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DCDS: A Real-time Data Capture and Personalized Decision Support System for Heart Failure Patients in Skilled Nursing Facilities

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Abstract.

Heart disease is the leading cause of death in the United States. Heart failure disease management can improve health outcomes for elderly community dwelling patients with heart failure. This paper describes DCDS, a real-time data capture and personalized decision support system for a Randomized Controlled Trial Investigating the Effect of a Heart Failure Disease Management Program (HF-DMP) in Skilled Nursing Facilities (SNF). SNF is a study funded by the NIH National Heart, Lung, and Blood Institute (NHLBI). The HF-DMP involves proactive weekly monitoring, evaluation, and management, following National HF Guidelines. DCDS collects a wide variety of data including 7 elements considered standard of care for patients with heart failure: documentation of left ventricular function, tracking of weight and symptoms, medication titration, discharge instructions, 7 day follow up appointment post SNF discharge and patient education. We present the design and implementation of DCDS and describe our preliminary testing results.

Introduction

Heart failure (HF) is an important healthcare issue because of its high prevalence, mortality, morbidity, and cost of care. With the aging of the population, the impact of HF is expected to increase substantially, due to the fact that more older Americans are hospitalized for HF than for any other medical condition. More than 5 million people in the United States have heart failure. One in 9 deaths in 2009 included heart failure as a contributing cause. About half of people who develop heart failure die within 5 years of diagnosis. Overall, HF costs the nation an estimated 32 billion each year [2, 3, 4]. The trial of Heart Failure Disease Management Program in Skilled Nursing Facilities (SNF Study) is a study funded by the National Heart, Lung, and Blood Institute (NHLBI) [5] to evaluate if management of HF in SNFs could improve patient-centered outcomes and reduce hospitalization. A wide variety of data relevant to patient disease management is collected in this study. Thus, it calls for a data management system which accommodates a variety of data types as well as unique data capture needs, such as complicated medication entry. Access to clinical data is another key part in making a personalized healthcare strategy and enhancing the operation and adjustment of HF-DMP. To support real-time healthcare decision, a set of data analysis functionalities such as validation, retrieval, and visualization is required.

An economical, flexible, and scalable data entry system for capturing patient information which supports interoperation plays an important role in large scale, multi-center clinical trials. Unlike paper- or document-based forms, rapidly-deployed web-based electronic interfaces have the advantage of ensuring data quality through built-in data validation mechanisms. In addition, a well-designed electronic system can provide intuitive data visualization and better support health care decision making. While REDCap [1] (Research Electronic Data Capture) is a well-known data capture tool which meets a large percentage of SNF Study needs, there are unique features that REDCap does not provide.

To address this, we present a Real-time Data Capture and Personalized Decision Support System (DCDS) for SNF Study, focusing on real-time data capture and personalized decision support. DCDS supports automated score calculation, visualization of symptoms, and medication history retrieval. Patients benefit from the system because intuitive visualization of symptoms by caregivers may lead to enhanced care, improved outcomes, and reduced risk of death. The caregivers benefit from the system because it is easier for them to make sense of voluminous data and make prompt clinical decisions.

1 Background

Real-time Health Care Decision Support. Access to real-time and meaningful data at the point of care is one of the biggest challenges of the 21st century. In healthcare, a real-time clinical decision support (CDS) system that is shareable across healthcare delivery settings over large geographic regions plays an important role in improving outcomes. CDS technology has been demonstrated to improve the quality and safety of patient care, and is believed to

be an integral component in improving outcomes [6, 7]. With a CDS system, caregivers can make treatment decisions for a patient based on real-time data. A real-time CDS system brings together data from multiple sources and provides tools for clinicians to access and analyse such data. Properly implemented, it enables patients and caregivers to make timely and informed clinical decisions.

SNF Study is a multi-center clinical trial that focuses on the immediate post-acute patient with HF (i.e. 30 days post hospital discharge) and the immediate post-SNF discharge (i.e. 60 days post SNF admission). The study focus on a vulnerable time period when the patient transitions from one care setting to the next. In addition, patients with HF can have a change in condition fairly rapidly. Therefore, a real-time CDS can be highly beneficial.

