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Quality of Sample Testing in the Laboratory Unit: Current Situation and Strategies for Improvement

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ABSTRACT

The purpose of this study was to understand the status quo of quality sample testing in the laboratory unit. A quantitative research method was used. An extensive laboratory documents (protocol, worksheets, laboratory analytical plan, standard operating procedures and manuals) review was performed and a networking approach to both management and lab staff at all levels was reviewed in order to identify all non-conformities occurred in the past three years. Results identified 36 number of results deviated from reference standards among different test performed, 400 number of samples lost, the number of laboratory personnel who were not sufficiently trained to take the task properly decreased from 16 in 2016 to 6 in 2018 after conducting training on laboratory quality management system, 36 controlled documents including sample management standard operating procedure, bench job aids were missing and 8 customer complains about the delay of results and quality laboratory of services have been identified.

KEYWORDS

Keywords, laboratory, quality, sample testing

INTRODUCTION

The laboratory is a complex system involving many steps of activity and many people. The complexity of the system requires that processes and procedures be performed properly. The quality of sample testing in the laboratory has become a very important topic in ensuring accuracy, reliability and timeliness of laboratory results in turn improves quality of product and services. The economic welfare and survival of the pharmaceutical industries, hospitals, academic and research institutions depends on quality of laboratory results they produce which depend fundamentally on the quality of raw materials, workforce and management practices that define the quality policy of the organization.

The laboratory provides evidence -based decision making on whether the product or service to be accepted or not and the world has gathered together to harmonize its laboratory practices and guides the launching of international standards and accreditation, good laboratory practices (GLP) and international standards for testing laboratories such as ISO 17025.

There has been growing awareness for the significance of the quality of laboratory testing (stuart S. et al., 2010). This awareness is represented through the appearance of several definitions, explaining exactly what quality of sample testing should be in the laboratory (Yadav ks, Chakraboty B et al., 2013). Very few articles have been written to demonstrate the significance of quality of sample testing in the laboratory with the relations to quality results, product improvement and patient care.

The laboratory unit is experiencing several problems such as deviation of results from standards, sample management, documentation and record-keeping. However, due to insufficient planned and systematic activities focused on

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providing confidence that quality requirements are fulfilled, many laboratories are facing a number of challenges (WHO, 2009).

A study conducted to identify the current situation of sample testing in the laboratory unit in question and determine strategies for improvement.

2. METHODS

A retrospective study was conducted, applying quantitative research methods, between September 2016 to November 2018.

Data were collected by laboratory staff dedicated to improving the quality of services in the laboratory unit.

An extensive laboratory document review was conducted and networking approach to both management and laboratory personnel at all levels was adopted to attempt to identify all nonconformities occurring in the laboratory over the past three years.

Reports were reviewed from international conferences, the WHO and other organizations, national laboratory strategic plans, national laboratory quality assurance documents, occurrence management documents and risk management documents. For all reports of nonconformity, basic descriptive data were captured regarding the occurrence. An effort was made to identify the gaps, which were likely the causes of the nonconformities.

Table 1. Data collected in laboratory units for 2016, 2017 and 2018 including number of deviations, number of lost samples, number of trained and competent personnel, number of missing controlled documents and number of customer complaints

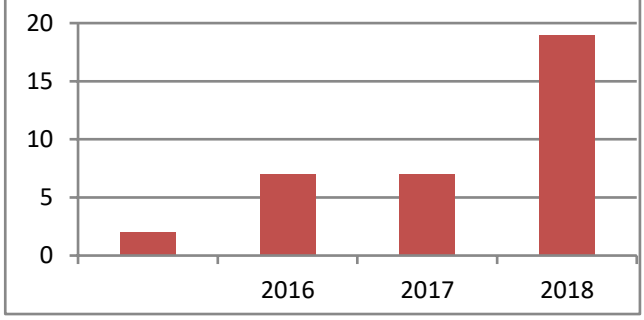
	Years data collected			Total
Variable	2016	2017	2018	
Number of deviations	10	7	19	36
Number of samples lost	218	146	36	400
Number of trained and competent personnel	0.50%	0.75%	0.92%	2.17%
Number of missing controlled documents (eg,SOPs)	0.58%	0.43%	0.18%	1.19%
Customer complaints	4	1	3	8

