

WHO online Pilot training program on External Quality Assurance for Immunohaematology Laboratory in Blood Establishments for countries in SEAR

Participant Countries:



18th -20th of November 2021

Program Overview

The online pilot webinar program is designed to provide an in-depth knowledge and technical aspects of organising an External quality assurance programme for Immunohaematology Laboratory in Blood Establishments at national level for the countries in the South-east Asian region

Objectives

- To provide stepwise approach to plan and develop a national level EQAS program in immunohaematology
- To provide the technical inputs to organise an EQAS program in immunohaematology

Who can attend?

Transfusion medicine specialists, Pathologists, Blood Bank officers, Blood Bank technologists, Quality managers, Health/ Blood Regulatory authorities

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External Quality Assurance for Immunohaematology Laboratory in Blood Establishments for countries in SEAR

WHO – Online Pilot webinar series in Association with Department of Transfusion Medicine and Immunohematology, St John's Medical College, Bangalore, India

Day 1; 18th November 2021

Time GMT-Hrs. (IST)	Opening Session	
5:30am – 6:00am (11:00am -11:30am)	Inauguration Welcome address <ul style="list-style-type: none"> Introduction to the WHO training Global and regional scenario 	Dr. Sitalakshmi Subramanian, St. John's Medical College, Bangalore, INDIA Dr. Aparna Singh Shah -WHO, SEARO Dr Yuyun S Maryuningsih-WHO, HQ =

Time GMT-Hrs. (IST)	Topic	Speaker	Moderators
6:00am - 6:30am (11:30am – 12 Noon)	Introduction to EQAS	Dr. Sandy Walker, NRL, Australia	Dr. Sukesh C Nair Dr. Teguh Triyono Dr. Md Ashdul Islam Dr. Sitalakshmi Subramanian Dr Shamee Shastri Dr. Aparna Singh Shah
6:30am-7:00am (12 Noon - 12.30pm)	Establishment of EQAS	Dr. Joy Mammen, Vellore, India	
7:00am-7:30am (12.30pm – 1:00pm)	Needs assessment and role of stake holders	Dr. Rekha Manandhar, Nepal	
7:30am - 8:00am (1:00pm - 1:30pm)	Q/A session		
8:00am – 8:30am (1:30pm – 2:00pm)	Role of documentation	Dr. Nusret Nuri Solaz, Turkey	
8:30am – 9:00am (2:00pm - 2.30pm)	Role of Information management	Dr. Joy Mammen	
9:00am – 9:30am (2.30 – 3pm)	Q/A session Feedback		

Time GMT-Hrs (IST)	Day 2; 19 th November 2021		
5:30am – 6:00am (11:00am -11:30am)	Overcoming challenges in establishing EQAS program in resource limited settings	Dr. Md Ashadul Islam, Bangladesh	Dr. Rekha Manandhar Dr. Teguh Triyono Sandy Walker Dr. RK Chaudhary Dr. Sitalakshmi Subramanian Dr. Aparna Singh Shah
6:00am - 6:30am (11:30am – 12 Noon)	Design and operation Technical aspects of operation	Dr. Gajendra Gupta, Jaipur, India	
6:30am-7:00am (12 Noon - 12.30pm)	Designing format and performance monitoring	Dr. Sukesh C Nair, Vellore, India	
7:00am-7:30am (12.30pm – 1:00pm)	Q/A session		
7:30am - 8:00am (1:00pm - 1:30pm)	EQAS for Quality improvement	Dr. Teguh Triyono, Indonesia	
8:00am – 8:30am (1:30pm – 2:00pm)	Q/A session Feedback		

Day 3; 20th November 2021

Time GMT-Hrs. (IST)	Topic	Speaker	Moderators
5:30am – 6:00am (11:00am -11:30am)	EQAS for education and training	Dr. Narinder Naidu, Mumbai, India	Dr Gajendra Gupta Dr Joy Mammen Dr. Sitalakshmi Subramanian Dr. Aparna Singh Shah
6:00am - 7:00am (11:30am – 12:30 pm)	Case Discussion in Immunohaematology	Dr. RK Chaudhary, Lucknow, India Dr. Sanmukh Joshi, Surat, India Dr. Shamee Shastry, Manipal, India	
7:00am - 8:00am (12:30pm - 1:30pm)	Panel Discussion and the Way forward		Dr. Aparna Singh Shah Dr Sandy Walker Dr. Shamee Shastry Dr. Rekha Manandhar Dr. Md Ashadul Islam Dr. Teguh Triyono Dr. Suresh C Nair Dr. Joy Mammen Dr. Narinder Naidu Dr. Gajendra Gupta Dr. Sitalakshmi Subramanian Dr. R K Chaudhary Dr. Sanmukh Joshi Dr Nusrat Nuri Solaz
8:00am (1:30pm)	Q/A session Feedback		

Report on WHO ONLINE PILOT TRAINING ON EQAS IN IMMUNOHEMATOLOGY FOR BLOOD ESTABLISHMENTS

18 Nov to 20 Nov 2021

**Coordinated by Regional Office for South East Asia – WHO (New Delhi) and
St John's Medical College, Bangalore**

Day 1

(Video recordings available for all three days)

The Message of the Regional director Dr Poonam Khetrarpal Singh on the occasion of World blood donor day 2021 was shared with the participants.

