Refining your Therapist Driven Protocols & Clinical Guidelines of Care

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Objectives

- Recognize how guideline and protocol revisions can improve your clinical impact and better match patient populations you serve.

Disclosures

- This presentation was supported by an unrestricted educational grant from Dräger.
- I have no relevant financial or non-financial relationships pertinent to the topic being presented.
What we will cover

- Key components of protocols and guidelines
- Application and value
- Life cycle of protocols
- Role and process of revision
- Gathering and sharing data

Protocol or Guidelines?

**Clinical Protocol Requirements**
- Bedside instrument to reduce practice variation, reduce costs, integrate performance improvement, and allow for positive outcomes... (Fuss & Pasquale 1998)
- A precise and detailed plan...
- Initiated based on the patient meeting specific criteria defined in the protocol.
- Full adherence to the protocol is required.
- Routinely reviewed and revised to determine adherence to evidence and ensure clinical efficacy and safety.

**Clinical Practice Guideline Requirements**
- Systematically developed statements that are used to assist practitioners and patients decide about appropriate healthcare for specific clinical circumstances - IOM (1990)
- Operational tool to assist in clinical decision...
- Source of continuity, quality of care, range of acceptable practices and options.
- Guiding a course of action...
- Based on procedures or clinical conditions
- Based on systematic review of the evidence...

Respiratory Therapy Protocols

Respiratory therapy protocols are used to institute, or modify a patient care plan following a predefined and structured set of physician orders. They include instructions or interventions in which the respiratory therapist is allowed to initiate, discontinue, refine, transition, or reinitiate therapy as the patient’s medical condition dictates. Protocols are generally written in algorithmic form, are based on scientific evidence, and include guidelines and options at decision points along with clearly stated outcome objectives.

Current medical literature supports the use of respiratory therapy protocols as an effective tool for producing improved patient outcomes and appropriate allocation of services. Based on their demonstrated efficacy, it is the position of the American Association for Respiratory Care that institution-approved protocols should be used by respiratory therapists as the standard of care for providing respiratory therapy services under qualified medical direction.

Effective 05/16/91
Revised 07/97
Revised 04/03
Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs)

- Establish transparency
- Manage conflict of interest
- Multidisciplinary, balanced guidelines group
- Use of systematic reviews
- Establish evidence foundations, rating strength of recommendations
- Articulate recommendations precisely
- Update when new evidence suggests need for modifications

The Value of RT-Driven Protocols

**Environments**
- Adult, Pediatric, Neonatal ICU's
- Adult intermediate and step down units
- Emergency Dept.
- LTAC
- Adult, Peds Acute care

**Application**
- Vent liberation
- Early mobilization
- Aerosol, Bronchial hygiene, Lung inflation
- O2 Therapy

**Benefits**
- Appropriate utilization
- Cost savings
- Lower labor costs
- Reduction in readmissions
- Reduced unnecessary care
What to do...

- Prepare well
- Involve relevant people
- Evidence based
- Feasible & attractive
- Identify the challenges to implement change
  - Develop strategies, measures linked to the problem
  - Define measures of performance & success
- Monitor performance


Implementation and Maintenance of Respiratory Care Protocols Requires...

- A) Use of written protocols with sound scientific basis.
- B) Strong medical director support.
- C) Intensive education of respiratory care practitioners.
- D) Medical staff approval and confidence in the protocol.
- E) Frequent auditing of outcomes and continuing education.
- F) Adjustment of protocol to meet needs and new scientific evidence.

Respiratory Care Protocols, ACCP Position Paper*

Accepted by the Respiratory Care Section Steering Committee, Chicago, Illinois, 10/27/92.

Patterns and Factors Associated With Respiratory Care Protocol Use

- From the RT’s, MD’s, & RT Manager perspective, protocols enhance:
  - Cost
  - Quality
  - RT job satisfaction
  - RT workload
  - MD satisfaction
  - MD workload
  - Patient satisfaction

- Protocol use enhanced by stakeholder support, strong quality practices and robust EMR/information systems.
Do You Have a Need to Revise?

