The Use of Non-Interruptive Alerts for Improving the Use of Clinical Decision Rules in the Emergency Department: A Cluster Randomized Controlled Trial

Principal Investigator:
Keaton Morgan, MD[1,2,3]

Other Investigators:
Kensaku Kawamoto, MD, PhD, MHS[1,2]
Devin Horton, MD[2,4]
Polina V. Kukhareva, PhD, MPH, MS[1,2]
Troy Madsen, MD[3]
Phillip B. Warner, MS[1,2]

Institutional affiliations:
[1] – Department of Biomedical Informatics, University of Utah, Salt Lake City, Utah, USA
[2] – University of Utah Health, Salt Lake City, Utah, USA
[3] - Department of Surgery, University of Utah, Salt Lake City, Utah, USA
[4] – Department of Internal Medicine, University of Utah, Salt Lake City, Utah, USA

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I. BACKGROUND AND SIGNIFICANCE

The increased use of computed tomography (CT) imaging studies in the acute care setting has been a growing concern in recent decades, with overall use of CT increasing 330% from 1996 to 2007.[1] This trend has been identified as a key area of improvement in delivering high quality, low cost care and is an area of active research and public health focus.[2] One suggested method for addressing the issue is the use of validated clinical decision rules that risk stratify patients and provide evidence-based guidance on diagnostic imaging for a variety of conditions in the acute care setting. The American College of Emergency Physicians (ACEP), for example, has advocated the use of several of these rules in best practice clinical guidelines[3] and their Choosing Wisely recommendations.[2]

Despite these efforts, the adoption rates of clinical decision rules in acute care is low. Buchanan et al.,[4] for example, performed a study at the University of Utah from 2010-2015 that demonstrated that over 25% of patients had diagnostic testing for pulmonary embolism even though it was not recommended by clinical decision rules. Similar results have been found at other institutions,[5,6] with an estimated 33% of CT scans performed for suspected pulmonary being potentially avoidable, if clinical decision rules were universally adopted.[6]

There is some evidence that clinical decision support (CDS) can be used to improve the utilization rates of clinical decision rules,[7–9] but results from these studies are mixed and there is a great need for more high quality studies on the subject.[10–12] Wang et al.,[13] for example, performed a systematic review and meta-analysis on the impact of pulmonary embolism decision rules on CT use and yield. Out of eight total studies included, there was only one randomized controlled trial and only one of the seven observation studies was rated as high quality. Overall, the authors concluded that implementation of the Wells' Criteria for Pulmonary Embolism through CDS was associated with a modest increase in CT angiography diagnostic yield but there was "a lack of cluster-randomization trials to confirm efficacy of clinical decision rules for pulmonary embolism."[13]

There is also a need for studying novel CDS delivery methods for the recommendation of decision rules. An overwhelming majority of the published studies utilize pop-up alerts,[7] forced data entry at order placement[13] or a combination of the two.[11] There is evidence, however, that these CDS delivery methods may not be optimal. Westafer et al.,[14] for example, performed a qualitative study looking at provider reported barriers to applying clinical decision rules for pulmonary embolism. Three important barriers they identified were 1) lack of knowledge of rule application 2) timing of the CDS (i.e. too late in the workflow) and 3) alert fatigue. There is a need for implementing and studying CDS methods that address these barriers.

In this study, we plan to evaluate the impact of non-interruptive alerts on the use of clinical decision rules in the emergency department. Providers will be randomly split into an intervention and control groups. The intervention will be patient-specific, non-interruptive alerts suggesting the use of one or more clinical decision rules plus listing the suggested clinical decision rules on the default screen of an EHR-integrated medical reference tool (MDCalc Connect). The alerts will be Epic Storyboard Best Practice Advisory alerts and will include a link for launching the MDCalc Connect app from the alert.

This intervention represents a novel CDS approach that effectively addresses the three aforementioned barriers to clinical decision rule application (lack of knowledge, CDS timing and alert fatigue). In addition, this study will add a randomized controlled trial to an important area of research currently lacking high quality clinical trials.

II. STUDY OBJECTIVE(S); INCLUDING SPECIFIC AIMS AND/OR HYPOTHESES

This study is an extension of a planned quality improvement project that aims to promote standard of care by increasing the use of evidence-based clinical decision rules amongst emergency medicine providers in the University of Utah Emergency Department. Patient-specific information from the EHR will be used to recommend the use of relevant clinical decision rules to emergency medicine providers at the point-of-care. These recommendations will be in the form of non-interruptive alerts with one-click access to the suggested decision rules through the MDCalc Connect EHR add-on application.

