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Developing healthcare rule-based expert systems: Case study of a heart failure telemonitoring system☆

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ABSTRACT

Background: The use of expert systems to generate automated alerts and patient instructions based on telemonitoring data could enable increased self-care and improve clinical management. However, of great importance is the development of the rule set to ensure safe and clinically relevant alerts and instructions are sent. The purpose of this work was to develop a rule-based expert system for a heart failure mobile phone-based telemonitoring system, to evaluate the expert system, and to generalize the lessons learned from the development process for use in other healthcare applications.

Methods: Semi-structured interviews were conducted with 10 heart failure clinicians to inform the development of a draft heart failure rule set for alerts and patient instructions. The draft rule set was validated and refined with 9 additional interviews with heart failure clinicians. Finally, the clinical champion of the project vetted the rule set. The concerns voiced by the clinicians during the interviews were noted, and methods to mitigate these concerns were employed. The rule set was then evaluated as part of a 6-month randomized controlled trial of a mobile phone-based heart failure telemonitoring system ($n = 50$ for each of the telemonitoring and control groups).

Results: The developed expert system generated alerts and instructions based on the patient's weight, blood pressure, heart rate, and symptoms. During the trial, 1620 alerts were generated, which led to various clinical actions including 105 medication changes/instructions. The findings from the trial indicated the rule set was associated with improved quality of life and self-care.

Conclusions: A rule set was developed with extensive input by heart failure clinicians. The results from the trial indicated the rule set was associated with significantly increased self-care and improved the clinical management of heart failure. The developed rule set can

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be used as a basis for other heart failure telemonitoring systems, but should be validated and modified as necessary. In addition, the process used to develop the rule set can be generalized and applied to create robust and complete rule sets for other healthcare expert systems.

1. Introduction

The increasing prevalence of chronic diseases, such as heart failure, as the population ages is expected to result in a severe shortage in healthcare resources including nurses, physicians, and hospital beds [1–3]. Telemonitoring is a promising tool that can potentially alleviate some of the burden on the healthcare system by empowering patients to care for themselves and enabling more efficient clinical care, such as through automated alerts at the earliest sign of deteriorating patient health.

Currently, computerized clinical decision support systems exist for heart failure diagnosis and treatment plans. The rule sets for these systems can be based on clinical practice guidelines [4–6]. Although methods to transform clinical practice guidelines for use in decision support have been developed [7,8], no guidelines presently exist that are comprehensive enough for direct use in the relatively new area of automated heart failure patient decision support and alerting systems (e.g., to create patient instructions for each possible combination of symptoms, blood pressure, and weight readings). Furthermore, even if such guidelines did exist, clinical input during the development of computerized clinical practice guidelines would be important to bridge the "gap between the guideline text and clinical practice" [9]. That is, rule sets need to take into consideration each healthcare institution's own workflow and policies, as well as the individuality of the patients. The clinical input could be implemented through various user-centered design processes, such as participatory design, usability testing, or contextual design [10–12].

An *expert system* is a "knowledge-intensive program that solves a problem by capturing the expertise of a human in limited domains of knowledge and experience" [13]. Expert systems have been used in a variety of fields, including medicine, space, and business [14–18]. For rule-based expert systems, the knowledge from experts is translated by a knowledge engineer into a set of rules [19].

The purpose of this work was to develop a rule-based expert system for a heart failure mobile phone-based telemonitoring system. The expert system would be used to automatically generate appropriate alerts for clinicians and patients, as well as to generate suitable patient instructions. This expert system would be fundamentally different from existing clinical decision support tools available to healthcare providers for diagnosis and management because it would function independently of the clinician with automated alerts being sent directly to the patient and to the clinician. This article describes the process used to create the heart failure rule set, the resultant rule set, and the lessons learned. To determine the efficacy of the rule set, it was incorporated into a heart failure telemonitoring system that was evaluated in a randomized controlled trial. The effects of the rule set on the trial results are also summarized below. Details of the trial results have been published elsewhere [20,21].

2. Methods

The University Health Network (UHN) Research Ethics Board approved both the development process of the heart failure telemonitoring system, including the rule set, and the randomized controlled trial. All individuals participating in this research provided informed consent.

