Case Report ■

Computerizing Guidelines to Improve Care and Patient Outcomes: The Example of Heart Failure

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Abstract Increasing amounts of medical knowledge, clinical data, and patient expectations have created a fertile environment for developing and using clinical practice guidelines. Electronic medical records have provided an opportunity to invoke guidelines during the everyday practice of clinical medicine to improve health care quality and control costs. In this paper, efforts to incorporate complex guidelines [those for heart failure from the Agency for Health Care Policy and Research (AHCPR)] into a network of physicians' interactive microcomputer workstations are reported. The task proved difficult because the guidelines often lack explicit definitions (e.g., for symptom severity and adverse events) that are necessary to navigate the AHCPR algorithm. They also focus more on errors of omission (not doing the right thing) than on errors of commission (doing the wrong thing) and do not account for comorbid conditions, concurrent drug therapy, or the timing of most interventions and follow-up. As they stand, the heart failure guidelines give good general guidance to individual practitioners, but cannot be used to assess quality of care without extensive "translation" into the local environment. Specific recommendations are made so that future guidelines will prove useful to a wide range of prospective users.

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Health care providers have always striven to minimize errors and maximize patient benefits. In this regard, the Information Age has created a double-edge sword. Although we know more about the causes of disease and have more diagnostic and therapeutic options, there is too much information in the hundreds of medical journals for clinicians to digest. At the same time, there are mountains of patient data from ever-expanding numbers of diagnostic tests and imaging studies. Patients are often dazzled by this high technology and come to clinical encounters with great expectations that may put pressure on clinicians to perform all relevant diagnostic tests and to prescribe the latest, most expensive treatments. This has fed the explosive growth in health care costs, and yet there remains enormous variation in medical practice[1] and patient outcomes.[2]

High health care costs, and evidence of practice variation, and patient demands for high-quality care have stimulated federal agencies and professional organizations to develop clinical practice guidelines.[3] These guidelines, defined as systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances,[4] usually target clinicians, but could also be used by hospitals, managed care organizations, payers, regulators, and researchers to assess provider performance, improve decision making, and optimize patient outcomes. Meanwhile, recent advances

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in medical informatics could help clinicians manage massive amounts of patient data,[5,6] while providing a means for accessing the medical literature[7] and knowledge bases[8,9] and implementing practice guidelines.[5,10] The degree to which these systems can foster adherence to guidelines will depend on their ability to access and store appropriate data and automate the guideline logic.

In this paper, we describe our attempt to implement one set of guidelines, those from the Agency for Health Care Policy and Research (AHCPR) for treating heart failure,[11] using a network of microcomputer workstations at one urban teaching hospital.[12] We discuss our successes and failures and make recommendations for future guideline development.

Physicians' Workstations

In 1988, we installed a network of physicians' order-writing microcomputer workstations in an urban public hospital containing a mature, comprehensive electronic medical record system.[13,14] In a series of randomized controlled clinical trials on the inpatient general internal medicine service, we examined the ability of information, presented during workstation order-writing, to lower health care costs and improve health care quality. Using problem-specific menus and displaying patient-, problem-, and task-specific information that had reduced costs in prior outpatient studies,[15–17] the workstations were specifically designed to encourage efficient ordering. The workstations themselves had been studied in a randomized controlled trial, where physicians using them to write all inpatient orders generated 13% lower inpatient charges ($887 less per admission) and 11% shorter lengths of stay (0.9 days) with no diminution in quality of care when compared with control physicians who wrote orders in paper charts.[12]

Once the above study had been completed and the workstations had been used to write all inpatient orders, we have a potent platform for computerizing patient care guidelines and studying their effects. The guidelines were programmed into the workstation software (written in Advanced Revelation, Revelation Technologies, Stamford, CT) using an automated version of the CARE programming language that we had used in prior reminder studies.[10] For all of the subsequent workstation studies, the guidelines wrote suggested orders (with accompanying explanatory text) that the physicians could accept with a single keystroke or mouse click. In a controlled trial, physicians who received suggested orders for monitoring inpatient drug therapy doubled their compliance with no increase in costs or length of stay.[18] However, automating guidelines for providing preventive care to inpatients (such as performing a mammogram on a 50-year-old woman admitted for a urinary tract infection) had no effect on physician performance, primarily because the physicians viewed the inpatient service as an inappropriate venue for providing preventive care.[19] From this we concluded that automating the guidelines did not necessarily change physician practice; the content of the intervention was also important.

