Role of Laboratory Information System (LIS) in enhancing Quality in Hospital Laboratory Services.

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Abstract : *Treatment of each and every patient depends, to a great extent, on the laboratory reports generated. Diagnostic laboratories have an important role to play in ensuring quality and patient safety. The study was conducted in Biochemistry Laboratory of a tertiary care hospital. The study of work flow and data collection was done before and after the implementation of the Laboratory Information System (LIS). The introduction of LIS resulted in 23.7% improvement in adherence to Turn-Around Time (TAT), 86 % reduction in labeling errors, 90.2 % reduction in Missed Orders and 50 % reduction in Transcription errors. Totally the number of errors significantly reduced from 1 in 90 to 1 in 588 tests (11.1 in 1000 to 1.7 in 1000 tests) after the implementation of LIS.* ***Conclusion:*** *LIS contributes to improvement in the efficiency of the laboratory, reduction in laboratory errors, improvement in quality of patient care and consequently in Patient Safety.* ***Keywords:*** *LIS, Quality in Lab, Patient Safety, Laboratory errors, TAT*

INTRODUCTION

The Institute of Medicine defines healthcare quality as the extent to which health services provided to individuals and patient populations improve desired health outcomes. The care should be based on the strongest clinical evidence and provided in a technically and culturally competent manner with good communication and shared decision making[1]. Glasziou P reports a key objective of Evidence Based Medicine, which has a strong resonance in laboratory medicine, is the emphasis on improving the quality of the information on which decisions are based[2]. WHO cites quality assurance involves all measures that can be taken to improve laboratory efficiency and effectiveness, with a view to the maximum benefit to individual and community, as well as to ensure laboratory performance with minimal risk to laboratory workers[3]. Neuberger and Peters concluded that Clinicians desire a rapid, reliable and efficient service delivered at low cost[4].

Diagnostic laboratories have an important role to play in ensuring patient safety. As highlighted by Forsman, RW,"We know that, although the laboratory represents a small percentage of medical center costs, it leverages 6070% of all critical decisions, e.g. admission, discharge, and drug therapy."[5] Each specimen passes through many steps from collection to the delivery of test results. While safeguards are in place, many of these steps are often performed manually, adding time and risking errors that can compromise on patient safety. Medical error reduction has become a major focus for organized medicine since the publication of the Institute of Medicine's report on medical errors in 1999[1].

Dzik WH et alreported that one in every 165 blood samples collected were mislabeled, while one in every 1,968 samples were collected from the wrong patient and concluded that the rate of mis-labeled samples and mis-collected samples is 1000-10,000-fold more frequent than the risk of viral infection[6]. Carraro P and Plebani Mreported a total of 160 confirmed errors out of 51,746 analyses, 61.9% were pre-analytical errors, 15% were analytical, and 23.1% were post-analytical[7]. Stankovic AK concluded due to significant efforts on the part of both the laboratories and the manufacturers of laboratory equipment and reagents, the errors in the analytic phase of the total testing process now represent the smallest portion of testing errors [8].

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Laboratory errors may result in significant patient inconvenience or harm. Green SF reported that errors that occur in the pre-analytical phase of testing may account for up to 75% of total laboratory errors; 26% of these may have detrimental effects on patient care, which contribute to unnecessary investigations or inappropriate treatment, increase in lengths of hospital stay, as well as dissatisfaction with healthcare services[9]. The IOM Report 1999 reports that the recognition that preventable medical errors cause tens of thousands of US deaths annually has spurred the patient safety movement that seeks to create systems that are inherently error-preventing[11].

The Joint Commission International suggests the use of automated systems to prevent patient misidentification[10]. Careful design of the basic process of care and appropriate use of technology overcomes human fallibility, vulnerability to fatigue and environmental influences.

Public policy[11] and private groups[12] increasingly advocate use of health information technology (HIT) as an important element in efforts to transform the healthcare system, with potential contributions to patient safety, healthcare effectiveness and cost savings.

