Large Scale Implementation of a Respiratory Therapist–driven Protocol for Ventilator Weaning

E. WESLEY ELY, PATRICIA A. BENNETT, DAVID L. BOWTON, SEAN M. MURPHY, ALLISON M. FLORANCE, and EDWARD F. HAPONIK

Department of Internal Medicine, Section on Pulmonary/Critical Care Medicine, Wake Forest University School of Medicine, Winston-Salem, North Carolina

We prospectively investigated the large-scale implementation of a respiratory-therapist–driven protocol (TDP) that included 117 respiratory care practitioners (RCPs) managing 1,067 patients with respiratory failure over 9,048 patient days of mechanical ventilation. During a 12-mo period, we reintroduced a previously validated protocol that included a daily screen (DS) coupled with spontaneous breathing trials (SBTs) and physician prompt, as a TDP *without* daily input from a physician or "weaning team." With graded, staged educational interventions at 2-mo intervals, RCPs had a 97% completion rate and a 95% correct interpretation rate for the DS. The frequency with which patients who passed the DS underwent SBTs increased throughout the implementation process ($p < 0.001$). As the year progressed, RCPs more often considered SBTs once patients had passed a DS ($p < 0.001$), and physicians ordered more SBTs (46 versus 65%, $p = 0.004$). Overall, SBTs were ordered more often on the medicine than on the surgical services (81 versus 63%, $p = 0.001$), likely reflecting medical intensivists' prior use of this protocol. Important barriers to protocol compliance were identified through a questionnaire (89 respondents, 76%), and included: Physician unfamiliarity with the protocol, RCP inconsistency in seeking an order for an SBT from the physician, specific reasons cited by the physician for not advancing the patient to a SBT, and lack of stationary unit assignments by RCPs performing the protocol. We conclude that implementation of a validated weaning strategy is feasible as a TDP without daily supervision from a weaning physician or team. RCPs can appropriately perform and interpret DS data more than 95% of the time, but significant barriers to SBTs exist. Through a staged implementation process, using periodic reinforcement of all participants in ventilator management, improved compliance with this large-scale weaning protocol can be achieved. Ely EW, Bennett PA, Bowton DL, Murphy SM, Florance AM, Haponik EF. Large scale implementation of a respiratory therapist–driven protocol for ventilator weaning.

AM J RESPIR CRIT CARE MED 1999;159:439–446.

With heightened awareness of the importance of removing patients from mechanical ventilation, considerable research effort has been dedicated to defining the most appropriate and efficient method of weaning patients from a ventilator. In 1995, Esteban and colleagues (1) showed that spontaneous breathing trials (SBTs) were superior to pressure support or intermittent mandatory ventilation-based strategies. We conducted a prospective, randomized, controlled trial in which respiratory care practitioners (RCPs), nurses, and physicians identified patients who had recovered from respiratory failure through a two-step weaning protocol that incorporated a daily screen (DS) and a SBT (2). In comparison with conventional management by critical care physicians in a "closed ICU," use of this protocol shortened weaning time by 2 d, reduced the overall complication rate by 50%, and lowered the cost of ICU care by more than $5,000 per patient.

Although our original protocol documented the vital contributions of nonphysician health care professionals in the management of ventilated medical patients, it was conducted as a therapist-focused, rather than a therapist-driven, protocol (TDP). Other groups have stressed the importance of "weaning teams" (3) and TDPs (4, 5), but there are few data documenting the feasibility and/or steps necessary in implementing such protocols on a large scale with monitoring of protocol compliance. Kollef and coworkers (6, 7) and Wood and colleagues (8) have pioneered investigations involving weaning protocols and outcomes research in the ICU setting. We sought to prospectively monitor and describe the institution-wide implementation of our previously validated approach. Importantly, we reintroduced the protocol without the daily input of a weaning team, physician or RCP supervisor in order to test its feasibility as a TDP. Lastly, we wished to explore the challenges of modifying RCPs and physicians' practice styles in the "out of study" setting over an entire year's period.

(*Received in original form May 29, 1998 and in revised form September 4, 1998*)

Correspondence and requests for reprints should be addressed to E. Wesley Ely, M.D., M.P.H., Section of Allergy, Pulmonary, and Critical Care Medicine, Department of Internal Medicine, Vanderbilt University School of Medicine, Room 913 Oxford House, Nashville, TN 37232-4760.

METHODS

Patients

The study population comprised patients admitted to the medical, surgical, and coronary intensive care units (ICUs) of our 840-bed University Medical Center between March 1997 and February 1998. Patients in the cardiothoracic surgical ICU were enrolled only if they continued receiving ventilation after 24 h, as they are routinely managed during the first day with a rapid "wean to extubation" protocol. Bone marrow transplant and neurosurgical ICUs were excluded because of other ongoing research investigations in those units.

Study Protocol

The protocol (2) was endorsed for widespread implementation by all of the hospital's ICU directors, nursing coordinators, and the Department of Respiratory Care. The overall approach remained as the previously validated two-step process of daily screens (DSs) followed by spontaneous breathing trials (SBTs) when patients had recovered sufficiently to pass a DS (APPENDIX 1) (2). As opposed to the original investigation in which a "study physician" (not directly involved in patient care) oversaw SBTs, the current approach reintroduced the protocol as a TDP without direct, daily physician or "weaning team" supervision. RCPs evaluated patients each morning between 6:00 and 7:00 A.M., and it was their responsibility to record DS results on a bedside data collection form (APPENDIX 2). RCPs also communicated successful passing of a DS to managing physicians in an effort to obtain a physician order for a SBT. During the study period 117 RCPs rotated through different ICUs; they did not remain dedicated to any particular unit or pod. RCPs were allowed to change the $F_{I_{O_2}}$, level of PEEP, and advance to a SBT once a physician order had been obtained.

