

Developing and Implementing Computerized Protocols for Standardization of Clinical Decisions

Alan H. Morris, MD

Humans have only a limited ability to incorporate information in decision making. In certain situations, the mismatch between this limitation and the availability of extensive information contributes to the varying performance and high error rate of clinical decision makers. Variation in clinical practice is due in part to clinicians' poor compliance with guidelines and recommended therapies. The use of decision-support tools is a response to both the information revolution and poor compliance. Computerized protocols used to deliver decision support can be configured to contain much more detail than textual guidelines or paper-based flow diagrams. Such protocols can generate patient-specific instructions for therapy that can be carried out with little interclinician variability; however, clinicians must be willing to modify personal styles of clinical management. Protocols need not be perfect. Several defensible and reasonable approaches are available for clinical problems. However, one of these reasonable approaches must be chosen and incorporated into the protocol to promote consistent clinical decisions. This reasoning is the basis of an explicit method of decision support that allows the rigorous evaluation of interventions, including use of the protocols themselves. Computerized protocols for mechanical ventilation and management of intravenous fluid and hemodynamic factors in patients with the acute respiratory distress syndrome provide case studies for this discussion.

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For the author affiliation and current address, see end of text.

Humans have a limited ability to incorporate information in decision making (1, 2). Our short-term memory can simultaneously retain—and therefore optimally utilize—only four to seven data constructs; attempts to use larger amounts of information at one time lead to ineffective decision making (3). This limitation stands in striking contrast to the hundreds of variables encountered by clinicians in the clinical environment. The mismatch between human limitation and excess information almost certainly contributes to unnecessary variation in clinical practice (4–9), clinical error (10–22), and poor compliance with guidelines (23–27).

In this paper, I consider the problems created by this mismatch and describe a computer-based decision-support system that successfully combines rules based on credible evidence with specific data from individual patients. I also review key social, psycho-

logical, and administrative elements that have made development of this system possible.

Variation and the Standardization of Practice

Variation in clinical practice persists even when guidelines based on reputable evidence are available (28, 29). Harm can result when clinicians do not comply with standard practice (9, 30, 31). Of note, much of current clinical practice has not yet been shown to produce more good than harm (18, 32–34). Widespread distribution of evidence-based guidelines (35, 36) and education programs (24, 37–40) have had only a limited effect on low clinician compliance, and patient compliance (41) and hospital compliance (42) are almost as low. Unaided human decision makers do not possess the consistency of behavior or the accuracy of perception necessary for the consistent delivery of recommended therapies (10, 43–48).

Standardization of clinical decisions is needed not only for clinical practice but also for rigorous clinical research (49). Many interventions of clinical value have relatively small effects, with odds ratios of 3.0 or less (50). Systematically conducted clinical trials are necessary to recognize these small effects and to identify ineffective clinical care elements (50, 51). Without explicit methods, however, the fundamental scientific requirement of replicability of results (48, 49) cannot be achieved. An *explicit method* contains enough detail to generate specific instructions (patient-specific orders) without requiring judgments by a clinician. It is driven by patient data and generates the same instruction for a given set of input data. Any form of guideline or protocol can theoretically contain enough detail to constitute an explicit method. In practice, however, paper-based versions of any protocols but the simplest ones (for example, vaccination schedules or treatment of hypokalemia in a patient receiving digitalis and diuretics) cannot be made explicit and therefore remain dependent on clinician judgment.

The need to standardize decisions provides a counterpoint to the equally compelling need to deliver individualized, patient-specific treatment. Un-

Table 1. Decision-Support Products and Attributes

Decision-Support Product	Focus	Output	Explicit Method for Standard Decisions	Explicit Method That Can Be Transferred to Other Hospitals
Guideline	Conceptual	Suggestions for clinical consideration	No	No
Critical path	Intermediate outcome steps	Timetable, reminders	No	No
Paper protocol	Clinical care process	Suggestions, instructions (general and specific)	Unlikely	Unlikely
Computerized protocol (for example, for mechanical ventilation)—patient data-driven	Clinical care process	Dynamic, patient-specific, standing orders	Yes	Yes

expectedly, the discussed computerized protocols, which are explicit, detailed, and patient data-driven, can simultaneously achieve standardization of clinical decision making and individualization of patient therapy (52). Clinical care (the treatment a patient receives) is determined by clinical caregivers' decisions and by each patient's individualized expression of his or her illness (52). Consider an explicit method for mechanical ventilation—for example, a computerized protocol—that is used to standardize clinical decisions for two patients. The treatment given to one of the patients, who responded to positive end-expiratory pressure, would differ from that given to the other patient, who did not; treatments would differ even though the same explicit decision-making rules were used to standardize clinical decisions for both patients. The clinical care delivered to patients through computerized protocol instructions is therefore individualized (patient-specific) although decision making is standardized.

