Content Sheet 17-1: Overview of Information Management

Role in quality management systems

Information management is a system that incorporates all the processes needed for effectively managing data—both incoming and outgoing patient information. The information management system may be entirely paper-based, computer-based, or a combination of both.

Whatever technology is employed, information management is another of t vital essentials of a quality system, and closely related to Documents and Records (Module 16).

Remember that data, and in particular test results, are the final product of the laboratory. Laboratory directors need to ensure that the laboratory has an effective information management system in place in order to achieve accessibility, accuracy, timeliness, security, confidentiality, and privacy of patient information.

Important elements

When planning and developing an information management system, whether it is a manual paper-based system or an electronic system, there are some important elements to consider:

- unique identifiers for patients and samples
- standardized test request forms (requisitions)
- logs and worksheets
- checking processes to assure accuracy of data recording and transmission
- protection against loss of data
- protection of patient confidentiality and privacy
- effective reporting systems
- effective and timely communication.

Content Sheet 17-2: Elements of Information Management

Unique identifiers

A unique identifier is an important tool for managing information, and careful thought should be given for how best to assign identifiers to patients and samples within the information management system.

Patient identifiers—Sometimes hospitalized patients are assigned a unique identifier upon admission, to be used for the duration of the hospital stay. A patient may get a new number each time he/she is seen or admitted. In other settings, the unique identifier may be assigned to the patient on a more permanent basis, to be used each time the patient has any health care.

Sample identifiers—Laboratories need to assign unique identifiers to patient samples so they can be tracked throughout the laboratory.

The method for generating and assigning unique identifiers within an information management system will depend on many factors. Some commercially available computer systems for laboratories have a numbering system built in to the software. Laboratories using paper-based systems will need to establish their own system.

An example of a simple system for generating unique identifiers is as follows.

Consider using a number consisting of the year, the month, the day, and a four digit number: YYMMDDXXXX. At the beginning of each day, the last four digits start with the number 0001.

For example, the number 0905130047 can be read 04 05 13 0047, and it would represent: sample #47, received on May 13, 2009.

To avoid confusion or mix-up of samples use the sample's full identifying number throughout the laboratory. At a minimum, the unique number will need to be used on all aliquots of the sample, on the request form, the laboratory register or log, and the result sheet.

Whatever system a laboratory chooses, unique identifiers should be used to eliminate confusion and mix-up of samples, and make samples and information easier to find.

Test request forms, logs, and worksheets

The test request form is where the entire testing process begins, and is important for both paper and electronic systems. To optimize test requests:

- standardize the test form—the form should indicate all information that needs to be provided when ordering and submitting a test request, and sufficient space for recording the information; (ISO 15189 requirements for the request form are addressed in Module 16, Documents and Records);
- ensure the request form is completed—when the request form is incomplete, communicate with the requestor to try to secure the needed information. it may become necessary to refuse non-urgent test examination until the form is completed.

Logs that allow for recording data at the time of arrival of the sample in the laboratory are very important, as are worksheets that document which patient samples are being tested during a given procedure. In a paper-based system, this will be a written record, usually in a bound book. For an electronic system, logs and worksheets may be generated from the computer. Thought should be given as to what information should be recorded.

There are certain points in data handling where it is easy for errors to occur, such as manual transfer of patient data from requisition forms to logs, keyboard electronic entry of data into a computerized information system, or transcription 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 simple checking processes is to always have two people review data transcription to verify its accuracy. Some computerized systems have electronic checks requiring duplicate entry of data that are built into the system. If these duplicate entries do not match, an error alert is generated to the person entering the data.

Security

It is important to establish a means to protect against loss of data.
For paper-based systems, this will involve using safe materials for recording and storing the records properly. For computerized systems, scheduled or regular backup processes become very important.

It is of utmost importance to safeguard a patient's privacy, and, in this regard, security measures must be taken to protect the confidentiality of laboratory data. Laboratory directors are responsible for putting policies and procedures in place to assure confidentiality of patient information is protected.

Reporting systems

The product of a laboratory is the test result, or the report. Give sufficient attention to the reporting mechanism to ensure that it is timely, accurate, legible, and easily understood.