Daily screening (DS). A "readiness to wean" screen was added to the original protocol in order to prompt RCPs to wean patients' positive end-expiratory pressure (PEEP), fraction of expired oxygen ($F_{I_{O_2}}$), and ventilator frequency. These steps were made only after approval from managing physicians, using monitoring parameters (i.e., termination criteria) identical to those described below for SBTs. The "readiness to wean" screen was considered passed when the patient's minute ventilation was < 15 L/min, $F_{I_{O_2}}$ was $< 60\%$, and PEEP was < 10 cm H_2O. The DS used in the original investigation (2) was the next step in the protocol. All five of the following criteria had to be met in order to pass the DS: the ratio of partial pressure of oxygen to the $F_{I_{O_2}}$ ($Pa_{O_2}/F_{I_{O_2}}$) had to exceed 200; the PEEP could not exceed 5 cm H_2O; there had to be an adequate cough during suctioning (i.e., airway reflexes had to be intact); the ratio of respiratory frequency to the tidal volume could not exceed 105 breaths/min/L; and no continuous infusion of vasopressor agents or sedatives could be used (Dopamine could be given in doses not exceeding 5 μg/kg body weight/min, and intermittent bolus dosing of sedatives were allowed). To measure f/V_T, a continuous positive airway pressure of 5 cm H_2O with no mandatory breaths from the ventilator was supplied, and pressure support was removed for 1 min (a criterion that differed from the original description of the test) (9). Minute ventilation and respiratory rate were measured by the Puritan-Bennett 7200 (Puritan Bennett, Carlsbad, CA) or the Siemens 900 (Siemens, Berlin, Germany) mechanical ventilator, and tidal volume was obtained by dividing the minute ventilation by the respiratory frequency. Weekly bedside "spot checks" were conducted to monitor RCP's technique of performing the DS (including the f/V_T measurement) as well as their calculating the f/V_T, $Pa_{O_2}/F_{I_{O_2}}$ ratio, and assessment of an intact gag reflex.

Spontaneous breathing trials (SBTs). Patients who successfully passed a DS underwent a SBT later that morning if their managing physician gave the RCP an order to proceed. Despite the lack of complications from SBT attempts during the original investigation, many attending physicians at the time of hospitalwide reintroduction of this protocol regarded such notification prior to a SBT as necessary. They expressed concerns about the frequent rotations of RCPs among ICUs and the possibility that physicians may be relatively unfamiliar with some RCPs who would otherwise be making decisions for a SBT. During the SBT, ventilatory support was removed and the patient was allowed to breathe through either a T-tube or ventilator circuit using "flow triggering" (rather than triggering by pressure) and continuous positive airway pressure of 5 cm H_2O. No changes were made in the $F_{I_{O_2}}$ or the level of PEEP. The SBT was initiated and monitored by the RCP and nurse caring for the patient, with cardiac monitoring and pulse oximetry throughout. The SBT was terminated by the RCP, nurse, or physician if any of the following criteria were met: a respiratory rate > 35 breaths/min for 5 min or longer, an arterial oxygen saturation $< 90\%$ for more than 30 s, a heart rate > 140 beats/min, sustained changes in the heart rate of 20% in either direction, a systolic blood pressure > 180 mm Hg or < 90 mm Hg, increased anxiety, or diaphoresis. A trial was considered successful when the patient could breathe without mechanical ventilation for 30 min to 2 h. This duration was altered from that of the original investigation, which required completion of 2 h of spontaneous breathing, and was prompted by data from a recent randomized, controlled trial (10). However, the default duration for a SBT was 2 h, and unless a physician specifically requested a shorter SBT, 120 min was used.

Physician prompt. Because of reluctance on the part of one physician group, we did not incorporate a physician prompt into the hospital-wide investigation (2).

Implementation Schedule and Educational Interventions

The protocol was reintroduced in a staged, graded process at 2-mo intervals (Table 1). The sequence was designed after consideration of the size of our ventilator service, ICU organizational structure, variability of work rounds and other ICU pod activities, the numbers of caregivers and existing communication channels, and other factors unique to our Medical Center. Implementation began during March and April 1997 with the comprehensive in-servicing of RCP supervisors, and included classroom-based as well as bedside, hands-on instruction. During May and June, the entire RCP staff ($n = 117$) was in-serviced in the same fashion. Didactic teaching and bedside, case-based instruction was used in all elements of the protocol, including conducting the DS, interpreting its different components, and initiating and conducting SBTs. Physician education was conducted during the months of July and August. Particular emphasis was placed upon the team approach to management. It was stressed that a dual responsibility existed on the part of RCPs and physicians in order to continue advancing their patients through the protocol. Physicians were made aware of published results of the previous investigation, that the information relating to DS would be available to them at the bedside on daily rounds, and that they would be contacted by RCPs when patients had passed DS and were ready for SBTs. During the months of September and October 1997, RCPs were provided feedback concerning compliance rates with the protocol. In addition, a survey was conducted to determine RCPs perceived barriers to the protocol. Further in-servicing of the RCPs was repeated at this time, addressing concerns communicated through the survey. During November and December 1997, we provided nursing in-servicing as well as physician feedback regarding protocol compliance. During the final interval in January and February 1998, a quality management coordinator (P.A.B.) and resident physician (S.M.M.) performed daily compliance checks. In addition, daily spot checks during rounds with physicians and nurses were performed by two key role models (an RCP supervisor and a resident physician [S.M.M.]) who assessed their awareness of the protocol and its role in patients' management. During this time, monthly meetings were also held with physician and nonphysician supervisors within the Respiratory Care Department. Frequent contacts

TABLE 1

IMPLEMENTATION SCHEDULE*

Interval No.	Time Interval (1997–1998)	Intervention
1	Mar/April	RCP supervisors' education
2	May/June	RCP staff in-servicing
3	July/Aug	Physician education
4	Sept/Oct	RCP feedback and survey
5	Nov/Dec	Nursing in-servicing; physician feedback
6	Jan/Feb	Daily compliance checks by quality management coordinator

* Alternative (institution-specific) sequences may be appropriate.

were made with the directors of surgical and medical ICU staff members.

