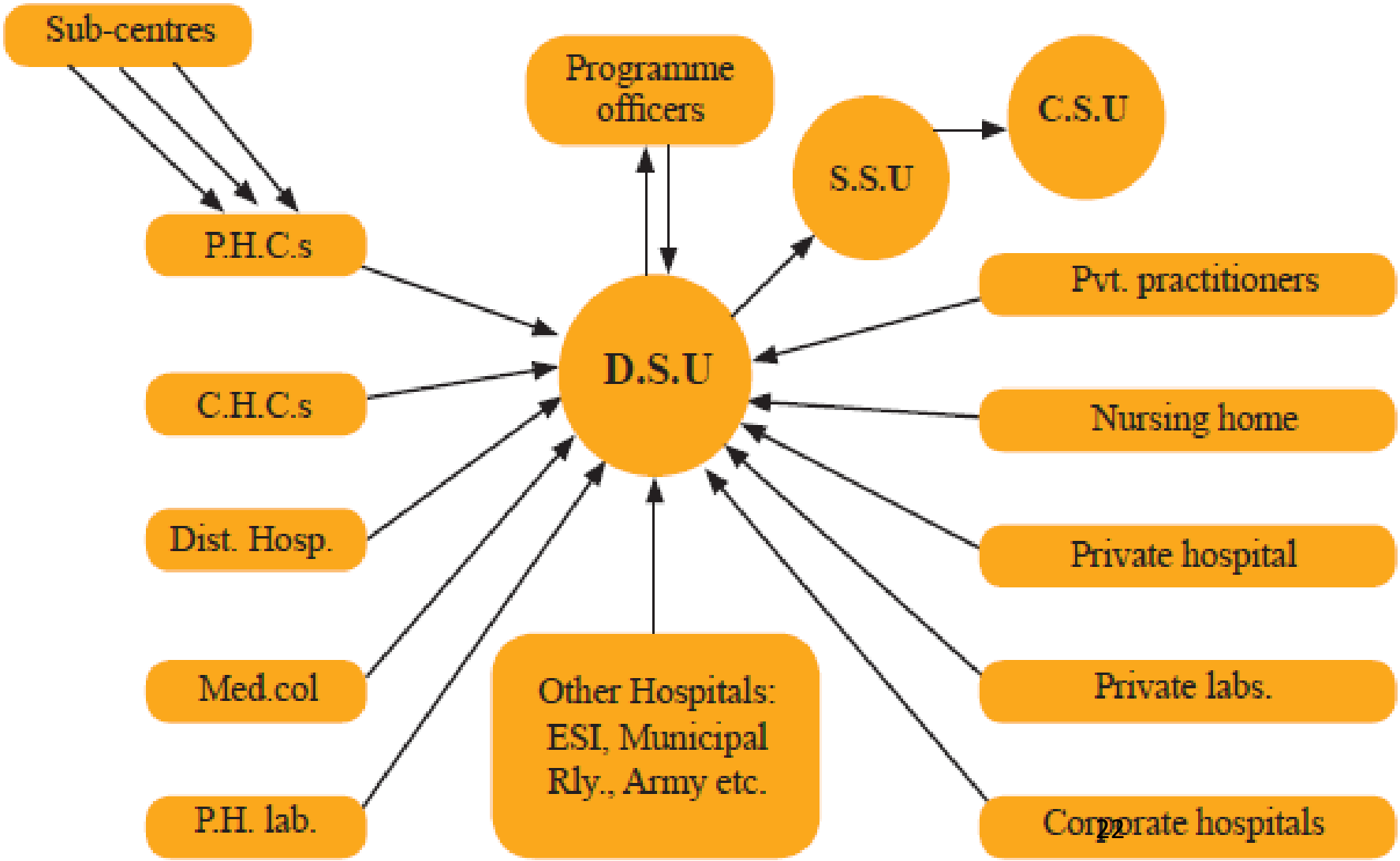
Services

Test Area	Tests to be conducted	Major Equipment Required
Clinical Pathology	Urine microscopy, chemistry and pregnancy test, Stool microscopy for ova, cysts and parasites Stool occult blood Stool Hanging drop for cholera Rapid stool test for cholera Semen analysis	Binocular Microscope, Urine analyser Centrifuge Bunsen burner with gas supply
Haematology	Microscopy of peripheral blood smear for blood cells & haemoparasites (malaria/filaria) Complete haemogram & cell count Blood grouping, cross matching, Coombs and hemoglobinopathies Coagulation profile Bone marrow examination	Binocular Microscope Automated Cell Counter (3 part/5 part) with nucleated RBC flag Automated Coagulometer Automated ESR analyser Haemoglobin HPLC machine (variant analyser)
Cytology	Fine-Needle Aspiration Cytology (FNAC) PAP smear examination CSF & body fluid cytology	Binocular Microscope Centrifuge

Test Area		Tests to be conducted	Major Equipment Required
Biochemistry		Quantitative analysis of routine biochemical parameters and special chemistry parameters (including hormones)	Automated Biochemistry analyser ISE based Electrolyte analyser Automated Hormone Immunoassay analyser (CLIA Based)
Microbiology	Bacteriology	Microscopy, Bacterial Culture & Antimicrobial susceptibility testing for clinical samples Microbiological analysis of Water (H2S test for screening, Coliform presence-absence (PA) test for confirmation)	Binocular Microscope Incubator Automated blood culture Automated bacterial ID/AST system Biosafety Cabinet Class II A2 (model conforming to NSF standards) Bunsen burner with gas supply Computer with scanner, printer, UPS Culture media
	Mycobacteriol-ogy (TB)	Microscopy for AFB CB-NAAT for mycobacteria	Binocular Microscope Fluorescent Microscope Biosafety Cabinet Class II A2 (model conforming to NSF standards) CB-NAAT Bunsen burner with gas supply
	Serology	ELISA, Rapid card tests	ELISA reader and washer VDRL rotator/shaker
	Molecular biology/ Virology (BSL-2)	Real Time PCR & Rapid diagnostic platforms for Influenza, COVID-19 and others Viral load for Hepatitis B & C	Real Time PCR machine Biosafety Cabinet Class II A2 (model conforming to NSF standards) PCR Workstation, ELISA reader and ELISA washer Microcentrifuge PCR hood/PCR workstation
	Media preparation room	Preparation of culture media	Electronic balance Hot plate Autoclave Bunsen burner with gas supply
	Washing & Sterilization area	Washing & sterilization of glassware Sterilization of biomedical waste	Autoclave Hot air oven
Sample receiving and reporting area		Sample acceptance and registration Report generation and delivery	Computer with scanner, printer, UPS

Routine sampling of air or surfaces for culture is not recommended. In special circumstances air culture using slit