Laboratory information system (LIS) is a rational database in which laboratory data are logically organized for rapid storage and retrieval. In principle LIS guides and records the passage of a sample through the laboratory, from its registration; through the programme of analyses; the validation of data, before the presentation and filing of the analytical results. Specific objectives of LIS include: Establishment of a paperless environment while maintaining a digital recording; optimize utilization of medical resources at the medical center; efficiency of medical care outcome and monitoring and control of the laboratory workflow process. Sihe Wang and Virginia Ho concluded that the direct interface of the instruments to the LIS showed that it had favorable effects on reducing laboratory errors [13].

METHODOLOGY

Study setting: The study was conducted in the Biochemistry laboratory of a 2050 bedded tertiary care hospital. **Study period:** June 2011 to May2012

(a) Pre intervention period (before implementation of LIS from June 2011 to Nov 2011)
(b) Post intervention period (after implementation of LIS from Dec

2011 to May 2012).

Study Objective: To study the impact of LIS on laboratory errors and Turn-Around Time and hence its role in enhancing quality in the laboratory services.

Analysis: Test for paired proportions using R-2.15.0 for testing statistical significance

RESULTS

The hospital under study has a HIS (Hospital Information System) in place, this includes modules for registration, billing and indenting. The hospital has also installed Pneumatic Transport System (PTS) for quick transportation of samples and to avoid any transportation errors.

Laboratory Information system (LIS) was implemented in the hospital with the objectives to improve the Turn-Around Time (TAT); faster retrieval of reports; reduction in the number of errors and to improve efficiency in laboratory work and hence continuous quality improvement. The LIS was implemented in 4 phases; in the first phase there was implementation of LIS in the Clinical Lab (Hematology Section); followed by Biochemistry, Microbiology and Pathology labs.

Work Flow in the pre implementation period:

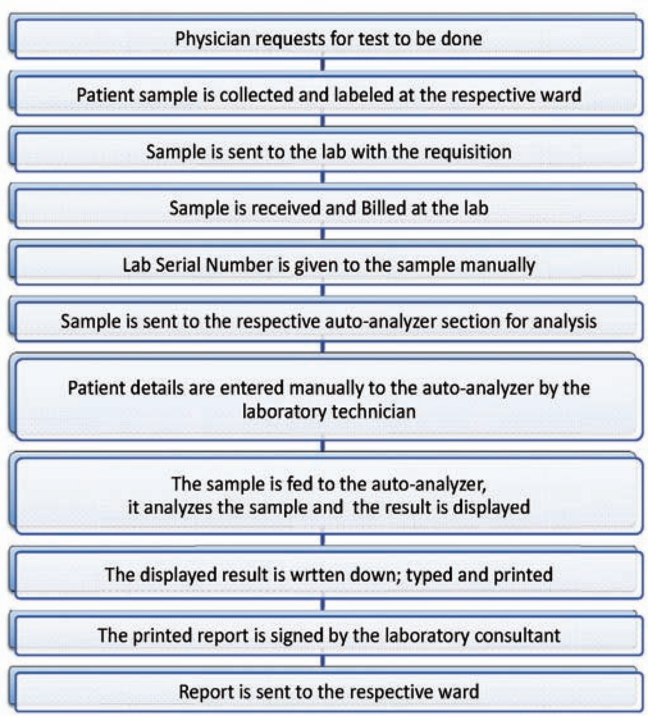

***Figure: 1** Work flow for in-patient samples in the Pre Implementation period*

The workflow for in-patient samples prior to the implementation of LIS is depicted in Figure: 1. The workflow for Out-patient samples was similar to workflow of in-patient samples except that billing and collection of samples was done at the Central Out-Patient Sample Collection Center located at the Out-patient Block of the Hospital and sent to the laboratory through PTS (Pneumatic Transport System).

The major constraints identified prior to the implementation of LIS were the manual elements such as;

1. Labeling of lab serial numbers to the samples,
2. Entering of patient details to the analyzers,
3. Typing of reports displayed by the analyzer and
4. Sending the typed reports.
5. In case of emergencies or critical reports, the reports were informed over telephone to the treating physicians.

