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# Human-centred design processes for clinical decision support: A pulmonary embolism case study

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ABSTRACT

*Background:* Clinical Decision Support Systems (CDSS) can make patient care more efficient, cost-effective, and guideline-concordant. Many are created by clinicians who understand the challenges, but may publish concepts before considering subtle but important design details. Human-Centred Design (HCD) approaches provide necessary methods ensuring solid CDSS design. This article highlights HCD approaches in a pulmonary embolism CDSS case study context.

*Methods:* This pulmonary embolism CDSS results from collaborative work between computer science, psychology, and medicine. HCD methods used include: evaluations of pre-clinical prototype recordings, iterative usability expert reviews with software refinement, formative usability testing, and (separately-published) clinical pilot study.

*Results:* HCD methods were instrumental in iteratively creating an easy to use and functionally-sound CDSS. Retrospective evaluations revealed that participants spent considerable time on items that were out of order from natural cognitive diagnostic workflows. Features missing between original and study version were noted, confusing interface elements reworked, and currently-active decision tree branches were visually emphasized. From iterative usability reviews, positioning of information within the decision tree was radically reworked, information separated into levels of support for different user groups, and supportive versus directive language issues addressed. Formative studies identified issues such as interface adjustments and hospital workflow integration.

*Conclusions:* Human-centred design approaches provide methods for integrating the skills and knowledge of many disciplines, illustrated by example in this pulmonary embolism CDSS creation. Advantages of leveraging many design guidelines as well as revealing new design considerations that would otherwise have remained hidden are described. The findings reported here support future CDSS design through HCD inclusion.

## 1. Introduction

Many clinical decision support systems (CDSS) exist to improve patient care. Improvements might include efficiency [1], cost effectiveness [2], or guideline-concordance [3,4] - the latter often yielding reduced inappropriate test orders [5] or patient outcomes, whether through reduced morbidity [6], mortality [7], or adverse events [8]. Many CDSS are developed and implemented by clinician champions with first-hand understanding of challenges in specific clinical domains. Some CDSS become successful and enjoy worldwide uptake.

Literature shows that successful CDSS implementations share specific features or considerations [9,10], and that careful design is necessary, as outlined in Bates' *Ten Commandments for Effective Clinical Decision Support* [11]. However, a clinician might enthusiastically publish their concepts without considering important design aspects or clear direction on details for effective CDSS design. Human-centred design (HCD) research/design methods and principles exist to ensure that a tool/product is easy to use, integrates into workflows, and is designed for target users at each development stage. HCD draws from well-established design principles in many disciplines (including usability [12], graphics [13], interface design [14], human factors & psychology [15]), and target users' context/experience. HCD thus

*Abbreviations:* HCD, human-centred design; CDSS, clinical decision support system; PE, pulmonary embolism; UT, usability testing

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creates a foundational methods ecosystem to ensure well-designed systems and experiences. Without application of HCD principles, the effectiveness of CDSS may be severely limited, not meet guidelines, or even cause more harm than good [16].

This article describes common HCD methods and case study focusing on a CDSS tool supporting pulmonary embolism diagnosis – an inherently challenging clinical area. We further provide HCD prescriptions that address Bates' *Commandments*. This article is relevant to any CDSS creation intending to be intuitive, evidence-based, and foundational for any clinical pathway.

## 2. Background

### 2.1. What is human-centred design?

The HCD approach is a collection of research/design methods to create usable tools and products, based on multi-sourced design principles. Table A1 outlines common HCD methods, each with strengths, weaknesses, and optimal usage. Fig. 1 connects different HCD methods to typical system design.

### 2.2. HCD in healthcare CDSS creation

Bates' *Ten Commandments for Effective Clinical Decision Support* provide a thorough CDSS design and deployment checklist, but lack practical guidance. HCD naturally complements those 'commandments', providing established design approaches. Table 1 illustrates the relationship between Bates' commandments and HCD.

Meanwhile, HCD is increasing in CDSS design. Examples include antibiotic prescribing [19], cardiovascular risk prevention [20], and HIV care pathways [21]. Many CDSS designers recognize HCD as essential, but authors mostly use limited approach(es) in isolation (Table 2). Our case study carefully applies and integrates *multiple* HCD methods to promote producing the best design possible.

### 2.3. Human-centred design for pulmonary embolism diagnosis

Pulmonary embolism (PE) is a blood clot in lung veins. This disease model is highly amenable to CDSS design given it's often ambiguous presentation [30], and the complex recommended PE diagnostic algorithms in the literature. Further, misdiagnosis is serious, with PE mortality rate (30–40 %) if diagnosis is missed [31], reducing to < 10% when treated [32]. Clinicians use different PE diagnosis prediction rules, including the Wells Score [33] and Pulmonary Embolism Rule Out Criteria (PERC) [34]. Fig. 2 shows how these prediction rules integrate with other PE diagnostic tests [35,36].

Common PE diagnostic tests include D-Dimer and computed tomography pulmonary angiogram (CTPA) diagnostic imaging test. D-Dimer is a non-invasive and relatively inexpensive blood test, but not specific for PE diagnosis. Further, D-Dimer can rule out PE for patients with low or moderate PE probability. CTPA is recommended for patients with high PE probability, is highly accurate, but involves dye contrast to reveal PE in the patient's scan, with potential side effects of both dye and radiation. Less commonly used are pulmonary ventilation/perfusion (VQ) scans, which can sometimes be used in place of CTPA [30].

Literature suggests some PE CDSS result in improved diagnostic outcomes [37,38], while others do not impact physician performance or patient outcomes [39,40]. Thus, it remains critical to consider different design elements to improve physician diagnostic performance, through determining system utility, understanding user needs and technical limitations, conducting ongoing evaluations, and demonstrating adoption [41]. In other words, a HCD approach is optimal if it integrates multiple methods to design successful diagnostic CDSS.