The WHO South-East Asia Region continues to accelerate action to ensure that everyone, everywhere has timely access to sufficient and secure blood and blood products, and safe transfusion services. Blood transfusions are required to treat and manage a range of health conditions that people from all countries, of all incomes, experience, from thalassemia and haemophilia, to complications during pregnancy and childbirth, severe trauma, and surgical procedures. And yet, globally, 42% of blood is collected in high-income countries, which are home to just 16% of the world's population. In lower-middle-income countries, the median blood donation rate is 6.8 per 1000 people. In low-income countries, it is five. The Region requires at least 2 million more units of blood every year, which must be mobilized from voluntary, non-remunerated donors. WHO is committed to supporting all countries in the Region to increase safe and secure donations, especially from the young – a key focus of this year's World Blood Donor Day celebration: "Give blood and keep the world beating".

The Region has in recent years made steady and sustained progress. All countries in the Region have developed national blood policies, which they continue to implement. Most countries have in place national guidelines on the appropriate clinical use of blood, which is critical to preventing unnecessary transfusions and efficiently utilizing available blood stocks. Based on data from the Global Database for Blood Safety, 100% of all blood donated in the Region is screened for transfusion transmitted infections. The proportion of blood donated by voluntary, non-remunerated donors is more than 80%. Between 2013 and 2018 the Region increased blood donations by 2.37 million units – the third highest increase globally. All countries in the Region are committed to achieving universal health coverage (UHC), which inter alia requires everyone, everywhere to have access to safe, sufficient and secure blood, blood products and services.

Amid the ongoing COVID-19 response, WHO will continue to support countries in the Region to maintain and strengthen blood donation and blood transfusion services. Over the past 18 months, all countries have implemented public awareness campaigns aimed at mobilizing voluntary, non-remunerated donations. Most Member States have facilitated transportation for donors, helping offset the impact of public health and social measures, which continue to be applied or relaxed based on epidemiological evidence. In all countries of the Region, management of blood stock inventory has been a key priority, helping ensure transfusion-dependent patients, such as those with thalassemia and sickle cell anaemia, do not suffer due to lack of blood. These and other interventions must continue to be strengthened, with a focus on consolidating and expanding supply, and enhancing haemovigilance.

As today's commemoration highlights, young people must be at the fore of blood recruitment strategies. Young people are full of idealism, enthusiasm and creativity. Region-wide, hundreds of millions of young people are looking to change their communities and countries for the better. Voluntary, non-remunerated and regular blood donation is one of the most effective, impactful ways that young people can save lives and improve people's health. To empower young people to act, increase overall donations, and achieve lasting generational change, intensified public outreach and engagement is essential. We can all contribute. Throughout the COVID-19 crisis, regular blood donors have continued to give, despite limited mobility and other challenges. Their extraordinary effort has increased health system resilience and must be celebrated for what it is – a lifesaving gift, and an expression of human solidarity. Throughout the COVID-19 response, but also beyond it, every person's contribution takes us one step closer to achieving UHC, the Flagship Priority and Sustainable Development Goal target that underpins all others. On World Blood Donor Day, WHO reiterates its commitment to support all countries in the Region to provide sufficient and secure blood and blood products, and safe transfusion services, to all who need them. The gift of life is ours to give.

Global scenario on external quality assurance in immunohematology laboratory by HQ Dr Yuyun Siti Maryuningsih

Blood transfusion is an essential and life-saving support within the health care system therefore, the safety of blood should be assured.

Development of guidelines on Availability, Safety and Quality of Blood, urges Member States to establish quality systems, for the processing of whole blood and blood components

Quality Assurance comprises everything that the laboratory does to assure a high-quality service to its users, through two kinds of process: Internal Quality Control (IQC) and External Quality Assessment (EQA).

WHO has launched the Quality Management Programme (QMP) for blood transfusion services in 2000, where addresses quality assessment as an integral component of a quality system

Quality assurance in Immunohaematology through an External Quality Assessment Scheme: National or Regional EQA schemes for blood transfusion safety focus primarily on blood group serology and testing for transfusion-transmissible infections

EQAS on Immunohematology for BE: blood group serology, antibody screening and crossmatch

Improve safety and reduce adverse reaction of blood transfusion

Part of ongoing improvement that is needed in line with patient safety demands and technological advances

WHO action framework for Blood 2020-23

Strategic direction to global efforts to address present barriers to safe blood

Listed Six strategic objectives (SOs) to cope the challenges

SO. No.3: Functioning and efficiently managed blood services

2023: Development of Guidance on quality assessment of blood products, associated substances, medical devices, and IVD

Training and country assistance in implementation of quality assessment

Concluding remarks

Safety, effectiveness and quality of blood transfusion is still a challenge, faced by some countries, especially low income countries.