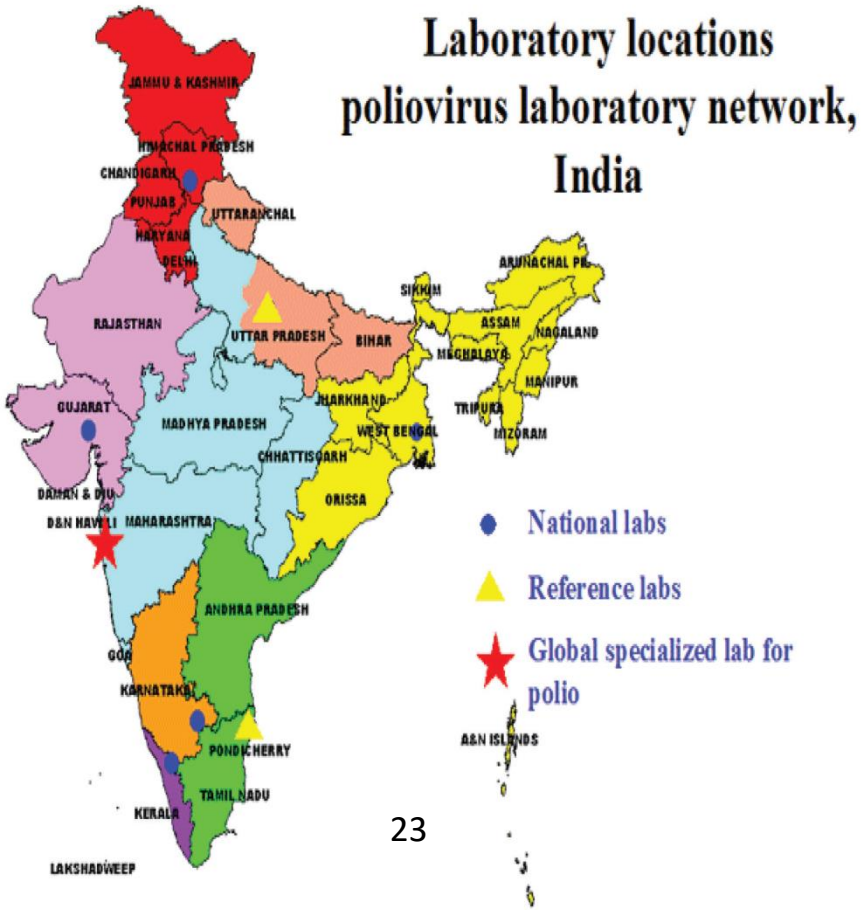
WEEKLY INFORMATION FLOW FROM PUBLIC HEALTH LABORATORY TO A REFERRAL CENTRE



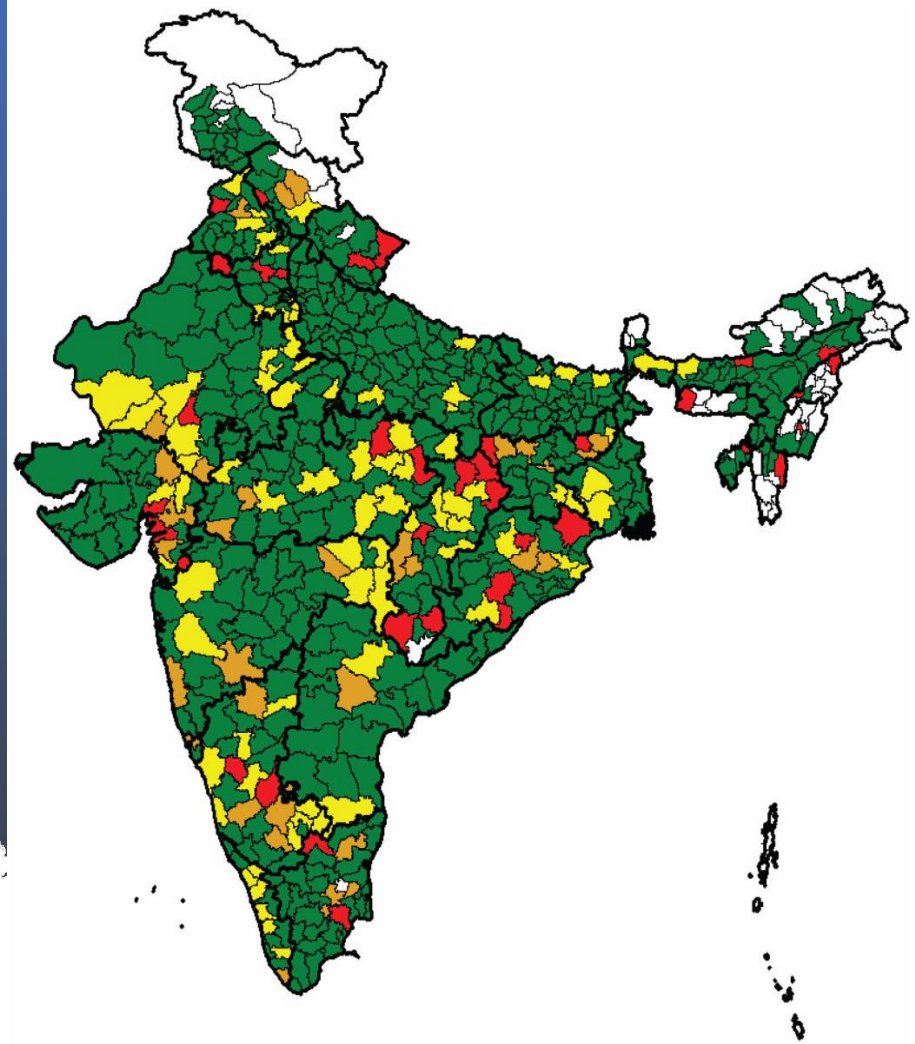
ROLE OF PHLS IN POLIO ERADICATION IN INDIA AND THE NATIONAL POLIO SURVEILLANCE PROJECT(CONTD..)

A network of accredited labs also supports this initiative.

Eight national laboratories constitute the India Poliovirus Laboratory Network, of which one is functioning as a global specialised laboratory and two as upgraded national laboratories performing intratypic differentiation of poliovirus isolates.



