

# Supporting Registration and Treatment of Clubfoot using Mobile Devices

Wei qin Chen and Dag Skjelvik

Department of Information Science and Media Studies, University of Bergen  
POB 7802, N-5020 Bergen, Norway

**Abstract.** In current congenital clubfoot treatment, clinicians use paper forms to register and monitor the treatment process. Routines for registration and archiving are scarce, and the guideline for treating clubfoot is not always followed strictly. This paper presents a PDA-based system (GenSupport) that can support the registration of patient information, supervise the treatment process, as well as provide advice during treatment. GenSupport has been evaluated in order to investigate the perceived usefulness of such a system. The evaluation results indicate that GenSupport has the possibility of improving the routines for registration and archiving of patient information as well as supporting the treatment of clubfoot. The advice provided by GenSupport was perceived particularly useful for inexperienced clinicians.

## 1 Introduction

Clinicians suffer almost universally from the problem of poor data quality, difficulty of access and bad communication. In addition, some individuals need support in decision-making. Therefore well-designed patient oriented information systems which improve the routines of registration and archiving of patient data and decision support systems which monitor and support treatments are desperately needed throughout the Health Service. In recent years, with the development of Internet and mobile technologies, research in healthcare has been shifted towards mobile Electronic health record and clinical decision support systems.

Clubfoot (Talipes equinovarus) is a congenital condition where the foot is deformed and turns inward and downward. It is the most common birth defect, and in most cases it is treated using mainly non-surgically methods. The Ponseti-Pirani method is now considered to be the worldwide standard of treating clubfoot [1]. In this method the Pirani score is for classifying the severity of the clubfoot and the Ponseti method for correction.

Pirani scoring is a standardized way of classifying a clubfoot. The score is built up of six clinical signs, where each sign is assigned a value as following: 0 - normal, 0.5 - moderately abnormal, 1 - severely abnormal. The final score is the sum of these values, ranging from 0 for a normal foot to 6 for a severe clubfoot.

With the use of regular cast, the Ponseti method corrects the clubfoot by weekly corrections supported by the cast. This treatment is guided by the results of Pirani-scoring of the clubfoot. After 5-8 weeks the foot is manipulated into the correct posi-

tion. In most cases the achilles tendon has to be cut in order to prolong it, this process is called tenotomy and is usually done before the last application of cast. The final part of the treatment is to use an orthosis (brace) at night until the foot stabilizes and is fully corrected. If the child is older than two years and surgery can be performed at the treating hospital, a small procedure called anterior tibialis transfer (ATT) is performed. After this procedure is performed, the child should not start using the brace.

The treatment of clubfoot using the Ponseti method is as of today not computer supported. The clinicians use paper forms to monitor the treatment. After the foot is scored, the results are plotted with a pen into a graph on paper. Classification results vary depending on the clinician performing it. Information registered about the patient is usually unstructured and archived in an ad-hoc manner and sometimes not archived at all. Thus, there are few possibilities to perform statistical analysis. The treatment process is in some cases ineffective because the Ponseti guideline is not followed strictly. Mistakes made by clinicians during treatment are often discovered too late and this can either corrupt or prolong the treatment process.

According to Osheroff et al.[2], the best opportunity for a computer-based system to deliver interventions is usually when the pertinent persons can be reached with the intervention and are prepared to act upon the information immediately. Handheld computers are the most versatile in stressful clinical environments, especially in those that are lack of infrastructure. Therefore we believe that a PDA-based system could improve the treatment by controlling registration of patient information, supervising the treatment process as well as providing advice during treatment. In this paper we present the design and evaluation of such a system (GenSupport).

## 2 Methodology and Related Research

The project described in this paper follows a design research methodology. Design research involves the analysis of the use and performance of designed artefacts to understand, to explain and frequently to improve upon the behaviour of aspects of information systems [3]. Design science research seeks to create innovations “through which the analysis, design, implementation, management and use of information systems can be effectively and efficiently accomplished” [3]. A general design science methodology includes cycles of identification of need, development and evaluation. In addition, a final conclusion phase can be added [4]. In this project, iterations of requirement analysis, development and evaluations have been conducted.

