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A monthly update of developments in critical care and intensive care medicine

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INSIDE

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Effects of Eliminating Daily Chest X-Rays in the ICU

ABSTRACT & COMMENTARY

By Saadia R. Akhtar, MD, MSc

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Dr. Akhtar reports no financial relationship to this field of study.

Synopsis: *This single center prospective observational study finds that the utility of a routine daily chest x-ray (CXR) for an ICU patient is quite limited. A change in practice to ordering CXR only when clinically indicated did not adversely impact patient outcome but reduced CXR volume and overall costs.*

Source: Hendrikse KA, et al. Low Value of Routine Chest Radiographs in a Mixed Medical-Surgical ICU. *Chest.* 2007;132: 823-828.

A PROSPECTIVE OBSERVATIONAL STUDY WAS CONDUCTED TO assess diagnostic and therapeutic efficacies of a daily routine CXR and to evaluate the impact of discontinuing this practice. The setting was a 10-bed mixed medical-surgical ICU of a non-academic teaching hospital in The Netherlands. A daily CXR was obtained on every ICU patient every day for 1 year. These CXRs were read independently by radiologists; images and reports were not available to the patient's attending physicians unless there was a new potentially life-threatening finding (eg, tension pneumothorax).

If the attending physician requested a CXR for a specific clinical indication close to the time the daily study CXR was obtained, this CXR was released for view; if the clinical indication arose at a different time, a new CXR was performed and made available to the physician. The authors documented data on specific new or progressive radiological findings (eg, malpositioning of hardware, infiltrates, pneumothorax, etc) and patient management decisions (adjustment of hardware, change in medications or ventilator settings, etc.) that were defined *a priori*. Finally, after a 1-year study period, routine daily CXRs were discontinued and both clinician practice and outcomes were observed for another 6 months. Cost estimates were determined *a priori* for each CXR, and standard statistical methods were employed.

There were 559 admissions in 486 patients during the 1-year study period, accounting for a total of 1780 daily routine CXRs; 907 additional clinically indicated CXRs were performed. Only 4.4% (79) of the daily routine CXRs, vs 15.2% (138) of the clinically indicated CXRs, revealed new or progressive radiological findings. This was independent of intubation status or admission type (medical vs surgical). Similarly, only 1.9% (33) of the daily routine CXRs, but 17.9% (162) of the clinically indicated CXRs, led to a change in patient management.

During the follow-up 6 month phase, 433 clinically indicated CXRs were performed during 274 admissions for 250 patients. That is, the total number of CXRs per patient per day decreased by about 50%. There was an associated cost reduction of $99,000 per year. There was no change in ICU length of stay, readmission rate, or hospital mortality noted, although the study was not designed or powered to truly detect differences in cost, ICU length of stay, readmission or mortality.

COMMENTARY

The ordering of a routine daily CXR for every ICU patient remains a common practice, despite prior work suggesting this may not be necessary.[1,2] The authors of the present article reasoned that because previous studies had been somewhat limited in terms of size, setting (most had been conducted at academic centers) or lack of blinding of attending physicians to the findings of daily CXRs, further research was indicated. Their prospective observational study is large, set in a non-academic center, and does blind attending physicians to the findings on daily CXRs. The latter is the greatest strength of this work: it allows the authors to demonstrate more clearly and robustly that clinical course and management are not often altered by knowledge of results of daily routine CXRs.

As might have been expected, the findings on clinically-indicated CXRs were much more likely to impact the course of care. Furthermore, between the 1-year study period and the 6-month follow-up phase, the number of clinically-indicated CXRs requested did not change, suggesting that the attending physicians' medical practice, standards and decision-making process were largely unaffected by the presence or absence of daily routine CXRs.

The authors address the limitations of their work thoroughly. The ideal would be a similar study but conducted at multiple centers with a randomized, controlled design and powered to detect differences in clinical outcomes (length of stay, readmission, specific morbidities such as complications of a missed pneumothorax or delay in treatment of pneumonia, and mortality). However, taken together with the current body of literature on the limited utility or lack of utility of routine daily CXRs, Hendrikse et al's work reinforces the need to break this old habit.

A recently released study of accepted indications for CXRs in ICU patients surveyed 82 French intensivists and found that over 50% of them did not feel a daily routine CXR was needed in an intubated patient.[3] I wonder what a similar survey in the U.S. would reveal about our beliefs and our practice. ■

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Special Feature

The Role of Weaning Parameters in 2008

By David J. Pierson, MD, Editor

What is Weaning?