To evaluate the efficacy of this quality improvement project, we will perform a cluster randomized controlled trial by splitting participating emergency medicine providers into intervention and control groups. A cluster randomized controlled trial (RCT) study design is necessary for two reasons: 1) there is a great need for RCTs on the study topic (as described in the Background and Significance section) and 2) three clinical decision rules included in the study are related to venous thromboembolic (VTE) disease, and it has been shown that COVID-19 infection increases the rates of VTE. Given the unpredictable and evolving nature of the COVID-19 pandemic, a before-after study design is a poor choice since the rates of VTE will likely be changing over time.

The specific aims are to determine 1) if the patient-specific non-interruptive alerts increase the use of clinical decision rules amongst emergency medicine providers and 2) if an increase in the use of clinical decision rules affects provider ordering habits. The ordering habits of interest will be tests relevant to the specific clinical decision rules included in the study and will be described in detail in the Data Analysis section of this protocol.

III. METHODS
A. Study Design
This study will be a single center, non-blinded, cluster randomized controlled trial. The study site will be the emergency department of a Level 1 trauma center and tertiary referral hospital. It has an annual patient volume of ~60,000 patient visits per year. All resident physicians and advanced practice providers practicing in the emergency department during the study period will be eligible for participation. Eligible participants will be split roughly evenly between intervention and control groups through a stratified random sampling technique. The intervention will be two-part: 1) a non-interruptive alert in the EHR recommending the use of one or more clinical decision rules and 2) a new default tab in the MDCalc Connect app that displays the same clinical decision rules recommended in the non-interruptive alert. Secondary analysis will include retrospective data up to one year prior to study initiation. This historical data will be used as an additional control.

B. Study Population

Provider Participation for RCT: The system will be implemented in the University of Utah Emergency Department. Up to 125 providers could be eligible for trial participation and will include all resident physicians and advanced practice clinicians (APCs) who practice in the role of emergency medicine provider at the study site during the study period. Providers will be split roughly evenly into intervention and control groups as part of a cluster randomized controlled trial. Only providers in the intervention group will receive the recommended decision rule alerts.

Provider participation for retrospective chart review: The same criteria as listed in the RCT description will be used to identify providers for retrospective chart review. This data will be used as a historical control and may include data up to 1 year prior to the RCT study start date. Up to 125 additional providers could meet inclusion criteria.

Patient participation for RCT: All patients evaluated in the University of Utah Emergency Department during the study period with a qualifying chief complaint and age 16 years or old will be eligible for participation in the trial. Up to 10,000 patients could be eligible for participation. The list of qualifying chief complaints was curated by a panel of clinical experts who have extensive experience with the decision rules included in the study. They selected chief complaints based off of likelihood of the chief complaint being relevant to the included clinical decision rules. For example, the Canadian CT Head Rule (which is used for patients with minor head trauma), includes chief complaints such as "fall", "head injury" and "motor vehicle collision."

Patient participation for retrospective chart review: The same criteria as described for the RCT will be used for patients in the retrospective chart review. This data will be used as a historical control and may include data up to 1 year prior to the RCT study start date. Up to 10,000 additional patients could be included in this portion of the study.

C. Assessment of Resources

This study is supported by clinical leadership, and the clinical decision rules selected for inclusion in the study are supported by hospital protocols, clinical leadership or both. We have estimated that a study period of four months will be the minimum duration required to reach statistical power of 0.80 or greater for the study's primary outcome (clinical decision rule usage).

D. Study Procedures

Cluster randomized trial: All eligible providers will be split into intervention and control groups prior to trial initiation using a randomized sampling technique. At study initiation, all providers in the intervention group will receive the clinical decision rule alerts + calculator suggestions in the MDCalc Connect app for all patients that meet inclusion criteria. Providers in the control group will not receive the alerts.

Intervention description: The intervention will contain two components: 1) a non-interruptive best practice advisory (BPA) in the Epic Storyboard and 2) a default suggested calculator tab in the MDCalc Connect app. Six clinical decision rules will be included: Canadian CT Head Rule,

Canadian C-spine Rule, HEART Score, PERC Rule, Wells' PE Criteria and Wells' DVT Criteria. Predefined criteria based on chief complaint, patient age and vital signs will be used to determine when a decision rule may be relevant in a patient encounter. When a patient meets all of the predefined criteria, the intervention will be triggered.

The non-interruptive alert will display in the Epic Storyboard column and will informs the user that a decision rule may be relevant to this patient encounter. For example, it may read "The PERC Rule may be relevant to this patient encounter." A hyperlink to the MDCalc application will be included in the alert. If the provider opens the MDCalc application, the recommended decision rule(s) will be displayed on the app home page. The function of the MDCalc app will otherwise be unaffected and the provider may use the app in its usual way.

The decision rules selected are supported by the American College of Emergency Physicians and the study site medical director leadership team and are considered standard of care. Use of the decision rules is expected to improve the quality of patient care and diagnostic yield of imaging studies and decrease the radiation exposure and cost of care for patients. The intervention alerts are not expected to impact any providers at the study site other than the providers participating in the study.

