THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

LABORATORY INFORMATION MANAGEMENT TRAINING

Module 1

Introduction to Laboratory Information Management

SUPRANATIONAL TB REFERENCE LABORATORY - UGANDA

Module Objectives

At the end of this module, participants will be able to:

- Discuss why Information Management is an important function in a medical laboratory
- Describe important elements of an information management system

Module Objectives…

- Discuss the common problems faced in laboratory information management?
- Explain the ISO 15189 requirements for information management in a medical laboratory

Role of Medical Laboratories in Disease Management

- Medical laboratories perform tests on clinical specimens in order to obtain **information** about the health of a patient

Role of Medical Laboratories in Disease Management..

THE PATIENT → Test selection → Sample Collection

Preexamination Phase

Sample Transport

Laboratory Analysis
Examination Phase

Report Creation

Report Transport

Result Interpretation Postexamination Phase

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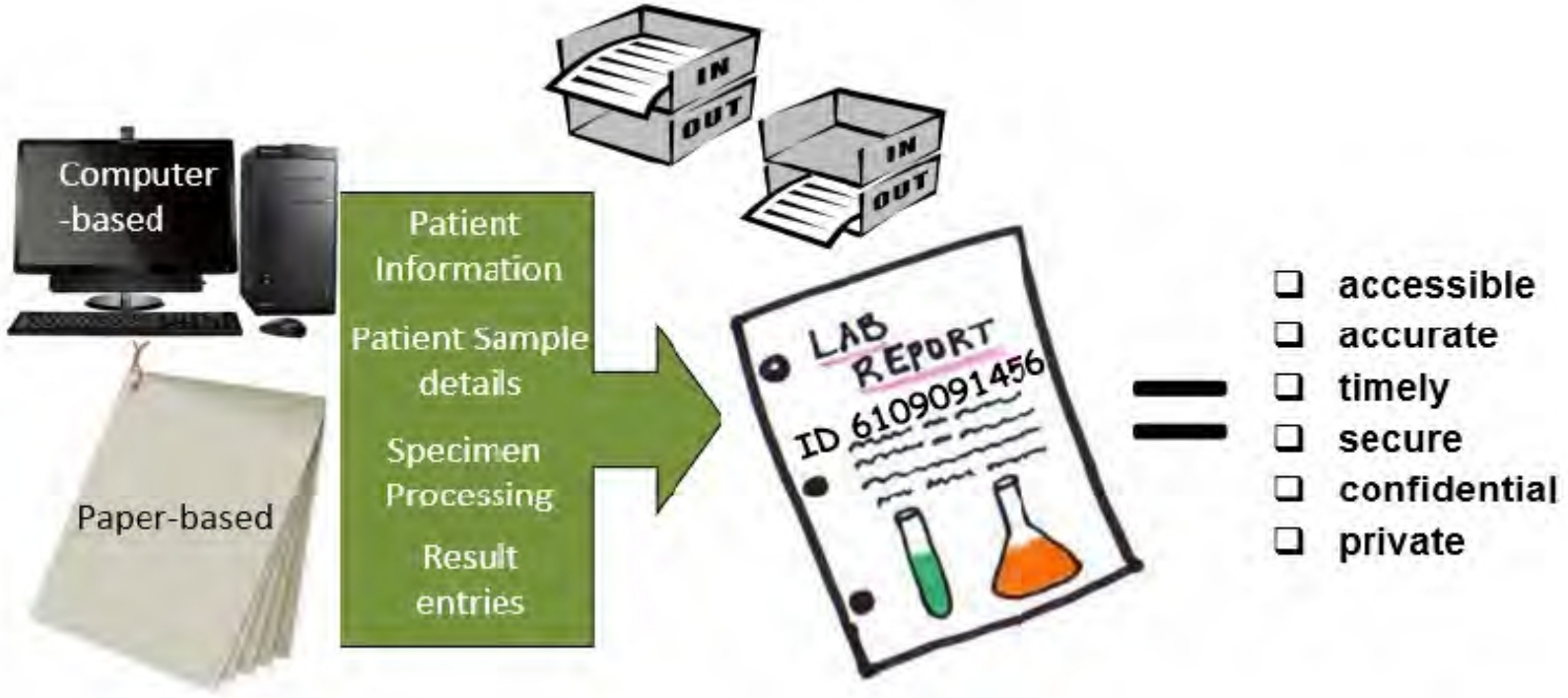
Need for Laboratory Information Management

- Remember that information, and in particular test results, are the final product of the laboratory
- Laboratory information management is a key function in a laboratory quality management system considering that the end product of the laboratory is information (test results)

