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# **Brief Communication**

# Text message alerts to emergency physicians identifying potential study candidates increase clinical trial enrollment

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#### ABSTRACT

Prospective enrollment of research subjects in the fast-paced emergency department (ED) is challenging. We sought to develop a software application to increase real-time clinical trial enrollment during an ED visit. The Prospective Intelligence System for Clinical Emergency Services (PISCES) scans the electronic health record during ED encounters for preselected clinical characteristics of potentially eligible study participants and notifies the treating physician via mobile phone text alerts. PISCES alerts began 3 months into a cluster randomized trial of an electronic health record–based risk stratification tool for pediatric abdominal pain in 11 Northern California EDs. We compared aggregate enrollment before (2577 eligible patients, October 2016 to December 2016) and after (12 049 eligible patients, January 2017 to January 2018) PISCES implementation. Enrollment increased from 10.8% to 21.1% following PISCES implementations (P < .001). PISCES significantly increased study enrollment and can serve as a valuable tool to assist prospective research enrollment in the ED.

Key words: text messaging, emergency services, clinical trial, patient selection, alert fatigue, health personnel

# INTRODUCTION

Prospective trials in the emergency department (ED) can be challenging for many reasons. The environment of the ED can be chaotic and unpredictable.<sup>1,2</sup> Patients enter the ED with a variety of complaints, length of stay is variable, and treatment needs are often time-sensitive.<sup>1-4</sup> As a result, it can be challenging for ED providers to recognize patients who meet eligibility criteria for research studies and complete their enrollment.

To our knowledge, there are few systems available to aid research enrollment in the ED, and little is known about the effectiveness of these recruitment techniques.<sup>2</sup> One prior study sent

research alerts based on patient chief complaints when admitted to the ED; however, this method required research staff to monitor these alerts and inform providers of potential eligibility.<sup>2</sup> Unfortunately, it is often not feasible to have a research assistant or volunteer data assistant in the community ED setting.

To address the challenges of prospective provider participation in research in a community ED setting and increase study enrollment, our team developed a software application to notify physicians via automated text message alerts if their patient is potentially eligible for a prospective study. This report describes this system and its impact on study enrollment.

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# MATERIALS AND METHODS

#### Setting and population

This project was undertaken in 11 community EDs across Kaiser Permanente Northern California (KPNC). KPNC is a large integrated healthcare delivery system providing medical care to over 4 million members, about 33% of the population in areas served.<sup>5</sup> The median annual ED census in 2017 was 66 000 visits (interquartile range [IQR], 41 000-97 000) across the 11 participating facilities. The median annual census for patients 5-20 years of age was 9000 (IQR 5000-13 500), ranging from 3000 to 22 000. KPNC uses a single electronic health record (EHR) (Epic, Verona, WI), fully deployed in 2009.<sup>6</sup> In 2016, KPNC began distributing iPhones to all ED physicians for clinical use.

This study was conducted from October 2016 to January 2018 as part of a larger cluster randomized pragmatic clinical trial on the impact of clinical decision support on management of pediatric patients with abdominal pain in the ED (NCT02633735). Study enrollment was completed by treating physicians using a web-based application, RISTRA (RIsk STRAtification), embedded in the EHR. RISTRA is an electronic clinical decision support tool that uses clinician entered data regarding the patient's clinical presentation and physical exam findings.<sup>7</sup> Available EHR data were automatically prepopulated when available and clinicians were asked to verify for accuracy.<sup>8</sup> Upon completion of enrollment, physicians at intervention sites received clinical decision support including risk estimates for appendicitis and recommended next steps in care.9 Ongoing education was provided to physicians regarding study progress, promotional posters were placed at physician work stations, and providers were given small gift cards for enrollment in the pragmatic trial.

Eligible study patients were 5-20 years of age with a chief complaint of abdominal pain and no preexisting exclusion characteristics listed in the EHR (current pregnancy, prior abdominal surgery, trauma, ED visit in past 7 days for abdominal pain, or select comorbidities). This study was approved by the KPNC Institutional Review Board with a waiver of informed consent.

#### Alert system

To enhance RISTRA enrollment rates for the pediatric abdominal pain study, the Prospective Intelligence System for Clinical Emergency Services (PISCES) was developed and implemented in January 2017. To notify physicians that an assigned patient is potentially eligible for the study, PISCES sent automated real-time text message alerts to the physician's iPhone. Text message alerts were used to minimize EHR alert fatigue and allow research staff to receive text alerts for monitoring and troubleshooting purposes.