We are currently using these workstations in our primary care general medicine practice to automate guidelines for heart disease, pulmonary insufficiency, and hypertension. A randomized controlled trial is being conducted to evaluate the use of guidelines to suggest orders for drug therapy, nonpharmacologic therapy, and diagnostic testing.

The AHCPR Heart Failure Guidelines

The heart failure guidelines for this study were based primarily on the AHCPR's publication *Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction*.[11] Where necessary, we supplemented them with guidelines published by the American College of Cardiology, an extensive review of the published literature, and a local consensus panel of cardiologists and general internists.

To identify eligible patients and navigate the AHCPR algorithm, we mainly used data that are routinely available from the Regenstrief Medical Record System.[14] These data included diagnoses (from any inpatient, outpatient, or emergency department site), inpatient and outpatient vital signs, diagnostic test results (captured electronically from the clinical laboratory and all imaging services), and prescriptions filled at the inpatient or outpatient pharmacy. Where absolutely necessary, information was requested from the ordering physician. For the heart failure guidelines, a physician was asked to enter only the patient's blood pressure and weight that day and the patient's New York Heart Association (NYHA) functional class.[20]

Difficulties Encountered Automating the AHCPR Heart Failure Guidelines

Table 1 shows the 16 primary actions recommended by the AHCPR guidelines. Of these, only one (initial evaluation) was programmed into the workstations with minimal or no changes. Six were not included in the workstations because they dealt with inpatient care, revascularization, and cardiac transplantation and therefore were not relevant to outpatient drug

Table 1 ■

Original Action Points of the Agency for Health Care Policy and Research (AHCPR) Heart Failure Guidelines and Changes Necessitated to Program Them into the Workstations

AHCPR Heart Failure Guideline Action	Algorithm Changed?*				Comments about Workstation Guidelines
	Y	?	N	E	
Initial evaluation			X		Simple presence or absence of selected test results
Alternative diagnosis identified?				X	Eligibility depends on objective echocardiographic criteria
Requires hospital management?				X	This is an outpatient drug management program
Initiate diuretics	X				Most specific signs and symptoms not in electronic record; relies on change in weight
Measure left ventricular dysfunction		X			Relies on left ventricle measurements other than ejection fraction or text of cardiac imaging studies
Consider diastolic dysfunction		X			Uses echocardiogram results, but decisions are based on explicit thresholds of measurements
Patient and family counseling		X			Patient education text can be printed from workstations; reminders to discuss specific risk factors and behaviors
Initial pharmacologic management		X			Local opinion favors lisinopril as default ACE† inhibitor; otherwise, no differences
Contraindication to bypass?				X	Outpatient drug management program only
No angina, no myocardial infarction: refer to counseling				X	Outpatient drug management program only
No angina, but prior myocardial infarction: stress testing and possibly catheterize	X				Local cardiologists and general internists disagree with invasive testing for asymptomatic patients
Angina: cardiac angiography	X				Local practice is to refer mainly younger patients and those who have refractory angia for catheterization
Revascularize				X	Once catheterization is done, agree with indications
Good outcome? → follow-up	X				AHCPR guidelines have few objective criteria for "doing well"; judgment by physician using symptom history; workstation guidelines use NYHA‡ class to rate functional status
Additional drug management		X			Need explicit definition of "continued symptoms" and "volume overload" to navigate branch points
Cardiac transplantation				X	Outpatient drug management program only

