

# The Scientific Basis for Protocol-Directed Respiratory Care

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## Introduction

### Criteria for Establishing the Scientific Basis for Protocol-Directed Respiratory Care

Are Respiratory Protocols Effective in Providing ICU Care?

Are Respiratory Protocols Effective in Providing Non-ICU Care?

### Summary

As defined by the American Association for Respiratory Care, respiratory care protocols are “guidelines, usually written in algorithmic form, for providing respiratory therapy services.” The need for protocols has been framed by the frequent occurrence of misallocation of respiratory care, consisting both of over-ordering (ie, prescribing respiratory care that is unlikely to confer benefit) and under-ordering services (ie, failing to prescribe services that would be expected to offer benefit). In this context, the current paper reviews available studies regarding the effectiveness of respiratory care protocols. Such studies can be organized into those assessing respiratory care treatments in the ICU, and those addressing non-ICU respiratory care. In the ICU, studies have addressed sampling both ABGs and liberating patients from mechanical ventilation; in the latter activity, multiple concordant randomized controlled trials have shown that weaning protocols implemented by respiratory therapists and/or nurses can accelerate patients’ liberation from mechanical ventilation, with shorter stay and lower cost. Outside of the ICU, studies have addressed the effectiveness of respiratory care protocols in guiding the use of supplemental oxygen, bronchopulmonary hygiene, bronchodilator use, and of assessing patient for step-down unit placement. All such studies have shown that respiratory care protocols are effective. Furthermore, 2 concordant randomized controlled trials have shown that comprehensive respiratory care protocol programs can enhance the allocation of respiratory care services, with concomitant savings and no excess adverse outcomes. Overall, while the overwhelming weight of available evidence supports the effectiveness of respiratory care protocols, gaps in current understanding remain, especially regarding settings outside the acute care hospital (eg, geriatric care, palliative care, and extended care facilities). In the same spirit that engendered the Sugarloaf Conference to assess the effectiveness of respiratory care, further assessment of the effectiveness of respiratory care protocols is encouraged and expected.

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## Introduction

Respiratory care protocols are used and taught widely, and, based on the large volume of supportive evidence, have arguably become a standard of respiratory care.<sup>1,2</sup> For example, in a survey of respiratory therapy (RT) managers, 98% reported using protocols in their institutions,<sup>2,3</sup> and in the 2005 American Association for Respiratory Care Human Resources Survey,<sup>4</sup> 90% of respiratory therapist respondents reported having delivered care by a protocol. As further evidence that protocols are widely accepted in respiratory care practice, a recent survey of RT program directors indicated that 96% and 95%, respectively, of baccalaureate and associate programs teach protocol use.<sup>5</sup> Finally, in the 2009 American Association for Respiratory Care Human Resources Survey, 84.8% of responding hospitals reported using oxygen protocols, 77.7% reported using mechanical ventilation protocols, and 60.9% reported using bronchodilator protocols.<sup>6</sup>

The widespread acceptance of RT protocols is based on substantial supportive evidence, which, in keeping with the evidence-based focus of this New Horizons Symposium, invites consideration and critical review of the scientific basis of RT protocols. The current paper considers this issue by reviewing first the criteria for assessing the scientific basis of RT protocols, and then by analyzing the available evidence that bears on this question. The specific issue of ventilator discontinuation protocols has also been recently reviewed.<sup>7</sup>

### Criteria for Establishing the Scientific Basis for Protocol-Directed Respiratory Care

In considering the scientific effectiveness of RT protocols, 2 main criteria must be satisfied:

- The respiratory treatments administered within RT protocols must provide clinical benefit for the conditions for which they are prescribed.
- RT protocols must allocate RT treatments appropriately (ie, the result of RT protocol use is that patients likely to benefit from RT treatments are ordered to receive such treatments and conversely, that patients who are unlikely to benefit from RT treatments are *not* ordered to receive RT treatments).