STOOL SAMPLE COLLECTION WITHIN 14 DAYS



(AFP Alert, June 2012)

LIST OF PRIORITY DISEASES REQUIRING LAB CONFIRMATION

Types of diseases	Bacterial	Viral	Other causative agents
Epidemic-prone diseases	Acute Diarrhoeal Diseases (Cholera)	Viral haemorrhagic fevers	Scrub typhus
	Typhoid	Avian influenza	
	Shigellosis	Dengue, Dengue Haemorrhagic Fever (DHF)	
	Meningococcal meningitis	Chikungunya	
	Plague	Mumps	
	Leptospirosis	Rubella	
	Diphtheria	Acute Encephalitis Syndrome (Japanese Encephalitis)	
	Pertussis	Kyasanur Forest Disease	
Diseases targeted for eradication or elimination	Yaws	Poliomyelitis (Acute Flaccid Paralysis)	
		Measles	
Endemic epidemics/ other diseases of public health importance	Tuberculosis	HIV	Malaria
	Meningitis	Acute viral Hepatitis – HBV, HCV	Kala Azar
	Enteric fever		
	Syphilis		

Source: Adapted from (WHO, September 2008)

LABORATORY TESTS AT VARIOUS LEVELS

The Government of India revised its Indian Public Health Standards (IPHS) guidelines in 2012 for various levels of facilities and the services (including laboratory testing) that is to be available at each level.

The following table tries to showcase the kind of laboratory tests available to diagnose diseases at each level in the Indian public healthcare delivery system.

Recommended types of tests by disease and levels

Levels	Diseases	Types of tests
Primary Health Centre (PHC)	Cholera	- Macroscopic examination (rice water stool) - Microscopic examination for "shooting star" pattern for *V. cholerae (Hanging drop preparation)*
	Malaria	Rapid Diagnostic Kit (RDK) for Pf malaria in endemic districts Blood smear for Malaria parasite (Mp)
	Meningitis	- Macroscopic (straw coloured, cobweb formation, haemorrhagic) and microscopic examination (direct & after Gram staining on sediment from centrifugation)
	Diarrhoea with blood	- Macroscopic examination (specks of blood/stool mixed with blood)
	Tuberculosis	- Smear for Acid-fast bacilli (AFB)
	Gonococcus	- Microscopic examination after Gram stain on urethral pus
	Syphilis/Yaws	RPR Tests

LABORATORY TESTS AT VARIOUS LEVELS (CONTD..)

Recommended types of tests by disease and levels

Levels	Diseases	Types of tests
Community Health Centre (CHC)	Cholera	- Macroscopic examination (rice water stool) - Microscopic examination for "shooting star" pattern for *V. cholerae (Hanging drop preparation)*
	Tuberculosis	Smear for AFB
	Malaria	Blood smear for Mp
	Gonococcus	- Microscopic examination after Gram stain on urethral pus
	Diarrhoea with blood	Stool analysis for occult blood
	Typhoid	WIDAL
	Syphilis	VDRL
	Diphtheria	Smear for KLB

LABORATORY TESTS AT VARIOUS LEVELS (CONTD..)

Recommended types of tests by disease and levels

Levels	Diseases	Types of tests
Sub-district Hospital (SDH)	Cholera	· Microscopic examination for "shooting star" pattern for *V. cholerae (Hanging drop preparation)*
	Malaria	Blood smear for Mp
	Filaria	Blood smear for filaria parasite
	Meningitis	Gram's stain for Meningococci
	Diphtheria	Smear for KLB
	Tuberculosis	Smear for AFB
	Syphilis	RPR Test
	Typhoid	WIDAL
	Viral Hepatitis	Rapid test for HBsAg, HCV
	HIV/AIDS	Rapid test for HIV

LABORATORY TESTS AT VARIOUS LEVELS (CONTD..)

Recommended types of tests by disease and levels

Levels	Diseases	Types of tests
District Hospital (DH)	Cholera	- Microscopic examination for "shooting star" pattern for *V. cholerae* (Hanging drop preparation), Stool culture for V. Cholerae
	Diarrhoea with blood	Test for occult blood Stool culture for other bacterial enteropathogene – both culture and sensitivity
	Malaria	Blood smear for Mp
	Filaria	Blood smear for filaria parasite
	Meningitis	Gram's stain for Meningococci
	Diphtheria	Smear for KLB
	Tuberculosis	Smear for AFB and Culture
	Syphilis	RPR Card Test
	Typhoid	WIDAL
	Viral Hepatitis	ELISA test for HBsAg, HCV
	HIV/AIDS	ELISA test for HIV
	Leptospirosis	Serology test, ELISA
	Brucellosis	Serology test and culture

Source: (IDSP, 2011)

ADVANTAGES AND DISADVANTAGES OF DIAGNOSTIC TESTS

Diagnostic tests have several advantages and disadvantages and need to be selected as per the local epidemiology as well as the test itself.
One should keep in mind the outcome of the test before selecting the test.

Diagnostic test	Advantage	Disadvantage
Culture based tests	Allow isolation and further manipulation of the strain for antimicrobial susceptibility testing, strain typing, preservation of strain for reference purposes.	Time taking, Depends on the viability of the agent and the validity of the test.
Serology based tests	Rapid, Easy to perform, Can differentiate between acute (IgM) and late (IgG) response	Do not allow the strain isolation, Time of infection not always clear Delayed response (false negative during Seroconversion period) Sensitivity and specificity of the kit needs to be checked as per the local epidemiological data
Microscopy	Rapid, Allows the clinician to initiate the antimicrobial therapy	Sensitivity depends upon the number of organisms present in the sample Problem of correlating between colonisation and infection also viability and hence may lead to overtreatment Does not allow the isolation of the agent
Molecular based tests	Rapid, Allow strain typing and epidemiological correlation in case of source tracing	Time of infection not always clear, Sensitivity and specificity depends on local epidemiological data Problem of correlating between colonisation and infection and also viability, Do not allow isolation of the agent, Expensive

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NATIONAL QUALITY ASSURANCE STANDARDS
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Objectives:

National Quality Assurance Standards for Integrated Public Health Laboratories aim to:

