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Risk Assessment and its Analysis in Relation to ISO 15189:2012- An Experience of a Tertiary Care Teaching Hospital Laboratory

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Abstract

Laboratory plays an important role in diagnosis; thus, test reports must be reliable and accurate. The working of laboratory tests involves various processes which may cause errors at pre-analytical, analytical and post-analytical phases of testing. Hence the study was planned to evaluate errors or risks and its analysis in laboratory. The format was prepared for risk assessment and shared to various sections of laboratory to obtain data from five years to assess laboratory activities for risk assessment outlined required control measures. The criteria for risk assessment were fixed and data was analyzed based on that and observed maximum severity in the year 2019 for post analytical consideration category compared to others. The present study emphasizes on risk identification, calculation of incidence and establishing protocol for control measures. This study provides guidelines for risk assessment and also encourages laboratory to develop system for laboratory inherent risks to improve quality of testing and ultimately patient diagnosis and prognosis.

Keywords: Risk assessments, Laboratory errors, Control measure, Post analytical considerations.

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1. Introduction

As per ISO 31000: 2009, Risk is an effect of uncertainty on objectives whether positive or negative or they can be referred to as unhappy outcome of unrecognized, unintentional and not managed errors [1-2]. This uncertainty consists of measurable and immeasurable risk as work is always done for measurable risk calculations which may be "incomplete" and but it is not known how they are incomplete. The concept of risk is not new in industries, but it is just new for healthcare services and medical checkup in laboratory [3]. To emphasize this Donald Rumsfeld said "there are Known Knowns, there are Known Unknowns, but there are also Unknown Unknowns" [2]. Evaluation of risk is dependent on probability of harm and severity of harm. Thus, laboratory need to identify risks to: 1) reduce undesired impact and potential failure in laboratory activities 2) achieve purpose of running laboratory and bringing about improvement by acting on opportunities [4-5]. Testing of

patient sample occurs in large number and involves many different processes. Errors can occur at any point in the laboratories, hence the need for careful examination of laboratory weakness [6].

Laboratories therefore must take precautionary measures to ensure that the results obtained are reliable and accurate [6]. Laboratory cannot predict, whether small error may affect less, or it will have a huge impact on the outcome of the results. Sample analysis derives information which is used for making patient related decision, thus laboratory information which is not accurate may result in poor outcome [7]. Hence it is necessary for laboratory to take initiative to establish strong and good risk assessment process which will help to protect from injuries, to prevent accidents for overall and safe working of the laboratory [7]. The risk management process comprises of five important steps, which are risk identification, risk assessment, risk control, record-keeping and review [8-9]. This knowledge emphasis on risk management has become an essential need for taking action and addressing risks. Therefore, this observational study was planned with the intend to evaluate the potential link between laboratory test results and patient safety. The aim of this study is to assess and analyze risk in relation to ISO 15189: 2012 in a tertiary care hospital.

2. Objectives

- To find the incidence of risk in the various laboratory activities.
- To obtain data from each laboratory section in shared format
- To establish a protocol to control the identified risk in laboratories.

3. Materials and Methods

3.1. Study setting

A medical college with accredited hospital laboratory (As per ISO 15189) of a tertiary care hospital.

3.2. Study Design

Observational study

3.3. Ethics approval

Institutional ethics committee approval was taken for scientific and ethical content (EC No 166).

3.4. Study population

In this study five-year data of risk assessment was used for analysis

3.5. Methodology

The observational study was conducted by analyzing data from 2018 to 2022 at tertiary care hospital laboratory. All the sections (hematology, cytology, clinical pathology, histopathology, clinical biochemistry, microbiology) of laboratory were selected for the present study as a model of risk assessment. All activities of the laboratory were assessed starting with sample collection to report release. A table was prepared to find probability of risk. Once risk was identified observations were noted depending on specific laboratory activity, it pertains to specimen ordering, specimen requirement, transport, specimen handling and processing, result interpretation, reporting and other post analytical considerations. The data format was shared with all the sections of laboratory for collection of data. The collected data was used for calculating incidence (%) and probability of harm. Assessment criteria or Risk matrix was set for laboratory and circulated to all sections as follows:

- Occasional/Minor (<1%)
- Moderate (1-2%) and
- Frequently (2-3%)
- Severe (>3%) depending on percentage.

Benchmark for incidence was fixed at 1% and if any identified risk crosses the benchmark, the respective sections was instructed to take measures for control of that particular risk element.