Patient-specific care contrasts with time-driven decision-support tools, such as a clinical pathway that requires extubation within 36 hours and discharge from the hospital within a specified time. Unlike explicit methods driven by patient data (25, 53–58), time-driven tools raise legitimate concerns about patient-invariant (“cookbook”) care. One of the most attractive features of the use of point-of-care computerized protocols is their ability to individualize patient care while standardizing clinical decisions with an explicit method.

The LDS Hospital Experience

Two computerized protocols developed at LDS Hospital, Salt Lake City, Utah, form the case studies for this discussion. The first protocol standardizes bedside decisions for mechanical ventilation of patients with the acute respiratory distress syndrome (ARDS). These decision-support tools were initially developed for a randomized clinical trial of extracorporeal carbon dioxide removal in patients with ARDS (53). The tools were subsequently exported to 10 other hospitals (in 8 cities in 7 states) uninvolved in the development and were then evaluated

in a randomized clinical trial of mechanical ventilation in patients with ARDS (54).

The second protocol standardizes bedside clinical decisions for intravenous fluid and hemodynamic support. These protocols were recently developed for a projected randomized clinical trial of pulmonary artery catheters by the NIH/NHLBI (National Institutes of Health/ National Heart, Lung, and Blood Institute) ARDS Clinical Network (55).

Varieties of Decision Support

Guidelines and protocols can effectively support clinical decision making (56) and can favorably influence clinician performance and patient outcome (28, 57–59). These decision-support tools have been functionally categorized as “reminders,” as “consultants,” or as “educational” (60). Thousands of decision-support tools with different names, focuses, and outputs are currently available to clinical practitioners. However, they often lack specific instructions for many of the scenarios encountered in clinical practice (**Table 1**). Most guidelines and algorithms (including guidelines generated by the Agency for Healthcare Research and Quality) are useful only in a conceptual sense (61–67); they neither standardize clinical decisions nor lead to uniform implementation of clinical interventions, although these are their ultimate goals (65, 67, 68). For example, it would be difficult to reduce variability with a protocol that required the clinician to determine whether the patient “looked septic” unless the state “looked septic” was explicitly defined by identifying the specific observations that lead to this clinical conclusion. When so defined, data that determine the presence of the state “looked septic” could be entered directly as inputs to a decision-support tool without the need for judgment by a clinician.

Computerized protocols used for complex clinical problems can contain much more detail than textual guidelines or paper-based flow diagrams (67). Increased detail allows point-of-care generation of patient-specific therapy instructions that can be carried out by different clinicians with almost no interclinician variability (69). This can make both formal

clinical inquiries (for example, randomized trials) and informal clinical inquiries (for example, some continuous quality improvement efforts or clinical practice evaluations) more robust (52, 69).

Explicit Computerized Protocols

Explicit rule-based computer systems are used in the most rigorous applications of algorithms in point-of-care clinical decision support (10, 25, 52–54, 67, 70–74). Computerized protocols have been shown to produce favorable changes in clinically important outcomes (10, 25, 27, 54, 57–59, 70, 72, 75–77). The immediacy of point-of-care decision support (67) differs from the more flexible time periods in which both decision trees (78) and computerized algorithms are implemented in consultative services (79). Although standardization of clinical decisions has been declared unreasonable (66), results from computerized protocol applications for mechanical ventilation suggest otherwise (53, 54, 73). Standardization of clinical decisions may have affected the conduct of certain randomized, controlled clinical trials (53, 54) in which success was previously thought to be unlikely (80). The computerized protocol strategy I describe falls within, or between, the categories of “reminders” and “consultants” outlined by Miller and Goodman (60).

At LDS Hospital, computerized mechanical ventilation protocols have been used to support more than 250 patients with ARDS (Figure 1) for more than 100 000 hours (52, 53, 73, 85). Compliance of LDS Hospital physicians with protocol instructions was 95% (54, 86). These computerized ARDS mechanical ventilation protocols have been exported to stand-alone bedside personal computers in 10 other

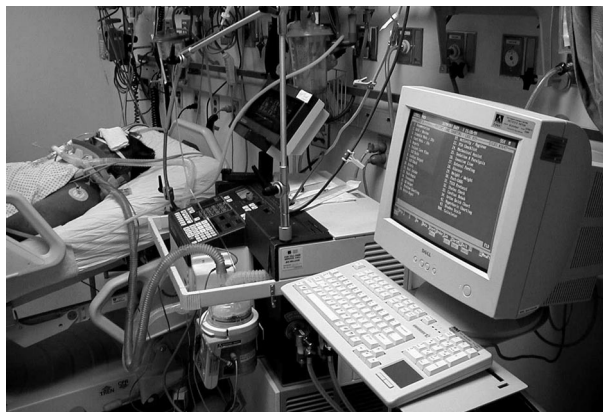


Figure 1. Bedside scene at LDS Hospital with a terminal of the HELP (Health Evaluation through Logical Processing) hospital-wide electronic patient data management system (81–84). Information is exchanged with the bedside nurse through the computer terminal. All nine intravenous pumps and the monitor above the bed are directly wired to the HELP system's integrated patient database. Data on such factors as intravenous flow, intravenous drug administration, and physiologic monitoring are automatically sampled. Other data are entered through the computer keyboard. Protocol instructions are displayed on the computer screen.



