Leveraging Dual Usability Methods to Evaluate Clinical Decision Support among Traumatic Brain Injury Patients

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Abstract

Background: Traumatic brain injury patients (TBI) are at increased risk of developing venous thromboembolism (VTE). Clinical decision support systems (CDSSs) may improve the utilization of VTE prophylaxis protocols yet suffer from poor compliance among end-users due to a lack of user-centered design.

Objective: The objective of this research work was to improve the content, design, and workflow integration of a TBI-CDSS based on feedback from the experts and end-users.

Methods: The CDSS was evaluated leveraging a dual usability approach. A set of usability experts (N=3) and trauma providers (N=5) performed the heuristic evaluation (HE) and end-user testing (E-UT). Data was collected through triangulation of methods and analyzed using qualitative (thematic) and quantitative (descriptive) analyses.

Results: We identified 145 total issues across both methods with 66 being unique i.e., 17 issues found by HE, 43 by E-UT, and 6 common ones. Thematic analysis was conducted on the unique issues (66) and was assigned to themes and subsequent sub-themes. We identified 13 unique themes. The three most identified themes were lack of supporting evidence (17 issues, representing 26% of the 66 issues), operational barriers arising from the test environment (11,17%), formatting inconsistencies, and lack of following standards (8, 12 %). The system's usability scale survey (SUS) score was 77.5 (std dev ±16) interpreted as an acceptable/good usability range.

Conclusions: Combining expert and end-user-driven usability evaluation methods led to the identification of a more comprehensive list of issues. This can facilitate the optimization of the TBI-CDSS, resulting in improved usability and care management. Clinical Trial: This component of the project is not a clinical trial. The study protocol was submitted to the University of Minnesota Institutional Review Board and given the determination of “Exempt” as secondary research for which consent is not required. The mixed methods investigation was given the determination of “Not Human Research” as a quality improvement activity.

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Keywords: Traumatic Brain Injury**;** Venous Thromboembolism; Clinical Decision Support System

(CDSS); Heuristic Evaluations**;** End-user-based usability testing.

Background and Significance

Traumatic brain injury (TBI) is one of the prominent causes of mortality and disability worldwide. In the United States alone, over 69,000 TBI-related deaths occurred in 2021. [1] TBI patients are at an increased risk of developing complications secondary to venous thromboembolism (VTE). [2] Fifty-four percent of patients with a TBI will develop a VTE in the absence of appropriate anticoagulation intervention. [3] Despite the significance of timely VTE prophylaxis administration, there has been a reluctance to implement anticoagulation in such patients, thus resulting in delays in timely intervention. [4-7]

Optimal utilization of VTE prophylaxis protocols manages the risk of VTE with the competing risk of progression of intracranial bleeding in patients following trauma [7]. However, there is variability in VTE prophylaxis protocols across trauma centers. [2] In an attempt to optimize VTE prophylaxis for the patient, institutional implementation of anticoagulation protocols has been shown to improve clinical outcomes. [2, 7, 8] To improve prophylactic anticoagulation of TBI patients without adversely affecting outcomes, integrating a clinical decision support system (CDSS) has emerged as an indispensable solution to inform providers of evidence based VTE prevention guidelines. [9] Existing literature cites improved patient outcomes when evidenced-based practices are followed, along with improved compliance with these practices through the utilization of CDSSs. [10-12]

CDSSs are electronic tools that aid providers in decision-making by integrating evidence-based recommendations into their daily workflow. [13, 14] When adhered to, these tools serve as an effective means of changing clinician behavior. [15-17] Integration of a CDSS in clinicians' workflow has the potential to improve the quality of medical care delivered if user optimization and workflow integration are considered when building, implementing, and maintaining CDSS. This

entails careful consideration around interoperability, speed, ease of deployment, affordability, conscientious design, and workflow integration-related consideration fields. [18]

Lack of user-centered design, interoperability, and implementation barriers hinder the widespread adoption of a CDSS. [19-21] There is a need for robust usability studies to address existing barriers and optimize the functionality of the CDSS according to users' needs. The objective of this study was to evaluate and optimize the usability of a TBI CDSS integrated into a U.S. Midwest ACS-verified trauma center. Usability issues in a TBI-VTE-CDSS were identified by leveraging a dual usability evaluation approach. We hypothesized that a combination of expert and end-user-driven methods of usability evaluation would help us identify a myriad of unique issues by each method in addition to the common findings identified between the two methods.

Methods

Overview of TBI-VTE prevention guidelines

The TBI-CDSS delivers a patient-centered outcomes research (PCOR) guideline for VTE prevention in patients with TBI, [2, 22] centered around the modified Berne-Norwood criteria. [8] Patients are categorized as low, moderate, or high risk for spontaneous progression of hemorrhage, with prophylactic treatment regimens tailored for each group, respectively. The TBI-CDSS is a modification of an original, natively developed COVID-19 CDSS logic model, which is currently translated to interoperable standards [16] (Figure 1). We chose this model because of two major reasons, (a) we have previous experience implementing the TBI VTE prevention guideline with success, [2] and (b) many of the data elements and artifacts (~80%) overlap with minimal additional mappings and technology build. The final CPG-on-FHIR COVID-19 CDSS included 108 data elements. The TBI CPG added 21 data elements specifically related to TBIs (e.g., intracranial pressure monitoring, neurosurgical consultation, craniotomy, head CT imaging, subdural hematoma, contusion, Glasgow Coma Scale).