3.6. Confounding factor

Communication with respective sections

3.7. Statistical Analysis

Categorical variable results were calculated by frequency and incidence in percentage

4. Results

As per statistical suggestions results were obtained from all the sections for observing the various laboratory activities. After identification of risk from each section, the requirement with frequency of the risk parameter was analysed for each section. Incidence and probability were considered as per given criteria in our study: occasional/Minor (<1%), moderate (1-2%) and frequently but not severe (2-3%) and severity (>3%). Number of errors mentioned under occasional, moderate, frequently and in severe section is against total number of samples. There number of parameters which showed severe risks were less in the year 2018; they belong to the category of other post analytical considerations in the sections of Microbiology, clinical biochemistry and clinical pathology section. The reason of the severe risk documented is because of all the sections include critical alert reporting and turnaround time under other post analytical process. The occurrence of severity was found to be maximum in the year 2019 compared to remaining 4 years data. It was found more in biochemistry section, which involves all processes of laboratory except result interpretation and result reporting. In the haematology section two moderate risks were observed under specimen requirement and other post analytical considerations and one each in cytology and clinical pathology section was under other post analytical considerations. Table 3 of 2020 shows, severe risk category which was found in other post analytical considerations in hematology and cytology sections respectively and moderate risk was observed under specimen ordering, requirement and processing in hematology, cytology and microbiology sections. Table 4, shows observations for the year 2021 severe risks category was found under specimen testing and other post analytical considerations one in each section (microbiology and cytology). Similarly moderate risk was observed for specimen testing, result interpretation and result reporting in microbiology, cytology, clinical pathology section. In 2022, severe category was observed for other post analytical

considerations in Microbiology, clinical biochemistry and cytology sections.

However, moderate risk was found for specimen requirement and other post analytical considerations only in hematology section.

5. Discussion

The biomedical laboratories monitored and assessed under physical, ergonomic, chemical, biological, and electrical areas. The risk assessment in the medical laboratory is gaining more attention day by day. Literature search indicates that more research in this area is necessary to spread awareness and to inculcate environment in the laboratories for risk estimation as per NABL (National accreditation board for laboratory testing and calibration) guidelines [4]. Risk is inherent in all laboratory tests and processes. In addition, because of the many steps involved in laboratory testing, the risk of error can be high. Therefore, it is important to evaluate and prioritise risks and determine the acceptable level of risk in the clinical lab [6]. Every laboratory has their own weakness during sample processing but understanding that weakness is the first step to move ahead for quality goal based on risk management. Thus, the present study was aimed to evaluate the different risks encountered in a medical laboratory setup. The risks were observed and analyzed under following procedures [(11)]. A cause or a result is never totally predictable. Risk is not a fixed measurement; and variable depending on various by events and is therefore susceptible to change. NABL document and few other authors mentioned following Risk Matrix in their article: 1-5: LOW, 6-10: MEDIUM-LOW, 11-15: MODERATE, 16-20: MODERATE-HIGH, 21-25: HIGH [2,3,11-12]. Following this matrix increases the likelihood of errors, and therefore we established our own benchmark for risk assessment and its analysis. As a result, our lab has made progress which appears to be satisfying in terms of lowering the risk matrix and developing new benchmarks. Indicators of outcome are:

- Incidence
- Probability of harm
- Control measure.

Risk can be estimated by factors like: 1) detectability 2) severity 3) occurrence. In present study frequently occurring and severe risk parameter were observed under other post analytical considerations as shown in Table 1,2,3,4, & 5. In 2019, clinical biochemistry and overall, many other sections of the laboratory accounts for maximum observations under severe risk in most of the activities or processes, found in table 2 when compared to table 1. This could be due to prompt observation of all the errors under laboratory activities or breach of established protocol for observing and monitoring error or over sighting of errors by laboratory staff about processes. Table no 3,4, & 5 show that data of the year 2020, 2021 and 2022 which showed a decreased error rate or risk as compared to 2018 and 2019. This reflects that the identification of the risks and control measures taken after 2019 were sufficient to reduce or eliminate risks occurring in the laboratory. Though maximum severe risk were found under post analytical considerations category, specimen ordering, specimen requirement, specimen processing and specimen testing activities cannot be ignored because moderate risk was observed in these areas too. The laboratory then started to develop procedure for monitoring activities. Control measures were documented and implemented at that time; therefore, laboratory must initiate long term practices regarding risk analysis and monitoring its control measure. The results of this present study demonstrate three major finding as the outcome of study. First, identified processes for risk assessment are valid for obtaining appropriate data. Second high percentages of risks were found to occur for other post analytical consideration which involves critical reporting and turnaround time. This observation forced laboratory staff to take appropriate measures to control these errors which then showed improvement over the next three years. The third major finding was use of effective vehicle (taking control measure) for controlling laboratory errors. Wasaif Alshammari et al., also carried out observational study to evaluate risk in two educational laboratories to highlight risk and results were used to improve laboratory quality and safety by taking control measures [8]. The control measures needed, such as on-going training, adhering to standard precautions according to laid down protocol, and establishing quality indicators, must be implemented to minimize risk parameters [8]. Rasoul Yarahmadi and Pravin Moridi et al., had similar observations in laboratory fields. They elaborated, communication with the respective section and the probability occurrence tool were considered sufficient and hence were included for assessment and analysis of risk as they enable for identification and implementation of actions to be taken in the future [13-14]. Fabiane Rodrigues da Silva et al., in their study stated that, for each risk, the impact of the proposed measures should also be assessed, taking into account (or not taking into account) events that occurred during the period which may have been associated with that risk [13-15].

