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Multi-Faceted Approach to Hypervirulent *C. difficile* Control

ABSTRACT & COMMENTARY

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This article originally appeared in the December 2007 issue of Infectious Disease Alert. *It was edited by Stan Deresinski, MD, FACP, and peer reviewed by Connie Price, MD. Dr. Deresinski is Clinical Professor of Medicine, Stanford University; Associate Chief of Infectious Diseases, Santa Clara Valley Medical Center, and Dr. Price is Assistant Professor, University of Colorado School of Medicine. Dr. Deresinski is on the speaker's bureau for Merck, Pharmacia, GlaxoSmithKline, Pfizer, Bayer, and Wyeth, and does research for Merck. Dr. Price reports no financial relationships relevant to this field of study.*

Synopsis: *Early identification, coupled with appropriate control measures, reduces the rate of* C. difficile *infection and the frequency of adverse events.*

Source: Muto CA et al. Control of an outbreak of infection with the hypervirulent *Clostridium difficile* BI strain in a university hospital using a comprehensive "bundle" approach. *Clin Infect Dis*. 2007;45:1266-1273.

BEGINNING IN 2000, THE UNIVERSITY OF PITTSBURGH MEDICAL Center (UPMC) Presbyterian experienced a marked increase in hospital-acquired *C. difficile* infection, from 2.7 infections per 1000 discharges (0.46 per 1000 patient days) in the two preceding years to 7.2 per 1000 discharges (1.17 per 1000 patients days). Concurrently, there was an increase of severe *C. difficile*-associated disease, defined as that resulting in colectomy or death from 0.15 cases per 1000 discharges to 0.60 per 100 discharges. REA typing of *C. difficile* isolates collected in 2001 showed that 51% were of two highly related types. Further testing of these isolates by the CDC showed that they were the hypervirulent BI strain.

Beginning in June 2000, the Infection Control Team, in cooperation with other relevant hospital departments, initiated a series of interventions aimed at reducing *C. difficile* transmission and use of antimicrobials associated with an increased risk of *C. difficile* dis-

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ease. Interventions included institution of a standardized education module, increased case surveillance, and a *C. difficile* management team that evaluated patients for illness severity and appropriate treatment. Specific infection control measures included environmental cleaning with dilute bleach, electronic alerts, hand hygiene with soap and water, and infection control audits of isolation practices. In addition, the duration of patient isolation was extended from the previous end point of cessation of diarrhea to the duration of hospitalization.

A targeted antimicrobial restriction initiative began in October 2002. The targeted antimicrobials were those that a previous investigation had shown to be associated with increased risk of *C. difficile* infection in that facility.[1] These included fluoroquinolones, ceftriaxone, and clindamycin.

There was a gradual decrease in hospital-acquired *C. difficile* infection. By 2006, the rate had declined to 3.0 per 1000 hospital discharges (0.46 per 1000 patient days). The rate of severe disease declined dramatically to 0.03 per 1000 hospital discharges. Use of targeted antimicrobials decreased by 54%. In a second survey of *C. difficile* conducted in 2005, 13.5% contained BI strain.

COMMENTARY

C. difficile is a common hospital-acquired pathogen that leads to significant morbidity and occasional mortality. There is mounting evidence that the severity of *C. difficile* disease is increasing, most likely due to an increasing prevalence of a particularly virulent strain, identified as BI. This strain has a gene deletion, leading to hyperproduction of *C. difficile* toxins A and B. In addition, it produces a novel binary toxin;[2] the majority of reported isolates have been resistant to fluoroquinolones. It is likely that both the increasing frequency and severity of *C. difficile* infection at UPMC-Presbyterian was associated with the introduction of this strain into the medical center, since the majority of stains analyzed in 2001 were of this type. Dissemination of BI strains has been associated with widespread outbreaks of severe *C. difficile* disease in both the United States[2] and Canada[3].