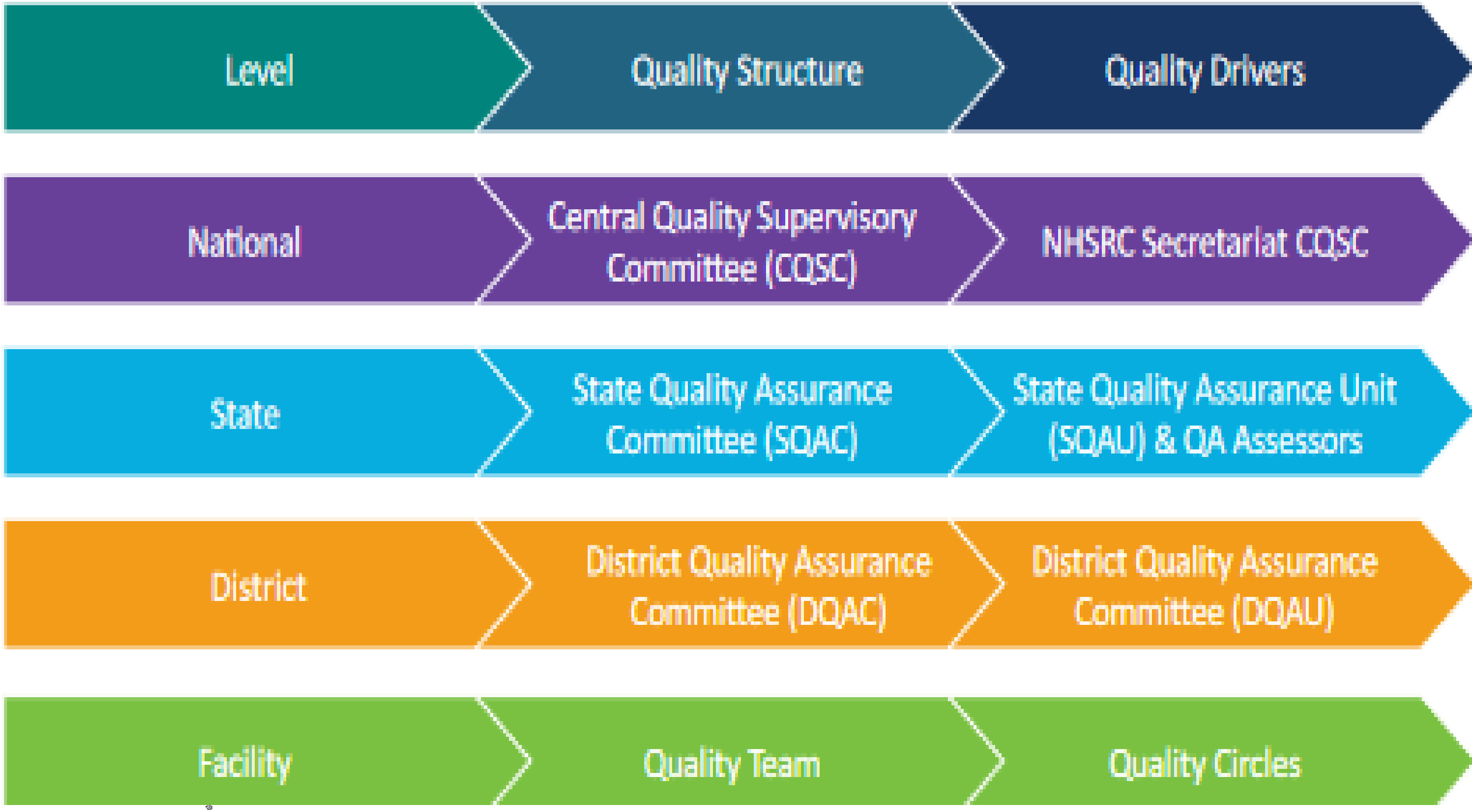
- Ensure the availability of comprehensive, accurate, rapid and quality diagnostics services.
- Reduce errors in laboratory processes and improve the efficiency of the treatment.
- Establish and improve quality management systems, leading to high service standards.
- Ensure excellence in relation to the current knowledge and technical development in laboratory functions.

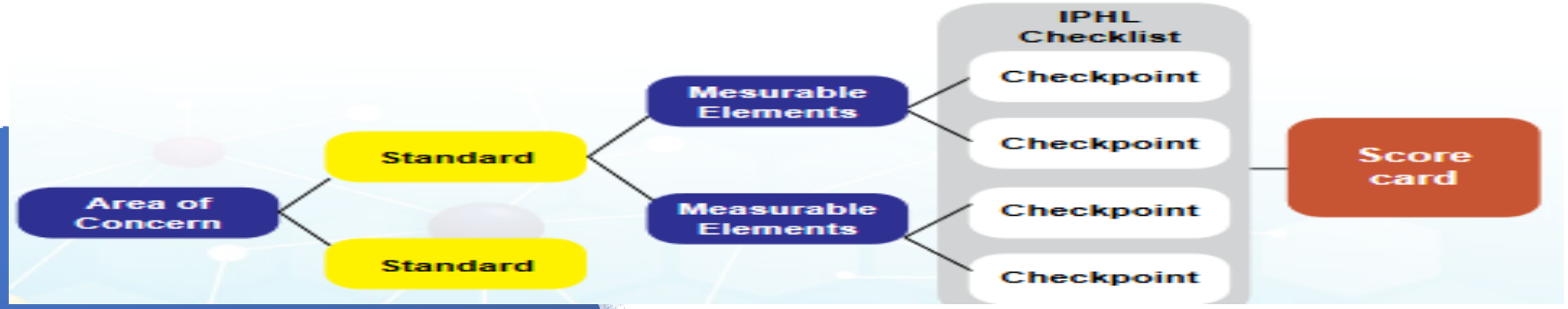
Scope

The National Quality Assurance Standards (NQAS) for IPHL would be applicable to standalone IPHL in a district or co-located with the District Hospital.

As per NQAS for District Hospital 2020 version, Laboratory standards and assessment checklist are part of the Assessor's Guidebook for a District Hospital. It includes quality improvement in sample collection, transportation, testing, reporting and clinical decision-making for all the tests mandated in District Hospital.

NQAS-DH-2020 standards and assessor's guidebook would continue to be applicable to such labs. which are not converted into IPHL. While NQAS certification for IPHL will be mandatory for all the laboratories set up providing diagnostic services as per IPHL guidelines.


Level
Quality Structure
Quality Drivers
National
Central Quality Supervisory Committee (CQSC)
NHSRC Secretariat CQSC
State
State Quality Assurance Committee (SQAC)
State Quality Assurance Unit (SQAU) & QA Assessors
District
District Quality Assurance Committee (DQAC)
District Quality Assurance Committee (DQAU)
Facility
Quality Team
Quality Circles



