CHAPTER 3

Results Management and Reporting of Data

I. Data management and reporting

Proper laboratory procedures are essential for correctly identifying and characterizing pathogens from patients with bacterial meningitis. However, even the best laboratory efforts are not useful if the results are not accurately reported to those who make policy and epidemic response decisions. The development of an accurate data reporting system requires quality data management: collection, recording, validation, and results feedback of important information about patients, specimens, and laboratory results.

II. Data management systems

A data management system can be as simple as a laboratory logbook or as complex as a computerized information system. Laboratories with small workloads may find that paper records are sufficient for their data management requirements. However, computerized information systems are recommended for laboratories that handle larger numbers of clinical specimens and isolates. Regardless of whether the data management system is paper or computerized, it should allow clinical and laboratory data to be accurately recorded, easily accessed and reported, and reliably stored. It is also important to keep laboratory data linked with epidemiological data to ensure the quality of results reported.

When considering computerized information systems, laboratory directors should consider the user preferences, hardware and maintenance requirements, software costs, local expertise needed to develop, install, refine, and maintain the system, and the costs of routine data backups. Computerized information systems should allow easy recording of data, formatting and editing of reports, and simple analyses such as frequencies and workload calculations. These basic analyses can help laboratory managers estimate operating costs and supply needs, and can also provide surveillance systems with useful summary information.

III. Request form and record keeping

Quality data management begins with the clinical request for laboratory testing. All clinical specimens and isolates should be accompanied by a standardized request form that includes the following information:

- Patient's name, date of birth, sex, and residence address
- Unique Identification Number. Examples include, Patient Hospital Number, Case Identification Number (for patients included in epidemiologic investigations or research studies), or Surveillance Identification Number (such as an EPID number).
- Patient's hospital, hospital address, and room number
- Physician's name and contact information
- Clinical diagnosis and relevant patient history

- Specimen type (clinical specimen or isolate)
- Anatomical site of specimen collected (CSF, blood, other)
- Date and time of specimen collection
- Test(s) requested
- Antimicrobial therapy the patient is receiving or has received, if any
- Immunization status for meningitis pathogens (*N. meningitidis*, *H. influenzae* serotype b, *S. pneumoniae*)
- Name and address for report recipient

Each specimen should have a label firmly attached to the specimen container bearing the following information:

- Patient's name
- Unique Identification Number
  - Be sure this number matches the number on the request and report forms.
- Date and time of specimen collection

Upon receiving a clinical specimen or isolate, the laboratory staff should enter the above information into the laboratory data management system. Additional information to be recorded includes:

- Date and time the clinical specimen or isolate arrives to the laboratory
- Number of items received in the laboratory
- Gram stain result
- Whether or not the treating clinician was notified of the Gram stain result within one (1) hour of the test result
- The date the specimen or isolate was stored by the laboratory
- The data the specimen or isolate was sent the national laboratory or regional reference laboratory

Other important information to record includes transport conditions (e.g., conservation of ideal temperature for transporting specimens and maintaining appropriate shipping conditions according to guidelines), condition of the specimen upon arrival (e.g., volume, possible contamination, compromised container, etc.), and any preparatory actions taken (e.g., aliquoting or centrifugation). The specimen should be given a unique laboratory identification number to be used in all subsequent procedures. It is important that the identification number be recorded on the request form, the specimen container, and in the data management system so that results are linked to the patient information.

Results for all tests performed on the clinical specimens and isolates should be entered into the data management system as soon as they are obtained. Any information regarding quality control and quality assurance (see Chapter 13: Quality Control and Quality Assurance) related to the tests should be recorded in the appropriate logbook or database.

IV. Data reporting

Another important function of the laboratory is to provide users with timely and accurate laboratory results. Users include physicians, surveillance units, disease control programs, local, state, district, regional, and national health departments, and outbreak investigation teams. Each of these users will need different information from the laboratory. For example, a surveillance unit in the African meningitis belt may need summaries of all patients with confirmed *N. meningitidis* by serogroup, while a physician treating a patient with bacterial meningitis may need rapid reporting of the pathogen and antimicrobial susceptibility testing results. Laboratory directors should work with users to develop a standardized report form, data formats, and regular reporting frequencies. The expected flow of information and communication method should be clearly agreed upon by both the laboratory and the data recipients. It is essential that efficient reporting mechanisms are established as the best laboratory efforts are futile if the information is not reported back to the patient's physician, surveillance team, etc. Furthermore, surveillance and study information must be reported to public health officials in order to affect public policy decisions.

Recommended reading

- ISO 15189:2007. Medical laboratories: requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization; 2007.
- Polio laboratory manual, fourth edition. WHO/IVB/04.10. World Health Organization, Geneva, 2004, p 157.