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Processes and Practices Improvement of Sample Receiving Counter at Government Clinical Laboratory in Sri Lanka

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ABSTRACT: Improving efficiency of a clinical laboratory service should be a first priority in healthcare development of any country. It plays a significant role as it facilitates diagnosing and treating diseases and finally to discharge the patients faster. Therefore, the reliability and the accuracy of a clinical laboratory should be guaranteed through a sound sample management. The aim of this study was to improve the process and practices of sample management at a sample receiving counter of a selected government clinical laboratory in Sri Lanka.

The study was an institution based interventional project. The research adopted mixed methods including a desk review, a checklist, focus group discussions and a staff satisfaction survey which was conducted among Medical Laboratory Technologists. Proportions, percentages and means were calculated for quantitative data and narrative analysis was done for the analysis of qualitative data.

The results indicated that the incidences of missing samples and request forms and sample handling time have been significantly reduced at post intervention. Performance of the routine counter activities including proper documentation, updating the notice boards, monitoring temperatures of sample storing refrigerators and consideration of rejection criteria in accepting the samples were significantly improved after the intervention. Staff satisfaction on overall sample handling process and practices was significantly improved after the intervention except the current practice of sample data management and facility availability to carry out duties. The study recommends modifying the counter layout with adequate expansion. It also recognized the necessity of implementing a Laboratory Information Management System for whole laboratory operation.

KEY WORDS: Clinical laboratory, Medical Laboratory Technologists, Interventions, Sample receiving counter, Sample management.

I. INTRODUCTION

Biological specimen refers to a sample taken from the human or animal body for investigation or study purpose (CLSI). Biological sample collection and handling should be performed with proper care to guarantee an accurate result at the end of the investigation. Sample management is one of the essential components in quality control of a clinical laboratory. Developing reliable, reproducible and rapid laboratory results in a cost effective manner will improve the quality of the laboratory service. Many factors including time of collection, containers, used preservatives and other additives, length of transit time affects the quality of the samples and the stability of biomarkers. Therefore careful handling is must in the initial collection stage of the sample management process [1]. Some samples may need special handling precautions such as immediate refrigeration, prevention from exposure to light and prompt delivery to the laboratory.

Following factors are identified as the key components in a proper sample management [2].

a) Obtaining of appropriate sample for testing
b) Correct inspection of samples carefully at the receipt
c) Test request and availability of adequate data
d) Labeling and preservation of samples
e) Prompt delivery to the laboratory
f) Storage, retention and dispose

Laboratory process can be divided into three phases including pre-analytical phase, analytical phase and post – analytical phase. Pre-analytical phase is more vulnerable to uncertainties, accidents and frequency of mistakes including missing samples or test requests, wrong or missing of sample identity, insufficient samples, in appropriate containers, in appropriate transport and storage

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conditions [3]. Hence, sample management at this point is considered as very critical. Furthermore, misplacement has been a common incidence reported at sample specimen counters [4] and this is mainly due to less attention and poor supervision of medical staff during the sample management process [5] Pre-analytical errors are estimated to account for 70% of all mistakes made in laboratory diagnostics. These evidences show the significance of accurate sample management at the initial stage [6].

Introducing an exact written protocol for the specimen handling was one of the proven remedies to mitigate the loss of specimens [7] Continuous education of medical staff and technology and infrastructures improvements are considered as the main factors which strengthened the sample management in clinical laboratories [8]. Identifying, monitoring and reducing pre analytical laboratory errors will add trust bounded reputation to the institution. In the Sri Lankan context, most researchers have concentrated on improving the sample management system by reducing occupational risk for healthcare workers, not for maximizing patient's satisfaction. Therefore, this interventional research project would generate an essential healthcare quality outer cover to the organization. Addressing the gaps that exist in the processes and practices of sample management will reduce unwanted complicated situations inside the institution increasing healthy rapport among the working staff.

II. METHODOLOGY

The project is an interventional study which was carried out from February to August, 2021. The study setting was a sample receiving counter of a government clinical laboratory in Sri Lanka. This study was conducted in three phases including, pre-intervention (phase I), intervention (phase II) and post-intervention (phase III).

In phase I, the process of sample management at the Sample Receiving Counter (SRC) was studied extensively and mapped. The tools used for the study included the following;

(1) The desk reviews secondary data regarding the number of samples received to the SRC daily and the information on missing incidences on samples and request forms. Following documents were assessed.

