

## Toward Leaner Tracheostomy Care: First Observe, Then Improve

Because of the seriousness of their illnesses and the marginal nature of their physiologic reserves, critically ill patients have a limited ability to tolerate anything less than the highest quality of care. It is no surprise, therefore, that the intensive care unit (ICU) became quickly recognized in the 1960s as an ideal laboratory for studying quality-improvement and systems redesign, long before publication of the Institute of Medicine's reports "To Err is Human"<sup>1</sup> in 2000 and "Crossing the Quality Chasm"<sup>2</sup> in 2001. Critical care providers always knew that their patients required the best of care. Consequently, ICU clinicians became pioneers in scrutinizing their systems of care, adopting the quality-improvement sciences developed in non-health-care industries, standardizing care, and rooting out unexplained practice variation. Some of the first studies that demonstrated the effectiveness of these approaches for improving medical care came from ICUs.<sup>3</sup>

Nowadays, most ICUs engage in some type of formalized process-improvement, either by their own initiative or in response to regulatory and payer mandates. One model for change is the Toyota Production System, wherein waste is identified and removed to promote a lean, efficient, and optimized work flow that ensures high-value outcomes.<sup>4</sup> But other approaches exist that share in common multidisciplinary-team designs that identify quality goals, galvanize team members, observe existing practices, describe ideal practice, shed non-validated preexisting ideas, and begin a process of Plan-Do-Study-Act, to move toward idealized systems of care.<sup>5</sup>

Considering the rich legacy of the ICU in process-improvement and the recent profusion of ventilator-associated pneumonia bundles, weaning protocols, and performance measures, it surprises me that tracheostomy care has largely avoided the flurry of ICU process-improvement efforts. True, major advances have occurred in tracheostomy tube design and from the advent of percutaneous tracheotomy. But fundamental questions still abound: when should tracheotomy be performed, in whom, and how? Answers remain missing because high-quality clinical trials have not addressed these questions. Fortunately, some hope exists that large multicenter prospective randomized controlled trials with rigorous designs may soon provide at least some evidence-based guidance for standardizing tracheostomy placement, as represented by the recently completed Tracheostomy Management in Critical Care ("TracMan") study (<http://www.tracman.org.uk>).

But because of a vast knowledge deficit, unanswered questions will persist regarding ideal approaches to tracheostomy decannulation; we don't even know how we are weaning patients now. Critical care trainees know that recommendations they receive for tracheostomy decannulation depend on who they ask. Otolaryngologists differ in their responses from trauma surgeons, who differ from pulmonary intensivists. Even among pulmonary intensivists I have noted little consensus about decannulation practices. When summarizing for a clinical review the evidence for decannulating a tracheostomy tube, I found a great deal of expert opinion but little empirical data for deriving standardized processes of care.<sup>6</sup>

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To improve this state of affairs, editorialists at this point usually call for more research, perhaps multicenter randomized trials, to establish an evidence base to develop clinical guidelines for directing tracheostomy decannulation. But I believe focused quality-improvement efforts promise a more efficient and valid opportunity for improving tracheostomy care than waiting for clinical trials that will most likely never be funded. This pragmatic approach first requires the Toyota Production System tactics of observation to learn our present decannulation practices. And this is the value of the study by Stelfox and colleagues published in this edition of *RESPIRATORY CARE*.<sup>7</sup> These investigators recognized our paucity of knowledge about how different clinicians make decisions for decannulating tracheostomy tubes. They conducted and previously published<sup>8</sup> a survey of ICU physicians and respiratory therapists (RTs), which established 5 patient factors clinicians use to determine decannulation readiness: oxygenation, level of consciousness, ability to tolerate tracheostomy tube capping, cough effectiveness, and secretions.

Because ICU care is team-based, however, the investigators asked the natural next question: do members of the team differ in how they make decannulation decisions? Because the previous survey data were coded by provider type, Stelfox and colleagues could compare, as reported in the present study, responses by RTs with those of ICU physicians, who were trained in intensive care medicine, pulmonary medicine, surgery, or anesthesiology.