This led to labeling errors; missed orders; transcription errors and delay in reports reaching the physician.

Work flow in the post implementation period:

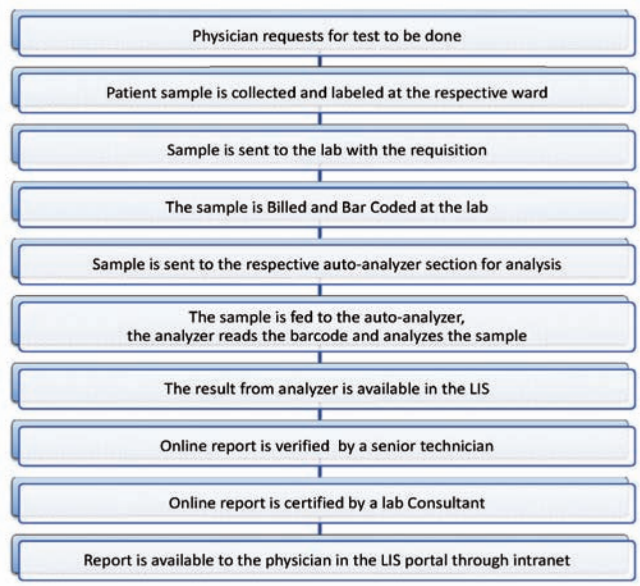

***Figure:** 2 Work flow post implementation period*

Work flow in the post implementation period is depicted by Figure: 2 for In-patient samples. The workflow of out-patient samples is similar to the workflow of in-patient samples except that they are billed, barcoded and collected at the Central Out-Patient Sample Collection Center.

Implementation of LIS: Laboratory Information System (LIS) was installed in the end of Nov 2011. The main features of LIS included Barcoding of samples and linking of LIS with software interface of all auto-analyzers in the lab. Barcoding of samples removes the manual labeling of samples, entry of patient details and tests required to the auto-analyzers; thus preventing labeling errors, misidentification of samples and missed orders. The linking of LIS to Software interface of auto-analyzers provides results directly in the system preventing manual typing of results.

The LIS has two modules- Lab module and care provider module. The Lab Module has Lab Master which can be accessed only by the In-Charge of the lab and the software provider. Training was given to all staff prior to the implementation of LIS. All staff are given login ID and password. Confidentiality of the reports and unauthorized access to the LIS is hence prevented. The laboratory technicians are given the authority to only verify the results, and the consultants are given authority to both verify and certify the results. The reports are first verified by a senior technician and then certified by a laboratory consultant with respective electronic signatures, therefore there is a double check before the reports reach the treating physician. The report is available in the intranet only after certification of the result by the laboratory consultant.

In the care provider module, the physician or the care provider has access to the LIS Report viewer through the intranet, which in-turn is password protected. Hence the report is quickly and easily accessible in LIS to the treating physician. The print out of the report when required can be taken either at the lab or at the patient care area.

The results obtained in the study are tabulated in the tables given below:

Table 1: *Number of Tests per month in the pre and post implementation period*

No. of Tests	Pre-Implementation Period	Post-Implementation Period
OP Tests per month	40891	47315
IP Tests per month	81783	85955
Total Tests per month	122674	133270
Total Tests	736044	799620

OP- Out-Patient, IP- In-Patient

The Total of number of tests done was 736044 and 799620 in the pre and post implementation period respectively. The percentage of inpatient tests compared to outpatient tests was higher in both the periods (66.7 % and 64.5% in the pre and post implementation period respectively). There was 15.7% increase in outpatient tests and 5.1% increase in the inpatient tests from pre to post implementation period.

