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Formative assessment and design of a complex clinical decision support tool for pulmonary embolism

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Abstract

Electronic health record (EHR)-based clinical decision support (CDS) tools are rolled out with the urgency to meet federal requirements without time for usability testing and refinement of the user interface. As part of a larger project to design, develop and integrate a pulmonary embolism CDS tool for emergency physicians, we conducted a formative assessment to determine providers' level of interest and input on designs and content. This was a study to conduct a formative assessment of emergency medicine (EM) physicians that included focus groups and key informant interviews. The focus of this study was twofold, to determine the general attitude towards CDS tool integration and the ideal integration point into the clinical workflow. To accomplish this, we first approached EM physicians in a focus group, then, during key informant interviews, we presented workflow designs and gave a scenario to help the providers visualise how the CDS tool works. Participants were asked questions regarding the trigger location, trigger words, integration into their workflow, perceived utility and heuristic of the tool. Results from the participants' survey responses to trigger location, perceived utility and efficiency, indicated that the providers felt the tool would be more of a hindrance than an aid. However, some providers commented that they had not had exposure to CDS tools but had used online calculators, and thought the tools would be helpful at the point-of-care if integrated into the EHR. Furthermore, there was a preference for an order entry wireframe. This study highlights several factors to consider when designing CDS tools: (1) formative assessment of EHR functionality and clinical environment workflow, (2) focus groups and key informative interviews to incorporate providers' perceptions of CDS and workflow integration and/or (3) the demonstration of proposed workflows through wireframes to help providers visualise design concepts.

Background

Emergency departments (EDs) across the nation are backed-up with long lines of patients. Patients with low-risk pulmonary embolism (PE) are waiting for unnecessary CT scans while high-risk patients, in need of urgent diagnosis, wait in the same long line. PE patient morbidity and mortality have improved and mortality rates dropped from 30% to between 2–10% due to timely diagnosis, triage and treatment of both, high-risk and low-risk patients.[1 2] However, since PE is a high-risk disease and can be difficult to diagnose, providers often overestimate patient risk and order unnecessary diagnostic tests.

The work up for PE typically includes physical examination, personal history, D-dimer assays and imaging tests.[3] The less risky and costly D-dimer tests have high sensitivity and negative predictive power among lower risk patients; nonetheless, physicians will often order the more complex lower extremity compression ultrasound (US) or CT pulmonary angiograms scans in these lower risk patients to rule out a PE diagnosis.[4–6] As a result, this has contributed to radiation dose rates, which have increased by a factor of 7.1 from 1980 to 2006.[7] Furthermore, these tests are more labour intensive and expensive for patients. Studies show that 80–90% of PE work ups are negative and costs per case diagnosed are unduly high for the patient.[8 9]

Thus, when considering a diagnosis of PE, a risk/benefit analysis for diagnostic testing must take place; clinical decision support (CDS) tools are helpful in this risk/benefit analysis. CDS is defined as anything that directly aids providers in clinical decision-making for individual patients.[10] Clinical prediction rules (CPRs) quantify the roles of history, physical examination and laboratory results in a patient's diagnosis, prognosis and likely response to treatment.[11] CPRs are point-of-care tools that can produce tailored risk assessments for each patient. Clinicians will use CPRs when decision-making is complex and the clinical stakes are high, or where there are opportunities to achieve cost savings without compromising patient care, making the risk/benefit analysis for PE a perfect application.[11]

A clinical decision support system (CDSS) is a computerised CDS tool that is frequently integrated into a clinical information system, such as an electronic health record (EHR). The CDSS incorporates individual patient data, a rules engine and a medical knowledge base, to produce a patient-specific assessment or recommendation of a management plan.[12 13] The most effective CDSSs are backed by a well-validated evidence-based rules engine and rigorous research.[14] Studies have shown that CDSSs can reduce prescribing of brand name antibiotics;[15] improve lipid management in patients with renal transplant;[16] improve compliance with guidelines for treating HIV;[17–19] and reduce ordering of tests when costs were displayed;[20] they also have age-specific alerts that have reduced inappropriate prescribing in the elderly. With the widespread adoption of the EHR under the federal incentive programme, Meaningful Use, there is a unique opportunity to improve adoption of CPRs by integrating them into a CDSS. If carefully designed and smoothly integrated into the EHR platforms, CDSS tools have proven to have an impact on reducing overutilisation of healthcare resources (tests and medication orders).[14 21–23]

