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PROCEDURES FOR REPORTING OF WORKLOAD, QUALITY CONTROL AND INVENTORY CONTROL

PROCEDURE FOR REPORTING WORKLOAD

1. Laboratory section shall accomplish a monthly workload report
2. The workload shall contain the number of examinations performed for the Laboratory. It should also show the number of different tests.
3. To get the total number of examinations performed, the staff can tally the tests performed by month.
4. Count the number of examinations performed according to the section. The count should be for each individual test offered and performed by the section.
5. Indicate the total number of examinations performed for each section and the total tests performed. Refer to the sample report in the following page. 6. Separate the requests of the Adult patients from Pediatric patients. Further segregate the Adults patients into Male and Female.

PROCEDURE FOR INVENTORY CONTROL REQUISITION OF SUPPLIES

1. The Laboratory shall submit to the Supply and Property Section a request for supplies/ materials needed by the Clinic Laboratory. The Medical Technologist staff shall prepare the document with the various sections.
2. Only items in the year's approved Procurement Management Plan can be included in the request.
3. The request shall include:
   a. The materials/supplies needed with description/ specification (eg. packaging, capacity per unit etc.)
   b. . Quantity needed for the quarter.

4. The request shall be accomplished in duplicate. The second copy shall serve as receiving copy and shall be kept in file. The document shall also be the reference document once the items are delivered.

RECEIVING OF DELIVERIES

1. Deliveries shall be received by the CMT for his/her representative.
2. The Administrative Officer or its representative shall be called when receiving the items
3. The specification, quantity and expiration date of the delivered items must be checked. Items that do not fit the Laboratory's standards should not be accepted.
4. The Administrative Officer shall sign the Invoice and Delivery Receipt. In case a delivery is made and the Administrative Officer is not available, the CMT or his/her representative can only sign the Delivery Receipt. Only the Administrative Officer has the authority to sign the Invoice.
5. Items delivered should be cross checked with the original requisition submitted to the Administrative Officer.
6. 7. In case when there is a need to use an item but the delivered goods has not yet been inspected, the Administrative Officer shall be informed that the item needs to be opened for the exigency of service. The Administrative Officer shall inform the Hospital Director that the said item has been opened. 8
7. . Opened items that are not yet inspected should be entered in the Inventory Card of the Section that shall use the material. The staff should note that it is uninspected.
8. After inspection of the AO, the materials/supplies shall be distributed to the various sections according to the section's request. The laboratory staff shall enter the items into the Section's Inventory Card.

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ENTRY OF NEWLY DELIVERED SUPPLIES TO THE INVENTORY CARD

1. Each section shall maintain an Inventory Card system for all supplies under their safekeeping.
2. 2. There shall be one card per material/reagent.
3. . An Individual Card should contain the following information: a. Date b. In – column indicating the number of new supplies received c. Out – column indicating the number of supplies opened to be used d. Bal – balance of unopened supplies d. Sign – signature of staff who received the new batch of supplies or opened a new box or set of the material. e. Date of disposal
4. The date of expiration of the supplies should be indicated adjacent to the number of items entered at the “In” column.
5. For entry of newly delivered items:
6. Place the date when the items were received by the section (Date-column).
    a. In the “In” column, place the quantity of the items that has been received.
    b. From the last entry, add the quantity indicated in the “Balance” column to the quantity that you have entered at the “In” column. The total should be placed in the “Balance” column on the date the new supplies have been entered.

OPENING A NEW BOX FROM THE SUPPLIES STOCK

1. Every time a new box or bottle is opened, the quantity of items taken from the supply stock should be recorded in the “Out” column. The quantity should be subtracted from the number indicated in the “Balance” column of the previous entry and this will be the new balance of the said materials.
2. 2. The date the new box or bottle was opened should be placed on the opened box or bottle.

INVENTORY OF STOCKS

1. On the first day of the month each section must conduct a physical inventory of supplies stock under their safekeeping.
2. The count of the physical inventory must match the balance of supplies at the Inventory Card for the said item.
3. In case there is a discrepancy, the matter should be investigated to trace as to what causes the difference between the physical inventory and the inventory card record.