3. RESULTS AND DISCUSSION

Deviations of laboratory results

It was observed that the number of deviations was high in 2016 (10) and 2018 (19) as shown in Table1. There was evidence of an association between un-calibrated instruments, trained personnel and deviation of results. These investigations represent a key issue in deciding whether outcomes may be released or rejected and form the basis for retesting and re-sampling.

Figure 1. Shows number of deviations of results obseved within 2016 and 2018



Deviation of laboratory results may occur when analysts make mistakes in following the method of analysis, use incorrect standards and/or simply miscalculate the data. The exact cause of analyst error or mistake can be difficult to determine specifically and it is unrealistic to expect that analyst error will always be determined and documented. The cause of laboratory deviations must be determined through a failure investigation or root cause analysis to identify the cause of the deviation. Once the nature of the out of specification result has been identified, testing procedures were discussed, instruments were examined and worksheets were reviewed. When appropriate, preventive maintenance as well as strategies for improvement was implemented to minimize future laboratory errors

Samples lost

A total of 400 samples were lost due to negligence, untrained personnel, who were responsible to receive and archive the samples. After corrective actions including training and a sample management log were introduced, samples lost decreased from 54.50% in 2016 to 36.50% in 2017 and to 9% in 2018.

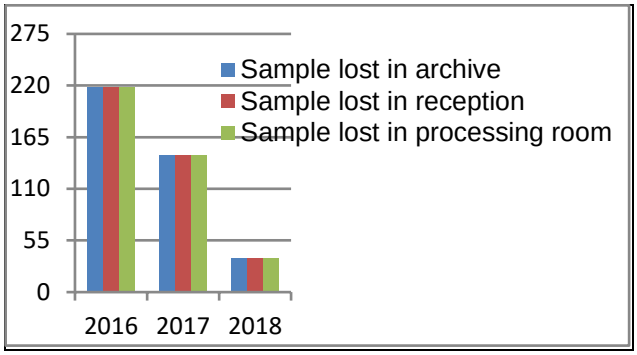


Figure2. Shows the number of samples lost between 2016 and 2018 in the laboratory unit from Reception, processing and Archive.

In 2016, a trend of lost samples was detected at the laboratory unit. Upon investigation, it was found that, on average, the laboratory could not account for 10 samples per week, or 40 samples per month, which was deemed unacceptable for quality service. To determine the cause of each lost or missing specimen, we formed a Lost Samples Review Committee in October 2016, made up of front-line laboratory supervisors, leads, and staff. Qualitative data revealed that the common responses to a lost specimen were, “Just redraw the specimen,” or “Ask the provider if they still need this result.” In essence, the culture tolerated lost specimens. The Lost Samples Project Team was comprised of six members with representation from the different laboratory unit sections. Their mission was to propose best practice solutions for the pre-analytic phase of laboratory work to prevent lost specimens, once root causes were identified. At the outset, the Lost Specimen Project Team posited two core questions:

- Why are specimens being lost?
- Why does the culture tolerate lost or missing specimens?

It was determined that the laboratory unit culture avoided looking externally for help because as a research centre, It was thought that outside help was not needed. After coming to this understanding, it was clear that other institutions or organizations’ efforts could be examined to help prevent lost specimens. In the fall of 2017, multiple site visits conducted at various facilities to learn how other organizations mitigated the risk of lost samples. To support this effort, standard laboratory site visit checklist was developed (See Figure 2) to ensure that the same questions were asked at each site. Three groups were formed and Twelve laboratories in academic institutions, local pharmaceutical industry and research institutions were visited laboratory leaders graciously welcomed us into their work spaces.