- Sample receiving register
- Incidences recording register

(2) A checklist was developed and used to measure the average time taken to handle 100 samples. Same checklist was used to check the performance of selected routine activities of SRC for 45 days.

(3) Focus group discussions were held with;

- Counter in-charge
- Residential Medical Laboratory Technologist (RMLT)
- Few members from supportive staff regarding routine practices and process of the SRC.

(4) Staff satisfaction survey

Interviewer administered questionnaire was used to measure MLTs' satisfaction regarding current sample management at the SRC, its processes and practices. The questionnaire was developed based on the expert opinion and literature review. The questionnaire was pre tested and validated. The questionnaire consisted of the following attributes with five-point Likert scale rating.

- Support provided by the laboratory management
- Guidance, supervision provided by the supervisors
- Facilities available to carry out the duties
- Training facilities given for knowledge and skill upgrade of laboratory staff
- Sample data management

Purposive sampling technique was used. 70 MLTs are working at the SRC on a roster basis and two MLTs have been allocated per day. The total population was recruited for the study.

During phase II, suitable interventions were developed and implemented. It included introduction of bar code system for sample labeling, development of Standard Operating Procedure (SOP) for sample handling, institutional workshops for MLTs to build the

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capacity on sample management and development of training calendars, one to one education and supervision of sample management and strengthening supervision and scheduling monthly meetings to discuss the arising issues at SRC.
Same tools were used to gather the data in phase III. Effectiveness of the applied interventions was measured at this phase. Data gathered from the questionnaire and checklist was analyzed from IBM SPSS (2021) software. Ethical and administrative approvals were obtained from the relevant authorities. Written consents were obtained from MLTs prior to the interview.

III. RESULTS AND DISCUSSION

Sample handling procedure was studied extensively and mapped as shown in Figure 1.