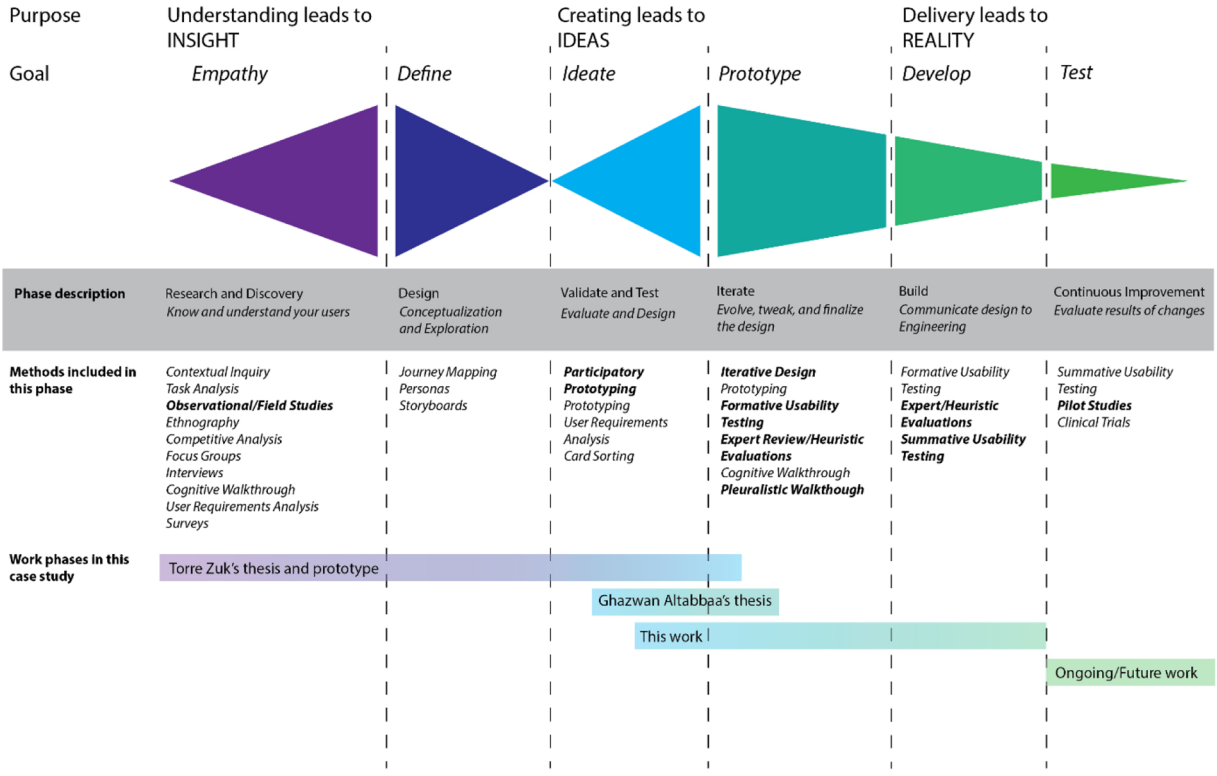


**Fig. 1.** Visual illustration of HCD flow with reference to the generally recognized "double diamond" of design [17]. Bolded methods were used in this case study and are covered in further detail. Timeline bars along the bottom illustrate approximately the phases of work described here and how they relate to the methods used.

**Table 1**
Bates et al.'s Commandments and How HCD relates.

| Bates' Commandment | Commandment Details | HCD Methods to Support |
|---|---|---|
| 1 Speed is Everything. | If decision support is wonderful but takes too long to appear, it will be useless. | Early-phase interviews and persona [18] development would very likely identify deal-breakers like this. |
| 2 Anticipate Needs and Deliver in Real Time. | Applications must anticipate clinician needs and bring information to clinicians at the time they need it. | Identification of these needs comes out in persona [18] development, journey maps – both which come from focus groups/ interviews and observations. |
| 3 Fit into the User's Workflow. | Success with alerts, guidelines, and algorithms depends substantially on integrating suggestions with practice. | Journey map development, based on focus group/interview and observational information, detail a user's workflow, ensuring that the CDSS will fit in. |
| 4 Little Things Can Make a Big Difference. | Usability matters – a lot. Developers must make it easy for a clinician to 'do the right thing'. | This comes directly from HCD, as usability testing is a key method used to uncover design issues. |
| 5 Recognize that Physicians Will Strongly Resist Stopping. | Physicians strongly resist suggestions not to carry out an action when an alternative is not offered. | Understanding the user is central to HCD, and these characteristics would come out in persona development. |
| 6 Changing Direction is Easier than Stopping. | Changing physician behaviour is especially effective when the issue […] is one the physician doesn't feel strongly about. | Persona development and understanding perceptions/priorities would help identify those elements. |
| 7 Simple Interventions Work Best. | If you cannot fit a guideline on a single screen, clinicians will not be happy about using it. Writers of paper-based guidelines do not have such constraints and tend to go on at some length. | We counter that simple design with carefully-applied interaction design principles (e.g., Shneiderman's *Golden Rules of Interface Design* [14]), is preferable to "everything on a single screen." |
| 8 Ask for Additional Information Only When You Really Need it. | To provide advanced decision support, one frequently needs data that are not already in the system and that only the physician can provide. […] the likelihood of success in implementing a computerized guideline is inversely proportional to the number of extra data elements needed. | Persona development and understanding the clinician's context, priorities, etc would help to identify this kind of issue well ahead of platform development. |
| 9 Monitor Impact, Get Feedback, and Respond. | If reminders are to be delivered, there should be a reasonable probability that they will be followed, although this can vary. For strongly "action-oriented" suggestions, we try to have clinicians respond positively more than 60 % of the time. | HCD approaches have iteration and constant course correction built in, directly mirroring this item. Also, strength of wording is a concept we identified during consults with physicians, and is commented on further in our discussion. |
| 10 Manage and Maintain Your Knowledge-based Systems. | Maintaining the knowledge within the system and managing the individual pieces of the system are critical to successful delivery of decision support. | Similar to item #9 – iteration and refinement are key features of HCD approaches. By building in necessary flexibility and ease of update into a CDSS, iteration on content can be facilitated with HCD. This item remains as this PE CDSS evolves with further iteration, pilot testing, and ongoing knowledge updates. |

## 3. Methods

This HCD approach was collaborative between computer science, psychology, and medicine. HCD methods used are shown in Table 3 (below). Earlier stages (including pre-clinical prototype evaluation) are published as graduate theses research [42–44] and are grayed-out.

This article focuses on steps beginning with recreating Zuk's prototype [42] for clinical use and study. The targets were to: (1) iteratively evaluate and refine the software conversion from academic prototype into a clinically-viable tool; (2) integrate the fully-developed tool in a clinical system; (3) study the tool's impact on patient care and health care delivery; (4) inform further tool iterations, and (5) support other CDSS designs. Method details follow Table 3.

### 3.1. Evaluations of the existing CDSS prototype

Before prototype re-development, Altabbaa's [44] prototype video recordings were further evaluated to understand user software interactions. Altabbaa's original focus was to evaluate relative effectiveness of a traditional didactic lecture on PE diagnosis with the prototype PE CDSS. The goal of re-evaluation was to identify usability issues study participants encountered while using the PE CDSS, as this establishes a baseline from which to plan further PE CDSS iteration. Usability heuristics [45] guided expert analysis, and usability/workflow issues were noted. Table 3 shows how subsequent steps informed further design recommendations.

### 3.2. Iterative tool re-development with integrated usability reviews

Internal Medicine and Emergency Department clinicians, medical students, and information visualization researchers were shown Zuk's prototype for ongoing iterative feedback and refinement. Re-development was conducted in collaboration with a University clinical tool development group [46] who specialize in integrating research objectives with clinical tool robustness.

### 3.3. Formative usability testing

We conducted formative usability testing (UT) with target user group representatives. Inclusion of UT complements ongoing usability reviews, as content matter experts (i.e., clinicians) are better equipped to address content and workflow details. The purpose was to qualitatively identify outstanding interface usability, clinical content, workflow, or technical issues.