Good blood transfusion laboratory practice, in Immunohematology and Transfusion Transmissible Infections testing is one of the challenges.

WHO has provided WHA Resolution and numbers of guidance documents related to quality system, as well as training module on Quality Management System that can assist countries to improve their quality system of blood transfusion chain.

Dissemination of guidance documents through workshops or webinars and training, plays key role to assist countries in implementation of EQAS and improving their blood

She highlighted the need for technical assistance and guidance to initiate EQAS program in immunohaematology

Overview of EQAS by Sandy Walker

EQAS is for quality improvement

EQAS and IQC are different

Quality assurance methods encompass all the stages of testing process

The role of EQAS provider and participant was discussed

Aim of EQAS

To assess the integrity of entire testing process

The panel samples must be correctly identified by the lab, tested appropriately and reported without error

Aim of EQAS is to monitor the performance of the lab by comparing the results with participating labs and reference results

It helps to identify errors and design trouble shooting activities

It offers self appraisal

Identify training needs

Evidence of competence assessment and continual improvement

How to choose a quality EQAS

Discussion on panel design

EQAS provider should have a functioning QMS

Organisation of EQAS:

Define and State the need for participation

Understand the different types of schemes and organisations

Understand the importance of material preparation

Explore assessment methods

Maintain quality of EQAS program

Key points

Participation in EQAS is essential to ensure accuracy

Organising agency must have a range of strengths

Preparation of material is key to organising a cost effective program

Sound statistical model

Use of technology

Knowledge and education to participants

Importance of EQAS

Evaluation of performance

Identification of problems

For accreditation

Education

For national programmes - Evidence based programming to influence policy decisionsStakeholders

Types of schemes

Quantitative to quantify one or more of the measurands of the proficiency test items

Qualitative to identify or describe one or more characteristics of the proficiency test item

Sequential where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the provider at intervals

Simultaneous scheme test items distributed for concurrent testing or measurement within a defined time period

Single exercise items provided on a single occasion

Continuous schemes where items are provided at regular intervals

Sampling where samples are taken for subsequent analysis

Needs assessment and Role of Stakeholders Dr Rekha Manandhar

She highlighted the existing blood transfusion services in Nepal

Nepal has 112 blood transfusion service centres (BTSC) in all 77 districts, where National Bureau for Blood Transfusion Services (NBBTS) at National Public Health Laboratory (NPHL) been designated as coordinating/regulatory body. To run BTSC in efficient manner and to enhance quality of services with long-term sustainability, a long-term planning is very much critical and would be important tool to meet the current challenges. NPHL have planned for the development of five year National strategic Plan (2021-2025) for safe blood transfusion services.

WHO plays a pivotal role in improving availability and accessibility of safe blood for all Member States. NPHL would like to revise the existing strategic plan in light of WHO framework to advance universal access to safe blood.

Key elements

Organisation of QMS

Training of staff

Role of EQAS

Report of Dr Solaz

OPERATING AN EQA SCHEME IN BLOOD GROUP SEROLOGY- Documentation & Internal Audit

Providing safe, sufficient, sustainable blood for the patients is the main duty of Blood Organizations.

Quality is the backbone for complying this duty and;

a. should be based on concrete scientific references as it is said "service is an art; quality is a science"

b. is not the only responsibility of practitioners but also policy makers and management should get responsibility too

c. cannot be risked so it needs double check; internal and external audit systems should be

Documentation can be defined as;

a. material that provides official information or evidence or that serves as a record

b. the process of classifying and evaluating texts, photographs, etc.

Based on above information documentation should be consisted of action and material. Any quality action without concrete document will be incomplete.

Main philosophy of documentation can be expressed as «Do what you document, and document what you do» implemented together

Documented quality action is important not only by scientific wise but also legal wise too.

Documentation types can be divided by 2 major topics;

- user documentation / technical documentation
- digital / hard copy documentation

Documentation of EQA is the corner stone of effective communication and understanding between the EQA system and the organization.

Documentation such as SOPs, forms, records, reports, etc. should be clearly understandable by the provider, organization and the practitioners

List of EQAS documentation in blood group serology

Preliminary questionnaire for participating laboratories

2. Registration form for participating laboratories

3. Techniques for the conversion of plasma to serum and preparation of Alsever's sol.

4. Product insert

5. Exercise instructions

6. Exercise results form

7. Exercise check list

8. Record of exercise distribution and return results

9. Exercise analysis and report

10. Numerical scoring systems

Internal auditing is the independent and objective evaluation of an organization's internal controls to effectively manage risk within its risk appetite.