Figure 3. Site visit observation checklist used during laboratories visit

Specimen receiving tour checklist

Section A: **TRASH BINS**	**Years data collected**			**Total**
What types of engineering controls are in places?	2016	2017	2018	
Covered or open top (check one) Covered open	10	7	19	36
Location of trash bins	218	146	36	400
Trash bins under the counter (check) Yes No	0.50 %	0.75%	0.92%	2.17%
Is trash sequestered? How long?	0.58 %	0.43%	0.18%	1.19%
What type of trash sequestered All Recycled Biohazard	4	1	3	8

A Missing Specimens Checklist and Policy was developed In order to root out lost/missing sample instead of tolerating them, laboratory staff required a tool delineating proper investigative steps, common failure points and processes for escalation and communication. To acknowledge the problem and indicate a desire for culture change, verbiage was changed from “lost” to “missing” specimens. For the purposes of this study, “missing” sample could be found, whereas “lost” implied there was no possibility for locating that sample. The goal was to promote dedication to exhausting every possibility before a viable specimen is determined to be lost.

Sustaining Continuous Improvement

The greatest change in the culture was that missing or lost samples were no longer tolerated. To support this change, deviations and problems continued to be monitored in real time and during monthly Lost sample Committee Meetings. With robust data sources at our disposal, small process tweaks were made and gaps identified in the laboratory systems. Most reassuring is that deviation is recognized and categorized to better understand the root cause.

As the missing and lost specimen numbers diminished, in early 2018, a standard work observation form was created and meeting times were used to observe staff in each step of the specimen receiving process. The goal was to see the work in process, coach in real time if deviations are observed and compile any weak points that required improvement. By observing staff doing the work, leaders reinforced the standard and demonstrated the importance of proper sample handling in ensuring patient safety. Sustaining a zero-tolerance culture for lost sample was a challenge especially when new staff members are on boarded, as a result training programme was introduced for new staff members.
venturing outside to other laboratory facilities helped the laboratory personnel to gain insights and helped to improve the practices through the experiences observed in partner laboratories. Although this project began in 2016, the laboratory personnel are constantly learning and fine tuning the processes to drive continuous improvement

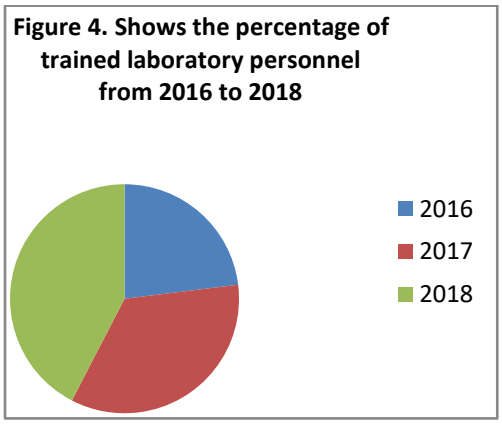
Staff competency

Laboratory staff competency is the ability of laboratory personnel to apply their skills, knowledge and experience to perform their laboratory duties correctly. In this study, in depth staff competency assessment is conducted by direct observations of test performance, including sample preparation, handling, processing and testing. Review of process records, review of training records, complaints and corrective actions. Ask laboratory personnel who perform a process regularly to explain how it works (the statements are compared to written procedures and compliance and deviations are noted for further clarification) How do laboratory

personnel monitor the records and reporting of the test results, review of intermediate test results and quality control records. Assess how they perform Preventive maintenance and keep records, direct observations of performance of instruments maintenance and function checks as well as problem solving skills.