Data Collection and Monitoring

A ventilator weaning protocol documentation form was developed (APPENDIX 2) that consisted of a top (white) copy and a bottom carbonless (yellow) copy. Forms were completed daily by RCPs on all mechanically ventilated patients in the protocol and were kept at patients' bedsides during their ICU stays. Upon ICU discharge, the white copy was placed in the medical record chart, and the yellow copy was mailed to the Respiratory Care Department's Quality Management Coordinator (P.A.B.) who entered all data into the computerized database. Monthly reports were designed and generated from the database, which enabled prospective, serial monitoring of RCP and physician compliance with the protocol.

Statistical Analysis

Proportions and rates (e.g., compliance data for the DS and SBT) were compared by the chi-square test. The Mann-Whitney U test was used to analyze lengths of stay and other continuous variables that were not normally distributed, and the two-tailed *t*-test was used to compare variables with normal distributions (11). The significance level was adjusted for multiple comparisons so that tests resulting in p values of 0.01 or less were considered to represent statistically significant comparisons. All data analyses were performed using SAS software (SAS Institute Inc., Cary, NC).

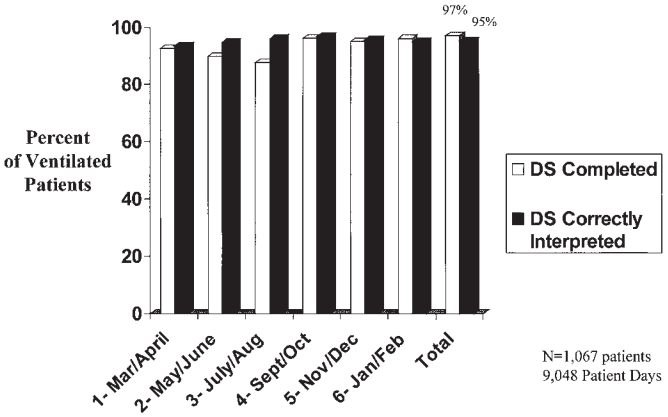


Figure 1. Histogram showing the percent of mechanically ventilated patients (n = 1,067 patients; 9,048 patient-ventilator days) who had completion of their daily screen and correct interpretation of the daily screen data by the respiratory care practitioners during each 2-mo implementation period. Total daily screen completion rate was 97% across the year of implementation with a 95% correct interpretation rate of the data within the daily screen ($p > 0.35$).

RESULTS

Demographic Variables

A total of 1,167 patients were enrolled in the protocol, and 9,048 patient days of mechanical ventilation were appraised. The mean age was 60.1 ± 16.9 (SD), and there were 605 men (56.7%) and 462 women (43.3%), 850 (79.7%) were Caucasian, 191 (17.9%) were African-American, 18 (1.6%) were Hispanic, and 7 (0.6%) were Asian. The principal causes of their respiratory failure are listed in Table 2.

Compliance with Daily Screening and Spontaneous Breathing Trials

Compliance with the protocol was monitored as described in METHODS. RCP completion of the DS varied little on average throughout the year, with an overall completion above 95% ($p = 0.35$) (Figure 1). Correct interpretation of the DS was also high (95% overall correct) ($p = 0.42$). Once the DS was completed and passed, the next step of the protocol was to assess the patient's ability to pass a SBT. Overall compliance rates in obtaining a SBT were initially low (10%), but they increased in the fifth and sixth months and remained fairly steady thereafter, so that approximately one-third of the patients underwent SBTs when they had sufficiently recovered from respiratory failure ($p < 0.001$) (Figure 2). In order to assess contributions of components of the protocol team and their roles in obtaining SBTs, we independently reviewed the performances of RCPs and physicians in the following manner. When patients passed the DS, the frequency with which RCPs entered any response (yes or no) on the data collection form (APPENDIX 2) in the row for a SBT was used as an indication that they had at least considered a SBT at the appropriate time. This rate of consideration of SBTs by RCPs is displayed

TABLE 2

CAUSES OF RESPIRATORY FAILURE IN 1,067 VENTILATED PATIENTS

Diagnosis	Frequency	%
CHF or MI	123	11.5
COPD or OSA	116	10.9
ARDS or MODS	154	14.4
CT surgery	95	8.9
General surgery	130	12.2
Trauma	135	12.7
Other*	314	29.5

Definition of abbreviations: ARDS = acute respiratory distress syndrome; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CT = cardiothoracic; MI = myocardial infarction; MODS = multiorgan dysfunction syndrome; OSA = obstructive sleep apnea.

* Indicates gastrointestinal bleeding, malignancy, diabetic ketoacidosis, drug overdose, seizures, meningitis, renal failure.