PISCES queried Epic web services every 15 minutes for new patients admitted to the 11 study EDs meeting predetermined age (5-20 years) and chief complaint (abdominal pain) parameters. ED chief complaint of abdominal pain was chosen based on a retrospective analysis that found a chief complaint of abdominal pain had 97% sensitivity for an ED diagnosis of appendicitis within the KPNC system.<sup>10</sup> PISCES alerts were designed to maximize sensitivity rather than specificity, though the tool could be modified based on enrollment criteria and study goals.

Upon detection of an admitted patient that met alert criteria, PI-SCES utilized the encounter ID to determine the patient's assigned ED provider. Using Verizon in Gmail, PISCES then sent an automated de-identified text message alert to the provider indicating their patient was possibly eligible for study enrollment. The text message read: "(CREST Study Alert) Please enroll via RISTRA prior to ordering imaging." The prototype of the PISCES alert system was derived and tested initially on a dataset as part of a larger prospective multicenter trial of electronic clinical decision support for pediatric traumatic brain injury.<sup>11</sup> In 84 tests across 8 facilities, we achieved a 90.5% delivery rate within 35 minutes of patient registration.

The research staff monitored alerts via a reporting dashboard showing all eligible patients detected in the EDs, the provider assigned to each patient, and the time of text message distribution. The database of provider phone numbers was maintained by the study staff and updated semiannually. Providers could opt out of the system by contacting the study staff or by using phone settings to block the PISCES phone number.

#### Outcomes

The primary outcome was the proportion of eligible patient encounters enrolled in the pediatric abdominal pain study via RISTRA. Fisher's exact tests were used to compare pre- and post-PISCES implementation raw enrollment rates.

Secondary outcomes included adjusted study enrollment rates and parameters measuring the efficiency of PISCES. Manual chart reviews were conducted for 555 encounters in which RISTRA was not activated but the patient was potentially eligible for the study as defined previously. Reviews were conducted between October 2016 and January 2017. Study team members reviewed the EHR record, focusing on ED provider notes to assess study eligibility according to the following criteria: 5-20 years of age, ED complaint abdominal pain, diffuse or right-sided pain for <5 days, no current pregnancy, no abdominal trauma, and no significant underlying abdominal diagnoses (eg, ulcerative colitis, Crohn's disease). The chart reviewdetermined rate of patients actually eligible for the study was applied to the full raw study cohort to generate adjusted study enrollment rates. To assess PISCES efficiency, we determined the median time from patient ED admission to text alert distribution and from provider assignment to text alert distribution.

## RESULTS

Over the study period, 517 providers received 1 or more PISCES notifications for the pediatric abdominal pain study. The median time from patient admission to text alert was 11 (IQR, 6-15) minutes and the median time from provider assignment to text alert was 8 (IQR, 4-12) minutes.

The pre-PISCES study period ran from October 2016 to December 2016 and the post-PISCES period ran from January 2017 to January 2018. The raw enrollment rate based on age, chief complaint, and automated exclusions increased from 10.8% (277 of 2577) before PISCES implementation to 21.1% (2546 of 12 049) after PI-SCES implementation (P < .001) (monthly enrollment rates shown in Figure 1). Individual facility rates ranged from 5.7% to 31.3% in the pre-PISCES period and from 18.3% to 36.2% in the post-PISCES period.

Manual chart review revealed that only 21.8% (95% confidence interval [CI], 18.3%-25.3%) of the potentially eligible population identified by PISCES but not enrolled in RISTRA would likely have been eligible for the larger study. The adjusted enrollment rate increased from 35.6% of adjusted eligible patients (95% CI, 32.2%-39.1%) to 55.1% (95% CI, 53.7%-56.6%) following PISCES implementation. The pre-PISCES monthly adjusted rates ranged from 33.6% to 37.8% compared with 48.9% to 60.5% after PISCES im-

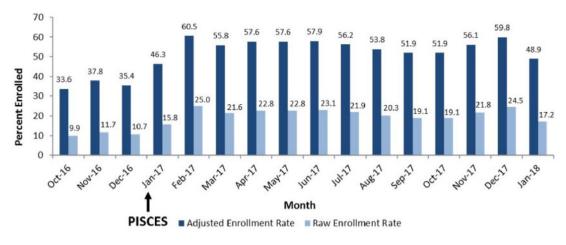


Figure 1. Enrollment and adjusted enrollment rates before and after Prospective Intelligence System for Clinical Emergency Services (PISCES) implementation.

plementation (Figure 1). Based on this chart review, we estimate that 61.7% of all PISCES alerts were for patients 5-20 years of age with abdominal pain who may have been ineligible for the larger study.