Need for Laboratory Information Management

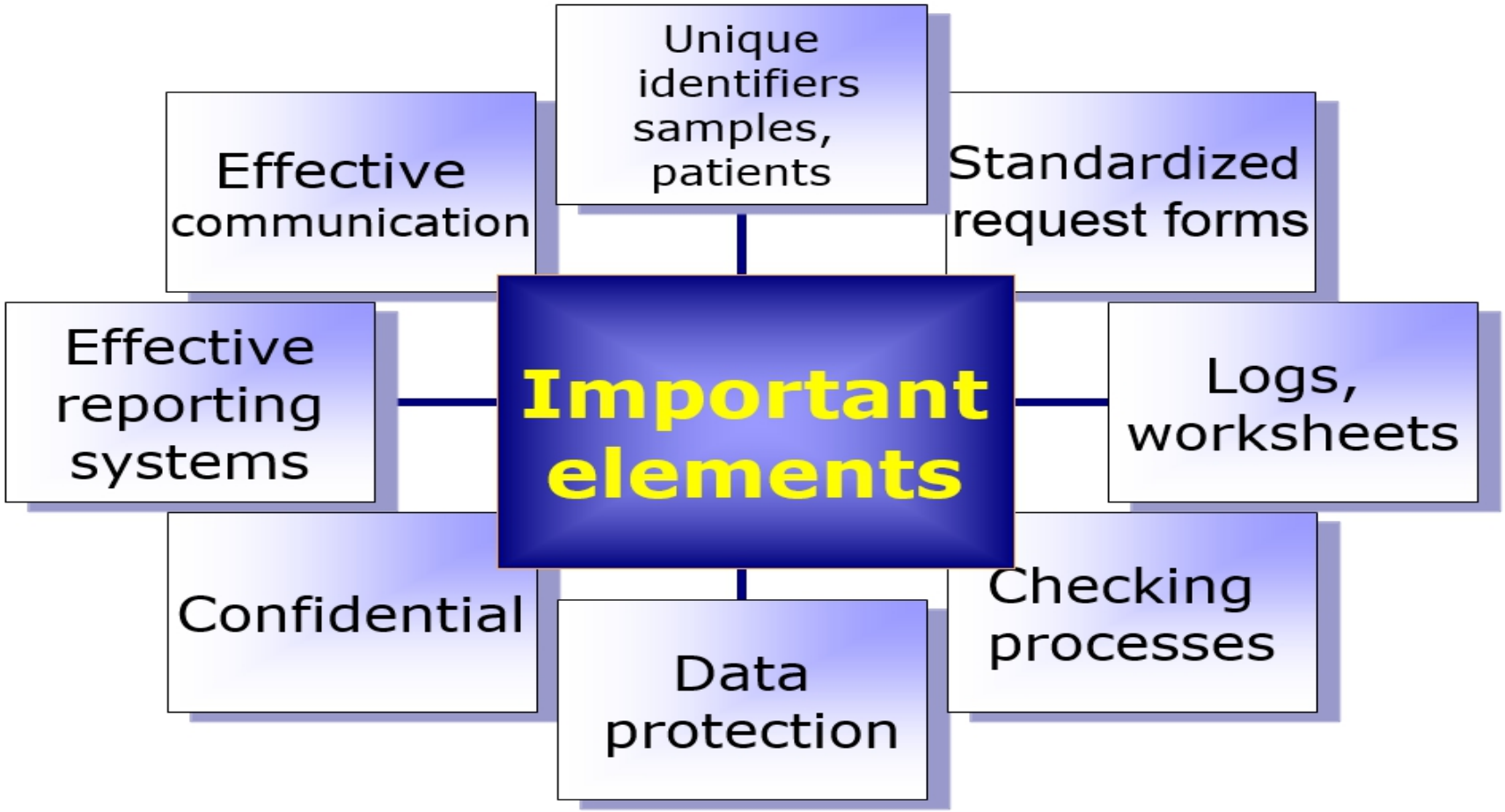
- Laboratory management needs to ensure that the laboratory has effective processes for managing data/information in order to achieve accessibility, accuracy, timeliness, security, confidentiality, and privacy of patient information.

Need for Laboratory Information Management….



- ❑ accessible
- ❑ accurate
- ❑ timely
- ❑ secure
- ❑ confidential
- ❑ private

Information Management Elements



Information Management Elements…

	**Patient identifiers —** Patients who are hospitalised must have a unique patient identifier, often bracelets are used. It is advisable that this unique patient identifier is used for the duration of the hospital stay.
	**Sample identifiers** —Unique identifiers must be allocated to patient samples, so they can be tracked throughout the laboratory.
	**Forms**: -- Standardise the test form—the form should indicate all information that needs to be provided when ordering and submitting a test request, and in the design there must be sufficient space for recording the information; make sure that it is completed correctly.

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Information Management Elements…

	**Logs and worksheets** must be kept. Recording data at the time of arrival of the sample in the laboratory are kept in a log book, while a worksheet is used to record which patient samples are being tested during a certain 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. One must decide as to what information should be recorded.

Information Management Elements…

	**Processes:** Errors can occur at any time when handling data. Put processes in place as precaution and protection against errors at these points. Implement formal checking processes to ensure the accuracy of data recording and transmission of handwritten or keyed information.
	**Data Protection:** Protect against loss of data. For paper-based systems, use safe materials for recording and storing the records properly. For computerized systems, regular backup processes are required. **Confidentiality**: Protect patient's privacy by implementing security measures to guard the confidentiality of laboratory data. Policies and procedures to assure confidentiality of patient information must be put in place and this is the responsibility of the laboratory director.

