The Effectiveness of Respiratory Care Protocols

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The principles underlying evidence-based practice are that treatments are effective and can offer benefit to patients. At the same time, optimal practice also avoids offering treatments for which evidence of efficacy is not available. In this regard, the goal of respiratory care protocols is to optimize the allocation of respiratory care services by prescribing to each patient treatments likely to confer benefit and avoiding those that do not. As reviewed in this paper, currently available evidence suggests that protocols (1) help minimize unnecessary arterial blood sampling, placement of arterial catheters, and bronchopulmonary hygiene therapies, (2) help optimize the process of weaning patients from mechanical ventilation, (3) help minimize waste of oxygen, (4) allocate respiratory care services better than does physician-directed care. *Key words: protocol, clinical practice guideline, respiratory care unit, evidence-based medicine.* [Respir Care 2004;49(7):761–765. © 2004 Daedalus Enterprises]

Introduction

Effective respiratory care involves delivering treatments that confer benefit to patients. From a systems perspective, effective respiratory care involves allocating respiratory therapy only to those patients likely to derive benefit and not providing treatments to individuals for whom the treatments are unlikely to confer benefit.[1,2] Put this way, the delivery of effective respiratory care requires that 2 main conditions are satisfied:

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James K Stoller MSc MD FAARC presented a version of this report at the 19th Annual New Horizons Symposium at the 49th International Respiratory Congress, held December 8–11, 2003, in Las Vegas, Nevada.

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1. The treatments have efficacy for the clinical problems that prompt their being ordered.
2. That respiratory therapy is allocated appropriately: that is, those patients likely to benefit from a given treatment are receiving appropriate treatments and those patients for whom the treatment is unlikely to confer benefit (because they do not have a condition for which the treatment has efficacy) do not receive the treatment.[1,2]

This line of reasoning provides a framework for examining the effectiveness of respiratory care protocols. Specifically, the criterion by which the effectiveness of protocols can be assessed is whether protocols enhance the allocation of respiratory care services. Also, in the context that respiratory therapists (RTs) are a scarce resource and the demand for their services often exceeds their availability, the effectiveness of protocols can also be assessed by whether they adjust the duration of therapy to assure that patients continue to receive therapy as long as needed but that therapy is curtailed or eliminated when a change in the patient's clinical status (ie, improvement) permits.

In the context of these criteria for effectiveness of respiratory care protocols, the present review considers

whether protocols are effective by examining available studies of respiratory care protocols over the range of clinical settings in which they have been studied: adult and pediatric intensive care units (ICUs) and non-ICU, adult, in-patient facilities. Effectiveness is assessed by whether protocol use enhances the allocation of respiratory care services. Also, the analysis considers the impact of protocol use on the number, duration, and costs of respiratory care treatments and the outcomes of patients managed with versus without respiratory care protocols.

Portions of this material were previously presented in my written summary of the 27th Donald F Egan Scientific Lecture, entitled "Are Respiratory Therapists Effective? Assessing the Evidence."[3]

Are Respiratory Care Protocols Effective in the Intensive Care Unit?

In the ICU, respiratory care practices to which protocols have been applied most widely include arterial blood gas (ABG) testing and weaning from mechanical ventilation.[4–11]

Considering ABGs, protocols are associated with enhanced rates of appropriate sampling and of placing indwelling arterial lines.[4,5] Available studies have been observational, using a before-and-after cohort design. For example, in an early study regarding RTs' effectiveness in determining when to sample ABGs of ICU patients, Browning et al[4] assessed the appropriateness of ABGs sampled during 3 intervals: before the implementation of an ABG sampling protocol, 1 month after implementation, and 3 months after implementation. The protocol was associated with improved ABG allocation: the rate of inappropriately ordered ABGs declined from 43% before implementation to 33% and 31%, respectively, at 1 month and 3 months after implementation. Most strikingly, when the investigators assessed the rate of inappropriate orders by the type of provider ordering the sample, RTs performed best. Specifically, at 1 month and 3 months, the RTs' rates of inappropriately ordered ABGs were 3% and 15%, respectively, whereas those rates for other providers were 45% and 37%, respectively.