Misallocation of RT treatments occurs when this last condition is not satisfied and consists of both “over-ordering” (ie, when patients are ordered to receive treatments that are unlikely to confer benefit) and of “under-ordering” (ie, when patients who are likely to benefit from RT treatments are not ordered to receive RT treatments).

In the context that the current paper focuses on the scientific basis of RT protocols, both types of outcome are

addressed; that is, that implementing RT protocols confers benefit (examples of which include enhancing liberation from mechanical ventilation, decreasing hospital stay, and lowering cost while preserving clinical benefit), and that implementing RT protocols optimizes allocation of RT treatments. The evidence is considered by the clinical venue in which the RT protocol is used; that is, first in adult and pediatric intensive care and then in non-ICU adult inpatient care. After review of the available evidence, attention turns to the remaining and unresolved questions that need further study.

Notably, portions of this material were previously presented in a written summary of the 27th Egan Lecture, entitled “Are Respiratory Therapists Effective?: Assessing the Evidence,”<sup>2</sup> and in an earlier New Horizons Symposium paper, entitled “The Effectiveness of Respiratory Care Protocols.”<sup>8</sup>

### Are Respiratory Protocols Effective in Providing ICU Care?

The respiratory-therapist-driven protocols that have most frequently been evaluated in the ICU setting include arterial blood gas (ABG) sampling and liberation from mechanical ventilation.<sup>9-18</sup> Using protocols for sampling ABGs has shown enhanced rates of correct indwelling arterial line placement and appropriate ABG sampling.<sup>9,10</sup> Specifically, Browning et al<sup>10</sup> evaluated respiratory therapists’ effectiveness in determining when to sample ABGs. With a “before-and-after” study design, the investigators assessed the appropriateness of ABGs sampled during 3 intervals: prior to protocol implementation, and 1 and 3 months post-implementation. Using an ABG sampling protocol was associated with improved allocation of services (ie, the rate of inappropriately ordered ABGs declined from 43% before to 33% and 31% at 1 and 3 months, respectively). This study also focused on the assessment of inappropriate ABG orders by type of provider. Strikingly, after protocols were implemented, respiratory therapists had rates of inappropriately ordered ABGs of 3% and 15% after 1 and 3 months post-implementation, whereas other providers generated markedly higher rates: 45% and 37% at 1 and 3 months, respectively.

Subsequent studies have confirmed the value of protocols in improving the allocation of ABGs in the ICU, and in directing the placement of indwelling arterial catheters. Pilon et al<sup>12</sup> conducted an observational cohort study with a before-and-after design, in which the rate of appropriately drawn ABGs increased from 44% at baseline to 78% and 79% at 2 and 13 months after protocol implementation, respectively. Associated benefits with implementing the aforementioned protocol included a reduced mean number of ABGs drawn per patient per day (from 4.9 to 2.4–3.1,  $P < .001$ ), and a concomitant cost savings of \$19.18

Canadian per patient per day. There were no identifiable adverse effects on clinical outcomes.

Ozgun et al<sup>19</sup> also evaluated the impact of implementing an arterial catheter placement protocol in the ICU. Protocol use was associated with a reduction of arterial catheter placement, from 29.3% of patients (prior to protocol implementation) to 13.7% (after protocol implementation), and with a nonsignificant trend toward fewer ABGs drawn per patient (from 7.0 to 5.6,  $P = .90$ ). Use of protocols was unaccompanied by adverse outcomes, such as prolonged ICU stay or increases in ICU or hospital mortality rate.

