A Framework for IT Support of Clinical Laboratory Standards

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ABSTRACT

This article presents SmartSOP, a framework for IT support of clinical laboratory standards. Adoption of laboratory standards and good practices is critical for ensuring high-quality health services, but clinical labs are dealing with many challenges in following lab standards. The proposed IT framework facilitates an easy access to standardised procedures, monitoring their execution and recording laboratory test results. The SmartSOP framework has been positively evaluated by clinical practitioners from a hospital in Nigeria. The results of the evaluation indicate that lab scientists are likely to adopt SmartSOP if they are provided with relevant training and equipment.

KEYWORDS

Clinical Laboratory, Knowledge Representation, Mobile Application, Natural Language Processing, Ontology, SmartSOP, Standard Operating Procedures (SOP), Standardisation

INTRODUCTION

Efficient and reliable laboratory services are essential components of well-functioning health systems. High-quality laboratory testing is critical for patient care, prevention, disease surveillance and outbreak investigations (Gershy-Damet et al., 2010). “The modern world is threatened with growing outbreaks of known, emerging, or unknown diseases. Poliomyelitis, meningitis, measles, influenza, Ebola virus disease and, lately, Zika virus disease are some of the diseases that the international community has been dealing with. In our preparedness and response to these threats, the role of public health laboratories is crucial” (WHO, 2017).

Hospitals worldwide are striving to improve the quality of their lab testing process because of its significance in the total quality of care delivered to patients. One of the attempts made by health organizations is to standardize the laboratory practices through the development and implementation of Standard Operating Procedures (SOPs). The need for SOPs arises from challenges currently faced by clinical laboratories. For example, different microbiology laboratories use different databases, tools, algorithms, and interpretive criteria for microbial identification, thereby making data exchange between different systems and laboratories problematic (Public Health England, 2015). Laboratories use these SOPs for “correct test selection, sample collection, and handling, while standardized test terminology and units of traceability to ISO standard 17511 are required to ensure equivalency of measurement results” (Tate, Johnson, Barth, & Panteghini, 2014). However, the availability of guidance documents does not guarantee their use in the laboratories (Francke, Smit, de Veer, & Mistiaen, 2008).
There are many challenges to performing clinical tests. Here, the authors refer to several common laboratory issues pertinent to laboratory standards that can be addressed through the use of better IT support by clinical laboratories:

1. Laboratories often lack well-written SOPs (Fitzgibbon & Wallis, 2014). SOPs are vital to ensure all techniques and processes in the laboratory are standardized, thereby contributing to reproducibility and ensuring quality data.
2. Following laboratory standards requires specialist knowledge. Upgrades of laboratory equipment necessitate changes in existing SOPs. Regular review, training, and competency assessment of staff on the SOPs is a frequent obstacle (Fitzgibbon & Wallis, 2014).
3. Hospital-specific deviations from generic SOPs are not always standardised and well documented.
4. SOPs are inherently ambiguous because they are expressed in natural languages which are not designed for an accurate exchange of information (Soldatova et al., 2014). The representation of SOPs may use non-standardized terminology, which leads to difficulty in the computational comparison of procedures and also in the reproducibility of the results (Brinkman et al., 2010).
5. One of the major problems faced by practitioners is the inconvenience of finding required information quickly in the SOP document. These documents are provided as free text either in PDF or MS Word formats, with pages ranging from 12 to more than 50. The laboratory technicians find navigating through such documents time consuming, and the search interferes with the actual testing process (Maikore, Selenge, Olayinka, Abbott, & Soldatova, 2017).

Unfortunately, few developing countries have established laboratory quality standards that are affordable and easy to implement and monitor. For example, the quality of available clinical laboratory services in the African region remains a serious challenge (Gershy-Damet et al., 2010). In an attempt to provide a better support to clinical laboratories in general, and particularly in Africa, and to improve the quality of laboratory practices, the authors propose a framework for IT support of clinical laboratory standards (see “The SmartSOP Framework” Section). The proposed framework facilitates compliance with existing standards and good laboratory practices by:

- Providing laboratory technicians with an easy and secure access to SOPs during the actual process of testing in a clinical laboratory
- Enabling the recording and monitoring of the completed steps specified in SOPs
- Facilitating the recording and sharing of laboratory test results

The authors demonstrate the utility of the proposed framework through an implemented prototype, named SmartSOP, which is designed to support the work of clinical practitioners. SmartSOP has been positively evaluated by clinical practitioners from a hospital in Nigeria (see the Evaluation section).

The main contributions the authors present in this paper are:

1. A cost-efficient SmartSOP framework for IT support of clinical laboratories, and its implementation as a prototype (see Figure 1).
2. The seamless integration of the three components (the ontology OCL-SOP, the translator, and the mobile application) into one system.
3. The significantly enhanced functionality of the mobile application, e.g. providing access to video tutorials and databases.
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