INTERNATIONAL QUALITY ASSURANCE EFFORTS

HOW THE WORLD DOES IT

BY

PROFESSOR FOLAYAN ESAN

EXECUTIVE DIRECTOR

INSTITUTE OF GENETIC CHEMISTRY AND LABORATORY MEDICINE

TERMINOLOGY (WHO)

- QUALITY ASSURANCE. The total process that guarantees that the final results reported by a laboratory are as accurate as possible
- QUALITY CONTROL. Those measures that must be included during each test run to verify that the test is working properly
- QUALITY ASSESSMENT. A means of determining the quality of results. It is usually an external evaluation of a laboratory performance using proficiency panels.

NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (NEQAS)

- PRIMARY OBJECTIVES.
- To assess the quality of laboratory performance on a nationwide basis
- To provide assurance to consumers that lab results are reliable

NEQAS

- SECONDARY OBJECTIVES.
- Identify common errors & recommend corrective measures
- Encourage good lab practice using standardised procedures, appropriate definitions & high quality reagents
- Encourage implementation of QA & QC measures
- Stimulate information exchange among labs nationally & internationally
- Provide updated information on new developments in diagnostics & related matters

SETTING UP NEQAS

- Advertise the scheme widely
- Enlist support of professional societies
- Explain scheme purpose; stress educational benefits
- Emphasize that scheme gives participants a tool to help them improve their results
- Offer advise & follow up visits in case of persistent problems
- Introduce a module on quality assurance in training courses for laboratory technicians & students

ORGANISING LABORATORY

- STAFF.
- Prepare, dispense and label the specimens
- Pack the specimens for dispatch
- Prepare paper-work, record and collate returned reports
- Maintain an address register of participating laboratories
- Analyse data & prepare summaries of results
- Provide feedback especially in cases of bad performance
- Oversee the whole operation

RESPONSIBILITIES OF ORGANISER & PARTICIPANTS IN EQAS

- ORGANISER
- Advertise Programme
- Register participants
- Prepare distribution panels, instructions & report forms
- Compile data & analyse results
- Send intended results to participants
- Produce a general report
- Intervene where necessary

- PARTICIPANTS
- Enrol in the programme
- Test samples as instructed & return report form
- Compare results
- Contact organiser as needed

UK NEQAS

- HISTORY
- IQC procedures introduced widely in the 1960s led to local studies of between-laboratory comparabilty
- Some became local & regional schemes developing experience & expertise in scheme design, operation & management
- Awareness of need for improved laboratory assurance increased among laboratories
- MoH accepted proposals (Whitehead & Lewis) for national activity
- National Quality Control Schemes for clinical chemistry & haematology established and first distributions from Birmingham & London started in 1969

UK NEQAS

- HISTORY (contd)
- DoH recognised the value of EQAs; it encouraged & nurtured the development of other schemes under the Advisory Committee on Assessment of Laboratory Standards (ACALS)
- Next two decades other UK NEQASs were developed & some existing EQAs were upgraded to NEQASs to cover all major disciplines in pathology
- Currently UK NEQAS comprises a network of over 35 Schemes & Sub-schemes operated from a network of 20 organising centres
- Covers quantitative, qualitative and interpretive investigations in the general & specialist areas of clinical chemistry, haematology, microbiology, immunology & anatomic pathology