These UT sessions included: (1) a brief pre-use interview with key demographic and previous PE diagnosis experience questions; (2) a 'first impressions' landing page and interface critique think-aloud (i.e., is the CDSS's utility and use clear?); (3) patient cases derived from Altabbaa's work (Table A2); and (4) a post-use interview gathering subjective feedback. Sessions were audio and video-recorded, complemented by written notes targeting usability matters [45]. Researchers reviewed session notes and recordings, listing issues. Initial headings were suggested, used, and refined as analysis progressed. Headings included issue areas: usability, clinical content, workflow, and technical. After consolidating repeat items, a ranked list of outstanding issues was created.

## 4. Results

Below we describe results from HCD steps that follow Zuk's and Altabbaa's theses. For previous results, we refer the reader to Zuk's and Altabbaa's theses [42–44].

**Table 2**
Examples of HCD methods used in CDSS design.

| | Field observations | Focus Groups & Interviews | Paper prototype or Iterative Design Evaluation | Usability testing or Expert Reviews | Simulation Studies (variation of Prototype evaluation) | Implement changes | Test/Evaluate tool, e.g., Pilot studies |
|---|---|---|---|---|---|---|---|
| Thursdky and Mahemoff - Antibiotic Prescriptions [19] | ✓ | | ✓ | | | ✓ | ✓ |
| Carroll, Marsden - Cardiovascular Risk Prevention [20] | | | | ✓ | | ✓ | |
| Catalani, Green – HIV Care Pathways [22] | ✓ | | | ✓ | | ✓ | ✓ |
| Khan, Sundas et al – Pulmonary Embolism [23] | ✓ | ✓ | ✓ | ✓ | | | |
| Drescher et al – Pulmonary Embolism [24] | | | | | | | ✓ |
| Raja et al – Pulmonary Embolism [25] | | | | | | | ✓ |
| Durieux et al – Venous Thromboembolism [26] | | | | | | | ✓ |
| Graham et al – Community Acquired Pneumonia, Neutropenic Fever [16] | | | | ✓ | | | |
| Jimenez et al – Pulmonary Embolism [27] | | | | | | | ✓ |
| Li et al – Primary Care CDSS [28] | | | ✓ | ✓ | ✓ | | |
| Hoonakker et al – PE Dx for ED [29] | ✓ | ✓ | ✓ | ✓ | | ✓ | |
| *This PE case study* | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

### 4.1. Evaluations of the CDSS prototype

Video recording re-analysis ($n$ = 15) provided important insights. Analyses included: (1) participant interaction feature tallies, and (2) qualitative recordings exploration, noting aspects causing participants difficulties or usability issues.

The session tutorial was not included in video recordings, thus tutorial-based tool exposure and guidance are unknown. The study tool version was intentionally simplified. Zuk's prototype features were tallied, showing no participants used:

- Wells score probability override
- Information tabs
- Probability viewer
- Likelihood Ratio (LR)-graph
- Natural frequency
- Population tool

Few participants mentioned risk probabilities, in vague terms before using the CDSS, or when considering test outcomes.

Most participants used the Wells Score to either: (1) answering questions in sequence, (2) answering questions as presented in sample cases, or (3) answering all questions except #2, considering it last. Most participants used decision tree steps, entering test results as they went. Some participants used the Wells Score, then either visually referenced the decision tree without further tool interaction, or chose their own assessment/treatment plan. A few issues were noted, specifically: (1) wording inconsistencies between decision tree ("normal"/"abnormal") versus tab-based test results ("positive"/"negative"). A few participants inadvertently moved decision tree elements, obscuring others.

Many participants (33 %) had considerable difficulty with Wells Score question two. A few verbalized one response, but entered oppositely. One (senior) physician needed researcher intervention:

> *P16: […] Alternative diagnosis is less likely than pulmonary embolism… uh, um. This is a confusing question […] I think I've got it wrong. She could have a pulmonary embolism, but she could also just have pleuritic pain from her Lupus. So, um, I guess I'll say that alternative diagnosis is…less likely. So I'll say, no? I don't know if I'm doing this wrong.*

This confusion around Wells question two is notable, as the answer completely changes diagnostic recommendations.

Three key design recommendations resulted:

(1) The tree should remain stationary, preventing accidental blocking (occlusion).
(2) Decision tree affordances (e.g., interactivity clues) might highlight the relationship between interface features.
(3) Decision tree use may improve with graying-out elements outside the current pathway.

### 4.2. Iterative tool re-development with integrated usability reviews

This resulted in design recommendations detailing key interactive elements to support CDSS use with informative but un-intrusive colour-blind-safe colour schemes. Key feedback included: (1) displaying tests rather than test results in the decision tree to highlight PE likelihood, (2) information separation into three levels to support multiple user group (i.e., emergency physicians, acute/community/rural physicians, and residents/medical students) needs. Finally, philosophical differences emerged, with some medical experts advocating for more directive/prescriptive approach with 'best practice' guideline compliance failure consequences. Others promoted supportive/transparent approaches leaving treatment plan decisions to the user.

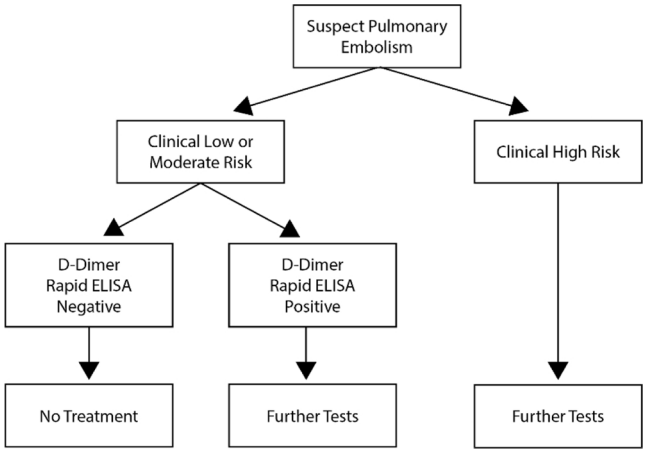


**Fig. 2.** PE clinical decision tree from Stein (2006), recreated with permission.

### 4.3. Formative usability testing

Six individuals, representing general physicians, thoracic surgeons, internal medicine specialists, and a nurse practitioner participated. Role experience ranged from four months to 25+ years, representing a wide vocation spectrum, experience, and expertise. All participants indicated current use of CDSS, including 'Up-to-Date'®, MDCalc©, tools within the electronic medical record (EMR), or paper-based tools. Figs. 3–5 show the revised tool.

Outstanding issues found under each pre-defined heading included: confusing interface elements, and potential clinical workflow conflicts. Table A3 (Appendix A) summarizes all issues collated.

Participants identified usability issues including confusing interface elements – some lacking clear actionable steps. Some participants expressed confusion about where to start – the "none of these exclusions apply" checkbox insufficiently drew user attention (Fig. 5). Several study participants were unsure if the "Previous Step" button was clickable, as it appeared non-functional gray. Some participants who disagreed with D-Dimer orders were unsure how to proceed.

For clinical content issues, most significant feedback was regarding workflow conflicts with the CTPE patient handout. Several identified that it spoke about CT risks *after* the test, thereby lacking value. Other study participants indicated that they would not provide a 'CT scan risks handout, instead discussing with the patient, as appropriate.