*Y = yes; ? = similar, but not exactly the same; N = no; E = excluded from workstation guideline program.
†ACE = angiotensin converting enzyme.
‡NYHA = New York Heart Association.[20]

therapy. Of the remaining nine actions, four required substantial modification (e.g., changes in type of data used to trigger actions) and five required moderate modification to be automated in the workstations (most often by supplying specificity to definitions and treatment indications). For example, the AHCPR guidelines define left ventricular systolic dysfunction as having a left ventricular ejection fraction (by echocardiography) of "less than 35–40%."[11] This allows debate as to whether the guidelines apply to patients who have ejection fractions in the 35–40% range. Also, ejection fractions are not reported on our echocardiograms (despite the cardiologists at Indiana University being among the first developers of echocardiography[21]) because of their imperfect correlation with true ejection fractions. Although our local echocardiographers do report left ventricular size, fractional shortening, and fractional area change, the AHCPR guidelines do not use these measurements. Moreover, the guidelines provide no other alternative definition of left ventricular systolic dysfunction, which makes our confirmation of the diagnosis of heart failure, and eligibility for guideline algorithms, problematic.

Therefore, we defined left ventricular systolic dysfunction broadly using multiple sources of information and strict criteria: the diagnosis of heart failure recorded at any clinical encounter or on a chest radiograph, or any cardiac imaging study (echocardiogram, scintigram, or angiogram) with a left ventricular end diastolic diameter more than 6 cm or read as "left ventricular dysfunction," "left ventricular enlargement," "left ventricular volume overload," "generalized wall motion abnormality," or "low ejection fraction." Thus, the eligibility criteria on the AHCPR guidelines had to be "translated" into our local practice using available data. We used broad definitions, including diagnoses and other nonobjective criteria, to maximize sensitivity (and not miss

patients who might benefit from the guidelines' suggestions), allowing (and encouraging) the physician to refuse any inappropriate suggested orders.

The AHCPR guidelines also suffer from their failure to explicitly define many of the algorithm's branch points. Although this may be acceptable for guidelines that provide general guidance to individual practitioners, automating them to assess and improve clinical performance is difficult if eligibility for each decision is unclear (and therefore debatable). For example, the AHCPR guidelines state, "Digoxin should be added to the therapeutic regimen of those patients whose symptoms persist despite optimum doses of ACE inhibitors and diuretics." Operationalizing this rule requires explicit information about the presence and severity of symptoms and a definition of optimum doses of angiotensin converting enzyme (ACE) inhibitors and diuretics. We therefore required that the physician report the patient's NYHA functional class[20] and arbitrarily defined "persistent symptoms" as NYHA class III or class IV symptoms. We defined "optimum doses of ACE inhibitors and diuretics" with a complex rule that took into account drug dosages and the patient's blood pressure, renal function, and weight.

Like many conditions, heart failure ranges from asymptomatic to fatal, and treatment decisions change dramatically as the condition worsens. We therefore programmed the workstations to vary the strength of the recommendation with the condition's severity and the cost–benefit ratio of the available therapies. We accomplished this by making the default response to suggested orders be "order" for stronger recommendations (i.e., hitting the "enter" key or mouse button would accept the suggested order) and "omit" for weaker recommendations. In the example in Figure 1, hitting the enter key for enalapril orders it, whereas hitting the enter key for the pneumococcal vaccine order results in no action (omit the order).

The AHCPR Heart Failure Guidelines frequently hinge on data that are not routinely stored in most electronic record systems in a useful format (i.e., coded). For example, although the guidelines clearly state that ACE inhibitors should be used early and increased to maximum tolerated doses, the algorithm warns against using them for patients who have a "history of adverse reactions or intolerance." Similarly, the decision to perform coronary angiography on a patient who has concomitant angina hinges, according to the AHCPR guidelines, on the patient's having "exercise-limiting angina, angina that occurs frequently at rest, or recurrent episodes of acute pulmonary edema." Although such rules are useful to individual practitioners who can make these judgments during clinical encounters and act accordingly,

