Chapter 11 overview

An essential part of the work of every laboratory is to record and manage the test results, quality assurance data, and related information that establishes the output and performance of the laboratory. Laboratory protocols should be in place to clearly outline the processes and methods for generating and maintaining records. The frequency and manner in which laboratory results are reported will vary according to the needs of the recipient, which may be the submitter, local and national public health partners, or WHO Regional offices.

Specific guidance in the area of data management and the preparation and distribution of reports are covered in this chapter. An overview of laboratory quality assurance and quality control, accreditation requirements, and related quality systems such as document control are described in chapter 12. In addition to recording relevant data and results, the laboratory is responsible for the analysis and interpretation of results, identification of epidemiologic patterns or trends, and the preparation of regular reports. The preparation and transmission of sequence information to global databases (MeaNS/RubeNS) is provided in chapter 7.

The term, data management, encompasses several activities and processes, and is an essential component of any disease surveillance system. WHO regional offices will provide details of specific data reporting requirements appropriate to the level and activities of WHO measles and rubella laboratories within each regional laboratory network.

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11.1 Data management goals

Maintenance of laboratory records that are accurate and relevant requires good management practices and a clear designation of responsibilities. The success or failure of any public health or disease control initiative depends on establishing and maintaining a good information exchange system, with accurate and timely data being provided for appropriate action. The importance of good laboratory data management cannot be overstated.

In order to create an efficient data management system, the following operational consideration should guide decision-making:

- The meaning of the information generated
- What information needs to be provided outside of the laboratory
- Who needs the information
- How frequently the information needs to be transmitted
- How frequently the data is analysed, summarised and distributed

Every laboratory will need to determine the processes and documentation required to transform data, records, and related laboratory activities into:

- Test results, provided in a report form, to the EPI programme and to the submitter or the organization that requested the testing
- Annual reports or progress reports for the director or head of the institute
- Summary reports consisting of activities and data that help justify continued support and funding

The documentation that is required to meet the goals above should be concise and complete, avoiding unnecessary information and excessive data entry to reduce omissions and errors.

The next step in data management is to decide how the information should be physically recorded and stored. All laboratories maintain laboratory results books or ledgers. These are often in the form of paper records, recorded line by line, with information entered into specific columns. Such records, or line-listings, contain all the information relating to the specimen or case.
For laboratories with a small workload, paper records are sufficient to meet all the reporting requirements. For laboratories with larger workloads it is often more convenient to establish a computer record system. In accordance with Regional network requirements, a simple spreadsheet system (using software such as Excel), reflecting the line-listing of paper records, may be sufficient for some laboratories. Although useful for some types of analysis, computer spreadsheets are not very easy to manipulate when using large amounts of information. For large amounts of information, it is better to establish a computer database.

The software and hardware selected to computerize laboratory record keeping is beyond the scope of this manual. However, the manager should seek out available options that provide low cost and that can be maintained through local expertise. At a minimum, the system should be user-friendly, allow rapid and accurate access to selected records, have the capability to perform simple calculations, such as frequencies and time intervals, and have functions available to create tables and graphs. Data entry should include drop-down menus where feasible. Ideally, laboratory records systems should include:

- The ability to detect errors in the information entered
- Routine backup of data
- Routine analysis and reporting

In designing any recording and reporting system for laboratory results, it is essential to request input from colleagues in all areas related to disease surveillance and control so that the system is understood and functions well across departments and to higher levels of the organization. The information flow should be clearly established from one level to the next so that none of the intended recipients are missed. Information can also be “broadcast” or sent to several recipients at different levels at the same time.

Once a pattern of information flow is established, it is very important that it be followed without exception. The system should undergo review periodically to make sure that it is functioning well and whether improvements can be made. If any changes are made to the system, it is essential that all parties involved are informed of the changes and agree to them.
11.2 Data recorded for incoming samples (accessioning)

A case investigation form is completed for each suspected measles or rubella case investigated. A separate laboratory request form should be completed at the time of specimen collection and should accompany all specimens sent to the laboratory. Information on specimen labels must be carefully checked to ensure that it matches information on the request forms. The information that should be included can be viewed on the template for a laboratory request form, Annex 11.1.

Upon receipt of a specimen the laboratory should record the following information:

- date specimen received in laboratory
- adequacy of specimen (e.g. volume)
- condition of specimen (integrity of container, temperature)
- processing steps if appropriate (elution, separation, centrifugation)
- storage location

Any problems or issues with the timeliness of samples or the condition or adequacy of the specimen should be communicated immediately to the EPI manager.