DCDS: Data Capture and Decision Support System. DCDS is built on the OnWARD [8] framework, a dynamic, secure, rapidly-deployed, and web-based form generator supporting data capture for large-scale multi-center clinical studies. For example, it has been successfully deployed in other clinical trials such as the Heart Biomarker Evaluation in Apnea Treatment trial (HeartBEAT,1RC2HL101417), a multi-institution Phase II clinical trial funded through the American Recovery and Revitalization Act (ARRA). OnWARD is developed using the agile methodology, involving regular communication with researchers/clinicians to collect requirements and update/improve the system progressively. OnWARD automatically translates structured specification of data format into web-based input forms without requiring deeper technical expertise. Thus, OnWARD can be quickly deployed and customized for different types of studies. DCDS inherits the following features from OnWARD:

- Flexible backend database selection. DCDS has an independent backend relational database designated by an investigator to support data entry, retrieval, and validation. This feature allows easy deployment/reuse of existing databases as well as providing complete control by the investigator.
- Dynamic form generation. For every data form, the data types, ranges and data distributions (such as text box, drop-down list) for all data entry points are transcribed into an XML file with specific format, which is in turn translated into an electronic data entry form by DCDS.
- Input validation. To ensure data quality, mechanism for validations on data types and ranges are implemented in DCDS at the time of data entry. Uniqueness of patient identifier are validated to avoid duplicated IDs among different patients.
- Branching logic. This is used to skip certain questions depending on the answers to previous questions. For example, in the medical history form, if the user chooses "no" for the question "Myocardial Infarction," the next question "If yes, date of most recent MI" will be hidden from the user. The branching logic skip patterns are specified as metadata in the format of (question; condition; value; skip-question; default-value).

Trial of Heart Failure Disease Management in Skilled Nursing Facilities. HF challenges our clinical management skills because of unpredictable exacerbations, frequent hospital utilization, and complicated therapeutic regimens [9]. HF patients discharged to SNF have a higher rehospitalization rate and mortality than those discharged home [10], which is surprising since SNF are a major site of transitional care, from hospital to home, for older adults. The SNF Study is a randomized trial in which SNF physicians are randomized to either the HF-DMP managed by HFNA or usual care (UC). Quality initiatives to improve HF care in SNF can be vital to reduce rehospitalization and improve health outcomes for older adults. Although HF-DMP have been shown to reduce rehospitalization in other settings [11, 12], the effectiveness of HF-DMPs has not been studied in SNF. Since the SNF environment is highly regulated and programs are increasingly influenced by financial aspects, HF-DMP must both benefit patient outcomes and be affordable.

Research in SNFs is uniquely challenging. Each facility is its own entity with its own policies and procedures. Although multiple participating SNFs may be owned by the same company, there is considerable variability. A web-based system is exceedingly important to ease data collection burden at multiple sites with flexible software and computer access for study staff.

2 Challenges of DCDS

The HF-DMP is based on best practices for HF care, including documentation of left ventricular ejection fraction (in the form medical history), symptom and activity assessment, weights and dietary surveillance three times a week, medication titration, patient and caregiver education, discharge instructions, and a 7 day follow up visit post-SNF discharge. A specialist trained in Heart Failure Nurse Advocate (HFNA) works closely with physicians and ensures

fidelity of the intervention. Researchers in the SNF Study designed a wide variety of data collection forms to capture patient data in both UC and the HF-DMP group. Those forms fall into three categories (Figure 1): red color for shared forms, green for HF-DMP, and yellow for UC.

- Forms which are used once for baseline descriptive data, such as patient demographics and medical history.
- Forms which are used to collect outcomes data, which clinicians are investigating change over time. Such form include the Kansas City Cardiomyopathy Questionnaire (KCCQ) and Self Care in Heart Failure Index (SCHFI) forms. Clinicians collect the data at baseline and then at the end of the study after 60 days. The changes in scores for health status (KCCQ) and a patient's ability to manage their heart failure (SCHFI) will help illustrate the usefulness of HF-DMP.
- Forms of HF-DMP, which are used 3 times a week and are interactive for assisting the HFNA in making clinical decisions by using the research protocol. These forms help the HFNA track HF signs, symptoms and weight so as to guide medication management. This kind of data informs the Research Nurse (RN) how to improve a patient's treatment and intervene if the patient is decompensating from HF. The RN can make treatment recommendations if indicated by the protocol. The UC group has the same data collection forms, but the data is collected by chart review and there is no interactive component in UC. The HFNA is not involved in UC data collection.