### 2.1 Clinical Decision Support Systems

Clinical decision support systems (CDSS) are computer systems designed to impact clinician decision making about individual patients at the point in time that these decisions are made [5]. The intention of a CDSS is to provide information to the clinicians in the decision making process rather than to provide correct “answers” and diagnoses to clinicians and consider the clinicians as passive users of the system.

Over the years research has been conducted in this area and many CDSS have been developed and some have been integrated in clinical practice. For example, Dugas et

al. [6] constructed a CDSS for hepatic surgery. The system provides decision support for the surgeon and the patient during risk assessment prior to critical surgery. Case-based reasoning was adopted to provide guidance in the risk assessment process. Dugas et al. also discussed success factors for a CDSS. The tool must be fast and easy to use, and the system must provide a comprehensible benefit for the user. The clinician's work flow must be integrated in the system, and the knowledge base should provide the clinician with the opportunity to view full patient data [6]. Similar to GenSupport, the Standards-based Shareable Active Guideline Environment (SAGE) computerizes clinical guidelines and providing decision support. A benefit of SAGE is that clinical guidelines can be encoded using standard terminologies and standards-based patient information models [7], amongst these HL7 and Snomed CT.

LogReg is a decision-support shell which runs on handheld computers [8]. This system utilizes decision models encoded in XML to provide decision support. Availability on the location at which the decisions are made is considered as the reason for choosing a mobile platform for the system. As in GenSupport, the system is entirely configured with the XML file and the configuration process does not involve programming or re-compilation of the system. Several XML files can be loaded in the system at the same time, available to the user. LogReg is intended for single encounters only, and does not provide decision support for treatments with multiple encounters.

The GenSupport system can be considered as a CDSS for clubfoot treatment. In addition, the system provides patient and treatment registration support in order to improve the routines for registration and archiving of patient information.

## 2.2 Mobile Healthcare Systems

Mobile devices are increasingly popular in the medical domain [9]. By 2013, it is expected that hospitals will use more mobile than stationary computers [10]. Mobile technologies can improve responsiveness in healthcare and increase productivity [11]. Size and mobility are key benefits of mobile devices. The portability of the mobile devices enables clinicians to access and register patient information wherever they prefer [9].

However, there are a few challenges in designing mobile healthcare systems. A small low-resolution screen and limited computational abilities makes it challenging to implement user-friendly and complex applications [11]. Slow entry of data is another problem with mobile devices [12]. Data entry is usually done with a pen directly on the device's screen by plotting letters on a keyboard displayed on the screen. Most mobile devices do not support efficient and effective handwriting recognition. Patient information and medical knowledge must be available at the mobile devices, thus data exchange is an important aspect of mobile healthcare. XML is a format suitable for data exchange across devices, platforms and organizational units, as long as they agree on the content of the data exchanged [11].

The PDA-based GenSupport system follows the principles of user-friendly mobile interface design. XML is used for describing the knowledge and information needed for clubfoot treatment.

### 3 The Design and Development of GenSupport

The design and development of GenSupport follows a user-centred approach [13]. The domain expert has been closely involved in the process. The project was carried out in an iterative and incremental manner and emphasized the communication among different stakeholders.

#### 3.1 Requirements

The requirements were gathered through meetings and low-fidelity mock-ups. The system should be able to:

- Allow clinicians to register core patient information,
- Allow clinicians to register attributes of the clubfoot,
- Provide treatment recommendations based on clubfoot treatment guideline and information registered by the clinicians using it,
- Run on a handheld device (e.g. PDA with Windows mobile OS).