2.1. *Development of the heart failure telemonitoring rule set*

The information from semi-structured individual interviews with 10 heart failure clinicians (three cardiologists, four nurse practitioners, and three clinical fellows) affiliated with the UHN Heart Function Clinic was used to develop a preliminary rule set. See Fig. 1. The clinicians interviewed constituted the majority of the physicians and nurse practitioners at the clinic. Each interview was between 30 and 45 min in duration. During the interviews, the clinicians were asked which parameters they thought would be necessary to include in the rule set (e.g., weight, blood pressure, and symptoms). The clinicians were also asked questions regarding the alerts and patient instructions that should be generated from the rule set. Patients were consulted during the development of the telemonitoring system through three rounds of usability testing. However, the creation of rule sets required in-depth clinical knowledge of heart failure and the inclusion of the clinical workflow. Therefore, patient input during the creation of the rule set was mainly regarding the wording of the patient messages.

After a preliminary rule set was developed from the interviews, a second round of interviews was performed as part of usability testing of the telemonitoring system with nine heart failure clinicians (three cardiologists, three nurse practitioners, and three fellows) from the Heart Function Clinic to verify the preliminary rule set. As part of the interview, each clinician was asked to review and comment on the symptoms questions, the alert messages, the patient instructions, and the proposed workflow regarding the alerts. Finally, the project's clinical champion vetted the rule set to ensure safety and appropriateness.

The transcripts of both rounds of interviews were analyzed using a conventional content analysis approach [22]. Two researchers (ES, CM) analyzed the transcripts independently and coded the transcripts with the software program NVivo version 7 (QSR International, Doncaster, Victoria, Australia). The common themes, concerns, and perceived challenges of implementing a rule set were discussed until a consensus was reached.

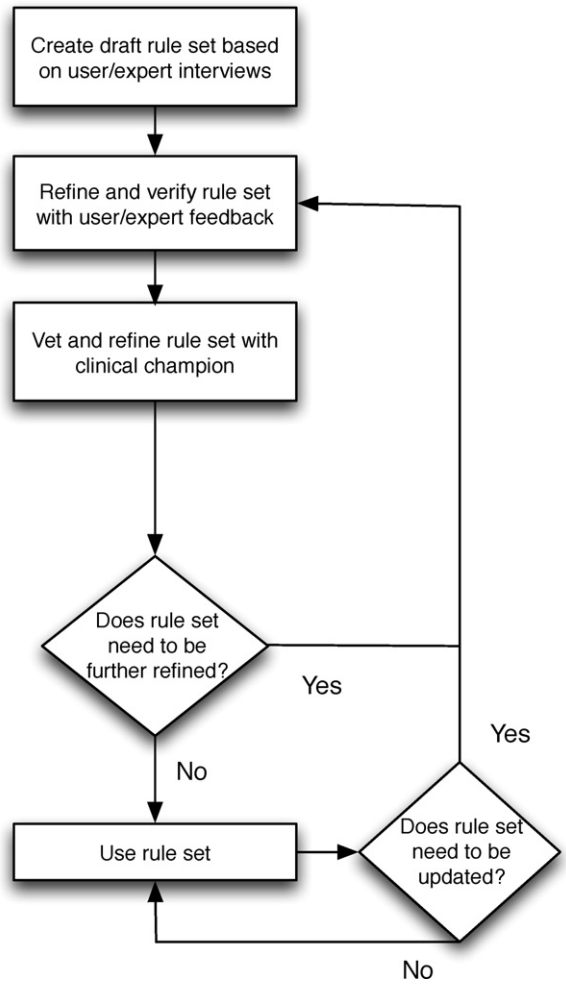

Fig. 1 – Iterative user-centered process for rule set development and maintenance.

2.2. *Evaluation of the heart failure telemonitoring rule set*

The rule set was incorporated into a mobile phone-based heart failure telemonitoring system that was evaluated through a randomized controlled trial registered at ClinicalTrials.gov (NCT00778986). One hundred participants were recruited from the UHN Heart Function Clinic between mid-September 2009 and February 2010 and randomized into the telemonitoring (TM) group ($n = 50$) and the standard care (SC) group ($n = 50$). Participants in the TM group used the telemonitoring system for 6 months in addition to receiving standard care. To be eligible for participation, patients had to be older than 18 years, not be on the heart transplantation list, be expected to survive more than 1 year, and have a left ventricular ejection fraction (LVEF) <40%.

The developed telemonitoring system enabled patients to take their weight, blood pressure, heart rate, and single-lead electrocardiogram (ECG) with wireless medical devices. Patients were provided with instructions on the mobile phone screen regarding which parameter to take next. The devices sent the data automatically through Bluetooth to the mobile phone. The patient was also prompted to answer a few yes/no questions on the mobile phone regarding symptoms. The values were then sent automatically from the mobile phone to the hospital data servers for analysis. Depending on the readings, an alert might be generated and sent to the patient's mobile phone. When an alert was generated, an email alert was sent to the mobile phone of the on-call clinician along with all relevant patient information. The patients were instructed to take all the readings each morning once they woke up, and to use the telemonitoring system during they day if they felt a change in their symptoms. The majority of the patients kept the system at home, although some took it with them on vacation, to the cottage, etc.

