Randomized Controlled Trial of Physician-directed versus Respiratory Therapy Consult Service-directed Respiratory Care to Adult Non-ICU Inpatients

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Although current evidence suggests that respiratory care protocols can enhance allocation of respiratory care services while conserving costs, a randomized trial is needed to address shortcomings of available studies. We therefore conducted a randomized controlled trial comparing respiratory care for adult non-ICU inpatients directed by a Respiratory Therapy Consult Service (RTCS) versus respiratory care by managing physicians. Eligible subjects were adult non-ICU inpatients whose physicians had prescribed specific respiratory care services. Consecutive eligible patients were approached for consent, after which a blocked randomization strategy was used to assign patients to (*1*) Physician-directed respiratory care, in which the prescribed physician respiratory care orders were maintained (n = 74), or (*2*) RTCS-directed respiratory care, in which the physician's respiratory care orders were preempted by a respiratory care plan generated by the RTCS (n = 71). Specifically, these patients were evaluated by an RTCS therapist evaluator whose respiratory care plan was based on sign/symptom-based algorithms drafted to comply with the American Association for Respiratory Care (AARC) Clinical Practice Guidelines. Appropriateness of respiratory care orders was assessed as agreement between the prescribed respiratory care plan and an algorithm-based "standard care plan" generated by an expert therapist who was blind to the patient's actual orders. The compared groups were similar at baseline regarding demographic features, admission diagnostic category, smoking status, and Triage Score (mean, 3.8 ± 0.9 SD [RTCS] versus 3.7 ± 1.0). Similarly, no differences were observed between RTCS-directed and physician-directed respiratory care regarding hospital mortality rate (5.7 versus 5.6%), hospital length of stay (7.9 ± 9.0 versus 7.7 ± 7.3 d), total number of respiratory care treatments delivered (30.3 ± 30 versus 31.6 ± 30.5), or days requiring respiratory care (4.2 ± 5.2 versus 4.1 ± 3.6). Notably, using both a stringent (S) and a liberal (L) criterion for agreement, RTCS-directed respiratory care demonstrated better agreement with the "standard care plan" (82 ± 17% [S] and 86 ± 16% [L]) than did physician-directed respiratory care (64 ± 21% [S] and 72 ± 23% [L]) ($p < 0.001$). Finally, the true cost of respiratory care treatments was slightly lower with RTCS-directed respiratory care (mean, $235.70 versus $255.70/pt, p = 0.61). We conclude that (*1*) compared with physician-directed respiratory care, the RTCS prescribed a similar number and duration of respiratory care services at a slight savings (that did not achieve statistical significance) and without any increased adverse events; and (*2*) compared with physician-directed respiratory care, RTCS-directed respiratory care showed greater agreement with Clinical Practice Guideline-based algorithms. 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 CRIT CARE MED 1998;158:1068–1075.

As clinical practice guidelines have generally become popular strategies to enhance the process of care (1, 2), so too have therapist-driven protocols (TDPs) become widely adopted for a broad range of respiratory care services. Indeed, available studies offer two lines of evidence that TDPs have efficacy, namely, (*1*) use of therapist-driven protocols can lessen overordering of respiratory care services (3, 4), and (*2*) use of TDPs can maintain or lessen the costs of providing respiratory care while improving the allocation of respiratory care services (5–7).

Although the volume of supportive studies and the strength of supportive evidence has grown steadily, uncertainty about the efficacy of therapist-driven protocols persists, in part because of several methodologic shortcomings of available studies. Specifically, with the exception of a recent randomized

(*Received in original form September 18, 1997 and in revised form May 26, 1998*)

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Am J Respir Crit Care Med Vol 158. pp 1068–1075, 1998
Internet address: www.atsjournals.org

trial assessing protocol-based weaning from mechanical ventilation (8), available studies are limited to descriptive reports or to observational cohort studies in which control groups are usually historical and only occasionally concurrent (3, 5–7). To our knowledge, no randomized controlled trial has examined the efficacy of TDPs for respiratory care outside the ICU. Second, available studies frequently fail to stratify compared groups regarding their severity of illness and their need for respiratory care services, so that baseline similarity of compared groups is not assured (3, 9). Furthermore, in instances when risk stratification has been undertaken in observational studies, recipients of TDP-directed care have had higher degrees of acuity than recipients of physician-directed care, consistent with physicians' practice of seeking consultative help with sicker patients while self-managing patients with more straightforward problems (5). In short, these remaining reservations about the efficacy of therapist-driven protocols stem from a lack of an adequately designed randomized controlled trial (10). To address this shortcoming, the current study presents a randomized controlled trial comparing respiratory care for adult non-ICU inpatients directed by an algorithm-based respiratory therapy consult service versus respiratory care ordered by physicians. This study addresses the following specific questions: (*1*) As the primary outcome measure, was the rate of appropriate respiratory care orders (i.e., those complying with Clinical Practice Guideline-based algorithms) enhanced by use of a respiratory therapy consult service (RTCS)? (*2*) As secondary outcome measures, were the hospital survival rate and measures of utilization of services (including costs) enhanced by use of a respiratory therapy consult service?