Figure 2. Bedside scene at an external hospital with a stand-alone personal computer system. The LDS Hospital HELP (Health Evaluation through Logical Processing) ventilation protocols for patients with the acute respiratory distress syndrome were exported to this system, which is not directly connected to a hospital or intensive care unit database. All data are entered through the computer keyboard. Protocol instructions are displayed on the computer screen.

hospitals (Figure 2). These other hospitals have used the protocols to standardize clinical decision making for 103 patients with ARDS in a recently completed clinical trial (54, 87); physician compliance was 94%. A total of 38 546 instructions were generated during 32 055 hours of application (36% of instructions were for positive end-expiratory pressure, 40% were for fraction of inspiratory oxygen, 6% were for tidal volume, 12% were for ventilatory rate, and 4% were for minute ventilation) (54). Physicians objected to only 0.3% of the 38 546 instructions. Survival was comparable in the two experimental groups, but barotrauma was significantly less likely in the group that received standardized decisions from the computerized protocol. The 94% rate of physician compliance is much higher than the 30% to 60% rate seen in studies of computerized decision support protocols for antibiotic and diabetes guidelines (25, 27). These results indicate that an explicit method of care can be effectively transferred to different geographically dispersed clinical settings and can significantly reduce patient morbidity (54).

A rule-based computerized protocol for management of intravenous fluid and hemodynamic factors in patients with ARDS is being developed for the NIH/NHLBI ARDS Clinical Network. One page, from a recent 50-page flow diagram version, illustrates the protocol's structure (Figure 3). This protocol is being developed with a process previously used to create the mechanical ventilation protocols (85, 88).

Incentives To Use Protocols

The high rates of clinician compliance seen with our protocols may have been caused by many factors, including 1) a scholarly commitment to re-