The health outcome data were obtained through patient charts, the hospital's electronic health records, and pre- and post-trial patient questionnaires. The process outcome data (e.g., number of alerts sent and number of clinical interventions) were obtained through manual tracking of clinical actions during the trial and retrieving information from the data servers. Semi-structured interviews were conducted post-trial with all the clinicians involved in the study (three cardiologists and two nurse practitioners) and 22 of the patients who used the telemonitoring system.

3. Results

3.1. *Heart failure telemonitoring rule set*

3.1.1. *Features of the rule set*

Each interviewed heart failure clinician agreed the parameters listed in Table 1 should be monitored at the patient's home. Patients were asked to take their weight, blood pressure, and symptoms daily, and ECG readings weekly. Although there was some debate on the necessity for all patients to take their blood pressure daily, it was decided all patients should be asked to take their blood pressure daily to help them establish a routine and to simplify the rule set. Clinicians were be able to set the patient's acceptable weight, blood pressure, and

Table 1 – Important parameters for monitoring identified through interviews with heart failure clinicians.

Parameter	Time and frequency of measurement
Weight	Daily, first thing in the morning after the patient relieves themselves in the washroom and undresses
Blood pressure and heart rate	First thing in the morning and when the patient exhibits symptoms during the rest of the day. Clinicians thought the required frequency of blood pressure and heart rate measurement depended on the individual patient, varying from daily to weekly
Symptoms	Daily, first thing in the morning and when the patient exhibits symptoms during the rest of the day
ECG	Weekly, first thing in the morning and when the patient exhibits symptoms during the rest of the day

