Abstract: One of the major principles in healthcare is patient safety. Any intervention in healthcare should be safe, regardless of its benefits. The implementation of laboratory information system (LIS) has a multidimensional effect on the healthcare system. LIS plays a role in medical informatics, consumer informatics and translational bioinformatics. Nevertheless, implementation of LIS impacts patient safety in many different aspects. The aim of this paper is to investigate how patient safety can be improved by laboratory information system. The author conducted this review by searching PubMed, Google Scholar, and the World Wide Web (reports, blogs, news) for articles published in English on the following keywords were searched: laboratory information system, patient safety, and quality. We found that there is a broad framework of dimensions to evaluate LIS. The framework is based on two concepts: brain-to-brain loop process, and HOT-fit dimensions. The brain-to-brain loop process can be divided into five phases: 1) pre-test, 2) pre-analytic, 3) analytic, 4) post-analytic and 5) post-test phases. In each phase, LIS provides functions to facilitate performing different tasks. In the HOT-fit model, there are three broad dimensions that need to be analyzed and considered in LIS. These are: 1) Human dimension, 2) Organizational dimensions, and 3) Technology dimensions. LIS plays a critical role in patient safety in the components of this framework. We concluded that Implementation of LIS has certainly a multidimensional impact on patient safety in different aspects on informatics. This includes LIS roles in three field of health informatics: medical informatics, consumer informatics and translational bioinformatics. LIS can integrate these fields to provide safer healthcare.

Keywords: Laboratory Information System, LIS, Patient Safety, Health Informatics, Bioinformatics

1. Introduction

In March 2018, based on aggregated data of approximately 5000 healthcare providers in the US, the Emergency Care Research Institute (ECRI) reported the top 10 patient safety concerns. The first concern of patient safety was diagnostic errors [1]. Underlying causes may include miscommunication, misinterpretation, and missing results [2, 3]. Laboratory managers need to effectively implement methods and tools to reduce diagnostic errors.

On the other hand, laboratory managers are expected to reduce operational cost. The “protecting access to Medicare act (PAMA)” of 2014 mandated cost reduction in healthcare, especially laboratory cost, nursing care and few other special medical services. The act puts constraints on lab managers. In spite of the need to improve quality and safety, laboratories need to reduce human resource cost. One alternative solution is the proper implementation of laboratory information system (LIS) with laboratory automation [4].

Laboratory information system (LIS) is one of the core components of electronic health record (EHR). The main purpose of LIS is to facilitate communication between healthcare providers and laboratories. LIS is proven to provide robust reporting of lab test results that can easily reach to the point of care in accurate and instant fashion. In addition, LIS provides analyses of results with interpretation of trends visually such as graphs showing blood sugar control of patients over several months. LIS also serves as a decision support to providers. On broader scope, LIS data can be aggregated to enlighten providers about issues and threats such as monitoring the numbers of cases of antibiotic resistant
bacteria. With these benefits of LIS, it is generally agreed that LIS is an essential component of EHR [5].

It is not easy to measure the impact of LIS on patient safety. In spite of the potential benefits of LIS, patient safety is a complex concept that is difficult to measure quantitatively. In a systematic review describing the effect of health information technology (IT) on patient outcomes, many issues in research have been raised [6]. A major issue is the lack of unified clear metrics to measure patient safety. And hence, different research studies have analyzed the topic from different angles. Some studies focused on specific IT functions, mostly commonly the “clinical decision support system” (CDSS). Other studies focused on one area of the clinical services, such as outpatients, inpatients, ICU care, etc. Many other papers targeted very specific outcomes, such as anticoagulant therapy, or antibiotic use. On the other side, LIS is variable. Different LIS vendors provide different functions limiting the ability to generalize the results of a given study. This is a challenging reality to any researcher in the field [6].

The aim of this paper is to investigate how patient safety can be improved by laboratory information system.

2. Materials and Methods

A search was conducted using the search engines: PubMed, Google Scholar, and the World Wide Web (reports, blogs, news). The following keywords were searched: laboratory information system, patient safety, and quality. The results were limited to papers published in English. Nineteen relevant articles are read and analyzed.

3. Results

The results are divided under four subtitles. First, a general conceptual framework of implementation of LIS is described. Second, aspects of patient safety and quality improvement are listed. Third, error prevention of LIS is discussed. Lastly, the future laboratory practice is described.

3.1. Conceptual Framework for LIS Implementation to Improve Safety

Patient safety is a major concern of health services, including EHR. LIS is not immune to safety concern. The implementation of LIS does not solve all issues of laboratory tests and reporting. As a matter of fact, LIS may introduce new challenges to providers that have not been existed before. One of the most common issue of LIS (and EHR in general) is the over dependence on the system. This might be a patient safety threat if system downtime occurs. If providers do not have appropriate alternatives methods to handle laboratory work during system downtime, patient safety may suffer [7].

In a review article, Yusof describes a broad framework of dimensions to evaluate LIS. The framework is based on two concepts: brain-to-brain loop process, and HOT-fit dimensions. The brain-to-brain loop process analyzes all steps from requesting a lab test to interpreting results and finally taking decisions for patient management. The process can be divided into 5 phases: 1) pre-test, 2) pre-analytic, 3) analytic, 4) post-analytic and 5) post-test phases. In each phase, LIS provides functions to facilitate performing different tasks. In the HOT-fit model, there are three broad dimensions that need to be analyzed and considered in LIS. These are: 1) Human dimension, 2) Organizational dimension, and 3) Technology dimension. Accordingly, patient safety needs to be considered in all different phases of the brain-to-brain process and the three dimensions of the HOT-fit model [8]. Details of these different aspects within the models are beyond the scope of this paper. It suffices to consider the complexity of LIS implementation and its impact of every aspect within the conceptual model as it applies to patient safety.

