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Disease surveillance system evaluation as a model for improved integration and standardization of the laboratory component in the Field Epidemiology and Laboratory Training Program (FELTP) curriculum worldwide

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Abstract

Integration of laboratory training into the Centers for Disease Control and Prevention's (CDC) Field Epidemiology Training Program (FETP) began in 2004 and has advanced the training of laboratory scientists worldwide on the basic principles of epidemiology, disease surveillance, and outbreak investigation. The laboratory component of the FE(L)TP training has traditionally been disease specific, revolving around classroom and bench training on laboratory methods, and field placement in areas where services are needed. There is however a need to improve the integration of epidemiology elements used in surveillance, outbreak investigation, and evaluation activities with specific measurable laboratory activities that could in turn impact the overall disease surveillance and response. A systematic and clear evaluation guideline for the laboratory components of disease surveillance systems alongside the corresponding epidemiological indicators can better identify, address, and mitigate weaknesses that may exist in the entire surveillance system, and also help to integrate and standardize the FE(L)TP curriculum content. The institution of laboratory Quality Management System principles linked to a comprehensive surveillance evaluation scheme will result in improved disease surveillance, response, and overall laboratory capacity over time.

Keywords

FE(L)TP; surveillance system evaluation; laboratory indicators; laboratory QMS; laboratory assessment; capacity development

Introduction

The Field Epidemiology Training Program (FETP) is modeled on the Center for Disease Control and Prevention's (CDC) Epidemic Intelligence Service (EIS) program and it combines classroom teaching with field experience in training epidemiologists on disease surveillance and response.[1] Worldwide, over 50 such programs exist.[2] The introduction of

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry.

the ‘L’ or laboratory training as a component of the FETP is relatively new and was first introduced into an established FETP in Africa in 2004 in response to poor laboratory systems and structures in these settings.[3] Most FETPs at present are academic in nature, are administered by the respective Ministry of Health (MOH) and academic institutions in each country, and award a Master’s degree to graduates. Examples include the Kenya, South Africa, Tanzania, and Nigeria FE(L)TPs. The general aim of the laboratory component is to bridge the gap that often exists between the epidemiology part of disease surveillance and outbreak investigation and the corresponding laboratory components of these activities. Linkage between these essential parts would result in improved surveillance and outbreak response, better programmatic outcomes, and strengthened networks and health systems. The curriculum design in these programs is generally based on competencies, deliverables, learning activities, and field placement.

A key competency requirement for the students (residents) of any FETP is the evaluation of a national disease surveillance system. A national disease surveillance system is described as the sum of all surveillance activities to monitor diseases with high burden, to detect outbreaks of epidemic-prone diseases, and to monitor progress toward eradication targets.[4] The evaluation of a disease surveillance system generally follows the model proposed by the CDC standard guidelines and updates[5,6] and provides the basis for system description, system assessment, and system improvement. These guidelines are a roadmap to specific measures and observations used to characterize any disease surveillance system.

Over the years, many surveillance systems have been evaluated throughout the world as part of the FETPs or as the target of other monitoring and evaluation activities. The CDC guidelines describe several attributes or characteristics of the system by which to gauge the system performance. These attributes fall into broad categories such as system flexibility, acceptability, simplicity, representativeness, timeliness, stability, and sensitivity among others. By gathering objective evidence by which to rate and evaluate these attributes for each disease system, one can conclude whether the surveillance system is effective or not or which elements are weak and need further support. Many laboratory functions can also fall into these attribute categories and do in fact have a direct effect on some system attributes, such as timeliness. But only limited descriptions exist for many of these laboratory elements that have potential impact on all the system attributes. A comprehensive list of these elements can significantly assist the system evaluation as described in the CDC guidelines by either laboratory personnel or by those without a laboratory background. Improved identification and appropriate linkages with important laboratory contributors to a disease surveillance system would have desired outcomes. First, the evaluation of disease surveillance systems, with the aid of a clear list of laboratory indicators, can be used by FE(L)TP epidemiologists and laboratory scientists alike for a more thorough assessment of national surveillance systems. Such an evaluation can be similarly used in clinical laboratories that may also be involved in disease surveillance or are part of a national laboratory surveillance and response network. This can in turn lead to more targeted interventions and effective, sustainable improvements in the surveillance system over time. Second, the creation of a clear guideline addressing the appropriate laboratory measures in national surveillance systems can be used as a model for better integration and

standardization of the joint laboratory and epidemiology components in the FE(L)TP curriculum, activities, and projects.