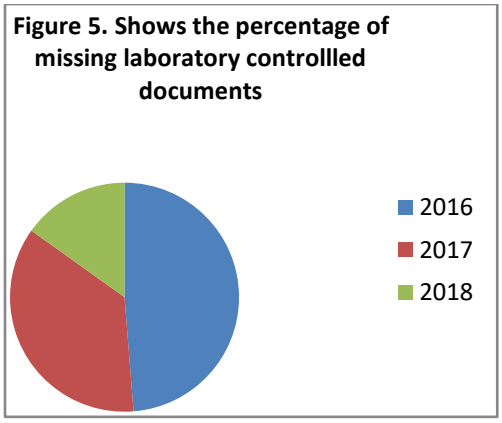
It was observed that 50% of laboratory personnel were not competent therefore refresher training conducted to remind and equip laboratory personnel with necessary tool that would help them to perform their tasks properly.

The percentage of trained personnel, competent capable of performing their duties and responsibilities were increasing from 0.50% in 2016 to 0.75% in 2017 and 0.92% in 2018.



Controlled documents

Laboratory controlled documents are policies, processes and procedures documents which must be available, up to date (current) and authorized by the management, and reviewed and signed by the laboratory staffs. The data shows that the number of missing standard operating procedures and manuals decreased from 0.58% in 2016 to 0.43% in 2017 and 0.18% in 2018.



Laboratory documents provide written information about policies, processes and procedures. Laboratory quality policy as a documented statement of overall intentions and direction defined by organization. It is always tell what to do, including a laboratory mission, goals and purpose and it serve as the framework for laboratory quality system.

Processes are the steps involved in carrying out quality policies. ISO 9000 (4.3.1) defines a process (how it happens) as a set of interrelated or interacting activities that transform a sample test request (input) into a test result (output), which can be represented in a flow chart with a series of steps to indicate how events should occur over a period of time.

Procedures are the specific activities of a process and are the performance of the test. A procedure tells how to do it and shows the step-by-step instructions that laboratory personnel should meticulously follow for each activity. Standard operating procedures (SOPs) are often used to indicate these detailed instructions on how to carry out procedure while Job aids and work instructions are shortened versions of standard operating procedure that can be posted on bench for easy referencing on performing a procedure. They are meant to supplement and not to replace the standard operating procedure.

Customer complaints

Eight customer complaints were identified and these were mainly caused by deviations of results from reference standard and sample management. Customer satisfaction can be used as a tool to identify factors that contribute to poor quality of laboratory services and are important components of a laboratory quality assurance program. Since customers are the end user of laboratory outcomes, obtaining their opinion and lessons provides opportunities to identify areas of improvement in the laboratory. Therefore, information obtained from customers should be used in process improvement and action plan for development.

4. CONCLUSION

Sample management in the laboratory need a systematic approach which includes responsibilities, methods of communication and maintenance of essential records and documentation. Documenting laboratory processes provides basis for control and improve operations, drive innovation and

achieve higher product conformity and less variation, fewer defects, waste, rework and human error. It also improve productivity, efficiency and effectiveness.

Laboratory staff competency facilitates the most effective use of laboratory personnel to achieve institution/organization and individual goals. The objective of staff competency is to build high performance workplace and maintain an environment for quality excellence. Every laboratory personnel performing work affecting product and service quality shall be competent on the basis of education, training, skills, and experience.

5. **RECOMMENDATIONS FOR NEXT STEPS**

Based on the findings of this study, recommendations for next steps are as follows:

Best Practice Recommendations

Incorporating the data compiled from site visits, four major areas of focus for reducing and preventing lost samples were established: facility design, couriers, staffing and workflow. Each of these areas is dependent upon the others; one area cannot succeed without the proper functioning of the other areas. Following are the best practices determined.

Facility Design

Maintaining a transparent and thoughtfully organized workspace is essential to proper sample management. In reviewing site visit data, it was clear that a single receiving location per site, coupled with open sightlines above and below work stations, would improve specimen receiving and tracking in the laboratory.

During site visits, laboratories utilizing a single point of entry along with a designated site for courier drop offs enabled laboratory staff to efficiently triage incoming specimens. This approach ensured that all expected specimens were accounted for, allowed for the determination as to which specimens were time or temperature sensitive and permitted the distribution of all specimens to their proper destinations for processing. Furthermore, those laboratories that located the functions of Specimen Receiving and Send Out in close proximity were able to efficiently receive couriers with specimens and distribute those specimens using a first-in/first-out methodology. Use of a water spider delivery cart helped to move specimens quickly to each testing and storage section. This system reduced the number of touches on a specimen, as well as the number of points at which an error or lost specimen could occur.