### 4.4. Current PE CDSS

Figs. 3–5 show the current tool. It guides clinicians from exclusions through Wells Score, PERC, D-Dimer, and Imaging (CTPA/VQ-Scan) with varying levels (i.e., two-second, two-minute, and reference information) of next-step recommendations throughout. This guidance is further supported with an interactive decision tree highlighting this patient's risk of PE at each diagnostic step.

## 5. Discussion

Building on previous HCD work, this article demonstrates the value and benefits of HCD approaches in creating CDSS through describing a PE tool design and development case study. Key HCD methods were summarized, with those used in this PE CDSS noted in Table A1.

Revelations into CDSS design were possible through HCD approaches used here that otherwise would likely have remained hidden and extend beyond what is found in literature, including: (1) accommodating the likely range of users through careful interface design, (2) distinguishing between supportive and directive language, (3) importance of phrasing and cognitive workflow integration, (4) criticality of a well-designed user interface (UI), and (5) CDSS scope considerations.

### 5.1. Likely tool users

HCD revealed a wide range of potential users with variable experience, knowledge, and support needs. This PE CDSS employs well-known, key interface design principles [14] of details-on-demand and overview-and-context, initially providing high-level information with details available through interaction. This also addresses Bates' seventh commandment by providing multiple levels of content depending on user information needs and time constraints.

This interface design detail attention is key to successful CDSS development, implementation, and evaluations, but is often missed. In many cases, a CDSS works for a specific user subset (e.g., ED physicians [23]) or specific tests (e.g., only the Wells score [24]), resulting in limited scope of use. This PE CDSS guides a variety of users in different practice settings from initial inclusion/exclusion criteria, through Wells, PERC, D-Dimer/VQ scans, and CTPA steps.

### 5.2. Directive vs. supportive guidance

This HCD approach also revealed key distinctions between supportive and directive language. Directive language (e.g., 'Proceed to a D-Dimer') may seem straight-forward to influence clinical decision making, and aligns with literature identifying it as key for successful CDS implementations [9]. In contrast, very few clinicians in this CDSS development appreciated their (sometimes considerable) expertise/experience ignored or overruled. Directed users may consequently ignore well-intentioned guidance. Instead, clinician participants (in this PE CDSS effort as well as other related projects) preferred credible, supporting information enriching their final decisions. This is noted in literature [10,25] but not mentioned or emphasized elsewhere [9,24]. In one article, distinction is made between instructing physician actions versus critiquing their decisions, allowing reconsideration of plans [26]. This PE CDSS design uses supportive instructive language and limited actionable options, but ultimately leaves adherence to the physician's discretion. This aligns with Bates' fifth commandment – "Recognize that Physicians will Strongly Resist Stopping" [11].

### 5.3. Phrasing and cognitive workflow integration

The original Wells score nicely assists clinicians to decide whether to pursue a PE diagnosis [33] and illustrates this issue. Questions are ordered by descending point values. HCD revealed this ordering as human-inefficient, as the second question contains a confusing double-negative – considering all symptoms together, applying clinical judgement to ultimately determine the final score and next diagnostic steps. UT prior to Wells dissemination may have revealed these cognitive issues. Fortunately, UT and other HCD methods are becoming necessary for clinically-viable CDSS development efforts [47]. The original Wells score exists throughout clinics, medical literature, and CDSS [23,24]. Meanwhile, the similar deep-vein thrombosis (DVT) Wells score tool relegates clinical judgement to the end, after all individual elements are completed [48] – as is the natural cognitive workflow. DVT items are grouped into "signs and symptoms of DVT, risk factors for DVT, and [*then*] potential alternate diagnosis" [49]. A lack of UT was noted in another PE CDSS tool as a possible cause of sub-par uptake [24]. There, authors reflected on the importance of integrating CDSS into existing workflows. Elsewhere, HCD played an integral role in PE CDSS development, where iterative focus groups and interviews provided feedback for early prototype re-development coupled with UT of an early design [23]. However, the original Wells score was used without mention of

**Table 3**
PE CDS tool development methods, results, and design implications summary (previous work grayed-out).

| Methodology | Goals/Purpose | Key Results | Design Implications |
|---|---|---|---|
| Observational field studies of existing practices and computer support with follow up questionnaire and contextual interviews | • To understand the target task (PE diagnosis) and cognitive steps involved | • The role and importance of uncertainty in evidence-based medicine (EBM) clinical decisions making<br>• The necessity to respect physician autonomy by providing CDSS that are supportive rather than directive<br>• A need for well-designed visualizations of uncertainty to support EBM clinical decision making | • Physicians are open to support but object to system suggestions that do not include fully-explained basis or were provided at the wrong moment<br>• Decision support tools should allow for easy modification of answers or final score to accommodate less than black-and-white parameters (e.g., blood pressure technically below 100 but considered high for this individual)<br>• Current and historical data points should be easily viewable to assist with clinical decision making<br>• The decision tree's presence appeared to instill confidence in less experienced user, and so might be useful as a teaching mechanism. |
| Participatory prototyping | • To engage users in iterative prototype reviews, discussions, and feedback sessions in order to translate ideas, workflows, and visual elements into visible artefacts (the PE CDS tool) (Nielsen, 1993) | • Low-, and later high-fidelity PE tool prototypes were created (three iterations in total) | • Interface and clinical content refinements to better support target user group needs |