The relative novelty of incorporation of the laboratory component into the FETPs has contributed to lack of a standard laboratory curriculum model from one FE(L)TP to next. The incorporation of a clear guideline for laboratory indicators and measures in support of the surveillance system evaluation activities and inclusion of laboratory assessment in the FE(L)TP curriculum can help bridge the gaps in these programs. Validated tools for laboratory assessment are readily available and can be adopted for this purpose. Examples of commonly used mechanisms for independent stand-alone laboratory evaluation and assessment include the ISO (International Standards Institute) and CLSI (Clinical Laboratory Standards Institute-formerly NCCLS) developed guidelines and questionnaires,[7–9] WHO's laboratory questionnaire,[10] and other measures for programmatic activities such as HIV/AIDS.[11] Laboratory system assessment is often based on the 12 Quality System Essentials (QSEs) that make up the larger laboratory Quality Management System (QMS).[8] Laboratory QMS is the sum of all activities that must be in place to insure quality in all laboratory functions. The QSEs address all pre-analytic, analytic, and post-analytic activities related to testing of samples in the laboratory.[8] We propose a set of clear laboratory indicators that can be used to better integrate the components of and improve the national disease surveillance system evaluation. These indicators can be used to develop standard laboratory curricula and laboratory systems-related projects for the FE(L)TPs and set the course for targeted national laboratory capacity-building activities.

Disease Surveillance System Evaluation

The standard disease surveillance system evaluation used by FETPs is based on CDC recommendations for monitoring the public health response system. This document was published in 1988 as *Guidelines for Evaluating Surveillance Systems*[5] and updated in 2001 in the *Morbidity and Mortality Weekly Report Recommendations* as *Updated Guidelines for Evaluating Public Health Surveillance Systems*.[6] Under these guidelines, evaluation activities are divided into several major tasks that help in describing the system and its importance, focus the evaluation design and purpose, identify stakeholders, gather credible evidence of system performance, and finally describe and measure the most important attributes linked to performance.

Important surveillance attributes that are assessed include measures of each system's simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness, and stability. These variables individually and in sum determine the quality or effectiveness of the system being evaluated. Most disease surveillance systems, including both chronic and infectious diseases, have laboratory components and activities that generate supportive and confirmatory evidence of disease. Some surveillance systems may be more laboratory based. These include serologic surveillance and monitoring of targeted animal populations for enzootic diseases or epizootic events, and also survey activities that depend on examination of disease markers or indicators such as specific antibodies to infectious agents in sentinel populations.

The surveillance evaluation guidelines are ultimately intended as tools to help generate improved data for measuring the true burden of disease; to monitor disease trends; to plan and implement evidence-based policies, programs, and practices; to allocate appropriate resources; and to set the stage for epidemiological research. Only a few attributes of the surveillance evaluation scheme, however, clearly address supporting laboratory variables and indicators. We propose the elaboration of specific and well-defined laboratory metrics to match and link to the other components of the surveillance system to bridge the gap more effectively between the two types of variables and measures – one epidemiologic or program based and the other laboratory based.

Laboratory Indicators in Surveillance System Evaluation

Although the various attributes used in the surveillance system evaluation address strengths and weaknesses in terms of the program targets and health policies and activities, corresponding laboratory indicators also need to be evaluated as an integral part of the surveillance system. Table 1 shows a summary of surveillance system attributes and the likely corresponding laboratory measures. This list can be used by epidemiologists and laboratory scientists in carrying out disease surveillance system evaluations.

An objective evaluation of the laboratory functions and indicators of quality as part of the larger surveillance system measures can point out the system strengths and weaknesses on a more comprehensive basis. Evaluation of laboratory measures and indicators as they relate to disease surveillance and investigation can form the basis for recommending measures and activities to improve the quality of laboratory results. Clinical labs that adopt and use many of the key items in the proposed scheme may also benefit from the information gathered in such an evaluation. Linked laboratory indicators can be used to monitor performance and laboratory contributions to targeted surveillance systems.