A PE CPR, the Wells criteria, has been derived and validated in numerous settings. In fact, the Wells rule

for diagnosing PE is the most extensively validated CPR in the field of thrombosis. The Wells criteria consider several factors based on history and physical examination to estimate the patient's pretest probability of PE (table 1). Using these characteristics, the Wells CPR stratifies the patient's pretest probability of PE as low, moderate or high. This has the potential to rule out 70–80% of patients without further testing.[25 26] However, the branching logic of the Wells CPR makes it challenging to apply reliably at the point-of-care[3]—a challenge that EHRs are well positioned to address. In fact, the most recent clinical guidelines of the American College of Emergency Physicians highlighted the potential for EHRs to address this pressing problem, calling for "future studies investigating the use of computer support aids in facilitating pretest probability (PE) assessment".[27]

But there yet continue to be shortfalls in the PE CDS integration into the EHR. Penaloza *et al*[28] found that the majority of residents in the ED did not use the PE and deep vein thrombosis (DVT) Wells rule appropriately and misdiagnosed DVT. But with appropriate CDS implementation, Drescher *et al* (2009) found that use of an electronic CPR for the evaluation of suspected PE in the ED was associated with an improved yield of positive CTs. However, the tool was poorly accepted by physicians, with utilisation rates of only 27%, and the system was later removed from the EHR because of this clinician resistance.[29] In order to implement a PE CDS tool effectively, it is necessary to assess the complexity of the ED workflow through formative assessment.

In our study, we developed a PE Wells criteria CDS tool using a user-centred design method. Using the research team's previous experience in creating CDS tools, we applied the same principles to the ED in order to develop the PE CDS tool. As part of a larger project to design, develop and integrate a PE CDS tool for emergency physicians, we conducted a formative assessment survey to determine providers' level of interest. As stated previously, literature shows that attempts to roll out a PE CDS tool showed poor adoption and compliance with the tool. With our approach, we hypothesised that an increase in adoption will be achieved by incorporation of feedback from front-line physicians.

Table 1 Wells CPR for PE[3 8 24]

Clinical characteristic of PE	Score
Clinical signs and symptoms of DVT (minimum of leg swelling and pain with palpation of the deep veins)	3
PE as or more likely than an alternative diagnosis	3
Heart rate greater than 100	1.5
Immobilisation in the past 4 days or surgery in the previous 4 weeks	1.5
Previous DVT/PE	1.5
Haemoptysis	1
Malignancy (in treatment, treated in the past 6 months, or palliative)	1

PE probability: <2 is low, 2–6 is moderate, >6 is high.
CPR, clinical prediction rule; DVT, deep vein thrombosis; PE, pulmonary embolism.

Methods

The project took place at a tertiary academic institution between 2013 and 2014. The design and development of the PE CPR tool involved a multidisciplinary team of key stakeholders in internal and emergency medicine (EM), informaticists and quality officers. Formative assessment activities typically require 4–5 participants with an emphasis on iterative phases of feedback, and this allows a practitioner to discover 80% of a product's usability problems.[30] Using user centred and adaptive principals to web and health information technology design, we developed the PE tool through three phases: (1) focus groups to gain feedback on documented workflow and compliance barriers, (2) key informant interviews on wireframes of the tool and (3) usability testing of the initial prototype, which is discussed in a separate article.[31]

Focus group: discussion of barriers to workflow

The initial focus group was conducted with a few members of the study team and EM physicians. A detailed email invitation for a focus group discussion was sent to the research administrator in the ED to help gather a small group of providers with roughly equal distribution of attendings and residents. Interested participants, including three EM attendings and two residents, were notified to the project coordinator. One focus group session was conducted in the ED and the entire session lasted 1 hour. Study members present included the principal investigator and two project coordinators. The discussion was facilitated by the principal study investigator, who explained the purpose and format of the discussion at the beginning of the session. The project coordinators hand wrote notes and observations from the providers and compared notes to compile into one document, which was later typed up. General themes of the focus group included usefulness of a CDS tool, flow of the tool and general feedback on the Wells PE CPR. Questions were formulated by the aforementioned key stakeholders and are summarised in the Results section.

Observation of current workflow: where are the handoffs and human computer interaction?