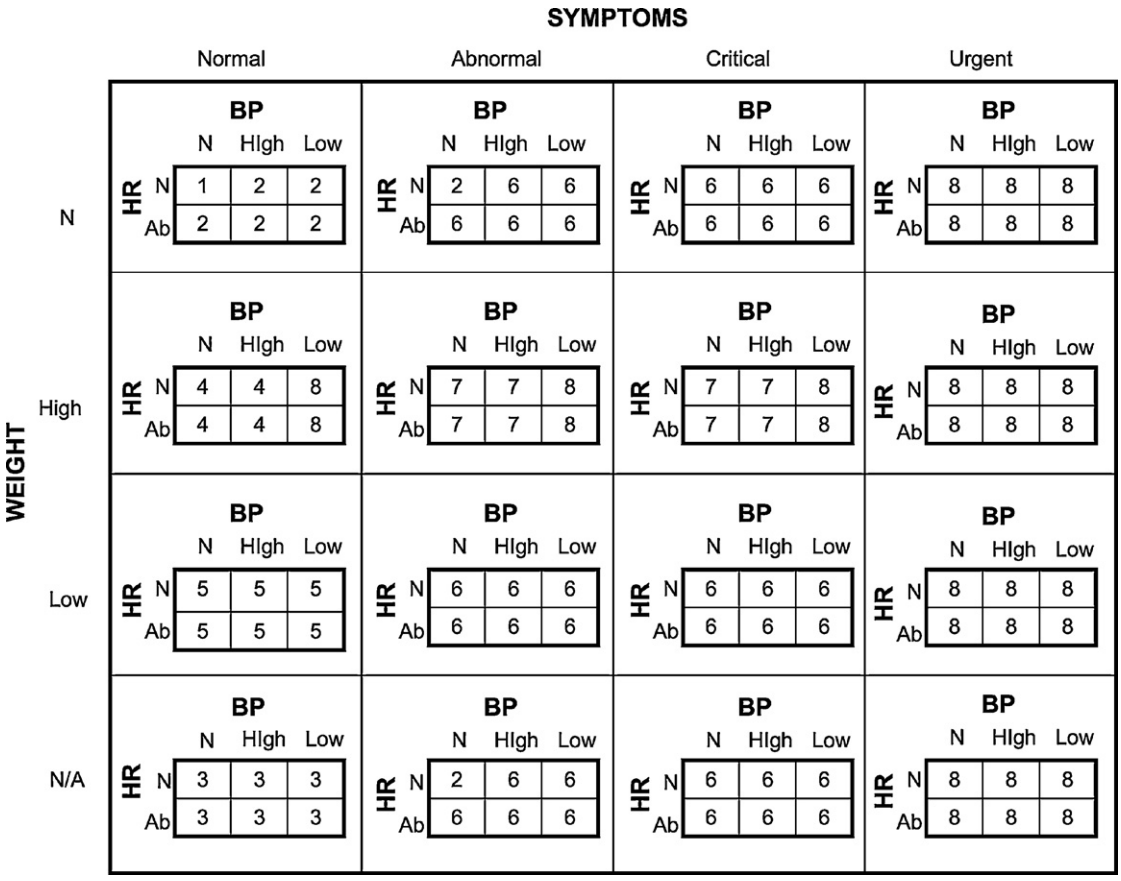

Fig. 2 – Matrix of outcome states from possible combinations of measurements (BP, blood pressure; HR, heart rate; N, normal; Ab, abnormal; N/A, not applicable). The numbers represent various patient alert messages (see Table 3).

heart rate range and the acceptable change in weight from 1 day to the other (defaulted to 3 pounds). Different alerts were generated depending on which parameters were above or below the thresholds values, as well as any entered symptoms (categorized as abnormal, critical, and urgent). The ECG information was solely used for clinical review and was not factored into the alert being generated.

3.1.2. *Defining the rule set*

A matrix of possible outcome states from all combinations of measurements was created to fully define the rule set for the expert system. See Fig. 2. The alert message and actions associated with each outcome state were validated during the second round of clinician interviews, and vetted by the project's clinical champion. For example, if a patient has a low blood pressure of 77/45 mmHg, a weight gain of 3 pounds from yesterday, and feels short of breath, then the corresponding outcome state is represented by "8" in Fig. 2. This represents the most urgent state. The alert message "Have someone drive you to the local Emergency Department or call 911 now" would appear on the patient's telemonitoring mobile phone, an email alert would be sent to the on-call clinician, and an automated phone call would be sent to the patient's home telephone informing them to call 911 or go to the Emergency Department. For all outcomes states except "1" (everything is normal state), an email alert was sent to the on-call clinician. The corresponding alert messages sent to the patient for each outcome state are listed in Table 3.

The alert messages often included a reminder to the patients to contact the Heart Function Clinic or their family physician, or go to the emergency department, if they felt they should. This reminder was provided to encourage the patients to seek medical attention when necessary, which is a self-care management action often neglected by heart failure patients. The reminder was also a safety precaution in case the clinician managing the alerts did not call the patient immediately after receiving the alert. Also noteworthy was the ability of the clinicians to decide if each patient should receive automated reminders from the telemonitoring system to take extra diuretic medication if there was a substantial weight increase from 1 day to the next. Some patients were already instructed by their clinicians to automatically take an extra dose of diuretic medication under certain circumstances. The reminder from the telemonitoring system to take the extra diuretic medication was set by the clinicians for individual patients if they believed it was appropriate.

Symptoms were classified as urgent if the patient answered yes to having fainted and/or to their ICD (implantable cardioverter defibrillator) going off. Critical symptoms included the patient's breathing at night worsening and/or feeling more chest pain than usual. Feeling more tired than usual and being more short of breath than usual were classified as abnormal symptoms. If the patient answered positively to any of the

Table 2 – Demographic and clinical characteristics of patient participants.

Characteristic	TM group ($n = 50$)	SC group ($n = 50$)
Age, years (SD)	55.1 (13.7)	52.3 (13.7)
Gender		
Male	41 (82%)	38 (76%)
Female	9 (18%)	12 (24%)
Ethnicity		
Caucasian	39 (78%)	33 (66%)
African Canadian	5 (10%)	4 (8%)
South East Asian	2 (4%)	2 (4%)
Chinese	0	3 (6%)
Other	4 (8%)	8 (16%)
NYHA class		
II	21 (42%)	22 (44%)
II/III	6 (12%)	5 (10%)
III	21 (42%)	21 (42%)
IV	2 (4%)	2 (4%)
LVEF, % (SD)	27.1 (7.8)	27.0 (9.9)

above symptoms, four additional symptom questions were asked to provide supplementary information to their clinicians. However, the symptoms classification was not changed based on these additional questions. The four additional questions asked the following information: (1) were their ankles swollen, (2) did they feel heart palpitations, (3) the number of pillows they used to sleep, and (4) did they stop any of their daily activities due to their health.

After each reading was transmitted to the mobile phone or set of symptom questions were answered, the patient was asked if it was taken first thing in the morning or otherwise. The rule set always used the morning weight reading for each day to generate the alerts because after the patient consumed any food or liquids, the weight reading was no longer valid. If the patient did not take a morning weight reading that day, then the weight would be set to Not Applicable (N/A in Fig. 2).