#### 3.2 Patient Information

Core patient information is registered and stored in the system; this contains general information about the patient and clubfoot treatment guideline specific information. The clinician can register new patients and edit existing ones as well as search for registered patients and encounters. The general patient information is standardized information which is adapted from the data model of OpenMRS (<http://www.openmrs.org>) and includes Name of the patient, Residence / Address, Next of kin, Health center, and ID numbers. The clubfoot specific information includes history of encounters (dates, scores, actions).

#### 3.3 Domain Knowledge (Clubfoot Treatment Guideline)

The domain knowledge acquisition process was carried out in several iterations. First, the domain expert provided a diagram describing how clubfoot is treated. This diagram described the entire process of clubfoot treatment, in addition to all the phases of the treatment.

The diagram was later converted to a workflow of clubfoot treatment. This workflow shows all steps possible for the clinician to go through at each encounter. Preconditions determine when it is appropriate to include a step in the workflow. For example, the step “Pirani score right foot” would not be included in the workflow for a patient when only the left foot is affected.

The rules for providing treatment recommendations were extracted and represented in a decision tree (Fig. 1). The decision tree is composed of two kinds of nodes; internal nodes and leaf nodes. Internal nodes have a list of child nodes, while the leaf nodes have a list of statements. Each recommendation is a suggestion from GenSupport to the clinician to perform a certain action such as “Cast right foot for three

weeks” or “Perform tenotomy on left foot” In addition to suggesting which actions to perform, GenSupport can also provide warning (e.g. “Warning! Check treatment of right foot”) and error messages (e.g. “ERROR! Check treatment of left foot”). A warning message is given when something could be wrong, i.e. when there are reasons for suspecting that the treatment is not progressing as normal and special measures must be taken to prevent the treatment going wrong. When something indicates that the treatment most likely has gone wrong, an error message is provided to the user.

The workflow and decision tree were used further in the knowledge engineering process as a communicating artefact to communicate with the domain expert.

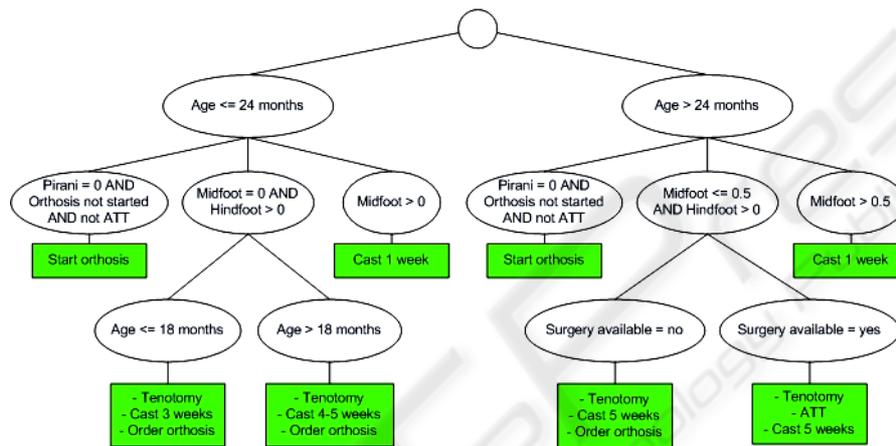


Fig. 1. Decision tree for clubfoot treatment.

### 3.4 Rule Engine

A specific rule engine (Eval3RulesEngine) was implemented for PDAs. This rule engine is based on an external library Eval3 which parses expressions represented by strings, and returns the truth value of the expression. When the Eval3RulesEngine runs, it parses the decision tree depth-first and evaluates the conditions of the rule at each node. Internal nodes evaluated as true will be expanded, whilst the tree will be cut at those internal nodes having a condition evaluated as false. When a leaf node is evaluated as true, its statement will be placed on the agenda of the Eval3RulesEngine. The agenda is a list of the statements contained in the leaf nodes evaluated as true. This list is available after the execution is finished. The rules engine parses the full decision tree, not stopping at the first leaf node evaluated as true.

### 3.5 Recommendations

When the clinician is provided with the recommendations for treatment, s/he can choose to reject the recommendations, plan actions according to the recommendations or add actions manually (Fig. 2).