On the basis of our prior experience (5), we hypothesized that a suitably organized and administered respiratory therapy consult service could enhance the appropriateness of respiratory care orders while maintaining or improving clinical outcomes and costs of care compared with usual physician-directed care.

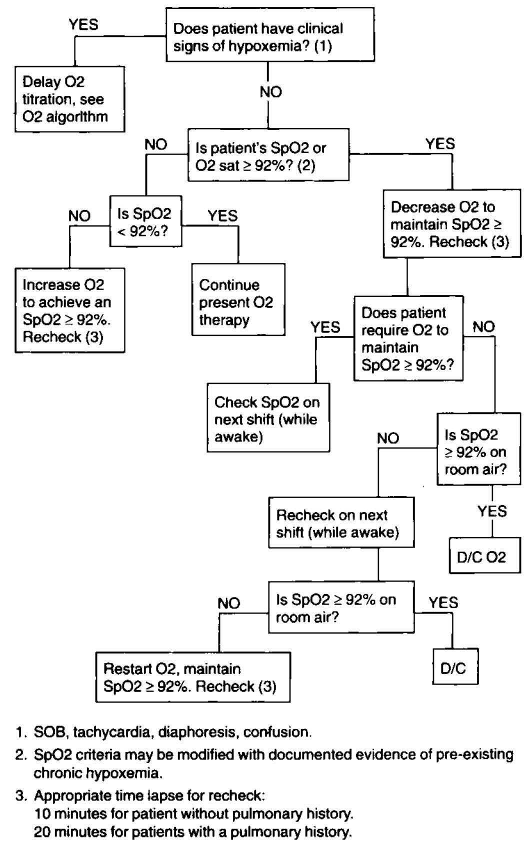

Figure 1. Algorithm specifying titration of supplemental oxygen. The algorithm has a branched logic format and is based on physiologic principles and the Clinical Practice Guideline regarding supplemental oxygen therapy published by the American Association for Respiratory Care (13).

METHODS

Study Design and Eligibility Criteria

The study is a randomized controlled trial in which study subjects were randomly allocated to receive respiratory care ordered by their managing physicians (physician-directed respiratory care) versus respiratory care specified by the Cleveland Clinic Respiratory Therapy Consult Service (RTCS), a long-standing activity of the Section of Respiratory Therapy in the Department of Pulmonary and Critical Care Medicine (5, 11, 12).

The structure and operation of the RTCS have been described previously (11). Briefly, the goal of the RTCS is to maximize the appropriate allocation of respiratory care services. To this end, the RTCS consists of four main elements:

1. A series of algorithms (11) that are indexed to respiratory signs and symptoms and are used to prescribe specific respiratory care treatments. As exemplified in Figure 1 (11), the algorithms have a branched-chain logic format and execute the indications for respiratory care specified by the American Association for Respiratory Care (AARC) Clinical Practice Guidelines (11, 13, 14). Because the algorithms implement Clinical Practice Guidelines, they are regarded to represent current standards for respiratory care. As described previously (5, 11), all of the algorithms are published in a pocket-sized handbook, which was distributed to all house officers and fellows at the Cleveland Clinic Foundation before the current study began and to all therapists in the Section of Respiratory Therapy. Written communication to all Cleveland Clinic physicians by the medical director (J.K.S.) before study inception explained the algorithms and encouraged their routine use. As previously described, respiratory therapists underwent extensive orientation regarding the algorithms to optimize their uniform application.
2. A Triage Score, which is an instrument designed to stratify patients according to the severity of their respiratory conditions and the intensity of respiratory care they require (15). As previously described (11, 15) and presented in Figure 2, the Triage Score rating instrument specifies a focused history and physical examination, on the basis of which patients are rated on eight separate axes (pulmonary history, surgical status on the current admission, chest radiograph findings, respiratory pattern, mental status, character of breath sounds, strength of cough, and ambulatory status). Ratings within each axis are zero to four points maximum, with greater points assigned for greater degrees of derangement. On the basis of their Triage Points (0 to 32), patients are assigned one of five Triage Score strata, where Triage Score 1 ($>$ 20 Triage Points) denotes the greatest degree of respiratory illness and Triage Score 5 ($\leqslant$ 5 Triage Points) denotes the mildest degree of respiratory illness. The Triage Score has been shown to correlate significantly with important measures of the need for respiratory care services (e.g., days requiring respiratory care, number of respiratory care treatments required, and the hospital length of stay) and demonstrates consistent trends with overall mortality rate (15).
3. A group of therapist evaluators, who are Registered Respiratory Therapists and who see each RTCS patient in a timely fashion, perform an evaluation and assign a Triage Score and a respiratory care plan. Urgent or simple respiratory care treatments (e.g., providing supplemental oxygen or an urgently needed inhaled bronchodilator treatment) may be executed by the therapist evaluator, but elective and more time-consuming respiratory treatments (e.g., bronchopulmonary hygiene) are communicated to an implementing therapist.
4. Implementing therapists, who administer the respiratory care treatments specified by the therapist evaluator's respiratory care plan.