In addition, the study team observed the clinical workflow in the ED and etched out maps to imitate a patient encounter with a possible pulmonary embolus diagnosis. The diagram showed the patient's path through the emergency room from the triage nurse assessment until the emergency physician's assessment and orders (figure 1).

Key informant interviews on wireframes: ideal trigger location

The next phase was to draft the different workflow wireframes, based on the feedback from the focus groups, to gather feedback from providers. In approaching the design of a PE CDS tool, we found a unique set of workflow limitations and opportunities that apply specifically to EM physicians. For example, the physician workflow can vary widely for the same diagnosis. A patient may initially have classic presenting symptoms for a PE (leg swelling, shortness of breath, malignancy), which would

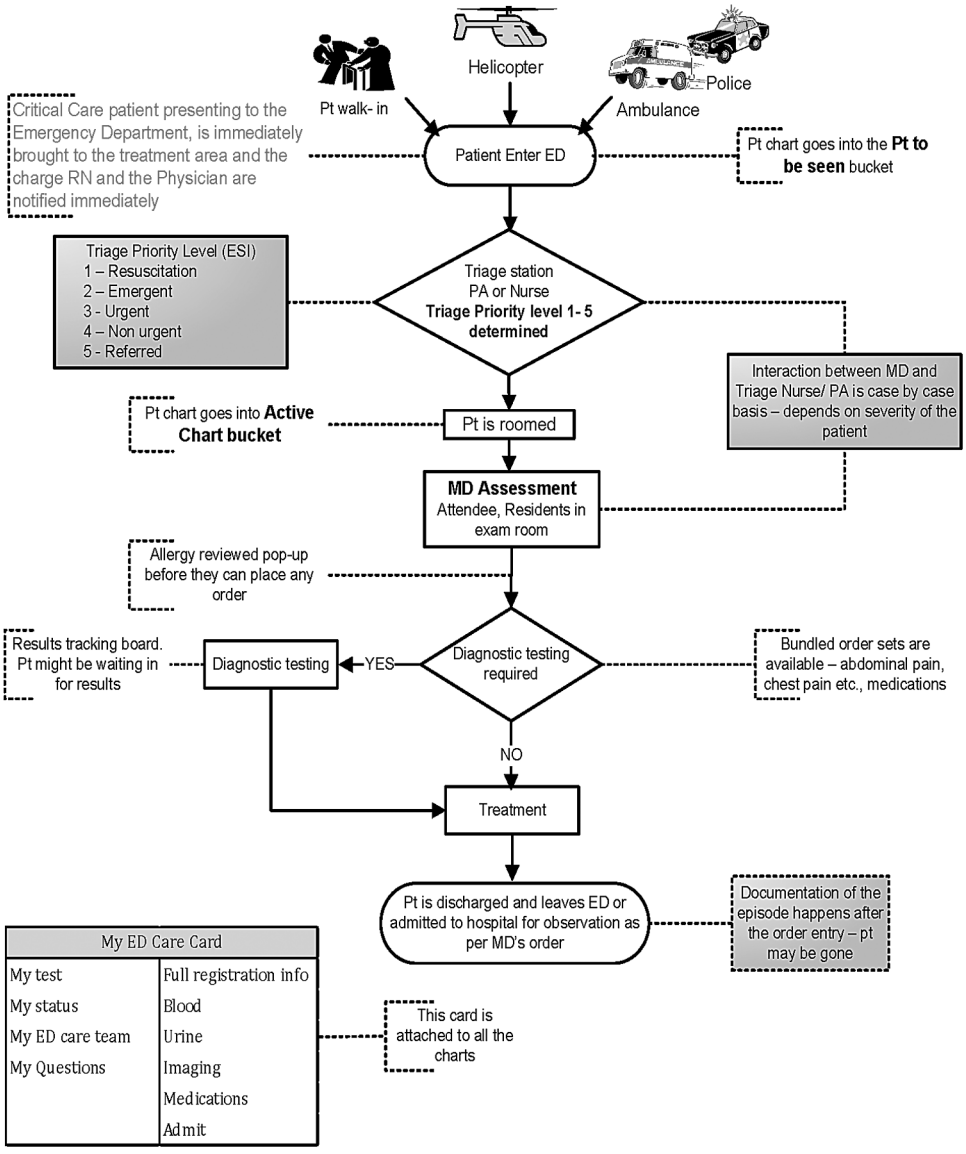

Figure 1 ED workflow (ED, emergency department; ESI, emergency severity index; PA, physician assistant; Pt, patient; RN, registered nurse).