6. Limitations

- Impact of outcome has to be analyzed.
- Control measures were taken for specific error or risk. Laboratory need to prepare protocol to review of the control measures initiated.
- Risk mitigation need to be analyzed.
- Missed information if any from sections as LIS do not catch the errors.

Table 1: Data format shared with all the sections of laboratory for collection of data.

Sr. No	Process/ Requirement	Requirement	Risk	Incidence	Probability of harm	Measures for control
1	Specimen ordering	Exam number, Lab number.				
2	Specimen requirement	As Specified in Primary Sample Collection Manual				
3	Specimen transport	Safe transport				
4	Specimen processing &handling	Correct entry of patient details. Sample check before run.				
5	Specimen testing	Calibrated instrument. 'Pass' before sample run. IQC acceptable. EQA satisfactory. Proper storage of reagents.				
6	Result interpretation	Knowledge and Competence about interpreting machine printout.				
7	Result reporting	Correct entry of results. Dilution, Reporting within time.				
8	Other post analytical consideration	Alert critical values information, Turnaround Time.				

Table 2: Risk management data for the year 2018.

Year	Criteria	Microbiology	Clinical Biochemistry	Hematology	Histopathology	Cytology	Clinical Pathalogy
2018	Occasional/ Minor	7	7	6	8	8	7
	Moderate	0	0	2(specimen requirement & other post analytical	0	0	0
	Frequently	0	0	0	0	0	0
	Severe	1 (other Post analytical)	1 (other Post analytical)	0	0	0	1 (other Post analytical)

Table 3: Risk management data for the year 2019.

Year	Criteria	Microbiology	Clinical Biochemistry	Hematology	Histopathology	Cytology	Clinical Pathalogy
2019	Occasional/ Minor	7	2	6	8	7	7
	Moderate	1	0	2(specimen requirement & other post analytical	0	0	0
	Frequently	0	0	0	0	0	0
	Severe	0	6	0	0	1(other post analytical)	1 (other Post analytical)

Table 4: Risk management data for the year 2020.

Year	Criteria	Microbiology	Clinical Biochemistry	Hematology	Histopathology	Cytology	Clinical Pathalogy
2020	Occasional/ Minor	7	8	6	8	6	8
	Moderate	1(Result reporting)	0	1(specimen ordering)	0	1 (specimen processing)	0
	Frequently	0	0	0	0	0	0
	Severe	0	0	1(other post analytical)	0	1(other post analytical)	

Table 5: Risk management data for the year 2021.

Year	Criteria	Microbiology	Clinical Biochemistry	Hematology	Histopathology	Cytology	Clinical Pathalogy
2021	Occasional/ Minor	6	8	8	8	6	7
	Moderate	1(Result reporting)	0	0	0	1 (Result interpretation & Reporting)	1 (specimen testing)
	Frequently	0	0	0	0	0	0
	Severe	1(specimen testing)	0	0	0	1(other post analytical)	0

Table 6: Risk management data for the year 2022.

