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Performance of computerized protocols for the management of arterial oxygenation in an intensive care unit

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Abstract

Computerized protocols were created to direct the management of arterial oxygenation in critically ill ICU patients and have now been applied routinely, 24 hours a day, in the care of 80 such patients. The protocols used routine clinical information to generate specific instructions for therapy. We evaluated 21,347 instructions by measuring how many were correct and how often they were followed by the clinical staff. Instructions were followed 63.9% of the time in the first 8 patients and 92.3% in the subsequent 72 patients. Instruction accuracy improved after the initial 8 patients, increasing from 71.5% of total instructions to 92.8%. Instruction inaccuracy was primarily caused by software errors and inaccurate and untimely entry of clinical data into the computer. Software errors decreased from 7.2% in the first 8 patients to 0.8% in subsequent patients, while data entry problems decreased from 7.5% to 4.2%. We also assessed compliance with the protocols in a subset of 12 patients (2637 instructions) as a function of 1) the mode of ventilatory support, 2) whether the instruction was to increase or decrease the intensity of therapy or to wait for an interval of time and 3) whether the instruction was 'correct' or 'incorrect'. The mode of ventilatory support did not affect compliance with protocol instructions. Instructions to wait were more likely to be followed than instructions to change therapy. Ninety-seven percent of the correct instructions were followed and 27% of the incorrect instructions were followed. The major problem in creating the protocols was obtaining clinician agreement on protocol logic and their commitment to utilize it clinically. The major problem in implementing the protocols was obtaining accurate and timely data entry. We conclude that computerized protocols can direct the clinical care of critically ill patients in a manner that is acceptable to clinicians.

Introduction

Adult respiratory distress syndrome (ARDS) is a form of respiratory failure characterized clinically by severe hypoxemia, diffuse infiltrates on chest radiograph, and decreased lung compliance. In its most severe form it has a survival of about 10%. In 1984, Gattinoni et al. reported a 77% survival in this subset of ARDS patients using a new form of therapy [1]. The new therapy included pressure controlled inverse ratio ventilation (PCIRV) and low frequency positive pressure ventilation with extracorporeal CO_2 removal (ECCO2R). Its goal was to reduce the peak and average pressures applied to the lungs by mechanical ventilators. The extraordinary survival reported with this new therapy and the fact that it was the result of an uncontrolled trial led to the design of a prospective randomized controlled clinical trial comparing PCIRV and ECCO2R with traditional positive pressure ventilatory support. The trial was executed at the LDS Hospital from 1987 to 1991. During

the design phase of this trial it became obvious that the novelty of extracorporeal support could cause increased interest among the clinical staff, resulting in a difference in the intensity of care between patients receiving ECCO2R and patients receiving traditional ventilatory care. This created the possibility that differences in the intensity of therapy would bias the outcome of the study. To assure equivalency of care in both the control and new therapy limbs of the study, protocols were developed to control the management of arterial oxygenation in all study patients [2–4].

The protocols were first developed and tested as paper flow diagrams. The tested and refined protocols were then computerized taking advantage of a large, centralized computerized patient data base at the LDS Hospital (the HELP system) [2, 5–7]. Clinical data is routinely stored in this data base; as a result, manual entry of data specifically needed to operate the protocols was minimized. The computerized protocols assessed elements of the patients' clinical status and laboratory data and automatically generated therapy instructions which were then displayed on bedside computer terminals. The protocols were used to care for patients 24 hours a day in a clinical intensive care unit (ICU) by the routine clinical staff and not by a research team. Once introduced into the clinical setting, the protocols have continually evolved in response to 1) the identification of errors in logic and programming, 2) unanticipated clinical circumstances, 3) disagreement between the clinical staff and the protocol instructions and 4) an increase in the number of aspects of clinical care covered by the protocols. As expected, protocol evolution was most rapid in the start up phase (first 8 patients) when the computerized protocols were untested and the clinical staff was adjusting to computerized protocol care. Thus, the logic used for the first patient was not identical to that used for the last patient. The changes in logic were, however, applied in parallel to both the control and new therapy groups ensuring the equivalency of care in the two groups.

Indices of computerized protocol performance for the first 16 patients were analyzed and reported in 1989 [3]. The clinical staff followed computerized protocol instructions 63.9% of the time for the first 8 (start up) patients, and 91.8% of the time for the remaining 8 patients [3]. The major problem in creating the protocols was obtaining physician agreement on a standard protocol. This meant the physicians had to give up approaches to therapy that were a matter of style and agree on a detailed, standard approach to patient care. The purpose of this paper is to report on the performance of the computerized protocols on all patients in whom they were used. We will use information, with permission, from two earlier reports [3, 4].