Internal audit should monitor that any weaknesses identified are also addressed.

Check lists are the essential tools of effective internal auditing

Internal audit is aimed to check all parts of the tests such as equipment, test materials, procedures, etc. in blood group serology

It will be wise to establish an internal audit system which is in a harmonization with EQA.

Internal audit should be based on a concrete plan and results should be evaluated periodically

Continuous process control and improvement are essential for effective internal audit.

Basics of internal audit in Blood group serology

For which tests

b. By which technics

- c. By which equipment
- d. How often
- e. How many
- f. By whom

Learning outcome on documentation

1. should be established realistically; do what you document, and document what you do
2. should be clearly understandable by all related parties
3. should be secured by high consideration (digital / hard copy)
4. is important both for medical and legal aspects

Learning outcome on Internal audit

should be independent and objective

2. should check all parts of the tests
3. should be in a harmonization with EQA
4. should be in continuous process control

Information management in EQAS DR Joy Mammen

Data is generated throughout the cycle of EQAS schemes

It is important to capture and manage data from two perspectives

Organisers perspective –

Customer relationship management

Survey management

Subscription management

Reports and statistics

Participants perspective

Profile management

Result submission

Report generation

Implementing a system to manage data is the key to efficient operation

Day 2

EQAS in Resource limited settings Dr Ashaul Islam

Learning objective:

To promote participation of BTS laboratories in appropriate EQA schemes

The core areas discussed were:

Principles of EQA

Objectives of EQA

Benefits of EQA

Organization and process of EQA

WHO-EQA schemes

Challenges in implementation of EQA

Overcome the challenges in implementation of EQA

Key points:

External quality assessment provides confidence in the overall performance in the laboratory

EQA is one of the tools used to monitor and improve quality

The external quality assessment of a laboratory's performance using samples of known but undisclosed content, and including comparison against other laboratories

Organisation of EQAS involves

Transport of specimens

Testing by participating laboratories

Turnaround time

Documentation of results and feedback

Improvement of performance

Basis of success of EQAS scheme

Voluntary participation

Confidentiality of individual report

Avoiding provocative statements

Identify unsatisfactory performers in groups/ individuals to identify trends

Providing educational opportunities

Organizer acts as adviser rather than enforcer

Benefits to participating labs

Comparison of performance and results

Minimization of errors

Self-appraisal

Objective evidence of quality

Identification of training needs

Challenges in implementation of EQAS

Inadequate infrastructure

Inadequate Logistics support

Good quality testing reagents and Kits in place?

Well functioning Equipment's?

Lack of skill manpower

Periodic training of manpower?
 Unwillingness of the participating laboratory
 Lack of initiatives from the participating laboratory
 Commitment of Transfusion Medicine Expert?
 Directives from the National Blood Centre/National Health authority?
 Strong commitment from the government sector?
 Resource allocation and financial support from the government?
 Not included this issue in the annual operational plan
 Not include this issue in the Governmental revenue budget
 How to overcome the challenges
 Motivate local health authority to allocate additional space for EQAS or
 Identify small area in the participating laboratory for EQAS in small scale
 Resource mobilization for logistic, reagents, kits & equipment from the National health authority/NBC/WHO or
 Utilization of Local Blood Transfusion fund (Participating Laboratory) for successful completion of above function
 Request WHO & International EQAS Scheme by national health authority/ NBC for organizing training program for
 capacity development & skill manpower
 Advocacy program for motivate participating laboratory for active participation in EQAS –Program
 In house motivation as well as intense counseling is needed for Transfusion Medicine Expert to be self motivated for
 EQAS-Program
 Strengthening of the activities of Blood Transfusion services by Transfusion Medicine faculty to create environment for
 directive regarding EQAS from NBC/National Health Authority
 Strong recommendation from WHO and International EQAS is needed for government commitment as well as allocate
 financial support for EQAS-program
 Initiative should be taken to include EQAS –issue in Annual Operation Plan
 Financial allocation will be included in the Governmental Revenue Budget
 Request WHO and International EQAS –Scheme to establish at least one NQAS centre or RQAS centre in resource limited
 setting for further countrywide EQAS-Program
 Periodic training and monitoring can be organized by WHO and NBC with the help of International EQAS-Scheme for the
 participating laboratory personnel
 Rigorous monitoring can be done by the National Health Authority/NBC or National Safe Blood Transfusion
 Program(NSBTP)
 Organize/ arrange frequent orientation and advocacy program to involve more Transfusion Medicine Department/Blood
 Transfusion Centre in EQAS-program
 EQAS- Bangladesh Perspective
 Blood Transfusion Services started in Bangladesh on 1st March 1950 in Dhaka Medical College Hospital
 Blood Transfusion Service Committee formed in 1952
 Government framed a By-Law named Blood Transfusion by-Law in 1954 to run the activities of the Blood Transfusion
 Services of Bangladesh
 Bangladesh National Council of Blood Transfusion formed in 1976
 Government reorganized Blood Transfusion Service as National Safe Blood Transfusion Program (NSBTP) from 31st
 December-2019
 “Safe Blood Transfusion Act” passed in the parliament in 10th april-2002 as “Safe Blood Transfusion Act-2002”
 Rules of this law has been completed and SRO-issue on 17th June-2008 as “ Safe Blood Transfusion Rules-2008”
 “National Blood Policy” approved by the government and gazette from the government press on 28th November-2013
 Starting National Safe Blood Transfusion Program