3.1.3. *Clinicians' concerns on implementation of an expert system*

During the development process, clinicians expressed concerns associated with patient safety and legal liability with using an expert system. The main concerns are summarized below.

1 Inappropriate patient instructions
Clinicians were concerned the instructions sent to the patient could be inappropriate for the situation because of improperly constructed rules, patient errors when taking measurements, or system failure. In particular, they were concerned the alerts would be false positives and would result in patients going to the emergency department unnecessarily. This could lead to patients becoming desensitized to the alerts.
2 Clinicians unable to follow-up with alerts
One of the most common concerns was clinicians would not have the time to follow-up with all the alerts being generated. "We are busy people and I think we need to have someone dedicated to this. I do not believe that an attending will be able to handle this." Clinicians thought a dedicated nurse practitioner would be best suited to manage all the alerts. The clinicians were also particularly concerned about managing the alerts during off-hours and if they were on vacation.
3 Individualization per patient
Heart failure management decisions are highly dependent on each individual patient. Clinicians stressed the most appropriate decisions could be made by first knowing the specific patient. A clinician stated, "and that's so individualized... our patients are very sick because of the type of patients that are referred and so they're blood pressure is often 90 (mmHg) and we don't bat an eyelash and in another setting, 90, it's time to call a code". Another clinician summarized their concern as, "the only fear I have is you've got people making decisions who may not know the patient and how is that going to reflect on outcomes in patients".
4 Legal liability
Clinicians were concerned there would be legal implications if they did not act quickly after receiving an alert their patient's health was decompensating. "They see the message and right away have to respond. We can't be late 2 or 3 h. We can't. Even if it's a trivial thing, someone has to do it. And that's the reason that a designated person should be in charge of it." The clinicians believed a required component of the system was a method to record their actions (e.g., contacting the patient by phone) after receiving an alert as legal documentation. Some clinicians also stated they could not trust the system was sending the emails or the patient received the alert.

3.1.4. *Mitigating clinicians' concerns*

Some of the challenges and concerns revealed in the interviews were mitigated during the development of the rule set by employing the following methods.

1 Developing a matrix of possible outcomes
The information from the first set of interviews was used to create a matrix detailing a draft rule set. The matrix accounted for all scenarios by specifying the alerts and instructions for all possible combinations of the parameters to be monitored (i.e., symptoms, weight, blood pressure, and heart rate). Each cell of the matrix was categorized into one of several different possible outcomes. This was

Table 3 – Number of alert/instruction messages sent to patients.

Alert number	Patient message	Number of messages sent to patients
1	"Your measurements are fine today"	4578
2–3	"If you feel worse later today, use the system to take symptoms"	601
4	"Contact HF Clinic/family Dr. Go to Emerg Dept if you feel you should" or "Follow doc's orders: take extra 40 mg lasix now. Restrict salt & fluids" (message depends on if the clinician indicated in the patient's profile that the patient had been instructed to increase the lasix dose by themselves in these circumstances)	418
5	"Contact the Heart Function Clinic or your family doctor"	341
6	"Contact HF Clinic/family Dr. Go to Emerg Dept if you feel you should"	210
7	"Contact HF Clinic/family Dr. Go to Emerg Dept if you feel you should" or "Follow Dr.'s orders:take 40 mg lasix.Call HF Clin. Go to Emerg if need be" (message depends on if the clinician indicated in the patient's profile that the patient had been instructed to increase the lasix dose by themselves in these circumstances)	50
8	"Have someone drive you to the local Emergency Department or call 911 now"	0

done to help organize and simplify the complex decision-making process, and to ensure uncommon situations were not missed. See Fig. 2.

2 Identifying a clinical champion
When conflicting information was obtained through the interviews (usually related to health provider preferences), the head of the Heart Function Clinic, who was the clinical champion of the project, was asked to make an executive clinical decision (e.g., exact circumstances when a clinical alert would be sent).

3 Validating the draft rule set
Nine heart failure specialists validated the draft rule set to help ensure it was clinically appropriate. During the individual interviews, clinicians were presented with the parameters to be monitored (including the specific symptom questions) as well as the patient alerts and instructions that would be generated from different combinations of symptoms and abnormal readings. The clinicians were asked to voice any concerns and suggestions to improve the rule set. The concerns and suggestions were incorporated into the final version of the rule set.