- Improvement or changes to present process?
  - Outside of your primary domain, e.g. OR, PACU
- New areas of application?
  - Clinical areas or patient populations previously not using protocols
- Newer technologies needing incorporation?
  - Delivery devices, monitoring
- **Better evidence?**

Protocol Life Cycles

- Identified Need...
- Generalized agreement between key change agents...
- Investigation, networking, plagiarizing...
- Gain support
- Refinement of key elements
- Pilot
- Revise, Implement
- Monitor
- Refine and Revise

Bounce-Backs & Bounce-Ups

- Impacts quality, outcomes, and operations
  - ICU readmissions 2%-4% nationally. Brown et al. (2012)
  - Higher among post-operative cardio-vascular patients (2%-8%). Van Diepen et al. (2014)
- Outcomes-related complications
  - Mortality (12.9% vs. 2.4%). Magruder et al. (2015)
  - LOS, Cost of care, Access
- **2014 – TCV**
  - 25 readmissions in 6 months
  - 50% attributable to respiratory complications
  - Esophagectomy pts. at highest risk

References:
Brown et al. 2012 AJRCCM
Van Diepen et al. 2014 Critical Care
Data capture and analysis is an integral part of the process

- How do you determine your impact?
- Try and design your EMR tool with consideration for:
  - Ease of input for your bedside providers
  - Guidance through your protocol
  - Drop down, conditional logic
    - Quantifiable
    - Compare groups
  - Outcomes analysis

Example - EMR Severity Assessment Score

<table>
<thead>
<tr>
<th>Clinical Findings</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tachycardia</td>
<td>0</td>
</tr>
<tr>
<td>Low O2 Saturation</td>
<td>0</td>
</tr>
<tr>
<td>Auscultation</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory Pattern/ABG</td>
<td>1</td>
</tr>
<tr>
<td>Pulmonary Edema</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory Distress Score</td>
<td>2</td>
</tr>
<tr>
<td>Temperature</td>
<td>1</td>
</tr>
<tr>
<td>Activity Level</td>
<td>0</td>
</tr>
<tr>
<td>Oxygen Level</td>
<td>0</td>
</tr>
<tr>
<td>Scores</td>
<td></td>
</tr>
<tr>
<td>Delayed Hydration Score</td>
<td>0</td>
</tr>
<tr>
<td>Venous Therapy Score</td>
<td>1</td>
</tr>
<tr>
<td>Lactate Score</td>
<td>3</td>
</tr>
</tbody>
</table>
Select Interventions, Medications, Delivery Device
Choose Aerosol, lung expansion or bronchopulmonary hygiene pathways, Medications as appropriate.

- Sympathomimetic agent
- Anticholinergics
- Combine with anti-inflammatory if history of Asthma, COPD (if used daily)

Administer therapy per baseline guidelines and frequency, escalate or reduce care as appropriate.

Pt. education (disease mgmt/respiratory interventions) as appropriate.

Plan Considerations:
1. Discontinue protocol if improvement is observed and sustained over a 72 hour period. Re-evaluate 24 hrs after discontinuation.
2. Review/refine respiratory home regimens prior to d/c of protocol.
3. Evaluate Response or Outcome Achievement every 12-24 hrs, (q12 hrs for severe risk)

Tell Your Story...
- Your Team
- Unit (MD’s, Nursing, Others...)
- Medical Leadership
- Administrative Leadership
- Learners

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Respiratory Therapy, Selection, Application and Response

Physician Order for: “Respiratory Therapist to Evaluate and Initiate Care per Protocol”
Impact of a Respiratory Therapy Assess-and-Treat Protocol on Adult Cardiothoracic ICU Readmissions

Retrospective Analysis
- 1400 adult cardiac and thoracic postoperative patients
- January – November 2015 – Control Group, Physician Ordered Respiratory Therapy (730 pts.)
- December 2015 – October 2016 – Experimental Group, Respiratory Therapy Assess & Treat Protocol (RTAT) (670 pts.)