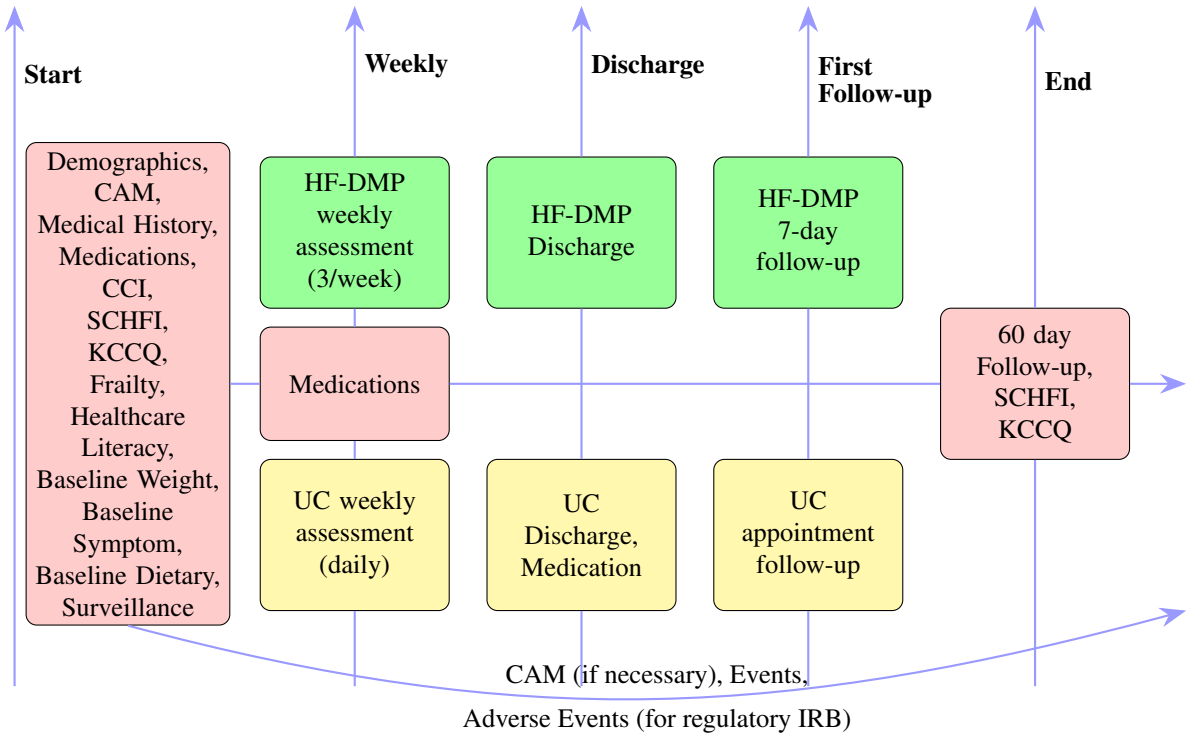

Figure 1: Overview of data collection forms in SNF Study.

Although the general OnWARD framework can fit most of what the SNF Study needs, there still remains a set of challenges. A fundamental challenge in the field of clinical decision support is to determine what characteristics of data make them effective in supporting particular clinical decisions. In HF care, patient's weight, clinical symptoms, and medication titration are significant in evaluating the status of patients and determine their response to medical therapy. Whether the system facilitates appropriate access to such data affects the effectiveness in supporting clinical decision making.

2.1 Trending Graph Generation

Tracking patient's weight, signs and symptoms is important for determining the clinical status of patients and gauging their response to medical therapy. The HFNA protocol weights on each patient 3 times a week and recommends

a dietary strategy based on the available SNF menu. The HFNA also assesses patient's symptoms and activities to assist treatment decisions. However, isolated symptom or weight measure such as "swelling," "dyspnea," and "70lbs" is useless when it is evaluated beyond the context of a patient's condition over time. In this case, trending graph generation is needed for DCDS. Using clinical data collected from patients at bedside, graphs are automatically generated to allow the HFNA to compare changes over time. Trending graphs provide visual clues about trends, gaps and clusters and compare multiple data sets at once that words and equations cannot offer. Based on trending graphs, study nurse can quickly draw conclusions and follow protocols to intervene on a patient's change in condition in a timely manner.

2.2 Auto-calculation

In SNF Study, several forms require the calculation of scores based on patient surveys such as Demographics, KCCQ, Frailty, and Charlson Commodity Index. These scores form the basis for understanding patient conditions and information about the dynamics of disease when collected over time. The calculation of clinical scores has previously relied on Microsoft Excel, which calculates the scores based on data entered by study staff. Calculations in Excel needs cumbersome operations, which made errors easily, such as referring to the wrong cells or choosing the wrong data area. Automating the calculating process, which is a vital component of DCDS, not only saves time, but also avoids errors.