Methods

The HELP system

The HELP information system at LDS Hospital runs on a network of 10 Tandem fault tolerant computer processors using the Guardian Operating System with 3.4 gigabytes of disk storage distributed over 14 disk drives [5–7]. The 8 drives handling clinical data are mirrored to reduce the possibility of data loss. Eighteen Charles River Data Systems (CRDS) minicomputers are interfaced to the Tandem serving as multiplexers and pre-processors. All clinical and laboratory information on each patient is stored in the integrated data base and is, therefore, available for review, report generation, and computer decision making.

The data dictionary of the HELP system is a hierarchial representation of data elements known as PTXT. Patient demographic and clinical data is stored in coded form in a variety of active and archived files. Most of the programs which manipulate the data base are written in PTXT Application Language (PAL) [6], a structured programming language similar to Pascal. A few of the programs that require access to more fundamental operating systems functions (such as interprocess communication) are written in the Tandem Application Language (TAL), a structured programming language similar to C.

Protocol implementation

Paper-based protocols were developed by a team of 14 physicians and nurses from the pulmonary, critical care, and anesthesiology departments. The current protocols cover about 25 pages of flow diagrams and the computerized version has approximately 12,000 lines of PAL code.

Discrete values of arterial oxygen pressure (or, alternatively, bedside pulse oximetry data) trigger protocol execution, resulting in the generation of a specific instruction for therapy (Fig. 1). An example of a specific instruction is 'Increase the inspired oxygen fraction (FIO2) by 10% from 50% to 60%'. The instructions are based on patient data (e.g. vital signs, respiratory care parameters, and blood gas data) stored in the centralized data base. Protocol instructions, which are also stored in the data base, are reviewed at the patient's bedside terminal through the use of menus. These menus also allow the clinical care user to review data, to manually activate the protocols and generate new instructions for therapy using the most recent patient data base, and to suspend protocol use when medical problems not addressed by the protocols demand attention. The protocol logic operates in the background and does not interfere with use of the bedside terminal for other tasks such as nurse and respiratory care charting.

Performance evaluation

The protocols were used in an intensive care unit by the routine clinical staff, who would either follow or not follow an instruction. All instructions for 80 consecutive patients managed with the computerized protocols were reviewed and were categorized as 1) whether or not the instruction was correct and 2) whether or not the instruction was followed. Since the paper based protocols created by the clinical team represented the desired medical logic, the therapy instructions derived from the paper diagrams were considered to be the 'correct' instructions. When the computer instruction differed from the paper protocol instructions they were classified as 'incorrect'.

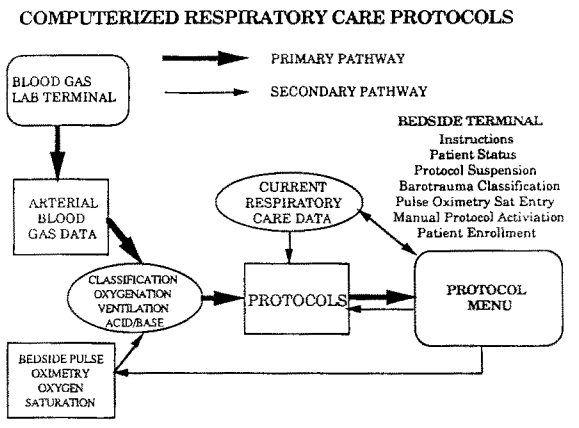

Fig. 1. Basic organization of the computerized protocols. Originally published in the Proceedings of the Thirteenth Annual Symposium on Computer Applications in Medical Care, IEEE Computer Society Press, Los Alamitos, CA, 1989, pp. 588–592 [3].

Instructions classified as 'incorrect' and all clinical actions which differed from computerized protocol instructions (correct instructions not followed) were examined by two individuals (SEH and CJW) and classified into one of the following categories:

Correct instructions
(not followed by the clinical staff)

Clinical staff digressions from the protocol: Correct protocol instructions which were interpreted incorrectly or ignored or with which the clinicians disagreed. Clinicians at the bedside were allowed to over-ride protocol instructions when the medical problem was not covered by the protocol, when the patient was unstable and required immediate intervention, and when it was thought to be medically justified to challenge the instruction. When physicians challenged the protocol logic, the issues were discussed by the entire team and the objection resolved.