Establishment of EQAS program Dr Gajendra Gupta

Objectives

To understand the setting up , organization and coordination of EQAS program.

- To learn how to document quality manual, SOP and processes for the program.
- Sample preparation, storage, transport and quality control.
- Statistical analysis of results

Key points

Organizational set up for EQAS.

- Policies, SOPs, processes for EQAS.
- Sample preparation, storage, transport, reporting and analysis.
- Reporting of EQAS.

Aim of proficiency testing program

To provide a proficiency testing program that will allow participants to identify and rectify any inaccuracy in their Blood Bank practice

Objective

To design and implement a program that will evaluate performance of Immunohaematology laboratories, Transfusion transmitted infection testing and hematological quality testing of blood and blood components of blood banks and their longitudinal performance by appropriate analysis and provision of providing report to the participants

- Identify potential inaccuracies that occur in “Transfusion Medicine ” practice Immunohaematology, TTI Testing and Haematology Testing reflection of education, training and quality assurance practice
- To establish the effectiveness and comparability of different methodologies and evaluation of performance characteristics of a method

Objectives of EQAS

Identification of differences between laboratories and identifying reason for the same

- Provide education and training as interventions to improve participants
- Source, prepare and distribution materials of necessary stability and homogeneity in a cost effective manner to provide the challenge to the participants
- To eventually improve national standards and harmonize practice of transfusion medicine among the participants and demonstrates impact on patient care.

Benefit to Participating Blood Bank:

- Identify and evaluate the capabilities of Blood Bank
- Guide Blood Bank in corrective action and improvement
- Provide continuing education to Blood Bank staff on standard diagnostic methods.
- Raise awareness of the successes and challenges in Blood Bank practice
- Provide information for advocacy

Summary

1. Initial step - setting up committees.
2. Resource planning - set up of centre and HR.
3. Quality policies, SOP and procedures documentation.
4. Steps of sample preparation. Storage, packing, transport and analysis.
5. Reporting

The session included video demonstration of the entire process of preparing the sample for EQAS, packing, transportation, statistical analysis and report preparation

Role of EQAS for Quality improvement – Dr Teguh Triyono

Transfusion of safe blood Involves a number of processes.

There is a risk of error in each process from the selection of blood donors, the collection, processing and testing of donated blood, the testing of specimens from potential transfusion recipients, and the issue of compatible blood and its administration to the recipient.

Errors in IH lab may be due to

- Inadequate procedures for identification of donor specimens
- incorrect storage or use of inappropriate reagents
- improper equipment maintenance
- poor testing practices
- inaccuracies in recording or transcription
- improper procurement practices
- inadequate staff training.

The implementation of a quality system in the laboratory minimizes errors and ensures

- Appropriate tests are performed on the correct samples
- Accurate results are obtained
- Correct blood product is provided for the correct patient at the correct time.

Quality control processes to be followed by IH labs:

Participation in atleast one EQAS programme with periodic assessment

Daily use of positive and negative controls to monitor analytical performance

Internal quality control of equipments, reagents, procedures

Regular inspections to ensure compliance with required standards

EQAS is the The external assessment of a laboratory's overall performance in testing exercise material of known, but undisclosed, content and comparison with the performance of other laboratories that have tested the same material.

The objectives of EQAS are:

- assess laboratory performance and the ability to determine the correct results
- identify any errors in the laboratory
- stimulate laboratory personnel to improve their performance and the use of standard methods
- encourage the establishment and implementation of quality systems with the relevant standards

EQAS results are:

- are collated and accuracy scores are determined.
- These should be communicated to all participating laboratories (in coded or uncoded form, according to local agreements) in order to enable each laboratory to compare its own quality standards with those of a large number of other laboratories

EQAS report

- EQA provides a "snapshot" of laboratories' performance and, inevitably, the information reported back to them can give only a retrospective view of performance at the time the exercise was completed.
- Each participating laboratory should receive an individual confidential report stating the expected results of the exercise, together with its own results.
- A simple analysis of the number of laboratories that obtained, or failed to obtain, the expected results may also be included in this initial report.