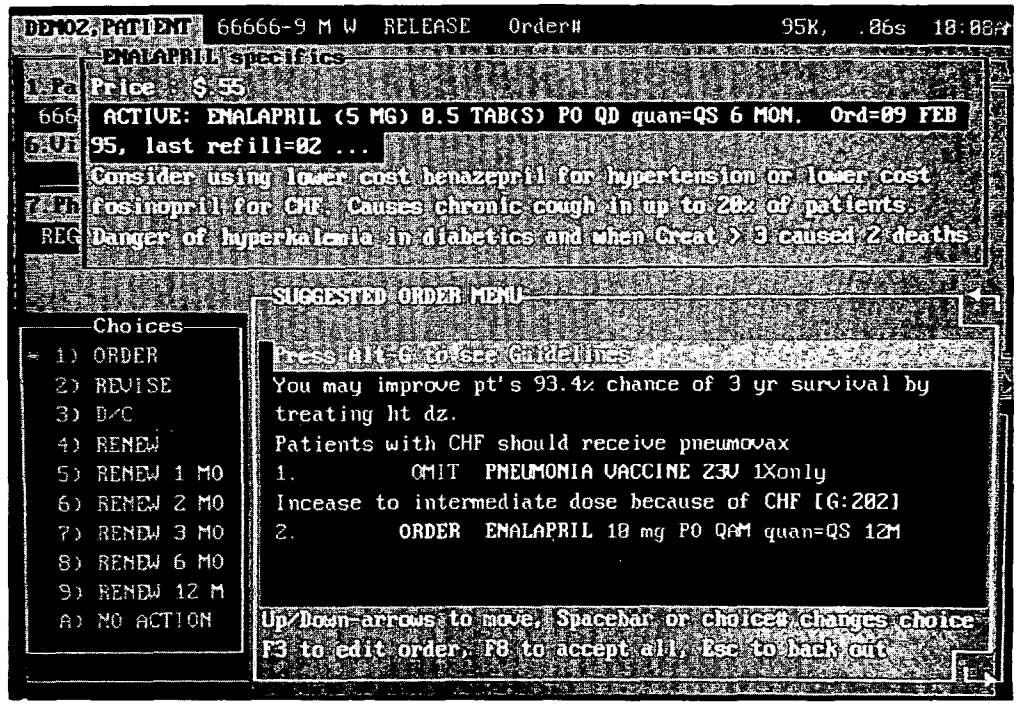

Figure 1 Workstation order-writing screen with a window open showing suggested orders for a patient who has heart failure and varying default conditions (order vs omit) based on the strengths of the recommendations. The top line contains patient identifiers. The next box down is a window that gives information about the drug highlighted in the box below: price, prescription data if the drug is currently active, and information or warnings. The contents of this window can be scrolled up or down via the instructions at its bottom. The large box in the lower right corner is a window of all suggested orders with default actions (e.g., omit or order, dosages, and guideline references and comments). The box in the lower left corner is a menu of choices for processing the currently highlighted suggested order.

other users of guidelines will have great difficulty assessing the appropriateness of ACE inhibitors if the necessary historical and symptom data are not routinely collected and stored in some standard format. Simple measures of heart failure symptoms do exist (e.g., the NYHA classification scheme[20]), as do more complex questionnaires.[22]

Moreover, even when appropriate data are available, the AHCPR Heart Failure Guidelines frequently lack clear definitions of states ("drug intolerance") or modifiers ("frequently"). How many bouts of pulmonary edema constitute "recurring episodes?" Such vague terms, which McDonald and Overhage[23] label "weasel words," make the objective assessment of compliance with the guidelines difficult. This could engender endless debates over patient eligibility. Therefore, the AHCPR heart failure algorithm can be automated only if branch points are redefined in terms of explicit values of readily available information (test results, vital signs, diagnoses, and drug therapy).

Heart failure is frequently not an isolated phenomenon; dealing with comorbid conditions is perhaps the most difficult aspect of caring for such patients. Yet the AHCPR guidelines ignore most comorbid conditions. For example, there is no discussion of appropriate therapy for concomitant ischemic heart disease other than a brief discussion of revascularization surgery. Yet much of the heart failure in this country is associated with ischemic heart disease,[24] and nitrates have a role in the therapy for both ischemic heart disease and heart failure. What is the role of beta-blockers for patients who are not candidates for surgical revascularization or who refuse it? When should beta-adrenergic blockers or calcium channel blockers be avoided because of their negative inotropic effects? Valvular heart disease is also ignored for the most part, yet ACE inhibitors are strongly indicated for treating heart failure related to aortic and mitral insufficiency and should be avoided in aortic stenosis.[25] The AHCPR guidelines do emphasize controlling hypertension, but there is no discussion of its treatment beyond diuretics and ACE inhibitors. How should patients who have both systolic dysfunction and left ventricular hypertrophy be treated? This combination is not uncommon, given the prevalence of hypertension.