CCF RESPIRATORY THERAPY EVALUATION

Date: ____________

Time: ____________ Ht.: ______

Diagnosis: ____________ Age: ______

Respiratory Therapist: ____________

IMPRINT/LABEL

CHART ASSESSMENT

Clinical Findings	0	x	1	x	2	x	3	x	4	x	Points
Pulmonary History	(−) History (−) Smoking		Smoking history < 1 pk a day		Smoking history ≥ 1 pk a day		Pulmonary disease (acute or chronic)		Severe or chronic with exacerbation		
Surgical status	No surgery		General surgery		Lower abdominal		Thoracic or upper abdominal		Thoracic with pulmonary disease		
Chest X-ray	Clear or not indicated		Chronic radiographic changes		Infiltrates, atelectasis or pleural effusions		Infiltrations in more than one lobe		Infiltrate + atelectasis and/or pleural effusion		

LAB TEST: Date: ___ / ___ / ___ WBC ____ Hb ____ Plts ____

Date:	pH	HCO3	PaCO2	PaO2	HCO3	Sat / FiO2
___ / ___ / ___						

PULMONARY FUNCTION TEST: Minimal Pred. VC ________ VC______ PEAK FLOW ________

SpO2 / FiO2

Vital Signs: HR ______ BP ______ RR ______

TEMPERATURE (24 hr. max) ____________

PATIENT ASSESSMENT

	0	x	1	x	2	x	3	x	4	x	Points
Respiratory Pattern	Regular pattern RR 12–20		Increased RR 21–25		Dyspnea on exertion, irregular pattern RR 26–30		Decreased vital capacity* RR 31–35		Severe SOB, use of accessory muscles RR > 35		
Mental Status	Alert, oriented, cooperative		Lethargic, follows commands		Confused, does not follow commands		Obtunded		Comatose		
Breath Sounds	Clear to muscultation		Decreased unilaterally		Decreased bilaterally		Crackles in the bases		Wheezing and/or rhonchi		
Cough	Strong, spontaneous, non-productive		Strong, productive		Weak, non-productive		Weak, productive or weak with rhonchi		No spontaneous cough or may require suctioning		
Level of Activity	Ambulatory		Ambulatory with assistance		Non-ambulatory		Paraplegic		Quadriplegic		

Total Points ______

*VC ≤ to minimal predicted: Predicted Ideal Body Weight (males: 50 + 2.4 x inches > 60) (females 45 + (2.4 x inches > 60) Multiply above ideal body wt. x 15cc for min. pred. VC

TRIAGE 1	TRIAGE 2	TRIAGE 3	TRIAGE 4	TRIAGE 5
>20	(16–20)	(11–15)	(6–10)	(0–5)

TRIAGE # ______

Figure 2. Triage Score rating form. The Triage Score (15) rates severity of respiratory condition and the intensity of need for respiratory care services. The Triage Score is based on a 32-point ordinal score rating each of eight separate axes as zero to four points each, four points being assigned for the greatest degree of clinical derangement on each axis. The total points (0 to 32) are categorized into five Triage Scores, where Triage 1 ($>$ 20 total points) denotes the highest severity and Triage 5 ($\leqslant$ 5 points) the lowest.

The Respiratory Therapy Consult Service has been operational in the Cleveland Clinic Hospital since early 1992 and has been available at physicians' discretion on a hospital-wide basis since July 1992. On the basis of earlier observations (5), a hospital policy in August 1994 mandated RTCS oversight of respiratory care orders for almost all adult non-ICU inpatients in the Cleveland Clinic Hospital. This policy has been implemented in a staged manner (i.e., by adding successive wards periodically) since that time.

Because mandatory use of the RTCS on some hospital wards precluded conduct of a randomized trial on those wards, eligible subjects for this study were restricted to adult ($\geqslant$ 21 yr of age) inpatients on one of eight non-ICU wards where the RTCS was not yet uniformly implemented and for whom the managing physicians had prescribed specific respiratory care services (i.e., type of therapy, frequency, and duration of therapy). On day shifts when the therapist investigator (D.H.) was available for study recruitment (approximately once a week), consecutive patients for whom the managing physicians had ordered respiratory care services were approached for their consent to participate. After consenting to participate, patients were randomized to receive the respiratory care specified by their physicians ("physician-directed respiratory care") or to receive a Respiratory Therapy Consult Service ("RTCS-directed care"). In this latter group, respiratory care was delivered as ordered by the RTCS therapist evaluator, who was blind to the physicians' orders and whose orders preempted the existing physicians' orders for respiratory care before any respiratory care services were delivered.

To assure equal distribution within specific disease categories for both groups, the randomization was performed in a blocked design in which subjects were allocated to either physician-directed care or to the RTCS within seven admitting diagnostic categories: chronic obstructive lung disease, asthma, acute cardiac care (i.e., ischemia and/or arrhythmia), upper abdominal surgery, lower abdominal surgery, thoracic surgery, and other. Assignment to physician-directed or RTCS-directed care was determined by drawing a sealed envelope from the balanced set of envelopes for that patient's diagnostic group.