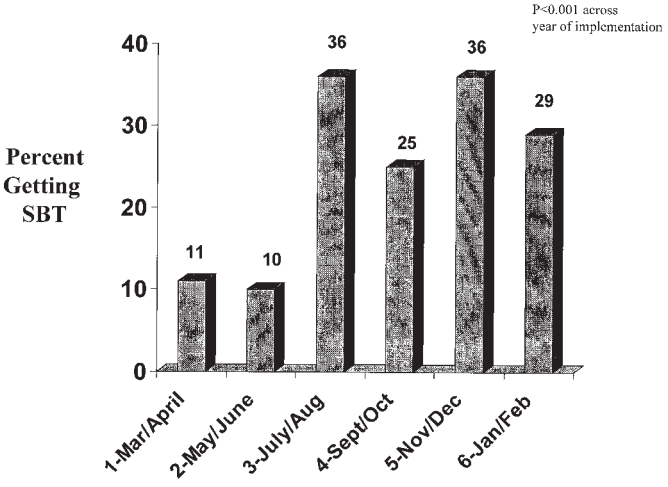


Figure 2. Histogram showing the percent of patients who received a spontaneous breathing trial after having passed the daily screen. Periods 1 to 6 on the *x*-axis represent the six 2-mo intervals of implementation, which demonstrated a statistically significant improvement in spontaneous breathing trial compliance rates across the year ($p < 0.001$).

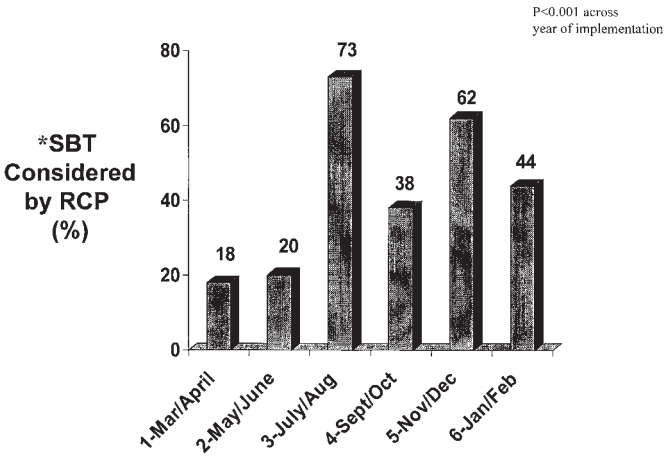


Figure 3. Histogram showing the frequency with which spontaneous breathing trials were considered by respiratory care practitioners after the patients had passed the daily screen. Periods 1 to 6 on the *x*-axis represent the six 2-mo periods of implementation, which demonstrated a statistically significant improvement in the frequency with which our respiratory care practitioners considered spontaneous breathing trials ($p < 0.001$).

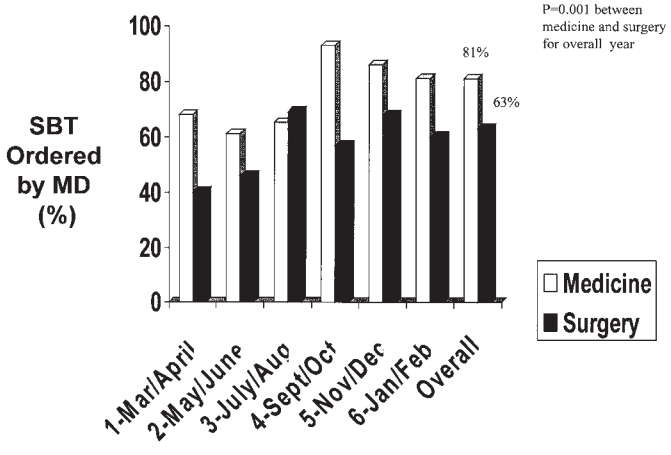


Figure 5. Histogram showing the percent of time that spontaneous breathing trials were ordered by medical versus surgical physicians once approached by respiratory care practitioners with data that their patients had passed the daily screen. Periods 1 to 6 on the *x*-axis represent the six 2-mo periods of implementation. When the overall year of data were considered, the compliance rate with spontaneous breathing trials was 81% for medicine versus 63% for surgery ($p = 0.001$).

in Figure 3. Initially, SBTs were considered infrequently (18%), but these rates increased ($p < 0.001$). When RCPs approached physicians for a SBT order, the frequency with which "yes" was entered on the data collection form is displayed in Figure 4. Physicians' compliance rates (i.e., their ordering SBTs) increased after the fourth month of implementation and ranged from 46 to 67% ($p = 0.004$). Specific reasons physicians would forego SBTs in patients passing DSs were not recorded consistently. To determine whether the frequency of ordering SBTs differed in relation to physician specialty, we compared medical and surgical performance (Figure 5). Across the year of implementation, SBTs were more often ordered on the medicine services (81 versus 63%, $p = 0.001$).

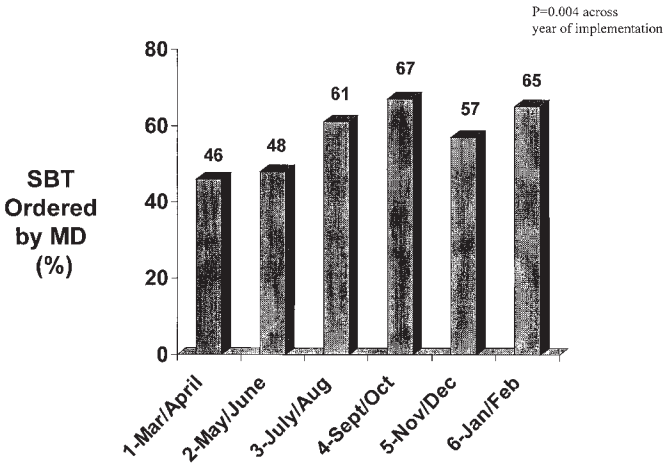


Figure 4. Histogram showing the percent of time that spontaneous breathing trials were ordered by physicians once approached by respiratory care practitioners with data that their patients had passed the daily screen. Periods 1 to 6 on the *x*-axis represent the six 2-mo periods of implementation, which demonstrated a statistically significant improvement in the frequency of physician-ordered spontaneous breathing trial rates ($p = 0.004$).

