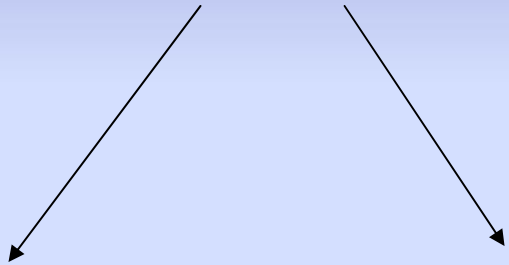
Microbiology Quality Control

Quality Systems in the Clinical Lab.

- **Quality Assurance (QA)**



Quality Control (QC)

Quality Improvement (QI)

Quality Control ???

- Continual monitoring of working practices, equipment & reagents so as to detecting & correcting defects

- => Maintains **reliable / timely** analytical
- performance (result / outcome)
- => More patient-care-oriented approach

Stages of laboratory activities

- The QC program must ensure optimum patient specimens and result integrity throughout the 3 stages processes:

- 1. Pre-analytical
- 2. Analytical
- 3. Post-analytical

Three stages of activities

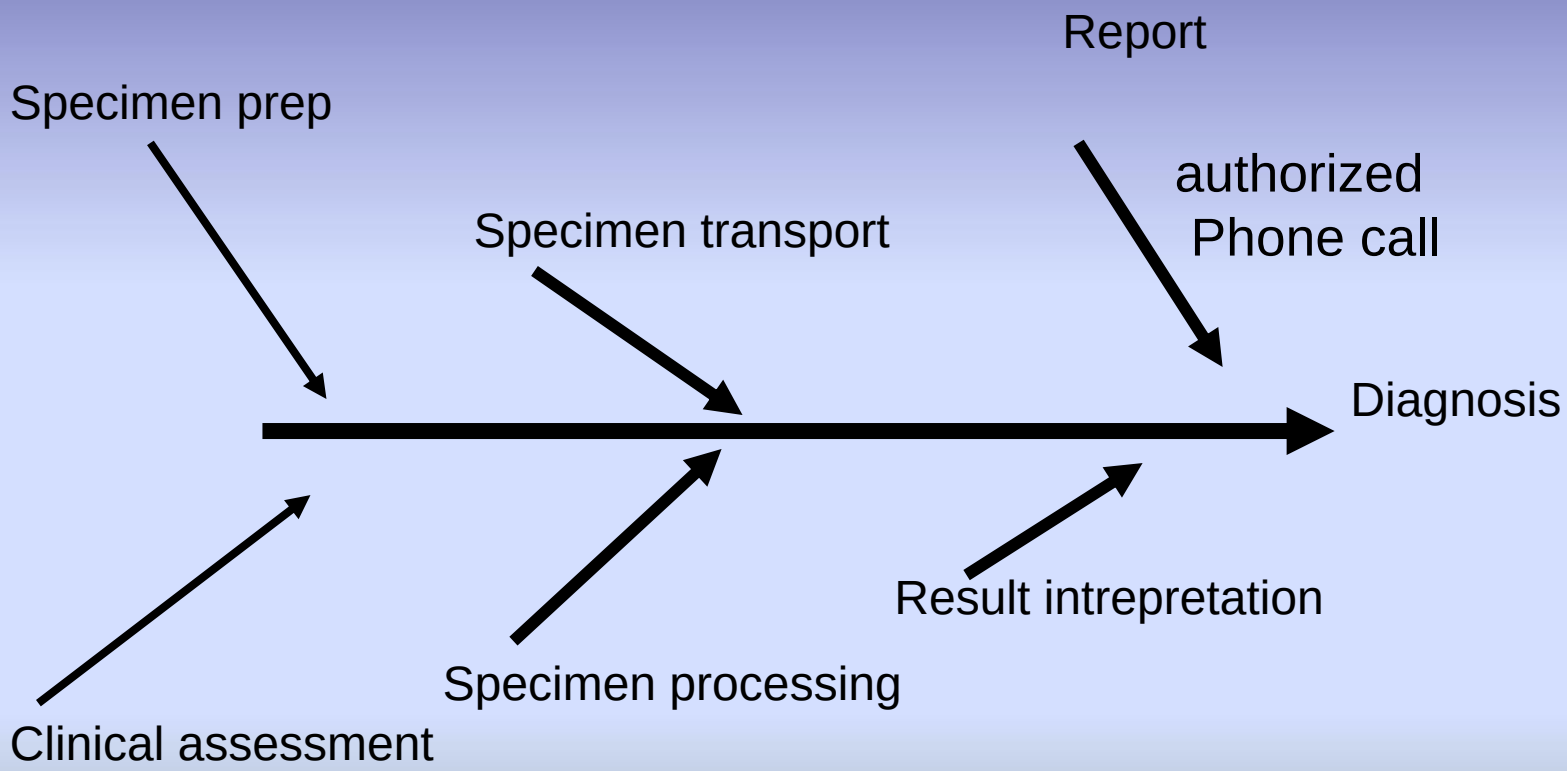
Table 1- Three stages of activities that affect outcome of laboratory testing:

Stage	Activities
Preanalytical	Test ordering
	Order transcription
	Patient preparation
	Specimen collection
	Specimen identification
	Specimen transport
Analytical	Sample testing (ID & ST)
Post-analytical	Result transcription
	Result intrepretation
	Action taken on basis of result

A quality outcome can be interrupted or destroyed at any point in the process.

Fishbone diagram-

display important components of a process



Fishbone diagram

- Examination of a process from fishbone diagram help show **potential weaknesses** and reveal how improvements in the process might be achieved

Quality indicators

- Data elements that discriminate between a system that is operating & one that is flawed
- Examples
- Sputum: appropriate collection
  - » If specimens with more than 25 epithelial cell Low Power Field
- Urine: appropriate collection
  - – If No. of cultures with mixed (=/>3) organisms

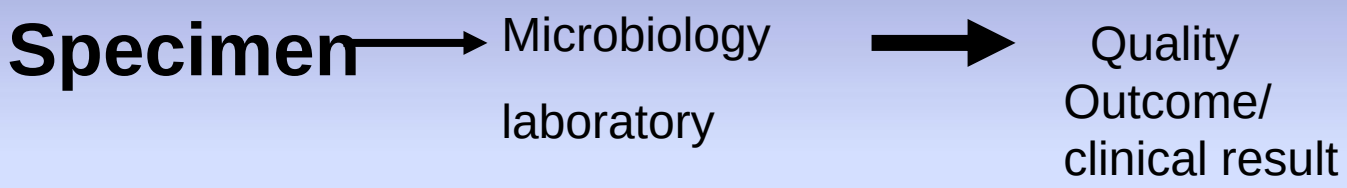
Quality Control Program

- Quality of the specimen
- Procedure manual
- Personnel
- Media
- Instruments
- Reagent
- Quality assessment

  -Internal audit

  -Profeciency testing/external quality assessment

Quality of the specimen



- Health care value of the information provided by clinical microbiology lab is being significantly compromised by **inappropriate specimens**

Quality of the specimen

- Inappropriate specimens:
  - Submission of contaminated specimens
  - Delay in specimen delivery
  - Viral culture without transport media
  - Collection of specimens from inappropriate body sites
- =>Collection of microbiology specimens is generally not under direct control of lab.

Quality of the specimen

- Specify specimens rejection criteria
- eg.specimen container leaking, Specimen in wrong medium, Non-sterile container for culture
- put-up or reception bench should strictly follow these criteria
- Monitoring the specific nursing unit & education, training to improve collection or transport procedures
- In case any doubt, consult microbiologist

Procedure manual

- Must contain all test methods performed by the laboratory
- e.g. 2 specific format:
  - College of American Pathologists (CAP)
  - Clinical Laboratory Improvement Act 88 (CLIA 88)