As another example of therapy allocated by protocol in the ICU, the effectiveness of mechanical ventilation liberation protocols has been examined in 5 randomized controlled trials. Four of these studies evaluated outcomes in adults,<sup>14,15,17,18</sup> and one in a pediatric population.<sup>16</sup> One of the trials<sup>18</sup> assessed a protocol for weaning from noninvasive ventilation. In the first of the 4 trials performed in adults, Kollef et al<sup>17</sup> allocated 357 subjects in 4 ICUs to receive physician-directed versus protocol-directed weaning. The utilization of a weaning protocol significantly shortened duration of mechanical ventilation (mean 69 h vs 102 h,  $P = .03$ ) and showed a trend toward lower costs (by \$42,960). There were no adverse effects associated with protocol use.

In a second randomized controlled trial in adults, Ely et al<sup>14</sup> assessed the outcomes of mechanically ventilated patients who were weaned using 2 different strategies. The first strategy consisted of usual physician-directed care, while the second included daily assessments of weanability, followed by spontaneous breathing trials (SBTs) administered by respiratory therapists. As in the prior study, the use of protocols was clearly beneficial. Specifically, the second strategy was associated with a shortened weaning time (by a median of 2 d,  $P < .001$ ) and a reduction of total duration of mechanical ventilation (by 1.5 days,  $P < .003$ ).

A third randomized controlled trial, published by Marelich et al,<sup>15</sup> compared outcomes from protocol-based weaning by respiratory therapists and nurses versus usual physician-directed weaning. Specifically, a group of 129 adult patients were allocated to protocol-based weaning, in which respiratory therapists and nurses assessed patients' candidacy for SBTs, conducted and evaluated the outcomes of such SBTs, and then recommended eventual discontinuation of mechanical ventilation to treating physicians. In the other group, comprised of 124 patients managed by physician-directed weaning, assessments and orders were implemented only by treating physicians. As in the earlier trials, significant benefits of protocol-based weaning were shown. These benefits included a shorter duration of mechanical ventilation (median 68 h vs 124 h,  $P < .001$ , risk ratio favoring protocols 1.67,  $P = .009$ , after correction for Acute Physiology and Chronic Health

Evaluation scores, age, duration of respiratory failure before weaning, and diagnosis), a shorter interval between achieving criteria for discontinuation of ventilation and actual discontinuation ( $P = .006$ ), and a shorter interval between starting mechanical ventilation and meeting discontinuation criteria (median 42 h vs 79 h,  $P < .001$ ). Notably, these benefits were achieved without significant differences in adverse clinical outcomes, such as increased rates of weaning failure or hospital mortality.

Finally, Duan et al<sup>18</sup> randomized 73 adults with acute respiratory failure being managed with noninvasive ventilation to a weaning protocol administered by respiratory therapists ( $n = 37$ ) versus physician-directed weaning ( $n = 36$ ). Use of the protocol was associated with significant reductions in ICU stay (by a mean 2.3 d,  $P = .02$ ), total duration of noninvasive ventilation (by a mean 1.8 d,  $P < .001$ ), and duration of noninvasive ventilation after randomization (by a mean 1.9 d,  $P < .001$ ).

Other studies of RT-protocol-based liberation from mechanical ventilation have shown mixed results, with one observational study supporting benefit<sup>20</sup> and another pseudo-randomized study not showing benefit.<sup>21</sup> As the authors noted in the latter study, the level of physician staffing of the ICU was "generous" enough (ie, 2 attending physicians and 10 physicians-in-training staffed a closed 14-bed ICU) to obscure any possible incremental impact of protocols. Others have interpreted these results to suggest that the administration of weaning protocols by respiratory therapists has equal efficacy to physician-directed weaning, but that the impact of respiratory-therapist-administered protocols is obscured by a high level of physician staffing.<sup>7</sup>

A Cochrane systematic review<sup>22</sup> has recently assessed the impact of weaning protocols on important ICU outcomes, like total duration of mechanical ventilation, hospital mortality, ICU and hospital stay, and ICU or hospital costs. The meta-analysis assessed 11 trials with a total of 1,971 subjects, and showed that use of protocols conferred the benefits of shorter total durations of mechanical ventilation, of weaning, and of ICU stay. Neither economic savings nor shorter hospital stay was associated with using weaning protocols, and no excess adverse events (eg, reintubation, tracheostomy, or self-extubation) were observed.