Blood transfusion is a typical example of laboratory service. There are different levels of implementing information systems in the service of blood transfusion. These levels range from: automation of work processes in cross-matching of blood, bar-code identification of patients and blood components, and virtual blood bank systems. In addition, computerized provider order entry (CPOE) and clinical decision support system (CDSS) play roles of improving patient safety by providing the most recent information to physicians enabling them to make better decisions in patient care. It has been demonstrated that errors in blood transfusion occur in the clinical side and in the lab. Implementation of information system has positive effect in reducing errors in blood transfusion [9].

3.2. LIS Improves Quality and Safety

There are several aspects of patient safety that can be improved with the appropriate implementation of LIS. As discussed above in the brain-to-brain loop model, these aspects of safety can be pre-analytic, analytic, and post-analytic. Common functions of LIS are shown in (Table 1) with summary of aspects of improvement in safety [10].

| Table 1. Common function of LIS with safety issues and aspects of improvement in regard to patient safety. Adapted from [10]. |
| LIS Function | Safety issue | Improvement |
|---------------|--------------|-------------|
| Data repository | Documentation | Better data integrity, accuracy, completion, consistency, precision, and quality |
| Computerized provider order entry | Inconsistent requisitions | Eliminate illegibility, consistency, providing relevant clinical information |
| Clinical workflow management | Issues in shortage of supplies and test reagents | Efficiency and effectiveness of work |
| Specimen tracking | Delay in test processing | Specimen tracking, improving turn-around time |
| Rule-based verification | Incomplete test results | Eliminate release of incomplete test results |
| Alerts | Common preventable errors | Notify physicians of common issues |
LIS needs to be integrated with the EHR with interfaces allowing accurate reporting of test results with improvement of turn-around time [11]. Integrated LIS with EHR showed threefold improvement of speed of lab test ordering as compared with non-integrated systems [12].

More patients are using patient portals and they access laboratory test results directly. LIS plays a direct role in consumer health informatics. Patients may face issue with interpretation of test results which are often available before they visit their clinicians. A decision support function for patients has been investigated with promising results. There is high acceptance rate of patients with better patient engagement and safety [13]. LIS provides better documentation and allows possible data mining [14].

### 3.3. LIS Reduces Errors

Laboratory automation can reduce errors of pre-analytic, analytic and post-analytic phases. In the pre-analytic phase, LIS can reduce patient misidentification, labeling errors, lost specimens, misplaced and delayed samples. In the post-analytic phase, LIS improves data transcription and results reporting, presentation and communication with providers [15]. Corrections such as amended reports are much more reliable in LIS [16].

Downtime in laboratory information system is a source of threat to patient safety. Alternative solutions during downtime can be phone calls, printed requisitions, and faxed reports. In Columbia University Medical Center, standard operating procedures were created to deal with IT downtime. All tests done during IT downtime had scannable code to save them in the system at later time. The system allowed recording the correct time and date of any tests done during IT downtime. Staff were trained to deal with such an event [17]. Back-up plan during IT downtime is recommended for pathology and cytology reporting [18].

### 3.4. Future Laboratory Medicine and LIS

Few new trends are changing the practice of laboratory medicine. The first is the implementation of sophisticated molecular testing; and the second is the concept of personalized medicine. Both trends are closely related; and are based on testing the “Nano” level characteristics in patients to appropriately adjust the best-fit treatment [19]. In recent years, biological data such as DNA analysis, genomics and proteomics are being incorporated in the analytic phase of laboratory test interpretations. Bioinformatics is a growing area that is expected to have a significant impact on healthcare. LIS may integrate these complex biological data in a relevant and useful format for physicians and patients [20].

Automation, robotics and telepathology are promising technologies that needs robust LIS to be implemented safely [21]. Lastly, the concept of value-based practice needs powerful LIS to integrate benefits and estimate value of laboratory work [22]. In spite of the enthusiasm of the future, safety with LIS comes first!

### 4. Conclusion

Implementation of LIS has certainly a multidimensional impact on patient safety. In one view, LIS plays different roles in three field of health informatics: medical informatics, consumer informatics and translational bioinformatics. LIS can integrate these fields to provide safer healthcare.

LIS is a complex system that can be divided technically to 5 different phases: pre-test, pre-analytic, analytic, post-analytic and post-test phases. In each of these phases, there are different tasks the LIS facilitates and impact quality and safety. Examples of LIS functions that improve safety are many including data repository, clinical workflow management, specimen tracking, rule-based verification, alerts, bar coding, result viewing, result presentation and charting, evidence-based practice, and instrument interfaces. In addition, LIS can reduce diagnostic errors including pre-analytic, analytic and post-analytic ones. With the emerging technology of genomics, and proteomics, LIS can integrate these data in the analytic phase to produce meaningful reports to providers and patients.

This paper highlights the impact of LIS on aspects of patient safety. Some of the aspects have been empirically proven, and others remain theoretical and assumed. This is a limitation of this paper. The conducted search is not comprehensive of all published articles in the field. Part of the limitation is the complexity of the laboratory information system (LIS) with overlapping impact on medical informatics, consumer informatics and translational bioinformatics.

The future of laboratory practice is expected to implement new technologies such as molecular testing, genetics, and proteomics. Laboratory automation, and robotics are already being implemented. The concept of personalized medicine and value-based practice need robust LIS to integrate the huge data generated from these new sources. The future will soon be a reality. However, patient safety with LIS is required.

### Conflict of Interest

The authors declare that they have no competing interests.
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