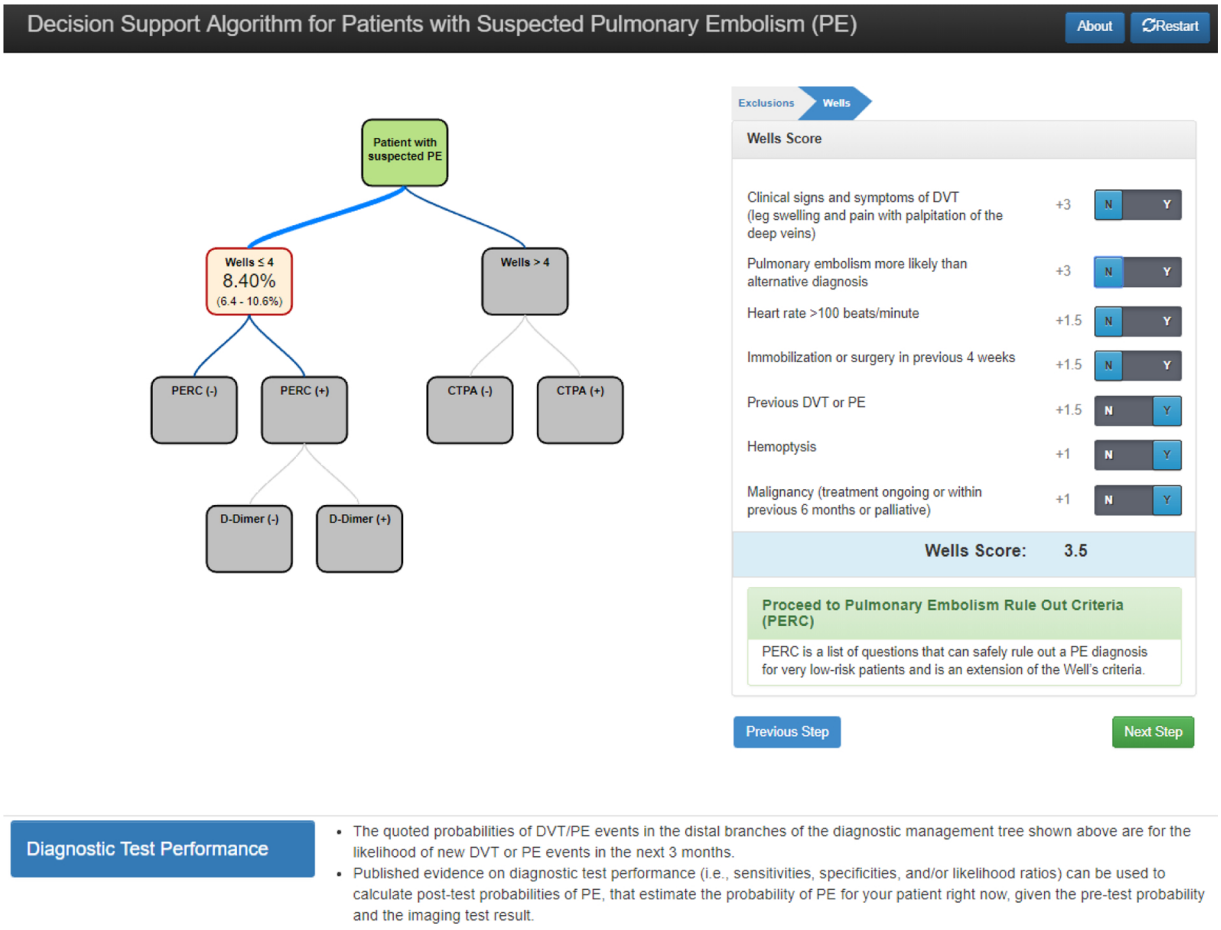


**Fig. 3.** PE CDSS at a Wells score step as used by formative usability testing participants.

the key issues identified here.

Workflow integration (by supporting the entire PE diagnostic workflow in a consistent interface), and recognizing variable workflows and users, as noted in Bates' third commandment [11], were key for this PE CDSS. It operates as a stand-alone or linked to computerized ordering systems.

### 5.4. Well-designed user interfaces are critical

User interface (UI) design is critical to ensure clinically-viable CDSS. Importance and impact of UI design is also in the literature, where attention to "use of colours and layout" are recognized elements of successful CDSS development [47]. In other CDSS developments, UI issues (e.g., unavailability of appropriate actions/options in CDSS workflow) can contribute to adverse medical events [16]. Meanwhile, many PE CDSS implementations completely ignore the UI as a potential contributor to uptake, usability, or effectiveness issues [27,50]. Elsewhere, *all* CDSS are seen as "cumbersome" [51], implying interface design is irrelevant.

Throughout this PE CDSS development, the focus was to provide an interface cognitively in-line with user expectations. As Bates et al. state, "little things can make a big difference" [11].

### 5.5. CDSS scope

In the literature, PE CDSS implementations appear with varied scope – some used only one or two tests (i.e., Wells score, D-Dimer, PERC, VQ scan, and CTPA), – while others integrate multiple. In 2014, a comprehensive (i.e., D-Dimer, CTPA, VQ scan) PE workup was studied, but did not appear to include the Wells score [27]. Elsewhere, CDSS was triggered on CTPA order entry, guided the ordering physician, but did not provide CTPA recommendations [25].

This PE CDSS includes all tests and guides users from Wells score through PERC, D-Dimer, VQ-Scan, CPTA decision support, and diagnosis. This expanded scope of this comprehensive interface captures more workflow and provides efficient and consistent support than single-test tools. It also supports Bates' third commandment – fit into the user's workflow [11].

### 5.6. Limitations

This endeavor has some limitations. This tool development took advantage of HCD best practices to ensure a solid design, with some features present as a direct result of HCD approaches, but does not directly compare with a parallel non-HCD tool development effort. Claims to HCD-based tool design advantages were noted in our literature review, above. Comparative studies are interesting and can be considered for future work. We hope this PE CDSS remains relevant to other hospitals and use contexts. Systems-level evaluations are underway including a stepwise pre-post intervention pilot study of this tool as integrated into a local EMR, with impact assessments on actual PE work-ups (published separately).

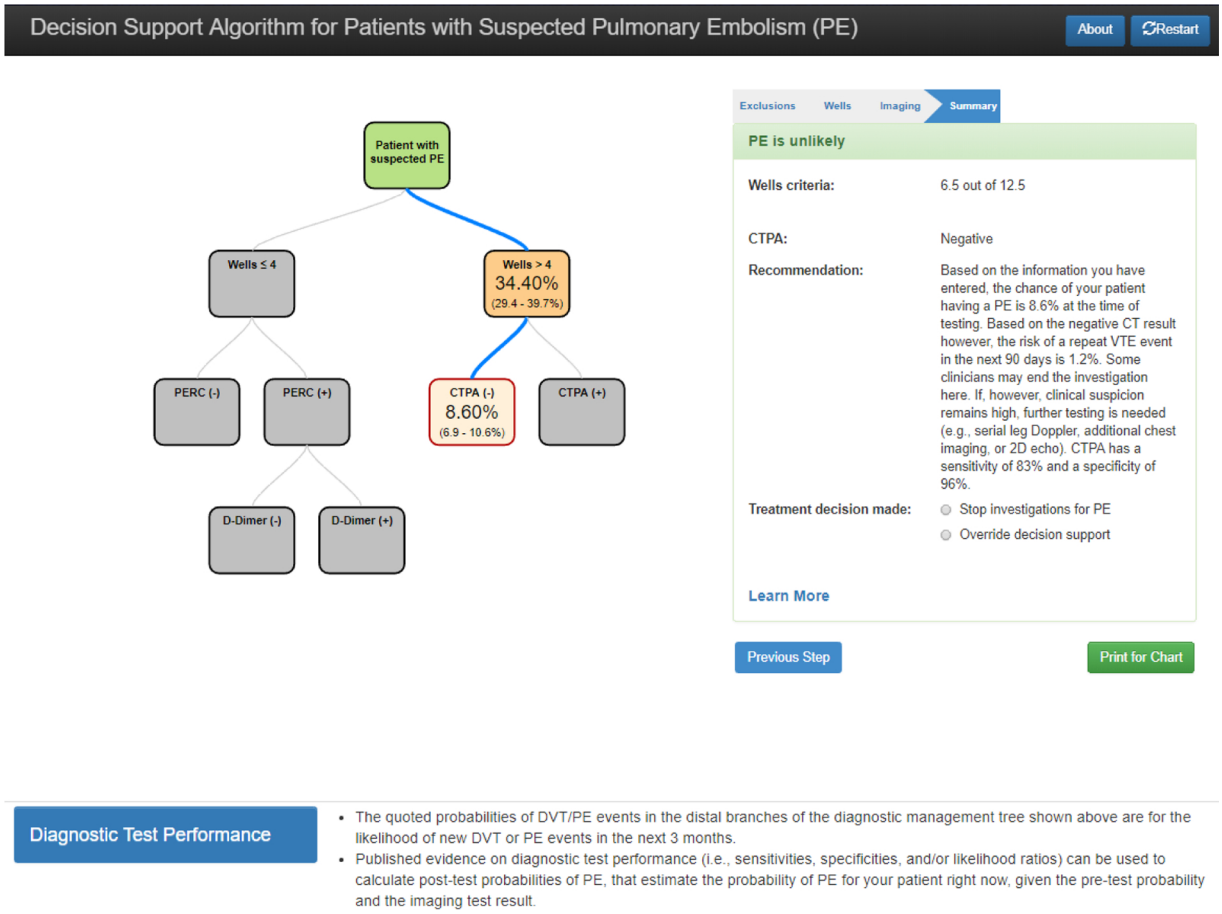


**Fig. 4.** PE CDSS Summary page as used by participants in formative usability testing.

### 5.7. Conclusions

A comprehensive HCD approach that integrates the full spectrum of design and testing methods is needed in healthcare-related CDSS design. We present a PE CDSS design case study highlighting the critical value of HCD. This approach provides the missing guide to create successful CDSS, and facilitates further application to other potential disease models.