Figure 1. Clinical decision support system logic model for venous thromboembolism prevention among traumatic brain injury patients. ***S06: 2024 ICD-10-CM Diagnosis Code S06***

Given the logic model, patients will enter the system by admission under predetermined diagnoses, generally falling under the TBI category. Our target population is adult patients admitted with an acute traumatic brain injury defined as International Classification of Disease 10 Clinical Modification (ICD-10-CM): S06.1 – S06.9 or S06.A. Patients who died within 24 hours of hospital admission and patients documented as “comfort cares” during the first 72 hours of hospitalization will be excluded. Additionally, patients with a pre-existing VTE or inferior vena cava (IVC) filter at the time of admission, and patients with a mechanical heart valve or ventricular assist device will be excluded from the final analysis.

The CDSS is provided in the subsequent 72 hours (dependent on risk stratification) and is administered in the form of seven alerts (Figure 1). Descriptions of the seven alerts deployed at various points in time, stratified by level of risk, is provided in Figure 2.

Figure 2. Description of seven alerts in TBI-CDSS

Study settings

Our foundational usability evaluation-related research work was conducted by a team of researchers from the University of Minnesota (UMN) and associated health systems i.e., M Health Fairview and affiliated hospitals (MHFV), which consisted of 9 state verified trauma centers, including the flagship UMN as an ACS-verified level 2 trauma center.

Data-collection

Expert-based usability evaluations:

Heuristic evaluations (HE) leveraging Nielsen's 10 Usability Heuristics for User Interface Design were employed. [23] The initial round of HE was conducted on screenshots of the user interface that researchers independently evaluated.

Three experts with varied backgrounds i.e., a physician informatics/usability expert (RR); a hospitalist with content and CDSS-related expertise (SS); and an undergraduate in neuroscience (SF)) conducted the evaluation independently. We then had a debriefing session to walk through findings from individual users, removing any duplicates. Once we had a final, consolidated, clean list of unique issues, each evaluator did the severity ranking of each issue (6). A 0 to 4 rating scale was used to rate the severity of usability problems (0 = I don't agree that this is a usability problem at all; 1 = Cosmetic problem only: need not be fixed unless extra time is available on project; 2 = Minor usability problem: fixing this should be given low priority; 3 = Major usability problem: important to fix, so should be given high priority; 4 = Usability catastrophe: imperative to fix this before product can be released) [24]. While assigning the severity score usability problem, three factors were taken into consideration: the frequency with which the problem occurs, the impact of the problem, and the persistence of the problem. The team reconvened in a severity scoring session where a scoring consensus was reached for each problem after mutual deliberations. The whole process of HE was iterative in nature where issues identified were addressed sequentially.

End-users' based usability testing:

End-users' based usability testing (E-UT) was conducted with actual end-users i.e., trauma providers from MHFV systems. Purposive sampling was employed for recruitment purposes by sharing about the TBI-CDSS usability study through emails, discussions during meetings, word of mouth, etc. Scenario based-usability testing was done with individual end-users along with our usability team comprised of up to 5 team members i.e., a moderator (1), facilitators-IT experts both from the MHVF, and the vendors who helped with build (2-3); and a note taker (1). Each session was

conducted on Zoom (Zoom Inc, San Jose, CA) and lasted up to 90 minutes. Signed written informed consent was obtained to screen and audio record the session, with the speech-to-text transcription feature turned on. Each recording was saved on a secured and encrypted UMN device. The IRB determined that this study (STUDY00017107) meets the criteria for exemption from IRB review.

In the scenario-based guided usability testing, we asked users to perform certain tasks on three unique test patients corresponding to three risk grounds: low, medium, and high. Two to four scenarios were associated with each test patient for a total of 9 scenarios, which required each user to perform a few pre-defined, sequential tasks. Participants were asked to think out loud as they interacted with the TBI-CDSS in Epic testing environment (Epic Inc, Verona, WI). Once each scenario and relevant task was completed, participants were asked a few questions to elaborate on their experience and complete a single ease survey questionnaire (REDCap Consortium, Nashville, Tennessee). At the end of the session, participants completed a systems usability scale survey (SUS) [25] and were asked to share their overall experience with the tool. Each participant later received a $50 gift card for the participation.

Building test patients and testing in Epic test environment

Our team of experts were comprised of builders/IT specialists (SB, PM, MS) and clinicians (SS, RR, CT), who helped with building the three master test patients stratified by risk level (Table 1). Copies of the master test patients were made to be used in each usability session.

