

The Duration of Antibiotic Therapy for Early VAP (DATE) Trial: A Surgical Infection Society Multicenter Randomized Clinical Trial of 4 vs. 7 Days of Definitive Antibiotic Therapy for Early Ventilator-Associated Pneumonia in the Surgical Intensive Care Unit

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# Objective

The specific aim is to determine whether 4 days of antibiotic therapy is non-inferior to 7 days of antibiotic therapy for the treatment of early VAP with regards to recurrence and superior with regards to antibiotic exposure time.

## Background

The prevalence of multidrug resistant (MDR) pathogens in ICUs worldwide has reached epidemic proportions.

**Ventilator-Associated Pneumonia (VAP)** is the most common serious infection in mechanically ventilated critically ill patients. Approximately one half of antibiotic prescriptions in the Intensive Care Unit (ICU) are related to VAP. Shortening the duration of antimicrobial therapy for VAP represents one strategy to curtail the emergence of MDR pathogens.

Early VAP (< 7 days after intubation) comprises the majority of cases of pneumonia diagnosed in the ICU. Compared to patients who develop late VAP, patients with early VAP are more likely to be infected with community-acquired pathogens and demonstrate microbiological resolution after relatively short (i.e., 3–5 day) courses of therapy. Therefore, this multicenter randomized controlled trial was designed with the Surgical Infection Society to determine whether a shorter course of antibiotic therapy (i.e., 4 days) is non-inferior to longer therapy (i.e., 7 days) for the treatment of early VAP in critically ill surgical patients.

#### Methods

Saint Francis Hospital was invited to participate in a multicenter, randomized study lead by the University of Miami.

- Any patient that meets inclusion criteria will be asked to enroll. Randomization will occur using a computer generated block pattern and will occur at the hospital level.
- Empiric antibiotic therapy will be instituted as soon as possible following diagnosis of suspected pneumonia by the clinical team. The default antibiotic will be based on the local institutional antibiogram and practice.
- The treatment team may choose to extend the duration of antibiotic therapy based on clinical circumstances. Clinical decisions will take precedence over study group assignment. Clinical decision-making will supersede any study procedures or protocols.

### Data and Enrollment

This study is now open for enrollment.