### Implementation of a Clinical Decision Support System using a Service Model: Results of a Feasibility Study

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#### Abstract

Numerous studies have shown that the quality of health care is inadequate, and healthcare organizations are increasingly turning to clinical decision support systems (CDSS) to address this problem. In implementing CDSS, a highly promising architectural approach is the use of decision support services. However, there are few reported examples of successful implementations of operational CDSS using this approach. Here, we describe how Hospital Italiano de Buenos Aires evaluated the feasibility of using the SEBASTIAN clinical decision support Web service to implement a CDSS integrated with its electronic medical record system. The feasibility study consisted of three stages: first, end-user acceptability testing of the proposed CDSS through focus groups; second, the design and implementation of the system through integration of SEBASTIAN and the authoring of new rules; and finally, validation of system performance and accuracy. Through this study, we found that it is feasible to implement CDSS using a service-based approach. The CDSS is now under evaluation in a randomized controlled trial. The processes and lessons learned from this initiative are discussed.

#### Keywords:

Health information system, Clinical Decision Support System (CDSS), Reminder systems, Computerized medical records systems

#### Introduction

A significant gap exists between actual clinical practice and optimal patient care. Numerous studies have shown that the quality of health care is variable and often inadequate [1, 2]. To address these deficiencies in care, healthcare organizations are increasingly turning to clinical decision support systems (CDSS) that provide clinicians with patient-specific assessments for recommendations to aid clinical decision making [3, 4]

Wright and Sittig describe four distinct architectural phases for decision support: [5]

1. Standalone decision support systems.

- 2. Integrated systems.
- 3. Standards-based systems.
- 4. Service models.

SEBASTIAN is an example of a clinical decision support technology that supports the latest, service-based architectural approach to CDSS implementation[6]. Developed at Duke University, SEBASTIAN is a clinical decision support Web service whose interface is now the basis of the HL7 Decision Support Service draft standard.[7] SEBASTIAN places a standardized interface in front of clinical decision support knowledge modules and makes only limited demands on how relevant patient data are collected or on how decision support inferences are communicated to end-users. Despite this promising, potentially highly scalable approach to decision support, very little has been published related to experiences using this approach to implementing CDSS.[6, 8]

The Hospital Italiano de Buenos Aires (HIBA) is a non-profit academic medical center founded in 1853, with over 1,500 physicians and 3,500 employees. HIBA has a network of two hospitals with 750 beds (200 for intensive care), 500 home care patients under care, and 23 clinics. It has an insurance plan that covers approximately 150,000 people and also coordinates insurance for another 1,500,000 people who are covered by affiliated insurers. Each year over 38,000 inpatients (pediatric and adult) are admitted to its hospitals that are located in Buenos Aires and its suburbs. HIBA has more than 2,200,000 outpatient visits annually from patients from across Argentina and Latin America.

In 1998, HIBA began to implement a Healthcare Information System (HIS) by integrating clinical information with the administrative applications that were already in use. HIS was completely developed in-house and currently collects and leverages the clinical and administration information related to health care for HIBA. Within HIS, the Electronic Health Record (EHR) is a fully-implemented Web-based, problemoriented, patient-centred record with customized functionalities depending on the level of care (outpatient, inpatient, emergency care and home care) [9] This EHR system includes a computerized provider order entry (CPOE) system, available throughout the HIBA network. In the ambulatory setting, CDSS was previously used only for prescriptions, but not for preventive care.

The HIBA information infrastructure includes a terminology server that allows the mapping of local vocabularies to SNOMED CT. This terminology server allows for the structured capture of approximately 80% of diagnoses [10, 11].

Within this existing health information infrastructure, the aim of this study was to evaluate the feasibility of implementing a CDSS for preventive care using a service model. Given our institution's collaborative ties with relevant investigators at Duke University, we chose the SEBASTIAN decision support Web service to conduct this evaluation.

#### **Materials and Methods**

**Design:** A feasibility study was performed to assess the necessary changes in processes and systems for the implementation of a services-based approach to CDSS.

For this test, the study was divided into three phases:

#### 1. System usability evaluation through focus groups

In order to determine the preferences of physicians on how to interact with the CDSS, we conducted focus groups to evaluate the acceptance of different reminders by primary care physicians (PCPs).

Two focus groups were conducted. In each focus group, there were two internists, two family medicine practitioners, and two pediatricians. The group was led by a moderator and a qualitative evaluation expert. Each meeting was recorded and analyzed by the statistical and epidemiology group of HIBA.

### 2. Integration of SEBASTIAN with Hospital Italiano Health Information System

SEBASTIAN is an acronym for System for Evidence-Based Advice through Simultaneous Transaction with an Intelligent Agent across a Network[6]. It interacts synchronously with client software applications to deliver decision support over the Internet. The framework is implemented as a Java servlet and is hosted by the Apache Tomcat servlet container.

SEBASTIAN uses a patient information model based on the Health Level 7 (HL7) Reference Information Model (RIM), the same reference model used in the HIBA system. Concepts are identified using standard vocabularies like SNOMED-CT, the same reference vocabulary used in HIBA. Patients are modeled as entities described by demographic and "act" data, where an act refers to any act or service constituting health care services, such as an encounter, diagnosis, or procedure.

Medical knowledge in SEBASTIAN is captured in XML documents known as Executable Knowledge Modules (EKMs). Each module specifies the data requirements for assessing a patient, the patient specific conclusions that will be returned by the module, and the logic that will be utilized to generate the conclusions using the specified patient data. EKM results are the primary objects returned to client systems following the evaluation of a patient.