Outcome Variables and Duration of Mechanical Ventilation

During DS assessments, there were no complications detected such as temporally associated self-extubations, prolonged desaturations, or hemodynamic instability, and only one reported possible complication (0.1%) from a SBT. In the latter instance, approximately 1 h after a failed 45-min SBT attempt, a trauma patient experienced a transient episode of desaturation and hypotension, which resolved after a fluid bolus and increase in $F_{I_{O_2}}$. However, cardiopulmonary instability persisted, and the patient died 48 h later from suspected nosocomial pneumonia and sepsis. Once patients passed the DS ($n = 722$), 41% ($n = 298$) consistently passed the DS, whereas 59% ($n = 424$) fluctuated between passing and not passing the DS. When the DS was passed and a SBT was obtained, patients would pass the SBT 75.4% of the time, a rate that did not vary over the six 2-mo periods of implementation or among services and units ($p = 0.297$). The length of time from intubation to undergoing a SBT, for those who were evaluated with a SBT, over each of the consecutive 2-mo periods was 4, 3, 3, 4, 3, and 4 d, respectively ($p = 0.45$). After passing the DS, the median length of time patients remained on the ventilator was 3 d (interquartile ranges, 0 to 13 d). After passing the SBTs ($n = 234$), the median length of time patients remained on the ventilator was 1 d (interquartile ranges, 0 to 8 d). These rates did not vary significantly during implementation or among different patient populations and ICUs ($p = 0.27$). Patients' lengths of stay on mechanical ventilation are summarized in Table 3 and did not vary significantly throughout the six 2-mo periods of implementation ($p = 0.17$). In addition, the median length of stay on mechanical ventilation for the first 6-mo period of protocol use was 5.7 d (interquartile ranges, 2 to 15) versus 6.6 d (2 to 17) for the second 6-mo period ($p = 0.32$). Overall complications of mechanical ventilation included reintubation within 48 h in 149 patients (14%), tracheostomy in 192 patients (18%), and prolonged mechanical ventilation > 21 d in 139 patients (13%). Outcomes of these 1,067 mechanically ventilated patients included 352 (33%) who were extubated and successfully discharged home, 117 (11%) went

TABLE 3

LENGTH OF STAY ON MECHANICAL VENTILATION*

Time Period (1997–1998)	Median (*d*)	Interquartile Ranges (25th–75th)
Mar/April	6	1 to 13
May/June	5	2 to 13
July/Aug	5	2 to 15
Sept/Oct	7	2 to 20
Nov/Dec	6	2 to 17
Jan/Feb	7	2 to 20

* $p = 0.17$.

home with home health services, 235 (22%) went to skilled nursing facilities, and 363 (34%) died during their hospitalizations.

Respiratory Care Practitioner Questionnaire

During the fourth phase of program implementation (September and October 1997), a questionnaire was administered to all 117 RCPs in order to assess their perceptions of the most common obstacles to the protocol and as an intervention to prompt RCPs to increase compliance rates. Eighty-nine (76%) RCPs responded to the questionnaire. The most commonly cited barriers to obtaining SBTs were: (*1*) RCPs thought house officers were uncomfortable advancing patients to SBTs without direct attending input (76% of respondents); (*2*) RCPs admitted that they were not consistent enough in seeking a SBT order from physicians (67%); (*3*) physicians had particular reasons for not moving patients on to SBTs despite their having passed a DS (67%); (*4*) RCPs thought that their continued rotation through all of the ICUs (rather than being dedicated to one ICU pod or location) was a detriment to protocol compliance (42%); (*5*) RCPs thought that there was inadequate "shift change" reporting of patients' status within the protocol among the therapists, hindering compliance and awareness of daily protocol management (36%); (*6*) some RCPs felt that this activity was not in their job description (16%).

DISCUSSION

This experience demonstrates the feasibility and challenges of implementing a previously validated protocol for discontinuation of mechanical ventilation. Although TDPs were relatively infrequently used in Respiratory Care Departments as recently as a decade ago, the latest surveys conducted by the American Association of Respiratory Care (12, 13) have indicated that as much as 60% of participating hospitals were currently using TDPs, and one-third of those had begun using TDPs during the previous year. Several editorials and overviews address the scope of TDPs, but few data have detailed the frequency of use of TDPs, implementation steps, or their impact upon ventilator weaning or management (4, 5, 8, 14). We reintroduced a two-step process of DS and SBT assessments (2) in our institution as a TDP. The lack of an overseeing "study physician," use of additional "readiness to wean" screen, and other freedom of RCPs to make these adjustments represented other important differences from our original protocol. We have prospectively documented RCPs' competence in performing and interpreting the DS, as well as improvement in RCP and physician compliance rates in using SBT assessments in their patients who have recovered from respiratory failure. This experience demonstrated that a commitment to the successful implementation of the TDP was necessary on the part of the hospital and its administration in order to insure its success. The initial outlay of resources, including dedicated monitoring staff, computer support, and the time of RCPs to attend in-services, was essential. In addition, we have identified significant practical barriers to protocol implementation. Although many aspects of this experience are unique to our Medical Center, several observations have important implications for institutions currently dealing with the need for a more systematic approach to mechanical ventilation.