Table 2: *Percentage of Errors in Pre and Post Implementation period*

% of Errors	Pre-Implementation Period	Post-Implementation Period	P Value
Labeling Errors	0.5%	0.07%	<0.001
Missed Orders	0.51%	0.05%	<0.001
Transcription errors	0.1%	0.05%	<0.001
Total Errors	1.11%	0.17%	

The types of errors identified were pre-analytical errors which included labeling errors and missed orders and post analytical errors included transcription errors. The total number of errors identified was 8170 and 1359 in the pre and post implementation periods respectively. The percentages of errors in the pre-implementation period were 45.1%, 45.9% and 9 % of labeling errors, missed orders and transcription errors respectively. The percentages of errors in the post-implementation period were 41.2%, 29.4% and 29.4% of labeling errors, missed orders and transcription errors respectively. The pre-analytical errors were higher than the post-analytical errors (90% and 70.6% in the pre and post implementation periods). After implementation of LIS there was a statistically significant reduction of labeling errors, missed orders and transcription errors.

Table 3: *Number of tests adhering to Turn-Around Time*

	Pre-Implementation Period	Post-Implementation Period	P value
Total No. of Tests	736044	799620	
No. tests adhering to TAT (%)	559400 (76%)	751645 (94%)	<0.001

TAT is defined as the time taken from the sample registration to result reporting. TAT was fixed for each test based on the time required for analysis of sample and reporting. The TAT was noted for all tests before and after the implementation of LIS. The Percentage of tests adhering to TAT significantly increased from 76% to 94%. (P<0.001)

DISCUSSION

The Department of Clinical Biochemistry performs most of the critical laboratory tests required for the diagnosis, monitoring and treatment of patients. It offers comprehensive and specialized laboratory services. Evaluation of LIS is complicated; hence we could measure only few parameters. The implementation of LIS brought a major change in the workflow of the lab. It reduced manual elements of labeling, feeding patient details to auto-analyzers through barcoding and typing of reports through interface linking. The reports certified by the lab consultant are immediately available in the LIS care provider module at the physician's end, therefore reducing the delay which occurred due to transporting of reports.

The numbers of In-patient Biochemical tests conducted were more than out-patients tests.

There was 8.6% increase in the number of tests done in the post implementation period compared to the pre implementation period (Table1).

A Labeling Error was considered when a sample was identified with a wrong patient details or when the sample was given a wrong lab serial number. The percentage of Labeling Errors reduced significantly from 0.5% in the pre to 0.07% in the post implementation period (86% Reduction) (P<0.001) (Table 2). This reduction is attributed to computerized barcoding.

Aileen P et al concluded that Bar code technology significantly reduced the rate of specimen identification errors and labeling errors fell from 5.45 in 10,000 before implementation to 3.2 in 10,000 after implementation of LIS[14]. A study by Hayden et alshowed a decline of mislabeled specimens from 0.03% to 0.005% in a 12 month full Computer-Assisted Bar-Coding System implementation[15]. Susan R. Snyder concluded barcoding is effective for reducing patient specimen and laboratory testing identication errors in diverse hospital settings and is recommended as an evidence-based "best practice."[16]

The reading of the barcode by the auto-analyzers prevented any tests being missed due to wrong entry of tests prior to analysis. The number of Missed Orders significantly reduced from 0.51% in pre to 0.05% in post implementation period (90.2% Reduction) (P<0.001) (Table 2).

The linking of LIS with software interface of all auto-analyzers in the lab prevented transcription errors by avoiding manual typing of results displayed by the analyzer. The number of Transcription Errors significantly reduced from 0.1% in pre to 0.05% in post implementation period (50% reduction) (P<0.001) (Table 2). An Australian survey conducted by Khoury M, Burnett L and McKay MA showed a transcription error rate up to 39%[17]. Eric G. Poon et al concluded that Transcription errors were completely eliminated on units which used bar-code eMAR, while the error rate was 6.1% on units that did not use it[18].

The pre-analytical errors were higher than the post-analytical errors. Stankovic AKalso reports laboratory testing errors occur most frequently in the pre-analytic phase[8]. Totally the number of errors significantly reduced from 1 in 90 to 1 in 588 tests (11.1 in 1000 to 1.7 in 1000 tests) after the implementation of LIS. Studies have shown that the frequencies of laboratory error rates vary greatly- one error identified every: a) 330–1000 events, b) 900–2074 patients and c) 214–8316 laboratory results[19].