Study Outcomes

The primary study outcome measure was agreement between the patient's initial respiratory care plan (specified either by the managing physicians or by the RTCS) and a "standard respiratory care plan." This "standard care plan" was formulated based upon the Clinical Practice Guideline-based algorithms and was generated by one of the therapist investigators (D.H.), who was expert in applying the algorithms. To defend against bias, the therapist investigator drafting the "standard care plan" was kept blind to the actual care plan written by the service managing the patients' respiratory care (RTCS or physicians) and was blind to the patient's randomized group assignment. Also, to minimize the possibility that differences in respiratory care plans could be due to changing patient conditions over time, the therapist investigator evaluated the subject and drafted the care plan close in time (i.e., within 6 h) to when the actual respiratory care orders were written.

In evaluating agreement between the algorithm-based respiratory care plan (the "standard care plan" generated by the study investigator) and the plan of the managing service, two different levels of agreement were defined a priori: "stringent" agreement and "liberal" agreement. The types of available respiratory care treatments that constituted the specific respiratory care plans are presented in Table 1. Six distinct categories of treatment and 15 specific therapies were available. To satisfy the criteria for "stringent" agreement, the standard care plan and the patient's actual initial respiratory care plan had to agree exactly on all categories (e.g., use of bronchodilators, chest physiotherapy, etc.) and on all specific therapies (i.e., use of both identical drugs and delivery systems). Alternately, "liberal" agreement was achieved if the compared respiratory care plans were identical regarding the categories of therapy even though the specific therapies within each category may have differed (e.g., use of small-volume nebulizer versus metered-dose inhaler, albuterol versus ipratropium, etc.). Perfect agreement was defined as agreement with the standard care plan on all six treatment categories and was calculated for both the stringent and the liberal criteria.

Secondary outcome measures included hospital survival rate and measures of utilization of services (namely, length of hospital stay, duration of need for respiratory care, and cost of respiratory care services). Costs of care were derived from time-motion analyses to estimate the actual cost of services and supplies for each respiratory care modality. Costs were tallied using a computerized cost-accounting system (Transition Systems, Boston, MA). The number and types of respiratory care services provided was tracked using a management information system for respiratory care (CliniVision; Nellcor-Puritan-Bennett, Carlsbad, CA).

Statistical Methods

The study was designed utilizing the results of our recent observational study of RTCS versus physician-directed respiratory care (5). In that study, the standard deviations of the percent of initial orders that were discordant with the standardized plan were 26 and 36% for the RTCS and physician-ordered respiratory care groups, respectively.

TABLE 1

TYPES OF RESPIRATORY CARE TREATMENTS

Category of Treatment	Specific Treatment	Route of Administration
Bronchodilator	Albuterol	Small-volume nebulizer
	Ipratropium bromide	Small-volume nebulizer
	Albuterol	MDI*
	Ipratropium bromide	MDI
Bronchopulmonary hygiene	Percussion and vibration	
	Postural drainage	
Hyperinflation therapy	Incentive spirometry	
	Continuous positive airway pressure/positive expiratory pressure	
	Intermittent positive pressure breathing	
Supplemental oxygen	Low flow (e.g., nasal cannula)	
	High flow (e.g., Venturi mask)	
Oxygen monitoring	Arterial blood gas	
	Intermittent pulse oximetry	
	Continuous pulse oximetry	
Suctioning	Oral or nasotracheal	

* Metered-dose inhaler.

Assuming similar variability for the primary outcome in the current study, which was the mean percent of stringent agreement with the "standard respiratory care plan," we had approximately 80% power to detect a difference of 15% or more between the two groups at the 0.05 significance level using Wilcoxon's rank-sum test with a planned sample size of 75 patients per group.

Because the variables were not normally distributed, we compared the RTCS and physician-directed respiratory care groups on the continuous outcomes of percent agreement with the "standard respiratory care plan," length of stay, number of respiratory modes and treatments, and both costs of and days receiving respiratory care with Wilcoxon's rank-sum test. For categorical variables, the groups were compared with a Chi-square test or Fisher's exact test.

The association between categorical baseline features and the proportion of agreement with the "standard respiratory care plan" was assessed using Wilcoxon's rank-sum test for variables with two categories and the Kruskal-Wallis test for variables with more than two categories. For continuous baseline variables, the association with the proportion agreement and the "standard respiratory care plan" was assessed with Spearman's correlation coefficient.

Predictors of perfect agreement with the "standard respiratory care plan" were analyzed in a multivariable logistic regression model. Adjusted estimates of the relative risk of perfect agreement with the "standard respiratory care plan" were obtained using the Cochran Mantel-Haenszel formula.

A significance level of 0.05 was used for each hypothesis. When comparing the RTCS and physician-directed respiratory care groups on percent agreement within each of the six respiratory care categories, a correction for multiple testing was made and a significance criterion of $p < 0.0083$, or 0.05/6, was used.

The study was approved by the Investigational Review Board of the Cleveland Clinic Foundation.