Compliance with the Protocol

Although other investigators have reported initiation of various weaning algorithms (15–17), little published information about the details of compliance with such protocols exists. The first step of our approach involved the RCPs' morning assessment using the DS of weaning parameters. After the first few months of implementation, RCPs demonstrated remarkable consistency in this effort, with a $> 95\%$ performance rate in collection of the DS data and correct interpretation of whether or not the patients had passed the DS (Figure 1). Although these compliance rates are impressive, they were achieved in a setting in which many RCPs had been involved in our original investigation. Therefore, they were familiar with how to conduct and calculate the measurements involved in the DS. Achieving such high compliance with a group as large as 117 RCPs is comforting, although the amount of work necessary to attain such success should not be underestimated by institutions in their initial phases of implementation. Others have reported compliance rates less than 40% during weaning protocol introduction (18).

The second step of the protocol involved SBTs in patients who had recovered from respiratory failure (using passing the DS as the marker of recovery). At this point it became apparent that barriers existed in compliance with the protocol. It has been seen in Figure 2 that initially only 10% of patients who had passed their DS received a SBT, and that a significant improvement occurred, especially after the fourth month. RCPs and physicians (Figures 3 and 4) contributed to this initial low compliance rate, and each group showed significant improvements in their SBT compliance rates over time. However, there appeared to be a "ceiling effect" from our implementation in that there was not an incremental increase in compliance at the end of the year of implementation despite increased familiarity with the protocol. One limitation of our report is that we did not institute direct, daily supervision of the RCPs in their patient assessments prior to or during performance of SBTs. Thus, we have appraised the frequency, but not the accuracy, of RCP behaviors. In the absence of an independent, prospective review of all patients, the frequencies of protocol violations on the part of RCPs or physicians are unknown. Among physician specialties, we detected variations in their frequencies of ordering SBTs, with higher rates on the medicine than on the surgical services. Although these differences might reflect varying patient populations, management philosophies, or other undefined factors, they also reflect a higher baseline level of familiarity of some medicine staff through their exposure to the protocol during the prior study. The SBT rate in surgical patients is especially remarkable when it is considered that the current implementation represented the first extension of SBTs to this population.

The increment in compliance for both RCPs and physicians after the fourth month of implementation coincided with the period at which in-services to all members of these groups had been completed, and underscores the importance of interventions directed toward all protocol participants. The relative plateau in compliance following this "surge" probably reflects reinforcement of instruction to these groups. Alternatively,

this finding might suggest that a maximum impact of our intervention is achievable by 6 mo, and that other approaches would be needed to effect higher compliance rates. Interestingly, it appears that in-servicing physicians would adversely impact the next SBT. Mechanical ventilator-associated complication rates included a reintubation rate of 14%, tracheostomy rate of 18%, and prolonged mechanical ventilator stay ($>$ 21 d) of 13%. The current investigation did not compare management with this TDP with a control group, nor was it our purpose to restudy the efficacy and cost savings of the protocol. Rather, we attempted to appraise the complicated interplay of program implementation and the challenges of effecting changes in physician and nonphysician behaviors. Important differences from the original investigation that preclude a direct comparison of outcomes measures included a major shift in the patient population, more than one third of whom were trauma and other surgical patients, the lack of prospectively recorded severity of illness indicators, and marked expansion in the participating staff of physicians, RCPs, and nurses. Future investigations that include severity of illness measurements, complication rates, and protocol compliance rates should attempt to determine whether a varying impact on outcomes is achieved at different levels of protocol compliance. That the protocol was successful and safe in surgical ICU patients and accepted 63% of the time by surgeons overall during the first year is important new information, extending the relevance of this approach beyond the medical and coronary ICUs.

Additional Caveats

Implementation proved to be a dynamic process in which an initial plan was modified based upon the prospective monitoring of compliance with its components and feedback from all participating groups of caregivers. It is possible that alternative approaches might have more effectively promoted use of SBTs; the components and sequencing of our program were designed specifically for unique aspects of our ICU structure and staffing, and would be expected to vary among institutions. Varying sizes and administrative structures of both academic and community medical centers might be expected to have intrinsic challenges in implementation of this and other protocols. Differences in the number of RCPs and RCP experience could have dramatic differences in the results presented in this investigation. Protocol implementation (and acceptance) might be considerably easier in smaller, self-contained units with fewer staff and more direct communication channels. As in other circumstances in which new care modalities are introduced, obtaining the "buy in" of key physicians, RCPs, and nurses (i.e., the opinion leaders) is a major element of successful protocol implementation (19, 20), and was a factor in our experience.

Avoiding personnel changes as much as possible is desirable: devoting the same therapists to one unit who would be knowledgeable of the protocol and who will interact with the physicians and nurses in a comfortable and consistent manner would likely be helpful (3). It was also apparent that overly rigid interpretation of the "rules" of the protocol seemed counterproductive (APPENDIX 1 and APPENDIX 2). For example, determining on consecutive days that a patient failed the DS because the Pa_{O_2}/FI_{O_2} ratio was 198 (rather than being $>$ 200) or their f/VT was 107 (rather than being $<$ 105) was felt to be inappropriate because some patients do not fit within the confines of specified "cutoffs" or thresholds (21–24). Continuing to advance patients through the protocol at this point and assessing their ability to breathe with a SBT may be successful in many of these circumstances. We believe that active dialogue among participants in care can effectively identify these situations, and that the protocol should not be implemented in ways that compromise clinical judgment. Lastly, future randomized investigations in this important line of research might compare outcomes and cost effectiveness of patient management strategies that are therapist-driven with those of a dedicated weaning team.