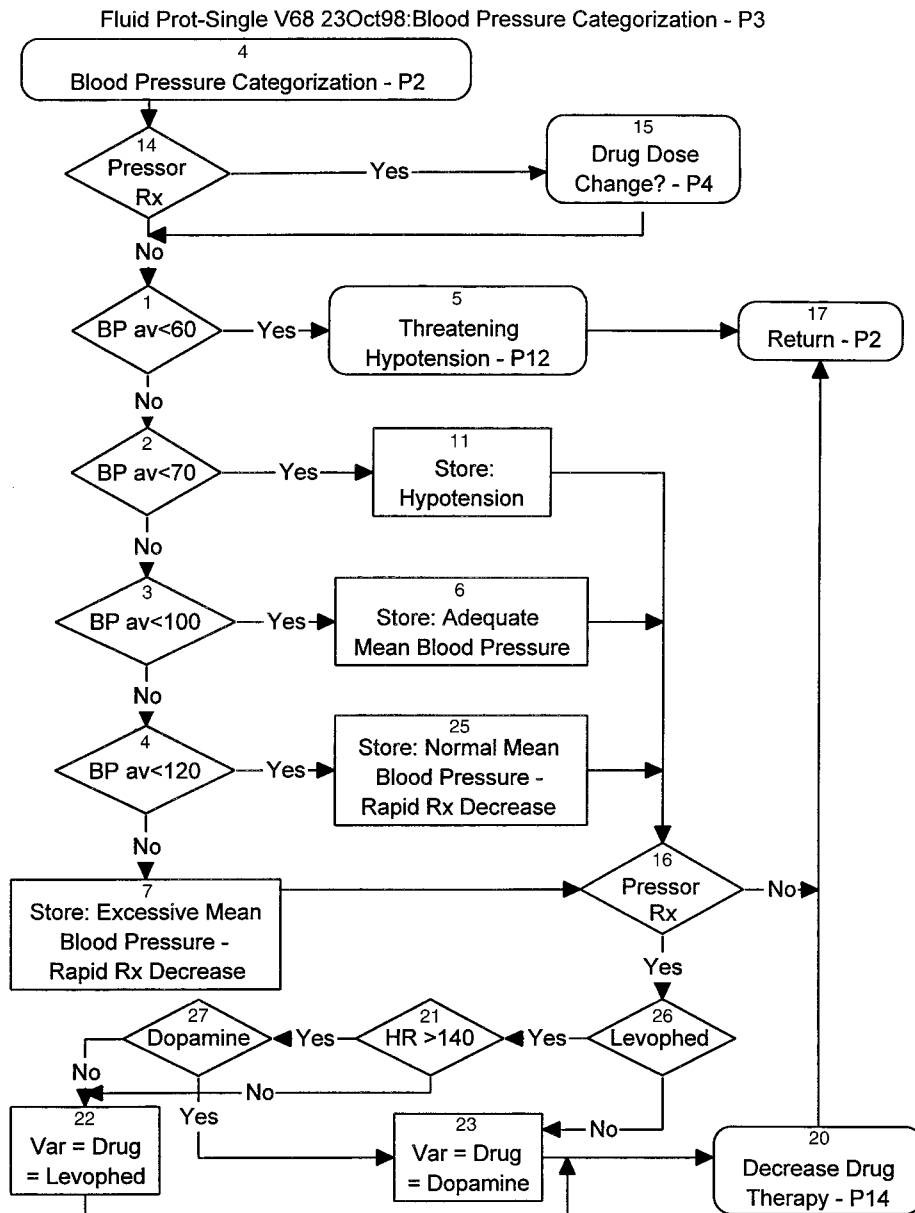


Figure 3. Selected page from a protocol for management of intravenous fluid and hemodynamic factors in patients in the intensive care unit. The protocol, which is more than 50 pages long, is currently being tested and refined. The numbers at the top of each logical element serve to identify the element. The round-cornered rectangles are subroutines (lower-level protocols). Levophed (norepinephrine bitartrate) is manufactured by Abbott Laboratories, North Chicago, Illinois. av = average; BP = blood pressure; HR = heart rate; Rx = drug; Var = variable.

search, expressed through physician willingness to join a formal clinical investigation of an explicit computerized protocol; 2) payment for enrolling patients; 3) recognition that reliable outcome data are lacking for many therapeutic options; 4) previous favorable patient outcomes at LDS Hospital (>35 000 hours of use in 111 patients with ARDS when we began the clinical trial in other hospitals) (54); 5) prestige derived from association with research centers; 6) influence of senior clinicians; 7) commitment to continuous quality improvement; 8) recognition that standardization of clinical process can improve efficiency; 9) acceptance of the need to standardize clinical processes in order to reduce

costs; 10) perceived educational value of rigorous clinical process monitoring; 11) use of protocols for physician performance review; 12) administrative pressure; 13) peer pressure due to changing standards of care; and 14) perception of standardization of decision making as a benefit in itself (this has been true for about 10 years at LDS Hospital).

Barriers to Protocol Use

At the same time, experienced physicians are cautious about adopting new clinical practices and resist the introduction of standardized methods of

care. On the basis of experience with computerized protocols, we and others have found various impediments to physician compliance with guidelines or protocols: 1) lack of appreciation of the limitations of human decision making and the small number of variables on which decisions depend (1–3, 52); 2) disproportionate impact of dramatic personal (anecdotal) experiences (1, 2); 3) exclusion of practitioners from the protocol development process (66); 4) the tendency to focus on infrequent but possible clinical scenarios that are not accommodated by protocol logic (66); 5) use of guidelines primarily for purposes other than improving the quality of care and patient outcome (for example, for cost containment) (66); 6) failure to account for all important possibilities in the clinical situation (74); 7) imposing burdens, such as excessive data entry requirements, without counterbalancing benefits (52, 66); 8) hubris (excessive pride) among clinicians defending their autonomy; 9) concern that protocol logic is not correct (protocols need not be perfect—a demand for the unknowable “right way” frequently distracts attention from the necessary step of choosing one defensible and reasonable clinical approach [10, 52, 65–67, 69]); 10) excessive complexity (52, 66); 11) the culture of a medical care community that has relied on the expert (authoritarian) method of decision making for thousands of years (66, 85, 86); 12) concern about a reduced role for clinicians in medical practice (66); and 13) insufficient technological infrastructure (absence of functional electronic patient records) (74).

Other barriers to implementation of standard clinical decision making might be considered legitimate. For example, it could be counterproductive to standardize the response to infrequent clinical problems. Clinician training may be impaired if students thoughtlessly, like automatons, followed “cookbook” (patient invariant) treatment. Innovation could be stifled, particularly because reimbursement will probably be linked to execution of standard practice guidelines. Finally, standardization may be perceived as an attack on the assumption of clinicians that they possess special, ineffable wisdom in clinical matters and its corollary that patients receive the best outcome when physicians independently use their best clinical judgment (89, 90). However, most of these arguments do not withstand careful scrutiny. The chances of uncovering better therapies for infrequently encountered clinical problems will increase with systematic application of different strategies over large geographic areas. By using the entire medical community as a laboratory in which to apply explicit methods, we are more likely to resolve clinical uncertainties for many uncommon problems. (For the rarest problems, however, it seems reasonable to eschew standardization

and to place our hope in the serendipitous clinical observation of a dramatic response or in advances in reductionist scientific research.) To those who are afraid of demeaning the clinical training of students, I respond that an explicit method, when used wisely, can be an effective tool for teaching principles of decision making and those of clinical practice. In addition, the experience of developing and using explicit protocols can be a powerful learning experience for practicing clinicians. Finally, clinical errors are common and contribute to unfavorable patient outcome and excessive health care costs (10–20); they are often due to poorly designed systems of care rather than individual physician incompetence. Standardization of clinical decision-making systems reduces opportunities for human error (91–94).