Lastly, laboratory focused activities, such as quality improvement projects, can be incorporated into the laboratory curriculum as deliverables or as outcomes for the laboratory scientists in the FE(L)TPs or in any pre- and in-service laboratory training program, such as those for clinical laboratory scientists. These activities can also be used independently to complement laboratory assessments and capacity-building activities that use the laboratory QMS framework.

Targeted Activities to Improve Laboratory Results and Surveillance System Quality

Through several approaches, FE(L)TPs can improve the quality of laboratory functions, including testing and capacity development. Laboratory bench training is part of the curriculum used by some FE(L)TPs to improve laboratory residents' level of technical skills and knowledge. Training on new diagnostic tools and methods to respond to priority diseases is necessary to build capacity, however training activities are generally technology driven and disease focused. They may not always address the wider (systems) issues in laboratory quality. The addition of laboratory QMS training to the curriculum addresses the overall quality system components that directly or indirectly impact disease surveillance.

Quality system variables include many indicators, from staff training and competence in performing laboratory assays, to sample collection, transport, and quality control and assurance, to documentation and reporting or dissemination of results (Table 1). Many fundamental activities are deemed critical to obtaining reliable, valid, laboratory results and timely reporting. These include proper sample collection, transport, and results documentation and dissemination. They fall in the pre- and post-analytic phases of sample management and quality assurance, as well as in the analytic phase (Figure 1).

QSEs address the requirements for quality results and products in all phases of the quality assurance cycle. They cover the following 12 areas: personnel, organization, documents and records, process control, assessment and audit, equipment, purchasing and inventory, information management, occurrence management, process improvement, facilities and safety, and customer service and satisfaction (Figure 2). With proper guidance and mentorship, laboratory residents in the FE(L)TPs can use the appropriate QSEs as tools for targeting key laboratory indicators for disease surveillance system improvements. These activities can be part of the ongoing projects and competencies of the FE(L)TPs or any other laboratory training program, and will contribute to the development of national laboratory systems and capacities.

Conclusion

We propose the evaluation of disease surveillance systems as an entry point for integration of epidemiology and laboratory components in the standard FE(L)TP curriculum. Surveillance system evaluation provides a natural framework for this synthesis, as it is a fundamental activity in the FE(L)TP curriculum and validated guidelines are available. Other unexplored opportunities and possibilities may exist for laboratory integration into FETP curriculum and activities. These include the presence of clear definitions, strategies, and organization of the joint laboratory and epidemiology processes during disease outbreak investigations, plus additional improvements in designing planned epidemiologic studies, especially those with substantial laboratory contributions. These activities naturally require effective collaboration between laboratory scientists and epidemiologists, and they help build capacities that strengthen the overall surveillance system.

The weaknesses found in laboratory-related surveillance activities can be addressed as part of recommendations through FE(L)TP reports and findings or separately as part of national/sub-national laboratory assessments and audits performed internally by institutions or by independent assessment bodies. Recommendations from either effort will require appropriate laboratory QMS intervention measures, including training, continuous monitoring, and evaluation. The capacity for and feasibility of performing laboratory assessment to obtain key objective information on quality measures and surveillance capabilities is commonly dependent on several factors. These include national and local laws and regulations governing clinical, public health, and other laboratories; national laboratory (strategic) planning; a competent workforce that is sufficient in number; and finally support and guidance from key health and governmental authorities.

FE(L)TPs serve an important function by creating cadres of well-trained epidemiologists and laboratory scientists who not only can conduct proper surveillance and disease investigation, but can also address the elements of good laboratory practice and laboratory quality management. Placement of laboratory residents from FE(L)T programs at central national reference levels and at sub-national laboratories would in the long term build a sustainable culture of quality as skills are passed on to other laboratory scientists during pre-service and in-service training.