The report should provide all information needed by the health care provider or the public health official using the data, and include any comments that are appropriate, such as "sample haemolyzed" or "repeat sample." It should be

verified and signed by the appropriate laboratory staff.

Whether issuing paper-based or computer-based test reports, laboratories must assure reports arrive on time to the right person. Reports might be delivered by laboratory staff to the hospital ward, by courier or by mail to an off-site facility, or through electronic mechanisms using a sophisticated LIMS. A telephone is often used to give urgent results. A record of the telephone call must be kept and should include the caller's signature, date and time, and whenever possible, the recipient's name. Telephone results should be followed by a written report.

The test result report reflects the laboratory's image to the client, the test requestor, and to others who may use or need it.

Communication considerations

When planning for paper-based or computer-based information systems, be sure to consider the need for a good system for communicating within and external to the laboratory. This is especially important in larger organizations. It may be necessary to devise a system for passing along information between staff covering different shifts or areas of the laboratory to make sure important details are not overlooked. The laboratory might also need to develop a policy for communicating with its customers, such as health care providers, central reference laboratories, and official agencies. The policy should describe what communication channels need to be followed, and when, and state who has authority to communicate with the different levels of customers.

Common problems

There are many points where problems can occur when managing laboratory information. The laboratory should carefully consider potential problems and plan on how to avoid them. Some of the most common problems are:

- incomplete data for test interpretation, or insufficient or illegible identification. Systems should be designed to minimize this occurrence; for example, when using electronic systems, it is possible to design fields so that if information is missing, data entry cannot be completed;
- forms that are inadequately designed to meet laboratory and client needs;
- standardized forms prepared by others may not be suitable for all laboratories;
- inability to retrieve data due to poor archiving processes or insufficient back-up of computerized information;
- poor data organization, which may hinder later data analysis efforts to meet research or other needs;
- incompatibility between computerized information systems and equipment or other electronic systems, resulting in problems with data transmission.

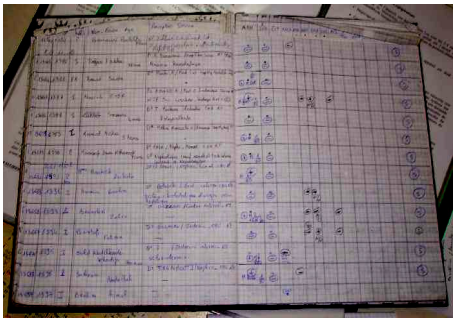
Content Sheet 17-3: Manual Paper-based Systems

Developing a manual system

Financial constraints may require that a laboratory use a manual, paper-based system for all its information management. Careful planning, attention to detail, and awareness of problems can allow for the development of a good paper-based system that will provide satisfactory service.

Registers, logs and worksheets

Manual registers, logs and worksheets are widely used, and most laboratorians are very familiar with use of manual systems for managing samples through the laboratory. Even laboratories with some computerization will often have partially or totally handwritten worksheets.



Laboratory registers or sample logs take many forms, and almost all laboratories will have one that has been in use. When reviewing information management needs, consider whether an existing register is satisfactory, or whether it should be redesigned.

Registers and logs with good design are:

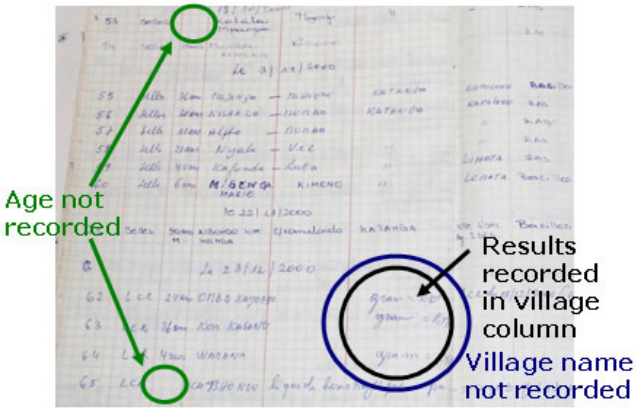
- practical to use and easy to complete;
- make it easy to find the data;
- make summarizing data and writing reports easier.