Subsequent studies have confirmed the value of protocols in improving ICU ABG allocation and in directing the placement of indwelling arterial catheters. For example, Pilon et al[6] conducted an observational cohort study in which the rate of appropriately drawn ABGs increased from 44% at baseline to 78–79% at 2–13 months after implementing an ABG protocol. Other benefits associated with the ABG protocol included a decrease in the mean number of ABGs drawn per patient per day (from 4.9 to 2.4−3.1, $p < 0.001$) and a concomitant cost savings of $19.18 (Canadian) per patient per day, with no identified adverse effects on outcome.

Ozgun et al[7] studied the impact of a protocol that addressed when to place an indwelling arterial catheter. The protocol was associated with a lower rate of catheter placement (decreased from 29.3% of ICU patients before the protocol to 13.7% after protocol implementation) and a trend toward fewer ABGs per patient (decreased from 7.0 to 5.6, $p = 0.9$). Again, these benefits were achieved without adverse effects on ICU stay, ICU survival, or hospital survival).

Regarding weaning from mechanical ventilation, the effectiveness of protocols has been examined in 3 randomized controlled trials with adult patients[8–10] and 1 with pediatric patients.[11]

In the first of the 3 trials with adults, Kollef et al[8] allocated 357 patients in 4 ICUs to receive either physician-directed weaning or protocol-directed weaning. Benefits of the protocol included significantly shorter duration of mechanical ventilation (mean 69 vs 102 h, $p = 0.029$) and a trend toward lower costs (by $42,960). The protocol had no identified adverse effects.

In the second trial with adults Ely et al[9] assessed the outcomes of mechanically ventilated patients who were weaned using usual physician-directed care versus those undergoing daily assessments of weanability and, if deemed suitable, a standard spontaneous breathing trial (SBT) administered by an RT. As in the earlier trial by Kollef et al,[8] the protocol was beneficial. Specifically, daily RT-assessment of weanability and subsequent RT-directed weaning after physician approval were associated with shorter weaning time (by a median of 2 d, $p < 0.001$) and shorter total duration of mechanical ventilation (by 1.5 d, $p < 0.003$).

Most recently, in the third randomized controlled trial, which resembled the study by Kollef et al,[8] Marelich et al[10] compared outcomes from protocol-based weaning by RTs and nurses versus usual physician-directed weaning. In the group of 129 patients allocated to protocol-based weaning, RTs and nurses assessed patients' candidacy for SBT, conducted and assessed the outcomes of the SBTs, and if the patient succeeded in a 30-min SBT, the RT recommended to the physician that mechanical ventilation be discontinued. With the 124 patients managed by physician-directed weaning, weaning assessments and orders were implemented only on explicit physician orders. As in the 2 earlier trials, the study results showed significant benefits from protocol-based weaning, including:

1. A shorter duration of mechanical ventilation: median 68 vs 124 h ($p = 0.0001$) and risk ratio favoring protocols 1.67 ($p = 0.009$) after correction for Acute Physiology and Chronic Health Evaluation (APACHE) score, age, duration of respiratory failure before weaning, and diagnosis

2. A shorter interval between achieving criteria for discontinuation of ventilation and actual discontinuation (p = 0.006), and

3. A shorter interval between starting mechanical ventilation and meeting discontinuation criteria (median 42 vs 79 h, p = 0.0001).

Those benefits were achieved without significant differences in rates of weaning failure or hospital mortality.

Taken together, the latter evidence supports the effectiveness of protocols in enhancing the likelihood of liberating adult patients from mechanical ventilation and in accelerating such weaning. On the basis of those concordant results, weaning protocols are now widely employed in adult critical care.

In contrast to the evidence that protocol use enhances weaning in adults, a single multicenter, randomized controlled trial with pediatric patients failed to show that protocols enhanced the likelihood of weaning success or, among those children who weaned successfully, that extubation was accelerated. Specifically, in a 10-center randomized trial Randolph et al[11] randomly allocated 182 children (< 18 y old) on mechanical ventilation for at least 24 h to 3 groups. The study included:

1. A pressure-support ventilation protocol, in which the level of pressure support was decreased by 2 cm H_2O every 4 h, down to ≤ 16 cm H_2O, at which point an SBT was undertaken (n = 62)

2. A volume-controlled ventilation protocol, in which volume was set to achieve an exhaled tidal volume of 5–7 mL/kg, and once peak inspiratory pressure fell below 20 cm H_2O, fraction of inspired oxygen (F_{IO_2}) was < 0.50, and positive end-expiratory pressure was ≤ 5 cm H_2O, an SBT was undertaken (n = 60), and

3. A control group, in which weaning was conducted at physician discretion.

There was no statistically significant difference in weaning success rate between the 3 groups, with failure rates of 15%, 24%, and 17%, respectively (p = 0.44). Similarly, among the children successfully liberated from mechanical ventilation, the duration of ventilation did not differ between the 3 groups: the median duration of ventilation was 1.6 d in the pressure-support group, 1.8 d in the volume-controlled ventilation group, and 2.0 d in the control group (p = 0.75).