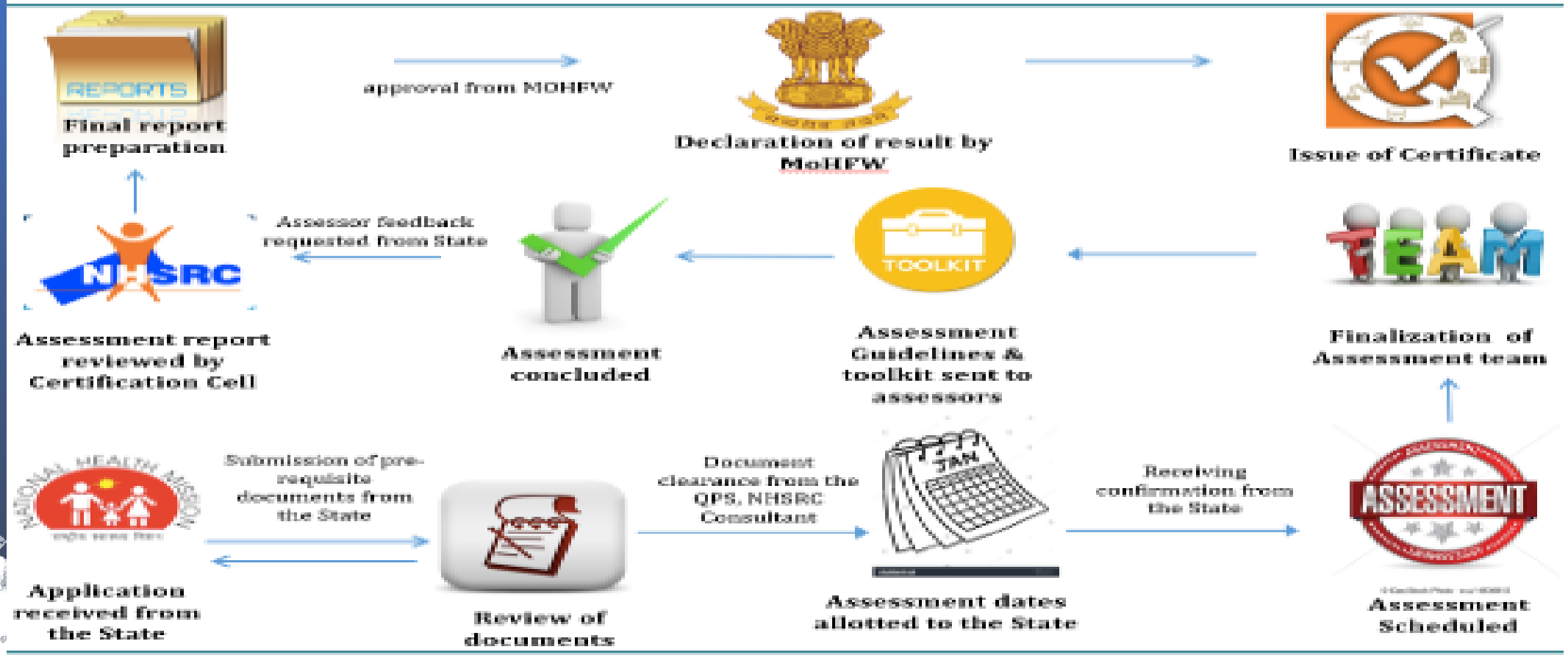


Figure 7 : National Certification Process

IPHL Score Card			
Area of Concern wise Score			IPHL Score
A	Service Provision	50%	50%
B	Patient Rights	50%	
C	Inputs	50%	
D	Support Services	50%	
E	Clinical Services	50%	
F	Infection Control	50%	
G	Quality Management	50%	
H	Outcome	50%	

Figure 3: Schematic representation of Area of Concern wise and Overall IPHL score card

Reference No.	Standards & Measurable Element	IPHL Score
Area of Concern - A Service Provision		
Standard A1	Facility Provides Integrated Diagnostic Laboratory Services as per mandate	50%
Standard A2	Facility provides support services to linked spokes	50%
Area of Concern - B Patient Rights		
Standard B1	The service provided at facility are accessible and affordable	50%
Standard B2	The service provided at facility are acceptable	50%
Standard B3	The facility has defined framework for ethical management including dilemmas confronted during delivery of services at public health facilities.	50%
Area of Concern - C Inputs		
Standard C1	The facility has infrastructure for delivery of assured services, and available infrastructure meets the prevalent norms	50%
Standard C2	The facility ensures the physical safety of the infrastructure.	50%
Standard C3	The facility has established Programme for fire safety and other disaster	50%

National Quality Assurance Standards Checklist for Integrated Public Health Laboratory (IPHL)						
Reference No.	**Measurable Element**	**Checkpoint**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Service Provision						
Standard A1	**Facility provides Integrated Diagnostic Laboratory Services as per mandate**					
ME A1.1	Facility provides comprehensive set of Laboratory services	Availability of Haematology services		SI/RR	Hb%, TC, DLC, Platelet, Red Cell Indices, ESR, BG & Rh typing, Blood cross matching, Peripheral blood film, Reticulocyte count, AEC, Prothrombin time (PT) & International Normalised Ratio (INR), Activated partial thromboplastin time	
		Availability of Biochemistry services		SI/RR	Fibrinogen Degradation Product (FDP) test, D-Dimer, Coombs test direct & indirect with titre, Sickling test for screening of sickle cell anaemia, rapid sickle cell test, DCIP test for screening HbE hemoglobinopathy, G6PD enzyme deficiency	

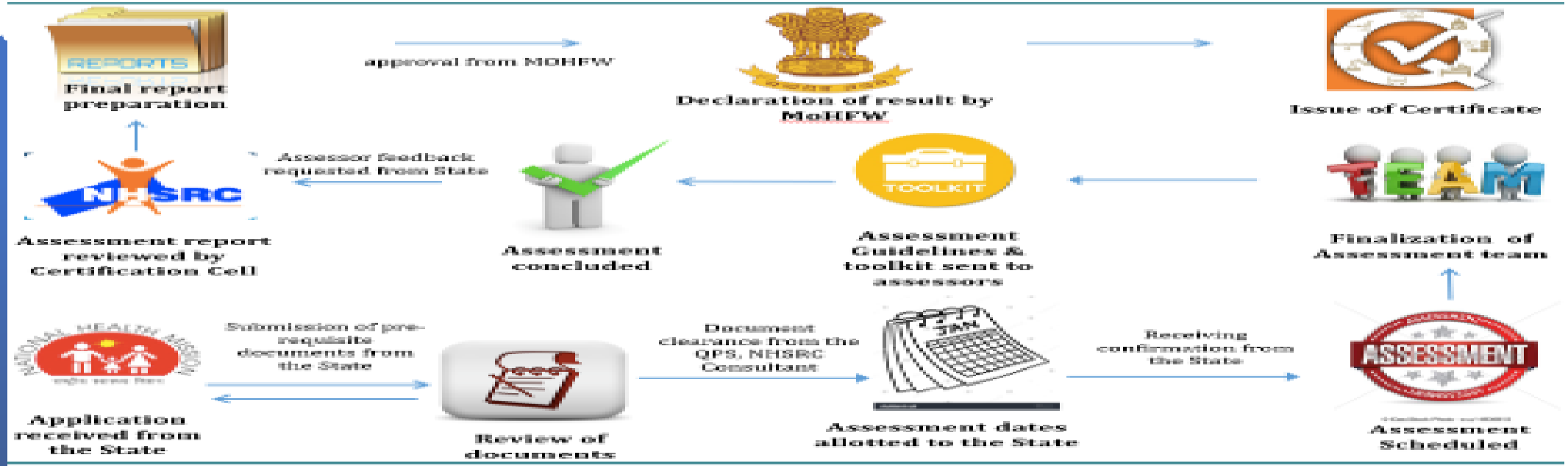


Figure 7 : National Certification Process

Standard G3	Facility have established internal and external quality assurance programs wherever it is critical to quality.	
ME G3.1 Internal Quality Assurance	Facility has established internal quality assurance program at relevant departments	**Applicable to all the departments & special focus on lab services**
ME G3.2 External Quality Assurance	Facility has established external assurance programs at relevant departments	**Applicable to Diagnostic & Pharmacy Services**
ME G3.3 Use of Checklist	Facility has established system for use of check lists in different departments and services	**Applicable to all departments**

StandardG 3	Facility have established internal and external quality assurance programs wherever it is critical to quality.	
ME G3.4 Action Planning	Actions are planned to address the gaps observed during quality assurance process	**Applicable to all the departments**
ME G3.5 Quality improvement	Planned actions are implemented through Quality improvement cycles (PDCA)	**Applicable to all the department**

Expectation

- Accurate Report
- Within turn around time

Why IQC & EQA (External Quality Assessment)

- IQC- Precision
- EQA- Accuracy

QCP – Quality Control Plan

- Documented strategy to control the quality of a measuring system
  - ➢ Minimize failures
  - ➢ Detect non conformities
  - ➢ Implementation of corrective action.

