

Eliciting requirements for a tablet-based data entry and reporting system for use in clinical microbiology laboratories to facilitate blood culture analysis: a case study

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Abstract

Sepsis is a large health care burden on a global scale with 1.8 million documented cases yearly. Furthermore, sepsis is associated with a high mortality rate. However, an early initiation of the correct antimicrobial treatment improves the survival rate.

A new molecular based diagnostic test named MultiplexBCT is currently under development. Furthermore, a tablet-based data entry and reporting system is being developed to facilitate the workflow of the MultiplexBCT test.

This study identified system requirements for the tablet-based data entry and reporting system through an observational study conducted at two clinical microbiology laboratories in the US. Three system requirements were elicited; communication of data with the laboratory information system, communication of test results to the treating staff, and the support of barcodes.

The three system requirements form the foundation for further development of the tablet-based data entry and reporting system.

Keywords:

Medical Informatics, Sepsis, Handheld Computer.

Introduction

In many patients, bloodstream infection is commonly associated with sepsis. Sepsis is a large health care burden on a global scale, and is associated with a high mortality for patients that are severely affected [1]. A yearly incidence of 1.8 million cases of sepsis has been documented. However sepsis is difficult to diagnose, and it has been estimated that the actual incidence rate is at 18 million cases yearly, which makes sepsis a leading cause of death [2]. Furthermore, the incidence of sepsis is increasing [1]. Depending on the state of disease, sepsis is classified into three categories: sepsis, severe sepsis (sepsis leading to organ dysfunction), and septic shock (severe sepsis, and hypotension despite attempted fluid resuscitation) [3].

A study estimated that for the US in 1995 there were 751,000 cases of severe sepsis, causing 215,000 deaths, corresponding to a mortality of about 30% [4]. Further, this study estimated that the average cost for treatment was \$22,100 for each severe sepsis case, leading to an annual expense of \$16.7 billion in the US. This implies that sepsis is a large economic burden on a global scale.

International guidelines recommend that a treatment based on broad-spectrum antibiotics be initiated within 1 hour after a patient is diagnosed with severe sepsis or septic shock [3]. A study has shown that for patients in septic shock each hour of Scandinavian Conference on Health Informatics 2013, Copenhagen, Denmark, August 20, 2013

delay in initiation of an effective antimicrobial treatment leads to an increased risk of mortality [5]. Furthermore, another study analyzed the treatment of patients with septic shock and found that about 20% of the patients initially received an inappropriate antimicrobial therapy [6]. In these patients, the survival rate was 10.3% compared to 52% in patients who initially received an appropriate antimicrobial therapy [6]. Similar considerations apply to patients with bloodstream infections generally.

For identifying the microorganism causing bloodstream infection, and thereby guiding the antimicrobial treatment, the use of blood cultures is considered the gold standard [7,8]. A limitation of blood cultures is that they are dependent on the bacterial growth rate. Blood cultures will typically be ready for analysis after a period of 6 to 48 hours [9]. Using conventional, culture-based methods, a period of 24 to 72 hours is required before the causative microorganism can be identified and its antimicrobial susceptibility can be tested [8]. As these results become available, they can be used for interim and final adjustment of the antibacterial treatment.

New diagnostic tools based on molecular techniques allow for a faster identification of the microorganisms causing bloodstream infections in comparison to the conventional use of blood cultures [7,8,9]. These molecular tests have the potential to improve the treatment of patients with bloodstream infection-associated sepsis by allowing a faster initiation of an effective antimicrobial therapy. The new diagnostic tools are limited in some aspects, as they are labor intensive, and can only be used to identify a limited range of bacteria [9]. Their use is therefore limited at the present time.

Fluorescence in situ hybridization (FISH) is a molecular technique that is used for identification of bacteria from blood cultures with bacterial and fungal growth. Compared to conventional blood culture analysis methods FISH based molecular tests allow for a faster identification of microorganisms [7].