MONTHLY CONSUMPTION REPORT

1. A Monthly Consumption Report is accomplished by each section indicating the unit consumed stocks on hand and expiration date for each individual reagent or supply under their care.
2. The unit consumed is the sum of all the supplies used during the month. It is computed by adding the quantity/number in the “Out’ column of the inventory card.
3. The report is submitted during the first week of the month and a copy of the report is kept at the main laboratory.

PROCEDURE FOR REPORTING QUALITY CONTROLS

1. . Introduction Quality control (QC) in a clinical laboratory plays an important role in detecting deficiencies and reducing errors in the laboratory's analytical process prior to the release of a patient's results. The purpose of quality control in the clinical laboratory is to ensure that the results being reported are accurate and precise. There have been many developments in the laboratory testing system. These are pre-analytic (sample processing), analytic (chemical analysis of analyte) and post-

analytic (data management) after the introduction of total laboratory automation (TLA)

2. Sources of Laboratory Errors There are a number of potential errors which can affect the quality of the clinical laboratory results. These errors can occur in pre-analytical, analytical and post-analytical phases. All the three phases can be targeted individually for improving quality, although it is well published that most errors occur in the pre- and post-analytical phases.

2.1. **Pre-analytical Phase**

These are the errors which occur in the pre-analytical phase and create an impact on the patient's sample before it is analyzed in the laboratory. There are several things which can go wrong from the time when the sample is collected from the patient till it is transported to the laboratory for analysis.

These errors are as follows:

- Wrong patient information: The particulars such as name, gender, age, ward, patient's posture, effects of exercise, dietary effects, medical history, pregnancy, effects of drugs and alcohol etc. can affect the values of analytes.
- Improper collection of the blood sample: The results will be affected if the sample is collected in a vacutainer other than the one which is recommended for analysis of a particular analyte for e.g. vacutainer containing sodium citrate is used in place of sodium fluoride for analysis of plasma glucose
- Inadequate quantity of the sample: An insufficient quantity of sample cannot be processed for all the analytes which have been requested by the clinician.
- Improper handling of the sample: Improper handling of the sample can lead to hemolysis of the sample before it reaches the laboratory for analysis. Grossly hemolyzed samples should always be rejected as lyses of blood cells leads to release of certain intracellular chemicals and enzymes which will lead to increase in

levels of potassium, phosphates and transaminases.

- Incorrect sample storage: If a sample has not been properly stored or a blood sample has been left overnight before being sent to the laboratory, it will become hemolyzed in 24 hours especially at a warm temperature.
- **Other factors:** Heat and exposure to light can change the actual value of many analytes in routine clinical chemistry such as photo-degradation of bilirubin by light exposure.

2.2. **Analytical Phase**

The analytical phase begins from the time when the patient's specimen is prepared for analysis to the time when the test result becomes available. Potential analytical errors which may affect the quality of the results obtained include sample measurement, sample pre-treatment, reagent volume measurement, sample and reagent mixing, incubation, reaction timing, and calculations. These errors may arise in conjunction with the supplementary use of analytical equipment such as glassware, pipettes etc., which may not have been properly washed and calibrated.

2.3. **Post-Analytical Phase**

Post-analytical phase mainly deals with the reporting of results after the completion of the analytical phase in a timely manner and in an accepted format that can be understood and correctly interpreted by health care professionals. The most common post-analytical errors include the reports being not legible and also delay in delivering the reports to the clinician or the patients.

3. Quality Control in Laboratory Quality control is an aspect of quality assessment that is used to maintain the quality in the laboratory. This can be done with the help of internal quality control and external quality control [1].

3.1. **Internal Quality Control**

Internal quality control (IQC) is performed daily in the laboratory and involves the use of calibrated glassware, reagents and equipment. The laboratory staff should be qualified professionals. There is a recommendation to use at least two control levels for each analyte. The samples are internally evaluated in the laboratory. The main purpose of IQC is the precision (repeatability or reproducibility) of the method.