### DISCUSSION

Prospective enrollment of patients in research, especially in community ED settings, remains a challenge for many studies due to the fast-paced, demanding environment of the ED. The use of text message alerts in other aspects of health care, such as patient treatment reminders, has been shown to be effective.<sup>12–14</sup> However, the use of text message alerts for enhancing clinical trial enrollment has not been well studied.

The PISCES system developed in this study is a novel way to notify providers of potentially eligible study participants and its implementation nearly doubled the raw study enrollment rate, while the adjusted enrollment rate increased to over 50%. To assess whether there were any significant temporal changes in the rate of actually eligible patients in the unenrolled population, we conducted an audit in February 2019 that demonstrated a stable proportion compared with the reviews in 2016.

One of the key benefits of PISCES is its automated efficiency. Other studies have used notification systems that page a member of the research team, who then must call the treating provider regarding a potential study candidate.<sup>2</sup> The automated mechanisms of the PISCES system allows for immediate notification of providers upon patient assignment (median 8 minutes) and eliminates the need for research staff to be on duty—allowing alerts to be sent 24 hours a day.

Additionally, the system is scalable and modifiable to accommodate multiple large-scale projects and aims. In addition to the alerts being used in the pediatric abdominal pain study, PISCES alerts are also now being used in a KPNC study on acute coronary syndrome in the ED. As chest pain is one of the most common reasons for ED visits in the United States,<sup>15</sup> the use of an automated research alert system was beneficial. PISCES could also be used to alert providers of projects requiring consent or to inform them of shared decisionmaking opportunities. Furthermore, our study team has recently enhanced the functionality of PISCES to send multiple alerts per study. For example, a white blood cell count is required for calculation of appendicitis risk in the pediatric abdominal pain study. PI-SCES alerts have now been developed to notify the physician when an eligible patient arrives to the ED, and also when the patient's white blood cell count is done, count resulted -directing the provider to return to RISTRA for clinical decision support. Notifying providers multiple times per study, and about multiple studies, would not be feasible on this scale if the notifications were not automated.

Another advantage of the PISCES system is that the alerts are brief and relatively unobtrusive, minimizing impact on provider workflow. The short text message informs the provider of research opportunities, but its interruption of patient care is minimal, in contrast to some best practice alerts.<sup>16</sup> The use of text messages, rather than best practice alerts, differentiates the research alerts from others routinely seen during the shift, helping to prevent alert fatigue. Eventually, if the number of studies using PISCES alerts continues to increase, we plan to develop further notification options to prevent text message alert fatigue, such as notifying providers when they are assigned to a potentially eligible patient only once every 24 hours for each study.

A final advantage of the PISCES alert system is the ability to easily modify the text message language. Because this notification system was built for research purposes, it has the capability to be easily adapted to meet study needs. PISCES can send different text alerts based on patient characteristics (eg, chief complaint of abdominal pain vs chest pain) for multiple studies, include room numbers, and change as a research study progresses.

#### Limitations

There are a few limitations to both PISCES implementation and the enrollment study. First, maintaining an updated list of phone numbers can be challenging. We are not notified when new physicians receive iPhones or when physicians change numbers. As a result, continued maintenance is necessary, and some physicians did not receive alerts until notifying the research team of their new phone number. Additionally, the PISCES system depends on providers carrying their phones during a shift. In KPNC EDs, providers are incentivized to do so by other clinical benefits, including the ability to take clinical images at the bedside. Technical issues with the PISCES servers can result in delayed or missed PISCES alerts, although this is infrequent. The effect of substantial expansion of PISCES on EHR performance has also not been determined. Furthermore, while there is a potential for alert fatigue,<sup>16</sup> we hope to develop notification options to mitigate this issue, as mentioned previously. Also, while this study was feasible within the KPNC integrated healthcare system, its generalizability may be limited by the infrastructure available at other facilities.

## CONCLUSION

PISCES, a text-alert system for research enrollment in community EDs, successfully utilized EHR web services to identify potential study participants and notify ED providers via automated text message alerts. The use of PISCES significantly increased the enrollment rate of the prospective pragmatic trial and expanded the reach of the research staff. This study demonstrates the value of using text message alerts to emergency physicians to assist in prospective research enrollment in the ED.

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## **AUTHOR CONTRIBUTIONS**

ASR, MER, EOK, ABK, DRV, and DWB obtained research funding. LES, EMW, DRV, and DWB conceptualized and designed the study. ASR, UKC, LB, DRV, and DWB developed the PISCES system. EMW performed the programming and analysis. LES drafted the initial manuscript. EMW, ASR, UKC, LB, MER, EOK, ABK, DRV, and DWB critically reviewed the manuscript for important intellectual content. DWB oversaw the study as a whole. All authors approved the final manuscript as submitted.

## **CONFLICT OF INTEREST STATEMENT**

None declared.

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