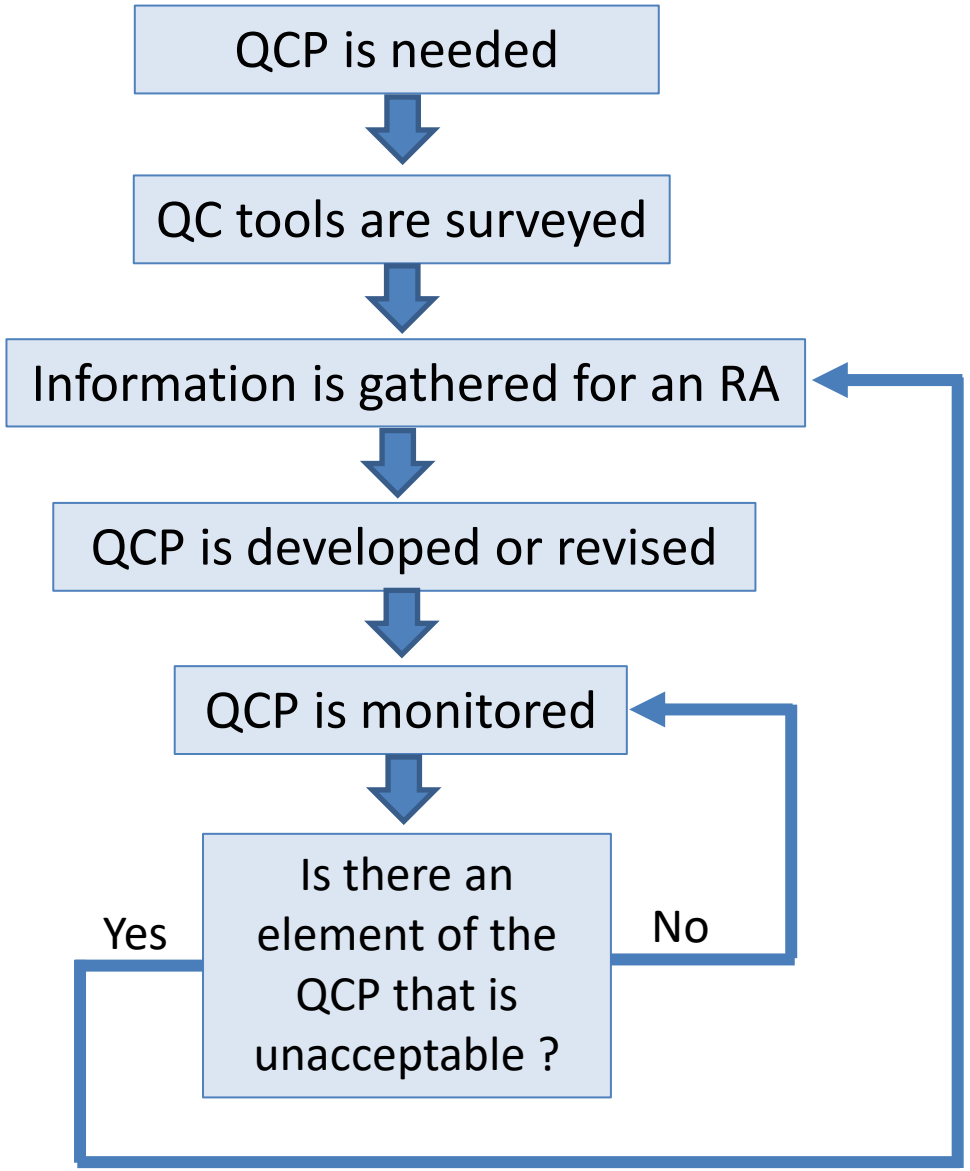
Purpose

MITIGATION OF OCCURRENCE OF ERRORS

APPROPRIATE QUALITY RESULTS OF PATIENTS

INFORMATION IS MEANINGFUL FOR CLINICAL DECISION.

Continual Improvement (Quality Control Plan)



Aims of an EQA

To provide an inter-laboratory comparison:

- allows participants to identify problems with their testing process
- identifies improvement opportunities
- increases awareness of quality benefits

External Quality Assessment

A system for objectively checking the laboratory's performance using an external agency or facility