The AHCPR Heart Failure Guidelines deal mostly with errors of omission (e.g., not using ACE inhibitors, diuretics, or digoxin), while ignoring many errors of commission. Yet the inappropriate use of common drugs can sometimes be dangerous, such as prescribing potassium supplements or potassium-sparing diuretics for patients who have renal insufficiency. Some drugs, such as nonsteroidal anti-inflammatory drugs, can also exacerbate heart failure. Drug use information and diagnoses are already stored in many electronic record systems and could trigger suggestions related to comorbid conditions and coincidental therapy.[5,10,26]

The AHCPR guidelines' discussion of follow-up monitoring for patients is disappointing as well. The guidelines strongly encourage collecting information about symptoms, vital signs, and medication compliance, but there is little discussion of how persistent symptoms should trigger additional therapy. For example, the guidelines suggest adding digoxin "when needed." How should eligibility for digoxin be objectively defined? And what if digoxin proves insufficient in alleviating the patient's symptoms? When should digoxin concentrations be measured? Should a second-line diuretic be added? Should nitrates be prescribed to lower left ventricular pre-load? Other than suggesting that the doctor and the patient consider cardiac transplantation, clearly the last resort, the AHCPR guidelines do not deal with refractory heart failure.

This critique of the AHCPR Heart Failure Guidelines should recognize that there is much that is right with them. The algorithm is straightforward, cutting through the mountain of sometimes conflicting literature and the flood of proprietary interests bombarding clinicians. The guidelines also report the strength of the evidence supporting each recommendation, which is critical to understanding the current state of heart failure care and directions for future research. The algorithm is not overly complex and makes reasonable demands on the clinician for gathering information, although, as mentioned above, more specific details about symptoms and adverse events are required.

Recommendations

The AHCPR Heart Failure Guidelines serve as an excellent, evidence-based review of the current state of the art for treating heart failure due to systolic dysfunction. As written, however, they are only general guides for individual practitioners because *they lack explicit definitions and specificity,* especially for symptoms and adverse clinical events. *They do not consider the likelihood that a patient will benefit* when suggesting specific therapy and/or diagnostic testing, and *they ignore the impact of comorbid conditions and coincidental drug therapy.* It is therefore difficult, if not impossible, for third parties to use the guidelines in assessing and improving clinician performance. Table 2 lists specific problems we encountered when pro-

Table 2 ■

Summary of Problems Encountered When Programming the Agency for Health Care Policy and Research (AHCPR) Heart Failure Guidelines into the Workstations and How They Were Solved

Problem Encountered	Local Solutions
Definition of heart failure relied on a single echocardiographic parameter that was not available locally	Use multiple available indicators (diagnoses, readings of chest radiographs, and left ventricular enlargement or dysfunction on cardiac imaging studies)
Branch points are not always explicitly defined	Apply definitions approved by local consensus panel of cardiologists and general internists
Does not explicitly define severity of disease or symptoms	Require physicians to record NYHA* class whenever writing workstation orders for eligible patients; use class as a severity indicator to trigger suggested orders or vary default response between "order" and "omit"
Branch and decision points sometimes rely on data not routinely available	Where possible, use available data that are equivalent to those called for by the guideline, or require physician to enter needed data
Comorbid conditions not considered	Expand guidelines with additional rules and treatment suggestions as approved by consensus panel
Concurrent drug therapy not considered	Expand guidelines with additional rules and treatment suggestions as approved by consensus panel
Little discussion of patient follow-up	Expand guidelines with additional rules for follow-up testing and changes in treatment as approved by consensus panel

*NYHA = New York Heart Association.[20]

gramming the AHCPR guidelines into the workstations and how these problems were solved locally.