In conclusion, having a protocol validated to result in better patient outcomes, increased safety, and cost savings does not assure its immediate acceptance, even within the institution where it was designed. In addition, suboptimal compliance with this protocol may not improve outcome, though a control arm was not present for comparison in this large series. Through large-scale implementation of our program, we found that it was essential to have an awareness of not only specific elements of mechanical ventilation and weaning, but also general barriers to modifying the behavior of health professionals. Through graded steps every 2 mo during the year of implementation, we have seen improvements in protocol compliance and remarkable consistency ($>$ 95%) on the part of RCPs in obtaining and interpreting the DS of weaning parameters. Important barriers to obtaining SBTs were identified and addressed, and RCP and physician performance in proceeding to SBTs improved. Through diligence and the passage of time, an ongoing change of culture can be achieved that allows protocol implementation and appropriate modification of bedside behavior for both physicians and RCPs.

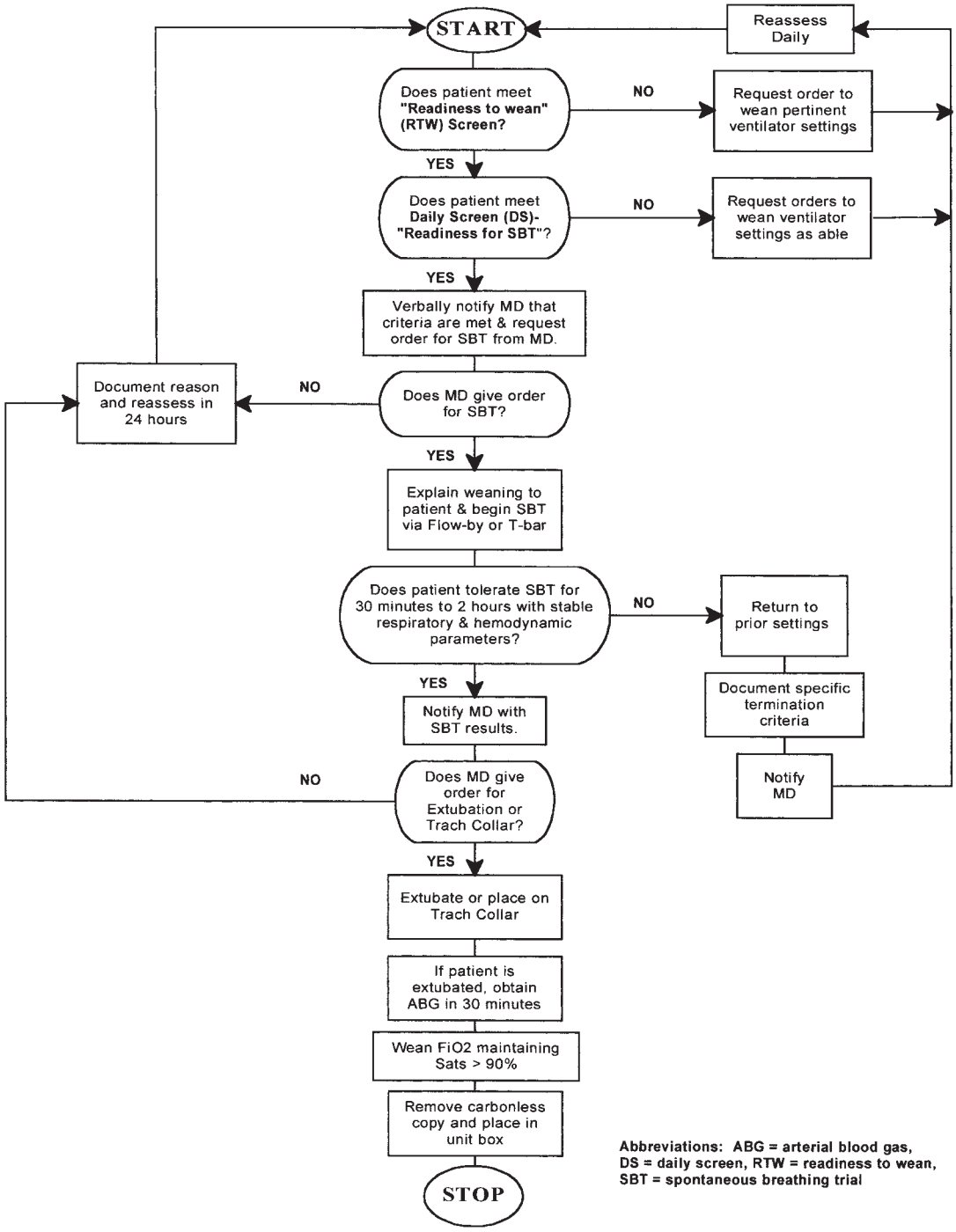
***Acknowledgment*:** We would like to thank the departments of respiratory care and the 117 respiratory care practitioners who worked to overcome the barriers to implementation of this patient management protocol.