EQA Participation

- Recommended for all laboratories
- Required by ISO

ISO 15189:2022 Clause 7.3.7.3

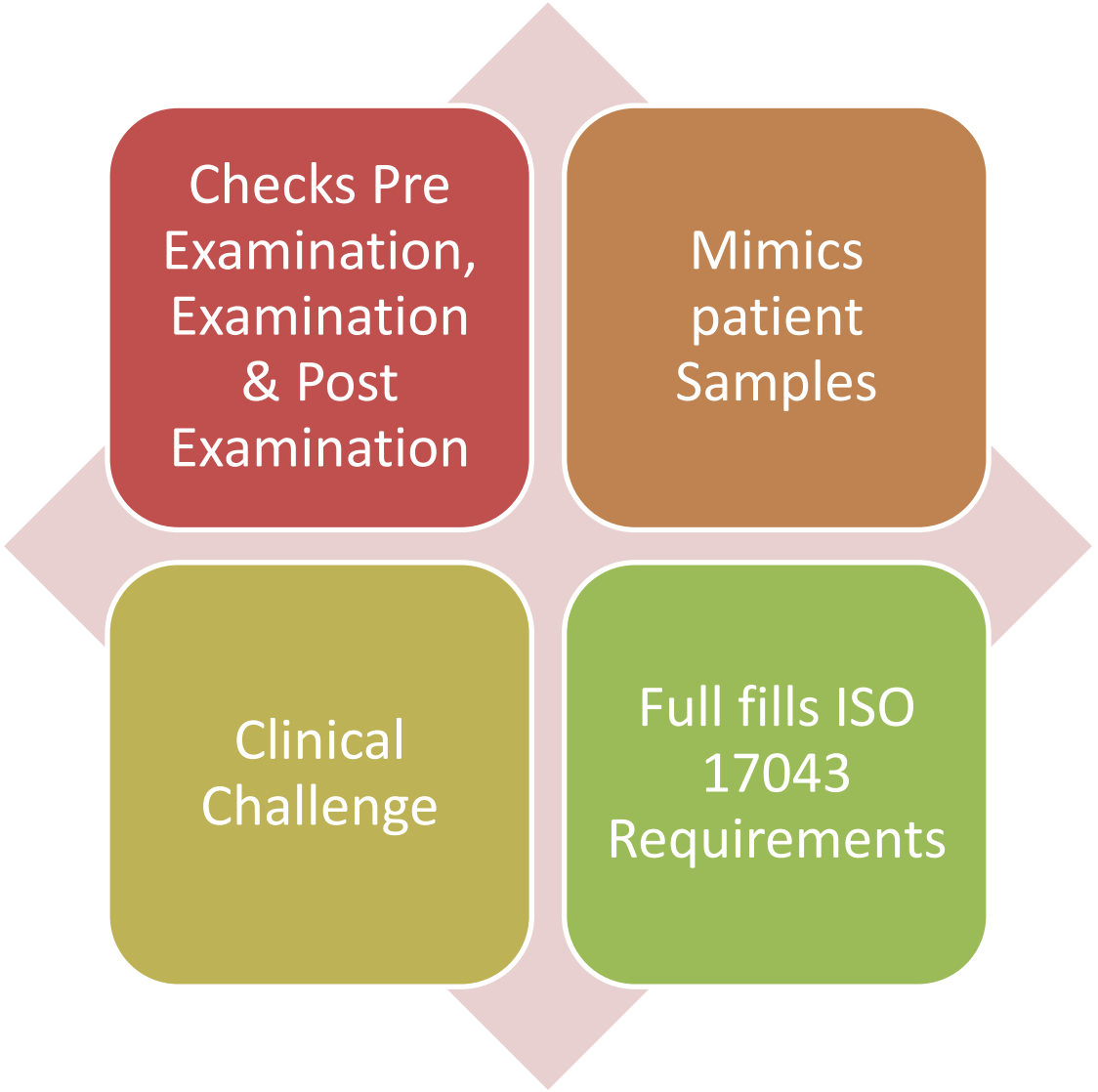
- Comparison of results with other labs
- EQA
- Procedure
  - Enrollment
  - Participation
  - Performance
- Sample processed by person involved in examination

External Quality Assurance Scheme (EQAS)