Table 1. Patient Risk Stratification Modified Berne-Norwood Criteria-

	Test patient # 1	**Test patient # 2**	**Test patient # 3**
	Low Risk	**Moderate Risk**	**High Risk**
	Subdural hematoma 2 mm No moderate or high-	Subdural or epidural hematoma > 8 mm Contusion or intraventricular hemorrhage > 2 cm Multiple contusions per lobe	Placement of an intracranial pressure monitor and / or Craniotomy. Evidence of progression at 72 hours

	risk criteria	Subarachnoid hemorrhage with abnormal CT Evidence of progression at 24 hours	
	Initiate pharmacologic prophylaxis if repeat head computed tomography (CT) stable at 24 hours	Initiate pharmacologic prophylaxis if head CT stable at 72 hours	Consider placement of an inferior vena cava filter

[a]Not all elements are necessary for every table, simply omit the irrelevant

The purpose of the testing was to receive user feedback effectively and efficiently, ensuring that the testing context matches as much as possible with the user interactions in the real world. Leveraging the Epic test (TST) environment to create a simulated environment came with a few constraints. For instance, refresh time frames were artificially shortened to decrease time spent in the testing session. Users had to click refresh and were asked to give the system time to refresh to allow the applications team to enter specific information. This limitation led to radiology report content to the minimal and relevant only to the specific task which is usually not the case.

Data analysis

The respective data was analyzed both qualitatively and quantitively as described.

Qualitative analysis:

We compiled all the issues identified by each method as one consolidated list. This included data collected through HE and E-UT. First, a subset of the issue was coded independently by two individuals (RR, SF) at a more granular level and a codebook was generated after agreeing by both coders and applied to the full list of issues. We refrained from double coding. We cataloged the lowest-level codes into higher level and sub-themes and themes to get a more holistic understanding of TBI-CDSS.

Quantitative analysis:

The primary focus was on data collected from the SEQ survey, SUS survey. We performed descriptive analysis reporting mean and standard deviations.

Results

End-users' characteristics

Five trauma providers participated in the individual usability testing session. Predominantly. The detailed characteristics are described in table 2.

Table 2. Demographics of participants

	Characteristics	**n (%)**
Sex		
	Male	2 (40)
	Female	3 (60)
Role		
	MD	4 (80)
	[a]APP	1 (20)
Specialty		
	Trauma surgery	3 (60)
	Neurosurgery	1 (20)
	Neurocritical care	1 (20)
Comfort with technology		
	Expert	4 (80)
	Intermediate	1 (20)

MD, medical doctor; [a]*APP,* advanced practice provider.

Usability-related findings from the two methods

We identified a set of common as well as unique issues using two methods i.e., heuristic evaluation with experts and usability testing with end-users.

Findings from heuristics evaluation:

Thirty-seven heuristic violations (23 unique, 14 duplicates) were identified across three experts. We were able to map them to seven of the ten possible heuristics violations as shown in Figure 3.

Figure 3. The seven heuristic principles violated

The results showed that 30% of possible heuristics were responsible for ~74% of all violations, the Pareto principle. Three heuristics that represented the most violations were (i) consistency and standards (n=8, 35%), (ii) help and documentation (n=5, 22%), and (iii) recognition rather than recall (n=4,17%). Out of 23 unique, we found cosmetic (6) and minor (17) issues only (Figure 4).

Figure 4. The Pareto chart of Heuristics principles violation and the severity ranking

Findings from usability testing:

We identified 108 issues (49 unique and 59 duplicates). Out of 49 issues, we found cosmetic (6); minor (20); major (10), and catastrophic (2) issues. The remaining 11 were considered operational and not ranked. The single-ease question score ranged between 5-6.6 (1 (very difficult) to 7 (very easy). The SUS score was 77.5 (SD ±16) interpreted as an acceptable/good usability range (Figure 5).

Figure 5. Systems usability scale interpreted as an acceptable/ good usability range. Image source (used with permission from measuring web source)

Between the two methods, we identified a total of 145 issues with 66 unique ones i.e., 17 by HE 43 by the end users, and 6 common ones from each method. Thematic analysis was done on all the unique issues eliminating those arising from the constraints of the TST (66-11=55).

Ranking of usability issues

We ranked 55 unique usability issues on a severity scale from 0-4, where 20% (11) were marked as

cosmetic; 58% (32) were identified as minor; 18% (10) as major, and 4 % (2) as catastrophic issues. We found both cosmetic and minor issues from both HE and E-UT, however, the identification of severe and catastrophic issues was solely from the usability sessions with the end users.

Thematic analysis

Thematic analysis was conducted on 66 unique issues identified through heuristic evaluations and usability testing. Eleven issues arising from TST constraints were eliminated. We identified 13 unique themes i.e., lack of supporting evidence, operational barriers arising from the test environment, formatting inconsistencies and lack of following standards, suboptimal data retrieval and display, lack of user control, lacking language clarity, order set-related suboptimal usability, language inconsistencies, best practice alert lacking patient-specific details, clinicians missing critical information and or action, unfamiliarity with the full clinical context, infinite ordering loop leading to error and having redundant option(s). The three most identified themes were lack of supporting evidence (17, 26%), operational barriers arising from the test environment (11, 17%), formatting inconsistencies, and lack of following standards (8, 12 %). (Figure 6)

Figure 6. Thematic analysis distribution

Lack of supporting evidence refers to the end-user's request to integrate and access evidence-based citations throughout the CDSS. Of the 17 usability issues about evidence-based medicine, 14 were identified by end-users and 3 were identified by experts. Examples include users disagreeing with threshold values and requesting evidence-based medicine citations and users requesting the ability of the CDSS tool to be explained.