Most critically ill patients require mechanical ventilation, and, according to one large survey, the weaning process occupies about 40% of the time that patients spend connected to the ventilator.[1] Yet how "weaning" is defined varies a great deal. In the strictest sense weaning should refer to the gradual withdrawal of positive-pressure ventilation and its replacement by the patient's own spontaneous breathing. Most of us broaden this to mean the process of discontinuing ventilatory support, irrespective of its pace or difficulty. However, by "weaning" many clinicians actually mean "extubation," lumping together two processes—liberation from mechanical ventilation and removal of the artificial airway. This imprecision muddies the water for both conceptual understanding and bedside application, and the resulting confusion extends throughout the literature on weaning.[2]

When the subject of ventilator weaning was last discussed in one of these essays 6 years ago,[3] new international evidence-based weaning guidelines had just been released by a combined task force of the American College of Chest Physicians, the Society of Critical Care Medicine, and the American Association for Respiratory Care.[4] These landmark guidelines triggered a paradigm shift with respect to discontinuation of mechanical ventilation, from "predicting" (that is, deciding on the basis of clinical and physiological indices when weaning should commence) to "checking" (that is, finding out by means of an empirical trial of spontaneous breathing whether the patient was ready to be liberated from ventilatory support). Although publication of new studies, analyses, and guidelines has continued apace,[5] nothing has appeared since publication of the ACCP-SCCM-AARC guidelines to overturn or substantially change this new 21st-century approach to weaning.

The shift from predicting when a patient was ready for a trial of weaning—using various measures and indices collectively referred to as weaning parameters—to an empirical trial of spontaneous breathing to find out whether he or she is ready, has meant that weaning parameters are no longer used routinely in many ICUs. Are weaning parameters still useful? This essay examines the present status of these measurements, including how they may be integrated into the current evidence-based weaning process, and what their findings mean clinically when a spontaneous breathing trial (SBT) is unsuccessful.

What Are The Important Weaning Parameters And What Do Their Results Mean?

The most comprehensive review of weaning parameters I have seen is one by Epstein in the *Respiratory Care Clinics of North America*, published in 2000.[6] In it, the author describes some 50 different assessments that have been studied in the prediction of successful weaning. Included are measures of oxygenation and gas exchange, measures of capacity and load both simple and complex, various integrative indices (some of them fairly complicated, requiring special apparatus), and clinical factors such as mental status and cough effectiveness. Although some centers have adopted specialized measurements such as the airway occlusion pressure ($P_{0.1}$) in routine management, the weaning parameters used most widely are those initially introduced by Sahn and Lakshminarayan[7] and by Yang and Tobin.[8]

Sahn and Lakshminarayan[7] performed simple bedside measurements on 100 consecutive patients whose managing physicians were about to discontinue ventilatory support, and found that the presence of all 4 of the following findings predicted successful weaning in every instance:

- Vital capacity (VC) at least 10 mL/kg
- Maximal inspiratory pressure (MIP) at least -30 cm H_2O
- Resting minute ventilation requirement 10 L/min or less
- Ability to double this resting minute ventilation during a 15-sec period of voluntary hyperpnea

The first 3 of these threshold values are generally used, while the last (which requires extra effort and a cooperative patient) is less often applied today. To these routine measurements was added the rapid shallow breathing index (RSBI), reported by Yang and Tobin,[8] which is the spontaneous respiratory rate divided by the average spontaneous tidal volume (f/VT) assessed during a short period of spontaneous unassisted breathing. For example, in a patient with spontaneous respiratory rate 24 breaths/min and average tidal volume of 400 mL (0.4 L), the RSBI would be 24 divided by 0.4, or 60. Compared with numerous other measurements and

combinations of measurements, these investigators found that an RSBI >105 was the best predictor of a failed weaning attempt. Over the last 15 years, the RSBI has become probably the most commonly used weaning parameter.