Overall, in contrast to the results from trials with adult patients,[8–10] the Randolph et al[11] study failed to show a benefit from weaning protocols with children. Though the reasons for the discordance of the results of the 3 adult trials are unclear, it is possible that the brief duration of mechanical ventilation among the control children (median 2 d) makes it difficult to show significant acceleration of weaning.

Are Respiratory Care Protocols Effective in Providing Non-ICU Adult In-patient Care?

The effectiveness of protocols in guiding appropriate allocation of non-ICU adult in-patient care has been evaluated in observational studies for several individual therapies (eg, oxygen administration and titration,[12,13] and bronchopulmonary hygiene[14,15]) and, in both observational studies and randomized trials, for the overall appropriate allocation of respiratory care services.

As an example of an observational study regarding a single respiratory care service, Komara and Stoller[12] evaluated the impact of an RT-administered treatment protocol for titrating supplemental oxygen with postoperative patients. The study compared the duration and cost of supplemental oxygen use, using a convenience sample of 20 postoperative patients whose oxygen was titrated by RTs according to a protocol, versus 20 patients whose oxygen was managed by their physicians. Several protocol benefits were observed. Specifically, the duration of postoperative oxygen (ie, until the patient achieved a room-air S_{pO_2} ≥ 92%) was shorter (mean 2.1 ± 0.64 vs 3.45 ± 1.28 d, p < 0.003), the associated costs of administering oxygen (eg, RTs' time, cannula, and oximeter depreciation) were lower (mean total savings $389.52, p < 0.003), and no adverse effects were observed. Those results support the effectiveness of an RT-implemented oxygen titration protocol to enhance allocation of respiratory care services.

In a community hospital setting, Konschak et al[13] reported similar benefits of decreased oxygen utilization with an oxygen protocol. Specifically, for patients on a single hospital ward, the oxygen protocol was associated with a shorter duration of unneeded oxygen (by 3.87 d, p < 0.05), less wasted oxygen per patient (by 15,294 L, p < 0.05), and lower cost/patient of oxygen used when no longer needed (by $4.47 per patient, for a total hospital savings of $7,915 per year).

To assess the impact of a protocol on the allocation of bronchial hygiene therapy, Shapiro et al[14] studied patterns of bronchial hygiene therapy, utilization before and after implementing protocols that were overseen by the medical director. The protocols brought a 61% reduction of bronchial hygiene therapy outside of the ICU, with a concomitant savings of > $250,000 and no identified adverse effects. Specifically, the number of bronchial hygiene therapies decreased from 60,713 to 23,594, but overall hospital mortality during the compared interval (1983–1986) did not change, and "no valid instance of increased patient morbidity attributable to differences in bronchial hygiene therapy was brought to the attention of the medical director."[14]

In a later randomized trial that examined the impact of physician review of bronchial hygiene orders, Alexander et al[15] observed a similar (52%) reduction in bronchial

hygiene orders that fell outside of protocol indications. Specifically, 101 patients ordered to receive unindicated chest physiotherapy were randomly allocated either to a group in which the pulmonary fellow called the ordering physician regarding the orders ($n = 47$) or to a group in which the ordered therapy was delivered as prescribed ($n = 54$). The intervention group underwent 45% fewer chest physiotherapy treatments than the control group, with a concomitant savings of at least $176,000, and no change in mortality or hospital stay. Like the results of earlier studies,[14] these findings suggest that a protocol-based intervention to avoid inappropriate respiratory care orders can improve allocation. Although physicians-in-training provided the intervention in the latter study, other studies suggest that RTs can also be highly effective in that role.[16–21]

Beyond these studies regarding single respiratory care modalities, early observational studies suggested that protocols could lessen misallocated respiratory care services overall without compromising care or clinical benefit. For example, in 1981 Nielsen-Tietsort et al[16] proposed "a new therapy delivery system: the respiratory care protocol" at the Lutheran Medical Center in Wheat Ridge, Colorado. In 1986, Zibrak et al[17] reported the results of a historical control study in which implementation of guidelines by RTs was associated with marked reductions in all categories of respiratory therapy (by 55–92%) with no change in hospital morbidity or mortality from pulmonary disorders. In the subset of patients undergoing coronary artery revascularization, protocol use was associated with shorter mean hospital stay (by 5.0 d) and a lower rate of pulmonary complications (16.7 vs 5.5%).