## Author statement

**Julie Babione** contributed to the conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Wrechelle Ocampo** contributed to the acquisition of data, analysis and interpretation of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Sydney Haubrich** contributed design of the study, acquisition of data, analysis and interpretation of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Connie Yang** contributed to the acquisition of data, analysis and interpretation of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Torre Zuk** contributed to the conception and design of the study, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Jaime Kaufman** contributed to the conception and design of the study, acquisition of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Sheelagh Carpendale** contributed to the conception and design of the study, interpretation of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**William Ghali** contributed to the conception and design of the study, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

**Ghazwan Altabbaa** contributed to the conception and design of the study, analysis and interpretation of data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

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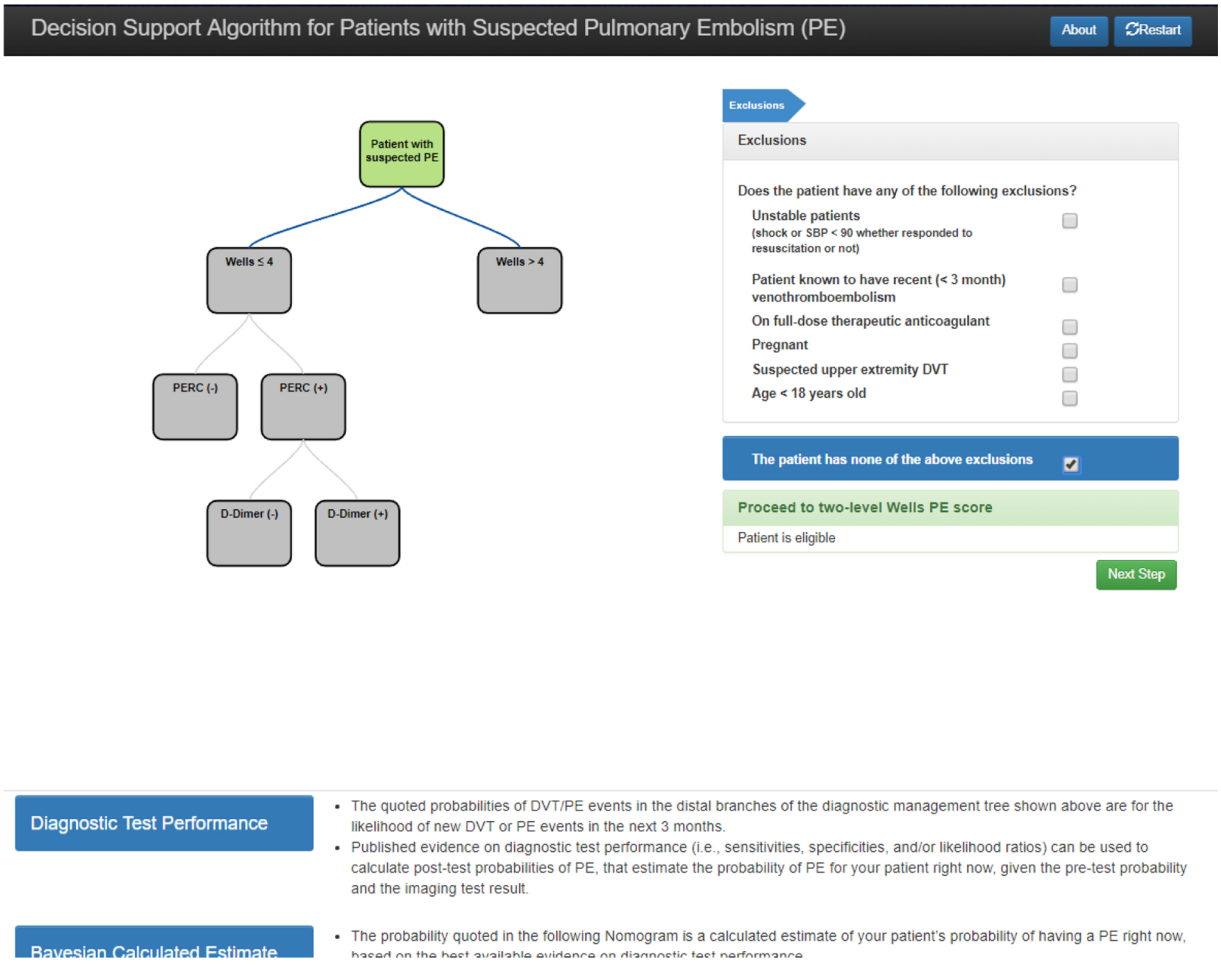


**Fig. 5.** Exclusions page that caused some participants confusion.

Summary Table

**What is already known**

- Clinical decision support systems have the potential to standardize and improve patient care
- Human-centred design is a mature approach to developing solid systems and user experiences, but is seldomly employed in CDSS creation efforts
- Pulmonary embolism is tricky to diagnose, warranting the use of decision aids to guide physicians using up-to-date knowledge and best practices
- Human-centred design approach to CDSS design can facilitate creation of efficient, effective, and easy-to-use systems

**What this study added to our knowledge**

- Attention to design details can result in better CDSS implementations
- Human-centred design approaches brought key insights to light, facilitating creation of an intuitive and easy-to-use PE CDSS
- HCD approaches can operationalize existing guidelines (e.g., commandments) for CDSS design

## Declaration of Competing Interest

None of the authors of this article have any conflicts of interest to disclose.