Important Process Elements and Steps in Protocol Development

The development and implementation of robust computerized protocols at LDS Hospital (**Figure 1**) and implementation in 10 other hospitals (**Figure 2**) were based on the following important elements (85, 88, 95, 96).

1. A rationale or imperative (66). In 1985, I proposed that an explicit protocol would ensure experimental rigor in a randomized clinical trial of extracorporeal carbon dioxide removal (53, 97). My colleagues embraced this proposal, driven in part by our previous experience with the difficulties in carrying out clinical investigation of extracorporeal support for patients with ARDS (98).

2. Adoption of a decision-making clinician’s perspective (66). The perspective of the clinician who must decide between alternatives with unknown outcomes differs dramatically from that of guideline developers who know or assume the outcome of a particular protocol step during the consensus development process (66).

3. Credible clinical leadership (66). Clinician acceptance of a decision-support tool is likely only if the tool is personally supported by a respected clinician. During development of the ARDS ventilation protocols, I was the principal investigator of an NIH grant for the study, the director of research of the pulmonary division of the LDS Hospital, and the former teacher of most of the participating clinicians and investigators. At most of the collaborating academic centers, a team of LDS Hospital clinician-investigators was present at the bedside of the first patient enrolled in the protocol. This direct involvement provided important support to collaborating clinicians who had legitimate concerns about

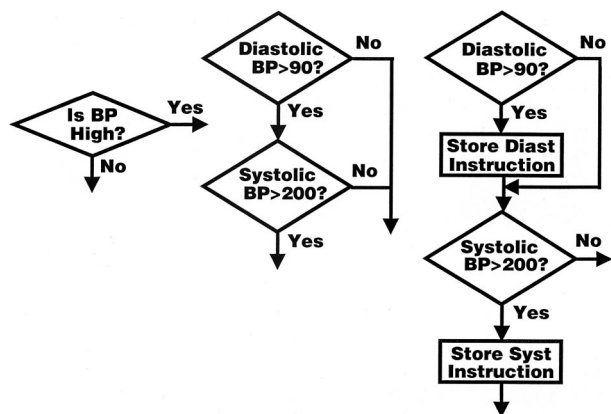


Figure 4. Specific use of terms in protocols. The judgmental term *high* in the left panel has been made explicit by the thresholds in the middle panel (200 mm Hg and 90 mm Hg). The use of inexplicit terms makes protocol application variable because clinician judgment at the bedside must make up for the lack of specificity. The middle panel shows the specific thresholds for defining “high BP” and requires both systolic and diastolic hypertension for a “Yes” response. There are only two outputs. The more detailed, right panel shows the specific thresholds for defining “high BP” independently by using systolic hypertension or diastolic hypertension. Different therapeutic responses will follow systolic hypertension (“Store Syst Instruction”) and diastolic hypertension (“Store Diast Instruction”). There are four outputs (no hypertension; diastolic hypertension; systolic hypertension; diastolic and systolic hypertension). BP = blood pressure (mm Hg); Diast = diastolic; Syst = systolic.

following explicit, computer-generated instructions to manage a complex clinical problem.

4. Clinician involvement and benefit (66). Clinicians who will be using the protocol must be involved in its development from the beginning. In addition, ways in which the protocol will benefit clinicians (for example, by generating data reports that become part of the medical record) must be maximized. Clinicians provide important input to protocols at two distinct times: during protocol use and during protocol development. During use, clinicians review all protocol instructions at the bedside. Instructions are not automatically implemented; a clinician must first read them and find them acceptable. Because no protocol is likely to incorporate rules for all of the rare clinical scenarios that may be encountered, we rely on clinicians to identify such scenarios (99). Therefore, this is an *open-loop* servo-controlled system in which a clinician with the ability to refuse an instruction is always involved. This type of system is widely accepted in medicine for all consultative services. Of note, however, the concurrent requirement that clinicians specify a legitimate reason for declining an instruction minimizes abuse of the clinician’s freedom to refuse.

During protocol development, clinicians also have creative input, but that input is separated in both space and time from the point and time of specific decision making. Articulation of the specific variables and rules necessary for an explicit computerized protocol involves an extensive investment of time, thought, and expertise by several clinicians.

The published and unpublished expert information and opinion ultimately included in the protocol thus constitute a kind of collective wisdom, because they far exceed the thought and knowledge that most individual clinicians can bring to the bedside at the point when a specific clinical decision is made (52, 61–63, 65–67).

5. Use of explicit logic, rules, and thresholds for variables (64, 66, 67). Specific rules are most easily executed with quantified variables, and they should be used whenever possible. At the bedside, measurements of these variables should activate the protocol. Protocol developers should avoid the use of terms that require judgment or opinion or are otherwise inexplicit (Figure 4). Use of such terms, sometimes called “weasel words” (67, 100), has been described as “waffling” (74) and is common in clinical algorithms (101–103). Examples from guidelines for asthma include “closely monitor,” “inadequate response,” “consider ipratropium nebulizers,” and “avoid high airway pressures.”