TABLE 2

BASELINE CHARACTERISTICS OF RANDOMIZED GROUPS

Feature	RTCS-directed Respiratory Care (*n = 71*)	Physician-directed Respiratory Care (*n = 74*)	Total (*n = 145*)
Age, mean (median) ± SD	62.9 (65) ± 15.9	60.1 (61) ± 16.6	61.5 (6) ± 16.3
Male, %	59	46	52
Surgery on current admission, % yes	9.9	21.6	15.9
Triage points, mean (median) ± SD	9.1 (9) ± 4.1	9.1 (8) ± 4.9	9.1 (9) ± 4.5
Triage Score, mean (median) ± SD	3.8 (4) ± 0.9	3.7 (4) ± 1.0	3.8 (4) ± 1.0
Admission diagnostic category, %*			
COPD	15.5	13.5	14.5
Asthma	12.7	9.5	11.0
Cardiac care	35.2	27.0	31.0
Thoracic surgery	5.6	8.1	6.9
Upper abdominal surgery	2.8	0	1.4
Lower abdominal surgery	0	4.1	2.1
Other	28.2	37.8	33.1
Smoking status, %			
Ex-smoker	22	23	23
Current smoker	22	19	21
Nonsmoker	56	58	56
Triage Score categories, %			
Triage 1 > 20 pts	0	2.7	1.4
Triage 2 16–20 pts	7.0	8.1	7.6
Triage 3 11–15 pts	29.6	25.7	27.6
Triage 4 6–10 pts	36.6	39.2	37.9
Triage 5 1–5 pts	26.8	24.3	25.5

* Used for stratified randomization.

TABLE 3

TREATMENT AND OUTCOME CHARACTERISTICS OF COMPARED GROUPS*

Procedure	RTCS-directed Respiratory Care* (*n = 71*)	Physician-directed Respiratory Care* (*n = 74*)	p Value†
Hospital length of stay	7.9 (5) ± 9.0	7.7 (5) ± 7.3	0.73
Hospital mortality, %	5.7	5.6	0.99‡
Respiratory care treatment modes used, n	2.8 (3) ± 1.2	2.9 (3) ± 1.1	0.60
Total number of respiratory care treatments	30.3 (20) ± 30	31.6 (21) ± 30.5	0.62
Costs per patient of respiratory care treatments	$235.70 (130.20) ± 242.70	$255.70 (152.20) ± 274.00	0.61
Days receiving respiratory care	4.2 (3) ± 5.2	4.1 (3) ± 3.6	0.91

* Values are means ± SD with medians shown in parentheses.
† Wilcoxon's rank-sum test.
‡ Fisher's exact test.

RESULTS

Consent was sought from 147 patients, of whom 145 were enrolled in the study (two patients who were randomized to the intervention group declined, one citing insurance concerns and one who preferred physician-directed care). Seventy-one patients were therefore allocated to RTCS-directed respiratory care (intervention group) and 74 patients received physician-directed respiratory care (control group).

The baseline characteristics of the compared groups and of the entire study population are presented in Table 2. Patients allocated to RTCS-directed and physician-directed respiratory care were similar with regard to age, sex, and smoking status. A minority of study subjects were undergoing surgery on the current admission, but more patients in the control group underwent surgery (21.6%) than in the intervention group (9.9%). Despite this, the blocked randomization strategy on admitting diagnostic categories successfully assured that the compared groups were similar regarding admitting diagnosis. Also, mean Triage Points and Triage Scores of the compared groups were similar.

In keeping with usual practice in academic medical centers, the physicians actually writing the orders for respiratory care were usually housestaff (97.3% in the control group and 91.4% in the intervention group). Attending physicians supervised the care of all study patients and actually wrote the respiratory care orders for 5.5% of all patients. A minority of study patients (15.9%) were under the primary care of a pulmonologist during the current hospitalization (18% control versus 12.7% intervention group).

The treatment and outcome features of the two groups are presented in Table 3. Hospital length of stay was similar, as were the days requiring respiratory care, which comprised 54% of total hospital days. The relative risk of mortality in the RTCS group was 1.04 (95% confidence interval [CI], 0.27 to 4.0; p = 0.99). The total number of respiratory care treatments and treatment categories per patient were also similar between the intervention and control groups. Despite the similarity in the volume of respiratory care services provided, RTCS-directed care cost was slightly less per patient (median, $130.20 per patient versus $152.20 per patient), though this difference failed to achieve statistical significance (p = 0.61). Though no differences regarding use or cost of individual respiratory care modalities achieved statistical significance, this $22 per patient median higher cost of physician-directed respiratory care appeared to reflect increased volume and duration of several respiratory care modalities, i.e., aerosol (used in 51 control versus 42 intervention group patients; median per patient cost, $93 versus $72), continuous oximetry (used in five versus four patients, median per patient cost $193 versus $124), and bedside spirometry (ordered for four versus zero patients; median per patient cost, $88 versus zero). (Notably, bedside spirometry was usually ordered when preoperative lung function was desired but scheduling or clinical circumstances precluded testing in the pulmonary function laboratory.) Though not producing a net cost excess in the intervention care group, several other therapies were used more by the RTCS, including incentive spirometry (used in 19 versus 14 patients; median per patient cost, $10.50 and $10.50), high-flow oxygen (used in 10 versus nine patients; median per patient cost, $148 versus $85), and suctioning (used in eight patients in both groups, but more frequently per patient in the RTCS-directed group; median per patient cost, $37 versus $13). Therapies for which there was little difference in volume, duration, or cost of use included arterial blood gases, bronchopulmonary hygiene, metered-dose inhaler, low-flow oxygen, and intermittent oximetry.