make the triage nurse an appropriate sentinel for triggering a tool (the nurse would alert the physician through the EHR to fill out the checklist when seeing the patient). Alternatively, the patient's presentation may initially be more subtle, with the first clinical suspicion of PE not arising until well after the patient has been examined by the physician, or after initial lab tests have been resulted. In this scenario, one could envision triggering the tool while the physician was entering the history and physical examination of the patient into the EHR. Therefore, we designed the first wireframe where the triage nurse would prefill a portion of the tool and alert the ED physician based on his/her initial assessment (figure 2). The second wireframe would trigger the Well's criteria to pop up when the physician was ordering a PE-related test including CT angiogram, Doppler US of the lower extremities and ventilation/perfusion (V/Q) scan (figure 3).

A survey was performed with key informant interviews to establish the best place to have the CDS trigger within the EHR. The providers in the ED were contacted via e-mail with help from departmental research administrators. The sample size had similar considerations as in the focus group, which was an equal distribution of attendings and residents; interested participants included five EM providers. Providers were referred to as medical attendings and residents; inclusion criteria were providers at the selected clinical practice site, full time employees and attendings or residents. Excluded from the study were providers who were not a part of the clinical practice site, part time providers and medical students.

The research team presented the two PE CDS wireframe designs to emergency attending physicians and residents, and gave a clinical scenario to help them visualise how the proposed CDS tool would work (proceed with test, order additional test, or consider alternative diagnosis). Participants were interviewed individually and asked questions regarding the trigger location, trigger words, integration into their workflow, perceived utility and heuristic character of the tool (length of time,

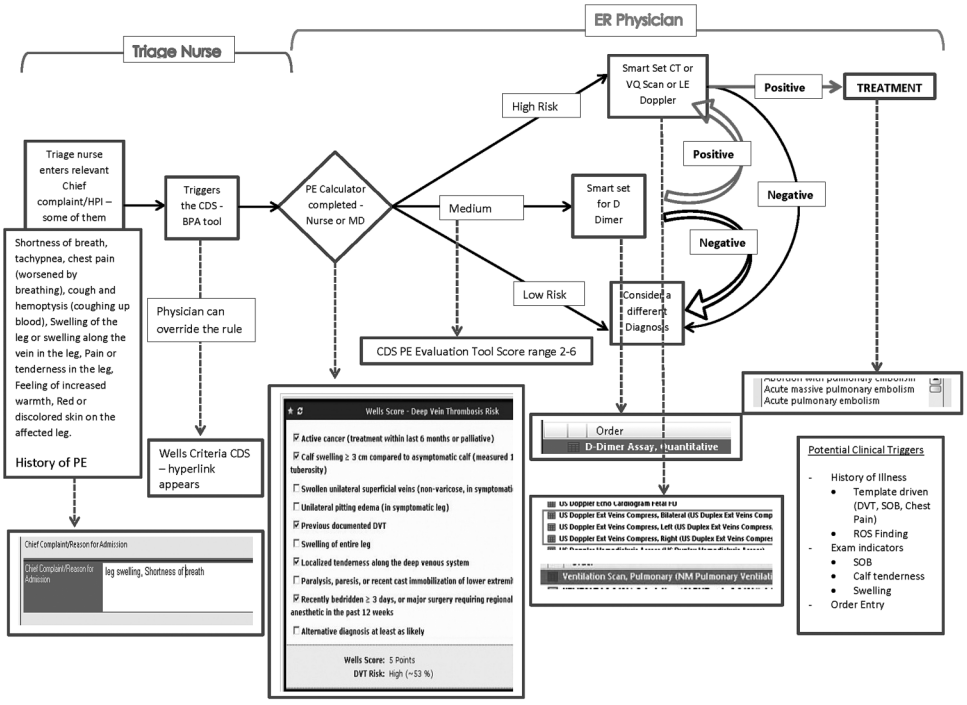

Figure 2 PE workflow when Triage Assessment Triggers Rule (BPA, best practice alert; CDS, clinical decision support; DVT, deep vein thrombosis; ER, emergency room; HPI, history of present illness; LE, lower extremity; NM, nuclear medicine; PE, pulmonary embolism; ROS, review of systems; SOB, shortness of breath; US, ultrasound; VQ, ventilation–perfusion).

number of display boxes, etc). Quantitative data were analysed with descriptive statistics (table 2) and qualitative data were thematically grouped.