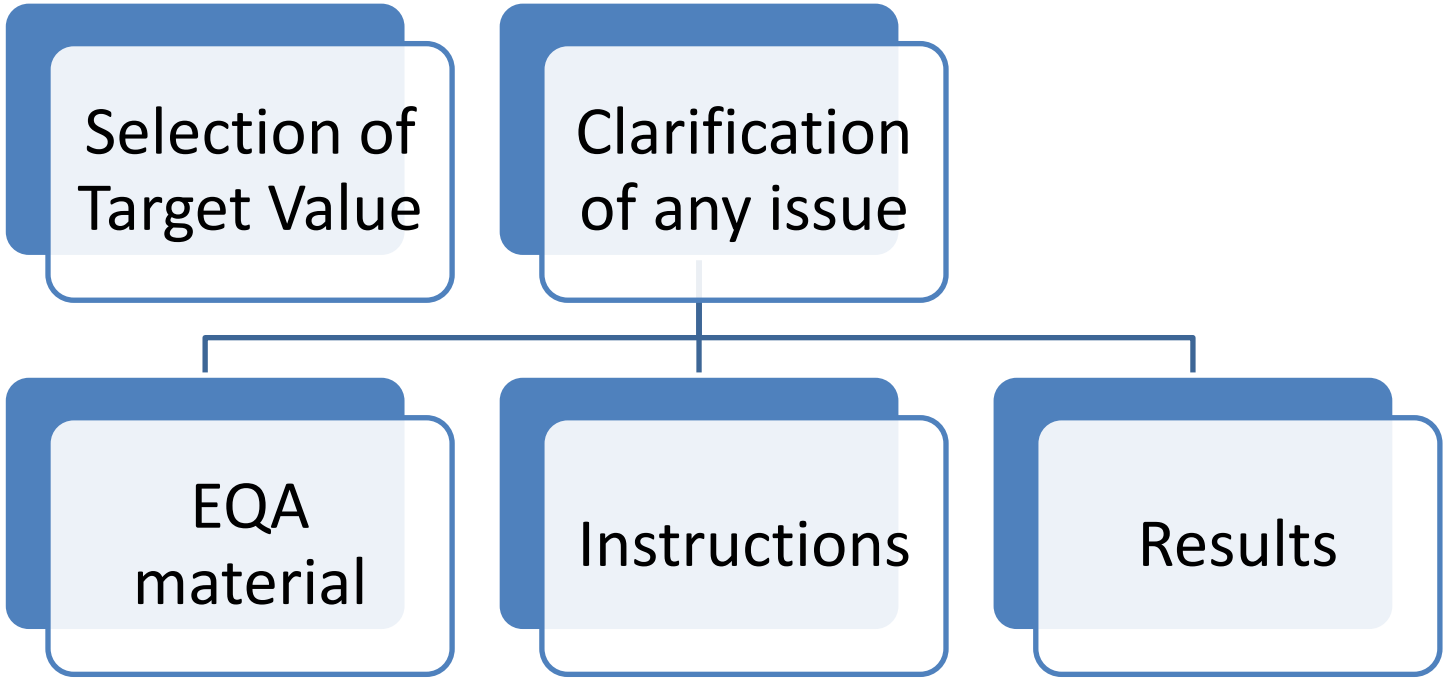
Quantitative- Z Score

Qualitative- Comparison with peer group or evaluation criteria

Selection of EQA Programme

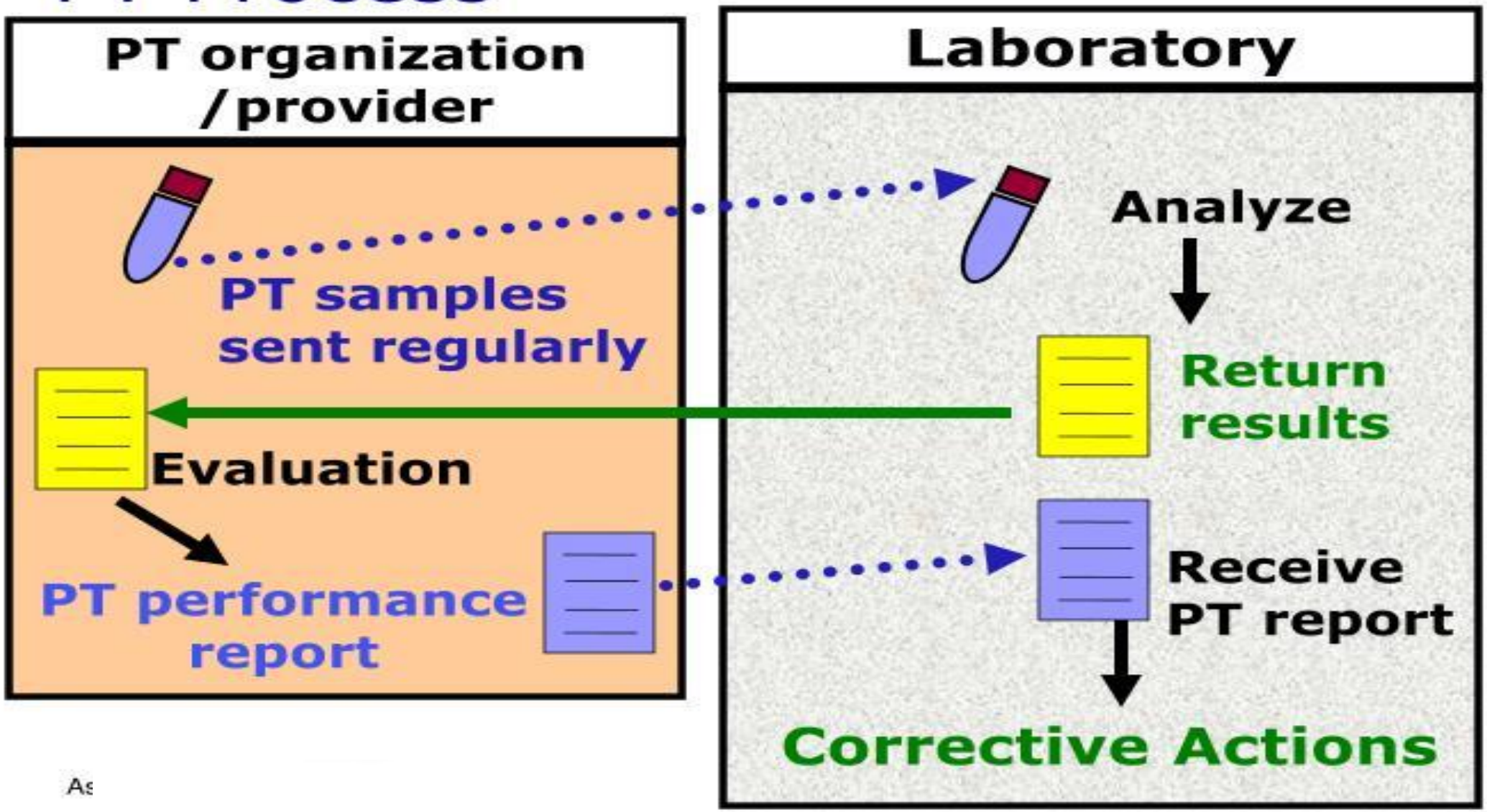


Communication with EQA provider



PT Process

Proficiency Testing

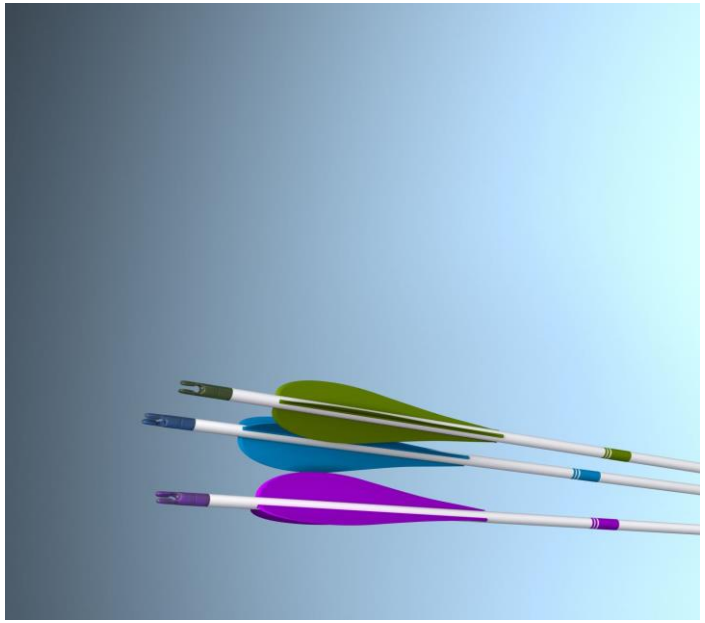


Management Process

- handle and analyze EQA samples
- treat EQA samples same as patient
- monitor and maintain records
- investigate deficiencies
- manage corrective action efforts
- communicate outcomes

Discussion with team

- Performance
- Precautions
- Training



Record Keeping

- Results
- Corrective action

PT Limitations

- PT results are affected by variables not related to patient samples
- PT will not detect all problems in the laboratory
- PT may not detect problems with pre- and postexamination procedures

EQA not Available

EXCHANGING SAMPLE WITH OTHER LABS

SPLIT SAMPLES

REFERENCES MATERIALS

EQAS PARTICIPATION: Govt Sector: Poor participation

IAMM EQAS, Bacteriology SGRH,
New Delhi: Total participants:840
(G164)

Mycology EQAS, PGIMER,
Chandigarh: Total 189 (G 78, p111)

JIPMER , Parasitology EQAS: 69 and
G 41, P 28

Summary

- EQA is a system for objectively checking the laboratory's performance using an external agency or facility
- All laboratories should participate in EQA
- Several methods of EQA in use
- EQA samples must be treated the same as patient samples

Key Messages

- EQA uses valuable resources, make best possible use
- EQA should not be punitive
- EQA should be viewed as educational
- EQA can help direct improvement efforts
- EQA is a critical element of a quality management system

PHL AND POLICY-MAKING

Evidence-based information to use in planning, implementation, monitoring and evaluation of public health programmes.

Outbreaks

Prevention and control of public health events require an efficient public health laboratory system.

improve the performance of laboratories in support of disease surveillance and response.

Outbreaks

Public health events

National Programmes

Immunization Programme

PHL AND POLICY-MAKING(CONTD.)

The laboratory data set the stage for an evidence based investigation and implementation of appropriate control interventions.

Monitoring of laboratory data for existing, emerging and re-emerging pathogens, as well as for drug resistance of pathogens that cause epidemics can provide early warning of public health events.

The laboratory data can provide evidence for introduction of new vaccines, updating of existing vaccine composition, and guidelines on treatment and prevention policies and protocols at both national and regional levels.

Building laboratory capacity, including networking at national and regional levels, is therefore essential for successful implementation of the IDSP strategy.

THANK YOU