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Biography

Thomas Rush (DrPH, MPH) is the laboratory resident advisor for the Centers for Disease Control and Prevention's (CDC) regional Field Epidemiology and Laboratory Training Program (FELTP) in South Caucasus. His experience covers teaching laboratory quality system, laboratory management, leadership, and administration. Rush was trained as a microbiologist and has worked in public health for the last 30 years.

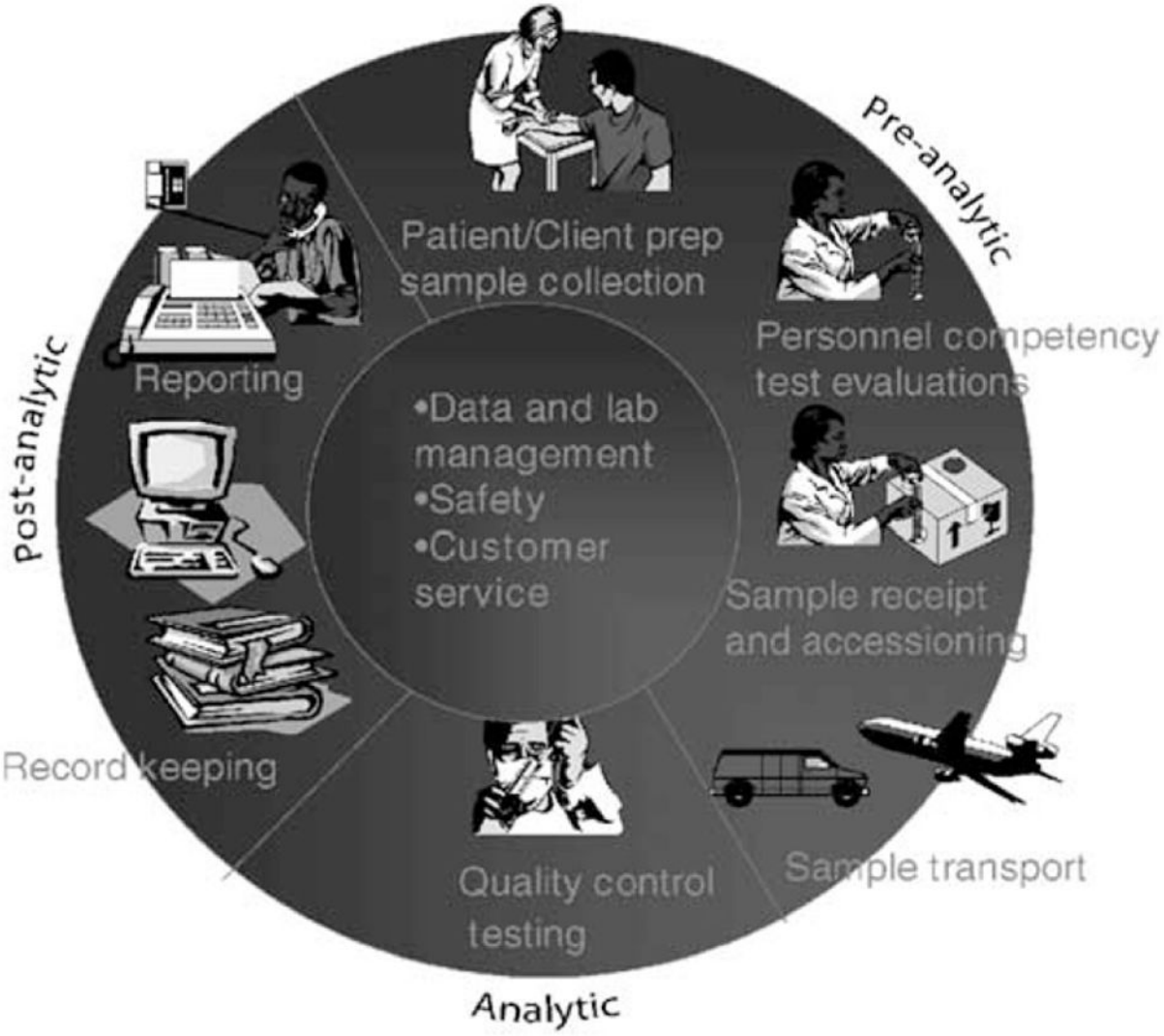

Figure 1.
The quality assurance cycle.