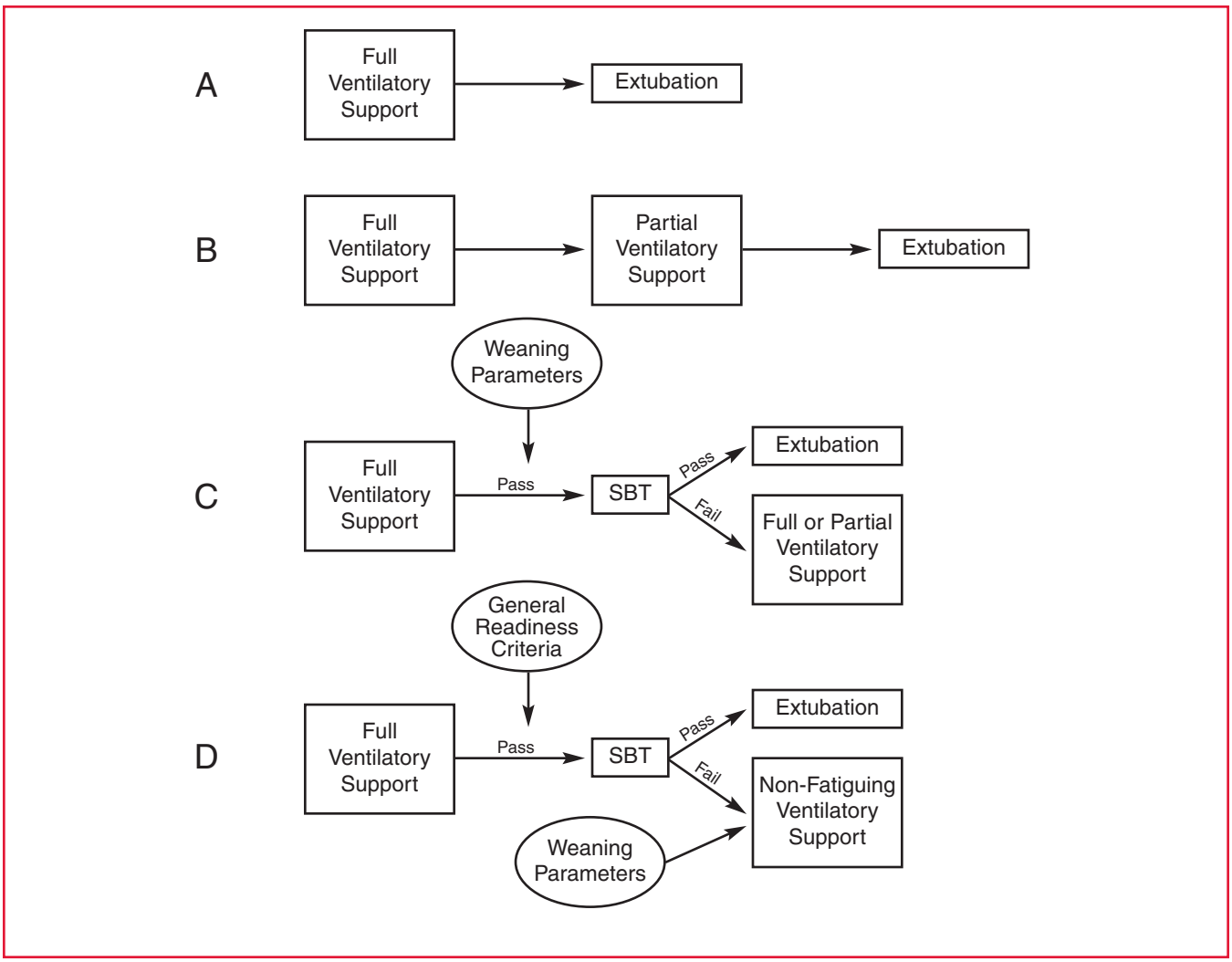
Weaning in the Era of Evidence-based Medicine

Although there have been hundreds of studies examining the efficacy of different weaning parameters in predicting when patients are ready for discontinuation of ventilatory support, no individual measurement or combination of measurements will detect all patients who could safely be weaned.[9] This is illustrated by two large, multicenter weaning trials published in the mid-1990s.[10,11] Each of these studies examined the relative efficacy of T-piece trials, pressure support, and intermittent mandatory ventilation as weaning strategies in patients considered difficult to wean by the clinicians managing them. Both studies required a 2-hour SBT for all patients during the screening phase to assure that they still needed ventilatory support—and in each case nearly three-fourths of all screened patients were found ineligible for study entry because they could simply be extubated after the SBT. This illustrates the fact that clinicians are often unable to tell whether a patient is ready for weaning and extubation, despite their experience and the results of various weaning parameters.