Incorrect instructions (followed or not followed)

Software error: Error in the software code.
Nonrepresentative data: Data in the computer data base that was incorrect or not 'representative' of

the patient's lung function, or missing at the time the protocol instruction was generated. For example, if changes had been made in the patients ventilator settings but had not been recorded and the protocols were activated, the instruction generated would be based on data that was not current and would be classified as 'incorrect' because of non-representative data.

Undefined protocol logic (undefined logic): Decisions made in sections of the protocols that were in development or which had been instituted in the paper based protocols but had not yet been computerized.

Cascade errors: Errors that occurred because a previous error had not been corrected before the next instruction was issued.

Other: Incorrect instructions caused by computer system problems or incorrect use of the computer protocols. Instructions where reasons for the error could not be identified were also included. Computer system issues included computer down time, and problems with the data drive mechanism. The data drive is a system tool which initiates a particular process whenever a specific data item is stored in the data base. This tool was originally used to activate the computer protocols whenever arterial blood gas data were stored for a protocol controlled patient. The tool proved to be unreliable and an alternate method of protocol initiation was developed and implemented after patient # 3.

We will, with permission, also report some data from a subset of the study population (12 patients, numbers 25 to 36) that was reported in 1990 [4] wherein we addressed the issues of whether compliance with the protocol instructions was affected by whether the instruction was correct, the direction of therapy (whether therapy intensity was increased or decreased or left unchanged) or the mode of ventilatory support. The term compliance is used only to indicate whether or not instructions were followed. The ventilatory support modes used in this clinical trial were: CPPV (Continuous Positive Pressure Ventilation), CPAP (Continuous Positive Airway Pressure), PCIRV (Pressure Control Inverse Ratio Ventilation), and $ECCO_2R$) (Low Frequency Positive Pressure Ventilation with Extracorporeal CO_2 Removal). Instructions in each of these modes were analyzed to determine if the mode of ventilation affected compliance with the computerized instructions. Individual patients may have been supported with more than one mode of ventilatory support.

Statistical analysis

A Chi-square test of independence was used to evaluate the frequency with which protocol instructions were followed or not followed as a function of instruction accuracy, direction of therapy, or the mode of ventilatory support. Significance was set at $p < 0.01$ because multiple comparisons were made. Mantel Haenszel Chi-Square analysis was used to evaluate compliance with protocol instructions as a function of time.

Results

Computerized protocols were used to manage arterial oxygenation in 80 ICU patients between September, 1987 and May, 1991. Fifty of these patients were not enrolled in the clinical trial comparing new and traditional ARDS therapy. Of 21,347 instructions issued on these 80 patients, 90.2% were classified as 'correct' and 89.7% were followed by the clinical staff (Table 1). Computerized protocols were used simultaneously with the paper based protocols for the first 16 patients (9/87 to 7/89) [3, 4]. After July, 1989 the computerized protocols were used exclusively with the paper based protocols being used only when the computer was unavailable or as a reference. Protocol performance for the first eight patients in the study differed, as a group, from the following 72 patients. Of 1892 instructions in the first 8 patients, 1352 instructions (71.5%) were classified as correct and only 1208 instructions (63.8%) were followed (correct instructions and instructions followed were not always the same) (Table 1). In the subsequent 72 patients 92.3% of 19,455 instructions were followed and 92.8% were correct (Table 1). There were 243 digressions from the protocols by the clinical staff over half of which occurred with the first eight patients.

There were 540 'incorrect' instructions with the

first 8 patients. Twenty-five percent of these incorrect instructions were caused by software errors and 26% by nonrepresentative data. For the subsequent 72 patients, there were 1399 'incorrect' instructions; 11% were due to software errors and 58% to nonrepresentative data. The number of software errors expressed as a percent of total instructions decreased from 7.2% in the first 8 patients to 0.8% for subsequent patients. The percent of incorrect instructions caused by nonrepresentative data decreased from 7.5% of total instructions for the first 8 patients to 4.2% for the remaining 72 patients (Table 1).

Figure 2 illustrates the percent of instructions that were followed by the clinical staff for each individual patient in sequence. There was a highly significant increase in compliance with protocol instructions with time ($P < 0.00001$).