Subject Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Physician Ordered Respiratory Care (Control)</th>
<th>Respiratory Therapy Assess and Treat Protocol (Experiment)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) years</td>
<td>64 (12.6)</td>
<td>68 (14.4)</td>
<td>0.69</td>
</tr>
<tr>
<td>M/F, n (%)</td>
<td>481 (66)</td>
<td>427 (64)</td>
<td>0.40</td>
</tr>
<tr>
<td>ICU LOS, median (IQR)</td>
<td>5.7 (4.6, 7.7)</td>
<td>5.1 (4.7, 6.2)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Hospital LOS, mean (SD)</td>
<td>3.0 (2.6)</td>
<td>2.1 (4.1)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Surgical Procedures, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aorta / Vascular</td>
<td>46 (6)</td>
<td>20 (3)</td>
<td>0.003*</td>
</tr>
<tr>
<td>CABG</td>
<td>219 (30)</td>
<td>131 (19)</td>
<td>0.12</td>
</tr>
<tr>
<td>Esophagectomy</td>
<td>28 (4)</td>
<td>66 (10)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Heart Transplant / VAD</td>
<td>32 (4)</td>
<td>5 (1)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Lung / Chest</td>
<td>39 (5)</td>
<td>84 (13)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Lung Transplant</td>
<td>30 (4)</td>
<td>16 (3)</td>
<td>0.56</td>
</tr>
<tr>
<td>VAD</td>
<td>5 (+1)</td>
<td>2 (+1)</td>
<td>0.35</td>
</tr>
<tr>
<td>Valve</td>
<td>534 (46)</td>
<td>236 (19)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Other</td>
<td>50 (6)</td>
<td>13 (2)</td>
<td>0.95</td>
</tr>
</tbody>
</table>

*P values for Chi-Square or exact likelihood test

All-Cause TCVPO Readmissions

<table>
<thead>
<tr>
<th>Respiratory Care Treatment Group</th>
<th>All-Cause Cardiothoracic ICU Readmission n (%)</th>
<th>No Cardiothoracic ICU Readmission n (%)</th>
<th>Total (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Ordered Respiratory Care (Control)</td>
<td>64 (8.8)</td>
<td>666 (91.2)</td>
<td>730</td>
</tr>
<tr>
<td>Respiratory Therapy Assess and Treat Protocol (Experiment)</td>
<td>39 (5.8)*</td>
<td>631 (94.2)</td>
<td>670</td>
</tr>
<tr>
<td>Total</td>
<td>103</td>
<td>1297</td>
<td>1400</td>
</tr>
</tbody>
</table>

*P (Fisher's exact) = 0.00
### Respiratory Related TCPO Readmissions

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Respiratory Related CVICU Readmission n (%)</th>
<th>CVICU Readmission with no Respiratory Related Component n (%)</th>
<th>Total (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Ordered Respiratory Care (Control Group)</td>
<td>34 (53)</td>
<td>30 (47)</td>
<td>64</td>
</tr>
<tr>
<td>RTAT Protocol (Experiment Group)</td>
<td>14 (36)*</td>
<td>25 (64)</td>
<td>39</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>48</strong></td>
<td><strong>55</strong></td>
<td><strong>103</strong></td>
</tr>
</tbody>
</table>

*P (two-tail) < 0.09

### Esophagectomy Readmissions

- Physician Ordered Respiratory Care
  - RTAT Protocol
  - No ICU Readmissions

### Esophagectomy sub-group compare - Total, Direct, Pharmacy, Respiratory, ICU costs

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Total Cost ($)</th>
<th>Direct Cost ($)</th>
<th>Pharmacy Cost ($)</th>
<th>Respiratory Cost ($)</th>
<th>ICU Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Ordered Respiratory Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
What Next? Refine the Tool, Expand to Surgical/Trauma population

- Physician Order for “Respiratory Therapy to Evaluate and Initiate Care per Protocol” w/...