The findings were interesting and somewhat encouraging. When presented with written patient scenarios, RTs and physicians tended to agree on the selection of patients for decannulation. Despite their differences in training and experience, the 2 practitioner disciplines making most of the decannulation decisions in the ICU—physicians and RTs—share a common foundation of knowledge for decision making. This observation seems encouraging for the future development of consensus-based decannulation standards of care. It was also interesting that clinicians largely agreed in their ranking of the importance of various patient factors for determining readiness to decannulate. Although the investigators correctly identified some differences (RTs valued higher the importance of patient ability to tolerate tube capping and valued lower the level of patient consciousness, as compared with physicians) the fact remains that broad concordance existed.

This level of agreement between physicians and RTs may demonstrate shared practice patterns gained through working together over many years. But it doesn't follow that agreement necessarily identifies best clinical practices. Maybe they agree, but they might be agreeing on misguided processes of care. But the study's findings in my view more likely support an accumulated experiential wisdom that guides decannulation decisions using the patient-related factors reported by the surveyed clinicians. I have this impression because respondents proposed a low failure rate for decannulation of 2–5%, which is similar to observed failure rates reported in the literature.<sup>9</sup> Had they demonstrated shared agreement with incorrect practices, I suspect these clinicians would have proposed a higher failure rate to match their real-life experiences generated by faulty practices.

If the study by Stelfox and associates demonstrates shared wisdom, we have taken the first step in making decannulation leaner and safer by observing what we presently do in the ICU. It now becomes important to make more observations to address more nuanced questions. How do we decannulate in special circumstances and for patients with various cardiopulmonary conditions? Although decannulation has a low failure rate, can we accelerate weaning and keep it similarly safe? How lean can we become?

Do we need randomized controlled trials to answer these questions? I don't think so. Quality-improvement efforts in health care often entail nonlinear, multi-component interventions in a complex social setting with a high dependence on interpersonal interactions within teams.<sup>10</sup> Controlled trials serve best in evaluating linear, tightly coupled, causal intervention-effect relationships, as represented by drug studies. Defining best clinical practices for tracheostomy care represents a highly complex and nonlinear challenge. If we follow our ICU performance-improvement paradigms, it is time for ICU clinicians to take the observational findings from the Stelfox et al study and start

developing algorithms and protocols for decannulation care and integrating them into coordinated team-based programs. Urgency for this approach exists because of the growing population of critically ill patients and their increasingly rapid transit from ICU to wards before tracheostomy decannulation occurs. Few ICU physicians follow their patients to provide tracheostomy care after ward transfer.<sup>11</sup> Moreover, ward nurses often have inadequate familiarity with tracheostomy care.<sup>12,13</sup> And, despite the absence of data, I am certain hospitalists cannot fill this void. Tracheostomy expertise must follow patients wherever they go in the hospital.

Previous studies demonstrated more rapid decannulation and improved outcomes when trained multidisciplinary teams with access to physician specialists and standardized protocols promoted adherence to bundled tracheostomy care.<sup>14–17</sup> Unfortunately, most institutions have not formed such teams,<sup>18</sup> but others have developed mature programs with RTs, physicians, speech therapists, nurses, and physiotherapists, and offer start-up resources for other institutions (eg, <http://www.tracheostomyteam.org>). I am confident that “tracheostomy teams” that monitor their experiences, initiate quality cycles, and share their outcomes and processes of care, would outpace any conceivable randomized controlled trial of tracheostomy decannulation. After all, Stelfox and colleagues observed that a great degree of consensus for best practices already exists. We appear to know what to do; now we need to do it effectively, efficiently, and in a timely manner. We can later create even leaner processes of care and incrementally refine our shared wisdom of best practices after we rotate through a few quality-improvement cycles. For tracheostomy decannulation care we have made our observations, and it is now time to Plan-Do-Study-Act.

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