Results of the expanded analysis for the subset of 12 patients are summarized in Tables 2 and 3. The clinical staff was slightly more likely to follow an instruction to wait (make no change in therapy) than to increase or decrease the intensity of therapy (Table 2). There was a trend suggesting they would be more likely to follow an instruction to increase therapy over one to decrease it but it was not statistically significant. The mode of ventilatory support did not affect the likelihood that the clinician would follow an instruction (Table 2). As expected, instruction accuracy had the dominant effect. The clinical staff was clearly more likely to follow a 'correct instruction' (97.5% followed) than an 'incorrect' one (27.3% followed). Because of the strong effect of instruction accuracy on compliance with the protocols, we also examined the effect of the direction of therapy instructions and the mode of ventilatory support using only the 'accurate' instructions (Table 3). The clinical staff was still statistically more likely to follow an instruction to 'wait' than to increase or decrease therapy intensity. Though the difference for a wait instruction was statistically significant, the differences between the wait instructions and instructions to increase or decrease therapy were clinically insignificant. Compliance with the protocols did not change with the mode of ventilatory support when only accurate instructions were analyzed.

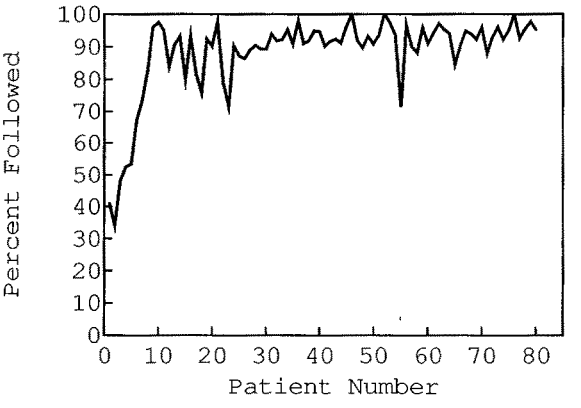

Fig. 2. Percent of computerized protocol instructions followed by the clinical staff calculated and displayed for each individual patient. Twenty-one patients were treated using paper based protocols before computerized protocols were instituted. Patient number one in this figure is the first patient in whom the computerized protocols were followed and the twenty-second patient treated with protocols.

Discussion

Issues relating to whether or not instructions were 'correct'

Protocol therapy instructions were classified as correct 90.2% of the time in the eighty patients (Table 1), and incorrect 9.8% of the time. The term incorrect is used only to indicate that a computerized instruction differed from what was intended based on the paper-based protocols; such instructions were not necessarily clinically inappropriate. The most common reason for an incorrect instruction was nonrepresentative data and the primary reason for nonrepresentative data was delayed computer data entry by the clinical staff. Delayed data entry resulted in a data base that was not likely to be representative of the patients true clinical state at the time the protocols were activated. Other causes of nonrepresentative data included data that was missing or incorrectly entered and data associated with transient instability of the patient. An interesting side effect of computer protocol use was an improvement in the accuracy of the patient's computerized medical record. Although the protocols were complex, the clinical staff learned to anticipate protocol instructions quite accurately making

it possible for them to recognize that a protocol instruction was based on erroneous data. It became common for the clinical staff to return to the patient's computerized medical record, edit the bad data, and generate a new protocol instruction using corrected data.

Occasionally a computer protocol instruction would be generated during a brief period of instability where the clinical data, though accurate, were not representative of the patient's steady state conditions. For example, minor manipulations like suctioning or turning the patient can cause transient drops in arterial oxygen saturation. Protocol instructions based on the transient data were considered incorrect. The clinical staff was instructed to ignore them and to generate a new therapy instruction by bedside activation of the protocols once the patient had stabilized. The problem of nonrepresentative data was recognized early in the use of the protocols and training programs were instituted to correct the problem. While improvement in the timely and accurate entry of data was achieved, the problem persists and, we expect the effect of training alone to be limited. In the complex and stressful setting of an ICU, patient care must retain the highest priority. Data entry of patient parameters may be delayed by urgent patient care needs. Automated data collection and recording is currently being tested in the ICU using a Medical Information Bus (MIB) system [8–10]. Implementation of the MIB may minimize this category of error. It will also alter the data collection environment, raising new possibilities and problems.

After the testing and debugging process that occurred primarily in the first 8 patients, software errors proved to be insignificant. Software errors were associated with 7.2% of all instructions in the first 8 patients and with only 0.8% of the instructions in subsequent patients. During the care of the first 8 patients the software was being updated to correspond with the current versions of the paper based protocols and, at the same time, was being tested, corrected, and refined. For the first 8 patients the clinical staff was actively using both the paper and computer versions of the protocol with the understanding that the paper protocol was to have precedence when conflicts were encountered. By the ninth patient the computerized protocols were sufficiently accurate to be used clinically and precedence was then given to the computerized protocol instructions. As new decision logic was added to the existing protocols, this process of testing and debugging the software was repeated.

