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Use of a remote clinical decision support service for a multicenter trial to implement prediction rules for children with minor blunt head trauma



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ABSTRACT

Objective: To evaluate the architecture, integration requirements, and execution characteristics of a remote clinical decision support (CDS) service used in a multicenter clinical trial. The trial tested the efficacy of implementing brain injury prediction rules for children with minor blunt head trauma. *Materials and Methods:* We integrated the Epic[®] electronic health record (EHR) with the Enterprise Clinical Rules Service (ECRS), a web-based CDS service, at two emergency departments. Patterns of CDS review included either a delayed, near-real-time review, where the physician viewed CDS recommendations generated by the nursing assessment, or a real-time review, where the physician viewed CDS triggered with zero delay when no recommendation was available in the EHR from the web-service. We assessed the execution characteristics of the integrated system and the source of the generated recommendations viewed by physicians.

Results: The ECRS mean execution time was 0.74 ± 0.72 s. Overall execution time was substantially different at the two sites, with mean total transaction times of 19.67 and 3.99 s. Of 1930 analyzed transactions from the two sites, 60% (310/521) of all physician documentation-initiated recommendations and 99% (1390/1409) of all nurse documentation-initiated recommendations originated from the remote web service.

Discussion: The remote CDS system was the source of recommendations in more than half of the real-time cases and virtually all the near-real-time cases. Comparisons are limited by allowable variation in user workflow and resolution of the EHR clock.

Conclusion: With maturation and adoption of standards for CDS services, remote CDS shows promise to decrease time-to-trial for multicenter evaluations of candidate decision support interventions.

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1. Introduction

Minor head trauma is a common presenting condition of children seen in emergency departments (EDs). Of approximately 600,000 children younger than 18 years presenting to EDs annually in the United States for blunt head trauma, more than 95% is minor (defined by Glasgow Coma Scale [GCS] scores of 14-15), with a very low associated prevalence of clinically important traumatic brain injuries (ciTBIs; here defined as a death, neurosurgical intervention, intubation for more than 24 h, or hospital admission for 2 or more nights due to the head trauma in association with a positive cranial computed tomography [CT] scan) [1–4]. However, because the use of ionizing radiation in children is associated with an increased lifetime risk of lethal malignancy of approximately 0.15%, cranial CT scans should be used judiciously in children with minor head trauma [5–8]. In order to facilitate clinician decisionmaking and balance the need to identify ciTBIs with the risk of malignancy from CT scans, the Pediatric Emergency Care Applied Research Network (PECARN) derived and validated prediction rules for children younger than two years and children 2 up to their 18th birthday that identify those at very low risk of ciTBIs who do not require CT scans, based on a series of patient history and physical examination findings (Fig. 1) [4].

Clinical decision support (CDS) based on the PECARN prediction rules could deliver personalized imaging recommendations based on the risks of ciTBI to clinicians at the point-of-care in real-time. PECARN provides an in vivo laboratory in which to evaluate the effectiveness of these prediction rules using computer-based CDS, with 17 of 18 sites having electronic health records (EHR) with CDS capabilities. However, we have previously described the sociotechnical challenges involved in creating a successful CDS intervention in the ED setting across multiple sites, including technical complexity, human factors, and organizational and process dimensions [9]. The implementation of a CDS intervention for a multicenter evaluation is complicated by heterogeneous EHRs, differing versions/configurations of a single vendor's EHR, varying technical capacity to conduct clinical research in an EHR production environment, and varying technical capacity of an institutional informatics staff to implement a CDS intervention. We describe one method to potentially decrease the complexity of implementing CDS interventions across multiple sites through the use of a novel remote CDS service.

2. Objective

Our objective was to evaluate the architecture, integration requirements, and execution characteristics of a remote CDS service used in a multicenter clinical trial, testing the effectiveness of an implementation of the PECARN traumatic brain injury (TBI) prediction rules for children with minor blunt head trauma. Researchers have emphasized the importance of characterizing these non-functional requirements of decision support systems, in addition to the outcomes they produce [10–15]. Compared with a vendor's native decision support system coupled tightly to an EHR, the performance of a remote CDS service in providing real-time recommendations, as would be required to evaluate the effectiveness of the PECARN TBI prediction rules, is unknown. Previously, web-service-based CDS has been used as a component in a regional architecture to support chronic care management [16-18], and recently to share preventive health alerts and reminders among disparate health systems [19]. With respect to multicenter evaluations, 'CDS as a service' might reduce the 'time-to-trial' (the time required to develop infrastructure necessary for conducting a clinical trial) by replacing multiple individual implementations of a CDS intervention with a 'write-once, run everywhere' paradigm. The time-sensitive nature of imaging recommendations in the ED setting of blunt head trauma provided an excellent opportunity to investigate the performance of remote CDS provided in an acute setting.

3. Materials and methods

3.1. Traumatic brain injury clinical decision support trial

The PECARN TBI prediction rule CDS trial was a multicenter clinical trial that included thirteen EDs either in the PECARN or in Kaiser Permanente's Clinical Research in Emergency Services and Treatments (CREST) network. Inclusion for sites receiving the CDS intervention was limited to those using the Epic® EHR (Epic Systems, Verona, WI) in order to minimize the complexity of the infrastructure and not introduce additional variation in implementation of the CDS. A total of ten sites implemented the CDS intervention. Two sites in the trial, Nationwide Children's Hospital (NCH-Columbus, OH) and Children's Hospital Colorado (CHCO-Aurora, CO), elected to receive the CDS via remote decision support services, backstopped by CDS implemented in the decision support module native to the Epic software installed at each site ("the Epic-based CDS"). The backstop ensured that the technical aims of the trial did not negatively impact the clinical research aims. The other trial sites received only the Epic-based CDS, electing not to participate in the remote CDS arm because of resource constraints, technical constraints, or other local policy considerations.

Risk Factor	Age in	Age in Years	
	0-2	2-18	
Glasgow Coma Scale (GCS) score less than 15	*	*	
Other signs of altered mental status	*	*	
Acting abnormally per parent	*		
Severe mechanism of injury	*	*	
History of loss of consciousness	* (≥ 5 sec)	* (Any)	
Occipital, parietal, or temporal scalp hematoma	*		
Palpable skull fracture	*		
Signs of basilar skull fracture		*	
Severe headache		*	
History of vomiting		*	

* Single asterisks denote inclusion of factor in age-specific prediction rule

Fig. 1. Risk factors in the two age-specific PECARN traumatic brain injury (TBI) prediction rules. Patients are at very low risk of clinically-important TBI if they have none of the age-specific findings. PECARN—Pediatric Emergency Care Applied Research Network.

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