2.3 Medication History

Medications play a pivotal role in heart failure management. National guidelines for HF-disease management clearly delineate medications and target doses that will result in the best patient outcome [13]. Titration of medication can indicate improved quality of care for patients. Titration of diuretics in response to volume overload can help avoid HF decompensation and hospital admission. Medication titration according to pre-determined protocols is an important part of the intervention. Therefore, it makes sense to record medication changes occurring in response to the HF-DMP and to UC, and subsequently determine the effect medication titration has on outcomes. A medication history database for tracking, analyzing, and monitoring is another key component of DCDS.

The weekly medication form in SNF keeps daily records of medication name, dosage and frequency of every medication for each patient. The unique features required of this form are as follows:

- Auto completion for medication names. Due to the fact that medication names are often complex terms, clinicians can make errors when inputting medication information. The addition of real-time auto completion on medication names is a necessary functionality to improve efficiency and reduce error in the weekly medication form.
- Auto retrieval of medication history. Medication regimens can be lengthy and capturing medication information for each visit can be cumbersome. Since many medications prescribed to a patient infrequently change substantially, it is efficient for clinicians to directly modify the current medication information using the medication information of the previous day.
- Easy modification of medication. Based on medication information from the previous day, clinicians may add or delete medications to the current medication list. They may also need to modify the dosage or frequency of an existing medication. A user-friendly data entry interface which facilitates history-based medication information capture is required.
- Tabular form. In contrast to list form, a tabular medication form which allows structured collection and representation of information about medication, dosage, and frequency through a dynamic interface is desirable. Moreover, since the total number of medications is not predetermined, DCDS needs to be able to dynamically add or delete rows from the table.

3 System Design and Implementation

In this section, we present the design and implementation of DCDS. Initial development of the DCDS workflow was accomplished with close collaboration between the SNF investigator team and the DCDS development team. Figure 2 illustrates the workflow, including data collecting, decision support, and care delivery. In the SNF Study, patient's clinical information is collected at bedside by the HFNA, and processed through DCDS to generate data reports to support HFNA management strategy.

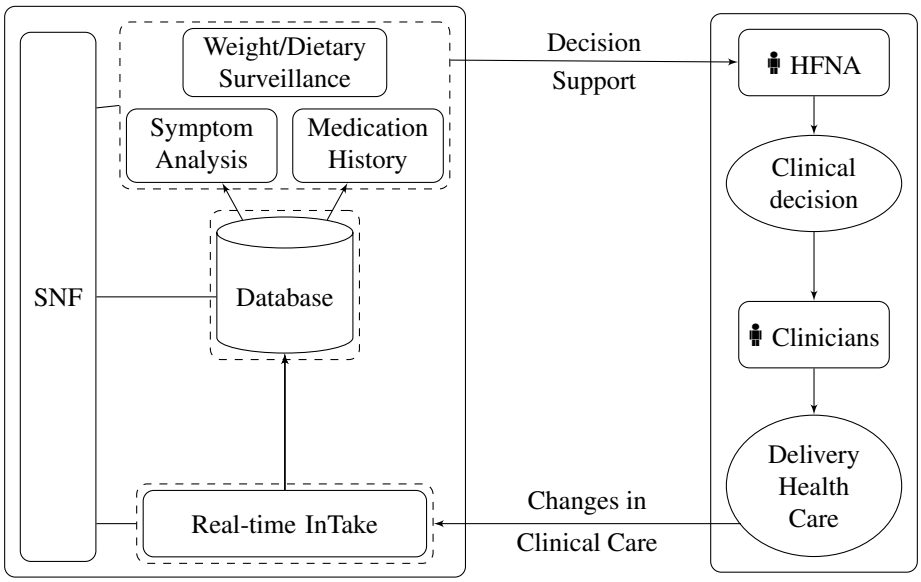

Figure 2: Overview of our Real-time Data Capture and Personalized Decision Support System. Nurses collect patient information and conduct a clinic assessment. Data is ingested into DCDS. The system then generates timely clinical reports of the patient, such as weights, symptoms, and medications history. HFNA uses these reports to support clinical decision making. The clinician then delivers care by making changes to patient's HF management if necessary. The HFNA captures changes to clinical care in DCDS. This work cycle is repeated during a patient's entire SNF stay.

DCDS is developed using the Ruby on Rails web application development framework. It involves three seamlessly integrated modules: Data Specification, Data Capture, and Decision Support. Data Specification is the key step before Data Capture. All the metadata forms are specified to facilitate dynamic form generation. The metadata specification is captured in Excel sheets, which are converted to XML specification files by DCDS. The XML files then are directly loaded to the relational database of DCDS. After loading of the data specification, DCDS dynamic form generation engine automatically displays the form content for Data Capture. In the review and reporting phase, DCDS' Decision Support component generates customizable reports using real-time data in the database.