TABLE 4

COMPARING RTCS AND PHYSICIAN-DIRECTED CARE GROUPS ON AGREEMENT WITH STANDARD CARE

Agreement Criterion	Possible Agreements on the Six Treatment Categories (*n*)	(%)	Frequency of Observed Agreement: RTCS (*n*)	(%)	Physician (*n*)	(%)	p Value
Stringent*	1/6	17	0	0	1	1	
	2/6	33	1	1	11	15	
	3/6	50	8	11	17	23	
	4/6	67	10	14	22	30	
	5/6	83	29	41	16	22	
	6/6	100	23	32	7	9	< 0.001†
			Percent agreement‡				
			82 (83) ± 17		64 (67) ± 21		< 0.001§
Liberal‖	1/6	17	0	0	1	1	
	2/6	33	1	1	9	12	
	3/6	50	4	6	11	15	
	4/6	67	9	13	13	18	
	5/6	83	26	37	24	32	
	6/6	100	31	44	16	22	< 0.001†
			Percent agreement‡				
			86 (83) ± 16		72 (83) ± 23		< 0.001§

* Stringent criterion requires complete agreement on all categories of respiratory care-prescribed and specific treatments (*see* Table 1).
† Groups compared on percent-perfect agreement (i.e., agreement on 6/6 treatment categories) with Chi-square test.
‡ Values are means ± SD with medians shown in parentheses.
§ Groups compared on median percent agreement with Wilcoxon's rank-sum test, where the unit of analysis is the percent-observed agreement for each subject (e.g., 17, 33, 50, 67, 83, or 100%).
‖ Liberal criterion requires agreement on all categories of respiratory care but allows discordance on specific treatments.

The results regarding agreement between the managing service's respiratory care orders and the "standard respiratory care plan" are presented in Table 4. For both the stringent and liberal criteria for agreement, RTCS-directed care achieved higher agreement with the "standard care plan." Using the stringent criterion (for which agreement was required on both the category of therapy and the specific treatments, as shown in Table 1), the RTCS achieved perfect agreement (agreeing on 6/6 modes) in 32% of patients versus 9% for the physician-directed care ($p < 0.001$, Chi-square test). At least near-perfect agreement (defined as agreeing on 5/6 or 6/6 treatment categories) was achieved in 73% (52/71) of the RTCS patients versus 31% (23/74) of the control group. The RTCS achieved a mean percent agreement of 82% compared with 64% for the control group ($p < 0.001$, Wilcoxon's rank-sum test).

Using the liberal criterion (which required agreement on the categories of respiratory therapy but not the specific treatments), agreement with the standard care for both groups was expectedly higher, but the RTCS again achieved higher agreement (mean of 86 versus 72%, $p < 0.001$). At least near-perfect agreement (i.e., on 5/6 or 6/6 modes) was achieved in 80% (57/71) of the intervention group patients versus 54% (40/74) of the control group.

Considering each of the individual respiratory care modes separately (Table 5), the observed agreement with the "standard care plan" was uniformly higher for RTCS-directed care than for physician-directed care. A statistical difference (using the $p < 0.0083$ criterion correcting for multiple testing) was found only for bronchodilator therapy, though trends towards significant differences were also observed for supplemental oxygen (stringent and liberal criteria) and oxygen monitoring (stringent criterion), both of which showed p values < 0.05. None of the baseline features (Table 2) was significantly associated with agreement between actual respiratory care orders and the "standard respiratory care plan."

Finally, multivariate logistic regression models were fit for predicting perfect agreement between the "standard care plan" and the actual respiratory care orders (i.e., agreement on all six respiratory care treatment categories, as shown in Table 1) using both stringent and liberal criteria for agreement. In the models for both stringent and liberal criteria, randomization group, sex, and admitting diagnosis category achieved significance. Adjusting for the sex and admitting diagnosis category, the odds of perfect agreement using the stringent criterion were 6.9 times higher (95% CI, 2.4 to 20) with RTCS-directed care than with physician-directed care, and 3.4 times higher (95% CI, 1.5 to 7.6) using the liberal criterion. Relative risk estimates for agreement between the RTCS and the "standard care plan" adjusting for sex and the admitting diagnosis were 3.8 (95% CI, 1.8 to 7.7) and 2.1 (95% CI, 1.3 to 3.5) for the stringent and liberal criteria, respectively.

TABLE 5

AGREEMENT BETWEEN MANAGING SERVICE AND "STANDARD RESPIRATORY CARE PLAN" FOR INDIVIDUAL RESPIRATORY CARE CATEGORIES

Respiratory Care Category	Agreement Criterion*	Percent Agreement		p Value†‡
		RTCS	Physician-directed	
Bronchodilator	Stringent	69	27	< 0.001
	Liberal	92	64	< 0.001
Bronchopulmonary hygiene	Stringent	83	70	0.07
	Liberal	83	70	0.07
Hyperinflation	Stringent	78	65	0.09
	Liberal	79	65	0.06
Supplemental oxygen	Stringent	87	74	0.04
	Liberal	87	74	0.04
Oxygen monitoring	Stringent	75	54	0.01
	Liberal	75	66	0.27
Suctioning	Stringent	100	93	0.06‡§
	Liberal	100	93	0.06‡§

* *See* Table 4 for description of criteria.
† Likelihood ratio Chi-square test unless otherwise indicated.
‡ By correction for multiple testing, significance is indicated by $p < 0.0083$.
§ Fisher's exact test.