The logbook or register can be supplemented by the use of daily logbooks. For example, a separate logbook might be used to keep track of the numbers of patients and samples, or a logbook could be developed that is organized by the type of test. For some specialties such as microbiology or parasitology, a laboratory might decide to keep a specific logbook showing the total number of tests and the percentage of positive results.

Registers and logbooks are unique sources of information for preparing statistics and reports, although they can be more cumbersome to use and less complete than a computerized information system.

Data entry

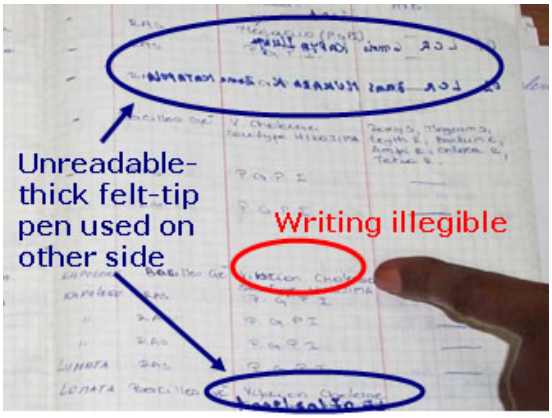
When using a paper system, it is important to emphasize to staff that all data entry must be complete. A computerized system usually requires that all "essential fields" contain data, but in handwritten records there is no check on this point.



Legibility

Illegible writing may be a problem, but it must be addressed; emphasize to employees the importance of legibility.

Carefully consider the ease of use, and legibility of the final report of results—it is the primary product of the laboratory, so make sure it is done properly and professionally.



Hand-written reports

When handwritten reports are issued, the laboratory needs a copy for its files or archives. Not having an exact copy of the report can lead to later problems, if errors in transcription occur.

It is imperative that the records be kept in a safe place where they can be easily retrieved.

Storing paper-based materials

When storing paper-based materials, keep in mind that the goals are to be able to find a result, trace a sample throughout its pathway in the entire process, and evaluate a problem or an occurrence to find its source.

Some useful rules to think about are:

- keep everything, but develop a system for when and how to discard (for example, after the appropriate established retention time, shred records to maintain patient confidentiality);
- ensure easy access to information by those who need it;
- use a logical system for filing;
- use numbers to help keep things in chronological order.

Paper is fragile, and vulnerable to water, fire, humidity, and vermin (rodents and insects). Use a storage area that will protect against these elements as much as possible.

Content Sheet 17-4: Computerized Laboratory Information Systems

Developing a computerized system

A computerized system for laboratory data is often called a laboratory information management system and is referred to by the acronym LIMS or LIS. The use of a computerized system is becoming more common in laboratories around the world. An appropriately designed and installed LIMS brings accuracy and accessibility to the flow of samples and data in the clinical laboratory.

There are a number of options available to those interested in developing a computerized laboratory information system. Some laboratories may elect to develop an in-house computer network, and use locally developed systems based on commercially available database software, such as Microsoft Access. Others may choose to purchase fully developed laboratory systems, which usually includes computers, software, and training.

One source of information that may be helpful for planning and implementing a LIMS is the Association for Public Health Laboratories *Guidebook for Implementation of Laboratory Information Systems in Resource Poor Settings.*[1]

Choosing a system

If the decisions about purchasing are made outside the laboratory, for example by the information system department, the laboratory director should provide information that will support selecting equipment that will best serve the needs of the laboratory. The most up-to-date hardware or software may not add to the functionality of the laboratory and can wind-up having to increase overhead, e.g., more data handling, in order to use LIMS systems that have been designed not for the laboratory but for the accounting or central supplies departments.

A LIMS with flexibility, adaptability, ease of evolution and support, and system speed will most benefit the laboratory. The speed issue is very critical as laboratorians will not use something that is slow or awkward, but if it saves time they will quickly "buy into" the project and aggressively move the process forward.

Advantages of computerized systems

A complete computerized information system will be able to handle all the basic information management needs. A computer system has the capacity to quickly and easily manage, analyze, and retrieve data. The computerized system offers some definite advantages over paper-based systems. Some of these advantages are listed below.