The imperfect performance of existing weaning parameters, and the problems identified with the published studies on the prediction of successful weaning, led the ACCP-SCCM-AARC consensus group[4] to conclude that performing an SBT was the only reliable way to determine whether a given patient was ready to come off the ventilator, in order to avoid unnecessary prolongation of mechanical ventilation. According to current guidelines, an SBT should be performed in any patient who meets the following 5 general readiness criteria:

- Evidence for some reversal of the underlying cause for acute respiratory failure
- Adequate arterial oxygenation (for example,

Figure 1: Evolution of Approach to Ventilator Weaning over the last 40 years. For explanation, see text. SBT, spontaneous breathing trial.



arterial PO_2 at least 60 mm Hg on 40% oxygen with positive end-expiratory pressure 5 cm H_2O or less)
- Acceptable acid-base balance (for example, arterial pH 7.25 or higher)
- Hemodynamic stability (absence of active myocardial ischemia, and blood pressure supportable without requirement for significant vasopressor support)
- Sufficient ventilatory drive and neuromuscular function to initiate an inspiratory effort

The evolution of the approach to weaning over the last 4 decades is illustrated schematically in Figure 1. Prior to 1970 clinical judgment was the main gauge of when a patient was ready to be removed from the ventilator and extubated (Figure 1A). Simultaneous with the emergence of weaning parameters in the mid-1970s was an approach, advocated by some, of progressively decreasing the proportion of the patient's overall work of breathing that was provided by the ventilator, reasoning that this transition would be facilitated by the return of spontaneous ventilatory capacity and would result in the earliest possible liberation from mechanical ventilation (Figure 1B). Using this approach, partial ventilatory support was provided initially by intermittent mandatory ventilation, and then beginning in the mid-1980s by pressure support.

Most commonly, however, as depicted in Figure 1C, patients were managed with full ventilatory support, usually via volume-targeted assist-control ventilation, with measurement of weaning parameters to screen for readiness for weaning. At many institutions, the performance of a fixed set of weaning parameters (in my department consisting of VC, MIP, VE, and RSBI) each morning on every ventilated patient comprised a substantial proportion of each ICU respiratory therapist's duties. The physicians managing the patient then decided whether to attempt weaning based on these weaning parameters. This attempt took the form of an SBT, with success or failure judged on clinical assessment (respiratory rate, heart rate, evident ventilatory effort, and general appearance) plus the findings on arterial blood gas analysis after 30 minutes. Patients who "passed" the SBT were extubated if there were no other contraindications, and those who "failed" were returned to full ventilatory support, and the whole process was repeated the next morning.

Today, based on the systematic review of available studies[5,9] and the lessons of the Brochard[10] and Esteban[11] studies about the accuracy of our ability to judge when someone is ready for weaning, the current approach (Figure 1D) dispenses with weaning parameters in making the initial decision to perform an SBT. Instead, the 5 general readiness criteria listed above are used. Patients who fail the SBT are returned to full ventilatory support—or at least to ventilator settings that eliminate evidence of air-hunger or ongoing work of breathing—and reassessed daily so long as the 5 conditions are met.[4] It is at this point that weaning parameters can be helpful—not in the decision to commence weaning but instead to sort out the reason(s) for failure (see Table 1).

Table 1: Clinical Implications of Inadequate Weaning Parameters in Patients Who Are Unable to Pass a Spontaneous Breathing Trial

- Low rapid shallow breathing index (eg, f/VT <40): inadequate ventilatory drive
- High rapid shallow breathing index (f/VT105): inability to meet work of breathing requirement to sustain current demand for minute ventilation
- Low vital capacity (<10 mL/kg) and/or maximum inspiratory pressure (<20-30 cm H_2O): respiratory muscle weakness
- High minute ventilation (>10-12 L/min):
  - -Hyperventilation ($PaCO_2$ <36 mm Hg)
  - -Hypermetabolism (CO_2 production substantially greater than 200-225 mL/min for average-sized patient)
  - -Excessive dead space ventilation (VD/VT >0.60-0.65)

A patient who makes no inspiratory effort when ventilatory support is interrupted, or generates an inadequate minute ventilation in the absence of tachypnea, can be assumed to have insufficient ventilatory drive as at least part of the problem. Most often this is due to narcotics and other drugs. When patients breathe rapidly and shallowly on removal or reduction of ventilatory support, or when they cannot generate more than half or three-fourths of the required minute ventilation, the necessary work of breathing exceeds their capabilities. This might be because of excessive work imposed by the breathing circuit (common with pre-1990s ICU ventilator models but less so today if they are set up and adjusted properly), a too-high minute ventilation requirement, airway obstruction, or ventilatory muscle weakness. The last is common, particularly after prolonged critical illness, and is further suggested by a low vital capacity and/or maximum inspiratory pressure.

