World Accreditation Day-2015

Published By
Bangladesh Accreditation Board (BAB)
Ministry of Industries
91, Motijheel C/A, (5th Floor)
Dhaka-1000

Published in
June, 2015

RIKS MANAGEMENT IN MEDICAL LABORATORY:

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We are talking about accreditation, why accreditation? For the benefit of human being. How accreditation helps human being? Accreditation helps to deliver quality test results. A quality test result means safe result. A safe result means low risk result. I will discuss how to assess risk and how to manage risk in releasing patient test result.

ISO 15189 20124.14.6 speaks about Risk management- "The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken"

Three lines sentence but there will be 3 million responsibilities for an accredited laboratory before releasing result.

- What is Risk ? A random event that has negative impact
- Risk has two components :Probability of occurrence &Severity
- What is the Risk DIMENSIONS-
  Harm-physical injury or dam
  -Hazard-source of harm
  -Severity-measure of consequences
  What is Risk concept ?

RISK ASSESSMENT METHOD?

- HORIZONTAL RISK ASSESSMENT
- VERTICAL RISK ASSESSMENT

HORIZONTAL RISK ASSESSMENT: Department or any functional activities, example: Phlebotomy area, bio chemistry, hematology, Microbiology etc testing lab or area

VERTICAL RISK ASSESSMENT: Test parameter wise

- Ex. Vertical risk analysis of coagulation test parameter, pre analytic phase, analytic
- phase and post analytic phase

RISK ASSESEMENT STEP:

- Step 1. Selection of risk method :

(a) It may be advisable to start with Horizontal risk assessment and then completing with vertical risk
(b) Vertical risk will take more time to complete the work but recommended to do that
c) While doing vertical risk many of the horizontal risk may be ignored

While selecting Vertical Risk, Critical Parameter must be given Priority
For example: K+. Na+, Bilirubin, Calcium, creatinine, etc

POSSIBLE RESPONSES TO RISK ANALYSIS FINDINGS::Access to comprehensive, quality healthcare services is important for the achievement of health equity and for increasing the quality of a healthy life for everyone. It is true that to ensure better healthcare and to develop a good healthcare management system in the country, we must need quality healthcare institutions - hospitals, clinics etc., ISO 15189 accredited medical laboratory services, and expert doctors and competent healthcare professionals; but have we considered using safe and quality medical devices as one of the prime contributors? Medical devices are being widely and deliberately used in every stage of healthcare system such as to produce technically valid test results in laboratory, to understand the patient situation by doctors, and to diagnose patient diseases and thereby delivering patient treatment.

A medical device is an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat

- Accept the risk - do nothing
- Reallocate resources
- Get more information
- Eliminate the risk entirely
- Mitigate the risk
- Have a contingency plan
- Transfer the risk

Some Risk example in the laboratory:

Pre Analytical:

- Not having Positive patient ID
- Not doing Verification of patient instruction
- Lab does not use standard evacuated collection device, there is a possibility of under filling.
- Lab does not use pediatric vials for sample collection
- Urine culture pots are not checked for contamination:
- Deterioration in improper transport
- In an hospital patients are identified by bed numbers, and often times beds are changed, the risk of collecting blood without multiple checks
- Beds are placed against the wall, leading to one arm becoming inaccessible and the other arm has infusions going on.

Example case

- Case: Due to over concentration of citrate the PT value was erroneous leading to postponement of surgery
- Case: A case of leukemia with normal counts was missed because the morphology of cells was distorted due to higher concentration of EDTA
- Phlebotomists drawing blood from indwelling (arterial, central venous) or umbilical lines should have thorough training. While drawing blood form indwelling lines or catheters errors due to dilution and or contamination from flushing solution should be avoided.

  When an intravenous solution is being administered in a patient's arm, blood should be drawn from the opposite arm. If an intravenous infusion is running in both arms, samples may be drawn after the intravenous infusion is turned off for at least two minutes before venipuncture and applying the tourniquet below the intravenous infusion

  o K-Oxalate & Na-F : Often used together. NaF inhibits glycolysis so it is important for blood glucose estimation. Cannot be used in enzyme assay as fluoride inhibits enzyme activity.

Analytical Phase query and Risk

- If I'm running QC only in the morning, how do I know the results are still acceptable at the end of the day? My control is out of control, but I have to release patient report
- What's my comfort level for test results to go back and assessing when a failure occurred?
- The lab does not do reverse grouping for blood grouping. Bombay blood was missed and patient did not get blood for an emergency operation as he was not aware of the rarity of the group.
- Coagulation tests are not performed within 4 h of collection. Even after delay plasma is not made platelet-free or kept frozen until test can be performed (at -200C for up to 2 weeks or at -700C for up to 6 months)

Post analytical examination:

Manual transcription

1. Delta checks
2. Retrospective review of QC data
3. Algorithm that check for inconsistent results
4. Delivering report based on first name
5. How much correct my biological reference

RISK SCORING: There are many tool, following tool can be adopted to score the risk level. So first assess the risk level categorized it based on severity and likelihood and then score it and prepare your priority to manage the risk.

Risk Evaluation

Risk matrix to determine risk level

Severity \ Likelihood	Remote	Occasional	Frequent
Major	Medium Risk	High Risk	High Risk
Moderate	Low Risk	Medium Risk	High Risk
Minor	Low Risk	Low Risk	Medium Risk

Severity \ Likelihood	Remote (1)	Occasional (2)	Frequent (3)
Minor (1)	1	2	3
Moderate (2)	2	4	6
Major (3)	3	6	9

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