# Computerized Practice Guidelines for Heart Failure Management: The *HeartMan* System

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*In this paper we discuss the initial stages of development and evaluation of the HeartMan system, a set of computerized practice guidelines for heart failure management. The concept of computerized guidelines as a hybrid of expert systems and practice guidelines methodologies and techniques is proposed. We show the results of the initial evaluation of the system, which are very promising, although the sample size is small, and the study is retrospective: Of 177 messages, 90% were considered appropriate, of which 97.5% would have been followed. Eight percent of the messages were classified as neutral, and 2% classified as inappropriate. The errors were correctable by changing the logic. The potential technical and sociological barriers to the complete development and clinical use of the system are discussed.*

## INTRODUCTION

Heart failure is the "pathophysiologic state in which an abnormality of cardiac function is responsible for the failure of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues and/or can do so only from an abnormally elevated filling pressure" [1]. It is a common disorder, easy to diagnose, but potentially lethal (10 to 30% mortality per year). In the United States, treatment of heart failure is estimated to cost $8 to 10 billion per year. Effective therapy exists, but is underused [2]. Thus, there are many good reasons to try to improve quality of care in this area. The Agency for Health Care Policy and Research (AHCPR), recognizing this need, published guidelines for the management of heart failure in June 1994 [3], as did the Canadian Cardiovascular Society shortly after [4]. Nevertheless, heart failure management has been an area where there has been no consensus traditionally, even in regard to general issues such as when to consult a cardiologist [5].

Practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances" [6]. The purpose of practice guidelines is to reduce unexplainable variation in practice patterns [7], with the expectation of improving quality and decreasing costs. Practice guidelines also have potential adverse effects [6]. An evidence-based approach to the development of practice guidelines is recommended. In the AHCPR guidelines [3], strength of evidence is graded from *A* (good evidence from well-conducted randomized controlled trials or cohort studies) to *C* (expert opinion only). Although well-documented strategies to develop guidelines have been described [8], effects on clinical practice remain largely unknown [9]. The difficulty with implementation is one of the main limitations to widespread use of practice guidelines [10]. Computerization is seen as one of the ways to overcome this problem [11].

Practice guidelines are congruent with continuous quality improvement (CQI) efforts by "specifying preferred methods of care" [12]. The use of computers can enhance CQI strategies by helping in the intense data processing needed in CQI, and because of the "limits to man's capabilities as an information processor" [13].

The concept of computerized practice guidelines is a hybrid of expert systems and practice guidelines, in the context of CQI. There has been previous work related to models for the computerization of practice guidelines [14]. In this paper we report on the design, development, and first formal evaluation of a set of computerized practice guidelines for heart failure management: the *HeartMan* system. We will also describe an assessment of the efforts necessary to put the system into practice in different clinical situations.

## METHODS

### Development of the System

The development of the *HeartMan* system can be divided into the following phases: 1) Selection of the model, the choice of modes of intervention and

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targeted areas of heart failure management to computerize. 2) Knowledge acquisition and representation. 3) Data representation. *HeartMan* is in an early stage of development and evaluation, i.e., combination of components into a system and initial evaluation, with retrospective patient data collected through chart review [15]. At this point in time, *HeartMan* is a prototype standalone system running in a PC environment under Windows.

### Selection of the model, modes of intervention and targeted areas to computerize

We decided to use a rule-based model because the sources of knowledge tended to be based on rules [3, 4], and we also wanted to concentrate on temporal trends instead of probabilities.

Modes of intervention can be divided into alerts, reminders, suggestions, and critiques [16, 17], with some overlap. *HeartMan* uses all four modalities.

We focused on moderate to severe systolic left ventricular dysfunction, as did the AHCPR guidelines [3]. Within our targeted area, the system attempts to cover the main aspects of heart failure management decisions for the outpatient (fig. 1).

- Data Documentation (4)
- Clinical Status (13)
- Lab and Other Diagnostic Procedure Results (13)
- Lab and Other Diagnostic Procedure Ordering: insufficient or excessive use (14)
- Medications: Drug-disease, drug-drug, and drug-lab (41)
- Non-medication Therapies (18)
  - Hospitalization/Referral/Scheduling
  - Therapeutic Procedures
  - Education

**Figure 1. Targeted areas for computerization, and number of rules in each area (103 total rules).**

### Knowledge acquisition and representation

The knowledge acquisition began with a literature review and sessions with the experts several months prior to the publication of the AHCPR guidelines. When these and the Canadian guidelines were available, we incorporated them into the knowledge base, with an emphasis on compliance with the AHCPR guidelines. Other literature sources were needed for individual rules. Lastly, the clinical experiences of a heart failure expert (EMG), a cardiologist (BEB), and a general internist (AM) were incorporated into the knowledge base.

Knowledge representation started with the writing of all rules in pseudocode (fig. 2). To computerize the rules, CLIPS expert system shell was used (fig. 3) [18], because of its flexibility for rule-based expert system construction. CLIPS has been used in several medical applications [19, 20, 21].