Fig. 2. Recommendations.

According to Osheroff et al. [2] there are standard reasons for rejecting treatment recommendations: MD disagrees with recommendation, recommendation already implemented, alert fired inappropriately, patient ineligible for recommended intervention, patient refuses recommended intervention, and others. These standard reasons are implemented in GenSupport. The clinician should also provide a comment explaining why the overriding was done.

It is not always possible or feasible to perform the recommended action instantly. This calls for the need to be able to plan the actions. In GenSupport it is possible for the clinician to postpone an action, and plan for when to perform it. A date must be specified, and the clinician should state a comment about why the action is postponed.

The clinicians are able to manually invoke an action if they believe that a certain action is correct to perform under the given conditions even though GenSupport has not suggested it. They can choose amongst the actions which are specified in the current guideline. When choosing an action manually, they should specify the reason for the choice.

## 4 Evaluation

The evaluation of GenSupport focuses on whether it is able to support the clubfoot treatment. First, a quantitative evaluation is conducted to test the quality of the recommendations given by the system. In this evaluation, we used the 17 patient data from a different orthopaedian than our domain expert to test the quality of the recommendations provided by the system. A qualitative evaluation was also conducted with three clinicians including our domain expert and two from another hospital, where the goal is to evaluate the usability and usefulness of GenSupport, in addition

to identifying issues in need of improvement.

#### 4.1 Quantitative Evaluation of Recommendations

Patient data were provided by another orthopaedian who works in a different hospital from the domain expert. A data set containing full treatment history on 17 patients having congenital clubfoot on right foot, left foot or both feet was used. These patients have been treated by this orthopaedian. The full treatment history is used to compare with the recommendations by GenSupport.

As shown in Table 1, GenSupport provided the same recommendations of the treatment as performed by the clinician on 5 of the 17 patients. On the other patients, the system advised to perform the tenotomy either before (7 of 17) or after (5 of 17) it was actually performed by the orthopaedian.

**Table 1.** Evaluation of the recommendations by GenSupport.

Status	Cases
Correct (identical with the treatment performed by the clinician)	5
Tenotomy advised before actually performed	7
Tenotomy advised later than actually performed	5

Since the data set used in this evaluation is from another orthopaedian than our domain expert, it is possible that there are small variances in how the different orthopaedians treat clubfoot. This can explain some of the incorrect cases in that evaluation.

According to the domain expert, the Ponseti expert group specifically recommends to perform tenotomy as soon as the midfoot score is 0. When the clinicians are in doubt about whether the procedure should be performed, they should perform it [1]. In seven of the cases investigated in this test, tenotomy was not performed according to the recommendations from the Ponseti expert group. In these cases, the recommendations were correct and the clinicians provided a sub-optimal treatment.

In five of the cases, the clinicians performed tenotomy earlier than GenSupport recommended. In these cases, there is no apparent pattern describing why the clinicians have acted as they have. The clinicians' actions are most likely based on factors not documented in the patient data available in this evaluation. It is reasonable to believe that the clinicians provided what was considered to be the best care for their patients in these cases.

#### 4.2 Qualitative Evaluation of Functionality and Usefulness

Qualitative evaluation methods such as think aloud, observation and semi-structured interviews were used in this part of the evaluation of GenSupport. All three clinicians (one is our domain expert and the other two are from a different hospital. They are referred as doctor 1, 2 and 3 respectively in the text) in the evaluation are experienced orthopaedians in treating clubfoot.

First, clinicians were observed while carrying out some pre-defined tasks and using the system with patients who have finished the treatment to assess whether the system gives the same advice as the clinician did when treating. After finishing this phase, semi-structured interviews with the clinicians involved in the evaluation were conducted to gather more information on the usability and usefulness of the system. The interviews and the think-aloud sessions have been audio recorded. The interviews have been transcribed.