6. Inclusion of all outcomes for which the protocol rules apply (67, 74). The decision-support tool must accommodate most clinical circumstances. For these circumstances, all paths that could describe the patient’s clinical course must be included in the protocol rules. Incompleteness of protocol rules, conditions, threshold values, variables, waiting periods, and reevaluation times will foster inconsistent execution, intermittent clinical use, and eventual disregard of the protocol.

7. Generation of explicit instructions (67). Standardized clinical decisions must, by definition, be clinician independent. Protocol instructions must therefore be explicit and unambiguous (Table 2). Saving time through use of computerized protocol instructions that function as dynamic standing physician’s orders frees the physician to concentrate on other things, such as high-level judgments not appropriate for protocols and communication with families.

8. Point-of-care application (67), which is a critical requirement for protocol use in routine clinical care or clinical research. Although point-of-care clinical computer systems that are highly integrated into hospital-wide information systems provide the

Table 2. One Computerized Protocol Instruction Iteration for Mechanical Ventilation in a Patient with the Acute Respiratory Distress Syndrome

Arterial oxygenation:
Reduce inspired oxygen by 10%, from 90% to 80%
Reassess oxygenation in 15 minutes
Ventilation and arterial pH:
Maintain tidal volume at 540 mL
Increase ventilatory rate by 3 breaths, from 22 to 25 per minute
Sample arterial blood in 15 minutes at 15:40 hr

most attractive and efficient environment (Figure 1), protocols can also be implemented with independent, stand-alone bedside computers (Figure 2) (54, 87, 104). In contrast, a paper-based protocol containing the detail necessary to qualify as an explicit method, although theoretically possible, is unlikely to be developed; even if developed it would probably be cumbersome to use.

9. The availability of accurate, precise, timely, and representative data (52). As in all clinical decisions, the generation of appropriate instructions by a computerized algorithm requires input data that are accurate (close to the truth) and precise (repeatable); however, these data must also be timely and representative. Implementation of timely data entry usually requires a change in behavior on the part of clinical staff, who often retain data in temporary formats (such as notes on paper, clothing, hands, or rubber gloves) and enter them later into medical records at convenient moments. The input data must also represent the steady-state function of the organ or system that is the object of the computerized protocol instruction. For example, timely entry of an accurate and precise pulse oximetry measurement would not be representative of lung function if it were obtained immediately after endotracheal tube suctioning.

10. Identification of specific reasons for clinician refusal to follow instructions. Identification, capture, and review of clinicians' reasons for declining an instruction have played a crucial role in the refinement process. Failure to identify such reasons results in lost opportunities; multiple failures preclude the development of a robust protocol (Figure 5). Clinicians' perceptions about the effects of protocols on patients, efficiency, cost, clinical risk, and other issues spawn strong opinions that are frequently poor representations of reality (43, 44). A credible monitoring and feedback program becomes a factual frame of reference that can tether strong opinions and allow dispassionate discussion.

11. Iterative refinement (66, 67). Information on the performance of protocols provides the grist for protocol refinement through a regular, iterative review process (Figure 5). A consensus committee decides whether a specific reason for declining an instruction represents a missing logical element, an error in protocol logic, a clinician mistake, or a clinician misinterpretation. If a logical element is missing, the consensus committee evaluates the probability that the particular problem will recur. If the logical omission concerns an event that will probably be encountered frequently, the committee supplies the missing element. If the event is uncommon—for example, if it will probably occur only once per year—the committee may decide to omit the element and rely on bedside clinicians to inter-