Formatting consistency and lack of following standards refers to the system's ability to present information clearly and concisely, with a consistent interface to ensure easy readability for the user. Of the 8 usability issues about formatting consistency & standards, 2 were identified by end-users and 6 were identified by experts. Examples include inconsistent and difficult-to-read text usage,

style, color, and sizes.

Suboptimal data retrieval and display refers to the system's ability to present information in a manner which reduces user cognitive burden, through increasing smooth and efficient navigation by auto-populating data (such as lab results). Of the 6 usability issues pertaining to easy retrieval & optimal display, they were all identified by end-users. Examples include users requesting lab/ imaging values and time of administration be incorporated into the CDSS.

Lack of user control refers to the flexible design of the system to ensure smooth interaction with the user. Of the 5 usability issues pertaining to user control, 2 were identified by end-users and 3 were identified by experts. Examples include users requesting the ability to navigate away from the tool and forgiveness when utilizing the CDSS.

Lacking language clarity refers to specifying verbiage to omit any confusion the user may have. Of the 4 usability issues about language clarity, 3 were identified by end-users and 1 was identified by experts. Examples include specifying verbiage used throughout the tool and utilizing specific phrases (i.e., the use of "active bleed" vs "new bleed" may imply two different ideas).

Order set-related suboptimal usability refers to any suboptimal interactions the user may encounter when interacting with the order set. Of the 4 usability issues about order set-related suboptimal usability, they were all identified by end-users. Examples include users requesting the tool display prompts regarding its functionality on a case-by-case basis and easy access to the admission order set.

Language inconsistencies refer to the consistent use of verbiage throughout the system. Of the 3 usability issues about language consistency, they were all identified by experts. Examples include discrepancies between verbiage used in the storyboard or title and the consistent use of terms implying the same definition (i.e., either "snooze" or "lockout time" should be used - not both).

BPA lacking patient-specific details refers to information the system does not include, which users

would like to be included. Of the 2 usability issues about BPA lacking patient-specific details, both were identified by end users. Examples include adding patient risk stratification to the BPA (i.e., changing the tool to be more diagnostic) and including crucial patient-specific lab values.

Clinicians missing critical information refers to ensuring a system design to ensure easy readability for the clinician. Of the 2 usability issues about eliminating the chance of clinicians missing critical information, 1 was identified by end-users and 1 was identified by experts. Examples include bolding information and making information more accessible to improve readability.

Unfamiliarity with the context refers to additional guidance presented to the clinician on the system. Of the 2 usability issues about unfamiliarity with context, both were identified by end-users. Examples include ensuring proper education and introduction of the tool to clinicians to ensure it does not interrupt their workflow.

Redundant option refers to options already included as a part of the system. Of the 1 usability issue about redundant options, it was identified by end-users. Examples include omitting the “already ordered complete” button.

An infinite ordering loop leading to error refers to an infinite loop that occurred when utilizing the system, during the beginning of its launch. It has since been resolved as of May 16, 2023. Of the 1 usability issue about the infinite ordering loop, it was identified by end-users. Examples include users noting their warranted frustration with the ordering process.

Clinicians most often identified issues relating to the readily apparent integration of evidence-based medicine into the CDSS, recognizing a need for the utilization of citations and principles. Clinicians frequently noted how the CDSS might disrupt their workflow. For practical feasibility, request the integration of critical lab/ imaging values and consistency in formatting throughout the tool to reduce user cognitive burden and ensure an efficient workflow. A compilation of unique usability issues categorized by theme is included in Multimedia Appendix 1.

Multimedia Appendix 1. Usability issues by theme

Examples of usability modifications

We report (Figure 7) a few examples of modifications we made based on the learnings from HE and E-UT.

Figure 7. Examples of modifications. Images included with approval from EPIC.

Discussion

Using a dual usability evaluation approach i.e., experts-driven heuristic evaluation and end-users-driven usability evaluation, we identified a variety of similar as well as unique issues across the TBI VTE CDSS. Out of all the unique issues (66) identified, the percentage attributed to each method was UT (43, 65%); HE (17, 26%), and UT and HE (6, 9%). Although the mean severity scores of the identified problems were not significantly different across the two methods, issues ranked severe and catastrophic were found exclusively from UT. Between the two methods, the most common issues were cataloged under lack of supporting evidence, operational barriers, and formatting consistency/ lack of following standards. HE mainly identified problems related to formatting consistency/ lack of following standards, user control, suboptimal language clarity and consistency, whereas UT led to the discovery of more heterogeneous issues with a lack of supporting evidence, operational barriers, and suboptimal data retrieval and display being the most common ones.

Using a combination of these two methods can identify a wider range of usability problems. This aligned with prior evidence that combining two methods of usability evaluation can facilitate the development of an optimal CDSS [26]. We found a majority of usability issues identified by UT were only identified by end-users as compared to experts. Despite identifying fewer issues, experts identified some of the more granular issues about layout, formatting, and consistency while users

were more concerned about bigger, more consequential issues such as not having the supporting evidence to increase their trust and confidence, fragmented workflow (primarily sending form test environment related constraints) the finding that validates results of the study by Jones et al.