Thus, the AHCPR Heart Failure Guidelines, as written, cannot be automated in any existing electronic medical record system. However, we do *not* recommend scrapping the tremendous work that the AHCPR put into creating these guidelines. Rather, we make the following recommendations to improve future versions of these and other clinical practice guidelines.

1. *Write all guideline rules in a simple "if-then-else" format with all of the parameters strictly defined using routinely collected clinical data.* At each branch point, guideline authors should ask themselves, "How can we tell whether this clinical situation exists? Where will the data come from? Are the data routinely collected, recorded, and accurate?" In some cases, the guideline authors may suggest the routine use of validated scales or questionnaires to collect information about symptoms, adverse reactions, and other subjective data.[20,22]

2. *Make algorithm logic hinge on explicitly defined values of accepted clinical parameters.* If branching depends on severity of symptoms, then severity should be strictly defined (e.g., NYHA class III symptoms as the threshold for adding digoxin to a regimen of maximum ACE inhibition). Similarly, insofar as they are supported by the literature, explicit threshold values should exist for all objective clinical parameters, such as left ventricular size or ejection fraction, when they are used to make specific treatment recommendations. The guidelines should make a *strong* statement supporting the documentation, in standard ways, of important symptoms, abnormalities on physical examination, and clinical events such as adverse drug reactions and drug allergies. For example, it might be wise for the guidelines to suggest obtaining echocardiograms for all patients who have suspected heart failure to obtain the necessary parameters to assess patient eligibility and severity of disease.

3. *Expect that local translation of the guidelines will be necessary, and help guide that process.* Local clinical practice may vary substantially, and medical record systems, whether electronic or paper, will vary in the types and amounts of data they have available. To be broadly applicable, definitions, eligibility, and recommendations of the AHCPR Heart Failure Guidelines may have to vary somewhat to be appropriate in each setting; the AHCPR may want to suggest how such local translation should proceed.

4. *Include rules about errors of commission and omission, and don't ignore common comorbid conditions.* The guidelines should consider coincidental drug therapy and recommend stopping those drugs that may be specifically contraindicated or may exacerbate heart failure. Moreover, one cannot ignore comorbid conditions, especially those such as chronic lung disease that share a common risk factor (smoking) and symptoms (dyspnea).

5. *Balance the costs of diagnosis and treatment (not only in terms of dollars) and consider the likelihood that individual patients will benefit from the guidelines' recommendations.* Recommendations should vary in

strength depending on individual patients' characteristics that make them more or less likely to benefit. Cost–benefit ratios will vary between patients, and, where possible, the algorithm should reflect this in explicit terms that will allow appropriate assessment of provider compliance.

6. *Finally, evaluate the resulting guidelines using real patients and representatives of all those who will use them.* Testing of the guidelines on real patient data should include busy practicing clinicians, as well as representatives of hospital quality improvement committees and managed care organizations, payers, and regulators. In many cases, adding a specialist in medical informatics would be clearly appropriate to ensure practical implementation. All evaluators should ask themselves, "Can we use these guidelines prospectively or retrospectively to improve the delivery of cardiac care and/or to evaluate its quality? Can we tell *when* they are appropriate and whether the clinician has complied with the recommendations?" Importantly, the guidelines should be evaluated using data from real patients in real clinical settings. Many of the problems enumerated above became obvious to us only when we tried programming the heart failure guidelines into our workstations and pilot-tested them on our own patients.

Conclusions

The movement to create and promulgate clinical practice guidelines is here to stay. Clinical care can benefit from guidelines in the same manner that many industries have benefitted from guidelines for quality production.[27] The AHCPR Heart Failure Guidelines have taken the practitioner's viewpoint, and as such they are a good beginning, a first-rate evidence-based clinical review. However, for guidelines to move beyond a purely educational role, definitions will have to be more explicit and standardized. Many iterations will no doubt be needed before guidelines are effective in helping to realize the dual goals of improving health care quality while controlling its cost.

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