4 Identifying the most appropriate on-call clinician
For the trial, the on-call clinician was the clinical champion of the project. She was the main cardiologist for the large majority of the patient participants, and therefore was familiar with the medical history and personalities of the participants. The intent was to have nurse practitioners as the on-call clinicians for any future implementation of the telemonitoring system because they would personally know the patients and they already closely follow high-risk patients.

5 Developing a method to document clinical actions
The clinician website to view patient information and set parameters also enabled the clinicians to record any actions they took, such as calling the patient.

3.2. *Randomized controlled trial results*

Table 2 summarizes the demographics and clinical characteristics of the patient participants, which are representative of the patient population attending the UHN Heart Function Clinic. Below is a summary of the process and health outcomes from the trial.

3.2.1. *Process outcomes*

On average, participants completed between 5 and 6 days of their possible daily readings per week throughout the 6 months. During the trial, 1620 alert messages/instructions were sent to the patients. Each time an alert message/instruction was sent to the patient, the on-call clinician also received an email alert. Low priority alerts were more frequently generated than the more urgent alerts (Table 3). The types and numbers of clinical actions that occurred directly due to the alerts are displayed in Table 4. It should be emphasized that these clinical interactions would not have occurred prior to the implementation of the telemonitoring system. The on-call clinician spent on average between 30 and 60 min a day calling patients due to the alerts. This was additional time spent by the clinician compared to prior to the implementation of the telemonitoring system.

3.2.2. *Health outcomes*

The primary health outcome measures included quality of life (measured with the Minnesota Living with Heart Failure Questionnaire [23]), Brain Natriuretic Peptide (BNP) values (surrogate for heart failure prognosis) [24], and self-care (measured with the Self-Care of Heart Failure Index [25]). The change in quality of life from baseline to post-study was significantly greater for the TM group compared to the SC group ($P = .05$). A between group analysis also found greater post-study self-care maintenance for the TM group ($P = .03$). BNP levels, self-care management, and left ventricular ejection fraction (LVEF) improved significantly for both groups from baseline to post-study, but did not show a between group difference. Being enrolled into the clinic was a confounder to the improvements from the telemonitoring. Patients who were new to the clinic (enrolled less than 6 months) showed greater improvements when compared with the patients who were enrolled into the clinic over 6 months (BNP $P = .003$; LVEF $P = .02$). A subgroup analysis, removing the 37 new patients (18 patients in the TM group and 19 patients in the SC group), found only the TM group had significant improvements in BNP values (decreased by 150 pg/mL, $P = .02$), LVEF (increased

Table 4 – Clinical process outcomes.

Process outcome	Occurrence over 6-month trial
Number of times clinicians logged onto website	101
Number of times clinicians phoned patient due to alerts	480
Number of times medication changed or medication instructions given	105
Number of times additional blood work ordered	26
Number of times clinic visit moved earlier	9
Number of times patients instructed to go to local emergency department	6
Number or times patients instructed to contact family physician	4

by 7.4%, $P = .005$), and self-care maintenance (increased by 7 points, $P = .05$) and management (increased by 10 points, $P = .03$). No differences in hospitalization or mortality rates (secondary outcome measures) were found between the TM and SC groups, but the trial was underpowered to detect changes in these measures. The detailed quantitative and qualitative results from the trial have been reported in separate publications [20,21].

4. Discussion

Heart failure clinicians participated extensively in the development of a rule set that generated patient alerts/instructions and alerts sent to an on-call clinician. The rule set was implemented in a heart failure telemonitoring expert system and evaluated with a randomized controlled trial. A large number of clinical actions resulted from the alerts generated by the rule set, particularly with respect to optimization of medication ($N = 105$ over the 6-month trial). The trial indicated improved quality of life and self-care were associated with the use of the expert system, and suggested it may improve BNP and LVEF.

4.1. *Impact of the rule set on clinical management*

The implementation of the rule set in the telemonitoring system had several significant effects on clinical management of heart failure patients. The most common clinical action taken from the alerts was medication titration, with the majority of these being an adjustment in the amount of diuretic medication being taken. Ordering of additional blood tests and moving the patient's heart function clinic visit earlier were less common outcomes from the alerts.