Because SEBASTIAN operates as a Web service, all services can be accessed by sending XML requests over HTTP. The core service offered is a patient evaluation service, in which patient data elements are received as the input and machineinterpretable decision support results are returned as the output.

In this phase of the study, the HIBA team and the Duke team held teleconferences to identify how SEBASTIAN could be used within the HIBA system, and the HIBA team implemented the required system modification work. The initial focus of this study was on the appropriate management of breast cancer screening and prevention.

#### 3. Validation study to evaluate system sensitivity and specificity

After completing the integration of SEBASTIAN with the HI-BA system, a study was conducted to validate the operation of the system [12].

The objective of this study was to measure the sensitivity and specificity of SEBASTIAN rules in the detection of mammogram completion, mammogram results (in terms of BIRADS values), patient risk factors, and exclusion criteria. This evaluation also assessed the accuracy of the generated recommendations. The gold standard was the manual review of the medical records. The population reviewed was female members of HI-BA's health maintenance organization who were enrolled for at least two years in the health system and were between 49 and 60 years of age. Manual review was done on 210 cases randomly selected from this population.

#### Results

Figure 1 outlines the timeline in which the three phases of the study were completed.



Figure 1- Study phases and completion dates

#### Usability

The results of the physician focus groups helped to inform the design of the CDSS user interface. Physicians preferred to view the reminders in the following way:

- Reminders displayed in a dedicated frame
- Accessed through main screen or from screen on problems
- No visually intrusive message (i.e., no pop-ups)
- Agile accessibility and handling



Figure 2 – Sample CDSS Screenshot. Availability of an active reminder for preventive services (breast cancer screening) is indicated by the red "PP" flag in the Important Information section. If the Physician clicks on any red marked section, a recommendation (i.e. order a mammogram) will be shown. If the physician agrees with the recommendation he would order it. In case of non-acceptance the reason should be explained.

- Possibility of personalizing the list of reminders displayed
- Possibility of printing reports as handouts for patients
- Ability to generate a list of patients with pending preventive care needs
- Possibility to graph data trends (for the patient)
- Prioritize patients with unmet care needs for clinic appointments

A screenshot illustrating the availability of one reminder is shown in Figure 2.

## Integration of SEBASTIAN with Hospital Italiano Health Information System

To use SEBASTIAN, the developer at HIBA first identified the set of knowledge modules that would best meet application needs. These knowledge modules are captured in XML documents, and they consist of maintenance, library, knowledge, and logic sections [6]. Most module sections are edited using a functionally rich Microsoft InfoPath<sup>™</sup> form. This authoring environment was used at HIBA to create and modify rules to enable results-based breast cancer screening.

In addition to developing the SEBASTIAN rules, the HIBA EHR system was configured to send SEBASTIAN the required patient information when an appropriate patient was potentially in need of a breast cancer screening reminder. To enable this data submission, it was necessary to develop a router that understood the demands of the SEBASTIAN rules and collected the required patient data. Also, the EHR system was adapted to parse the patient-specific care recommendations returned by SEBASTIAN for appropriate display in the EHR system. The information flow among the different system components is summarized in Figure 3.



Figure 3 - CDSS System Architecture

#### Validation study

After implementing the CDSS based on physician feedback, a validation study was conducted to assess the performance characteristics of SEBASTIAN rules. With respect to the detection of an existing mammography report, sensitivity was 94% with a specificity of 91%. For the recommendations generated by the rule for breast caner screening, sensitivity was 97% while the specificity was 72%. For detection of a correct mammography BIRADS score, the sensitivity was 69% and specificity was 70%. Finally, for appropriate detection of exclusion criteria, sensitivity was 100% and specificity was 98%.

The HIBA clinical oversight team considered these values of sensitivity and specificity more than acceptable for production level use of the CDSS. Moreover, in order to further improve CDSS performance, we addressed underlying problems that we identified the testing by incorporating new terminology, implementing new systems for diagnosis and procedure coding, and training pathologists and radiologists to ensure more accurate recoding of the data in the pathology and radiology reports, respectively, that were used by the CDSS.

#### Discussion

In this paper, we have described the implementation of a Web services approach to clinical decision support that provides effective mechanisms for the transformation of medical knowledge into a machine-interpretable form, and for making that knowledge easily accessible and usable for an external EHR system.

Before the implementation of new technology, it is mandatory to assess with focus groups or other qualitative methods the user's opinion to allow the acceptability and adherence to the use of the this new technology.

One of the strengths of this study is that it demonstrates that it is possible to use the same services-based clinical decision support engine across multiple applications and institutions. Specifically, the SEBASTIAN Web service approach has now been successfully implemented within an academic medical center in the United States[8] and a private teaching hospital in Argentina. Additionally, this study represents only the second published report of an operational implementation of decision support using a system that is the basis for the HL7 Decision Support Service draft standard. Through the implementation described in this paper, we have demonstrated that this system can not only be ported across institutions, but also across international boundaries as well. To accomplish this portability, however, it is essential to have common information models and data standards to exchange and understand the information contained in clinical data repositories.

This report is also significant in that it has shown the ability to use decision support to augment breast cancer screening that traditionally relies only on age and gender, to now also incorporate relevant previous pathologic and radiological findings into breast cancer screening recommendations. The incorporation of these additional data may improve the effectiveness of screening to detect breast cancer. We are currently conducting a randomized clinical trial (RCT) to evaluate the effectiveness of this data-augmented CDSS breast cancer screening resource.

#### Conclusion

In this study, we have demonstrated that it is feasible to take a services-based approach to clinical decision support and to implement it across institutional and national boundaries. Coupled with usability and system performance testing, we conclude that a clinical decision support service can enable the implementation of CDSS that is accurate and appropriately integrated with existing EHR systems and clinical workflows.

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