Procedure manual

CLIA 88	CAP
16-item format	NCCLS publication GP2
-course of action to be taken in the event that a test system becomes inoperable -criteria for proper collection, preservation, & transportation of specimens	
Manufacturer's product insert or procedure manual is acceptable if it includes all of the required CLIA 88 items	Package inserts are not acceptable to CAP, but a manufacturer's instrument manual that complies with NCCLS publication GP2 is acceptable

College of American Pathologists (CAP)

-should be available to, and used by personnel at the workbench

Principle

Clinical significance

Specimen type

Required reagents

Calibration

Quality control

Procedural steps

Calculations

Reference ranges

Interpretation (usage of result or indication of result)

Procedure manual

- The director must ensure that the collection of policies and technical protocols is complete, current & has been thoroughly reviewed by a knowledgeable person

Personnel

- Active participation by everyone working in the system is required to meet quality standards & continuously improve performance

- Assign responsibility / duties

Personnel

Personnel	Function
Quality Improvement Executive Committee	-Reviews and approves policies and procedures required to achieve quality improvement goals - Fosters interdisciplinary communication, facilitates problem solving and documents results of QA activities.
Microbiolog-ist	-Participates in monitoring and evaluating laboratory services. Provides recommendations for improving services; for example; The microbiologist must make many clinical decisions regarding collection and transmission of specimens. The extent of his/her role in the interpretation and utilization of microbiological information must also be considered
Technologists & Technician	Implements procedures and manages data in accordance with QA goals. Provides recommendations to director for improving services

Personnel

- **The employee's personnel records contain:**
  - Qualification & experience
  - The tasks & procedures that the employee is authorized to perform (dates of received training & competence tests)
  - Continuing education activities (attend some training program or workshop)
  - Regular meeting to keep staff informed of changes & to solicit their suggestion for improving the lab. service

Media

- Poor quality control (QC) of prepared media can adversely affect the performance
- => media produced in a microbiology department are performing to an acceptable standard, allowing optimum growth of specific organisms

Media

- The test program is based on the following basic parameters to be examined & recorded

- Physical characteristics: Microbiological performance
- colour
- clarity
- pH (test the pH with pH electrode)
- sterility (incubate for 24-48 hr at RT & 37 C)
- gel strength (test freshly poured & surface-dried plate with a wire loop, not too soft and hard)

Media

- Physical characteristics

Date	Medium	Lot #	Colour	Clarity	Gel	pH	sterility	Sign
2/5/02	Cho	X	Ok	Ok	Ok	Ok	ok	Jo
	MAC	xx	Ok	Ok	Ok	Ok	ok	Jo

Media

- **Microbiological performance-(CLSI)**

-**Nutrient medium** (bl , cho) must be tested the growth of one or two organisms

-**Selective media** should be tested with organisms which would be expected to grow and those organisms expected not to grow

-Test strains:

- American Type Culture Collection (ATCC) #
- selected as critical for each medium & suitable indicators for routine monitoring of performance

Media

- Labeling:

Date of preparation_____
Media_____
Lot No._____
Expiration Date_____
QC_____
Storage condition_____
Technologist_____

Instruments

- Specimen
  - eg

checking the percentage of CO2 in an incubator

checking the anaerobic chamber

checking temperature-dependent equipment such as heating blocks, water baths, refrigerators & freezers

- How??

Instruments

- Daily checking & record the data (chart)
- Daily & monthly maintenance program must be established
- A preventive maintenance program must be established as an additional control measure

eg:oiling & cleaning, replacing filters etc.

Frequency of maintenance??

- equipment is cleared or approved by (FDA)

not

- follow the frequency of maintenance & function check specified by the manufacturer

In-house schedule

FDA: **F**ood and **D**rug **A**dministration

Reagents

- **Daily**
  - Reagents should be tested each day of use with both **positive** & **negative** controls
  - **in-use reagent vial** is refrigerated at night but usually left at room temperature during the day & therefore has the opportunity to degrade while in use

Reagents

- **Weekly**

-reagents that are documented to have consistent & dependable results may be tested less frequently

-eg. Gram stain, is commonly tested weekly instead of daily

Reagents-examples undergo QC

- All stains
- Bacitracin
- beta-Lactamase
- CAMP
- Catalase
- Hippurate
- Optochin