122045 Stress importance of low-sodium diet

**If**: - (Sodium Retention Score >=5, current, *OR*
- NYHA class III or IV, current)
AND NOT
- First Visit

**Then**: Stress importance of low-sodium diet as a main element of therapy for this patient.

**Revisions: Dec. 19, 1994 (Dr. EM Gilbert).**
**Source: AHCPR Guidelines, page 44; Sessions with experts.**

**Figure 2. Example of Rule Pseudocode.**
**A rule with simple logic was selected.**

```
(defrule low-sodium  "122045 Importance of low sodium diet"
   (object (is-a VISIT)
        (date ?current-date)
        (order 1))
   (object (is-a VISIT)
        (date ?first-date&:(> ?current-date ?first-date))
        (status FIRST))
   (or   (object   (is-a RESULT)
                   (description SRS)
                   (date ?srs-date&:(= ?srs-date ?current-date))
                   (value ?srs-value&:(>= ?srs-value 5)))
         (object   (is-a RESULT)
                   (description NYHA)
                   (date ?nyha-date&:(= ?nyha-date ?current-date))
                   (value ?nyha-value&:(>= ?nyha-value 3))))
=>
(printout mydata   "122045|a|==>Stress importance of low-sodium diet in this patient.
   Reason: " crlf)
(printout mydata   "122045|b|Elements of high sodium retention and/or high NYHA
   functional class. " crlf))
```

**Figure 3. CLIPS Code for the rule in figure 2.**

### Data representation

An interface using Microsoft Access 2.0 database management system was built, in order to represent data, design the forms for data entry, and design the reports for system evaluation. We also used Access to write the code that supports the interaction with CLIPS. This interaction is done through text files in both directions. An example of patient data and the messages triggered for this patient visit is shown in figures 4 and 5.

## Evaluation of the System

The evaluation strategy of a system like *HeartMan* is difficult, because it attempts to evaluate both "a piece of software and a model" [22]. We had a general research question about the model: *Can a rule-based model represent knowledge in Heart Failure*

*Management?* Heart failure management is an unstructured domain, where there are many uncertainties. A probabilistic model would be potentially appealing, and some researchers have worked on such an approach for heart failure [23].

- 68 year-old gentleman, with a history of heart failure probably secondary to rheumatic valve disease (considered for medical treatment only, at this point in time). Chronic Atrial Fibrillation. Severely symptomatic in previous visit. Last ejection fraction = 19% *(very low)*.
- Treated with digoxin, captopril *(an ACE inhibitor)*, furosemide*(a diuretic)*, potassium supplements and warfarin *(an anticoagulant)*.
- This is the second visit to the clinic:
  - Dyspnea on moderate exertion. Blood pressure = 96/64. Heart rate = 56.
  - Serum potassium is 4.7 meq/l *(upper normal value)*.
  - A Holter electrocardiographic monitoring was done.

**Figure 4. Summary of patient data.**

- Caution in the use of digoxin. Reason: Current bradycardia.
- Risk of hyperkalemia due to serum potassium in the upper normal values, use of ACE inhibitors and potassium supplements or potassium-sparing diuretics.
- Holter monitoring was ordered after last visit or today. There is no documented reason to order it: For example, ventricular tachycardia or syncope unrelated to orthostatic hypotension. Please document the reason -- clinical research, other --.
- Consider pneumococcal vaccination, if no contraindications. Reason: no vaccination documented in the past, in a risk patient.

**Figure 5. Some of the messages for this visit.**

The results reported in this paper correspond to the first formal cycle of evaluation of the system, performed during its refinement phase. We did the refinement of the knowledge base using 10 patients. The last five cases were analyzed without changing the knowledge base (25 visits): we will refer to this group of 5 patients and 25 visits as the *formal evaluation* patients. The source of the patients was a random selection of eight cases from a list of 71 patients from the heart failure clinics. We also included two general cardiology patients with less severe symptoms in the formal evaluation group.

The analysis was done with patient information abstracted through chart review. Patient information and messages for the visit were then printed for the review, using Access reports. The messages were scored by a heart failure expert (EMG).

The variables considered were: 1) *Appropriateness of the message*: appropriate, neutral, or inappropriate. 2) If appropriate: *Would the expert act as instructed by this message?* 3) If inappropriate: *Would following this message create a life-threatening situation?*

The final question, after reviewing all the messages for the visit, was: *Should there have been any additional messages for this visit?*

## RESULTS

### Initial System Evaluation

The ages of the patients ranged from 49 to 73. The majority were male (9/10). The NYHA functional class varied from severely symptomatic to almost asymptomatic patients. The cardiac function was usually severely compromised. The etiology of heart failure varied, but most of the patients in the formal test group had coronary artery disease.

