QUALITY ASSURANCE PLANNING

A Practical Approach to Quality Management Systems

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OBJECTIVES

- *Describe the purpose of a Quality Assurance (QA) plan*
- *List the components of an effective QA plan*
- *Discuss the benefits of incorporating Quality System Essentials and other Quality Management System principles into a Microbiology QA plan*
- *Identify tools to use when developing an effective QA planning process*

QUALITY TERMINOLOGY

- *Quality control*
- *Quality assurance*
- *Quality improvement*
- *Quality indicators*
- *Quality management*

QUALITY TERMINOLOGY

- *Quality management systems*
- *Quality planning*
- *Quality system essentials*

DEFINITIONS : QUALITY CONTROL

- *A system designed to increase the probability that each result reported is valid and can be used with confidence by the physician*
- *Refers to activities that evaluate, monitor or regulate services*
- *QC procedures are designed to detect error*
  - *If acceptable, proceed with results*
  - *If unacceptable, evaluate test method and re-run test*

EXAMPLES OF QUALITY CONTROL

- *Running control samples*
- *Control charts*
- *Quality control statistics*

DEFINITIONS: QUALITY ASSURANCE

- A system for monitoring and evaluating all the various aspects of a service
- A set of activities designed to ensure that processes are adequate to meet testing objectives
- Includes pre-analytical and post-analytical components of service

EXAMPLES OF QUALITY ASSURANCE

- Quality Assurance plan
- Customer satisfaction survey
- Sample adequacy and collection data
- Turn around time

QUALITY IMPROVEMENT (CQI)

- A formal approach to the analysis of performance and systematic efforts to improve it.
- Involves prospective and retrospective reviews
- Focuses on systems or processes, not people

EXAMPLES OF QUALITY IMPROVEMENT

- Plan, Do, Check, Act (PDCA) cycle
- Six Sigma
- Process Improvement
- Continuous Quality Improvement (CQI)

QUALITY INDICATORS

- Observations, statistics, or other data defined by the organization that typified the performance of given work
- Must be measurable and objective

EXAMPLES OF QUALITY INDICATORS

- Turn around time
- Workload
- productivity

QUALITY MANAGEMENT

- *A way to continuously improve performance at every level of the organization*
- *All activities of the overall management function that determine quality policy objectives, implementing them by means such as quality assurance, and quality improvement within the system (NCCLS)*

QUALITY MANAGEMENT

- *Ensures that both the customer requirements and the organization's requirements are met*
- *Reviews interrelated processes within an organization*

EXAMPLES OF QUALITY MANAGEMENT

- *Cross cutting work teams*
- *Audits*
- *Quality monitoring*
- *Root cause analysis*

QUALITY MANAGEMENT SYSTEMS (QMS)

- *Management system to direct and control an organization with regard to quality*
- *All systems are stress participation, communication, and rewards and acknowledgment*

EXAMPLES OF QUALITY MANAGEMENT SYSTEMS

- *Total Quality management (Deming)*
- *Six sigma (Motorola)*

QUALITY SYSTEM ESSENTIALS (QSE'S)

- *The management infrastructure necessary to support any health care organization*

QUALITY PLANNING

- Part of a quality management focused on setting quality objectives and specifying operational processes
- Reflected in the document, the "Quality Plan"
  - Procedures, resources

PURPOSE OF A QA PLAN

- Process improvement
- Regulatory compliance
- To meet customer expectations
- Reduce costs by eliminating waste
- Improve laboratory performance by identifying sources of error

RELATIONSHIP OF STRATEGIC AND QA PLANS

QA planning is a component of Strategic planning

Quality plan has a shorter term focus

Strategic plan has a long range focus, usually 3-5 years

QA PLAN– A COOPERATIVE EFFORT

Need support form administration, pathologists, technologists, and all staff

Need clearly defined outcomes and responsibilities

Need to build trust for a QA plan to be effective

BENEFITS OF A QA PLAN

Improved test performance

Increased profitability

Increased customer satisfaction

Increased employee satisfaction

ATTRIBUTES OF A QA PLAN

Clearly defined goals

Realistic and feasible goals

Cost effective planning process (keep it simple)