3.1 Data Specification

Data Specification involves three types of metadata: variables, value domains, and permissible values. A form consists of a collection of variables, whose specification includes datatype, distribution, descriptive label, and value domain. The value domain of a variable has associated permissible values that determine which values are allowable for the specified domain. For a categorical value domain, each of its permissible values serves as an option of the drop-down menu list; for a numerical value domain, its permissible value specifies the valid range.

3.2 Data Capture

DCDS has built-in data capture features, such as data validation, multiple data type supporting, and branching logic. For the unique needs of SNF Study, we provide the following functions to improve the efficiency of data capture.

Auto Calculation for Clinical Scores. Calculation formulas are stored in the backend database. Each formula involves a number of questions in the same data entry form, divided into two groups: conditional questions and result questions. As a user enters data in the conditional questions from the web interface, a javascript function is triggered and automatically fills in the result entry with the correct value based on the formula. For example, in the KCCQ form (Figure 3), 10 scores are filled automatically based on the answers to the previous questions. This avoids the additional needs for using separate Microsoft Excel or any other calculation tools.

Auto Completion of Medication Names. A backend medication dictionary is imported beforehand. We extract the generic medication names from RxNorm [14], a normalized naming system for generic and branded medications provided by the National Library of Medicine (NLM). We built the "auto completion" function this way: When a user enters the first letters of a medication name, the system automatically pops up a list of all partially matched medication

names containing the input string as a substring for the user to choose.

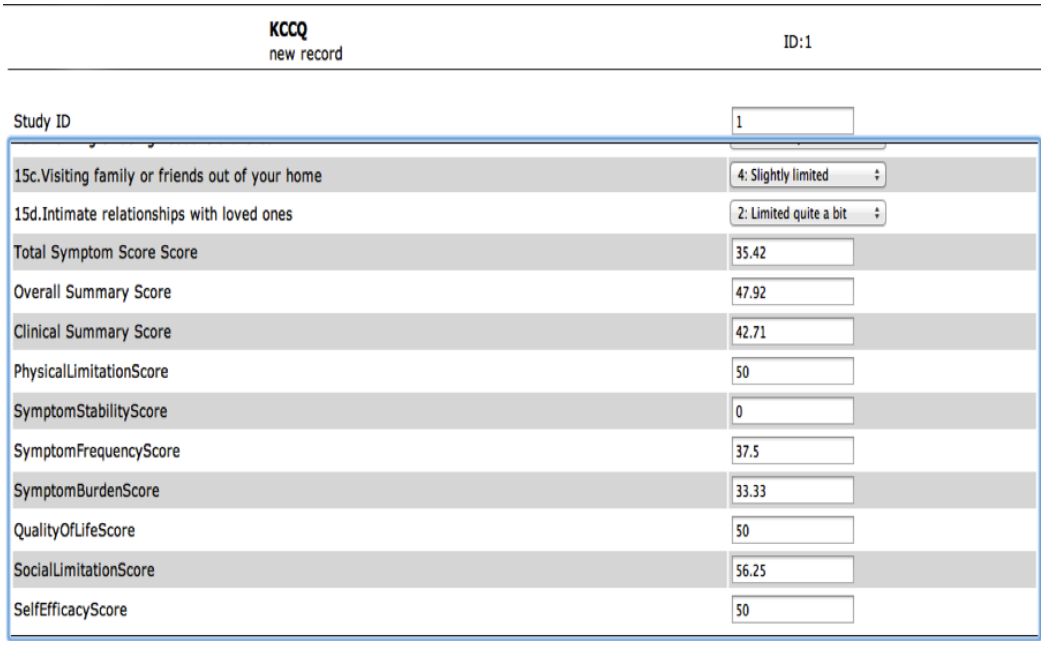

Figure 3: KCCQ Auto-calculation.