DISCUSSION

In the context that adherence to official clinical practice guidelines has been advocated as a way to implement currently recommended practice (1, 14), the results of the current research show that a RTCS can improve the allocation of respiratory care services compared with physician-directed respiratory care. Although this improved allocation was achieved by the RTCS without demonstrable adverse effects (e.g., higher cost, mortality rate, or hospital length of stay), it must be recognized that the power of the study to detect differences in these secondary outcome events—whether favorable or otherwise—was low (e.g., only 40% power to detect a length of stay difference of $\geqslant$ 2 d).

While confirming conclusions of earlier studies that respiratory care protocols have benefits, these findings extend experience with respiratory care protocols from this and other institutions in several ways (4, 7). First, to our knowledge, the current study is the first randomized trial to evaluate the efficacy of respiratory care protocols for non-ICU adult inpatients. Our findings complement those from a recent randomized trial of protocol-guided weaning, which showed that respiratory therapists and nurses using protocols can accelerate patients' freedom from mechanical ventilation compared with usual physician-directed care (8). Second, our findings agree with earlier observational studies showing that respiratory care practitioners can be effective allocators of respiratory care services (3, 5, 6, 9) and that respiratory care protocols can save costs (5, 8). Third, the current study addresses several methodologic shortcomings of earlier reports. Specifically, in our earlier observational study of RTCS- versus physician-directed respiratory care for adult non-ICU inpatients (5), baseline Triage Scores (15) were lower in the RTCS group (suggesting that physicians elected to self-manage patients with less severe respiratory care needs) (5), but length of stay was higher in the RTCS group. Because the total number of respiratory care treatments prescribed per patient was the same in the RTCS-directed and the physician-directed respiratory care groups, we attributed the higher length of hospital stay in the RTCS group to the patients' greater baseline acuity of illness rather than to an unfavorable effect of protocol-guided respiratory care (5). By demonstrating that hospital length of stay is the same in both groups when baseline Triage Scores are similar, the results of the current randomized controlled trial support this interpretation of earlier results and argue against concerns that use of a RTCS prolongs hospital length of stay.

Although the current study demonstrates that a Respiratory Therapy Consult Service can provide benefit by enhancing adherence to clinical practice guidelines for respiratory care, several potential limitations of this study warrant discussion. First, it might be said that because we examined compliance with respiratory care algorithms and because the respiratory care practitioners received specific training in use of the algorithms, the finding of greater agreement is not surprising but, rather, expected. However, we emphasize that the algorithms have been drafted to operationalize the AARC Clinical Practice Guidelines that represent widely accepted standards for respiratory care (13, 14). To this extent, compliance with the algorithms indicates compliance with currently recommended practice, and this study represents a comparison of different strategies to implement current practice guidelines, i.e., by usual physician-directed care versus by the Respiratory Therapy Consult Service. We also emphasize that the same algorithms used by the RTCS were distributed to all house officers and fellows in our institution as a pocket-sized handbook and that physicians were actively encouraged to use the algorithms in their prescribing respiratory care. Furthermore, since the inception of the RTCS in 1992, therapists have been encouraged to discuss the algorithms with physicians, and the RTCS has been the subject of many presentations to the housestaff, including Medical Grand Rounds.

Clearly, other strategies to achieve this higher level of compliance with recommended respiratory care practice could be proposed. For example, alternative approaches include intensive education directed to physicians-in-training regarding appropriate respiratory care prescribing and/or greater physician training in implementing algorithms. Although these alternative strategies may have appeal, impediments to their use in our institution include the difficulty of assembling the large numbers of medical and surgical house officers for a series of respiratory lectures, the need to repeat such training annually for each new class of house officers, and the resistance posed by physicians' general aversion to accepting and using practice guidelines (16). In contrast, features that recommend use of a RTCS implemented by respiratory care practitioners include respiratory care practitioners' disposition to successfully execute protocol-based care (3, 9), a stable corps of respiratory care practitioners for whom intensive training was more readily arranged, and a high level of respiratory care practitioner motivation. Although our results show the success of the RTCS in enhancing the allocation of respiratory care services compared with "usual medical care," they do not exclude the possibility that alternative strategies such as more intensive physician training could also effect similar improvements.