However, the strongest evidence supporting RTs' effectiveness in providing non-ICU in-patient respiratory care comes from 2 randomized controlled trials that compared the in-patient respiratory care protocol services and usual physician-directed care.[20,21] Both trials showed that in the context of a protocol service RT-directed care allows better allocation of respiratory care services than physician-directed care (Table 1). Stoller et al[20] conducted a randomized controlled trial in which 145 adult non-ICU in-

patients at the Cleveland Clinic Hospital were randomly allocated to receive respiratory care orders as placed by the managing physicians or to have their physicians' respiratory care orders pre-empted by those generated by an RT applying protocols. The protocols, which had the format of branched-logic diagrams, were developed to implement American Association for Respiratory Care clinical practice guidelines for the modalities used. The respiratory care protocols conferred several advantages over physician-directed care, including a higher rate of concordance with a gold standard respiratory care plan (82 vs 64% using stringent agreement criteria, $p < 0.001$) and a trend toward lower true median respiratory care costs/patient ($130 vs $152, $p = 0.51$).

More recently Kollef et al[21] reported similar findings in another randomized trial of respiratory care protocols. In that study 694 patients were allocated to one of 3 hospital firms according to their primary physicians' ward assignments. Unassigned patients were randomly allocated among the firms. On firm A (but not on firms B or C), the respiratory care plans were allocated by RTs using explicit protocols. In contrast, on firms B and C respiratory care orders were written by the managing physicians. The protocol was associated with fewer respiratory therapy treatments (A 10.7, B 12.4, C 12.3, $p = 0.009$), a greater percentage of bronchodilators administered via metered-dose inhaler (A 89%, B 77%, C 78%, $p = 0.01$), fewer respiratory therapy orders that were discordant with the protocol standard (A 24%, B 58%, C 58%, risk ratio 0.42, 95% confidence interval 0.33–0.53), and lower mean respiratory care charges (A $868, B $1,124, C $1,054, $p < 0.001$). As in the earlier randomized trial, these benefits were achieved without adverse impact.

Taken together, those 2 randomized, controlled trials (Table 1)[20,21] and earlier observational studies[16–19] demonstrate that RTs implementing protocol-based care can effectively allocate respiratory care services and that such protocol services improve allocation and lower costs, compared with traditional physician-directed respiratory care.

Table 1. Summary of Available Randomized Trials Regarding the Effectiveness of Respiratory Care Protocols

Clinical Activity	First Author	Year	Number of Patients	Findings
Weaning from mechanical ventilation	Kollef[8]	1997	357	Protocol was associated with shorter duration of mechanical ventilation
	Ely[9]	1996	300	Routine daily spontaneous-breathing-trial protocol was associated with shorter duration of mechanical ventilation
	Marelich[10]	2000	253	Protocol was associated with shorter duration of mechanical ventilation
Respiratory care services protocol	Stoller[20]	1998	145	Respiratory care consult service was associated with better allocation of respiratory care services, lower costs, and no adverse events
	Kollef[21]	2000	694	Respiratory-therapist-initiated treatment protocols were associated with fewer orders discordant with guidelines and with lower charges

Summary

Overall, the available evidence regarding respiratory care protocols suggests that protocols can confer several benefits, including:

1. Enhanced allocation of respiratory care services, including ABG sampling, arterial line placement, use of supplemental oxygen, bronchial hygiene therapies, and bronchodilators. The advantage of enhanced allocation can be achieved either by implementing protocols for individual respiratory treatments or by using a comprehensive protocol service, in which protocols guide the choice of respiratory treatments and the specific respiratory care plan.

2. In the case of weaning, protocols can accelerate patients' liberation from mechanical ventilation, with associated benefits of shorter ICU stay and cost savings.