The multi-faceted assault on *C. difficile* reported by Muto and colleagues was followed by both a significant reduction in disease incidence and disease severity. It's likely that control was the result of both the efforts to reduce transmission, such as case identification, isolation, and environmental cleaning, and the control of antimicrobial use.

As with many reports of successful programs directed against hospital-acquired infection, one is not able to assess the relative importance of individual interventions. They were introduced step-wise, and the decrease in *C. difficile* disease was gradual. However, insistence on purity of study design, during an epidemic in which major surgical procedures or death are potential outcomes, is a luxury that Infection Control programs don't have in the real world. ■

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Should We Continue Using Erythropoietin in the ICU?

ABSTRACT & COMMENTARY

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

This article originally appeared in the December 2007 issue of Critical Care Alert. *It was edited by David J. Pierson, MD, and peer reviewed by William Thompson, MD. Dr. Pierson is Professor, Pulmonary and Critical Care Medicine, Harborview Medical Center, University of Washington, and Dr. Thompson is Staff Pulmonologist, VA Medical Center; Associate Professor of Medicine, University of Washington. Drs. Pierson and Thompson report no financial relationships relevant to this field of study.*

Synopsis: *This randomized, double-blind, placebo-controlled trial demonstrates that administration of erythropoietin once a week for three weeks does not reduce the incidence of red blood cell transfusion in a mixed population of critically ill patients but is associated with an increased incidence of thrombotic events and a possible decrease in mortality in trauma patients.*

Source: Corwin HL, et al. Efficacy and safety of epoetin alfa in critically ill patients. *N Engl J Med*. 2007;357:965-976.

Previous trials have demonstrated that administration of recombinant erythropoietin to critically ill patients decreases the need for red blood cell transfusions and leads to higher hemoglobin values. Building on these trial results, Corwin and colleagues conducted a prospective, multicenter, randomized, double-blind trial to determine whether administration of a reduced dose of the erythropoietin was safe and effective in a mixed group of critically ill patients. They recruited medical, surgical, and trauma patients who were in the ICU for at least 48 hours and had hemoglobin levels less than 12 g/dL. Patients were excluded if they were expected to leave the ICU within a subsequent 48-hour period or had either active thrombotic disease, such as acute coronary ischemia or pulmonary embolism, or a history of the same.

Between 48 and 96 hours after admission, patients were randomized to receive 40,000 units of subcutaneous erythropoietin or placebo once a week for three weeks. The medication was not given if the patient's hemoglobin was above 12 mg/dL at the intended administration time. The primary end point was the percentage of patients receiving red blood cell transfusion between days 1 and 29 of the study. Secondary end points included the number of units transfused, mortality at days 29 and 140, and the change in hemoglobin values from baseline to day 29. The need for transfusion was at the discretion of each patient's treating physician, but Corwin et al provided guidelines recommending that physicians target a hemoglobin value between 7 and 9 mg/dL and not transfuse patients with values above the upper limit of that range.

There were 1460 patients enrolled in the study — 733 in the erythropoietin group and 727 in the placebo group. The groups were well matched except for the fact that the trauma patients were significantly younger than either the medical or surgical ICU patients. In the erythropoietin group, 28% of patients received only one dose of the study medication, 32% of patients received two doses, and 40% completed the entire three-week course.

There were no significant differences in the percentage of patients receiving transfusion (46% erythropoietin vs 48.3% placebo) or the number of units transfused in each group (4.5 ± 4.6 vs 4.3 ± 4.8 units). At day 29, the change in hemoglobin concentration was greater in the erythropoietin group than the placebo group (1.6 ± 2.0 g/dL vs 1.2 ± 1.8 g/dL), but by day 42, there were no significant differences in absolute hemoglobin concentrations. Mortality was lower among the patients treated with erythropoietin alfa (8.5% vs 11.4% at 29 days and 14.2% vs 16.8% at 140 days), with the largest differences in mortality seen in the trauma patients. There was an increased incidence of thrombotic events in the erythropoietin group (16.5% vs 11.5%, hazard ratio 1.4), with post-hoc analysis demonstrating that thrombosis largely occurred in those patients not on heparin prophylaxis.

