



# DOES A DAILY SPONTANEOUS BREATHING TRIAL GUIDELINE WORK BY ITSELF?

by *Herbert Patrick MD*

The peer-reviewed published research article selected to teach the scientific method in this issue's column is authored by T. Elizabeth Robertson, MD, Henry J. Mann, PharmD, Robert Hyzy, MD, Angela Rogers, MD, Ivor Douglas, MD, Aaron B. Waxman, MD, PhD, Craig Weinert, MD, MPH, Philip Alapat, MD, Kalpalatha K. Guntupalli, MD, Timothy G. Buchman, PhD, MD and the Partnership for Excellence in Critical Care (PECC). The title is: "Multicenter implementation of a consensus-developed, evidence-based, spontaneous breathing trial protocol." This article appeared in the October issue of *Critical Care Medicine* 2008; Volume 36 (Number 10): pages 2753-2762.

The Background or Introduction of the research project explains interest in the topic and why the topic is significant. The authors note that although evidence-based recommendations are part of advancing the science of medicine, few studies have been

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published describing how to successfully implement guidelines. Professional organizations have acknowledged the gaps in implementation of guidelines, especially in different types of hospitals. Associations, known as voluntary peer networks or partnerships, have formed to compile data on implementa-

tion of guidelines. The authors chose to use one of these partnerships based on 18 ICU's to compile the data for this report describing the selection, implementation process, and outcome of adopting a single consensus-developed, evidence-based, best practice for a daily spontaneous breathing trial (SBT).

The authors describe the aims of this research study to: 1) demonstrate the ability of the partnership members to synchronously implement a mutually agreed upon best practice, 2) assess heterogeneity in the implementation of the best practice across sites, and, 3) identify opportunities for further improvement. One of the questions being asked by the researchers was: is the daily SBT guideline sufficient by itself to achieve consistent and timely liberation from ventilator support? Note: The Question asked in a research project may have the possible answers: "yes" and "no" as in this study, or may be a numerical result. The preconceived

answer by the researchers to the Question is called the Hypothesis. The researchers implied that with proper experimental design and data gathering their hypothesis was yes, the SBT guideline is sufficient by itself to achieve consistent and timely liberation from ventilator support.

The Methods for the research project describe the study design, setting and steps to answer the Question. The study was approved by the Institutional Review Board at each of the participating institutions. Informed consent was waived as implementation of the uniform SBT guideline was judged to be a quality improvement project rather than a clinical trial. Each intubated patient was evaluated by both a respiratory therapist and nurse each day. The SBT guideline included three steps: 1) a safety screen to determine the patient's readiness for the SBT, 2) a two minute tolerance screen with CPAP = 5 cmH<sub>2</sub>O on flow-by to determine if the SBT should continue, and 3) a 30-120 minute SBT with PSV = 5 cmH<sub>2</sub>O and PEEP 5 cmH<sub>2</sub>O, unless ETT or trach size < 7.0 ID, then PSV = 8 cmH<sub>2</sub>O. A patient passed the SBT if all three steps were successful. The patient was placed back on full ventilator support if steps two or three failed. Physicians could order additional SBT's each day. Extubation after a successful SBT was not mandated but the researchers' data collection noted whether a patient was a candidate for extubation. Outcome *continued on next page*

measures included percentage of patients passing the SBT, percentage of patients extubated and percentage of patients re-intubated within 48 hours of extubation. Data were collected using Microsoft Access software and statistically analyzed by GraphPad Prism software with significance taken at  $p < 0.05$ .

The Results section compiles the data to answer the Questions. A total of 705 mechanically ventilated patients were studied among the eight institutions. Of 3,486 safety screens, 2,072 ( $2,072/3,486 = 59\%$ ) did not pass. Another 379 patients ( $379/3,486 = 11\%$ ) failed the two minute tolerance screen. There were 1,122 ( $1,122/3,486 = 34\%$ ) patients to begin the 30-120 minute SBT. Note this number of 1,122 patients is smaller than  $2,072 + 379 = 2,451$  because some patients did not continue to the SBT due to stopping after the safety screen or the two minute tolerance screen. The reintubation rate was 5.3%. There was no apparent correlation between the extubation rate and the reintubation rate at each institution, that is, the reintubation rate was not elevated when the extubation rate was elevated.

The Discussion/Reflections/Future Research starts with a summary discussion of the research. In the Discussion, the authors note that when a guideline is monitored by regulatory agencies, it becomes more widespread. However, the implementation by a peer network strengthened support for the project and motivated healthcare provider participation more than evidence-based scientific references. In Reflections, the authors noted that prior studies showed nursing- and respiratory therapy-driven guidelines have previously been shown to be effective and safe. The authors note that implementation of best practices guidelines should include all relevant professions from the design phase onward and physicians must be enthusiastic about granting authority and responsibility to those professionals. The authors reflected on several limitations to their study. First, of 18 members in the PECC, only 8 participated. Second, generalizability to nonacademic institutions is unknown. Future Research describes modifications to the project or new projects that would contribute to this research topic. The authors encourage others to reflect on the data from PECC conduct randomized trials of SBT in their ICUs.

The Conclusion is the final summary of the research project. This project demonstrated that implementation of evidence-based recommendations at the patient level remains a formidable challenge. The presence of a guideline for daily SBT's does not assure, by itself, that implementation would be successful. The answer to the Question was no, and the proposed hypothesis was incorrect.

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Conflicts of Interest are listed for all participating in authorship of the research project. Conflicts include advisory board membership, ownership of stock, and receipt of services, honoraria or gifts from companies related to the research project. The authors disclosed no potential conflicts of interest.

The Bibliography section includes references to support the research as included in the manuscript by reference number. For this research project, there were 38 references.

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