Internal audit

- **Aim**: Monitoring the performance of the **whole procedures**

- **Method:**

Laboratory activities (pre-analytic analytic & post-analytic) were examined

- Standards were set using laboratory standard operating procedures
- The findings were discussed
- the measured performance was reviewed
- an explanation for any deficiencies sought

Internal audit

Suboptimal performance/ any deficiencies

Laboratory methods

Urgent review

Human error

enchance checking

Profeciency testing/ quality assessment

- Profeciency testing/quality assessment
- Internally
- Externally

specimens of known content are introduced into the routine system by senior staff who receive & evaluate the reports

eg MM

Scheme

specimens of known content are sent to laboratory for EX. & the result are reported to organizing lab. & evaluated

United Kingdom National External Quality Assessment

(UKNEQAS)

Profeciency testing/ quality assessment

- Both scheme act as an indicator of the effectiveness of internal quality control program

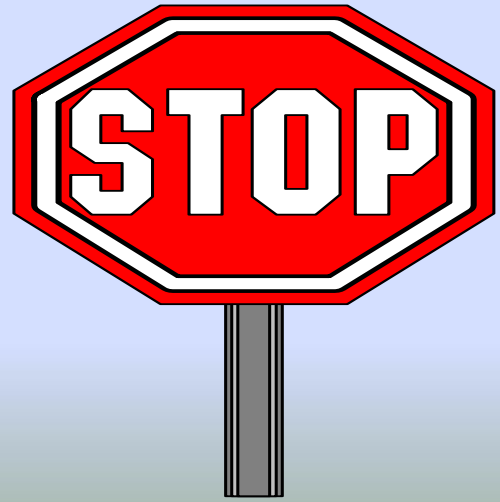
- Advantage of external quality assessment

  1/ provision of wide variety of organisms

  2/ stable specimens

  3/ chance to compare individual performance with other participants

How to set up a good Quality Control Program in Medical Microbiology Laboratory



QA:

Quality assurance

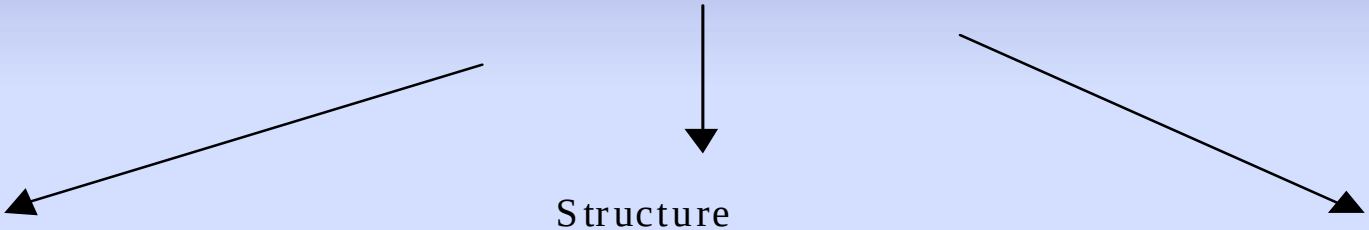
System for improving

Reliability

Efficiency

Utilization of produucts & services

In clinical microbiology, QA monitor the performance of equipment and reagents to examine the clinical value of services and information



Structure

adequacy of the workplace & the provisions required to do the job

Process:

Proficiency with which the work performed

Outcome

consequences of work performed

Media-antimicrobial susceptibility QC

- Specific strains of Haemophilus influenzae & Nesisseria gonorrhoeae
- Variables to control that can affect the accuracy of results

1 antibiotic potency

2 agar depth (Kirby-Bauer test)