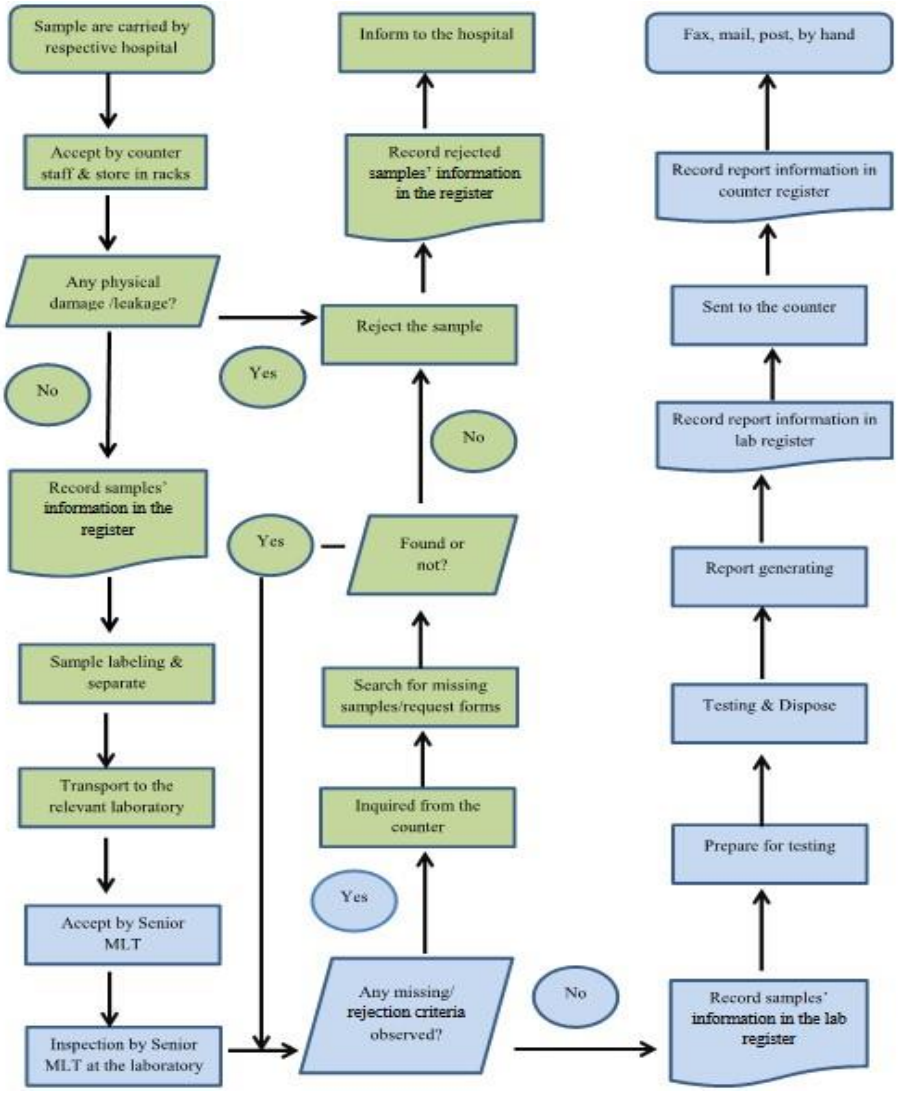

Figure 1: Overall Sample Management Procedure

Process Mapping (PM) is an important tool in identifying complex processes and it clearly indicates the existing gaps. PMs were reported from a wide range of healthcare settings and in laboratory service its usage is about 3% [9].
Following gaps were identified in the SRC using the tools introduced in the methodology part.

1. Missing incidences of samples and request forms
2. Long time taken for sample handling

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3. Inadequate MLT performance in routine counter activities
4. Lower staff satisfaction on current sample management

A. Missing incidences of samples and request forms

Following results were obtained by using a checklist as indicated in Table 1.

Table 1: Daily Missing Incidences of Samples and Request Forms

Average daily incidences recorded on missing of samples and request forms		Significance Z-test, p*
Pre-intervention (*n*=45)	Post-intervention (n=45)	
0.8%	0.14%	Z=8.89, p=0.00001

*Difference between two percentages for two proportion tests (z-test) was applied

Missing incidences were significantly reduced from 0.8% to 0.14% at $p<0.05$ significance level after intervention (Table 1).

B. Time Taken for Sample Handling at SRC

Table 2: Average Time Taken for Handling of 100 Samples (Min)

Pre-intervention (*n*=45)				Post-intervention (*n* =45)				Significance t test, p*
Mean	SD	Min	Max	Mean	SD	Min	Max	
310	12.58	285	342	125.96	9.55	104	154	t= -71.51, p= 0.00001

*paired t test was applied

As per the results obtained, time taken to handle the 100 number of samples was significantly reduced at phase III. Previous practice of sample labeling was manual. Introduction of a bar code system for the sample labeling ensured the availability of both sample and the request forms and at the same time it reduced the unnecessary efforts made to find the missing samples. Standardization of processes ensures the consistency of the sample handling procedure. Authors have mentioned that, SOP improves clarity, guarantees quality, promotes productivity, and boosts employee morale. Furthermore, standardization of the process of primary healthcare settings improves the efficiency of the exciting procedures. According to MLTs, previous practice was very complicated and it was associated with many unnecessary activities. Introduction of SOP provided clear direction to the health staff regarding sample management avoiding non-value added practices [10].

C. Performance of Routine Activities at the Sample Receiving Counter

There are few activities that are routinely practiced at a SRC as indicated in Table 3. It was found that out of total only 60% of MLTs thoroughly consider the rejection criteria at the receipt of samples. Figure 3 showed some common rejections criteria that are considered by MLTs in accepting samples. Almost all the MLTs consider physical leakages, hemolyzed blood samples or inappropriate containers but not about inadequate sample, lack of sample information and test requesting form with consultant signature.

During focus group discussion it was revealed that rejected samples have occupied considerable capacity of sample storing refrigerators. Making rejections at the time of receipt will minimize the unnecessary burden on handling of rejected samples. Therefore, rejection criteria need to be followed closely. Poor quality samples do not provide accurate results. However the sample rejection policies need to be implemented without compromising the patient care. The relevant hospitals need to be informed to resend a sample in order to maintain uninterrupted patient care. MLTs' consideration and attention on rejection criteria was significantly increased at phase III at $p<0.05$ significant level.