The finding from this study validates most of the claims from previous comparisons of HE and UT, [27-29] i.e. HE being more cost-effective in terms of time and resources and the ability of each method to identify distinct sets of usability issues with very small convergence rates (9% in our study). HE findings were limited to identifying problems rather than both strengths and weaknesses, which is contrary to what we found in UT where we came across both negative and positive comments from end users. For instance, users appreciated the fact that the premier questionnaire was very clear and covered the critical issue for risk profiling; alert verbiage was straightforward; CrCl value was apparent in the lab order results so they wouldn't have to navigate to find it.

There are some limitations associated with this study such as this usability evaluation was conducted at a single institute (M Heath Fairview) using a single electronic health system (Epic). The IT builders faced roadblocks due to constraints arising from the systems being hardwired and limited ability for system upgrades. We were, however, able to incorporate several build-related upgrades through close collaborations. As we did the test in the Epic TST, there were some constraints to which users had to adjust and spend extra time and effort, such as refresh time frames being artificially shortened to decrease testing time which resulted in some unusual behaviors. To simulate the passage of time, the user has to right-click anywhere and hit "Refresh" after responding to alerts, For the testing session, the test results/imaging reports are simplified and may appear shorter in length. We are still in the process of upgrading the tool based on what we have observed from our evaluations and through collecting feedback from end-users since the tool went live.

Utilizing dual usability evaluation methods leveraging both expert and end-users in the early phase of system development in an iterative manner helped us identify a diverse set of issues. We found

several usability issues of varying severity, relevant to each set of evaluators based on their experience and role. Through conducting this study and our continued efforts of collecting feedback from end-users, we have been able to optimize the design and functionality of the TBI-CDSS which aligns with clinicians' needs and workflows.

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Conflict of Interests

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Commonly Used Abbreviations

TBI: Traumatic brain injury

VTE: Venous thromboembolism

CDSS: Clinical Decision Support System (CDSS)

HE: Heuristic evaluations

E-UT: End-user based usability testing

References

1. Get the facts about TBI | Concussion | Traumatic Brain Injury | CDC Injury Center. 2023 [updated 2023-04-20T07:15:11Z]; Available from: https://www.cdc.gov/traumaticbraininjury/get_the_facts.html.

2. Tignanelli CJ, Gipson J, Nguyen A, Martinez R, Yang S, Reicks PL, et al. Implementation of a prophylactic anticoagulation guideline for patients with traumatic brain injury. Jt Comm J Qual Patient Saf; 2020 Apr;46(4):185-91. PMID: 31899154. doi: 10.1016/j.jcjq.2019.11.007.

3. Geerts WH, Code KI, Jay RM, Chen E, Szalai JP. A prospective study of venous thromboembolism after major trauma. N Engl J Med; 1994 Dec 15;331(24):1601-6. PMID: 7969340. doi: 10.1056/NEJM199412153312401.

4. Norwood SH, McAuley CE, Berne JD, Vallina VL, Kerns DB, Grahm TW, et al. Prospective evaluation of the safety of enoxaparin prophylaxis for venous thromboembolism in patients with intracranial hemorrhagic injuries. Archives of Surgery; 2002;137(6):696-702.

5. Wong H, Lovett N, Curry N, Shah K, Stanworth SJ. Antithrombotics in trauma: management strategies in the older patients. Journal of blood medicine; 2017:165-74.

6. Phelan HA. Pharmacologic venous thromboembolism prophylaxis after traumatic brain injury: a critical literature review. Journal of neurotrauma; 2012;29(10):1821-8.

7. Yorkgitis BK, Berndtson AE, Cross A, Kennedy R, Kochuba MP, Tignanelli C, et al. American Association for the Surgery of Trauma/American College of Surgeons-Committee on Trauma Clinical Protocol for inpatient venous thromboembolism prophylaxis after trauma. Journal of

Trauma and Acute Care Surgery. 2022;92(3):597-604.

8. Pastorek RA, Cripps MW, Bernstein IH, Scott WW, Madden CJ, Rickert KL, et al. The Parkland Protocol's modified Berne-Norwood criteria predict two tiers of risk for traumatic brain injury progression. J Neurotrauma; 2014 Oct 15;31(20):1737-43. PMID: 24945196. doi: 10.1089/neu.2014.3366.

9. Haut ER, Lau BD, Kraenzlin FS, Hobson DB, Kraus PS, Carolan HT, et al. Improved prophylaxis and decreased rates of preventable harm with the use of a mandatory computerized clinical decision support tool for prophylaxis for venous thromboembolism in trauma. Archives of surgery; 2012;147(10):901-7.

10. Macheel C, Reicks P, Sybrant C, Evans C, Farhat J, West MA, et al. Clinical decision support intervention for rib fracture treatment. Journal of the American College of Surgeons; 2020;231(2):249-56. e2.

11. Moja L, Friz HP, Capobussi M, Kwag K, Banzi R, Ruggiero F, et al. Effectiveness of a hospital-based computerized decision support system on clinician recommendations and patient outcomes: a randomized clinical trial. JAMA network open; 2019;2(12): e1917094-e.

