QUALITY MANAGEMENT IN A LOCAL PUBLIC HEALTH LABORATORY

Chaos to Quality

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FAIRFAX COUNTY HEALTH DEPARTMENT
FAIRFAX, VIRGINIA
OBJECTIVES

1. Provide an overview of Fairfax County Health Department Laboratory
2. Review strategies used in FCDHL to develop a more robust Quality Management System
4. Provide examples of resources and tools used by FCHDL to organize and streamline Quality Management Plan
FCHD lab is LPH performing over 200,000 clinical and environmental tests annually

- Clinical
  - STD, TB, foodborne illness (enteric pathogens & parasites), HIV, Hepatitis B, QFT
- Drugs of Abuse Screening
- Environmental Drinking Water
- Rabies
- Molecular testing for WNV, ZikaV in mosquito pools and Borrelia burgdorferi in ticks

Multiple regulatory bodies; CLIA, EPA, VaDEQ
**Population Served**

- Population - 1.14 Million
- Area - 390.97 sq. Miles
- Median Age - 35.7
- Foreign Born Population - 31.5%
- Persons 5+ who speak a language other than English at home - 39.5%
PARTNERS AND STAKEHOLDERS

INTERNAL CLIENTS
- Five Health Department Clinics
- Eight Fairfax County Agencies

EXTERNAL CLIENTS
- Neighboring jurisdictions
- Hospitals
- Local, Regional, State and National Parks
- Universities
- Private companies – Clarke (Mosquito Testing)
- Private Water System Operators
- Private Homeowners
- Dulles International Airport
FAIRFAX COUNTY HEALTH DEPARTMENT STAFF

- Lab Supervisors - 2

- Public Health Technologists
  - Full-time - 9
  - Part-time - 3

- LIS Administrator - 1

- Administrative Assistants
  - Admin IV - 1
  - Admin III - 2

- Courier
  - Full-Time - 1
  - Part-Time - 2

QUALITY MANAGER
FIRST STEPS

ASSESS CURRENT QMS

IDENTIFY ROADBLOCKS TO EFFECTIVENESS AND EFFICIENCY
- Organizational Structure
- Many documents in many formats in many places
- Infrequent monitoring of overall system
- Limited staff involvement
- Responsible persons

IDENTIFY RESOURCES AVAILABLE
- Monetary
- Instructional
DESIGNING AND IMPLEMENTING A QUALITY MANAGEMENT SYSTEM

- Realigning organizational structure
- Development of comprehensive Quality Assurance Manual
- Assess and enhance inventory methods
- Assess and enhance document control
- Promote Staff Involvement
ORGANIZATIONAL STRUCTURE

REALIGNMENT OF STAFF WITHIN ORGANIZATIONAL UNITS

CREATION OF CAREER LADDER FOR LABORATORY SCIENTISTS
  • Attract and retain qualified laboratory scientists
  • Provide career path for staff
CREATING A COMPREHENSIVE QUALITY ASSURANCE MANUAL

- CURRENT SYSTEMS IN PLACE

- Separate Manuals
  - Clinical QA Manual
  - Environmental QA Manual
  - Clinic QA Manual
  - Clinic Procedure Manuals
  - BSL3 Manual
  - Safety Manual
  - SOP Manuals
What resources are available?

- WHO/CLSI Quality Manual Template
- Ontario Laboratory Accreditation Division (OLA) Guidance for Laboratory Quality Manuals
- APHL “How to Write a Laboratory Quality Manual”
Creating a Comprehensive Quality Assurance Manual

- Assess current system
  - Identify documents appearing in multiple manuals
  - Identify documents that are specific to lab areas
  - Identify Documents relevant to the entire lab
    - Policies/Processes/Procedures
    - Requisitions/Forms
    - Position descriptions
    - Floor plans

- Determine QA Manual Structure
  - One all-encompassing manual
  - Individual manuals for each laboratory discipline
One QA Manuals vs Multiple QA Manuals?

**ONE MANUAL**
- Overarching policies, processes, and procedures in one place
- Environmentally preferable - less paper
- Easier to review and update one manual vs multiple manuals
- Easier for staff to refer to one manual vs multiple

**INDIVIDUAL MANUALS**
- Individual regulatory requirements
- Preferred format
COMPONENTS OF QA MANUAL

- QSEs
  - Relevant to all disciplines
  - Contain areas to individual disciplines
  - Differing regulatory requirements

INTRODUCTION

DEFINITIONS

QA Manual

TABLE OF CONTENTS

LIST OF ACRONYMS/ABBREVIATIONS
COMPREHENSIVE QUALITY ASSURANCE MANUAL

QSE

- QSE - Organization
- QSE - Facilities and Safety
- QSE - Equipment
- QSE - Purchasing and Inventory
- QSE - Process Management
- QSE - Assessments
- QSE - Personnel
- QSE - Customer Focus
- QSE - Nonconforming Event Management
- QSE - Continual Improvement
- QSE - Documents and Records
- QSE - Information Management

STRUCTURE

- QSE - Organization
- QSE - Personnel
- QSE - Equipment
- QSE - Facilities and Safety
- QSE - Purchasing and Inventory
- QSE - Information Management
- QSE - Documents and Records
- QSE - Nonconformance Management
- QSE - Assessments
- QSE - Process Improvements
- QSE - Customer Service

- QSE - Process Management
Work in progress

- Developing Supporting Documents
  - Appendices
  - Policies
  - Processes
  - Procedures
  - Forms
Purchased inventory system

- Monitor/Track inventory
  - Location
  - Items
  - Stock numbers
  - Pricing

- Facilitate purchasing
  - Alerts for re-ordering

- Track lot numbers and expiration dates

- Track vendor information
Purchased laboratory document control software

- Document control
- Equipment inventory and maintenance
- Personnel
- Competency assessment
- Training and testing
- Workflow development
PROMOTE STAFF INVOLVEMENT

- Creation of teams to assess and monitor quality in the lab
  - Staff participation
    - Expected to serve on at least one team
    - Part of performance evaluation
  - Oversight provided by laboratory managers
FCHD Laboratory Teams

Quality Assurance Team

- Developing internal audit checklists
- Identify quality initiatives
- Develop and provide staff training and quality improvement
- Identify metrics to measure quality initiatives
FCHD Laboratory Teams

Safety Team
- Perform routine safety audits
- Identify potential safety hazards
- Identify and develop areas for staff safety training

Webpage Team
- Develop, maintain, and update division web pages, internal and external
SUMMARY

- Quality Management is dependent on building a Quality Culture
  - Participation from all lab staff
    - Scientists
    - Administrative Assistants
    - Couriers
  - Input from partners and stakeholders
    - Customer Satisfaction Surveys
    - Suggestion box
    - LSIP Assessment
- Never-ending


o APHL. *How to Write a Quality Manual.* Silver Spring, MD: Association of Public Health Laboratories; 2017

o WHO. *Supplement to the Laboratory Quality Management System Training Toolkit, Module 16 – Documents and records.* 2013