Overall, the weight of available evidence supports the use of protocols to increase the likelihood of liberating adult patients from mechanical ventilation. In this context, an evidence-based guideline<sup>23</sup> for weaning and discontinuing mechanical ventilator support has endorsed the use of weaning protocols by non-physician healthcare providers: "Weaning/discontinuation protocols that are designed for non-physician healthcare professionals should be developed and implemented in ICUs." Furthermore, Prasad et al<sup>24</sup> have shown that use of protocols does not detract from

trainees' knowledge of mechanical ventilation, as assessed by performance on relevant questions on certifying examinations. Based on the aforementioned concordant results and recommendations, weaning protocols are employed widely in adult critical care and represent strong examples of the scientific basis of protocol-based respiratory care.

Contrary to the experience in adults, evidence supporting the benefits of protocols for weaning children is lacking. Specifically, a 10-center randomized trial performed by Randolph et al<sup>16</sup> randomly allocated 182 mechanically ventilated children (< 18 y old) for at least 24 h to one of 3 groups:

- A pressure support protocol, in which the level of pressure support was decreased by 2 cm H<sub>2</sub>O every 4 hours until the level of pressure support was  $\leq$  16 cm H<sub>2</sub>O, at which point a trial of spontaneous breathing was undertaken ( $n = 62$ )
- A volume-support 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<sub>2</sub>O with  $F_{IO_2} < 0.50$  and PEEP  $\leq$  5 cm H<sub>2</sub>O, an SBT was undertaken ( $n = 60$ )
- A control group, in which weaning was conducted at physician discretion

There was no difference in weaning success between the 3 groups, with failure rates of 15%, 24%, and 17%, respectively ( $P = .44$ ). Furthermore, among children successfully liberated from mechanical ventilation, the stay on mechanical ventilation did not differ between groups, with median durations of 1.6 d (pressure support group), 1.8 d (volume controlled), and 2.0 d (control group), respectively ( $P = .75$ ).

In summary, in contrast to the results from trials in adults,<sup>14,15,17,18</sup> studies in children fail to show the benefits of weaning protocols. Although the underlying reasons for this discordance remain unclear, it is possible that the very short duration of mechanical ventilation in control children (median 2 d) obscured the ability of protocols to accelerate weaning.

### Are Respiratory Protocols Effective in Providing Non-ICU Care?

The effectiveness of respiratory care protocols outside the ICU setting has been evaluated in many observational studies. Individual respiratory therapies, such as oxygen administration and monitoring,<sup>25,26</sup> bronchopulmonary hygiene,<sup>27,28</sup> bronchodilator use,<sup>29</sup> and step-down-unit patient assessment,<sup>30</sup> have been studied. Furthermore, the impact of these protocols on the overall allocation of respiratory care services has been evaluated in both observational and randomized trials.

In an observational study of postoperative patients in which a respiratory-therapist-driven oxygen titration protocol was compared with a strategy of O<sub>2</sub> titration managed by physicians, Komara and Stoller<sup>25</sup> showed several benefits of protocol-based care. Particularly, the time needed to achieve a room air postoperative  $S_{pO_2} \geq 92\%$  was shorter in the protocol group (mean  $2.1 \pm 0.64$  d vs  $3.45 \pm 1.28$  d,  $P < .003$ ). Also, the associated costs of administering oxygen (eg, respiratory therapists' time, cannula, oximeter depreciation) were lower (mean total savings of \$389.52,  $P < .003$ ), and no adverse effects were observed. These results support the effectiveness of a respiratory-therapist-implemented oxygen titration protocol to enhance the allocation of respiratory care services.