Incorrect instructions which occurred because of undefined protocol logic were associated with 4.8% of all instructions in the first 8 patients declining to 0.5% for the entire study group. Undefined logic refers to those areas of protocol logic that were not explicitly defined. For example, the current protocol logic contains the simple clinical question, 'Is paralysis needed?'. The patient parameters used and the clinical assumptions involved in answering this question have not been explicitly defined. Therefore, we have been unable to develop logic that would allow the computer to determine a patient's need for paralysis. One advantage of computerizing protocol logic is that it forces the careful examination of the factual and logical basis for every decision. In doing so, it forces the identification of underlying assumptions and deficiencies and becomes an effective method of clarifying the process of medical decision making.

Cascade errors were incorrect instructions which occurred because a previously counted error had not been corrected before another instruction was generated. For example: if the most recent value of PEEP was 25 cm H_2O, but the therapist erroneously charted 5 cm H_2O, an incorrect instruction would be generated. Additional incorrect instructions generated before the erroneous PEEP entry was corrected were counted as cascade errors. We did not isolate this category in the first 8 patients, but in the subsequent patients it accounted for 22% of the incorrect instructions. We believe that the majority of the cascade errors occurred as a function of nonrepresentative data with fewer errors a result of software problems. We do not, however, know the exact breakdown of the cascade errors as a function of the original error.

The incorrect instructions categorized as 'Other' included computer system problems, incorrect use of the computer protocols and instructions which could not be categorized elsewhere. Incorrect use

of the protocols included occurrences when the clinical staff incorrectly suspended or terminated suspension of the computer protocols. Protocol control is suspended for situations or processes which are outside the scope of protocol logic, such as patient transport, surgical procedures, dialysis, etc. We were able to find an explanation for all but 1.5% of the incorrect instructions.

The category 'Clinical Staff digressions' does not refer to incorrect instructions, but rather to correct instructions that were not followed. There were 144 (7.6%) such instances for the first 8 patients, 99 (0.5%) in the subsequent patients, and 243 (1.1%) for the total population of 80 patients. Disagreements with protocol instructions and unexplained failure to follow instructions were considered to be a function of the clinicians' treatment preference or style; such instances decreased as confidence in the protocols grew. Increases in digressions would occur when new logic was computerized and when new staff members rotated into the ICU and were introduced to protocol controlled patient care.

The major problems currently confronting use of computerized protocols are logistical: 1) inaccurate and delayed data entry, 2) misunderstandings by the clinical staff of the elements of therapy covered by the protocols, and 3) failure to master the technical aspects of operating the protocols. Correction of these problems would eliminate practically all of the remaining incorrect instructions.

Clinical staff adherence to protocols

Compliance with the protocols was evaluated by measuring how often the instructions were followed by the clinical staff. The percent of protocol instructions followed improved with time (Fig. 2, Table 1). The transinet drops in compliance seen in Fig. 2 are primarily a result of the introduction of new logic, rotation of new clinical staff into the ICU, and identification of previously unencountered clinical problems. They also occasionally occurred as a result of a small total number of instructions for a given patient. For example, patient 15 was under protocol care for only a short time receiving only 5 protocol instructions of which 4 instructions (80%) were followed.

In the subset of 12 patients (patients # 25–36), 89% of all instructions were followed. Instruction accuracy was the most important factor associated with protocol compliance (Tables 2 and 3). Instructions directing an increase in therapy intensity were followed 89.4% of the time and instructions directing a decrease in therapy were followed 86.5% of the time (Table 2). This difference was close to statistical significance ($p = 0.06$). Further data might confirm a slight preference by clinicians to increase therapy intensity over reducing it. When the clinician was instructed to remain at the current level of therapy (a wait instruction) compliance increased to 96.9% (Table 2).