Measurable positive effect on quality

Flexibility

ATTRIBUTES OF A QA PLAN

- Assigns responsibility
- Contains statement of how you will measure performance
- to be used for process improvement. Not to be confused with competency assessment and performance evaluation

COMPONENTS OF A QA PLAN

- Indicators of performance
- Criteria for each indicator
- Standard for each indicator
- Remedial action to be taken for each indicator

POTENTIAL INDICATORS

- What is required by law?
- What have the traditional indicators used by the laboratory?
- What are the most important customer service indicators?
- What are the important fiscal indicators?
- How are process improvements monitored?

MOST IMPORTANT INDICATORS

- Impact on patient care
- Impact on customer satisfaction
- Compliance with legal or regulatory requirements
- Feasibility of monitoring

NUMBER OF INDICATORS

- Based on resources available
- What information can be used effectively
- What indicators are absolutely necessary
- IT IS NOT FEASIBLE TO MONITOR EVERYTHING

CRITERIA AND DATA COLLECTION

- Defines how data will be collected
- Defines who will be collecting the data
- Defines how calculations will be made
- Explains terms used in the indicator
- Explains who has access to this data

LABORATORY STANDARDS

- Precisely defines expected performance
- Standards are based on objective data whenever possible
- Can be reviewed and adjusted as additional data is collected

REMEDIAL ACTIONS

- Identify actions that will correct the problem
- Use continuous quality improvement tool (for example the Plan, do, check, act cycle) to evaluate actions
- Be prepared to take additional steps as needed

PDCA CYCLE

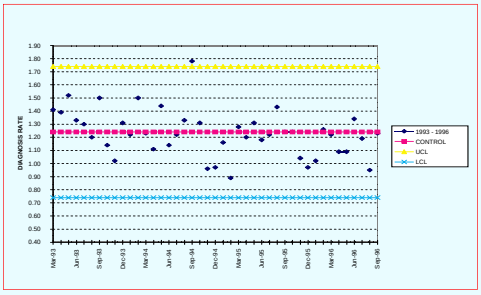
- Planning identifies indicators, criteria and standards
- Doing is the process of implementing a QA plan monitor
- Checking is comparing outcomes with expected standards
- Acting is taking steps to correct the problem

PDCA CYCLE

CONTROL CHARTS

- Consists of points that represent a statistic of measurement
- The mean of this statistic is calculated
- Standard error (deviation is calculated)
- Upper and lower control limits are defined that indicate output that is unlikely. Usually 2 or 3 standard deviations

CONTROL CHARTS



WHAT IS A QUALITY ASSURANCE PLANNING?

Quality Assurance is a "system for evaluating performance, as in the delivery of services or the quality of products provided to consumers, customers, or patients"

Quality Assurance plan is a component of a Quality system

A tool to make the plan operational

QUALITY MANAGEMENT SYSTEM TOOLS

Processes that provide a comprehensive approach to quality

- ***Quality System essentials (Clinical and Laboratory Standards Institute)***
- ***ISO 15189 (The International Organization for Standardization)***

QUALITY SYSTEM ESSENTIALS

- ***CLSI (NCCLS) document "Application of a Quality System Model for Laboratory Services (GP26-A3)***
- ***Model uses 12 essential services based on the 20 quality system elements in ISO 9001***
- ***Simplifies; uses language familiar to laboratories***

12 QUALITY SYSTEM ESSENTIALS

- ***Documents and records***
- ***Organization***
- ***Personnel***
- ***Equipment***
- ***Purchasing and inventory***
- ***Process control***
- ***Information management***
- ***Occurrence management***
- ***Assessments- internal and external***
- ***Process improvement***
- ***Facilities and safety***

DOCUMENTS AND RECORDS

- ***Identifies records and documents required for use in a quality management system.***
- ***This information is described in the Laboratory Quality Manual***
- ***Includes systems for controlling documents and records***

EXAMPLES OF DOCUMENTS AND RECORDS

- ***Quality manual***
- ***Procedure manuals***
- ***Lab wide policy statements***
- ***Records management***
  - ***Identification***
  - ***Storage and retrieval***
  - ***Retention and disposal***