<table>
<thead>
<tr>
<th>Name of the Lung Inflation Score calculated by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index None (0 pt)</td>
</tr>
</tbody>
</table>

Chest X-Ray

- Clear
- Chronic Changes
- Infiltrates
- Atelectasis

≥ 2

- One lobe
- Lobe

Surgical/Neuro Status

- None
- Abdominal Thoracic Inj,
- Thoracic surgery POD < 3
- Thoracic surgery POD > 4

Activity level

- Non-ambulatory
- Non-ambulatory, not able to self position
- Ambulatory

O₂ Level

- Room Air
- Up to 40% to maintain
- ≥ 40% to maintain

SpO₂

- ≥ 92%
- ≥ 92%

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Respiratory Therapy, Selection, Application and Response

Example - Adult Ventilator Guidelines

- Objective – To provide effective ventilator support in the safest manner possible for each individual patient.
  - Protective Mechanical Ventilation
    - Tidal Volume
    - PEEP
    - Plateau Pressure
    - Driving Pressure
    - Transpulmonary pressure
    - FiO₂

- Improvements - Discontinuation earlier...

- Flexibility in changing or weaning based on patient response
- Education/prehabilitation
- Lung recruitment
- Weaning
- Weaning in the safest manner possible for each individual patient
17 years...

- The amount of time to transition from research evidence to clinical practice...


Mechanical Ventilation

- Two-thirds of patients received lung protective ventilation when ARDS recognized

- Non-lung protective ventilation was not uncommon
  - 35% of ARDS patients received V<sub>T</sub> > 8 mL/kg PBW
  - 83% received PEEP < 12 cmH<sub>2</sub>O
  - P<sub> plateau</sub> measured < 50% time during passive ventilation

JAMA 2016, 315(8):789–800
Steps in Evidence Based Research

1. Asking answerable questions
2. Finding the best evidence
3. Critically appraising the evidence
4. Applying a decision
5. Evaluation


Evidence-Based Medicine framework

Paradigm Shift from Treatment to Prevention of ARDS

Yadav H et al. 2017, AJRCCM
Effect of Ventilation with Smaller $V_t$ in Patients without ARDS at Time of Initiating MV

- **Lung injury** developed in 13% High $V_t$ group vs. 4% Low $V_t$ group
- Absolute risk reduction = 9% (NNT = 11)

**Background**
- Time spent in ED represents a vulnerable period
- Pulmonary complications such as ARDS develop in > 20% of MV ED patients
- 14 hours passed in one study before low $V_t$ was initiated (Allison, JCC 2015, 30:341-343)
- Initial set $V_t$ is influential in setting the course for much of the duration of MV
- Setting $V_t > 1$ mL/kg PBW greater than what is recommended confers harm
- ED could be an important starting point for safe MV

**Primary Objective**
- To evaluate effectiveness of ED based lung protective MV protocol on reducing pulmonary complications.

**Lung injury**

<table>
<thead>
<tr>
<th></th>
<th>Protective</th>
<th>Control</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FeO2</td>
<td>90.0 ± 3.05</td>
<td>87.5 ± 4.30</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>PaO2</td>
<td>94.0 ± 1.10</td>
<td>88.0 ± 2.10</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>HR</td>
<td>110 ± 10</td>
<td>115 ± 15</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>BP</td>
<td>120/80</td>
<td>125/75</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Heart rate</td>
<td>110 ± 10</td>
<td>115 ± 15</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>BMI</td>
<td>25 ± 2</td>
<td>26 ± 3</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