**Functionality and Perceived Usefulness.** All the clinicians were generally satisfied with GenSupport. The clinicians had the same opinion about whether they believed they could benefit from using the system. Due to their high level of expertise, they did not believe they could benefit from getting treatment advice from this clinical decision support system. Doctor 1 and 2 believed that GenSupport would be best suited as a tool for training novice clinicians. They stated that *“The registration would be more efficient; (...) it would be a lot more reliable and efficient. When it comes to the treatment, it depends on how experienced one is. Those who are experienced know how to do the treatment. But it takes a long time to get experienced (...), for those who have few patients, and who have just started learning this would be very helpful. (...) Through a decision support system, an experienced person can convey his/her knowledge to others.”* *“I believe that in an environment where there are inexperienced nurses, physiotherapist or physicians who are going to treat a lot of patients, [GenSupport] can be useful in the beginning (...).”* Doctor 3 implied this by saying that he felt the system was not necessary because of his level of competence: *“I would not use it to get recommendations in the treatment I provide, because I feel that when you know how to do it, it is easy.”* A decision support system is an important tool to gather knowledge from experienced clinicians and use this knowledge to train less experienced ones [14]. Clinicians are highly educated professionals, and they have thorough training in the procedures they perform. A clinical decision support system might thus not be of much help to clinicians who have finished training, especially when the treatment procedure is easy to understand. However, decision making often becomes more complicated when the decision depends on many different variables, and then skilled clinicians might also benefit from a tool like GenSupport when the condition is more complex than in this evaluation.

All the clinicians identified an area which GenSupport could help improving: the current routines of registration and archiving data about the treatment. They stated that these routines currently do not work as supposed to, and that they often experienced that treatment data are not registered as it should be. Treatment data are registered insufficiently, or not at all. This problem is most likely caused by the hectic environment in which the clinicians work, since electronic medical records are used as a standard at all hospitals. GenSupport can help to improve the registration by “forcing” the clinicians to register proper treatment data while treating the patient.

**Experience with PDA.** One interesting findings from the evaluation is that none of the clinicians in the evaluation had difficulties using the handheld computer although none of them have any prior experience with PDAs. The soft keyboard which the users of the handheld computers can utilize to input text can be difficult for regular

users to get used to, since using it requires a high level of precision. Observation showed that the clinicians in the evaluation had no problems at all using the soft keyboard, even though they were not used to such a small user interface. This is most likely because the clinicians in the evaluation are skilled and experienced surgeons, who have extensive training in tasks requiring high precision.

When asked to compare mobile devices with desktop computers in the daily practice, doctor 2 emphasized that a handheld computer is easier to use and transport in a hectic clinical environment. “(...) *you can keep the handheld computer in your pocket when working with the patient (...)*”. He often works in several rooms, and appreciates the mobility of the handheld computer. Also, he pointed out that the handheld computers are more robust than a regular computer. They are resistant to dust and shock. Another advantage which he emphasized is the quick start-up time of the handheld computers, compared to a regular computer. While regular computers often need several minutes before being ready to use, handheld computers are ready almost instantaneously. The time saved can in some cases be both precious and valuable in a hectic environment.

## 5 Conclusions and Future Work

This paper presents the development and evaluation of GenSupport—a mobile system to support the registration and treatment of clubfoot. The system was found to be able to improve and simplify the registration process and “force” the medical personnel to follow routines more strictly. It is also considered to be an appropriate training tool. The system has been designed as a generic framework for supporting clinical guidelines and clubfoot is used as the first instance. To support another guideline, one only needs to replace the configuration XML file with a new one which contains the new guideline.

The system will be further developed based on the feedback from the evaluation. Some functions need to be revised and added. For example, adding functionality for scheduling encounters so that the clinicians can plan and follow up the treatment. To enhance the clinician’s confidence in the system, an explanation subsystem should be added to GenSupport in order to provide evidence and rationales for the recommendations”. In the near future, after we have made improvement on the system, we plan to conduct a thorough evaluation focusing on the practitioner performance and patient outcome [15].

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