As a second potential limitation of this study, it might be argued that although our results show that greater concordance with clinical practice guidelines is achieved by RTCS-directed respiratory care, clinical benefits have not been demonstrated. We believe that this interpretation overlooks emerging evidence that clinical practice-guideline-based respiratory care can lessen the amount of inappropriately administered respiratory care while reducing health care costs (5, 6, 11, 17). For example, using the same RTCS oxygen titration algorithm employed in the current study, we recently showed that respiratory care practitioner-directed management of postsurgical supplemental oxygen was associated with less overordering of supplemental oxygen and lower costs of oxygen administration and monitoring (17). Also, in a recent randomized controlled comparison of protocol-based weaning from mechanical ventilation by respiratory care practitioners and nurses versus physician-directed weaning, Kollef and colleagues (8) reported that protocol-based weaning was associated with a shorter duration of mechanical ventilation with a concomitant cost reduction of $42,960. As further evidence of the clinical value of respiratory care protocols, preliminary evidence from two institutions suggests that physicians regard respiratory care protocols as enhancing the care provided to their patients (18, 19). Specifically, a survey of medical house officers at the Cleveland Clinic Foundation showed that 97% of respondents believed that the RTCS enhanced the clinical care their patients received (18). Similarly, in a survey of attending and resident physicians, Messenger (19) reported that 64.8% of respondents felt that respiratory care practitioner-administered protocols helped patient management; 50% felt that the quality of care was thereby improved (versus 5.6% who felt that the quality of care was lessened); and 55.6% felt the appropriateness of care was improved (versus 5.6% who felt that appropriateness was lessened). On the basis of these and other supportive studies, we believe that a RTCS that implements clinical practice guideline-based care does confer clinical benefits.

A third potential limitation of this study is that because the study was conducted in an academic medical center with housestaff writing most of the respiratory care orders under attendings' oversight, our findings may not be generalizable to other clinical settings, e.g., in which senior physicians personally prescribe all respiratory care orders. Still, to the extent that misallocation of respiratory care orders has been demonstrated consistently in a variety of clinical settings (including both academic and private medical settings) (3–11), we believe that a method of enhancing allocation of respiratory care services is widely desirable. Our results show that the RTCS represents one such strategy.

Finally, our economic analysis tallied only the true costs of respiratory care services provided by the RTCS- versus physician-directed groups and showed only a nonsignificant trend toward lower cost for the RTCS-directed respiratory care. Notably, a more complete economic analysis of the RTCS would have also included the costs of implementing the program, training the respiratory care practitioners about the RTCS, and of the time expended by the evaluators. Similarly, a fuller economic comparison of RTCS- versus physician-directed respiratory care would have also included physician-related costs of prescribing respiratory care such as the cost of physicians' time to write respiratory care orders and assessing and titrating the patients' respiratory care needs. Indeed, the difficulty of measuring these additional costs of both RTCS- and physician-directed respiratory care led us to favor the simpler and more reliable, if less complete, economic analysis presented.

Our findings also raise several questions and concerns. First, failure of RTCS-directed respiratory care to achieve perfect agreement with the "standard care plan" indicates that misallocation has not been eliminated completely, even with a strategy in which respiratory care practitioners are trained extensively and in which substantial effort is directed to quality monitoring and improvement. Prior studies of concordance between two highly experienced therapist evaluators indicate moderate to excellent agreement beyond chance alone, with kappa values up to 0.79 (11). However, that agreement was imperfect even under the optimal condition of comparing two of our most experienced evaluators likely reflects the subjective nature of some of the decisions within the algorithms. Also, even though the "standard care plan" was generated based on a blinded evaluation that was completed within several hours of the managing service's orders, we cannot exclude the possibility that patients' changing clinical status over a few hours contributed to the discordance between the "standard care plan" and the actual orders, whether generated by physicians or by the RTCS. Finally, to the extent that even the best algorithm may not incorporate every relevant clinical detail needed to permit a treatment decision, some discordance from the algorithm may reflect practitioners' exercising their best judgment in individualizing respiratory care for their patients.

Another concern that has been raised is that having respiratory care protocols implemented by respiratory care practitioners may detract from the ability of physicians-in-training to learn how to prescribe respiratory care. Such a concern is ameliorated by having the formalized, written algorithms as a teaching instrument distributed to all house officers, thereby providing a valid alternative to the "see one, do one, teach one" approach to gaining clinical experience. Though little attention has been given to the educational impact of respiratory care protocols, a recent study surveying Cleveland Clinic house officers' opinions about the RTCS has shed some light on physicians' perceptions (18). When asked whether the RTCS enhanced or detracted from the clinical care of adult inpatients, 97% of 41 responding medical house officers indicated that clinical care was enhanced by the RTCS. When then asked whether the RTCS enhanced or detracted from their own education in providing respiratory care, 56% found that their education was enhanced, 32% felt that their education was impeded, and 12% expressed neither effect. Further study is needed to learn whether perceptions about the impact of the RTCS are real (i.e., whether house officers trained in institutions using respiratory care protocols have greater or poorer knowledge of respiratory care prescribing than others).

In summary, the results of this randomized controlled trial suggest that an RTCS, in which respiratory care practitioners prescribe respiratory therapy services based on algorithms designed to implement recommended respiratory care, can improve the appropriateness of respiratory care orders compared with usual physician-directed respiratory care. On the basis of these and similar earlier findings at our institution, the RTCS has been made mandatory for prescribing respiratory care to most adult non-ICU inpatients at the Cleveland Clinic Hospital.

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