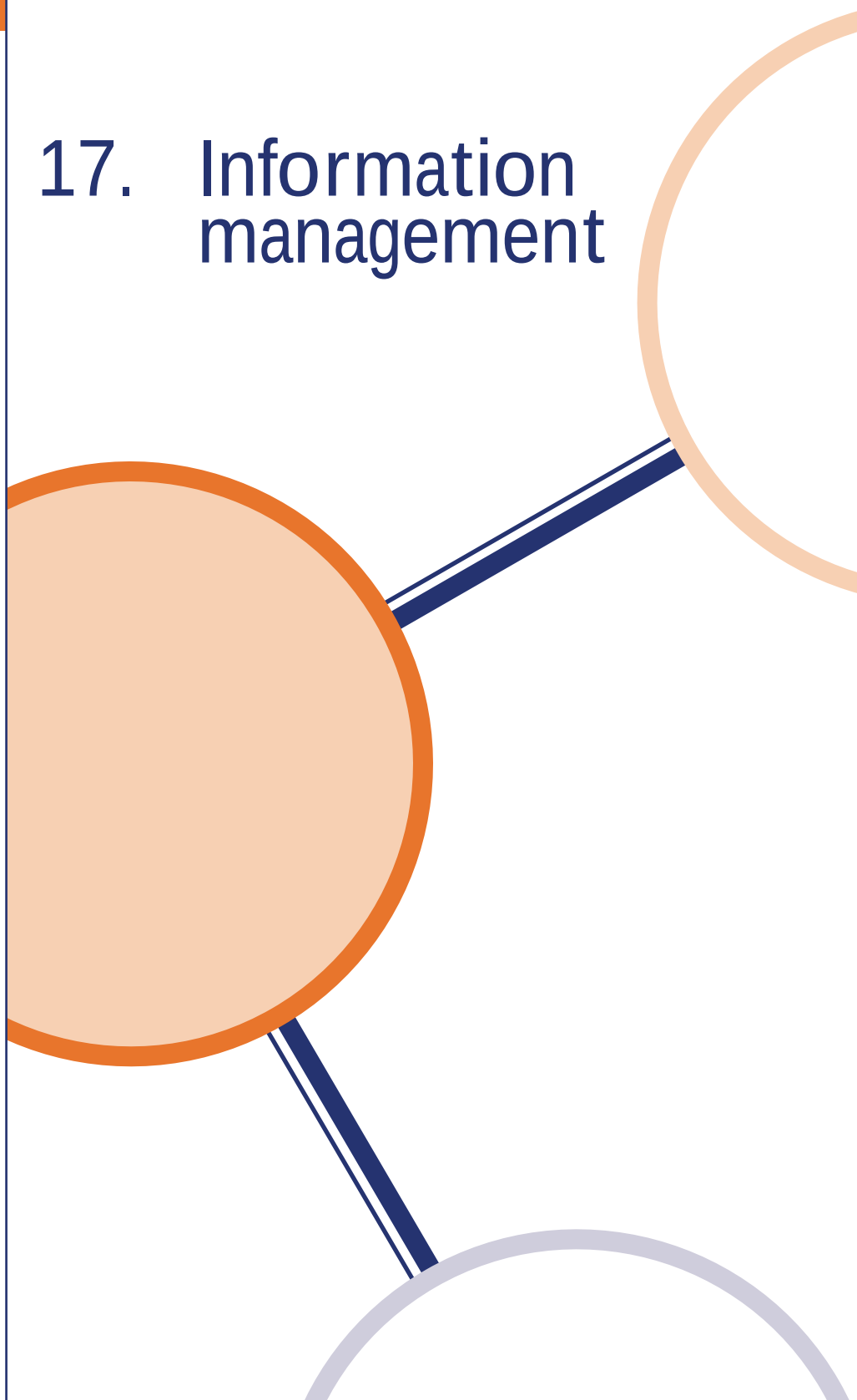
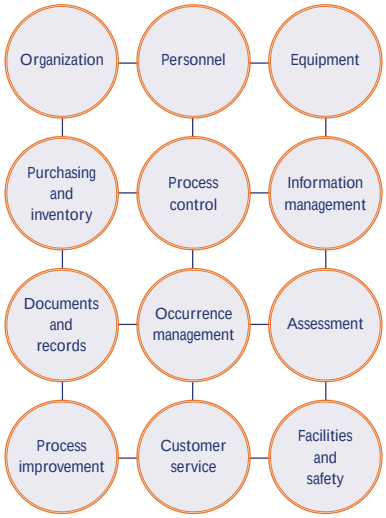
17. Information management



17-1: Overview

Role in quality management system

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 the essentials of a quality system, and is closely related to documents and records (Chapter 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.

17-2: Elements of information management

Unique identifiers

A unique identifier is an important tool for managing information, and careful thought should be given to 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 they are 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 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 will be 0001.

For example, the number 0905130047 can be read 09 05 13 0047, and it would represent sample number 47, received on 13 May 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 Chapter 16.
- 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 nonurgent 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 during 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 a simple checking process is to always have two people review data transcription to verify its accuracy. Some computerized systems have electronic checks built into the system that require duplicate entry of data. 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 ensure 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 haemolysed" 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 ensure 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 laboratory information management system. 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 others who may use or need the report.

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 that may not be suitable for all laboratories;
- inability to retrieve data due to poor archiving processes or insufficient backup 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.

17-3: Manual, paper-based systems

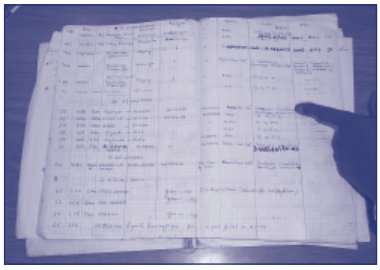
Developing a manual system

Financial constraints may require that a laboratory use a manual, paper-based system for all its information management. Careful planning, attention to detail nd 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.



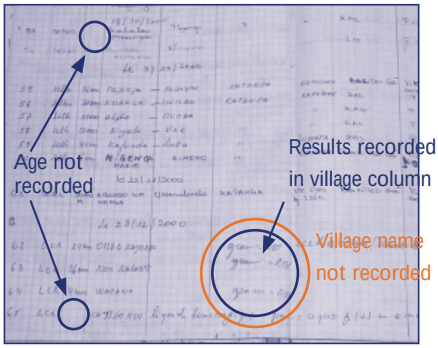
Registers and logs with good design:
- are practical to use and easy to complete
- make it easy to find the data
- make summarizing data and writing reports easier.

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. An example of a handwritten record book with missing data is shown in the following image.



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.

Handwritten 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 are 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.