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## Appendix A

*Methods overview table*

See

**Table A1**
Overview description of HCD methods, their intended uses, and potential weaknesses.

| Method | Description | When to use (design phase)/purpose | Result | Weaknesses |
|---|---|---|---|---|
| Contextual inquiry [52,53,54,55] | Interviews about and observations of the user's work practices in real-world contexts. | Early stages of the design process when project requires a deep, qualitative understand of the user and their working environment. | Detailed descriptions of the user's behaviour and work practices, including communication flows, task sequences, artifacts, tools, work culture, and physical environment. | Observation can affect user behaviour, interviews are subject to recall bias, time-consuming, expensive. |
| Task analysis [53,56] | Interviews about and observations of the user's specific tasks in real-world contexts. | Early stages of design process when project requires a deep, qualitative understanding of the user's specific tasks as they happen in the user's working environment along with predictive models of user task performance. | Flowcharts (or similar visuals) that depict user's tasks, subtasks, decision points, and human-system responses. | Does not provide insight into situations where users performs interwoven, continuous, or opportunistic tasks. |
| Field studies/ethnography [57,58] | Observations, interviews, and document analysis related to people in their natural environments. | Early stages of design process when project requires a comprehensive and empathetic understanding of the users and their world. | Deep insight into user lives, artifacts, and behaviours that influence their needs. | Time consuming, expensive |
| Competitive analysis [59,60] | User interviews about design landscape including user experiences, competitors, best practices, trends, and user demographics. | Early stages of design process when researcher needs to make informed decisions about own product or design strategy. | Improved understanding of the landscape in which a design will compete. This includes a comparison of strengths and weaknesses of the design with that of the competition. | Process is lengthy and ongoing as landscape changes when new competitors emerge. |
| Iterative design [53,58] | Repeated redesign of some or all system components in consultation with users and stakeholders. | Applicable throughout new product development process but preferably used in the earliest stages of development when a design needs refinement to improve its usability and quality. | A design or process that is the best solution for the task. | Process is lengthy since ongoing, no set endpoint. |
| Participatory prototyping [61] | Creating iterative prototypes by involving users in the design and review process. | As a check-back with target user groups to ensure that key feedback is accurately incorporated. | Visual and textual feedback related to content, usability, workflow integration, context, word choices, or any other part of the prototype. | Requires a collaborative environment to solicit both positive and negative participant feedback. |
| Prototyping [13] | Creating approximations of a design idea, initially low fidelity (e.g. paper, props) and later in the target medium. | To explore design ideas before committing significant resources to system development. | Feedback from representative users, stakeholders, and other designers. | If a prototype is mistaken for the final product, it may lead stakeholders to believe an incomplete system is ready to go. |
| Focus groups [62] | Facilitating a guided discussion with a group of target participants regarding their opinions, attitudes, and experiences. | Early in the HCD process when the project depends upon knowing the experience of the target user groups. | Thematically analyzed audio and video transcripts to bring forward to new iterations. | If the focus group environment is too formal, analysis may yield biased feedback. |
| Interviews [56] | Meeting directly with a participant to gather information about opinions, attitudes, and experiences. | Used for exploratory research. Can be used prior to or after design/development for input. | Thematically analyzed audio and video transcripts to bring forward to new iterations. | The interviewer needs to guide the session with the appropriate questions so interviewee can understand them. |
| Formative usability testing [63] | Continuous testing of prototypes to identify interface problems, quickly fix them, then retest with more participants. | Used early in the design process between changes in prototypes before a high-fidelity prototype. To evaluate a design ahead of real-world use to verify that design decisions (e.g., color choices, language, interactivity, layout, flow, content) do not cause the user any use difficulties. | Ongoing identification of problems that block users from completing a task. | Does not give statistically valid, repeatable metrics. Number of testers cannot be planned in advance. |
| Expert review/heuristic evaluation [64] | Team members with different disciplines and varying expertise on the subject matter conduct an informal usability inspection based on a set of agreed principles. | Done before user testing begins. Can be done with low-fidelity prototypes in middle phases of the design process. | A report that identifies features that are both consistent and inconsistent with heuristic principles. | Rarely identifies opportunities for major advances in design. When evaluators do identify problems, they are not always able to provide solutions. |

(*continued on next page*)

**Table A1** (*continued*)

| Method | Description | When to use (design phase)/purpose | Result | Weaknesses |
|---|---|---|---|---|
| Summative usability testing [65,66,67] | Observing and recording a participant using a digital application to complete a task. | Use when need to identify problems for end users that prevent them from completing a task. Can be done early or late in design process. | Thematically analyzed audio and video transcripts to bring forward to new iterations. | Requires experienced evaluators to design tasks that will detect problems and a sufficient number of participants to reach saturation with problem detection. |
| Cognitive walkthrough [57] | Give a user a task to evaluate whether an interface is easy to learn. | Use when evaluating "walk up and use" systems that should not require detailed explanations to operate (e.g. cash withdrawal machine, parking metre, train ticket kiosk). | Description of design issues and usability problems. | May not be as effective if user will use system more than once. |
| User requirements analysis [68,69] | Study of actions and cognitive processes required for a user to achieve a task. | Use when project requires an understanding of the current system, the information flows within it, problems for people, and opportunities that indicate user needs. | Detailed descriptions of high-level tasks, flow chart of system organization, logic model showing inputs and outputs, description of sequence of human activities. | Requires experienced evaluators to design tasks that will detect problems and a sufficient number of participants to reach saturation with problem detection. |
| Surveys [57,69] | Either a questionnaire or interview administered by the user designer or designer. | Use earlier in design process to gain large volumes of information from user groups to facilitate in-depth focus groups or interviews. | Self-reported personal characteristics of user group. | Self-report instruments don't always yield accurate reflection of true thoughts and feelings. |
| Card sorting [57] | Give small groups of users (3 − 5 people) cards to sort (30 − 100) and observe how they organize content. | Use when project requires an understanding of how users group things into categories. | Understanding of how users group things into categories and relate things to one another. | Complicated to moderate, rigour of method depends on rigour of analysis |
| Personas [18] | Takes information gathered from user studies (e.g., interviews, designer's own experiences, and other sources) to create a composite user. | Defined in early stages of a project and used throughout the design process. Use when direct user involvement is not always appropriate, complex, or demographic features create barriers (e.g., children). | Provides a concise description of a user's characteristics and what their goals are. Helps designers, developers, and stakeholders understand and focus efforts to suit each persona's needs. | Can include an excess of assumptions or biases if real user data is not readily available. Sometimes limits real-user input into designs until far into the project. |
| Journey Mapping [70] | Add a time dimension to personas, showing a user's experience with a product/business/workflow over time. Maps the user's needs, expectations, thoughts across many phases. | Used in early stages of a project to understand the user's context, define product touch points and opportunities. | A visual representation (map) of a user's experience with persona (and other) elements integrated. | A map is only as good as the data it is based on, and so can be subject to assumptions and biases. |

*Formative usability testing – sample Cases*

**Table A2**
Case scenarios provided to formative usability testing participants to guide their use of the PE CDSS.

| Scenario | Case Description | Vitals |
|---|---|---|
| Scenario A | Patient A is a 59 year old male admitted with a diagnosis of pneumonia. He presented with shortness of breath and low oxygen saturation. Initial chest x-ray on admission was diagnostic for pneumonic infiltrate and on day 2 post admission, he becomes more hypoxic. A repeat chest x-ray shows fluid overload. He has no recent history of immobility, but previously had a DVT in the right lower extremity 2 years ago that occurred 10 days post-surgery for a right bilateral total knee replacement. | HR – 97 bpm<br>BP – 123/82<br>SO2 – 65 %<br>Temperature – 40.1 °C |
| Scenario B | Patient B is a 48 year old female presenting to the ER with SOB and edema of the right lower extremity. Before presenting to the ER she was seen in an outpatient clinic where she was prescribed antibiotics for possible pneumonia. She has a history of DVT in left lower extremity 2 years ago that happened weeks after initiation therapy with hormonal replacement therapy for menstrual irregularities. She has no history of malignancy, and no immobility. | HR – 95 bpm<br>BP – 105/70<br>SO2 – 82 %<br>Temperature – 36.5 °C |
| Scenario C | Patient C is a 42 year old male who was admitted to the ICU with pneumonia and septic shock. Within a few days of his ICU stay, he was clinically improving in terms of sepsis and becoming hemodynamically stable, but then he developed respiratory distress requiring support with mechanical ventilation. Physical exam shows tachycardia and no signs of DVT. He has a history of nephrotic syndrome and unprovoked DVT in right lower extremity three years ago. | HR – 116 bpm<br>BP – 100/65<br>SO2 – 65 %<br>Temperature – 36.8 °F |