Benefits of EQAS to the participating labs

- identification of opportunities for improvement relating to laboratory processes
- comparison of a laboratory's own performance with that of other participating laboratories
- comparison of performance between different testing systems
- provision of information and education to improve performance
- encouragement of best practice
- opportunities to enhance the credibility of the laboratory and increase public confidence
- access to a network of laboratories for the exchange of information

Benefits of EQAS for Regulatory authorities

- establishment of a network of blood transfusion laboratories with a known standard of performance
- training and education of laboratory staff
- provision of useful information to assist in:
 - setting standards
 - reviewing testing strategies
 - postmarket surveillance of test kits, reagents, instruments — using resources effectively
 - improving public confidence in the blood transfusion service — supporting systems of accreditation.

Methods for improving and maintaining transfusion quality

Active reporting, structured investigation, and systematic resolution of transfusion-related errors are effective methods.

Continuous quality improvement

- Requires ongoing monitoring and review of the effectiveness of all elements of the quality system, using both internal and external mechanisms, to ensure that the defined quality standards are being met consistently
- External assessment of the quality system in the laboratory includes participation in an appropriate EQA programme and

Report on Designing Format and Performance Monitoring DR Sukesh

- To ensure accuracy towards blood safety the EQAS should cover all Process Requirements involved in an Immunohaematology Laboratory
- Designed to provide insight into the complete path of workflow of the laboratory, and not just the testing processes — all process requirements involved in a IH laboratory.
- To include long term follow-up of laboratory performance.
- To provide education to participants and promote quality improvement.
- o Educational/advisory comments can be part of the report.
- It is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

EQAS for IH may be :-

- Qualitative scheme — where the objective is to identify or describe one or more characteristics of the sample sent for testing or Semi-quantitative
- Simultaneous scheme — where samples are distributed for concurrent testing to all the labs within a defined time period or
- Continuous scheme — where samples for testing are provided at regular intervals

Interpretation on the results — data obtained is to be transformed to provide an interpretation

Parameters tested are:

- Blood grouping and Rh typing of recipient
- Blood grouping and Rh typing of Donor
- Crossmatch- Compatible/Incompatible with Reason for incompatibility, Saline/ Coombs
- Antibody testing that caused incompatibility
- ICT/ IAT (indirect Coombs/Antiglobulin test)- use of O pooled Screen cells (2/3 cells)
- Antibody identification
- Issue of compatible unit (Post analytical)

Recipient and donor sample will ensure

Sample acquisition, Processing, Testing, Result Validation and Interpretation

Proficiency test items should match in terms of matrix and is as closely as practicable to the type of sample encountered in routine testing.

Spiking samples

Use natural samples identified in blood bank (ideal)

Design for Compatibility testing:

- 3 donor units in addition to recipient, which will allow 4 grouping and Rh typing per round and 3 compatibility too.
- Only to use common phenotypes prevalent in the region
- Only to use cases with antibodies identified commonly to antigens in the region

How can EQAS provider Prevent collusion or falsification of results

- Have 3 different scenarios sent out simultaneously.
- May be beneficial depending on the number of participants as sample may be insufficient of a particular type to be sent out.

Performance evaluation

- Use a scoring system that is states at the error
- Scoring system of gaining points for error has worked out well for CMC EQAS

Day 3

Role of EQAS in Education, self appraisal and Quality improvement

Learning outcome:

To educate the pT provider on how to identify errors and guide participants in Root cause analysis, to create interlab comparison report to enable self assessment by participants and increase awareness of quality benefits

Key points

Collection of data, analysis of reports and identification of errors

Identifying lacumae in erring labs and thereby providing opportunities for improvement

Help participants identify problems in testing process and help with risk management

Role of EQAS in education

Main purpose is to improve performance

Education is the main role of EQAS

Errors could be due to incorrect technique, inappropriate reagents, transcription errors, equipment related

Role of EQAS in self assessment:

The participant is provided with an action sheet where the lab can record the nature of the problem, corrective and preventive action

The report provided by the EQAS provider can help the lab compare their performance with their peers and help in improve the standard of performance

Modes of education

Provide specific learning points on best practices

Holding annual scientific meetings and workshops

Review of guidelines

Communicate information generated by the scheme at national and international levels

The speaker provided information related to Indian Red Cross EQAS program and suitable examples of errors in immunohaematology testing and how it can help in self assessment and education

EQAS for Quality improvement: case study RK Chaudhary

The Chinese wisdom of “to win the battle, first know your enemy (incorrect result)” can also be applied in the context of an IH lab

Incorrect IH results have a negative impact on patient safety

Wrong ABO grouping resulting in HTR

Failure to detect anti-D in pregnant women

Wrong antibody titer in ABOi renal transplant

Objectives of EQAS

Implementation and maintenance of a quality and error management system is the most appropriate weapon

To assess laboratory performance and the ability to determine the correct results

To identify any errors in the laboratory

To stimulate laboratory personnel to improve their performance and the use of standard methods

To encourage the establishment and implementation of quality systems with the relevant standards

EQAS provide an objective judgment of results of individual laboratories by comparison with predetermined targets

Results from EQA participation are a standard quality indicator for individual laboratory performance

EQAS brings to light even low-frequency errors in lab procedures

Irregularities and error patterns that may be indicators of performance of individual test systems or reagents are revealed.