Couriers/sample transfer

In observing the courier workflow at the laboratory unit, multiple couriers were observed arriving and dropping off samples simultaneously. There was often inadequate workspace for the number of courier bags, and insufficient means to sort the specimens (e.g. clearly marked bins). Furthermore, there was no interfaced, real-time verification of specimen receipt (e.g. bar code). At the time of the study, the couriers were viewed as merely a means of transportation and some couriers received no training as to the needs and requirements of the laboratory and international air transport authority (IATA). Thus, courier accountability and reliability was low. In fact, the root cause analysis showed that at the time of this investigation, transport or delivery problems were the most common source of missing specimens and other deviations.

Site visit data indicated that best practice was to employ a single point of entry with one-way directional flow for couriers to enter and then exit the laboratory. Sign reading were pasted on doors and walls such as “Attention Couriers, Please, one at a time. Wait here until laboratory staff is available.” Some sites include a posted greeting card with the name of the laboratory staff member expected to interact with the courier to help encourage professional relationships and emphasize the value of interdependence. These actions were taken to create an environment of trust between couriers and laboratory staff to handle all samples with care.

Staffing

Staffing the receiving area was found to be a recurring challenge, as the schedule of the study did not accommodate staffing to workload or consider the appropriate mix of laboratory staff skill sets. Technical staff members were commonly pulled from testing areas to help in the receiving area and receiving staff members in the study were often pulled to field activities. Further stressing the system were high overtime rates due to open positions, and leaves of absence.

The best practice recommendations developed include

- flexible staffing to workload to meet the demands of frequent and infrequent specimen receiving times;
- establishing dedicated receiving and send out staff;
- separating processing and archiving activities from the receiving area;
- creating a Triage Greeter position to perform an in-person or “warm” hand off and warm pick up with couriers during pick up and retrieval. During these hand offs, the number of bags or individual items is conferred verbally between the courier and the greeter.

Workflow

This study revealed that the workflow in specimen receiving areas was unevenly distributed and job duties tended to be ambiguous. Due to space constraints, laboratory personnel were not able to employ a true first-in/first-out methodology. Furthermore, samples often were not received test-ready, but instead required additional processing.

With the aim of creating efficiency and clarity in the workflow, best practice recommendations included the addition of tools, such as a front-end receiving and processing automation line, a test tracking board for pending logs, and a Laboratory Information System collection manager indicating real time specimen receiving. It was also discovered that it is best to avoid placing garbage containers in or near specimen receiving areas and paths, or next to bench tops.

Progress Benchmarks

In reflecting upon the collective best practices, it was determined as a result of the site visits, that every deficiency cannot be address at once. Thus, change initiatives were prioritized based on the degree of impact and the resources required. Accordingly, some projects were fairly straightforward and easy to green light, whereas others required a more deliberate plan. The following is a high-level list of accomplishments to date:

Facility Design

- Clear, standard sized bins;
- No garbage containers permitted in the specimen receiving area.

Couriers

- One courier at a time with warm hand-off to and pick-up from Triage Greeter;
- Consolidation and simplification of courier routes;
- Daily printed schedule for arrival/delivery times along with timetable-enabled tracking;
- Dedicated spaces for courier bags and sample unloading;
- Drop-off log for courier and specimens/ samples not already tracked in our laboratory information system (LIS).

Staffing

- Comprehensive training for laboratory staff on handling and processing specimens;
- Staffing to workload;
- Dedicated staff for specimen receiving;

- Bag flattening protocol as part of standard work;
- Garbage sequestered for one week;
- Missing specimen form and pending log policy adopted system-wide;
- Added missing specimens to system-wide Daily Laboratory Leader Safety Call.

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