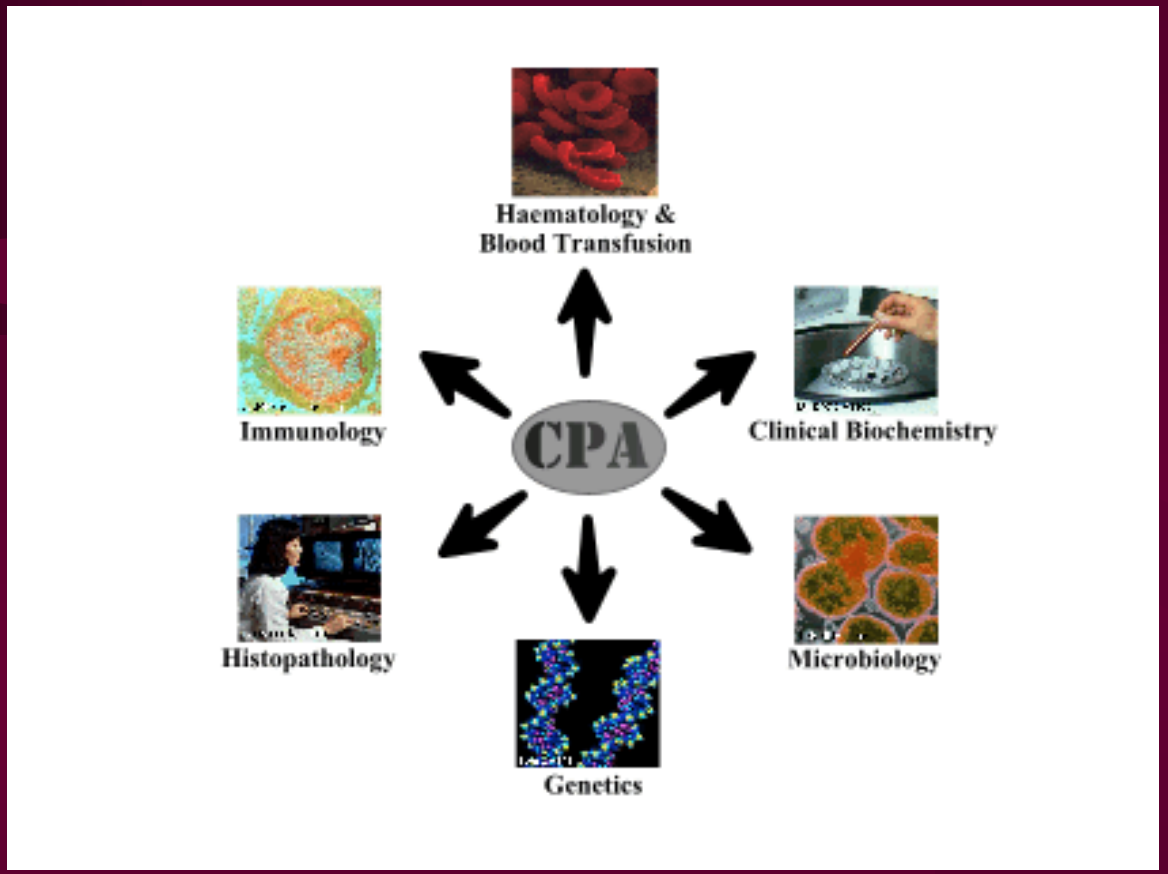
UK NEQAS

- Primary aim is educational
- Participants provided with independent, objective & impartial data on their performance which reflects the standard of their routine service
- Enables them to review this in conjunction with IQC & other information to take necessary corrective action
- NOT used for licensing purposes
- CPA accreditation requires EQA participation & has developed procedures to offer advice & assistance to labs with difficulties by scheme organisers &/or relevant National Quality Advisory Panel
- Panels are from the Joint Working Group on Quality Assurance who have executive responsibility for maintaining appropriate professional standards on behalf of the societies

UK NEQAS

- Helped to stimulate major improvements in between-laboratory concordance & provided guidance to laboratories
- Extends beyond UK to EU & world-wide
- Five are recognised as WHO Collaborating Centres operating International EQAs and providing education, training & consultancy services
- "UK NEQAS HAS DEVELOPED TO PROVIDE A MULTIDISCIPLINARY NETWORK OF EDUCATIONAL SCHEMES UNMATCHED IN ITS COMPREHENSIVENESS & QUALITY THROUGHOUT THE WORLD"

CLINICAL PATHOLOGY ACCREDITATION (UK) LTD



THE ROYAL COLLEGE OF PATHOLOGISTS

- MISSION:
- To promote exclusively the practice of pathology & to be responsible for maintaining standards through training, examinations & professional development.
- ACTIVITIES
- Oversees education & training of specialists in all branches
- Setting standards of practice
- Monitoring appointments of consultants in pathology
- Publication of guidelines on aspects of best practice
- Funding research in association with industry etc
- Advising government departments national organisations etc about pathology
- Promoting public understanding of patholgy