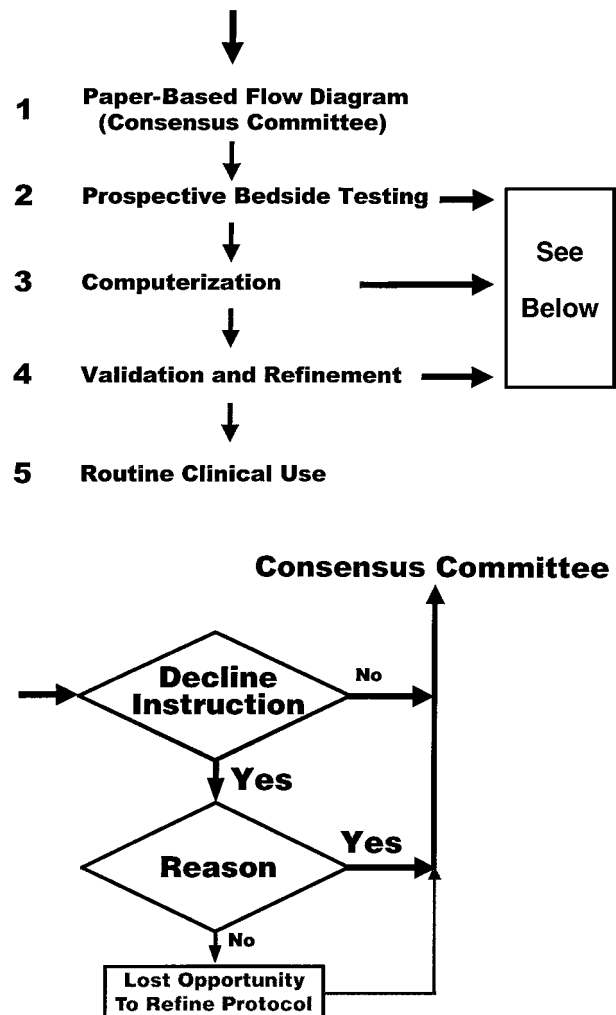


Figure 5. Protocol refinement through an iterative review process. **Top.** Before a robust protocol can routinely be used in clinical practice, four major levels of development take place: 1) consensus generation of a paper-based flow diagram, 2) prospective bedside testing of sections or of the entire paper-based flow diagram, 3) computerization of the paper-based flow diagram logic, and 4) validation and refinement of the computerized protocol. At levels 2, 3, and 4, problems must be identified. **Bottom.** Specific reasons for the problems, including clinician refusal to follow protocol instructions (“Decline Instruction”), must be captured and fed back to the consensus committee. If the specific reason for refusal to follow protocol instructions is not captured, an opportunity to refine the protocol is lost.

vene when the next event occurs. The principle is to strike a balance between a slightly simplified protocol that works satisfactorily and one that tries to cover every possible contingency but becomes so complex that it is difficult or impossible to maintain.

12. Simplicity (66). It is easy to add a single rule or logical element to a simple protocol element or protocol version that performs unsatisfactorily. The performance of the more complex version can then easily be compared with the performance of the previous simpler version. In contrast, a protocol that functions well but is cumbersome to use will be difficult to modify if its logic is excessively complicated. It is difficult and time-consuming to identify the elements that make no substantive contribution

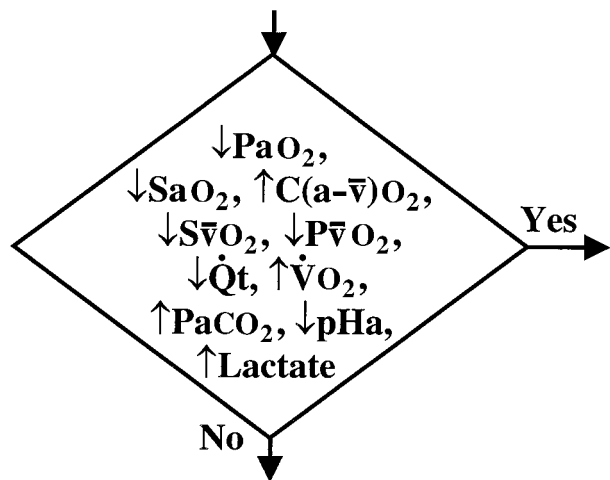


Figure 6. An unsatisfactory logical element for assessing deterioration in oxygenation of a patient with the acute respiratory distress syndrome. The element (a question, indicated by the diamond shape) was taken from one of the first handwritten versions of our mechanical ventilation oxygenation protocols, which dates from 1985. $C(a - \bar{v})O_2$ = (arterial – mixed venous) oxygen content difference; lactate = serum lactate concentration; $Paco_2$ = arterial carbon dioxide partial pressure; PaO_2 = arterial oxygen partial pressure; pHa = arterial pH; $P\bar{v}O_2$ = mixed venous oxygen partial pressure; Qt = cardiac output; SaO_2 = arterial oxygen saturation; $S\bar{v}O_2$ = mixed venous oxygen saturation; $\dot{V}O_2$ = oxygen consumption. There are 10 input variables within the unsatisfactory logical element. Each variable has 2 outcomes (yes or no). Thus, there are a total of 2^{10} outcome combinations, only 2 of which are reflected by the “Yes” and “No” of the unsatisfactory logical element.

to a protocol. For example, one early handwritten version of our mechanical ventilation protocol (**Figure 6**) contained a single question about oxygenation that included 10 elements that we taught our postdoctoral fellows to consider when evaluating oxygenation of the patient. This question had, therefore, 2^{10} outputs, of which only 2 were identified in the protocol flow diagram (**Figure 6**). Needless to say, the question was not effective. On the basis of encounters with clinicians at other institutions, I believe that such design flaws are common.

Protocol Review and Clinical and Technical Support

For successful implementation of explicit computer-based protocols, technical and clinical support must be available around the clock. Turnover of clinical staff inevitably means that clinicians unfamiliar with protocol use will participate in care, at least intermittently. Although clinical computer systems can operate without failure 99.5% of the time, technical support is necessary because no system is completely fail-safe. (Of course, failures also occur with traditional care; some examples are unavailability of clinicians due to workload, sickness, emergencies, and failure of pager battery or other equipment or unavailability, illegibility, and incompleteness of the paper medical record.) Backup for real-time com-

puter-based decision support must always be available but may be as basic as use of the traditional paper medical record until the electronic record is again functional.