12. Clinical Decision Support. 2022; Available from: https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html.

13. Loftus TJ, Altieri MS, Balch JA, Abbott KL, Choi J, Marwaha JS, et al. Artificial Intelligence–enabled Decision Support in Surgery: State-of-the-art and Future Directions. Annals of Surgery; 2023;278(1):51-8.

14. Nguyen AS, Yang S, Thielen BV, Techar K, Lorenzo RM, Berg C, et al. Clinical decision support intervention and time to imaging in older patients with traumatic brain injury. Journal of the American College of Surgeons; 2020;231(3):361-7. e2.

15. Durieux P, Nizard R, Ravaud P, Mounier N, Lepage E. A clinical decision support system for prevention of venous thromboembolism: effect on physician behavior. Jama; 2000;283(21):2816-21.

16. Shah S, Switzer S, Shippee ND, Wogensen P, Kosednar K, Jones E, et al. Implementation of an Anticoagulation Practice Guideline for COVID-19 via a Clinical Decision Support System in a Large Academic Health System and Its Evaluation: Observational Study. JMIR Med Inform; 2021;9(11): e30743. PMID: 34550900. doi: 10.2196/30743.

17. Kawamoto K, Lobach DF, editors. Clinical decision support provided within physician order entry systems: a systematic review of features effective for changing clinician behavior. AMIA Annual Symposium Proceedings; 2003: American Medical Informatics Association.

18. Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, Kroeker KI. An overview of clinical decision support systems: benefits, risks, and strategies for success. NPJ digital medicine; 2020;3(1):1-10.

19. Liberati EG, Ruggiero F, Galuppo L, Gorli M, González-Lorenzo M, Maraldi M, et al. What hinders the uptake of computerized decision support systems in hospitals? A qualitative study and framework for implementation. Implementation Science; 2017;12(1):1-13.

20. Khairat S, Marc D, Crosby W, Al Sanousi A. Reasons for Physicians Not Adopting Clinical Decision Support Systems: Critical Analysis. JMIR Med Inform; 2018 Apr 18;6(2): e24. PMID: 29669706. doi: 10.2196/medinform.8912.

21. Jones EK, Banks A, Melton GB, Porta CM, Tignanelli CJ. Barriers to and facilitators for acceptance of comprehensive clinical decision support system–driven care maps for patients with thoracic trauma: interview study among health care providers and nurses. JMIR human factors; 2022;9(1): e29019.

22. Rappold JF, Sheppard FR, Carmichael Ii SP, Cuschieri J, Ley E, Rangel E, et al. Venous thromboembolism prophylaxis in the trauma intensive care unit: an American Association for the

Surgery of Trauma Critical Care Committee Clinical Consensus Document. Trauma Surg Acute Care Open; 2021;6(1): e000643. PMID: 33718615. doi: 10.1136/tsaco-2020-000643.

23. 10 Usability Heuristics for User Interface Design. @nngroup; 2023; Available from: https://www.nngroup.com/articles/ten-usability-heuristics/.

24. Severity Ratings for Usability Problems: Article by Jakob Nielsen. @nngroup; 2023; Available from: https://www.nngroup.com/articles/how-to-rate-the-severity-of-usability-problems/.

25. Lewis JR. The system usability scale: past, present, and future. International Journal of Human–Computer Interaction. 2018;34(7):577-90.

26. Jones EK, Hultman G, Schmoke K, Ninkovic I, Dodge S, Bahr M, et al. Combined Expert and User-Driven Usability Assessment of Trauma Decision Support Systems Improves User-Centered Design. Surgery; 2022;172(5):1537-48.

27. Law L-C, Hvannberg ET, editors. Complementarity and convergence of heuristic evaluation and usability test: a case study of universal brokerage platform. Proceedings of the second Nordic conference on Human-computer interaction; 2002.