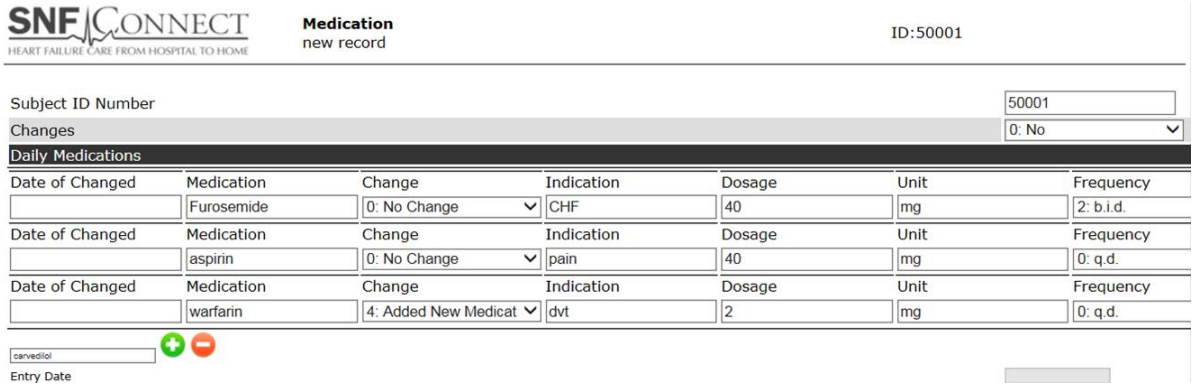

Figure 4: Medication Form.

Auto Retrieval of Past Medications. In the SNF Study, medication information is recorded daily. The automatic retrieval process is divided developed in these steps: When a user creates a new medication record, DCDS finds the previous record by date, and then automatically retrieves the medication history from that record and displays it in a table, as shown in Figure 4. Pre-processing is needed to make this process efficient: if a medication was labeled "discontinued," it would not be displayed.

Easing the Burden on Medication Modification. After retrieving the medical information from the previous record, DCDS provides users with the ability to make changes to each medication to generate a new medication order for the current day. They can increase or decrease the dosage or frequency by choosing the appropriate option in the drop-down menu. There is also an option named "Discontinue" in the drop-down, which is used to remove the corresponding medication from the order. The process of adding a new medication goes as follows. First enter in the medication name with the help of auto-completion; then click the "Add" button; then a new row with the medication name is added to the table. Other fields capturing dosage or frequency information need to be filled by the user. DCDS preserves each medication list from each day, which means that even if a medication is discontinued one day, the medication history is still preserved for the previous day. In this scenario, it does not overwrite the medication list and HFNA truly follows medication management trends.

3.3 Decision Support

To support clinical decision making, we designed several reporting tools to help data tracking and analyzing. Tabular form of medication history along with the changes in weight and symptoms provides an intuitive grasp of patient's condition and helps HFNA deliver appropriate care.

Tabular View for Medications. The form generation engine in DCDS provides two basic layouts: List View and Tabular View. The Tabular View displays a multi-row and multi-column layout. The medication form in SNF has eight columns: date of visit, medication, change, indication, dosage, unit, frequency, and change based on HFNA recommendation. Among the eight fields, "Date of Change" and "Medication" are two key fields. The "Change" field contains five options: no change, change in dosage, change in frequency, add new medication and discontinue. "Indication", "Dosage", and "Unit" fields are text fields. The "Frequency" field records medication frequency, which includes four options: once a day, twice a day, three times a day, or as needed. The last field "Other Frequency" is a text field as a supplement to the standard "Frequency" field.

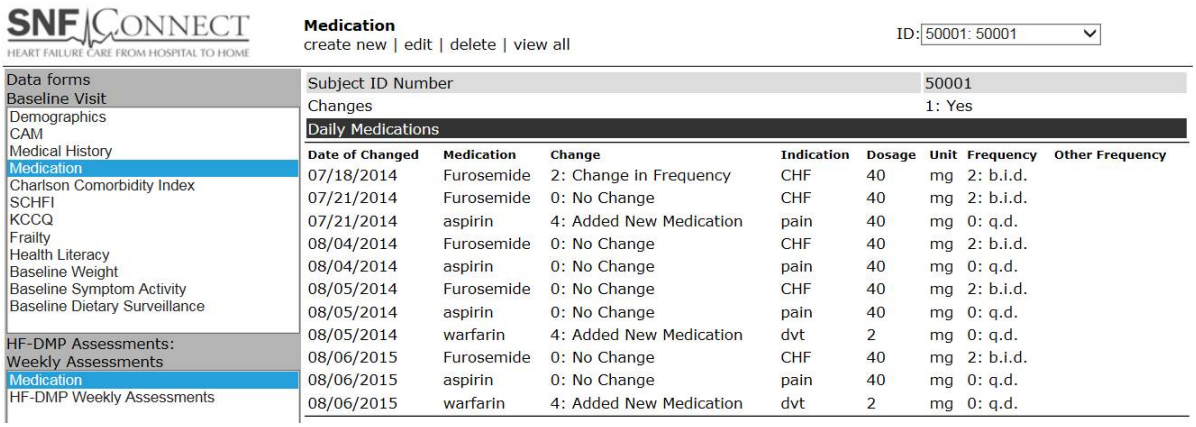

Figure 5: Medication History.