References

1. Esteban, A., F. Frutos, M. J. Tobin, I. Alia, J. F. Solsona, I. Valverdu, R. Fernandez, M. A. de la Cal, S. Benito, and R. Tomas. 1995. A comparison of four methods of weaning patients from mechanical ventilation. *N. Engl. J. Med.* 332:345–350.
2. Ely, E. W., A. M. Baker, D. P. Dunagan, H. L. Burke, A. C. Smith, P. T. Kelly, M. M. Johnson, R. W. Browder, D. L. Bowton, and E. F. Haponick. 1996. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *N. Engl. J. Med.* 335:1864–1869.
3. Cohen, I. L. 1994. Weaning from mechanical ventilation: the team approach and beyond. *Intensive Care Med.* 20:317–318.
4. Stoller, J. K. 1994. Why therapist-driven protocols? *Respir. Care* 39:706–708.
5. Weber, K., and S. Milligan. 1994. Therapist-driven protocols. *Respir. Care* 39:746–755.
6. Kollef, M. H., S. D. Shapiro, P. Silver, R. E. St. John, D. Prentice, S. Sauer, T. S. Ahrens, W. Shannon, and D. Baker-Clinkscale. 1997. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. *Crit. Care Med.* 25: 567–574.
7. Kollef, M. H. 1997. Outcomes research in the ICU setting. *Chest* 112: 870–871.
8. Wood, G., B. MacLeod, and S. Moffatt. 1995. Weaning from mechanical ventilation: physician-directed vs a respiratory-therapist-directed protocol. *Respir. Care* 40:219–224.
9. Yang, K. L., and M. J. Tobin. 1991. A prospective study of indexes predicting the outcome of trials of weaning from mechanical ventilation. *N. Engl. J. Med.* 324:1445–1450.
10. The Spanish Lung Failure Collaborative Group. 1997. Multicenter prospective comparison of 30 and 120 minute trials of weaning from mechanical ventilation (abstract). *Am. J. Respir. Crit. Care Med.* 155:A20.
11. Bland, M. 1987. An Introduction to Medical Statistics. Oxford University Press, Oxford, UK.
12. Jacobs, J. 1994. How are we doing with operational restructuring and therapist-driven protocols? *Am. Assoc. Respir. Care Times* 18:66–69.
13. Tietsort, J. 1998. Benchmarking report on use of TDPs. *Respir. Care Manager* 7:1–12.
14. Shrake, K. L., J. E. Scaggs, K. R. England, J. Q. Henkle, and L. E. Eagle-

ton. 1994. Benefits associated with a respiratory care assessment-treatment program: results of a pilot study. *Respir. Care* 39:715–724.
15. Saura, P., L. Blanch, J. Mestre, J. Valles, A. Artigas, and R. Fernandez. 1996. Clinical consequences of the implementation of a weaning protocol. *Intensive Care Med.* 22:1052–1056.
16. Burns, S. M., M. Marshall, J. E. Burns, B. Ryan, D. Wilmoth, R. Carpenter, A. Aloi, M. Wood, and J. D. Truwit. 1998. Design, testing, and results of an outcomes-managed approach to patients requiring prolonged mechanical ventilation. *Am. J. Crit. Care* 7:45–57.
17. Djunaedi, H., P. Cardinal, G. Greffe-Laliberte, G. Jones, B. McMath, and C. C. Snell. 1987. Does a ventilatory management protocol improve the care of ventilated patients? *Respir. Care* 42:604–610.
18. Schriefer, J. 1993. Reducing the length of stay for post-operative open heart surgical patients. *Quality Connect.* 2:8–9.
19. Soumerai, S. B., T. J. McLaughlin, J. H. Gurwitz, E. Guadagnoli, P. J. Hauptman, C. Borbas, N. Morris, B. McLaughlin, X. Gao, D. J. Willison, R. Asinger, and F. Gobel.. 1998. Effect of local medical opinion leaders on quality of care for acute myocardial infarction: a randomized controlled trial. *J.A.M.A.* 279:1358–1363.
20. Greco, P. J., and J. M. Eisenberg. 1993. Changing physicians' practices. *N. Engl. J. Med.* 329:1271–1273.
21. Jaeschke, R. Z., M. O. Meade, G. H. Guyatt, S. P. Keenan, and D. J. Cook. 1997. How to use diagnostic test articles in the intensive care unit: diagnosing weanability using f/Vt. *Crit. Care Med.* 25:1514–1521.
22. Epstein, S. K. 1995. Etiology of extubation failure and the predictive value of the rapid shallow breathing index. *Am. J. Respir. Crit. Care Med.* 152:545–549.
23. Epstein, S. K., and R. L. Ciubotaru. 1997. Influence of gender and endotracheal tube size on preextubation breathing pattern. *Am. J. Respir. Crit. Care Med.* 154:1647–1652.
24. Krieger, B. P., J. Isber, A. Breitenbucher, G. Throop, and P. Ershowsky. 1997. Serial measurements of the rapid-shallow-breathing index as a predictor of weaning outcome in elderly medical patients. *Chest* 112: 1029–1034.

APPENDIX 1
VENTILATOR WEANING PROTOCOL



Abbreviations: ABG = arterial blood gas, DS = daily screen, RTW = readiness to wean, SBT = spontaneous breathing trial

Wake Forest University School of Medicine
Department of Respiratory Care

APPENDIX 2
Ventilator Weaning Protocol Documentation

Please press firmly when charting, this is a two copy form.

Complete this section, when protocol is initiated.

Date enrolled in protocol: ____/____/____ Intubation date: ____/____/____ Hospital Admission date: ____/____/____ Medical record #: _____ _____

DATE/TIME:	/	/	/	/	/	/
Readiness to wean (RTW) Screen*:						
VE						
FiO2						
PEEP						
Passes Screen? (yes, no): (Note: Must pass all 3)						
Daily Screen (DS)**						
Readiness for SBT:						
Cough/Gag reflex present? (yes, no)						
Off Sedative Drip/Pressors (yes, no)						
PEEP						
PaO2 / FiO2 ratio						
f / Vt ratio						
Passes Screen? (yes, no): (Note: Must pass all 5) If yes, obtain MD order for SBT*.						
MD orders SBT*? (yes, no): If no, explain why in comments.						
SBT passed? (yes, no): If no, explain why in comments.						
Date Passes SBT: (Place sticker in chart, + call MD for orders)						
Date Extubated or to T-collar:						
Signature:						

DATE / TIME	COMMENTS	Initials	DATE / TIME	COMMENTS	Initials

SBT = Spontaneous breathing trial *RTW Screen Passing Criteria = VE < 15 FiO2 < .60 PEEP < 10 **DS Passing Criteria = PEEP ≤ 5 PaO2 / FiO2 ratio ≥ 200 f / Vt ratio ≤ 105

White copy to Medical Records Yellow copy to Department