*MV = Mechanical Ventilation*
Methods

- Pragmatic before/after quality improvement study design involving adult patients who had MV initiated in the ED
  - Excluded
    - Fulfillment of ARDS criteria during ED presentation
    - Discontinued from MV within 24 hours of presentation
- Two Groups
  - Preintervention group (n = 1,192)
  - MV LPV Protocol group (n = 513)
- RT initiated MV LPV protocol after intubation in the ED

Results

- ICU lung protective ventilation increased by 48% with RT driven CPG
Results

**Intra-op Protective lung ventilation (Low \( V_t \), PEEP > 5 cm H\(_2\)O, recruitment maneuvers)**

<table>
<thead>
<tr>
<th></th>
<th>Before Intubating</th>
<th>After Intubating</th>
<th>( V_t ) (mL/kg)</th>
<th>PEEP (cm H(_2)O)</th>
<th>Recruitment maneuvers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary endpoint</td>
<td>100%</td>
<td>100%</td>
<td>2.5</td>
<td>6</td>
<td>Yes</td>
</tr>
<tr>
<td>Secondary endpoints</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atelectasis</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Lung Injury</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NNT = 15

Protective mechanical ventilation in the non-injured lung: review and meta-analysis

**Table**

<table>
<thead>
<tr>
<th>Study</th>
<th>Long-term</th>
<th>Short-term</th>
<th>NNT</th>
<th>Cause of death</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>Long-term</td>
<td>60</td>
<td>80</td>
<td>15</td>
<td>0.05</td>
</tr>
<tr>
<td>Study 2</td>
<td>Short-term</td>
<td>40</td>
<td>60</td>
<td>10</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Atelectasis

Lung Infection

Acute Lung Injury NNT = 20 pts.
Department Staff must know how to Critically Appraise the Literature Supporting Guidelines...

- Validity of the study?
- Importance and application of the results?
- Will the results help me in caring for my patients?

Clinical Ladders are a Foundation for Protocols

- Clinical Ladders provide a pathway for continuing advancement within clinical practice.
- Promote individual growth of the professional respiratory therapist according to personal goals and stage of demonstrated respiratory therapy practice.
- Progression is associated with knowledge, skills, and behaviors that represent increasing expertise, responsibility, and maturity.

How about ABCDE? - Factors influencing airway, breathing, delirium, early mobility implementation...

- **Facilitators**
  - The bundle's quality and strength
  - Engagement of key implementation leaders
  - Performance of daily, interdisciplinary, rounds
  - Sustained and diverse educational efforts

- **Barriers**
  - Intervention-related issues (e.g., timing of trials, fear of adverse events)
  - Communication and care coordination challenges
  - Knowledge deficits
  - Workload concerns
  - Documentation burden

What to do...

- Prepare well
- Involve relevant people
- Evidence based
- Feasible & attractive
- Identify the challenges to implement change

- Define measures of performance & success
- Monitor performance
- Metrics, shared with all...
- Relentless, sustained commitment to the indicators...

Systematic Reviews of Interventions to Promote Implementation...What Works?

Consistently Effective

- Reminders
  - Daily, computer
  - Multifaceted
- Audit and Feedback
- Interactive education
- Workshops and practice

No Sustained Effect

- Educational materials alone
- Didactic lectures


Relative Risk of Death in the Hospital across Relevant Subsamples after Multivariate Adjustment — Survival Effect of Ventilation Pressures.

- Multilevel mediation analysis of 3562 pts from 9 trials
  - Initial predicting model: volume limited ventilation
  - Tested and refined from validation cohort of 336 pts from 4 RCT's comparing high vs low Vt values
  - Re-tested from validation cohort of 861 pts from a large RCT of low vs high Vt values
  - ΔP as independent variable associated with survival


Relative Risk of Death in the Hospital versus ΔP in the Combined Cohort after Multivariate Adjustment.

Summary

- Give your Protocols the strength they deserve
- Involve the advocates
- Do your homework - Evidence based
- Measure and monitor performance
- Share your story
- Be Relentless... sustained commitment to improvement