> "Maybe once a week, you really catch somebody sliding where you can intervene... It occurred to me, (without the telemonitoring system) I wouldn't have this phone call or this intervention." (Cardiologist 1)

Instructing the patients to go to the emergency department occurred only six times during the trial. However, these occurrences could have had significant impact on the health of the patients because they would have likely waited longer before seeking attention, leading to worse health outcomes. It is well documented that patients often do not seek timely medical attention when they have symptoms of worsening heart failure [26,27]. Included in these six instances when the cardiologist instructed the patient to go to the emergency department were two cases where patients discovered they had cancer. These patients likely discovered the cancer earlier due to the instructions by the cardiologist. In total, participants in the TM group went to the emergency department 16 times during the 6-month trial, while participants in the SC group visited the emergency department 11 times. However, the difference was not statistically significant ($P = .6$). It should be noted that although the message to visit the emergency department if the patient thought they should was generated several hundred times, the intent was to remind them of the option and not necessarily to recommend they should go.

For the trial, the clinical champion received and responded to the alerts, with another cardiologist managing the alerts when the clinical champion was away on vacation. For any future long-term use of the telemonitoring system, the intent is to have nurse practitioners manage the alerts. Nurse practitioners at the UHN Heart Function Clinic are well suited to manage the alerts because they know the patients, which the clinicians believe is an important aspect of telemonitoring. In addition, the nurse practitioners already closely monitor the high-risk patients through phone calls, emails, and clinic visits. During the post-trial interviews, the clinicians at the clinic expressed they believed the benefits of the telemonitoring system, such as the ability to better titrate mediation and immediate alerting of decompensation, outweighed the additional time required to manage the alerts. Although clinical workload would initially increase to manage the alerts, further research with a larger sample size is required to determine if telemonitoring later reduces clinical workload through decreased hospital admissions and length of hospitalization.

> "I think it is a reasonable workload for somebody who doesn't have already as full a workload as I have. So, I think that on an ongoing basis it would be ideally suited to a nurse practitioner as part of their job requirements." (Cardiologist 2)

The cardiologist managing the alerts usually called the patients whenever they received an email alert, which accounts for the high number of calls the cardiologists made to the patients. An example of an exception was when a low priority alert was sent and the cardiologist knew it was generated because the patient always had a slightly low blood pressure because of their medication. There were many more alerts sent than phone calls to the patients because patients sometimes took multiple readings consecutively (e.g., blood pressure readings), which generated multiple alerts. The alerts to the patients often included instructions to call the clinic or their family physician if they thought they should, in case the

clinician who was managing the alerts did not call them and also to promote self-care.

4.2. *Impact of the rule set on patient self-care*

The benefits found in the trial are likely from a combination of factors from telemonitoring, such as alerting the on-call clinician at the earliest sign of decompensation, additional physiological data for clinical decision-making, and increased awareness by the patient of their health condition through daily physiological measurements. However, it was evident from the post-trial interviews the expert system also led to positive self-care behavior changes. In particular, the automated patient instructions/alerts provided feedback to the patients at the most relevant times (i.e., teachable moments) [28]. The expert system reinforced in the patients the most appropriate action to take depending on the physiological measurements and symptoms. For example, the automated instruction to reduce salt and fluid intake helped patients to correlate salt and fluid intake with weight change and symptoms. As another example, the automated instruction to take an extra dose of diuretic medication reinforced previous instructions from the clinicians, which was necessary because many patients were uncomfortable with adjusting the diuretic medication dose without prior confirmation.

> "It really taught me what the correlation is between salt intake and weight and water retention. An above normal sodium intake will show up immediately the next day as a weight gain and then as you clear that out of your system it goes back." (Patient 1)

The patient participants adhered well to taking daily measurements, and the majority of them wanted to continue to use the system after the trial. Many participants expressed increased empowerment and self-confidence from using the system [20]. Only a few patients did not want to continue to use the system because they did not want to be "watched" long-term, even though they believed they learned more about self-care during the trial.

> "The monitoring system has become very important in my life. To not use it anymore almost makes me feel lost without it." (Patient 2)

4.3. *Previous use of expert systems in healthcare*

Although automated telemonitoring expert systems are a relatively new area of research, the use of expert systems for clinical decision support systems (CDSSs) has been previously studied. Garg et al. [29] performed a systematic review of the effects of CDSSs and found in 100 controlled trials, CDSSs improved practitioner performance in 64% of the studies. These CDSSs included diagnostic, reminder, disease management, and drug-dosing or prescribing systems. Similar results were found in the systematic review by Kawamoto et al. [30] of randomized controlled trials, where practitioner performance improved in 68% of the 70 studies reviewed.

Expert systems have also been used to positively affect the behaviour of patients, such as with respect to smoking and weight management [31,32]. The positive outcomes from the use of expert systems in these previous trials suggest well-designed tailored telemonitoring expert systems could also produce improved outcomes. The findings from our research support this hypothesis.