INSTITUTE OF BIOMEDICAL SCIENCE (IBMS)

- Founded in 1912; membership over 16,000
- Professional body for biomedical scientists in UK
- Aims to promote & develop biomedical science & practitioners
- Other Roles include
- setting standards of practice to protect patients
- liaison with government, media & universities
- promotion of public awareness
- Assessment of competence to practise
- Accreditation of university degrees

IBMS

- assessment of qualifications for registration with Health Professions Council
- updating members through scientific meetings & professional events
- organisation of CPD scheme
- issuing scientific & professional publications
- funding of research
- provision of assessors for interviews for senior jobs
- provision of legal & technical help for members
-

INTERNATIONALNSTANDARDS ORGANISATION (ISO)

- TO BE DISCUSSED BY SON PARTICPANTS

3 Terms and definitions

For purposes of this document the following terms and definitions apply. If a term and its definition is based on a source material reference (see 2), this is acknowledged in square brackets following the definition.

3.1 accreditation

procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

3.2 annual joint review

annual review of employee/employer requirements, undertaken to establish mutually acceptable objectives for a defined period of time

3.3 audit

systematic, independent and documented process for obtaining audit evidence and evaluating

it objectively to determine the extent to which audit criteria are fulfilled [ISO 9000:2000]

3.4 corrective action

action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE

Corrective action is taken to prevent reoccurrence whereas preventative action is taken to prevent

occurrence [ISO 9000:2000]

3.5 department

section of a laboratory in which a single pathology discipline pursues its activities

3.6 effectiveness
extent to which planned activities are realised and planned results achieved
[ISO 9000:2000]
NOTE
Clinical effectiveness is effectiveness applied to clinical activities
3.7 efficiency
relationship between the result achieved and the resources used [ISO 9000:2000]
3.8 examination
set of operations having the object of determining the value or characteristics of a property
NOTE
In some countries and disciplines (e.g. microbiology) examination is the total activity of a number of
tests, observations or measurements [ISO 15189:2003]
3.9 laboratory
competent person(s) with responsibility for, and authority over, a laboratory
[ISO 15189:2003]
grouping of departments
3.10 laboratory director
3.11 laboratory management
person(s) who manage the activities of the laboratory headed by the laboratory director
[ISO 15189:2003]
3.12 materials
consumables, calibrators, reagents, calibration material used in the performance of an examination

COLLEGE OF AMERICAN PATHOLOGISTS (CAP)

- CAP Laboratory Accreditation Programs
- Goal is to improve quality of clinical lab services through voluntary participation, professional peer review, education & compliance with established standards
- More than 6000 laboratories worldwide included
- Provides lab with sense of achievement, confidence in meeting the highest standards of practice & a process that focuses entire lab team on quality patient care

CAP

- The standards define:
- Director- qualifications, responsibilities & role
- Physical facilities & safety
- Quality Control & Performance Improvement
- Inspection Requirements

ASCP- CAREERS

- PATHOLOGIST
- a medical doctor who examines tissues and is responsible for the accuracy of laboratory tests.Pathologists interpret the results of these examinations and tests-information that is important for the patient's diagnosis and recovery. The pathologist and the patient's other doctors consult on which tests to order, test results and appropriate treatment.
- pathologists work in many areas of the medical laboratory, and a pathologist usually serves as the Director of the Laboratory

ASCP-CAREERS

- THE MEDICAL TECHNOLOGIST (MT)
- "I chose to be a medical technologist because I was interested in the science of the human body. I like my job because every day I know I helped improve somebody's quality of life.
- The medical technologist performs a full range of laboratory tests – from simple pre-marital tests, to more complex tests to uncover diseases such as AIDS, diabetes, and cancer. The medical technologist is also responsible for confirming the accuracy of test results and reports laboratory findings to the pathologist and other doctors.