Two cases presented highlighted the role of EQAS in improving quality of IH lab testing

Report on Case studies in EQAS DR Joshi

Anomalous ABO Blood grouping: Detection and resolution

Learning outcomes:

To apply the principles of quality control to detect anomalous results while performing routine blood grouping.

- investigate the case following the set protocol
- formulate strategy to conduct unique investigation as required for a case
- interpret the results obtained and classify the discrepancies with defined etiology

Anomalous blood grouping may be due to factors intrinsic or extrinsic to red cells

Anomalous grouping due to factors intrinsic to red cells

- Weak ABH antigens:
- Genetic variants
- Acquired loss of antigen
- de novo transformation in infections/
- cancers/ pregnancy
- Acquired B
- Exposed cryptantigens, T
- Acquired antigens in obstetric patient (new observation)

Anomalous grouping due to factors extrinsic to red cells

- Reagent Dependent Anomalies
- Contaminant antibodies in anti-sera (polyclonal)
- Chemicals, promoting specific antibody to react
- Chemicals, act as antigen to form complex attaching to RBCs

Follow set protocol

- Repeat preliminary grouping to confirm what has been observed by referring centre.
- Test RBCs with battery of reagent to putative antigen
- Titrate serum for antibody against putative antigen at 4C and 37C
- Determine the secretor status on saliva of the individual
- Perform absorption-elution experiment using antiserum showing putative antigen.
- Any additional test as relevant to the case findings such as I-i antigen status, family study

Key points

Grouping anomaly can be caused by a variety of reasons; could be due to the factors intrinsic or extrinsic to the RBCs.

Use of washed RBCs suspension, more than one reagent antiserum, reverse serum grouping, knowing clinical diagnosis are of paramount importance.

It may be also caused by a variety of artefacts, chemicals used as preservative

It needs to be resolved prior to transfusion as to prevent transfusion accident.

Weak or negative results with naked eye must be confirmed microscopically
If needed some more complex investigations like absorption elution, secretor status should be performed as per the case study requirement .
The reagent dependent anomaly needs to be investigated for proper ABO grouping as safe measure in transfusion practice.

Report on Case studies in EQAS DR Shamee Shastry

Error in Immunohematology lab may lead to
Delay in reporting
Delay in providing transfusion support
Serious or fatal transfusion reaction
Errors without clinical consequence may go undetected
EQAS – will help in knowing the type, incidence of errors
Part of Quality assurance system
To discuss the case scenarios related to EQAS in Immunohematology
To learn from mistakes and troubleshooting
Recommendations
EQA samples should be tested alongside routine samples by the laboratory staff who routinely performs the test
EQA/PT samples should be tested in the same manner as patient/donor samples
Whenever possible blinding can be implemented
Benefits
Indicates areas that need improvement
Identifies training needs
Preanalytical errors and consequences
Pre-analytical Phase: test request, patient and specimen identification, specimen collection, transport, accessioning and processing
The numbers don't lie: it's a significant problem
Pre-analytical phase accounts for 46% to 68.2% of errors observed during the Total Testing Process
Consequences:
Delay in reporting
Unnecessary redraws
Misdiagnosis
Fatal transfusion reactions
Delay in providing blood transfusion
Steps to prevent preanalytical errors
Phlebotomy education
Choosing appropriate products
Using appropriate technology
Adhering to standard guidelines
Developing clear, written procedures
Validating any new instrument or procedure
Monitoring quality indicators
Preventive measures
Correlate the immunohematology results with clinical details
Correlate it with other Lab results
Maintain cell panel from another manufacturer (one kit)
When in doubt repeat with kit from another manufacturer

Summary

Provides early warning for systematic problems associated with kits or operations
Indicates areas that need improvement
Identifies training needs