Though the available evidence supporting protocols is compelling and justifies current use of protocols in many clinical settings, gaps in current understanding exist and invite further research. For example, additional study is needed to assess the efficacy of protocols in several inpatient settings, such as in pediatric intensive care. Furthermore, little attention has been given to assessing protocol use in settings other than acute hospital-based care, such as palliative care, geriatric care, and extended care facilities. On this basis, my hope is that the present review and the other contributions in this New Horizons Symposium will help spur the additional needed investigation to clarify these issues.

REFERENCES

1. Stoller JK. The rationale for therapist-driven protocols. Respir Care Clin N Am 1996;2(1):1–14.
2. Stoller JK. The rationale for respiratory care protocols: an update. Respir Care 1998;43(9):719–723.
3. Stoller JK. 2000 Donald F. Egan Scientific Lecture. Are respiratory therapists effective? Assessing the evidence. Respir Care 2001;46(1):56–66.
4. Browning JA, Kaiser DL, Durbin CG Jr. The effect of guidelines on the appropriate use of arterial blood gas analysis in the intensive care unit. Respir Care 1989;34(4):269–276.
5. Rowley DD, Mayo DF, Durbin CG Jr. Initial experience with a respiratory therapist arterial line placement service. Respir Care 2000;45(5):482–485.
6. Pilon CS, Leathley M, London R, McLean S, Phang PT, Priestley R, et al. Practice guideline for arterial blood gas measurement in the intensive care unit decreases numbers and increases appropriateness of tests. Crit Care Med 1997;25(8):1308–1313.
7. Ozgun EM, Strange C, Silvestri GA. The impact of a standardized protocol for placement of indwelling arterial catheters. Respir Care 1999;44(10):1193–1197.
8. Kollef MH, Shapiro SD, Silver P, St John RE, Prentice D, Sauer S, et al. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. Crit Care Med 1997;25(4):567–574.
9. Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, et al. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. N Engl J Med 1996;335(25):1864–1869.
10. Marelich GP, Murin S, Battistella F, Inciardi J, Vierra T, Roby M. Protocol weaning of mechanical ventilation in medical and surgical patients by respiratory care practitioners and nurses: effect on weaning time and incidence of ventilator-associated pneumonia. Chest 2000;118(2):459–467.
11. Randolph AG, Wypij D, Venkataraman ST, Hanson JH, Gedeit RG, Meert KL, et al; Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network. Effect of mechanical ventilator weaning protocols on respiratory outcomes in infants and children: a randomized controlled trial. JAMA 2002;288(20):2561–2568.
12. Komara JJ Jr, Stoller JK. The impact of a postoperative oxygen therapy protocol on use of pulse oximetry and oxygen therapy. Respir Care 1995;40(11):1125–1129.
13. Konschak MR, Binder A, Binder RE. Oxygen therapy utilization in a community hospital: use of a protocol to improve oxygen administration and preserve resources. Respir Care 1999;44(5):506–511.
14. Shapiro BA, Cane RD, Peterson J, Weber D. Authoritative medical direction can assure cost-beneficial bronchial hygiene therapy. Chest 1988;93(5):1038–1042.
15. Alexander E, Weingarten S, Mohsenifar Z. Clinical strategies to reduce utilization of chest physiotherapy without compromising patient care. Chest 1996;110(3):430–432.
16. Nielsen-Tietsort J, Poole B, Creagh CE, Repsher LE. Respiratory care protocol: an approach to in-hospital respiratory therapy. Respir Care 1981;26(5):430–436.
17. Zibrak JD, Rossetti P, Wood E. Effect of reductions in respiratory therapy on patient outcome. N Engl J Med 1986;315(5):292–295.
18. Hart SK, Dubbs W, Gil A, Myers-Judy M. The effects of therapist-evaluation of orders and interaction with physicians on the appropriateness of respiratory care. Respir Care 1989;34(3):185–190.
19. Shrake KL, Scaggs JE, England KR, Henkle JQ, Eagleton LE. Benefits associated with a respiratory care assessment-treatment program: results of a pilot study. Respir Care 1994;39(7):715–724.
20. Stoller JK, Mascha EJ, Kester L, Haney D. Randomized controlled trial of physician-directed versus respiratory therapy consult service-directed respiratory care to adult non-ICU inpatients. Am J Respir Care Med 1998;158(4):1068–1075.
21. Kollef MH, Shapiro SD, Clinkscale D, Cracchiolo L, Clayton D, Wilner R, Hossin L. The effect of respiratory therapist-initiated treatment protocols on patient outcomes and resource utilization. Chest 2000;117(2):467–475.