In the community hospital setting, Konschak et al<sup>26</sup> reported similar benefits of decreased oxygen utilization using an oxygen protocol. Specifically, for patients on a single hospital ward, protocol use was associated with a shorter duration of unneeded oxygen by 3.87 days ( $P < .05$ ), less wasted oxygen per patient (by 15,294 L,  $P < .05$ ), 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).

The impact of protocols in allocating bronchial hygiene has also been evaluated. In a before-and-after study, Shapiro et al<sup>27</sup> assessed patterns of utilizing bronchial hygiene therapy before and after implementing protocols. The results showed that introducing protocols was associated with a 61% reduction of bronchial hygiene therapy outside of the ICU, with a concomitant cost savings of  $> \$250,000$ . No attributable adverse effects were associated with protocol use. Specifically, though the volume of therapies decreased from 60,713 to 23,594, overall hospital mortality over the study period (1983–1986) did not change, and no increase in patient morbidity attributable to differences in bronchial hygiene therapy was detected.

In a later randomized trial examining the impact of physician review of bronchial hygiene orders, Alexander et al<sup>28</sup> allocated 101 patients who had been ordered to receive non-indicated chest physiotherapy to 2 different groups. In the intervention group a pulmonary fellow called the ordering physician regarding the non-indicated orders ( $n = 47$ ). In the control group, patients received non-indicated bronchial hygiene 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 changes in mortality or hospital stay. As in the previously described studies,<sup>26</sup> 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 this study, experience in other studies suggests that respiratory therapists can also be highly effective in this role.<sup>30-36</sup>



## THE SCIENTIFIC BASIS FOR PROTOCOL-DIRECTED RESPIRATORY CARE

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

Clinical Activity	First Author	Year	<i>n</i>	Findings
Liberation from mechanical ventilation	Kollef <sup>17</sup>	1997	357	Use of protocols was associated with shorter duration of mechanical ventilation.
	Ely <sup>14</sup>	1996	300	Routine daily trials of spontaneous breathing trials were associated with shorter duration of mechanical ventilation.
	Marelich <sup>15</sup>	2000	253	Use of protocols shortened duration of mechanical ventilation.
Respiratory care protocol service	Stoller <sup>35</sup>	1998	145	Use of respiratory therapy consult service was associated with improved allocation of respiratory care service with lower costs, and no adverse events.
	Kollef <sup>36</sup>	2000	694	Use of respiratory protocol service was associated with fewer orders discordant with guidelines and lower charges.

(Data from reference 2.)

Kallam et al<sup>29</sup> compared the prescribing patterns and associated costs with physician-directed care versus suggested RT-protocol-administered care. Protocols would have lessened the frequency of bronchodilator administration (eg, from 63.6% administered every 4 h to 11.3% administered every 4 h,  $P < .001$ ) and the cost per patient ( $\$10.3 \pm 9.4/\text{patient}$  vs  $\$19.0 \pm 6.9/\text{patient}$ ,  $P < .001$ ).

Beyond studies addressing single respiratory care modalities, early observational studies using protocols that combined multiple interventions have shown that misallocation could be reduced without compromising care or decreasing effectiveness. For example, in 1981, Nielsen-Tietsort et al<sup>31</sup> proposed “a new therapy delivery system: the Respiratory Care Protocol” at the Lutheran Medical Center in Wheat Ridge, Colorado. In 1986, Zibrak et al<sup>32</sup> reported the results of a historical control study in which implementation of guidelines by respiratory therapists was associated with marked reductions in all categories of RT (by 55% to 92%), with no change in hospital morbidity and/or mortality from pulmonary disorders. In the subset of patients undergoing coronary artery revascularization, protocol use was associated with a reduction in the mean hospital stay, by 5.0 d, and a decreased rate of pulmonary complications, from 16.7% to 5.5%. Finally, in a before-and-after observational cohort study in step-down units, Harbrecht et al<sup>30</sup> showed that, although protocol use did not effect any significant change in overall mortality or rates of ICU admission, those patients receiving protocol-directed respiratory treatments experienced shortened ICU (mean duration 2.3 d vs 3.6 d,  $P < .002$ ) and hospital stay (mean 6.8 d vs 7.8 d,  $P < .02$ ).