Table 3: Routine Activities Performed at SRC

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Activity	Phase	Satisfied % (*n*=70)	Significance (z-test, p)*
1. Consideration of rejection criteria at the receipt of samples	Pre	(42) 60	Z=-4.83, p=0.00001
	Post	(66) 94.3	
2. Correct documentation	Pre	(20) 28.6	Z=-8.19, p=0.00001
	Post	(67) 95.71	
3. Correct sample labeling	Pre	(67) 95.7	Z=-1.75, p=0.08012
	Post	(70) 100	
4. Daily updating the notice boards	Pre	(32) 45.7	Z=-5.39, p=0.00001
	Post	(62) 88.6	
5. Monitoring temperatures of the refrigerator and documenting	Pre	(15) 21.4	Z=-4.64, p=0.00001
	Post	(42) 60	

*Difference between two percentages for two proportion tests (z-test) was applied

1) Consideration of rejection criteria in accepting sample for testing

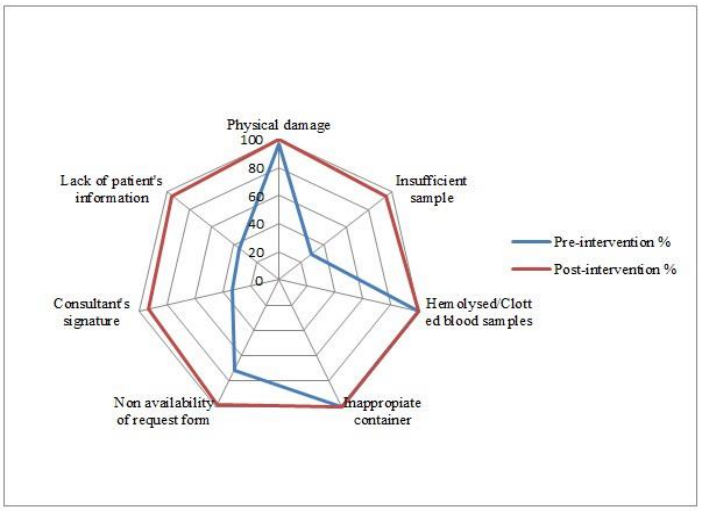

Figure 3: Documentation Performances in Pre and Post Intervention

Rejection criteria that should be considered in accepting samples for testing was improved at post intervention as shown in Figure 3.

2) Documentation of accepted sample information and rejected sample information

According to the quality management system model developed by Clinical & Laboratory Standard Institution (CLSI), reliable and accurate documentation has been emphasized as a fundamental principle of a clinical laboratory [11]. Those documented information need to be accurate, accessible and should be managed meticulously. According to WHO laboratory manual there are a considerable number of documentations exist and Figure 4 has indicated most essential related to sample management. As per the results obtained 28.6% of MLTs properly do the correct documentation as indicated in Table 3.

Figure 4 has indicated required information needs to be documented. Almost all of them have considered the patient's details and the date of receipt. But they rarely document the information on sample type received, time and test going to be performed. This information is essential in sample tracking too. Documentation of rejected sample information is also important as it facilitates

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reducing rejections ratios by informing the respective hospitals which ultimately promotes patient safety [12]. Current documentation practice is manual and as per the focus group discussion which is extremely time consuming. Researchers have found most laboratories in developing countries do not effectively manage the process of documentation. Standardization and electronic sample data management has been good interventions in establishing strategically effective and sustainably standardized document management systems [13].

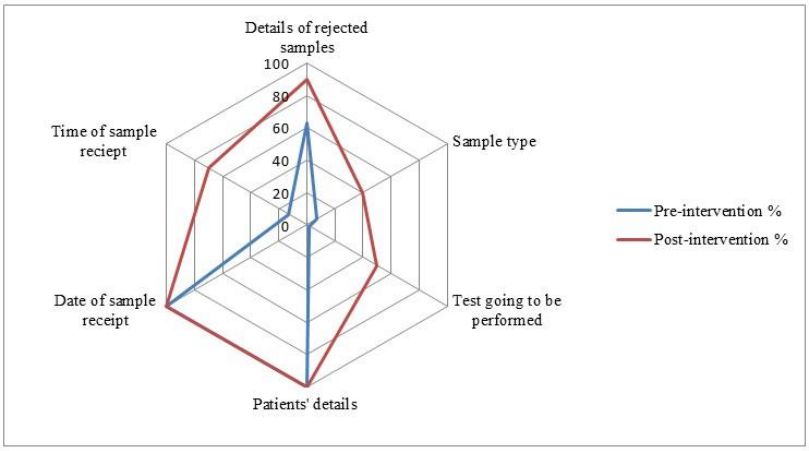

Figure 4: Documentation Performances in Pre and Post Intervention

Figure 4 visually shows that there is a post intervention improvement in documentation sample receiving time, sample type, test going to be performed and rejected sample information. And overall documentation was significantly improved at phase III $P<0.05$ significant level.