Information Management Elements…

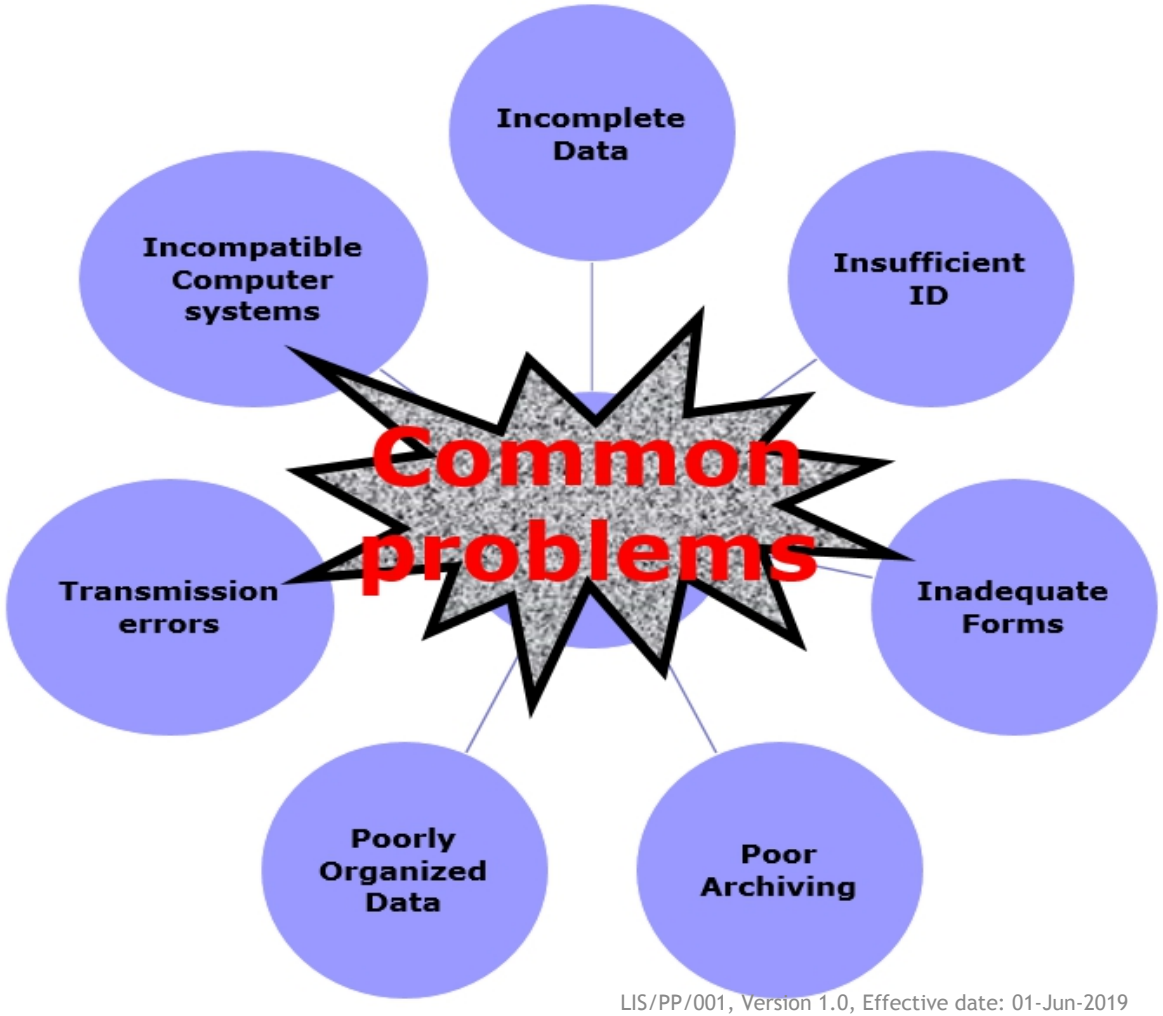
	**Reporting systems:** The test result, or the report is the final product of the laboratory. The test result must be issued timeously. It must also be accurate, legible, and easily understood. It should be verified and signed by the appropriate laboratory staff.
	**Communication:** When planning for paper-based or computer-based information systems, consider the need for a good communication system the enables a laboratory to connect both internally and externally.

Information Management 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.

Information Management Common Problems



ISO 15189 Information Management Requirements

The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.

The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

NOTE In this International Standard, "information systems" includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and stand alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.

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ISO 15189 Information Management Requirements…

The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:

a) access patient data and information;

b) enter patient data and examination results;

c) change patient data or examination results;

d) authorize the release of examination results and reports.

ISO 15189 Information Management Requirements…

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;

ISO 15189:2007
Medical laboratories

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ISO 15189 Information Management Requirements…

b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;

c) protected from unauthorized access;

d) safeguarded against tampering or loss;

e) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;

g) in compliance with national or international requirements regarding data protection.

The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.

When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

Exercise

- Why is Information Management an important function in a medical laboratory?
- Mention the key elements of laboratory information management

Exercise..

- What are some of the common problems faced in laboratory information management?
- What are the ISO 15189 requirements for information management in a medical laboratory?

Acknowledgments

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