Weight-Trending Graph. Tracking of weight over time is a key aspect of SNF Study. Doctors track weight closely for patients with HF because weight gain due to fluid retention is an early sign of decompensated HF. The information is used to prescribe medication to patient and also to review response to medications. For the purpose of usability and analysis, the graph needs to be as interactive as possible. We use Google Charts along with Javascript to fulfill this purpose. Google Charts fit our requirements and have proved useful. Javascript is used to dynamically show and hide the graph.

Figure 6: Weekly Weight.

Weight-Trending graph has the following elements:

- Intelligent Y-axis. The Y-axis of the graph, which represents the weight over different time intervals, adjusts

itself according to the present value range of weight so that small changes in weight are easily visible.

- Time Interval Adjustment. Graphing range can be switched from 1 day to 1 year according to the length of the period during which a patient is under observation. This way the HFNA can zoom in and out at different time intervals.
- Mouse Pointer Value. At any point, the graph shows the value of the weight with the date corresponding to the current position of mouse pointer.

Symptom Analysis. Various symptoms can be present for different patients in different ways. To know how these symptoms are changing over time for a particular patient proves to be of great importance in SNF Study. It makes sense to implement a chart or table that gives all the required information about various symptoms of a patient in a concise manner. This not only saves HFNA's time but also creates simplicity and improves recognition of changes in a patient condition.

Patient Symptom Report : Show Hide

Symptom	2013-11-12	2013-12-08	2013-12-09	2013-12-12	2013-12-13
Fatigue	=	=	=	=	+
Activity	=	X	=	N/A	+
Shortness of Breath	-	+	=	+	X
Chest Discomfort	-	=	=	X	X
Paroxysmal nocturnal dyspnea	-	-	=	=	N/A
Orthopnea	-	-	=	-	+
Cough	-	N/A	+	=	X
Jugular Venous Pressure	-	-	-	X	=
Bloat	+	+	-	+	-
Nausea	+	+	-	+	X
Loss of Appetite	+	X	+	+	N/A
Lower Extremity Edema	+	+	=	+	+
NYHA Class	1	1	2	3	4

Figure 7: Symptoms.

- Tabular Form. About 12 different symptoms are analyzed. Displaying such information in a chart may create confusion. Therefore it makes sense to follow a tabular form approach. It simplified the design and served the purpose beautifully.
- Symptom Progress. '+' indicates that the symptom has increased, '-' indicates that the symptom has deceased, '=' indicates that the symptom is the same as the previous, 'N/A' indicates that symptom progress is not available, 'X' indicates that symptom was not previously recorded so there is a lack of information to be shown.
- Colors. To make the table even more interactive, in addition to different symbols, we added appropriate background colors. Green indicates an improvement, red a worsening, yellow the same, gray no records, and white not available.

4 Results and Evaluation

In total, we created 22 clinical forms containing 584 questions and 175 branching logic in DCDS. The basic demographic form assigns a study identifier for easy tracking, which is used as the universal key for other 21 forms. We stored 4103 medication names in our backend database to enable auto completion of medication entry and 5 calculation formulas: Demographics, KCCQ, Frailty, SCHFI and Charlson Commodity Index. DCDS is presently used in 43 facilities in the Denver area. The SNF Study is still enrolling and currently (March 2016) it has enrolled 365 patients including 44 in Cleveland.

Elements	Number
Facilities	43
Patients	365
Forms	22
Questions	584
Branching Logic	175
Calculation Formulas	5
Medication	4103

Table 1: Summary of Results.

4.1 Evaluation

Compared to traditional paper-based method of data capture, structured electronic data capture has several advantages. It reduces the data collecting burden, supports quality reporting, improves the capability of informing researchers, and ultimately, enhances patient care. An important benefit of DCDS is that through the VPN, users can access the system anywhere. SNF staff usually goes to many facilities, including patients' homes. With easy access to the system, they can get on DCDS anywhere and do not need to return to the office to enter data.

In this section, we compare DCDS with Paper-Based method to evaluate the unique design of DCDS for HF-DMP study. We designed a survey to evaluate the two methods (paper froms vs DCDS), including aspects of entering, tracking, usability, customizability, consistency, and representation. We invited 3 professional research assistants and 2 nurses in the SNF Study to take the survey and collected their comments and notes about the two methods. Each participant did data entry using paper-based HF-DMP workflow (data was entered into DCDS later), then performed the same HF-DMP workflow on a different patient and directly captured data into DCDS.