COMMENTARY

The decision to use any treatment should always be driven by a consideration of the risk-to-benefit ratio. In light of the study by Corwin et al, it does not appear that erythropoietin fares well in this analysis. Regarding the benefits, there is insufficient evidence of clinical utility; the study described above showed no significant differences in the use of red blood cell transfusions and no clinically meaningful changes in hemoglobin concentrations.

Although earlier trials by this group did show a benefit in this regard, it should be remembered that in one trial,[1] erythropoietin decreased the need for transfusion by a very modest one unit over the course of admission, a difference of questionable clinical benefit. Supporters of erythropoietin use might point to the mortality benefit demonstrated in the trial described above, but the

observed difference was largely restricted to the trauma patients, and further work is necessary to confirm what can best be viewed as a preliminary result, particularly in light of a recent meta-analysis which showed no mortality benefit to erythropoietin administration.[2]

There is also reason for concern on the risk side of the equation. Earlier trials have shown evidence of increased thrombotic complications with higher doses of erythropoietin, and the study by Corwin et al now shows that even with administration of lower doses, there is still an increased risk of thrombotic events, particularly in those patients not on heparin prophylaxis.

When viewed in conjunction with the questionable clinical benefit, the increased risk of thrombotic events should prompt reconsideration of erythropoietin use in the care of critically ill patients. Future work may yet demonstrate further evidence of a mortality benefit as well as the reasons for such an effect, but until this work is complete, routine use of this medication is not warranted. ■

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Weight Gain: Predictor of Heart Failure Hospitalization

ABSTRACT & COMMENTARY

By Andrew Boyle, MBBS, PhD

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Dr. Boyle reports no financial relationships relevant to this field of study. This article originally appeared in the December 2007 issue of Clinical Cardiology Alert. *It was edited by Michael H. Crawford, MD, and peer reviewed by Rakesh Mishra, MD, FACC. Dr. Crawford is Professor of Medicine, Chief of Clinical Cardiology, University of California, San Francisco, and Dr. Mishra is Assistant Professor of Medicine, Weill Medical College, Cornell University; Assistant Attending Physician, NewYork-Presbyterian Hospital. Dr. Crawford is on the speaker's bureau for Pfizer, and Dr. Mishra reports no financial relationships relevant tot his field of study.*

Source: Chaudhry SI, et al. Patterns of weight change preceding hospitalization for heart failure. *Circulation*. 2007; 116:1549-1554.

Weight gain has long been used as a marker of fluid retention in heart failure patients. It is a cheap, simple test that can be performed daily in patients' homes. Heart failure hospital admissions are a considerable strain on health budgets and, therefore, a number of strategies aimed at preventing recurrent hospitalizations are being implemented. Increasingly, strategies for remote monitoring of patients who remain at home are being developed, and heart failure is an obvious target where these interventions may prevent hospitalization and reduce health care costs. However, studies delineating the pattern of weight gain in ambulatory heart failure patients using remote monitoring have been lacking.

Chaudhry and colleagues studied patients enrolled in a home-based remote heart failure monitoring program that consists of daily weight transmitted via telephone line to a central location that is monitored by trained cardiac nurses. From over 10,000 patients, 393 had at least one heart failure admission over the 18-month follow-up period. They were able to match 134 patients who had heart failure hospital admissions with 134 patients who did not with age, gender, weight at enrollment, NYHA class, and month of enrollment. Mean patient age was 74 years; 55% were female, and the vast majority of patients were in NYHA class III heart failure. They showed that patients started to increase weight by around 1 pound approximately 30 days before admission due to heart failure. This was maintained until 2 weeks before admission, when patients started to gain more weight, and this pattern accelerated in the week prior to admission. They showed that the amount of weight gained in this cohort predicted the likelihood of hospital admission for heart failure. Compared to those whose weight changed < 2 pounds, the odds ratio (OR) for heart failure admission for a weight gain of 2-5 lbs was 2.77, for weight gain 5-10 lbs OR was 4.46, and for > 10 lbs weight gain OR was 7.65. From the same cohort, they chose a group of patients who were admitted to hospital for non-heart failure reasons and matched them with a control cohort. There was no weight gain prior to non-heart failure admissions. Chaudhry et al concluded that increases in weight in moderate-to-severe heart failure patients are associated with subsequent admission for heart failure and occur at least one week before admission.