Results

Focus groups: discussion of barriers to workflow

Two main questions were addressed in the first focus group session, the usefulness of the tool in general and the ideal integration point for the tool. Regarding the usefulness of the tool, there was an overall positive consensus that an integrated CPR for PE would be useful in lowering CT scans and the rule would help in justification of ordering the scans. The following are examples of respondent feedback: "an iCPR would be useful in lowering CT scan rates", "would want a work around for the tool", "would be helpful in justifying CT scan orders", "would like to have a medication smartest to increase the usefulness of the tool," and "need a simple tool that is easily adaptable".

Providers stated that the tool would be most useful if it were integrated into their ordering workflow, as done in other similar CDS tools; integration into previously existing workflows was supported and well received. Specific responses regarding the integration of the tool into the current workflow were "the tool would be most helpful at ordering of the film/CT scan", "ED had a chest pain protocol and workflow mapped out. This tool could use a similar workflow". The consensus of EM physicians said that an integrated CPR for PE would be useful in lowering CT scans and the rule would help in justification of the ordering of the scans. The providers commented that they want the ability to work around the tool. Additional elements of usefulness would be a medication smart set.

The physicians were open to integration of the tool and agreed that the trigger of the tool would be best at order entry for imaging and CT scan because they are always worried about having a high risk patient with PE and overordering studies. Similar protocols for chest pain in the ED were developed and it was found that workflow mapping helped with the assessment. The most important factor in adoption of the tool by providers was to integrate a simplified tool.

Key informant interviews on wireframes: ideal trigger location

There were varying results in participants' survey responses to trigger location, perceived utility and efficiency. All of the providers noted that they had not been exposed to CDS tools. However, some commented that, while they have not had exposure to CDS tools, they used online calculators and thought the tools would be helpful at the point-of-care if integrated into the EHR. Providers' survey responses indicated a preference for an order entry workflow wireframe over nurse triage trigger. Qualitative feedback after presenting the two workflow wireframes generated a discussion of the perceived negative impact of the tool on clinical outcomes.

Respondents thought the tool was easy to use and not complex (table 2). However, there was concern that it would not integrate well into an emergency room workflow, which is evident by the fact that 60% of respondents disagreed with the statement, "I think that I would like to use this tool frequently".