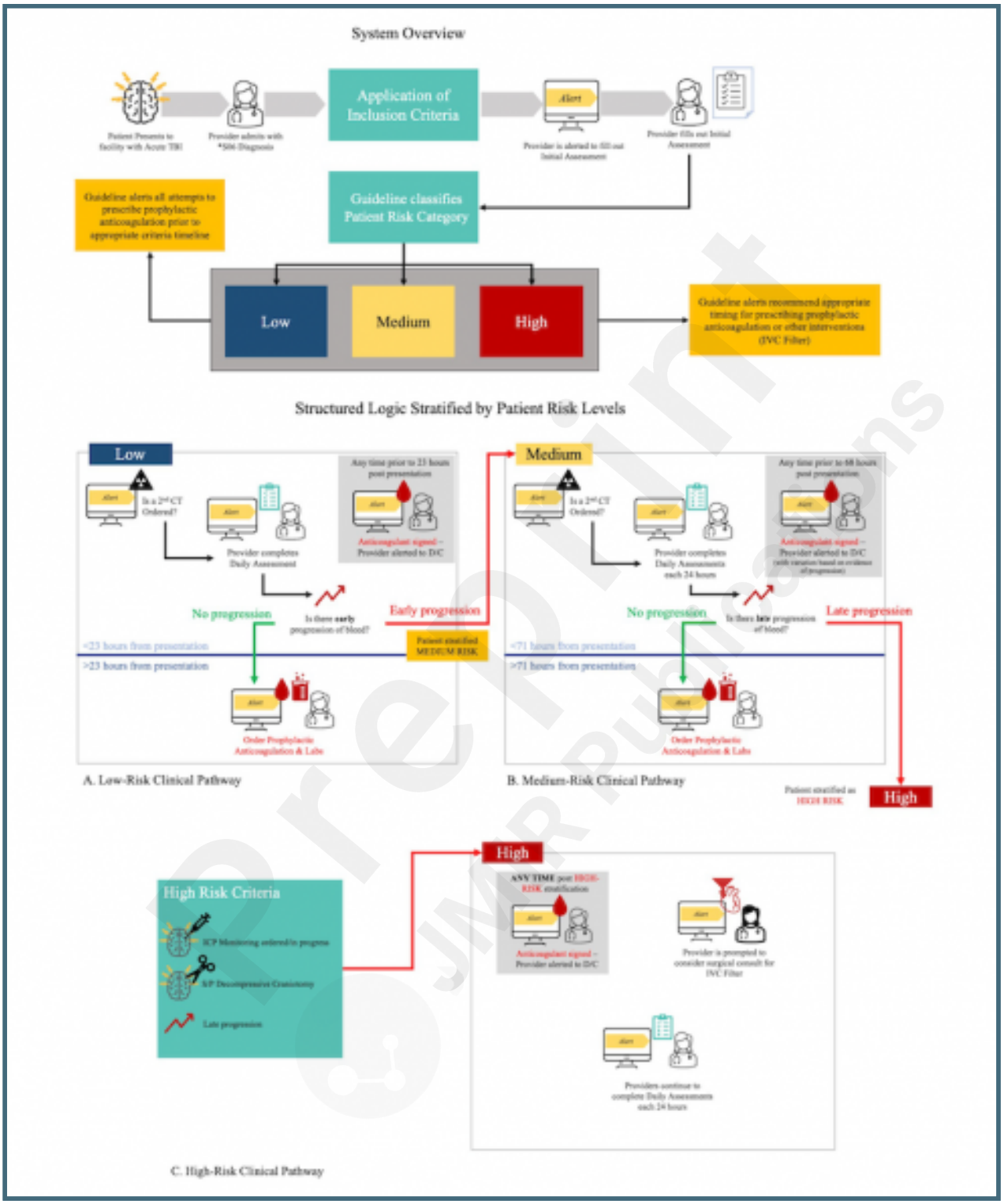
28. Bailey RW, Allan RW, Raiello P, editors. Usability testing vs. heuristic evaluation: A head-to-head comparison. Proceedings of the human factors society annual meeting; 1992: SAGE Publications Sage CA: Los Angeles, CA.

29. Desurvire HW. Faster, cheaper!! Are usability inspection methods as effective as empirical testing? Usability inspection methods; 1994. p. 173-202.