Questions for panel discussion from an EQAS organisers perspective

1. What are the minimum resources required to start a regional or national EQAS program in Immunohaematology JM
2. Is it a good idea to have one national EQAS program or two or three regional programs GG
3. If so, can the National EQAS provider support the regional providers. Do you think this will minimise sample transport related issues? GG
4. What should be the minimum number of participating labs NN
5. As EQAS providers, will it be required to plan additional sets of samples to be kept if labs report that they have not received samples or sample integrity lost etc? JM
6. What are the challenges in training the team, esp technical? SCN
7. Are there any ethical concerns to be kept in mind? SW
8. Explain the process of accreditation for EQAS providers SCN
9. Is there anything that the EQAS providers have learnt from Participants GG
10. Can we create a module for Organising EQAS program with the expertise available JM
11. Can international EQAS providers support national programs SW
12. What are the possible sources of funding? ASS
13. How do you think we can convince the government to support the EQAS programs? GG

Following are the question from Bangladesh (from a participating lab perspective)

1. What are the key elements to implement EQAS in your laboratory? RKC

2. What is the role of quality manager for EQAS SS
3. What guidance can we seek from WHO. ASS
4. What are troubleshooting we can face during implementing EQAS in individual laboratory? SJ

Questions from Nepal

1. How to keep on encouraging the participants for continuous response to EQAS program?
2. How to support to outliers and poor performers?
3. What is the best time interval to respond the result to the participants from the organizer once the samples get dispatched?

The above mentioned areas were discussed in details

Key points:

- Existing resources can be used for the purpose of organisation of EQAS
- Technical support from experts (EQAS providers) is available and the countries seeking technical support may represent through their country to Regional Office – WHO(SEARO) WHO will provide coordinate to facilitate the process

Creating an educational module on training for EQAS providers

List of speakers- WHO SEAR EQAS Online Pilot training program

1. **Dr. Joy Mammen** (joymammen@cmcvellore.ac.in)
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3. **Dr. Rekha Manandhar** (rekhadhar1@gmail.com)
Senior Consultant Pathologist, National Public Health Laboratory
Co-ordinator, NBBTS, Teku, Kathmandu, Nepal
4. **Dr. Gajendra Gupta** (guptagajendra@yahoo.com)
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5. **Dr. Narinder Naidu** (Narinder.naidu@yahoo.com)
Medical Director, Indian Red cross Society, Mumbai, India
6. **Dr. Nusrat Nuri Solaz** (n.solaz26@yahoo.com)
Vice President, AATM, Turkey
7. **Dr. Sandy Walker** (sandy@nrlquality.org.au)
Scientist, NRL Scientific consulting and Training, Australia
8. **Dr. Ashadul Islam** (dr.ashad59@gmail.com)
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10. **Dr. Sanmukh Joshi** (sanmukhj@yahoo.com)
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11. **Dr. R K Chaudhary** (rkcsppgi@gmail.com)
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12. **Dr. Shamee Shastri** (shameeshastry@gmail.com)
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13. **Dr. Aparna Singh Shah** (shahap@who.int)
Regional Advisor (Blood, Blood Products & Products of Human Origin) | Department of Health Systems Development | World Health Organization | Regional Office for South-East Asia | New Delhi, India
14. **Dr. Sitalakshmi Subramanian** (slvbs@yahoo.co.in)
Head, Laboratory Services, Professor, Department of Transfusion Medicine and Immunohaematology, St John's Medical College Hospital, Bangalore, India

GLOBAL SCENARIO ON EXTERNAL QUALITY ASSURANCE IN IMMUNOHEMATOLOGY LABORATORY

Yuyun Siti Maryuningsih
Team Lead for Blood and other Products of Human Origin
World Health Organization
November, 2021

The image shows a Zoom meeting grid with the following participants and teams:

- Top Right:** 16. Dr. Sitalakshmi S. (Video feed)
- Top Left:** Dr. Suresh C Nair (Video feed)
- Support Team-2:** A black box with the text "Support Team-2" and a red icon.
- 13. Dr. Aparna Singh Shah:** (Video feed)
- 12. Dr. Shamee Shastry:** (Video feed)
- 9. Dr. Teguh Triyono (teguh...):** (Video feed)
- 8. Dr. Ashadul Islam:** (Video feed)
- 7. Sandy Walker:** (Video feed)
- 14. Dr. Sitalakshmi Su:** (Video feed)
- St. John's Zoom Host:** (Logo with text "BECAUSE OF ME" and "जीविष्यति मयेवसो")
- St. John's Zoom Host:** (Logo with text "BECAUSE OF ME" and "जीविष्यति मयेवसो")
- 6. Dr. Nusrat Nur...:** (Text)
- 4. Dr. Gajendra G:** (Text)
- 6. Dr. Nusrat Nuri Solaz:** (Text)
- 4. Dr. Gajendra Gupta:** (Text)
- Support Team-3:** A black box with the text "Support Team-3" and a red icon.
- Dr. Joy Mammen:** (Video feed)
- Support Team-3:** A black box with the text "Support Team-3" and a red icon.
- 3. Dr. Rekha Manandhar:** (Text)
- 4. Dr. G:** (Text)