3.2. **External Quality Control**

External quality control (EQC) or proficiency testing (PT) is performed as a test of competency. It includes the participation of the laboratory in an external quality assessment scheme which provides samples for analysis every month. They must be analyzed by the laboratory professionals using the same procedures as used for testing of quality control samples and patient samples. The results obtained from analysis of EQC samples are reported to the outside agency running an external quality assessment scheme (EQAS). They then provide a report for the participating laboratory based on mean, coefficient of variation and standard deviation index of all the participating laboratories.

3.3. **Quality Control Charts (QC Charts**)

Quality control charts (QC charts) have historically been used to examine prior QC results within a particular range diagrammatically. QC charts are used to represent the values of control material within

the defined upper and lower limit.

The Levey Jennings (L-J) Chart

The use of the Levey Jennings chart (L-J chart) is one of the most used charts to monitor quality control results. It is a graphical method for displaying the values of controls. The control values are plotted versus the days of the month which are indicated on the x-axis and value of controls as mean±1SD, mean±2SD and mean±3SD are indicated on the y-axis. The deviation of the results from the mean especially, when the results are greater than±2SD from the mean, indicate the rejection of run.

3.4. **Westgard Rules**

It involves the use of multiple control rules which help in improving the performance of quality control. It also helps in deciding whether the analytical run is in control or out of control.

These are defined as follows:

- **Westgard 22S rule**: It is violated when 2 consecutive control values for the same level fall or both controls in the same run outside the mean±2SD. This run has to be rejected.
- **Westgard 41S rule:** It is violated if four consecutive control values exceed the same limit (mean + 1SD) and this may indicate the need to perform instrument maintenance or reagent calibration.
- **Westgard 13S rule:** It is violated when either of the two control values falls outside mean +3SD. The assay run is rejected when a single control value exceeds the mean plus 3SD or mean minus 3SD.
- **Westgard 4S rule:** It is violated when one control value exceeds the mean by +2SD and the other control value exceeds the mean by -2SD. The range between the two results will therefore exceed 4SD hence the run is rejected.
- **Westgard 10x rule:** This rule is violated when the last 10

consecutive control values are on the same side of the mean or target value. So the run has to be rejected.

4. Corrective Action and Preventive Action (CAPA)

Corrective action is that action which should be used to stop the occurrence of non-conformities. Preventive action is that which should give the opportunity to prevent potential non-conformities. Corrective action has to be taken when there is a problem. If a problem does not exist, preventive action has to be taken. Once the run is rejected on the basis of quality control results, the problem is to be solved by taking corrective action, so that results become accurate.

Corrective action starts with the root cause analysis which forms the most important part of corrective action. The root cause analysis should be done by the laboratory staff familiar with the problem. The results of the corrective action taken need to be recorded and monitoring should be done to verify the completion of actions taken and also to see its effectiveness. The corrective and preventive action process includes following steps [7]:

a) Reviewing and defining the problem or non-conformity.
b) Finding the cause of the problem.
c) Develop an action plan to correct the problem and prevent the recurrence.
d) Implementing the plan.
e) Evaluating the effectiveness of the correction in preventing the problem.

5. **Clinical Audit of the Laboratory**

In addition to participating in external quality assessment schemes, laboratories are also subject to clinical audit. This is a systematic and critical assessment of the general performance of the laboratory against its own declared standards and procedures and against nationally agreed standards. In the context of analytical procedures, the audit evaluates the laboratory performance in terms of the appropriateness of the use of the tests offered by the laboratory, the clinical interpretations of the results and the procedures that operate for the receipt, analysis and reporting of the test samples. The objective of the audit is to ensure that the patient receives the best possible care and support in a cost-effective way. The audit is normally undertaken by junior doctors, laboratory staff, and assessors from the agencies. Clinical audit is carried out primarily for the local benefit of the laboratory and its staff and ultimately for the patient.