Tests that allow for rapid detection of the causative microorganism from positive blood cultures, and thereby allow for a shorter time to notification, is an aspect that can shorten the length of hospital stay for patients with bloodstream infections [10]. However, other aspects such as blood culture transportation time, prioritization of doing the identification tests once a blood culture is positive with bacterial growth, and time for communicating a result to the treating physicians all play an important role in the time to notification [10]. Promptly communicating results from a FISH based test to clinicians has previously shown that it can lead to a reduction in mortality for patients with bloodstream infections [11].

A new FISH based test named MultiplexBCT (MBCT) is being developed, which aims to identify the most prevalent blood culture pathogens. While this test will still be dependent on the bacterial growth of blood cultures, it will be faster than conventional diagnostic methods, and this has the potential to enable a quicker adjustment of antimicrobial treatments.

A tablet-based data entry and reporting system will be developed to facilitate the clinical workflow of the MBCT test. The aim of the tablet-based system is to allow a rapid access for clinicians to the results of the MBCT test, and thereby allowing for a quicker adjustment of antimicrobial therapy if necessary. The focus of this paper will be on the tablet-based data entry and reporting system.

Mobility is an important aspect of clinical work in both wards and laboratories. The use of mobile technologies such as personal digital assistants has demonstrated that it can support the needs of mobility in health care work. Furthermore, such systems have been shown to bring benefits, where time is a crucial factor [12]. Therefore, we develop a tablet-based system.

It has been well documented, that the implementation of new IT systems can lead to large changes in workflow, which can be disruptive and lead to a decrease in efficiency [13]. For a successful implementation of IT systems in the health care sector, it is important to understand that new information systems often bring organizational changes [14]. As the tablet-based data entry and reporting system is not designed explicitly for one clinical microbiology laboratory, it must be flexible enough to meet the end users' different needs without restricting their workflow in a disruptive manner.

The objective of this study is to elicit system requirements for the tablet-based data entry and reporting system, which will ensure that the system supports the workflow of a blood culture analysis process in a clinical microbiology laboratory.

Materials and Methods

Data collection

All data was collected at two US clinical microbiology laboratories through an observational study. One of the microbiology laboratories processes approximately 90,000 blood cultures yearly and services four different hospitals. The other microbiology laboratory processes approximately 20,000 blood cultures yearly and services a single hospital.

Observational study

The goal of the observational study was to gain an understanding of the clinical workflow of blood culture analysis at US clinical microbiology laboratories.

At each laboratory, an experienced medical laboratory scientist (MLS) was observed, while conducting daily routines involved in blood culture analysis.

Before the observations began, the MLS was given a brief introduction to the purpose of the study, and how the observations would be carried out. Furthermore, the authors were given a tour of the laboratory so they were familiar with the physical location before the observations began.

The observation of the two MLS lasted for about 2 hours and 40 minutes, and 1 hour and 40 minutes respectively. Both observations took place in the morning, and started when the MLS began their work. The first two authors took part in the observational study and the data collection process.

An additional period of about 50 minutes at each clinical microbiology laboratory was used for semi-structured interviews, which aimed to clarify observed events, by

building an understanding of the complete diagnostic circle. The questions were structured into the following sections: blood culture sample collection, blood culture analysis, and communication of blood culture analysis results.

During the observations, the activities of the subjects were recorded. This included a note of the physical location where the activity took place, and a timestamp for each activity. After the observations had been conducted, the field notes were reviewed and digitalized.

For organizing the observations a semi-structured observation guide was used, which focused the observations into two main categories:

1. Analysis of blood cultures.
2. Communication of results.

By using a semi-structured observation guide, the observations focused on important events in regards to the process of blood culture analysis, while still allowing other relevant events to be observed.

Informal interviews took place during the observations between the observers and the MLS. The informal interviews were used to clarify some of the observed events.

The observed data was coded by themes as part of the analysis process through meaning condensation [15]. The themes were structured around the analysis of blood cultures and the communication of results, which was also the focus for the semi-structured observation guide. The data was managed by hand.

Results

The observational study clarified how the results of blood culture analysis were communicated from the microbiology laboratory to the treating staff. Furthermore, the use of IT systems to support the blood culture analysis workflow and communication of results was explored.