4.4. *Gap between guidelines and clinical practice*

The Heart Function Clinic follows best practices as outlined in clinical practice guidelines. However, the workflow and policies of the clinic had to be also incorporated into the rule sets. For example, the clinicians wanted an email alert to be sent to the on-call clinician even for very low priority alerts, such as if the patient had all normal readings but felt more tired than usual that day. As another example, instructions on how to seek medical attention could vary depending on different institutions, such as contacting a primary physician, cardiologist, clinic, etc.

In addition to accounting for workflow and policies, rule sets may also need to take into consideration individualization of patients. Patients have varying self-care capabilities, medical histories, and preferences rule sets may need to reflect. For instance, sending automatic reminders to take an extra dose of diuretic medication under certain circumstances was appropriate for some patients and not for others, depending on medical and personal factors. As a second example, the rule set had to account for some patients taking ECGs, while patients with ICDs were not given ECG recorders because they were not certified for use with ICDs. Furthermore, the target blood pressure, heart rate, and weight values were set for each patient and could be adjusted whenever necessary.

4.5. *Limitations*

Although great effort was taken to optimize the rule set, some necessary modifications to the expert system were discovered during the trial. For example, alerts were generated when patients lost several pounds of weight intentionally after taking extra diuretic medication. In this circumstance, a more appropriate patient message indicating the weight loss was likely due to the extra diuretic medication taken the day before should be used. Although no reported instances of missed patient decompensation by the expert system were reported during the trial, false positives were reported 57 times when patients pressed the wrong key accidentally when answering symptom questions. In particular, some patients accidentally pressed 1 instead of 0 when answering the question: *How many times did your ICD go off?* The high frequency of mistakes was due to the rest of the symptom questions being yes/no questions with 1 representing "no" and 2 representing "yes". Therefore, patients sometimes pressed 1 to indicate their ICD did not fire. In future versions of the telemonitoring system, the ICD question will be changed to a yes/no question to eliminate this problem. Ongoing improvements to rule sets should be anticipated when they are implemented. In addition, rule sets should be periodically updated and validated as the needs, workflow, and expectations of the users change and best-practices advance.

A shortcoming of the developed rule set is it cannot be simply applied for all heart failure telemonitoring systems without first validating its appropriateness. The developed

rule set was tailored for the policies and current workflow of the clinicians from the UHN Heart Function Clinic and has been validated through the trial for long-term implementation at the clinic. However, the iterative development process depicted in Fig. 1 can be used to develop and modify rule sets for other clinical settings, telemonitoring systems, and healthcare applications. In addition, the lessons learned from our study can help with development of successful rule sets. These include the need to identify a clinical champion at the very beginning of the project, to validate each draft rule set with the end users, to ensure all corner cases are included (e.g., through the use of a comprehensive matrix), and to account for the workflow and policies of the institution using the rule set.

Finally, the small screen of the mobile phone posed another limitation to creating the rule set. The messages sent to the patients on their mobile phones were often abbreviated and reduced in content in order to fit the messages onto the screen.

Summary points

What was already known on the topic

- Processes to create rule sets for healthcare expert systems have not been extensively studied.
- To our knowledge, there has not been a published rule set for expert systems for heart failure telemonitoring.
- Currently poor understanding of the concerns of patients and clinicians on using expert systems for telemonitoring and how to address these concerns.

What this study added to our knowledge

- A process for development of rule sets for healthcare expert systems.
- A rule set that can be used as a basis for heart failure telemonitoring systems that has been validated as feasible and beneficial in a randomized controlled trial.
- Clinician and patient concerns with using expert systems for heart failure telemonitoring and methods to mitigate these concerns.

5. Conclusions

A rule set for automated alerts and patient instructions for heart failure telemonitoring was developed with extensive input from heart failure clinicians. The rule set was evaluated through a randomized controlled trial. The trial findings indicate the rule set was associated with improved clinical management, self-care, and quality of life. Although the resultant heart failure rule set should not be applied verbatim to other clinical settings without validation, the development process and lessons learned can be applied to create rule sets for other clinical settings and for a variety of other health applications.

Authors' contributions

The corresponding author was the primary researcher involved in the development of the expert system and its evaluation, including the participant recruitment, maintenance of the telemonitoring system, data gathering, and data analysis. She also was the main author of the manuscript. The other authors provided advice and expertise throughout the research and creation of the manuscript. In addition, Dr. Heather Ross was the clinical champion of the project and responded to the clinical alerts during the trial. Caterina Masino helped during the recruitment of the patients and the qualitative analysis.

Conflicts of interest

The researcher who developed the expert system also was the study coordinator for the randomized controlled trial.

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