ORGANIZATION

- Documents management involvement in the quality process
- Includes quality planning
- Tracking and follow up systems
- Quality officer/ quality assurance staff

EXAMPLES OF ORGANIZATION

- Organizational chart, including levels of authority
- Quality Plan
  - Reviewed and approved by technical supervisor
  - Coordinated with overall laboratory and/or institution plan
  - Visible participation of management

PERSONNEL

- A laboratory's most valuable and costly resource
- Includes policies and processes for obtaining and retaining highly qualified personnel

EXAMPLES OF PERSONNEL

- Qualifications (transcript, CV)
- Position (job) descriptions
- Position (job) qualifications
- Training records/continuing education
- Competency assessments
- Recruitment and retention records

EQUIPMENT

- Process for the selection and acquisition of equipment
- Process for assuring the instrument is working properly
- Process for assurance maintenance of the instrument

EXAMPLES OF EQUIPMENT

- Selection and acquisition process
- Calibration records
- Validation and verification records
- Maintenance records
- Equipment inventory

PURCHASING AND INVENTORY

- Provides for an efficient, cost-effective operation
- Prevents interruption of services by identifying critical supplies and services

EXAMPLES OF PURCHASING AND INVENTORY

- Identification of critical supplies and services
- Vendor qualifications
- Purchase agreement review
- Inventory management
- Storage and handling
- Reference lab selection

PROCESS CONTROL

- Analysis and design of work processes
- Process documentation
- Process validation
- Incorporation of regulations, quality control, and outcome measures

EXAMPLES OF PROCESS CONTROL

- Flowcharts of processes
- Validation or verification studies
- Written procedures
- Process (statistical) control

INFORMATION MANAGEMENT

- Defines processes for receiving and handling patient information
  - Accessibility, security, and privacy for both paper and electronic records
- Defines the hardware and software needs
- Data tracking systems

EXAMPLES OF INFORMATION MANAGEMENT

- HIPAA records
- Computer security
- Computer system downtime
- Provision for downtime operation
- Defined authority levels

OCCURRENCE MANAGEMENT

- A process for the laboratory that allows anyone on staff to document and report problems or issues that may interfere with patient care services
- Focuses on analysis and trending of events, root cause analysis, and process improvement

EXAMPLES OF OCCURRENCE MANAGEMENT

- Practitioner or patient complaints
- Nonconforming QC events
- Nonconforming external assessments
- Reagent, supply, or instrument problems
- Safety issues
- PT failures

ASSESSMENTS- EXTERNAL AND INTERNAL

- External assessments are activities that evaluate the quality management system conducted outside the organization
- Internal assessments are activities that evaluate the quality management system conducted within the organization

EXAMPLES OF ASSESSMENTS- EXTERNAL AND INTERNAL

- External
  - Accreditation assessments
  - PT
- Internal
  - Monitoring of quality indicators
  - Internal audits

PROCESS REVIEW

- Collection of information from varied resources to identify opportunities for improvement
- Analysis of information and development of a process improvement plan
- Continuous quality Improvement

EXAMPLES OF PROCESS REVIEW

- Customer surveys results
- Feedback from employees
- Assessments, both internal and external
- Occurrence management
- Proficiency test results

CUSTOMER SERVICE

- *Identification of internal and external customers*
- *Evaluation of customer needs*
- *Capture customer feedback*

EXAMPLES OF CUSTOMER SERVICE

- *Identification of both external and internal customers*
- *Customer survey*
- *Meeting with physicians to determine needs*
- *Meetings with internal laboratory staff to determine needs*

FACILITIES AND SAFETY

- *Need to maintain a safe work environment that provides safety for all staff*
- *Organization of space to assure optimal workflow*
- *Ergonomic design*
- *Remodeling/safety updates/ safety inspections*

EXAMPLES OF FACILITIES AND SAFETY

- *Space allocation*
- *Facility design*
- *Maintenance of facility*
- *Safety program*
- *Ergonomics*
- *Safety audits*