When a high minute ventilation requirement is present (eg, exceeding 12-14 L/min for a normal $PaCO_2$) in a patient who fails an SBT, one or both of two basic physiologic processes may be present. Either CO_2 production is excessive (which indicates a systemic, metabolic problem, rather than a pulmonary problem), and/or there is excessive wasted ventilation (high dead

space, which suggests a pulmonary cause for the high minute ventilation requirement). Bedside assessment using an arterial blood specimen and a metabolic cart or other monitoring system can have practical value in sorting out these two mechanisms.

Measuring Weaning Parameterscine

Soo Hoo and Park[12] surveyed 102 respiratory therapists in 9 Los Angeles-area hospitals and found that there was great variation not only in which weaning parameters were used but also in the techniques used to measure them. For tests of spontaneous breathing, a few disconnected the patient from the ventilator—as done in both the classic studies mentioned[7,8]—but the great majority left the circuit intact, changed the ventilator settings, and simply took the readings off the ventilator's digital display. Various settings of CPAP and pressure support were used during the test of spontaneous breathing—from zero to 10 cm H_2O for each, in essentially every possible combination. In addition, there was great variation in the time the therapist waited before recording the weaning parameters—from within the first minute to >15 minutes.

The point here is that most of the time weaning parameters are no longer measured as intended (and studied) by their original proponents. Whatever methodological problems may exist in the published studies, it is by no means clear that any reported predictive value for the various weaning parameters carries over using these variations in technique. For example, in both classic studies,[7,8] respiratory rate and minute ventilation were directly measured over a full minute by the investigators, and the average tidal volume was calculated. The ventilator's digital readout of minute ventilation reflects a running estimate determined from rate and tidal volume over several breaths or some fixed (short) time interval, which varies and may or may not reflect what would be measured over a full minute.

In addition, a patient's spontaneous breathing pattern when ventilator breaths suddenly stop may take at least a couple of minutes to stabilize. The values for rate, tidal volume, and minute ventilation taken from the ventilator's digital readout during the first 30-60 seconds of spontaneous breathing may not reflect the patient's subsequent, stable breathing pattern. While minimizing circuit interruptions is important for infection control and other reasons, the clinician should wait a minimum of two minutes before determining rate, tidal volume, and minute ventilation in order to most accurately predict the patient's capabilities for purposes of weaning.

Weaning vs Extubation: A Word of Caution

Management of a patient with acute respiratory failure must deal satisfactorily with 4 separate processes:

- Oxygenation
- Ventilation
- Airway Protection
- Secretion Clearance

An SBT assesses only the first two of these processes. That is, a patient who passes an SBT is able to breathe without assistance and attain satisfactory oxygenation of the blood. However, although most patients who have recovered to this extent can also maintain an open upper airway and adequately clear respiratory secretions, there are some who cannot, and extubating such patients is likely to fail.

Coplin et al[13] studied brain-injured patients who met accepted criteria for weaning but who remained unconscious. The investigators noted 6 factors related to the need for airway care, in an attempt to derive a set of "extubation parameters" unrelated to the ability to maintain adequate oxygenation and ventilation. The 6 factors were the quantity, viscosity, and appearance of the suctioned secretions, the presence of a gag reflex, whether the patient coughed spontaneously without stimulation, and the frequency of airway suctioning. Of these, only the last 2 (absence of spontaneous cough, and requirement for suctioning at least every 2-3 hours) were statistically correlated with the need for re-intubation once the patients had been extubated. In a more recent study by Mokhlesi and colleagues,[14] of several factors examined, the only predictors of the need for reintubation among patients extubated following a successful SBT were moderate to copious secretions, a Glasgow Coma Scale score of 10 points or less, and an arterial PCO_2 >44 during the SBT.

Thus, although we still do not have very good ways to predict whether a patient can maintain a patent airway and adequately clear respiratory secretions after extubation, separate consideration beyond the results of an SBT should be given to this aspect of the process of liberation from ventilatory support. ■

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Arterial Line Insertions in the ICU: To Gown or Not To Gown?

ABSTRACT & COMMENTARY

By Andrew M. Luks, MD

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Dr. Luks reports no financial relationship to this field of study.