Evaluation of Decision-Support Performance

Computerized protocols, like all decision-support tools, are interventions. However, they differ from such interventions as drug therapy because they are directed at the decision-making process itself rather than at the actions that follow the decision (for example, drugs or mechanical ventilation mode). Like other interventions, decision-support protocols or algorithms must be systematically evaluated (61, 63, 66, 67, 105, 106). This is best done with randomized clinical trials (10, 54, 70, 107) that address issues of internal and external validity (50, 51, 108–110). Unfortunately, the widespread availability of most clinical decision-support tools (**Table 1**) has not been matched by their widespread adoption, and their efficacy has not been systematically evaluated (63, 85). Currently, the most potent impetus for use of decision-support tools seems to be financial (111).

Established protocols must be repeatedly reevaluated over time because of new medical knowledge and because secular changes occur in disease, diagnosis, and therapy in the community (61, 65, 66). A computerized protocol can be an explicit method that can easily be made the control arm of a randomized clinical trial of a new therapeutic approach, something that may be very difficult to do with traditionally applied therapies.

Protocol Tradeoffs and Compromises

Some believe that the tension between following general guidelines and allowing practitioners flexibility is an insoluble dilemma that requires tradeoffs (63–66). Acceptance of the validity of this tension depends on two assumptions: that medical practice always requires clinician independence and that this independence precludes rigorous adherence to guidelines. Of interest, most guidelines are not explicit enough or detailed enough to lead to anything approaching standardized clinical decisions (63, 65, 67, 74). In fact, because of their lack of explicit detail, most guidelines force local clinicians to fill in many implied or unstated rules. Although some physicians seem to applaud this flexibility and regional variation, I perceive it to be a major disadvantage in current guideline development. It fosters unnecessary between-institution variation in clinical

practice (4–9) and precludes the multi-institutional standardization necessary for the rigorous clinical evaluation of important clinical management problems that have resisted solution for decades (52).

I believe that the current emphasis on the tension between guideline goals and clinician flexibility is misplaced. The more important tension lies between the application of a rigorous, detailed method that produces standardized clinical decisions and the preservation of individualized, patient-specific therapy (52). The value of individualized guideline output is recognized (64, 67, 74, 112). What does not seem to be widely appreciated is the ability of a sufficiently detailed and explicit decision-support tool to simultaneously produce both standardized clinical decisions and individualized patient therapy (52).

Ethical Considerations

The principles of beneficence, nonmaleficence, autonomy, and distributive justice (113, 114) are satisfied by robust clinical care protocols (52, 115), in part because it has been shown that clinical use of computerized protocols leads to favorable clinical outcomes (10, 25, 27, 54, 57–59, 70, 72, 75–77) and increased adherence to clinical guidelines (116, 117). However, the use of computerized protocols in the context of distributed electronic medical records raises more complex ethical issues than those raised by the use of these protocols as interventions (60, 118).

Future Expectations and Unanswered Questions

I am encouraged by the evidence revealing that decision-support tools favorably change both clinician behavior and patient outcome. However, we cannot wait for the world's medical institutions to install extensive electronic data systems before we determine the effect of such tools on a wide range of important clinical outcomes. Rather, in my view, the results of such evaluations will inform and should influence future development and implementation of electronic clinical data systems in hospitals and medical care delivery systems. As an example of such an effort, my colleagues and I intend to eventually implement a World Wide Web protocol for standardization of decision making for intravenous fluid and hemodynamic management in critically ill patients.

Many questions about the use of these protocols remain unanswered. Can robust decision-support systems used mainly in the intensive care unit be

widely distributed? The successful transfer of our mechanical ventilation protocols to 10 hospitals for a randomized clinical trial suggests that they can; however, the extent to which such transfers can be taken remains to be demonstrated (54). Can systems that function in the intensive care unit be extended to less quantifiable, less complex, and less data-intensive problems? Does the success of protocol support for the challenging problems encountered in the intensive care unit suggest that the solutions for other, less convoluted decisions (including those encountered in the office setting) will be more easily achieved? The results of studies at the Regenstrief Institute for Health Care suggest that the latter may be true (66, 67), but much work remains to be done before we will know the answers to these and other questions.

Summary

The power of human decision making is limited. Excess information in complex clinical environments drives clinicians beyond these limits, increasing the likelihood of clinical errors. Explicit decision-support tools have favorable effects on clinician and patient outcomes. They have been implemented in diverse clinical environments and successfully transferred and used in geographically dispersed sites that were not involved in their initial development. However, various human factors and the paucity of distributed electronic clinical databases impede the widespread distribution of clinical decision-support tools. Regardless of these challenges, the documented benefit of the clinical application of decision-support tools and the rapid expansion of electronic clinical databases in hospitals and clinics promise an increasingly favorable environment for development, implementation, and use of such tools in clinical practice and research.

From LDS Hospital and University of Utah School of Medicine, Salt Lake City, Utah.

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