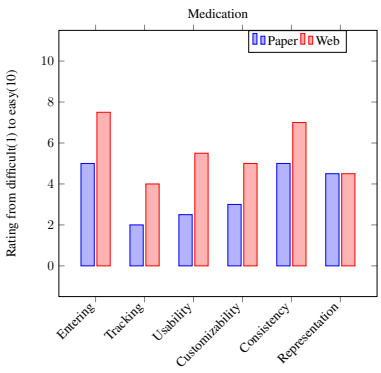

Figure 8: Medication.

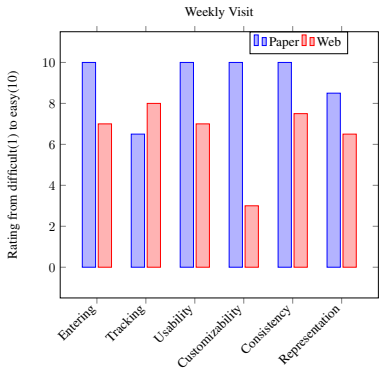

Figure 9: Weekly Visit.

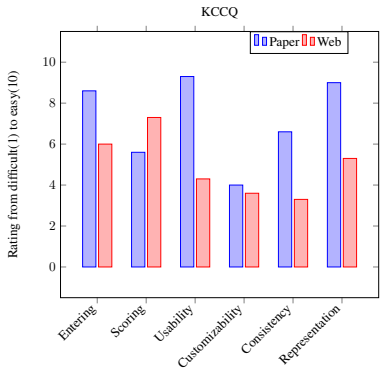

Figure 10: KCCQ.

In the figures: a) Entering denotes how long and easy to complete the forms; b1) Tracking(in medicatin and weekly visit) denotes how difficult to track the changes of symptom and weight; b2) Scoring(in KCCQ) denotes how difficult to track the changes of symptom and weight; c) Usability denotes overall usebility; d) Customizability denotes the overall customizability; e) Consistency denotes how difficult to make sure information you write is correct; f) Representation denotes how well the information represented.

Figures 8, 9, 10 show the average ratings of three selected forms: 1) Medication, 2) Weekly Visit and 3) KCCQ. Each form was rated on 6 aspects and each aspect was measured on a scale from 1-10 with 1 being the hardest and 10 the easiest. Figure 8 shows that the ratings of DCDS are way ahead of the paper-based method in all aspects. With respect to the testers' comments, "Didn't have to retype out names for DCDS" and "Takes a long time with the amount of meds" for paper-based method confirmed that DCDS is well-designed, as a result of auto completion of medication names and tabular view of the medication history. However, in Figures 9 and 10, the results are different. Our DCDS is only leading in tracking and scoring, which shows a gap from our expectation. From the comments and notes for these two forms, we found several reasons. These include: "Papers are easy to carry and write down any notes," "Booting up computers, login and access to web-based tools is cumbersome," "Patients are less willing to expand on answers when sitting in front of computers, which seems to be a more formal interview."

A detailed analysis revealed that participants preferred using DCDS in situations of cumbersome repeating input, long-

term tracking, or scoring. The results demonstrated that our design is practical and user-friendly. Another interesting finding is that patients are more willing to answer questions using a paper-based method. They prefer casually talking with a nurse rather than a formal interview in front of a computer.

5 Discussion

As we can see in the evaluation section, evaluators preferred using paper to record clinical information than using DCDS. It tooks more time to boot up the computer, connect to the VPN and sign into DCDS than to fill out a form. However, the results showed increased satisfaction with the ease of data entry, graphing for symptom tracking and auto calculation for clinical scores. The data processing done by DCDS made clinical decision making easier as data was presented in charts and graphic forms, making day to day comparisons of clinical data straightfoward. In addition, the advantages of DCDS are not obvious from one or two patient visits. As researchers become more familiar with DCDS, their efficiency likely increases. In the short-term, especially for a study such as SNF, users may spend more time in using DCDS. However, the long-term benefit in ease of exploring and managing clinical information of patients is important. Since all data are captured in DCDS on each patient, it provides a rich dataset for real-time data analysis.

Health care data standards are another important aspect which we need to consider and integrate into our DCDS in future work. Using the guideline of data standards, such as HL7, we can use standard terminologies, data formats, methods and protocols for data exchange, integration, representation, and decision support.

6 Conclusion

In this paper, we present DCDS, a real-time data capturing and personalized decision support system, for SNF Study to investigate the effectiveness of HF-DMP in improving outcomes for older frail heart failure patients undergoing post-acute rehabilitation. The results show that DCDS is clearly superior to existing manual approaches in data retrieval, data visualization, and easing the burden for cumbersome data entry.

Acknowledgement

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