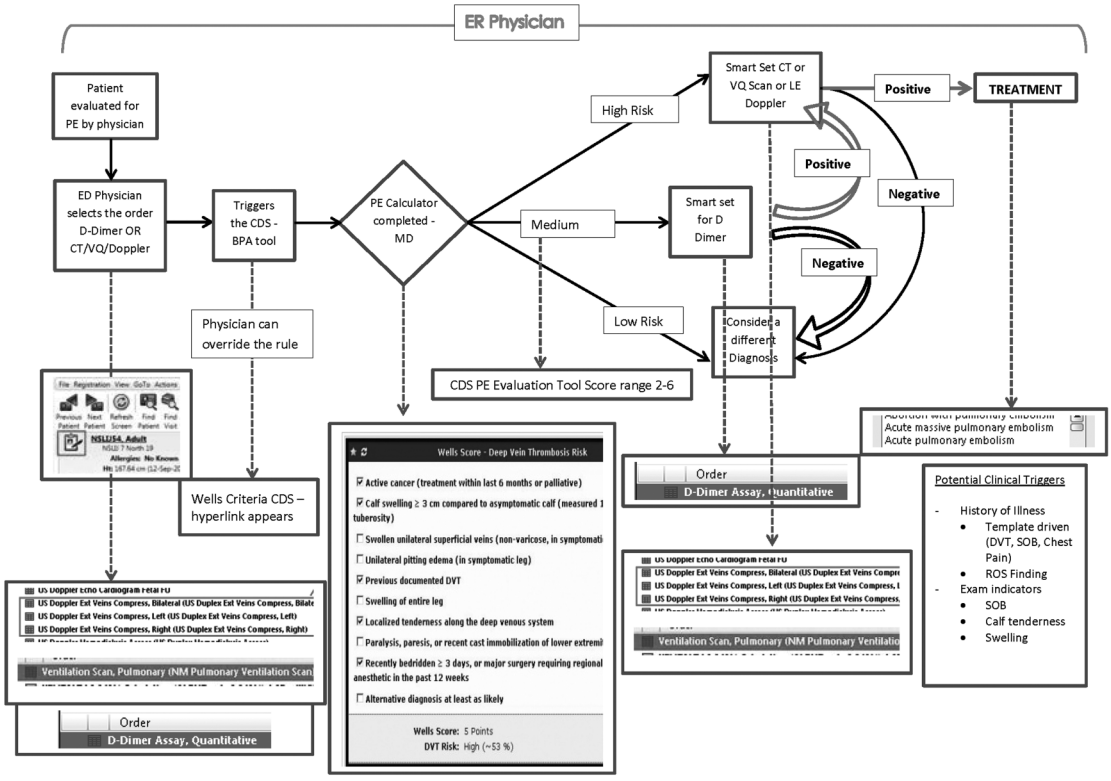

Figure 3 PE Workflow when Order Entry Triggers Rule (CDS, clinical decision support; DVT, deep vein thrombosis; ED, emergency department; ER, emergency room; PE, pulmonary embolism; US, ultrasound; VQ, ventilation–perfusion).

Participants were asked about Healthcare Information and Management Systems Society (HIMSS) measures, which included effectiveness of the tool in PE decision-making rather than their own clinical judgement. One respondent said, "If integrated, then yes, the PE tool would save on looking up EBM". Another respondent agreed that, "it [the tool] would give an objective percent level of risk given evidenced based medicine". In terms of efficiency and how it would speed up the process, participants remarked, "[it] decreases thought and consideration" and "the tool would speed up the process by providing the suggestion early on".

Discussion

We conducted a formative assessment on the preparedness of EM providers to incorporate CDS tools and received positive responses. Lessons learned include testing a PE rule that will be effective by implementing multiple ways of CDS development methodology including focus groups, formative assessment and multiple rounds of iterative edits to the prototype. Using iterative formative assessments and development paired with provider training, the CDS tool leverages user-centred design principles to overcome pervasive underutilisation of evidence-based medicine (EBM) and supports evidence-based practice at the point-of-care. The

Table 2 Residents'/attendees' survey data

Satisfaction/user experience (we ask them to pick their most favoured workflow and answer the questions to that one)	1: Strongly disagree and 5: strongly agree (% response rate)					
	1	2	3	4	5	Average
I think that I would like to use this tool frequently	20	40	20	20	0	2.4
I found the tool design unnecessarily complex	20	40	40	0	0	2.2
I think the tool will be easy to use	0	0	40	60	0	3.6
I think that I would need the support of a technical person to be able to use this tool	40	60	0	0	0	1.6
I found the various functions in this tool were well integrated	0	0	40	60	0	3.6
I thought there was too much inconsistency in this tool	20	40	40	0	0	2.2
I would imagine that most people would learn to use this tool very quickly	0	20	0	40	40	3.8
I found the tool's workflow very cumbersome to use	20	20	60	0	0	2.4
I would feel very confident using the workflow	0	0	40	40	20	3.8
I needed to learn a lot of things before I could get going with this system	40	40	20	0	0	1.8

ongoing trial will determine if this collaborative process will lead to higher rates of utilisation and EBM-guided use of testing in cases of PE.

This study highlights several factors to consider when conducting formative assessment of CDS tools: (1) focus groups around CDS awareness and integration can guide design development, (2) formative assessment with providers who have a strong knowledge of CDS tools may streamline development and/or (3) the demonstration of proposed workflow wireframes through a prototype to help providers better visualise design concepts.

There were a couple of limitations to the study. The user preferences may vary depending on institution, and willingness to complete the tool will depend on individual workflows and cultural norms. We had two independent coders, which might have introduced some bias to the results collected in the focus groups and qualitative key informant interviews. Providers participating in the study were mostly residents and attending physicians. We would like to incorporate triage nurses in the next assessment.

We used these preliminary data to conduct 'near-live' usability testing to simulate real-life ED workflow.[32] We are currently piloting the tool at one of our tertiary hospitals and tracking user acceptance and utilisation.

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