■ COMMENTARY

Although weight gain has long been a surrogate

for fluid retention in heart failure, the current study is important for several reasons. Firstly, they have demonstrated that a simple, safe test can be performed in patients' homes and remotely recorded accurately enough to allow prediction of a clinical event. This lends validity to the ongoing search for remote monitoring parameters for heart failure patients to prevent readmission. Secondly, it shows that fluid retention precedes admission to the hospital by quite a long time, with weight gain being seen in the week prior to admission, but may be seen as much as 30 days prior to admission. This delineates a window of opportunity wherein interventions may be initiated to prevent hospitalization (eg, increase diuretic dose), but this remains to be studied in prospective clinical trials.

The study is limited by the small number of patients included from the overall cohort. This was due to problems matching them with controls or by withdrawal due to early hospitalization in the initial 30 days, which was a pre-specified exclusion criterion. Also, the majority of patients were in NYHA class III and, therefore, the results may not be generally applicable to patients throughout the spectrum of heart failure. Additionally, Chaudhry et al did not assess any other clinical variables, such as shortness of breath or peripheral edema, which may also predict heart failure hospitalization. No conclusion can, therefore, be drawn about the relative contribution of weight gain over other clinically-reported symptoms in predicting heart failure hospitalization. However, the study is strengthened by how well the patients were matched with controls.

This study set the stage for a new era in heart failure trials utilizing remote monitoring for prevention of hospitalization. Chaudhry et al conclude that increases in body weight in a heart failure population are associated with hospitalization for heart failure, and that these changes are seen at least a week before admission. Remote monitoring of weight may identify a high-risk period during which interventions to avert decompensated heart failure may be beneficial. ■

Resolution of Chest X-ray Abnormalities for Pneumonia

ABSTRACT & COMMENTARY

By Dean L. Winslow, MD, FACP, FIDSA
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Dr. Winslow is a consultant for Bayer Diagnostics, and is on the speaker's bureau for GlaxoSmithKline and Pfizer.
This article originally appeared in the December 2007 issue of Infectious Disease Alert. *It was edited by Stan Deresinski, MD, and peer reviewed by Connie Price, MD.*

Synopsis: *Two hundred eighty-eight patients hospitalized with severe community-acquired pneumonia (CAP) were followed for 28 days in a prospective multicenter study. At day 7, 25% of patients had resolution of CXR abnormalities and 56% had improvement. At day 28, 53% of patients had resolution of CXR abnormalities and 78% had clinical cure. By multivariate analysis, delayed resolution of CXR abnormalities by day 7 was associated with multilobar disease, dullness to percussion by physical exam, elevated CRP (> 200 mg/L), and tachypnea (respiratory rate > 25/min.) on admission.*

Source: Bruns AH, et al. Patterns of resolution of chest radiograph abnormalities in adults hospitalized with severe community-acquired pneumonia. *Clin Infect Dis*. 2007;45:983-991.

THIS INTERESTING STUDY FROM THE NETHERLANDS prospectively evaluated 288 consecutive patients with severe CAP (ATS pneumonia severity index > 90) admitted to the hospital, on which clinical data and CXR's were available at admission, day 7, and day 28. Mean age of patients was 69.7 years, and 53.5% had comorbid conditions, including CHF, underlying neoplasm, cerebrovascular diseases, and renal disease. Of these patients, 21.5% had microbiologically-documented infection with pneumococcus, 9.7% had infection with an atypical pathogen, 51.4% had pneumonia of unknown etiology, 3.8% had infection with multiple pathogens, and 17.4% had infection with other pathogens, including gram-negative enteric organisms, or Pseudomonas, *S. aureus*, *H. influenzae*, or *M. catarrhalis*. Twenty (6.9%) patients died.