*Formative usability testing results*

**Table A3**
Complete results of formative UT.

| Issues | Recommendation |
|---|---|
| **Bugs**: *identified as technical issues within the system that caused errors, were causing visual artefacts, or technical oversights that needed to be addressed.* | |
| Several study participants noticed that the PDF generated through the 'Print for Chart' button contained diagnostic tests that had not been conducted for this patient, and sometimes even erroneous results for those tests. This is a significant issue, as it would indicate incorrect medical information that would likely impact patient care. | The PDF should only contain those tests that have been conducted for this patient, and only correct test results displayed. |
| The Wells score numbers "+1.5″ are visually cut off in the display. | Wells score numbers should not be cut off in any circumstances. |
| **Content issues**: *in addition to usability issues, the research team welcomed feedback from study participants (content matter experts) who identified clinically incorrect or ambiguous elements. This category also included any elements that were neither interface or bugs.* | |
| Missing brand information. | AHS branding information should be included in accordance with their branding guidelines. |
| Several study participants identified that the patient handout speaks about the risks of having a CT *after* the test has already been done. Other study participants indicated that they would not give a handout about the risks of having a CT, but instead would talk about it with the patient, if the situation was appropriate. | Remove the patient handout and patient handout link on the summary page altogether, as it is out of sync with the clinical workflow and superfluous to existing consent and patient information. |
| The Wells score is noted in the Summary page, but on the 'Print for Chart' PDF, only items that are marked "Y" in the Wells Score are noted, but the score itself is not. | This information inclusion is *clinically incorrect* and should be replaced by the numerical Wells score calculation. This Wells score should also be captured in the Excel progress/data-capturing spreadsheet. |
| Several study participants wanted to know the CTPE and D-Dimer sensitivity and specificity alongside the risk calculation information (inside the white box below the green recommendation header), not wanting to have to look in different places for this information. | Include the sensitivity and specificity information inside the white box below the green recommendation header. New text provided. |
| Most study participants, who do not regularly work in the Emergency Department, expressed confusion about what PERC was, having never heard of it or being unfamiliar about its purpose. | Add the text "PERC is a list of questions that can safely rule out a PE diagnosis for very low-risk patients and is an extension of the Wells criteria." This text should be placed in the (currently empty) white text box area below "Proceed to Pulmonary Embolism Rule Out Criteria (PERC)" on the Wells Score page when the score is less to or equal to 4 (i.e., the user is directed to the left side of the tree). |
| Several study participants were confused by the treatment option "Stop investigations" on the summary page, knowing that clinically, if PE had been ruled out, they would have to continue other investigations for other potential causes of the symptoms. | Change "Stop investigations" text to "Stop investigations for PE" on the Summary page. |
| As the decision to stop investigations or override decision support is part of the clinical diagnostic process for diagnosing PE, study participants strongly believed this should be part of the "Print for Chart" PDF that is generated. | Include the choices made on the "Treatment decision made" in the 'Print for Chart' PDF, in a new row in the chart, structured similarly to the rest of the table |
| Study participants expressed confusion around what the Print for Chart PDF document was showing them, indicating that they didn't know if this was generic or patient-specific. | The "Results Summary" text at the top of the 'Print for Chart' PDF should be changed to read "This patient's test results summary is as follows:" |
| Study participants were confused as to the role of PERC when they had already answered some questions for the Wells score, and sometimes confused as to why some of the items had already been filled out. | The PERC Rule title line (black text, just below the tabs) should be changed to "PERC Rule: partially completed from Wells score)" |
| **Usability issues**: | |
| Several study participants were confused about what to do with the tool on the first screen. The action item – "None of these exclusions apply" was not sufficiently visible to draw the user's attention. | Make the text "None of these exclusions apply" bold, and ensure that the text still fits nicely in the blue area that encloses it. |
| Many study participants did not see the "Learn More" link within the white text boxes, and so they were unaware of the potentially useful information in that section. | Increase the font of the "Learn More" hyperlink by two sizes, bold the text, and add an extra carriage-return between the text in the white box and this link. |

(*continued on next page*)

**Table A3** (*continued*)

| Issues | Recommendation |
|---|---|
| Several study participants expressed confusion and uncertainty about whether or not they could click the "Previous Step" button, as it is gray and therefore may seem non-functional. | The 'Previous Step' button should be made the same blue as the blue in the header 'tabs'. In the event that the 'Previous Step' is not accessible, existing colouring mechanisms to make the button colour less intense should be kept. Additionally, the 'Previous Step' text should be made white and bold – the same as the 'Next Step' currently is. |
| When study participants clicked on PubMed or other hyperlinks within the "Learn More" section, these links were opened in the *same* window as the tool, which would disrupt workflow and patient care. | All hyperlinks within the "Learn More" sections (i.e., below the fold) should open in a *new* tab (or window), with the same mechanism used for the current "Print Patient Handout" and "Print for Chart" buttons. |
| The Fagan Nomogram has a well-established and known aspect ratio of being "tall and narrow," which accurately displays numerical information within this representation. The aspect ratio of the Fagan Nomogram in the PE tool is "short and wide," which obscures the numerical information. | The aspect ratio of the Fagan Nomogram should be adjusted so that it is represented correctly. |
| The text in the 'Print for Chart' PDF table is currently centre-aligned. It is known that humans visually scan content faster if it is left aligned, and without hyphenation. | All text in the 'Print for Chart' PDF table should be left aligned and without any hyphenation. |
| Most study participants did not see that there was additional information below the tool's main content, as it was not visible on the screen. This issue was seen predominantly on a laptop computer, where the screen real estate may be smaller or have a different aspect ratio than what might be used in the hospital or during development. | The "More Information" content of the tool should be brought up so that it is more likely to be seen. This could be accomplished by reducing the amount of white space below the tool's main visual elements. |
| Several study participants felt constrained or that the tool was incomplete when it asked for reasons for overriding the decision support tool, and wanted to be able to add textual information. | A text box to support a short clinician note should be added below the "Treatment decision made:" item for this purpose. It should also be captured in the data collection table. |
| Most study participants indicated that they would be most likely to use CDSS if they were available on their phone, as this is a more guaranteed access to information than a desktop computer, which might not always be available. | The PE CDS tool should be made available, visually correct, and fully usable on a mobile platform. |

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