The proportion of the 103 possible rules that were evaluated at least once is the following: After the fifth patient, 50% of the rules had been evaluated. This percentage increased to only 58% after 5 more patients. These data are important in order to understand the percentage of the knowledge base that has actually been evaluated

The number of messages generated for the 25 visits in the formal evaluation was 177. One-hundred and fifty-nine (90%) were considered appropriate, 14 (8%) neutral, and 4 (2%) inappropriate.

The four inappropriate messages could be considered potentially life-threatening. One message with two occurrences was considered potentially life-threatening: "MAXIMUM acceptable interval for next visit is three months in patients who have been followed in the clinic for 30 to 90 days. Adapt this interval to the specific conditions of the patient." This message was considered potentially life-threatening because the reviewing expert felt that the patient should be followed more closely. A provider who received the alert might reschedule the patient for follow-up with an inappropriate interval.

Of the 14 neutral messages, six were considered so because a change in drug therapy was suggested (from ACE inhibitors to a combination of nitrates and/or hydralazine). The reason for this suggestion was a side effect with the ACE inhibitors. The expert thought the ACE inhibitors should be given another try. Four of the neutral messages were so classified because the system was using the *last* serum potassium, but this value was *old*. The other neutral messages were related to missing logic or an incorrect threshold.

The 159 appropriate messages were further classified based on whether the expert would have complied with them or not. The expert would have acted on 155 of them (97.5%), and not acted on 4 (2.5%). As an example, the reasons for not acting included a critique to the ordering of another cardiac imaging technique: the critique was appropriate, but the test was ordered as part of a clinical research protocol rather than for clinical decision making.

**Data sources**

We analyzed the sources of the information necessary for the rules, considering several levels of completeness of data capture. These are the results (fig. 6):

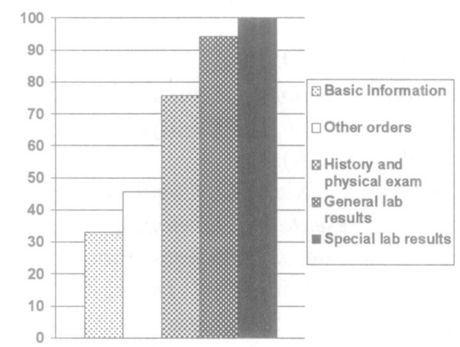


Figure 6. *Cumulative percentage* of rules that have enough information, as data sources increase. See explanation in text.

Level 1) <u>Basic information</u>: An ambulatory information system in its first stages would have demographic data, list of visits, problems, medications, and general clinical laboratory tests ordered. This would provide enough information for 34 rules (33%).

Level 2) <u>Other orders</u>: If a small additional effort was made to enter other diagnostic and therapeutic procedures ordered or performed (but not the results), 47 rules (46%) would have the necessary information.

Level 3) <u>History and physical exam</u>: If history and physical exam findings were available in a coded format as well, 78 rules (76%) could be used.

Level 4) <u>General laboratory results</u>: If general laboratory results were also available, then 97 rules (94%) would have the necessary information.

Level 5) <u>Special laboratory results</u>: This category includes the results of other diagnostic procedures (electrocardiogram, chest x-ray, and others). All the rules would have enough information if these results were also available.

If no extra data entry is assumed (only level "1" - basic information), but the information system can capture the general laboratory results directly, 51 rules (50%) would have enough information.

## DISCUSSION

The initial evaluation shows that the system behaves as designed. There also does not appear to be any intrinsic limitation for a rule-based model to represent knowledge in heart failure management: all the inaccuracies can be corrected by changing the logic. These results should be taken cautiously, because of the small sample and the retrospective nature of the initial study.

After we have enhanced the knowledge base with the suggestions of the experts, the system will be re-evaluated. An additional evaluation of the discrepancy or concordance between the decisions made by the treating physician, and the computerized system will be undertaken [14].

*How difficult would it be to put the HeartMan system into clinical use?* After the knowledge base is validated, there are still technical and sociological issues to be addressed.

First, the technical problems have to be carefully addressed. Some of the system's requirements are: complete, accurate and non-redundant data, knowledge base verification [24], integration into a more comprehensive ambulatory system, and vocabulary enhancement [25]. The need for a flexible but complex expert system shell must also be discussed.

Second, one important sociological barrier is the difficulty of direct physician data entry. Direct data entry is critical if we want to provide real-time feedback. Capture of all the information except for special laboratory results (level "4") may be a reasonable compromise if the providers are specially motivated. Using this approach, 94% of the rules can be implemented. A more pragmatic strategy, where simple information is entered in the computer but general laboratory results are retrieved directly, can still allow the implementation of half of the rules.

## CONCLUSIONS

We have reported our experience with the initial stages of development and evaluation of the *HeartMan* system, a set of computerized guidelines for heart failure management. The addition of evidence-based medicine, embedded in practice guidelines [3], into the usual heuristics of expert systems, and the use of expert systems to implement clinical practice guidelines, provide a turning point for both methodologies. We hope this combination can make both strategies more accessible, taking practice guidelines off of the shelves, and making expert systems more usable.

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