Synopsis: *Although the incidence of catheter-related bloodstream infections from arterial catheters is low, arterial catheters have similar colonization rates and catheter-related bloodstream infections as concurrently sited and identically managed central venous catheters.*

Source: Koh DBC, et al. *Crit Care Med.* 2008 [epub ahead of print] PMID: 18091549

Most of the attention on catheter-related bloodstream infections (CR-BSI) in the ICU focuses on central venous catheters (CVC), a bias that likely derives, in part, from the 2002 Centers for Disease Control guidelines which stipulate that arterial catheters (AC) have "low infection rates—rarely associated with bloodstream infections."[1] Koh and colleagues conducted a single-center, prospective cohort study to determine whether this approach is valid or whether more attention should be focused on the infective potential of ACs.

Over a 24-month period, the authors examined all ACs and CVCs inserted in ICU patients by attending and resident-level physicians using full barrier precautions (except in rare cases of extreme patient instability) and chlorhexidine skin preparation. Catheters were inserted in the ICU, operating room or emergency room and the authors excluded any catheters inserted at an outside hospital. Multiple AC brands were used and all sites were covered with a transparent sterile dressing and accessed only by ICU nursing staff. No antibiotic-coated or tunneled CVCs were included in the study. At the time of catheter removal (typically on discharge from the ICU to the wards), the distal 3 to 5 cm of the catheter was collected and sent for semi-quantitative culture. Results of patient blood cultures were also tracked during the study period. The authors defined catheter colonization as > 15 colony forming units on the catheter tip culture and CR-BSI as > 15 colony forming units plus a positive blood culture within 48 hours of catheter removal with the same microorganism and antibiotic sensitivity.

During the study period, 321 ACs were sited for an average of 3.4 + 3.5 days and observed for a total of 1082 catheter days, while 618 CVCs were sited for an average of 6.5 + 4.9 days and observed for 4040 catheter days. 5.3% of ACs and 11% o CVC were colonized with bacteria. The colonization and CR-BSI rates per 1,000 catheter days were 15.71 (95% CI 9.5-25.9) and 0.92 (95% CI 0.13 - 6.44), respectively for ACs and 16.83 (95% CI 13.3 - 21.3) and 2.23 (95% CI 1.12 - 4.44), respectively for CVCs. There was one instance of CR-BSI due to an AC and there were no statistically significant differences in colonization rates between ACs and CVCs. AC Colonization rates were higher when the catheters were inserted in the operating and emergency rooms, while there was a non-statistically significant trend toward higher AC colonization rates when catheters were inserted by residents rather than attending-level physicians and when catheters were inserted in the femoral sites. The majority (79%) of colonization events were due to coagulase-negative staphylococci while *Staphylococcus aureus*, *Corynebacterium* species and enterococcus accounted for the remainder of cases.

COMMENTARY

While full barrier precautions have become the standard of care and a standard practice for CVC insertions at our institution, it is not an infrequent occurrence to see resident or attending physicians inserting arterial catheters without being fully gowned or applying an appropriate sterile field to their work site. The patient's arm is sometimes positioned poorly on the edge of the bed with crumpled linen, wires, and the patient gown in close proximity to the insertion site. When asked why they used this approach on a particular patient, the majority of physicians typically respond with a comment that closely resembles that from the 2002 Centers for Disease Control guidelines regarding the low incidence of arterial catheter related infections. The data from Koh and colleagues should lead to reevaluation of such practices, particularly when one considers that this is not the first study to demonstrate similar rates of AC and CVC colonization in the ICU.[2] What is particularly noteworthy is that the ACs had a high rate of colonization equal to that of CVCs even though full barrier precautions were employed during their insertion. This would lead one to suspect that the colonization rates and perhaps even the CR-BSI rates, might, in fact, be higher when

poor sterile techniques are used with AC insertion.

It should be noted that full barrier precautions have not been shown to decrease the incidence of AC-related blood stream infections[3] and, as noted earlier, the increased colonization rates have not been associated with an increased rate of bloodstream infections. However, in an era when Medicare and other insurance providers will be cutting or eliminating reimbursement for preventable complications, such as catheter-related urinary tract infections, it is worth considering whether we need to improve the sterility of our arterial line insertion practices, particularly in patients we anticipate will require their catheters for long duration ICU stays. ■

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CME / CNE Questions

61. In Hendrikse et al's study of eliminating daily chest X-rays in an ICU:

a. attending physicians were never allowed to order CXRs
b. radiologists were permitted to notify attending physicians of a potentially life-threatening finding on a CXR
c. attending physicians had access to all CXR images but not to the radiologists' reports
d. patients were randomized to a daily routine CXR vs clinically-indicated CXRs
e. none of the above

62. Which of the following is true regarding the infective potential of arterial catheters?

a. full barrier precautions decrease the rate of catheter colonization
b. the rate of catheter colonization is similar to that for central venous catheters
c. antibiotic-coated arterial catheters decrease the risk of catheter colonization
d. arterial catheter-related blood stream infections are more common than central venous catheter-related blood stream infections.
e. The majority of catheter-related blood stream infections from arterial catheters are due to enterococcus.