Blood culture analysis workflow

Through the observational study, a generalization of the workflow for a MLS for the process of blood culture analysis was modeled, which is shown in Figure 1.

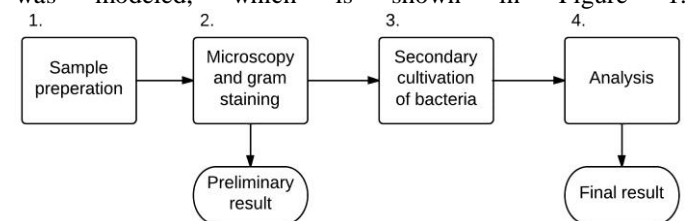


Figure 1 - Generalized model of the workflow, and the results produced during the blood culture analysis process.

The initial step of the blood culture analysis process was the preparation of microscopic slides with a sample from a blood culture bottle with bacterial growth.

In the second step of the workflow, the MLS conducted gram staining and microscopy of the positive blood culture sample, which produced a preliminary result. The preliminary result was initially entered into the laboratory information system (LIS), and in some cases, the result was also written onto a paper document. Thereafter, the MLS retrieved contact information for those who had to be informed of the preliminary result. The contact information was retrieved through other IT systems. The MLS would then call the treating staff and communicate the result. The treating staff was either a physician or nurse from the department that had requested the blood culture analysis. At one microbiology

laboratory, the results were also communicated to a Pharm. D. if the patient was on a pharmacy department watch list. At the other microbiology laboratory, the results were communicated to a Pharm. D. if the results identified certain types of bacteria. The MLS then documented the call in the LIS. The process of communicating results from the clinical microbiology laboratory to the treating staff is shown in Figure 2.

In the third step of the blood culture analysis process, the MLS did a secondary cultivation of bacteria, which was then incubated.

The last step of the workflow is the analysis of blood culture plates, where the cultivated bacteria are examined. By analyzing the blood culture plate results, and comparing with the results from microscopy and gram staining, the causative microorganism is identified. The blood plate analysis could be an iterative process, where more plates would have to be produced and additional tests carried out, before the microorganism was determined. This produced the final result of the blood culture analysis process.

When the MLS began the examination of blood culture plates the barcode was scanned, which loaded the patients information in the LIS. The MLS used an overview of the patient's previous microbiology results, as an important element in determining the results of the blood culture plate being examined. The result from analyzing a blood culture plate was documented in the LIS. Furthermore, when a final result was produced by identifying the causative microorganism the result was documented both in the LIS and on a paper document. In one case, a final result was communicated to the treating staff as described for the preliminary result, which is shown in Figure 2.

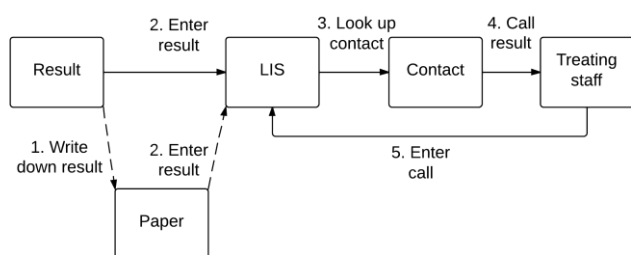


Figure 2 - Model representing the documentation and communication of results obtained during the blood culture analysis process. The numbering indicates the order of events. The dashed line indicates an optional event.

Analysis of workflow

Throughout the blood culture analysis process the use of various IT functions were an important part of the workflow. The IT systems were used for documentation of results, and to retrieve information about previous results, and to obtain information about whom the blood culture results should be communicated to. These functionalities can be used as a basis for system requirements, when designing a new system for data entry and communication of results for a clinical microbiology laboratory.

The LIS was accessed throughout the blood culture analysis process to provide an overview of information about the patient's previous microbiology results, and to document all new microbiology tests that were conducted throughout the process. It was observed that both preliminary and final results were documented in the LIS, but also on a paper document.

