

THE ESSENCE OF PROPER
LABORATORY
DOCUMENTATION AS IT
AFFECTS PATIENTS AND
PROGRAM MONITORING

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DOCUMENTS

Documents are official papers or books that give information about a particular event or process, that can be used as evidence or proof that an event has taken place.

Documentation is the act of recording something in a document

DOCUMENTS

- Records result from carrying out processes and procedures within the testing process; Records are everything used to capture information, activities or results when performing a procedure.
- **Allows for the continuous monitoring of the quality system.**

DOCUMENTS

In a medical laboratory setting, proper laboratory documentation and record keeping is a component of Good Laboratory Practices (GLP).

GOOD LABORATORY PRACTICE

- **DEFINITION**

GLP REFERS TO GENERAL BUT IMPORTANT GUIDELINES THAT SHOULD BE FOLLOWED TO ENSURE THAT A LABORATORY FACILITY MEETS THE EXPECTATIONS FOR PRODUCING QUALITY RESULTS

PURPOSE OF GOOD LABORATORY PRACTICE

To ensure that laboratory investigations are conducted under the conditions that allow the results of the investigation to be interpreted and presented to the medical community with confidence.

SCOPE

GLP are guidelines established to cover a variety of practices, including:

- the facility,
- the personnel,
- the testing process
- **DOCUMENT AND RECORD KEEPING**
- safety
- waste management

DOCUMENT TYPES

- Safety policies
- Laboratory request form
- Laboratory registers
- Laboratory worksheet
- Laboratory report forms
- Laboratory accident book
- Information from the kit manufacturer, references from journals and equipment service manuals.

All documents should be current and managed with a tracking system and consistent with National policy to assure uniformity and adequacy of data

DOCUMENTED ITEMS

- Standard Operating Procedures (SOPs)
- Specimens
- Results
- Corrective Actions
- Environmental Monitoring
- Inventory
- Equipment Monitoring
- Personnel items
- Orders
- Shipments

RECORDS

EXAMPLES

- Worksheets
- Test result reports
- Labels
- Temperature and maintenance charts
- Quality control results and charts
- QA activities with results and corrective action
- Inventory list

RECORD KEEPING

- The active transcriptional or electronic means of documentation
- Serves as a permanent and tangible testimony
- A fundamental and crucial entity of a diagnostic lab
- Often ignored or performed inefficiently
- Key in monitoring and evaluating laboratory activities, performance and staff competence
- Is not useful if incomplete
- Is not useful if improperly stored

WHY KEEP LAB RECORDS

- Proper record keeping is crucial to the integrity of assay results and reduces the risk of professional misconduct.
- Easy reference-evidence that lab assays have been performed on patient samples
- That assay procedure is performed in accordance to the SOP and the manufacturer instructions.
- Useful in patient follow up and help to predict treatment out come

WHY RECORD KEEPING?

- That lab commodities have been properly and appropriately used and applied for the appropriate assay
- Could have legal implication and responsibilities
- Source of data collection
- Health Planning and intervention
- Research purpose
- Monitoring of therapy

REQUIREMENTS FOR ADEQUATE RECORD KEEPING

Secure environment

- Note books-register, log book, binders
- Work sheets
- Filing system
- Electronic system
 - Computer and Data software
 - Other electronic devices

CRITERIA FOR ADEQUATE RECORD KEEPING

- It must be simple
 - Easy retrieval-use of binders
 - Clarity in recording
 - Right information
 - Safe
 - Durable
 - Back-up system
 - Confidential

LABORATORY FORM

Completed at enrollment to determine treatment plan

Completed at follow up as needed

Initiated during clinical evaluation and completed at the laboratory

Program record of all laboratory test results

A completed copy is kept at each of the following

Patient Record

Laboratory

M&E

ESSENCE OF PATIENTS LABORATORY DOCUMENTS AND RECORDS

- Laboratory document and records are the link between the lab, patient and the medical community
- Serve as references concerning what occurred in the laboratory
- Sources for the production of reports and is a permanent record that may be consulted after a number of years
- Relevant to and peculiar to a particular patient

ESSENCE OF LABORATORY DOCUMENTS IN PATIENT MONITORING

Monitoring Indicators

- HIV Status of Patients
 - HIV Diagnosis
- Treatment monitoring
 - CD4+ cell count.
 - Blood chemistry assays.
 - Hemoglobin and Full blood count.
 - Hepatitis B and C surface antigen (not yet free).
 - Viral load

LABORATORY DATA

- Laboratory data is extremely important to the ARV programme
- Determines client enrollment into the ARV programme
- Used in patient monitoring for
 - Response to treatment - CD4 count, Viral load
 - Drug toxicity- ARVs – Chemistry, hematology
 - Treatment failure and Resistance to ARVs - CD4 count, Viral load
 - OIs – TB, Cryptococci

LABORATORY DOCUMENT IN PROGRAM MONITORING

- **Measure of program input/Cost implication of program**
- **Assessment of program output**
- **Program success/failure**
- **Strategy for scale up**
- **Intervention i.e. PEP, Training /retraining**
- **Commodity projection**
- **Identification of gaps and lapses**
- **Provides accurate data as to national incidence and prevalence rates for HIV/AIDS**
- **Provide evidence of improved health care delivery in the nation**

INTEGRATING QA/QC INTO THE PROCESS

- Proper storage of forms and other documents in fire-proof filing cabinets

Importance of maintaining a Data Log Book

- Assists in the documentation of errors and corrections made to data collection forms
- Provides a summary of the type of errors made and who is responsible
- Identifies who needs re-training and in what area

RECORD RULES

- R-Record all patient information in a register and use indelible ink
- E-Each assay worksheets must be signed and dated by the person doing the work, your professional career and integrity lies on your written documentation
- C-Corroborate all entries by an additional, knowledgeable person, who reads, validates and dates all assay results

RECORD RULES

- O-Original entries should never be erased. If a mistake is made, draw a single or double line through the mistake and sign and date the correction.
- R-Review and retain all records. Records should be safely retained as long as necessary
- D-Data generated or stored on a computer must be printed out, permanently bound, signed and dated and corroborated.

CONCLUSION

- Data is a vital resource to any organization or programme
- Laboratory data is crucial to the success of the ACTION programme and so must be properly managed
- All ACTION personnel especially in the thematic areas must develop a **'quality data consciousness'**
- With quality data management, exchange of information is facilitated, understanding is increased, consistent answers are obtained, and operational effectiveness is improved.

REMEMBER IF IT IS NOT DOCUMENTED IT IS NOT DONE

THANK YOU FOR
COMING ALONG WITH
ME