Univariate analysis for delayed resolution of CXR abnormalities at day 28 showed the following parameters to be correlated: higher PSI, *S. pneumoniae* infection, multilobar pneumonia, PCO_2 < 30 mm Hg, CRP > 200 mg/L, and BUN > 10uM on admission. By multivariate analysis, delayed resolu-

tion of CXR abnormalities by day 28 was associated only with CRP > 200 mg/L on admission.

COMMENTARY

My experience in several large teaching hospitals over the last 20 years is that patients admitted with pneumonia often are subjected to routine daily CXR's during the first few days in the hospital, and generally every 3 days or so until hospital discharge, despite the presence of clinical improvement. This large, prospective, multicenter study conducted in immunocompetent adult patients hospitalized with CAP shows that only one-quarter of the patients resolved their CXR abnormalities by day 7 and approximately one-half did so by day 28. This study clearly suggests that frequent CXR's obtained prior to hospital discharge, in patients who are clinically improving, are unnecessary and unlikely to be useful. The study also suggests that one of the "old saws" many of us were taught during our Internal Medicine training (without any literature support) in the 1970s, which recommended deferring aggressive work-up of persistent radiographic abnormalities following CAP unless those abnormalities persisted beyond 6 weeks, was correct. While not specifically addressed in this study, it is likely that an interval as long as 8-12 weeks, following an episode of CAP, seems to be reasonable before performing follow-up radiography (including thoracic CT scans) or bronchoscopy to exclude noninfectious causes of persistent CXR abnormalities. ■

Barriers to Implementing the Leapfrog Recommendations

ABSTRACT & COMMENTARY

By David J. Pierson, MD

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Dr. Pierson reports no financial relationships relevant to this field of study.

This article originally appeared in the December 2007 issue of Critical Care Alert. *It was peer reviewed by William Thompson, MD.*

Synopsis: *In this survey of US hospitals, more than half did not have an identifiable ICU director. Loss of autonomy and income for admitting primary physicians were perceived as important barriers to implementation of the Leapfrog Group's ICU physician staffing guidelines.*

Source: Kahn JM, et al. Barriers to implementing the Leapfrog Group recommendations for intensivist physician staffing: A survey of intensive care unit directors. *J Crit Care*. 2007;22:97-103.

THIS PAPER REPORTS ON A TELEPHONE SURVEY OF US non-rural hospitals and the physician directors of their ICUs. Kahn and colleagues sought to determine the extent to which the recommendations of the Leapfrog Group about ICU staffing had been implemented, and to clarify the reasons for delays in, or resistance to, such implementation.

Sites were selected at random from hospitals participating in the database maintained by the Committee on Manpower for Pulmonary and Critical Care Societies, which includes US hospitals nationwide. Kahn et al stratified their target ICUs according to hospital size and the population served and classified the hospitals into either academic or community. Their survey addressed 4 domains with respect to the Leapfrog Group recommendations for intensivist staffing: knowledge and perceived utility of the recommendations, current compliance, potential barriers to implementing the recommendations, and possible solutions to these barriers. Seventy-two hospitals were surveyed in late 2003 and early 2004.

Among the 72 hospitals that were approached, 47 (65%) responded to initial telephone inquiries; 26 (55%) of these did not have an identifiable physician ICU director. The ICU directors of the remaining 21 hospitals were interviewed. Eleven (52%) of these considered themselves very familiar with the recommendations. Of the 20 physician ICU directors who answered questions about their respective hospitals' Leapfrog compliance, 8 (40%) considered their units to be Leapfrog-compliant, although only 5 of these ICUs (25%) actually proved to be compliant with all 4 recommendations. Of the 15 directors not in compliance, 13 indicated motivation to become so in the future.