Year	Criteria	Microbiology	Clinical Biochemistry	Hematology	Histopathology	Cytology	Clinical Pathalogy
2022	Occasional/ Minor	7	7	6	8	8	7
	Moderate	0	0	2 (specimen requirement & other post analytical)	0	0	0
	Frequently	0	0	0	0	0	0
	Severe	1(other post analytical)	1(other post analytical	0	0	0	1(other post analytical)

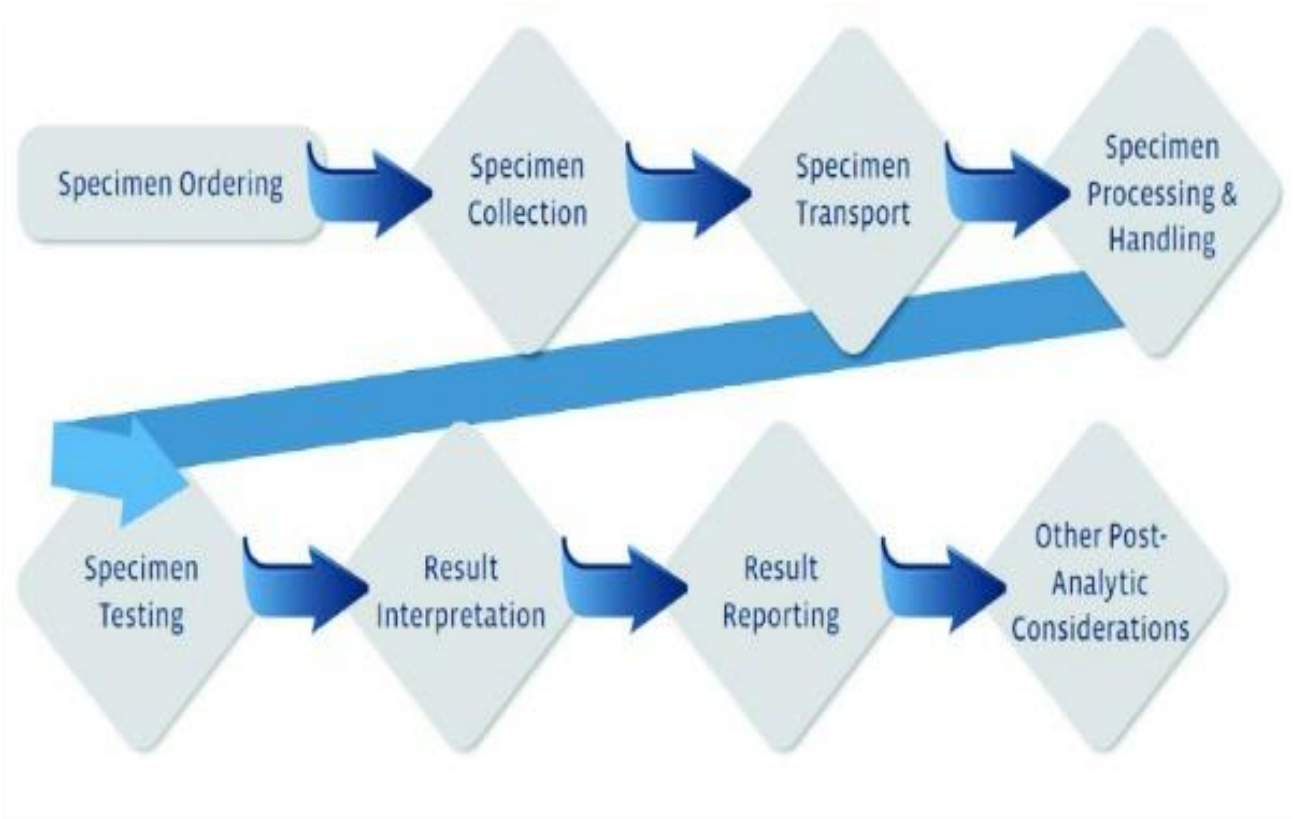

Figure 1: A process map showing key steps in the clinical diagnostic testing process [6,9-11].

7. Conclusions

The primary goal of this study was to demonstrate how risk assessment principles may be applied in the clinical laboratory to prevent errors and reduce patient harm. Clinical laboratories are a crucial component of the healthcare system. Risk parameters are not constant for assessment; as it can change in response to circumstances. Now it is clear that the different phases of laboratory diagnosis i.e Pre-analytical, Analytical and Post-analytical are unpredictable and have an impact on patient care.
As a result, it is important to concentrate on the following:

- Inspection of each stage of the laboratory technique or process.
- Take into account every single failure scenario.
- Create a backup plan for each failure scenario.
- Use quality indicators for the control of risk parameters

Thus, this study will be helpful to address frequent or severe risk areas and their control measures in our setup.

Further study:

1. To study risk mitigation
2. To Identify more areas of risk if any
3. To make protocol to monitor control measures for risk parameters

Conflict of interest

There is no conflict of interest.

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