There is no significant improvement in sample labeling and but there was an inadequacy of data mentioned which was improved at post intervention. Staff was very happy about the bar coding system as it was very convenient, efficient and reliable.

Notice boards should be updated mentioning the test availability then it is clearly visible to the visitors. Furthermore, it is convenient for the staff working at the counter too. Updating the notice board was significantly improved at $p<0.05$ significance level after intervention.

Different samples require different storing conditions as it significantly affects the test result. Therefore, cold chain management is a must. The temperatures of the refrigerators available at the counter should be monitored frequently and should timely calibrate if there are any deviations noticed. Routine monitoring of refrigerators was significantly improved after intervention at $p<0.05$ significance level. During the focus group discussion, it was noticed that drinking water bottles were stored with the patient's samples. After post intervention, staff seemed to be very concerned about following laboratory safety precautions and good practices.

D. Staff Satisfaction

Based on the socio demographic information obtained from the survey, the age of the MLTs' ranged from 25 years to 38 years with a mean age of 32 years and majority (95.7%) was female.

Table 4 indicates the staff satisfaction on a few selected attributes. Staff satisfaction on management support given was 67.1%. This was mainly due to the fact that management hadn't a protocol to cope with counter staff and poor supervision and less attention paid to the counter activities. There were no scheduled meetings to discuss the matters arising and to get the problems sorted out immediately. This attribute was improved at $p<0.05$ significant level. Staff satisfaction on guidance, supervision provided by supervisors was significantly improved at $p<0.05$ significant level after intervention.

Facilities to carry out the duties were not improved at the post intervention. RMLTs who are working in night shifts do not have a restroom. Inadequate space has created congestion inside the counter. Wash basin facilities are not adequate in the case of spilling and no separate area for screening of samples. Report issuing also takes place in the same area which creates a busy environment at the counter. There is no place to store the documents and hardly any space for documentary management. This shows the necessity of having layout expansion. However, budgetary limitation has hindered the development activities.

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Table 4: Staff Satisfaction on Selected Attributes on Sample Management at the counter

Attribute	Phase	Satisfied (*n*=70)	Significance (z-test, p)*
1. Expected support received by the laboratory management	Pre	(47) 67.1%	Z=-3.29 P=0.00096
	Post	(63) 90%	
2. Guidance, supervision provided by the supervisors	Pre	(42) 60%	Z= -4.34 P=0.00001
	Post	(64) 91.4%	
3. Facility availability to carry out the duties	Pre	(37) 52.9%	Z= -0.85 P=0.395
	Post	(42) 60%	
4. Training facilities given for laboratory staff capacity building	Pre	(35) 50%	Z= -6.08 P=0.00001
	Post	(67) 95.7%	
5. Sample data management	Pre	(42) 60%	Z= -1.61 P=0.107
	Post	(51) 72.8 %	

*Difference between two percentages for two proportion tests (z-test) was applied

It is essential to provide continuous education to the laboratory staff as this is prone to frequent changes and modifications. It is a known fact that provision of training is inadequate in the public sector comparable to the private sector [14]. Staff satisfaction on training facilities given was improved significantly at $p<0.001$.

Staff satisfaction on sample data management was not significantly improved after intervention. Still staff has to perform many paper documentary activities as there is no Laboratory Information Management System (LIMS) implemented yet. Sample tacking is very difficult and time consuming. Authors have shown that even in 2020 many laboratories in developing countries use conventional paper documentation for their operations. It clearly says that tiding of laboratory operations with a pen and a paper hinders the expansion of laboratory operation [15]. Therefore, LIMS has become a priority in order to improve the productivity traceability and the quality of work while minimizing the errors.

IV. CONCLUSION

The overall study showed that there is a significant reduction in sample and request form misplacement and the time taken for sample handling. Routine practice at the counter including consideration of rejection criteria at the receipt of samples, documentation, updating notice boards and monitoring temperatures of the refrigerators were significantly improved after intervention. Staff satisfaction was significantly improved for the selected attributes of laboratory management support given, guidance and supervision given, facility availability to carry out duties and training given except sample data management. The outcome evaluation showed that still there are few gaps remaining in order to improve the sample management system.

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