Turnaround time (TAT) is one of the most noticeable signs of laboratory service and is often used as a key performance indicator of laboratory performance. The adherence to TAT before the implementation of LIS was 76%. After the implementation of LIS, the reports are available in the LIS intranet portal to the treating physician immediately after they are certified by the lab consultant. The time is saved by avoiding manual lab serial number labeling, entering of patient details to auto-analyzers, typing of reports and transporting reports to respective wards. LIS also helps to keep an accurate track of the Turn-Around Time. The Adherence to TAT significantly increased to 94% that is there was an increase in the adherence to Turn-Around Time (TAT) by 23.7% in the post implementation period (Table 3). Studies reveals a 90% completion time (sample registration to result reporting) for common laboratory tests is suggested as an initial goal for acceptable TAT[20]. The CAP Q-Probes study on biochemical markers of myocardial injury TAT from 2004 collected data from 159 hospitals regarding the expectations of order to report TATs. The median (and inter-quartile range) physician expectation was 90% completion of TAT[21].

Few limitations included absence of physician order entry system, hence the physician cannot request online for a test. The human elements such as the labeling at the ward level done by the nursing staff and billing which is done by clerical staff can result in errors. All the biochemical tests are not automated because few special biochemical tests like Lactate, Pyruvate and G6PD are done manually.

CONCLUSION

Laboratory Information System is an important tool to improve and streamline the workflow of a laboratory. It helps to significantly reduce manual errors, i.e., labeling errors (86% reduction), missed orders (90.2% reduction) and transcription errors (50% reduction). It also helps to significantly improve adherence to Turn-Around Time as per the study. All these factors help to enhance quality in laboratory services and patient safety. Though the implementation of LIS appears costly and tedious process to implement, the benefits of accurate and timely reports justifies the implementation.

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DRUG PROFILE

Teneligliptin

Mechanism of Action: *The glucagon like peptide – 1 (GLP-1) is secreted from alimentary canal in response to meal that promotes insulin secretion from pancreas and regulates post meal blood sugar by controlling glucagon secretion. This is very rapidly degraded by the enzymatic activity of DPP-4 (Dipeptidyl peptidase) in the interstine resulting in a very short half life approximately 2 minutes.* ***Metabolism & Excretion:*** *CYP3A4 A cytochrome P450 isozyme & flavin-container monooxygenases (FMO1&FMO3) play major roles in the metabolism of teneligliptin about34.44% of teneligiptin is exerted unchanged via the kidney &the remaining 65.6%teneligiptin is metabolized & eliminated via renal & hepatic excretion.* ***Indication:*** *Teneligliptin is indicated as an adjuvant to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; usual adult dosage of Teneligliptin 20 mg administered orally once daily regardless of meals. The dose may be increased up to 40mg one daily while closely monitoring the clinical course. The drug can be used in combination with insulin sulphonylurea, met for min. pioglita one.* ***Special Population:*** *Safety and effectiveness of the drug in pediatric patients have not been established. Elderly patients often have physiological hypo functions and therefore Teneligliptin should be administered carefully with close monitoring. Renal Impairment: patients with renal impairment will not pose any significant safety risk. Teneligliptin can be administered to patients with renal impairment due to diabetic nephropathy without the need for dose adjustments.* ***Hepatic Impairment:*** *Teneligliptin in patients with mild to moderate hepatic impairment will not pose any significant safety risk. Thus, dose adjustment is not required in mild to moderate hepatic impairment.* ***Warning and precautions :*** *In patients with severe hepatic dysfunction and heart failure, risk of hypoglycemia may increase if co-administered with sulphonylurea or insulin. Hypoglycemia may occur in patient with adrenal insufficiency, malnutrition, insufficient dietary intake. QT prolongation may occur in patients having past history of arrhythmia, patient having heart disease I.e. congestive heart failure and patient having hypokalemia.* ***Adverse reactions:*** *Include hypoglycemia, hepatic dysfunction, interstitial pneumonia.*