Adding to the previously described observational studies, 2 randomized controlled trials provide the strongest level of evidence supporting protocol-directed respiratory care in non-ICU patients. Both trials compare the impact

of in-patient respiratory care protocol services, versus usual physician-directed care,<sup>35,36</sup> and show that respiratory-therapist-directed care allows better allocation of respiratory care services than physician-directed care, with trends toward lower cost and no excess adverse events (Table).

In the first of these trials, Stoller et al<sup>35</sup> randomly allocated 145 non-ICU adult in-patients admitted to the Cleveland Clinic Hospital to receive respiratory care orders directed by the managing physicians, or to have their physicians’ respiratory care orders pre-empted by those generated by a respiratory therapist using protocols. The protocols had a branching logic format, and were developed to operationalize American Association for Respiratory Care Clinical Practice Guidelines. Compared with physician-directed care, the use of respiratory care protocols conferred several advantages, including a higher rate of concordance with a gold standard respiratory care plan (82% vs 64%, using stringent agreement criteria,  $P < .001$ ), and a trend toward lower true median respiratory care costs/patient ( $\$130$  vs  $\$152$ ,  $P = .51$ ).

In the second randomized study, Kollef et al<sup>36</sup> reported similar findings. Specifically, 694 patients were allocated to one of 3 hospital firms, according to their primary physician’s ward assignments. Unassigned patients were randomly allocated among the firms. On firm A, respiratory care treatments were delivered using respiratory-therapist-driven protocols. Conversely, on firms B and C, respiratory care orders were written by the managing physicians. The study revealed that using respiratory-therapist-driven protocols (firm A) was associated with fewer RT treatments (10.7 for firm A vs 12.4 for firm B vs 12.3 for firm C,  $P = .009$ ), a greater percentage of bronchodilators administered via metered-dose inhaler (89% vs 77% vs 78%,  $P = .01$ ), fewer RT orders that were discordant with the protocol standard (24% vs 58% in firms B and C, risk

ratio 0.42, 95% CI 0.33–0.53), and lower respiratory care charges (mean \$868 vs \$1,124 vs \$1,054,  $P < .001$ ). As in the earlier randomized trial by Stoller et al.,<sup>35</sup> these benefits were achieved without any increase in adverse events.

In summary, these 2 randomized controlled trials<sup>35,36</sup> (see Table 1) and the earlier observational studies<sup>32-34</sup> strongly satisfy both criteria to establish the scientific basis of respiratory care protocols. Specifically, respiratory therapists implementing protocol-based care benefit patients, and the use of such protocols enhances allocation and lowers cost, compared with traditional physician-directed respiratory care.

### Summary

Overall, a substantial body of available evidence supports using respiratory care protocols. Their application has been associated with multiple benefits, including:

- Enhanced allocation of respiratory care services, which can be achieved by implementing protocols for individual respiratory tests or treatments (such as arterial blood sampling, arterial line placement, use of supplemental oxygen, bronchial hygiene techniques, and bronchodilators), or by using a comprehensive protocol (in which the choice of respiratory treatments and the specific respiratory care plan is guided by multiple algorithms).
- Accelerated liberation from mechanical ventilation, for which protocol use is associated with reduced duration of mechanical ventilation, reduced ICU stay, and cost savings.

While the available evidence that supports protocols is compelling and justifies their use in many clinical settings, gaps in current understanding persist and invite further research. For example, additional study is needed to assess the efficacy of protocols in several in-patient 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 in palliative care, geriatric care, and extended care facilities. On this basis, our hope is that this review and the other contributions in this New Horizons Symposium will help spur the additional needed investigation to clarify these issues.

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