3 pH

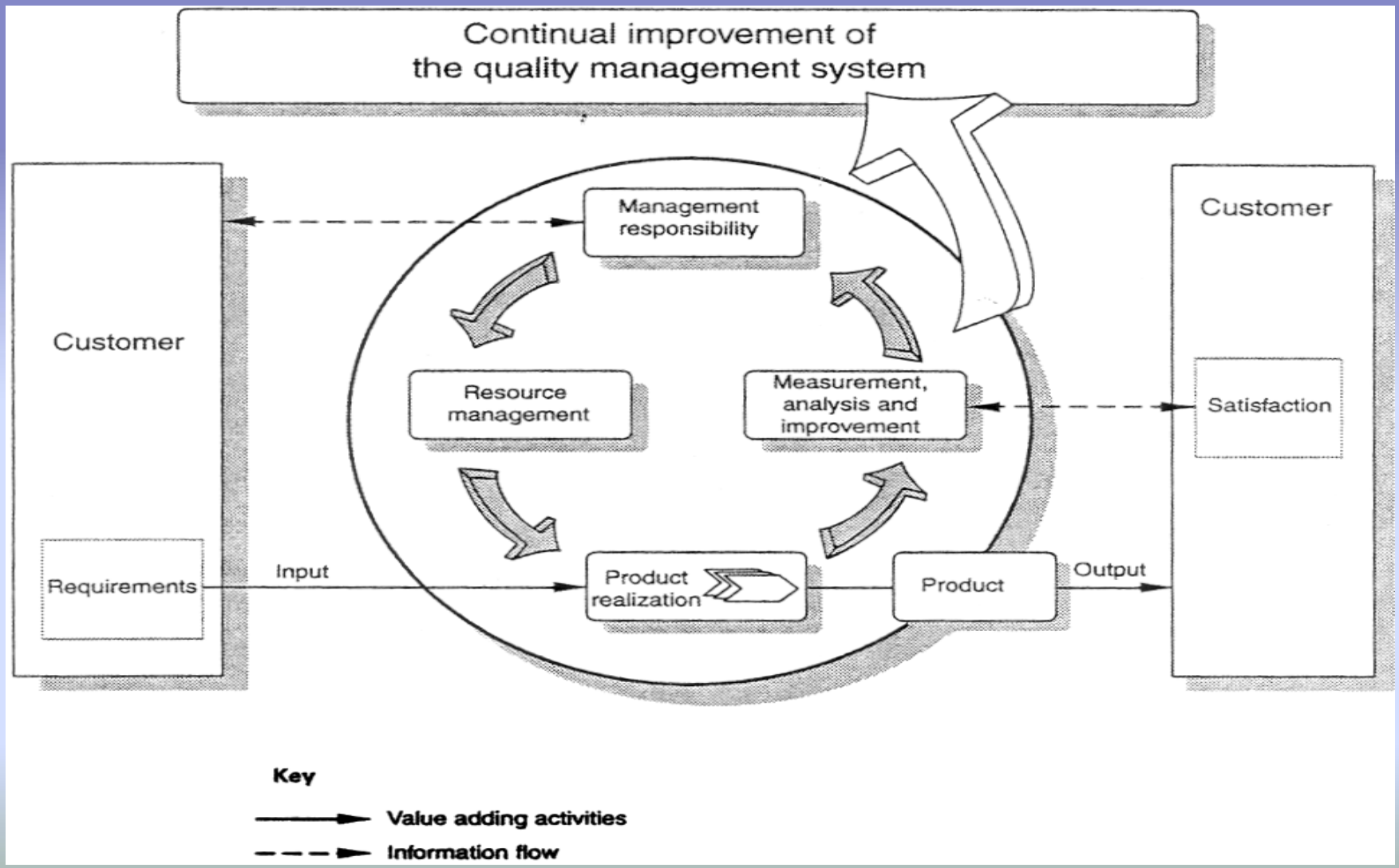
4 inoculum

5 incubation time & temperature

6 moisture

7 CO_2 concentration

Quality management system



3G

- Good laboratory practice (GLP)
- Good quality assurance
- Good communication

Good laboratory practices

Three phases of testing:

- 1) before testing (test ordering and specimen collection),
- 2) during testing (control testing, test performance, and result interpretation and recording), and
- 3) after testing (result reporting, documentation, confirmatory testing, and biohazard waste disposal).

-The End-