IV. DATA COLLECTION
Following the trial, data for analysis will be extracted from the University of Utah data warehouse, system logs and MDCalc Connnect application logs. This will include data for the RCT and the retrospective chart review, which will include identical inclusion criteria and outcomes as the RCT with a study period up to 1 year prior to RCT initiation. The outcome measures and the analysis approach are described in detail in the Data Analysis section.

V. DATA ANALYSIS
All primary and secondary outcomes will be compared between the intervention group and control group. Retrospective data up to one year prior to RCT initiation may be included as a historical control.

Alert-related outcomes: The primary outcome is the proportion of times a decision rule alert resulted in use of the decision rule by the provider in the MDCalc Connect app. This will be a composite calculation of all the individual clinical decision rules included in the study. The proportion of uses of individual clinical decision rules will serve as secondary outcomes and are listed below:

- Canadian CT Head Rule
- Canadian C-spine Rule
- HEART Score
- Wells' Criteria for Pulmonary Embolism
- PERC Rule for Pulmonary Embolism
- Wells' Criteria for DVT

We plan to include additional alert-related secondary outcomes such as app usage measures from the MDCalc Connect app logs (e.g. total app usages across the institution, total app usages for providers participating in the study, etc.). The same app usage measures from one year prior to the study period will also be analyzed as historical controls.

Process outcomes: The following process measures related to the decision rules will be included as secondary outcomes to analyze if/how the alerts and decision rule use affected provider test ordering habits.

1. Advanced imaging studies: Number of advanced imaging studies ordered that are relevant to decision rules included in the study. Specific advanced imaging studies will include: CTA chest w/ IV contrast, CT chest w/ contrast pulmonary arteries for pulmonary embolism, Head CT without IV contrast, CT C-spine without IV contrast and lower extremity duplex venous scans.
2. Laboratory tests: Number of lab tests completed relevant to the decision rules alerts. Specific lab tests will include: d-dimer and troponin.

Patient outcomes: The following patient outcomes will be included as secondary outcomes to analyze if/how the decision rule alerts affected clinical care:
- 30-day emergency department bounceback rates (i.e. a return ED visit within 30 days)
- Admission rates

Statistical power:

To estimate statistical power, we developed a simulation in R. We made the following assumptions for these calculations: 1) the number of eligible providers and patients will be ~50 and ~4000 (respectively) in a 4-month study period 2) the MDCalc Connect app use rate will increase from a baseline of 5% to 20% with the decision rule alert intervention and 3) the intra-class correlation coefficient (ICC) is 0.3. The ICC estimate was based off of published literature on the subject.[15] All the estimated statistical powers were calculated based on two-sided t-tests with a significance level of alpha = 0.05. With a 4-month study period, we estimate more than 82% power to detect a difference between the intervention and control groups for the primary outcome (calculator usage).

VI. DATA AND SAFETY MONITORING PLAN (if applicable)
Not applicable.

VII. STUDY LIMITATIONS
The primary limitation of this study is that supervising ("attending") physicians are not included in the randomization. Due to the staffing design at the study site, it was impossible to design a randomized controlled trial that included all providers (attendings, residents and ACPs). As such, attending physicians were excluded. Given that decisions are typically made jointly between the

attending and junior team member (resident or APC), we suspect this may impact the results of this study.

VIII. ETHICAL CONSIDERATIONS
Informed consent for participating providers and patients has been waived by the University of Utah IRB Committee. The risks for this study are considered no more than minimal. Benefits include: improved quality of patient care, improved diagnostic yield of imaging studies and decreased the radiation exposure and cost of care for patients. There will be no financial costs to study participants and no compensation will be provided.

IX. PLANS FOR DISSEMINATION OF FINDINGS
Findings will be submitted to a peer-reviewed journal upon study completion.

X. REFERENCES

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XI. Appendices
A. List if qualifying chief complaints:

Canadian CT Head
Fall
Motor Vehicle Accident
Motor Vehicle Crash
Motorcycle Crash
Motorcycle vs pedestrian
LOC (loss of consciousness)
Head Injury
Headache - Injury

Head injury - closed
Trauma
Canadian C-spine
Fall
Motor Vehicle Accident
Motor Vehicle Crash
Motorcycle Crash
Motorcycle vs pedestrian
Neck pain - injury
Neck injury
Trauma
HEART Score
Chest Pain
Chest pressure
Shortness of Breath
Breathing Problems
Difficulty breathing
Wells' PE Crietria and PERC Rule
Chest Pain
Shortness of Breath
Breathing Problems
Difficulty breathing
Hypoxemia
Hemoptysis
Wells' DVT Criteria
Leg Pain
Deep Vein Thrombosis
Leg Swelling
Swelling, Lower Extremity
Leg Pain - Other