- Error reduction—A well planned computer system, with check systems for errors, will help to alert the user of inconsistencies, and reduce the number of errors. It will also provide information that is legible.
- Quality control management—It becomes easy to keep good quality control records, perform analysis on QC data, and generate statistics automatically.
- Provision of options for data searching—A variety of parameters can be used for data

[1] Information about this guidebook is available at URL: http://www.aphl.org/aphlprograms/global/initiatives/Pages/lis.aspx

retrieval, e.g. it is usually possible to access data by name, by laboratory or patient number, and sometimes by test result or analysis performed. This kind of data searching is almost impossible with paper-based systems.

- Access to patient information—Most computer systems allow access to all recent laboratory data for a patient. This is very useful in the process of checking the most recent results against previous data to look for changes, which is a good practice, and helps to detect errors. Some computer systems give enough information to determine the admitting diagnosis or access other useful information related to the illness.
- Generate reports—It is easy to generate detailed, legible reports quickly. A LIMS will provide standardized (or customized) reports.
- Ability to track reports—A computer system makes it much easier to track reports; to know when work was finished, who performed the work, when the data was reviewed, and when the report was sent.
- Ability to track and analyze trends—The computer and its data bases provide very strong search capabilities, and with careful design it will be possible to retrieve and use large amounts of data effectively to track and analyze trends of various kinds.
- Improved capability for maintaining patient confidentiality—It is often easier to maintain confidentiality of laboratory data when using a computer than when dealing with a hand-written report form by establishing computer user codes that control access to the data.
- Financial management—Some systems will allow for financial management, for example, patient billing.
- Integration with sites outside the laboratory—A LIMS can be set up so that data comes into the laboratory system directly from a patient or client registration point. Data can be transmitted to many sites or interfaces as needed. Results can be provided directly to computers accessible to the health care provider or public health official. Computers can handle data entry into a national laboratory data base, and almost any other data application that is needed.
- Manufacturer-provided training—Purchased laboratory information systems often include on-site training for staff. To make the full use of the system, it is essential that either on-site training of all staff or training at the manufacturer's headquarters is provided.

Disadvantages It is important to remember that in spite of all of the advantages, computers do have disadvantages. Some of these are as follows.

- Training—Personnel training is required, and because of the complexity of LIMS, this training can be time consuming and expensive.
- Time to adapt to a new system—When starting up a computer system it may seem inconvenient and unwieldy to laboratory staff. Personnel accustomed to manual systems may be challenged by such tasks as correcting errors and uncertain of how to proceed when encountering situations where a field must be filled in.

- Cost—Purchase and maintenance are the most expensive parts of a computerized system, and the costs can be prohibitive in some settings. Additionally, some settings will not have good maintenance that is locally available. Surprisingly, computers use lots of paper, and the cost of materials must be planned for, as this can add up. Also remember that technology changes rapidly, and the life of a computer may not be more than a few years. This might require repurchase of computer equipment periodically in order to remain current and compatible with other systems.
- Physical restrictions—Adequate space and dedicated electrical requirements are necessary, as well as placement of the computer away from heat, humidity, and dust.
- Need for back-up system—All computer information must be carefully backed up. Loss of data due to a damaged disk or system crash cannot be tolerated, and backup systems will be critical.

Content Sheet 17-5: Summary

Information management system

Information management is a system that incorporates all the processes needed for effectively managing data—both incoming and outgoing patient information. The system can be either entirely paper-based, or it can be partly paper-based with some computer support, or it may be entirely electronic.

For either paper-based or computer systems, unique identifiers for patient samples will be needed. Standardized test request forms, logs, and worksheets are also important to both systems. In helping to prevent transcription errors, a checking process is beneficial.

When considering adding a computer-based system to a laboratory, cost is a big factor. In implementation, careful planning and training will help to ensure good results.

Key messages

A good information management system will:

- ensure that all data— the final product of the laboratory— is well managed;
- consider all the ways laboratory data will be used when planning a system;
- assure the accessibility, accuracy, timeliness, and security of data;
- ensure confidentiality and privacy of patient information.