The most significant barrier to implementation of the recommendations was concern over loss of control for physicians who would no longer be providing care to critically ill patients. Loss of income and

increased cost to hospital administration were other perceived barriers. Perceived measures of potential importance in overcoming these barriers included increasing the numbers of available intensivists, increasing funds from hospital administrators, and assistance from government and third parties.

COMMENTARY

The Leapfrog Group is a consortium of health care purchasers formed in 2000 to advocate for improved quality and safety in healthcare. For the ICUs of all US non-rural hospitals, the Leapfrog Group recommends the following as the standard for intensivist staffing:

- A board-certified or board-eligible intensivist physician should manage or co-manage all patients in the ICU;
- The intensivist should be present in the ICU during daylight hours, with no competing clinical duties;
- At other times, an intensivist should be able to return ICU pages within 5 minutes; and,
- Another physician, or a nonphysician extender such as a physician assistant or advance practice nurse certified in caring for critically ill patients, should always be available within 5 minutes of the ICU.

This study suggests that we are still a considerable way from implementing these recommendations. It points out a number of important barriers to such implementation, the most glaring of which is that over half of the hospitals surveyed did not even have an identifiable physician ICU director. As Kahn et al point out, without an ICU director to bring about change, there seems little likelihood that the Leapfrog Group's recommendations for physician staffing can be put into effect.

The cost of hiring intensivists — even if enough of them were readily available, something regarded by many as doubtful — is obviously a key obstacle to be overcome. However, this study points out that there are other important barriers, such as fear of loss of control and income on the part of primary physicians if their ICUs became "closed" through implementation of the Leapfrog guidelines.

Although quite a bit has been published in this subject area, the available evidence supporting the Leapfrog recommendations is hardly definitive, and considerable controversy remains as to whether their implementation would in fact improve the quality of ICU care and/or decrease adverse outcomes across the board. However, despite the limitations of this study, such as the small sample size and the fact that the survey was carried out 4 years ago in a rapidly evolving area, the message seems clear that major changes would have to take place in most US hospitals if the Leapfrog ICU recommendations were actually to be put into effect. ■

CME Questions

10. Based on the study by Bruhns et al, regarding the resolution of the chest X-ray (CXR) abnormalities after severe community-acquired pneumonia, which of the following is correct?

a. Patients admitted with community-acquired pneumonia should receive a CXR every three days to look for complications of pneumonia and signs of resolution.
b. Persistence of radiographic abnormalities was associated with an elevated CRP at the time of admission.
c. Patients with non-resolution of their CXR abnormalities by 21 days after an admission for pneumonia should undergo CT scanning of the chest regardless of their clinical symptoms.
d. Delayed resolution of CXR abnormalities occurred only in patients who were not clinically improving or who had clinical relapse.

11. According to the study by Kahn et al, which of the following was the most significant perceived barrier to implementation of the Leapfrog criteria?

a. Concern over decreased patient and family satisfaction with care.
b. Concern over increased governmental control of patient care.
c. Concern over loss of control for physicians who would no longer be providing care to critically-ill patients.
d. None of the above

12. In the report by Corwin et al, weekly doses of erythropoietin in ICU patients was associated with:

a. improved ICU and hospital survival in MICU patients.
b. decreased ICU length of stay.
c. decreased requirement for red blood cell transfusion during the ICU stay.
d. increased thrombotic complications.

Answers: 10. (b); 11. (c); 12. (d)

CME Objectives

The objectives of *Hospital Medicine Alert* are to:

• review pertinent safety, infection control, and quality improvement practices;

• discuss diagnosis and treatment of acute illness in the hospital setting; and

• review current data on diagnostic and therapeutic modalities for common inpatient problems. ■

CME Instructions

Physicians participate in this CME program by reading the issue, using the references for research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to the answer key to test their knowledge. To clarify confusion on any questions answered incorrectly, consult the source material. ■