Figure 2.
Quality System Essentials in the laboratory Quality Management System.

Table 1

Surveillance system evaluation attributes and corresponding laboratory indicators

Attributes	Epidemiology/Surveillance program indicators	Corresponding laboratory indicators[a]
Simplicity	• Amount and type of data • Number of organizations involved • Level of integration of system • Method of data collection • Extent of data management, analysis, and dissemination • Staff requirements • Maintenance of the surveillance system	• Test complexity • Test algorithm • Level of lab training needed to perform test • Specimen number required for diagnosis • Specimen collection and transportation ease or difficulty • Reporting of lab results ease or difficulty • Dissemination of laboratory results ease or difficulty
Flexibility	• Adaptability to changing needs, definitions, and conditions	• Test format or platform easily adaptable or changeable for given conditions • Adaptability of tests and assays to environmental factors and conditions • Adaptability of test to process improvement
Data quality	• Validity of data • Completeness of data • Sensitivity and predictive value positive of the system based on data	• Specimen quality, such as appropriate sample, and quantity • Transport conditions such as time in transport and temperatures • Test and assay characteristics such as sensitivity, specificity, Predictive Value of Positive (PVP), Predictive Value of Negative (PVN), testing reliability, and validity • Robustness of the testing algorithm • Quality, condition, and control of lab equipment and instrumentation and their upkeep • Presence and routine use of quality control samples, quality assurance, external quality assessment (EQA) Programs, and elements of lab Quality Management System (QMS) • Accurate laboratory documentation, reporting, and record keeping • Clearly understandable content, design, and accuracy of laboratory reports • Adequate staff training • Evidence of staff competence through EQA participation
Acceptability	• Willingness of stakeholders to participate in the surveillance system • Interview and report completion • Reporting rate • Timeliness of data reporting	• Laboratory's role and importance in disease surveillance and reporting • Quality of the lab assays • Complexity of the lab assays • Cost of laboratory testing • Frequency of lab testing and reporting

Attributes	Epidemiology/Surveillance program indicators	Corresponding laboratory indicators[a]
		• Confidentiality and privacy of test results observed • Responsiveness of lab to process improvement in testing and reporting frequencies
Sensitivity	• Occurrence of disease • Existence of case definitions • Existence of active surveillance • Quality of diagnosis and reporting of cases and those that are ruled out • Quality of data on health status	• Laboratory tests exist for the disease or condition • Tests are utilized properly • Assay sensitivity and specificity for screening and confirmatory tests are relatively high (>95%) • Ongoing laboratory testing is an integral part of the national surveillance and reporting system • Advanced assays exist especially for linking cases and finding common sources (molecular epidemiology)
Predictive value positive	• Confirmation of cases reported by system • Detection of true outbreaks/epidemics • Knowledge of baseline disease prevalence • Sensitivity and specificity of case definition • Existence of complete medical records, registries, death certificates, outbreak investigation records, communication of information	• Sensitivity and specificity of the screening and confirmatory tests • Prevalence of disease in the population • PVP for lab tests used • Complete lab records and documentation for test results • Percentage of samples that due to various reasons cannot be lab-confirmed and test negative for the disease of interest
Representativeness	• Characteristics of the population and demographics • Characteristics of the disease and its clinical course • Nature of medical and diagnostic practices • Existence of multiple data sources for comparison with reported incidence	• Number of laboratories performing diagnostic testing for the given disease or condition • Location of laboratories in given regions • Extent of laboratory services provided for given populations • Type and quality (sensitivity, specificity, PVP, PVN) of tests used in each location for the disease or condition • Lab QMS practices in regional and central laboratories
Timeliness	• Time interval between stages in diagnosis, reporting, and control/prevention for the given disease or condition • Disease characteristics and latency • ability to access data quickly	• Time requirements for specimen collection, transport, and testing • Turn-around time for laboratory results to physician or health agency • Existence of valid, reliable rapid tests for disease or condition • Existence of electronic laboratory-based surveillance system and rapid dissemination of data

[a]Correspondence may not necessarily be one to one between epidemiology and laboratory bulleted items.