Each specimen should be allocated a specific identification number that is entered in the laboratory ledger or “day book”, on the accompanying request form, and on the specimen vial or container. This may be an abbreviated version of the Identification Number for the case or a sequential unique laboratory number. This number must be used on all containers, centrifuge tubes, test tubes and vials throughout subsequent laboratory procedures. Different aliquots should also have separate numbers (may be derived from the laboratory number, and records kept as to where the aliquots are stored). If possible samples and aliquots should receive a barcode to reduce transcription errors. Each sample must have a link to the case identification number (such as Epi Info) used by the country’s surveillance programme.

11.3 Recording laboratory results

As soon as test results become available and have been reviewed, a record should be entered into the laboratory database. Most laboratories maintain some form of digital database, often on
dedicated computer servers that are backed up frequently to avoid loss of data and to facilitate interaction with requestors and with national and international databases (e.g., WHO). The results and additional information that are collected on each specimen should be entered into the record and include the following data at a minimum:

- Case identification number
- Laboratory identifier
- Date of assay
- Type of assay (IgM or IgG serology, diagnostic RT-PCR, genotyping RT-PCR, virus culture)
- Optical density readings (for serology) /Ct (for RT-PCR)
- Result of assay (pos/neg/indeterminate)
- Date result reported and to whom (requesting clinician, EPI manager, WHO)
- Aliquot of sample sent to the RRL? (If yes) *

*If an aliquot was forwarded to the RRL, then the following items should be included:
  - Name of RRL
  - Purpose of referral
  - Laboratory identifier
  - Date specimen forwarded to RRL
  - Date of reception of results from RRL
  - RRL result
  - Date of reporting and to whom

11.4 Information to accompany results and data to maintain in records

Worksheets can document the details of all samples being tested and the composition of the test during any given procedure. Recording details of all variables in any particular test or assay will allow analysis and development of trends which can aid in troubleshooting and in verifying the quality and performance of test procedures. A review of a laboratory’s raw data can be especially helpful during an on-site review for the WHO accreditation process for the GMRLN.
Worksheets can be paper-based system, where variables are recorded by hand on a printed worksheet. For an electronic system, worksheets may be generated from the computer and may be partially generated from the programme associated with the test/assay. Information to be recorded on a worksheet include:

- Type of test/assay
- Date of test performed, date of reporting results
- Name of operator, name of person validating test
- Lot numbers and expiry date of reagents/kits
- Reagent concentration and identity of diluent(s)
- Sample identification, treatment, condition, date of collection
- Control sample details: ID, date, lot number, reference value
- Validity of test/assay
- Results: raw data, calculated values/units
- Interpretation and final result to be reported
- Comments: record of any issues with assay and how they were resolved
- Attachments: Raw data print outs, digital images if generated

There are certain points in data handling when it is easy for transcription errors to occur, such as during manual transfer of data from patient history forms to worksheets or databases, keyboard data entry into a computerized information system, or data entry from worksheets to reports. The laboratory should put processes in place to safeguard against errors at these points.

Sometimes it may be necessary to adopt formal checking processes to ensure the accuracy of data recording and transmission of handwritten or keyed information. One example of a simple checking process is to always have two people review data transcription to verify its accuracy.

A common error occurs when the date format varies from a referring laboratory. Always request countries to specify the format their dates are recorded in, for example DD/MM/YYYY. Although some commonly used databases can be programmed to allow automatic conversion of date formats, error checking is still advisable.
11.5 Reporting to EPI teams and to WHO

Details of how and when laboratories report results to EPI managers should be arranged locally. Results necessary for appropriate case follow-up will be of an urgent nature whereas data generated to guide supplementary immunization activities should be compiled, analysed, and transmitted according to the timeframe established for the programme. In general, however, all results from suspected cases should be reported within a short turnaround time (3-7 days) as established by the national or regional guidelines. In the absence of recent cases, a positive result should be reported within 24 hours.

Monthly exchange of information may be helpful to the programme and to the laboratory for the purpose of comparing and reviewing the completeness of data for suspected cases. In addition, feedback related to the adequacy of samples and any problems encountered can help identify issues and challenges to timeliness of specimen arrival and reporting. All reports should be available to the EPI managers on request.

All national laboratories are requested to provide a report of results to WHO. This information is used to update country summaries, monitor laboratory performance and coordinate international agency activity. Data provided in the reports is essential to the coordination of the programme as a whole, and it must be a priority activity of all laboratories in the network to send reports in a timely and accurate manner.

Because of the amount of data involved and the time required to analyse the information it is essential that laboratories processing more than 100 specimens a year provide their reports in computer database format by e-mail. WHO HQ can provide a set of laboratory data management programmes suitable for most of the GMRLN laboratories.

Bibliography to Chapter 11

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