Information about whom results must be communicated to was available through the LIS, however for obtaining direct contact information another IT system had to be used.

Paper was used to make temporary notes four times during the observations: to note down a result that was produced without a computer nearby, to make a note that a patient's result should not be communicated to a Pharm. D., to make a note of who accepted a result through a phone call, and to make a note of a patient's data in the LIS.

The use of barcodes was an integral part of the workflow, as barcodes representing the patient's ID were placed on both blood culture bottles, and on blood culture plates. This meant that barcodes were scanned as a means of data entry whenever a patient's data was accessed through the LIS.

In summary, the following system requirements for the tablet-based data entry and reporting system can be defined, if the system is to support the existing use of IT functionalities:

- Communication of data with the LIS. This includes sending blood culture analysis results to the LIS, and receiving microbiology results obtained through the LIS, which can then be displayed to the user.
- Communication of results to the treating staff, which requested the blood culture analysis. Furthermore, the ability to communicate results to other staff depending on the laboratories blood culture analysis routines, e.g. a Pharm. D.
- Support the use of barcodes to enter information into the system, e.g., the patient ID.

Discussion

The results of this study are based on data collected through a single observational study at two different clinical microbiology laboratories in the US. This is a limitation, which must be considered when analyzing the results. However, it can be expected that the overall workflow for conducting blood culture analysis is similar for most clinical microbiology laboratories. For clinical microbiology laboratories that handle larger or smaller numbers of blood cultures, or are organized differently, the communication of blood culture analysis results may be different. The observational study can be conducted at other clinical microbiology departments until data saturation is achieved. This would allow the results to be considered widely generalizable.

Through the conducted observational study at two different clinical microbiology laboratories, a total of three system requirements were identified. These requirements are vital to fulfill if the tablet-based data entry and reporting system is to be successful in supporting the clinical workflow for the blood culture analysis process.

The tablet-based data entry and reporting system must be able to both send and receive blood culture results to the LIS in order to support the user's needs of submitting and retrieving test results. The ability to look at a patient's microbiology test history is an important aspect in the blood culture analysis process.

Double documentation of results occurred commonly during the blood culture analysis process. Both preliminary and final results were documented on paper and in the LIS. Furthermore, in one case a microscopy result was temporarily written on paper before being entered into the LIS. This is due to the nature of a microbiology laboratory, where not all test equipment is near a PC. Double documentation of results brings a risk of error, when the results from a paper document must be entered into a PC. By using a tablet-based system for data entry, and thereby taking advantage of the mobility it

offers, it is expected that double documentation can be reduced or possibly eliminated [16].

Barcodes were frequently used to enter a patient ID into an IT system throughout the blood culture analysis process. Barcode reading can be supported by utilizing the tablets built-in camera. However, the efficiency of tablet-based camera barcode scanning should be tested in clinical settings, as parameters such as lighting and barcode size may affect the scanning performance. Alternatively, an external barcode reader could be used, which connects to the tablet through Bluetooth or similar technology.

The tablet-based data entry and reporting system must be flexible enough to support changes in the clinical workflow, as exceptions to workflows often happen in the health care sector [17].

By letting the tablet-based data entry and reporting system communicate results directly to the treating staff, the notification time for blood culture results can be reduced. Additionally, the MBCT test will allow blood culture results to be available more quickly than conventional test methods, which in combination will lead to a reduced time to notification. This will pave the way for the antimicrobial treatment be optimized earlier, which can lead to an improved survival rate for sepsis patients [10,11].

Conclusion

The study identified three system requirements for a tablet-based data entry and reporting system, which must be fulfilled for a successful implementation of the system. The system requirements were identified through an observational study conducted at two clinical microbiology laboratories in the US. The generalizability of the results should be further explored. By implementing the system requirements, and letting the MBCT results be send directly to the treating staff through the tablet-based data entry and reporting system, the time for notification can likely be decreased. This can lead to faster optimization of the antimicrobial treatment, which in turn is likely to result in a higher survival rate for the sepsis patients. The system requirements presented in this study will build a foundation for further development of the tablet-based data entry and reporting system.

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