Since the effect of accuracy on compliance was so strong, we also analyzed the data using only the accurate instructions. When the instructions were

Table 1. Protocol performance summary

Patients	Total instructions	Number followed	Number 'correct'	Clinical staff digressions	Causes of incorrect instructions				
					Software errors	Nonrepresentative data	Undefined logic	Cascade errors	Other
1–8	1,892	1,208	1,352	144	136	141	91	Unknown	172
(% total instructions)		(63.8)	(71.5)	(7.6)	(7.2)	(7.5)	(4.8)		(9.1)
9–80	19,455	17,949	18,056	99	154	813	20	314	98
(% total instructions)		(92.3)	(92.8)	(0.5)	(0.8)	(4.2)	(0.1)	(1.6)	(0.5)
All patients	21,347	19,157	19,408	243	290	954	111	Unknown	270
(% total instructions)		(89.7)	(90.2)	(1.1)	(1.4)	(4.5)	(0.5)		(1.3)

See the text for definitions

Table 2. Effect of instruction accuracy, type of therapy instruction and mode of therapy on whether instructions are followed (12 patients – all instructions)

	Total instructions n	Instructions followed n (%)	Instructions not followed n (%)
Effect of instruction accuracy*			
Instruction 'correct'	2337	2278 (97.5)	59 (2.5)
Instruction 'incorrect'	300	82 (27.3)	218 (72.7)
Effect of therapy**			
Intensity increased	829	741 (89.4)	88 (10.6)
Intensity decreased	1284	1111 (86.5)	173 (13.5)
No change – wait	524	508 (96.9)	16 (3.1)
Effect of mode of therapy***			
CPPV	1914	1705 (89.1)	209 (10.9)
CPAP	349	313 (89.7)	36 (10.3)
PCIRV	128	125 (97.7)	3 (2.3)
$ECCO_2R$	246	217 (88.2)	29 (11.8)

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The 12 patients were patients 25–36.
* $p < 0.001$ by Chi-square test of independence
** $p < 0.001$ by Chi-square test of independence. An instruction to make no change – wait is statistically different from the other two instructions ($p < 0.02$). The difference between increasing and decreasing therapy was not significant, $p = 0.06$
*** $p = 0.02$

Table 3. Effect of type of therapy and mode of therapy on compliance with 'accurate' protocol instructions (12 patients – 'accurate' instructions only)

	Total instructions n	Instructions followed n (%)	Instructions not followed n (%)
Effect of therapy*			
Intensity increased	742	723 (97.4)	19 (2.6)
Intensity decreased	1102	1062 (96.4)	40 (3.6)
No change – wait	493	493 (100.0)	0 (0.0)*
Effect of mode of therapy**			
CPPV	1705	1657 (97.2)	48 (2.8)
CPAP	303	298 (98.3)	5 (1.7)
PCIRV	123	121 (98.4)	2 (1.6)
$ECCO_2R$	206	202 (98.1)	4 (1.9)

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The 12 patients were patients 25–36.
* $p < 0.001$ by Chi-square test of independence. The no change – wait instruction is significantly different from the other two instructions.
** $p = 0.52$ by Chi-square test of independence.

accurate, when there were no software errors and the data was current and correct, the percentage of instructions followed increased from 89.5% to 97.5% (Table 2). Analyzing only the accurate instructions, the pattern of compliance as a function of therapy intensity was unchanged (Table 3). The finding that wait instructions were followed more frequently than instructions to increase or decrease therapy is consistent with the feelings of the clinical staff that an instruction to wait is easier to follow than one to change therapy.

There was no difference in the degree of compliance with the protocols as a function of ventilatory support mode whether all instructions or only accurate instructions were analyzed [4] (Tables 2 and 3). There were slight differences among the modes in the distributions of the directions of therapy instructions but the differences were small and should not affect the preliminary conclusion that compliance with the protocols was unaffected by ventilatory support mode [4]. The sample size is too small, however, to be certain of this conclusion.

Of the 300 instructions (11.4% of the total) classified as incorrect (Table 2), eighty-two (27.3%) were followed by the clinical staff. This could be interpreted to suggest that the clinical staff blindly followed protocol instructions. We think this is not the case for the following reasons: 1) Since our protocols represent only one way of approaching therapy a computerized instruction that differed from the intended instruction may still have been clinically appropriate, 2) the therapeutic steps suggested by the protocol are small, for example, 'increase PEEP by 2 cm H_2O', and, thus, are unlikely to cause objections by the clinical staff, 3) no clinical errors as a result of protocol use were reported, 4) the clinical staff is sophisticated and unlikely to follow an instruction that violates good clinical judgement, and 5) the clinical outcomes were good (survival for the clinical trial patients was four times that of historical controls (39% vs 9%) [11]).

In summary, the development of protocol logic and the subsequent computerization requires the medical care provider to carefully examine the assumptions, preferences, biases, deficiencies, and information involved in the decision making process. The systematic and careful development of protocol logic and its acceptance by consensus are the most important factors in the success of our medical protocols. We believe that the most significant implication of this study is that protocol controlled care of critically ill patients is possible in spite of the complexity of the environment and the differing clinical styles of the clinicians.

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