63. Which of the following is most likely to be associated with the need for re-intubation after extubation following a successful spontaneous breathing trial?

a. need for airway suctioning every 2 hours prior to extubation
b. vital capacity 8 mL/kg
c. absence of a gag reflex
d. rapid shallow breathing index 105
e. minute ventilation 12 L/min

64. Which of the following is most predictive of successful liberation from mechanical ventilation?

a. a maximum inspiratory pressure of -30 cm H_2O
b. rapid shallow breathing index 80
c. vital capacity 12 mL/kg
d. minute ventilation requirement for normal blood gases, 10 L/min
e. acceptable vital signs and blood gases after spontaneous breathing for 30 minutes

Answers: 61 (b); 62 (b); 63 (a); 64 (e)

CME / CE Objectives

After reading each issue of *Critical Care Alert*, readers will be able to do the following:

- Identify the particular clinical, legal, or scientific issues related to critical care.
- Describe how those issues affect nurses, health care workers, hospitals, or the health care industry in general.
- Cite solutions to the problems associated with those issues.

In Future Issues: **Intensive Insulin and Colloids in Severe Sepsis**

Supplement to *Critical Care Alert*
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CRITICAL CARE ALERT™

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PHARMACOLOGY WATCH

Supplement to Clinical Cardiology Alert, Clinical Oncology Alert, Critical Care Alert, Infectious Disease Alert, Internal Medicine Alert, Neurology Alert, OB/GYN Clinical Alert, Primary Care Reports, Travel Medicine Advisor.

FDA Heightens Warnings on Chantix

In this issue: *Stop smoking drug Chantix rates stronger warning from FDA; Type 2 diabetes surgery on the way?; Vytorin study inconclusive; Influenza A virus found resistant to Tamiflu; FDA actions.*

The FDA has strengthened its warning on the stop smoking drug varenicline (Chantix). Last November the agency issued an Early Communication regarding reports of changes in behavior, agitation, depressed mood, suicidal ideation, and suicidal behavior in patients taking the drug. After review of recent reports, the agency now says that it appears increasingly likely that there may be an association between varenicline and neuropsychiatric symptoms. The FDA has asked Pfizer, the manufacturer of the drug, to elevate the prominence of these warnings on the package label, and the company along with the FDA is working on a Medication Guide for patients. The FDA is recommending that patients should tell their health-care providers about any history of psychiatric illness prior to starting varenicline. There is evidence that the drug may cause worsening of current psychiatric illness, and cause old psychiatric illness to reoccur. Moreover health-care professionals, patients, patients' families, and caregivers should be alert to monitor for changes in mood and behavior in patients treated with varenicline. The FDA warning also states that vivid, unusual, or strange dreams may occur while taking the drug and that patients may experience impairment of the ability to drive or operate heavy machinery. Varenicline was approved in May 2006 under the trade name Chantix by Pfizer Pharmaceuticals to ease withdrawal symptoms associated with smoking cessation.

Weight-loss Surgery Answer for Type 2 Diabetics?

Could surgery be the answer for type 2 diabetes? In a new study from Australia, 60 patients with type 2 diabetes and a BMI of 30-40 were randomized to adjustable gastric banding surgery or conventional therapy. Conventional therapy focused on weight loss by lifestyle changes. The main outcome measure was remission of type 2 diabetes and secondary measures included weight and components of the metabolic syndrome. Remission of type 2 diabetes was achieved by 22 patients in the surgical group (73%) vs 4 patients in the conventional therapy group (13%). Relative risk for remission in the surgical group was 5.5 (95% CI, 2.2-14.0). Surgical patients lost more weight, mean (SD) 20.7% (8.6%) vs 1.7% (5.2%) for the nonsurgical group at two years (P <.001). There were no serious complications in either group. The average weight loss to achieve remission of type 2 diabetes was 10%, which was achieved in 86% of the surgical patients and only 1% of the medical therapy patients. The authors conclude that for patients with type 2 diabetes, surgical therapy was more likely to achieve remission through greater weight loss. These results should be confirmed through larger, more diverse population and have long-term efficacy assessed (*JAMA* 2008;299:316-323). An accompanying editorial suggests that gastrointestinal tract surgery may offer a new goal in diabetes management—remission rather than just treatment. The editorialists also suggest that the cost and risks of such surgery must be balanced

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with the costs and risks of long-term diabetes management (*JAMA* 2008; 299:341-343).

