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SYSTEMS-LEVEL QUALITY IMPROVEMENT

A Call for Electronic Health Record-based Data Sharing for Clinical Trials in Critical Care

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Two recent, high-impact publications of pragmatic, cluster-randomized clinical trials highlight the risks of normal saline administration in hospitalized patients [1, 2]. For clinical informaticians and clinical trialists, they raise larger questions about how clinical trials should be conducted in the future.

Randomized, prospective, clinical trials have long been considered a gold standard for assessing causality in the medical literature. There are significant limitations to traditional clinical trials, such as high cost, delays in obtaining funding, large numbers of exclusion criteria, and inability to randomize and intervene in a timely manner in instances of delayed consent. By focusing interventions on highly-selected patients undergoing care delivered by expert clinicians, they may suffer from limited generalizability [3]. Given these long-standing concerns there has been increased interest in recent years in conducting more pragmatic clinical trials, which are designed to specifically address these issues [4–6]. Many of the features of pragmatic clinical trials are outlined at length in the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) and PRECIS-2 tools [7, 8].

A major challenge, even in pragmatic clinical trials, has been data collection and validation, including assessment of clinically-relevant clinical outcomes [9]. In the SALT-ED and SMART trials, data were collected and validated through extensive leverage of the electronic health record (EHR)— at significantly decreased cost and effort, compared to comparable studies.

Critical care medicine is practiced in a high-acuity and high-cost environment. Given these factors, proposed interventions and changes to clinical practice are often thoroughly vetted, in many instances in multiple studies, prior to achieving broad clinical implementation. Success stories have included lung protective ventilation, changes in sedation regimens to address intensive care unit delirium, among many others [10–12]. Conducting multiple, high-quality prospective, randomized clinical trials, often at multiple centers, may be a technically challenging and expensive process.

As more health systems transition to large, enterprise EHRs, clinical informaticians are presented with the opportunity to leverage tools that can be easily integrated in the EHR to facilitate clinical trials. Multi-center observational data sharing with EHR integration has been successfully performed in numerous fields, including, notably, perioperative outcomes research, via endeavors such as the Multi-Center Perioperative Outcomes Group and the Duke Clinical Research Institute [13–15]. These lessons and tools can be embedded within intensive care units, thereby enabling robust, multi-center clinical trials. As the SALT-ED and SMART studies have shown, these trials have the potential to drastically improve clinical practice. We would propose that efforts are urgently needed to create new, multi-center data sharing networks to leverage EHR data to facilitate pragmatic clinical trials in critical care.

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Compliance with Ethical Standards

Conflict of interest None.

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