

## A Win for the Learning Health System

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A central tenet of the learning health system philosophy is that evidence development should be part of care delivery. Furthermore, it should be possible to address difficult problems in the learning health system; health care–associated infections are such problems. They are among the most serious complications of health care, and are increasingly demonstrated to be avoidable.

Preventing infections caused by a virulent, antimicrobial-resistant pathogen, methicillin-resistant *Staphylococcus aureus* (MRSA), has been an especially high priority because of its morbidity and mortality, as well as its increasing prevalence, particularly among intensive care unit (ICU) patients. MRSA complicates more than 250,000 hospitalizations and contributes to almost one-quarter of the 80,000 deaths in the United States each year from hospital-acquired infections.<sup>1,2</sup> Three strategies to prevent these infections in ICUs are described in the literature—screening and isolating patients who carry the organism; screening and isolation, plus decolonization; and decolonization of all patients without any screening. There has been limited evidence to guide selection of one approach over another. Nonetheless, nine states mandate the first approach.

This is a problem the learning health system should be able to address, and we and our colleagues recently reported a head-to-head comparison of the three strategies.<sup>3</sup> The study of 43 hospitals and more than

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74,000 patients provided strong evidence that decolonizing all patients prevented 44 percent of blood stream infections.

The study design was straightforward—a pragmatic, cluster-randomized trial that randomized hospitals to one of the three prevention strategies. Although the design was straightforward, the study was extraordinary for several reasons beyond its large size. Important features included the fact that the study was embedded in the hospitals' routine care delivery system. It was implemented by the hospitals' own quality and infection prevention teams, ICU directors, and staff; there was active participation throughout by nursing departments, hospital pharmacies, supply chain managers, microbiology laboratories, and others; and an integrated information technology system both supported day-to-day implementation and served as the source for all of the outcome data. Most hospitals delegated institutional review board oversight to the lead institution. Finally, embedding the trial into the routine care delivery system meant that the total extra cost was less than \$3 million, a tiny fraction of the cost of a conventional clinical trial.

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All of these features were possible because the study was embedded in a single system, Hospital Corporation of America.

This study has four immediate lessons for the learning health system. First, embedding pragmatic clinical trials into routine practice settings provides information that can directly inform care delivery; it is important to design trials that fit clinical practice. Second, large networks of committed institutions that use interconnected, interoperable information systems can provide essential organizational, logistical, and data resources to learn from and compare the systematic introduction of medical practices in ways that have been effectively impossible until now. We should especially encourage evidence development programs in these venues. Third, randomization is sometimes necessary, and cluster randomization is especially well suited to pragmatic trials. It will be important to develop a clear understanding of when randomization is appropriate, and to ensure appropriate ethical oversight and protection of patients. Finally, high-quality delivery science is not free, even though it is inexpensive by the standards of both conventional clinical trials and the total cost of care. For the learning health system to become an effective national research and development system, it requires the financial and organizational support of the delivery systems it improves.

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#### **References**

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In this commentary, simultaneously released with a corresponding [New England Journal of Medicine article](#), Drs. Platt, Huang, and Perlin describe the implications for evidence generation in a learning health system demonstrated by the results from a recent randomized trial of MRSA prevention strategies within several allied hospitals. Their study grew out of a partnership facilitated by participation in the IOM Roundtable on Value & Science-Driven Health Care, for which Dr. Platt serves as co-chair of the IOM Clinical Effectiveness Research Innovation Collaborative and Dr. Perlin serves as co-chair of the IOM Digital Learning Collaborative. The commentary discussion touches on several concepts central to continuously improving care, including the potential gains from:

- Embedding pragmatic clinical trials into delivery systems' routine care practices;
- Harmonized evidence generation coordinated among institutions that share information systems;
- Systematic variation in care, sometimes including cluster randomization;
- Delivery systems' logistical and financial support of research and development.

Information on the IOM's Learning Health System work may be found at [www.iom.edu/learninghealthsystem](http://www.iom.edu/learninghealthsystem)