Vytorin Needs More Study

Vytorin has been in the news recently after Merck/Schering-Plough released the preliminary results of the Effect of Combined Ezetimibe and High-Dose Simvastatin vs Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia (ENHANCE) study. Vytorin is a combination of the statin simvastatin (Zocor) and ezetimibe (Zetia), a medication that blocks cholesterol absorption through the gut. The combination drug is better at lowering LDL than either drug alone, and it was hoped that this would translate to improved cardiovascular outcomes. ENHANCE randomized 720 patients with heterozygous familial hypercholesterolemia to treatment with either simvastatin 80 mg daily or Vytorin (simvastatin 80 mg plus ezetimibe 10 mg). Mean LDL cholesterol levels at baseline were 320 mg/dl. Simvastatin alone lowered LDL by 41% while Vytorin lowered LDL by 58%. The primary endpoint was change in mean carotid intima media thickness after two years of treatment. There was no difference in this primary endpoint or in the incidence of any adverse effects between the two treatment arms. ENHANCE was widely reported as a failure for Vytorin, and there were even reports that Vytorin increased the rate of plaque production, which was not the case. The study has been criticized because of its small size, atypical patient population, and primary outcome (carotid intimal media thickness) which is not a clinical outcome. The American College of Cardiology issued a statement on January 15 suggesting that "major clinical decisions not be made on the basis of the ENHANCE study alone." The FDA issued a statement on January 25 stating that it will conduct a review of Merck and Schering-Plough's trial once the final results of the study are available. Data from the ENHANCE study is due to be presented at the American College of Cardiology meeting in March.

Virus Resistant to Tamiflu Causing Concern

A small percentage of the influenza A virus causing illness worldwide this winter is resistant to oseltamivir (Tamiflu), according to the World Health Organization. Tamiflu-resistant forms have been found in European countries, Canada, and the US. Generally mutations of this sort attenuate the virus, making it less infectious; however this is not found be the case with the resistant strain of A/N1H1 known as A(H1N1 H274Y). The highest rate of resistance was found in Norway with 75% of isolated viruses showing resistance. The rate of resistance in the US was 3.8%. There are currently no plans to change recommendations for use of Tamiflu; however, WHO officials are "troubled by the discovery" according to the *New York Times*.

Choice of Antivirals for Flu

In other flu-related news, the CDC reports that primary care physicians frequently used inappropriate flu drugs during last year's flu season. A survey published in *MMWR* found that of 730 respondents, 54% prescribed anti-viral agents and of those, one quarter prescribed amantadine or rimantadine. These drugs are no longer recommended because of a high rate of viral resistance (MMWR 1/25/08:57(03); 61-65). Finally, the FDA has approved a real-time test for influenza A and B and RSV. The test, called ProFlu+ Assay produces results within about three hours, and has a 98% sensitivity, and 83% specificity. The assay is marketed by Prodesse Inc.

FDA Actions:

The FDA has strengthened its warning on the contraceptive patch Ortho Evra regarding the risk of venous thromboembolism. The warning is based on a study conducted by the Boston Collaborative Drug Surveillance Program that showed that the patch was associated with a higher risk of venous thromboembolism than oral contraceptive pills.

The FDA has taken the strongest stance yet against the use of over-the-counter cough and cold products for children younger than two years of age. On January 17 the agency issued a Public Health Advisory for parents and caregivers recommending that the products should not be used to treat infants and children because of reports of serious adverse events including death, convulsions, rapid heart rates, and decreased levels of consciousness. The agency continues to review use of these medications on children aged two to 11.

The FDA has warned seven pharmacy operations that produce "bio-identical hormone replacement therapy" that claims of their products' effectiveness may be false and misleading because they are not supported by medical evidence. These products are frequently compounded by large pharmacy operations and contain estrogen, progesterone, and estriol. Claims range from reduced risk of stroke, cancer, and lower rates of Alzheimer's disease associated with products. Compounded drugs are not reviewed by the FDA for safety and effectiveness however misleading claims violate federal laws. The FDA considers the term "bio-identical" a marketing term which implies benefit for which there's no medical or scientific basis. Compounding pharmacy that do not address these violations are subject to further enforcement according to the FDA press release. ■