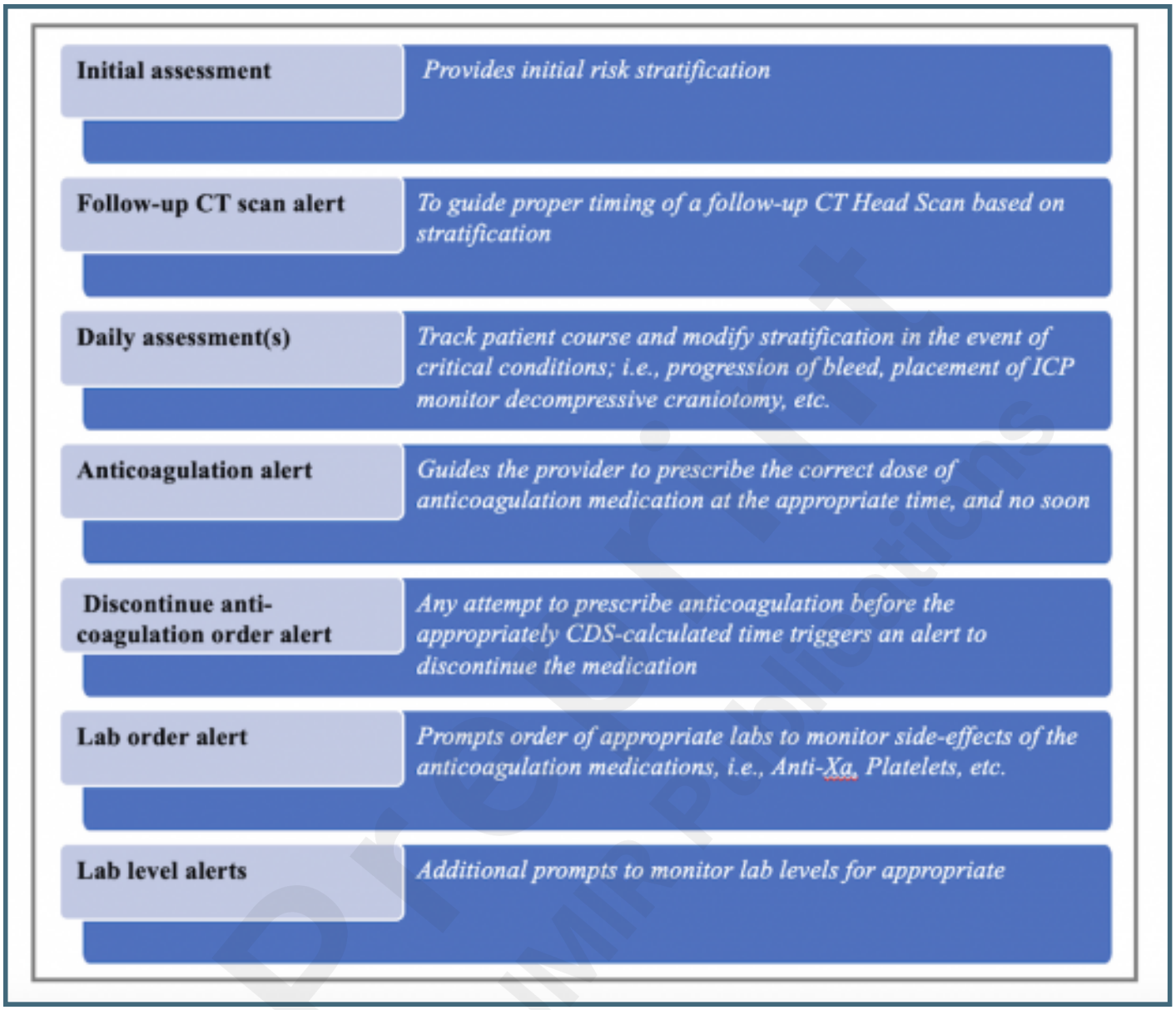
Supplementary Files

Figures

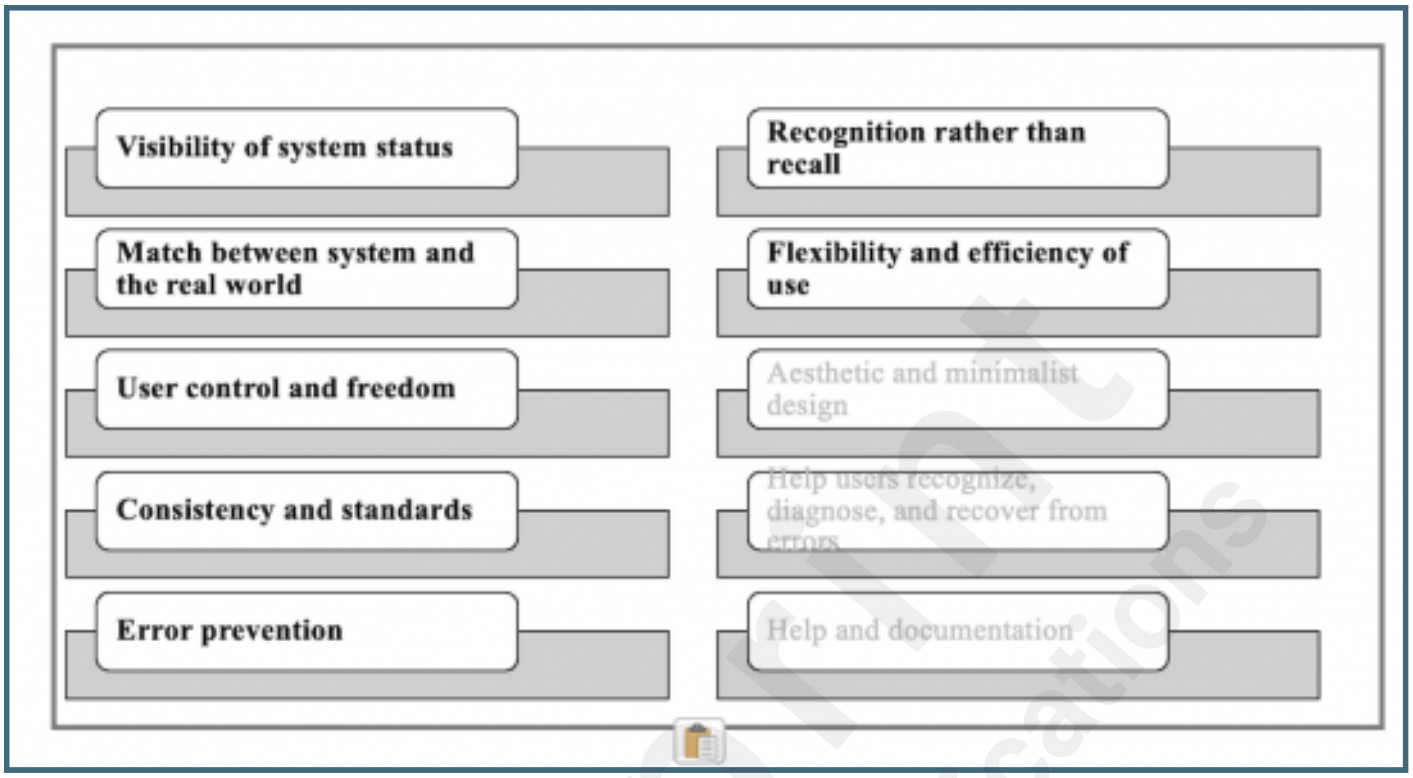
Clinical decision support system logic model for venous thromboembolism prevention.



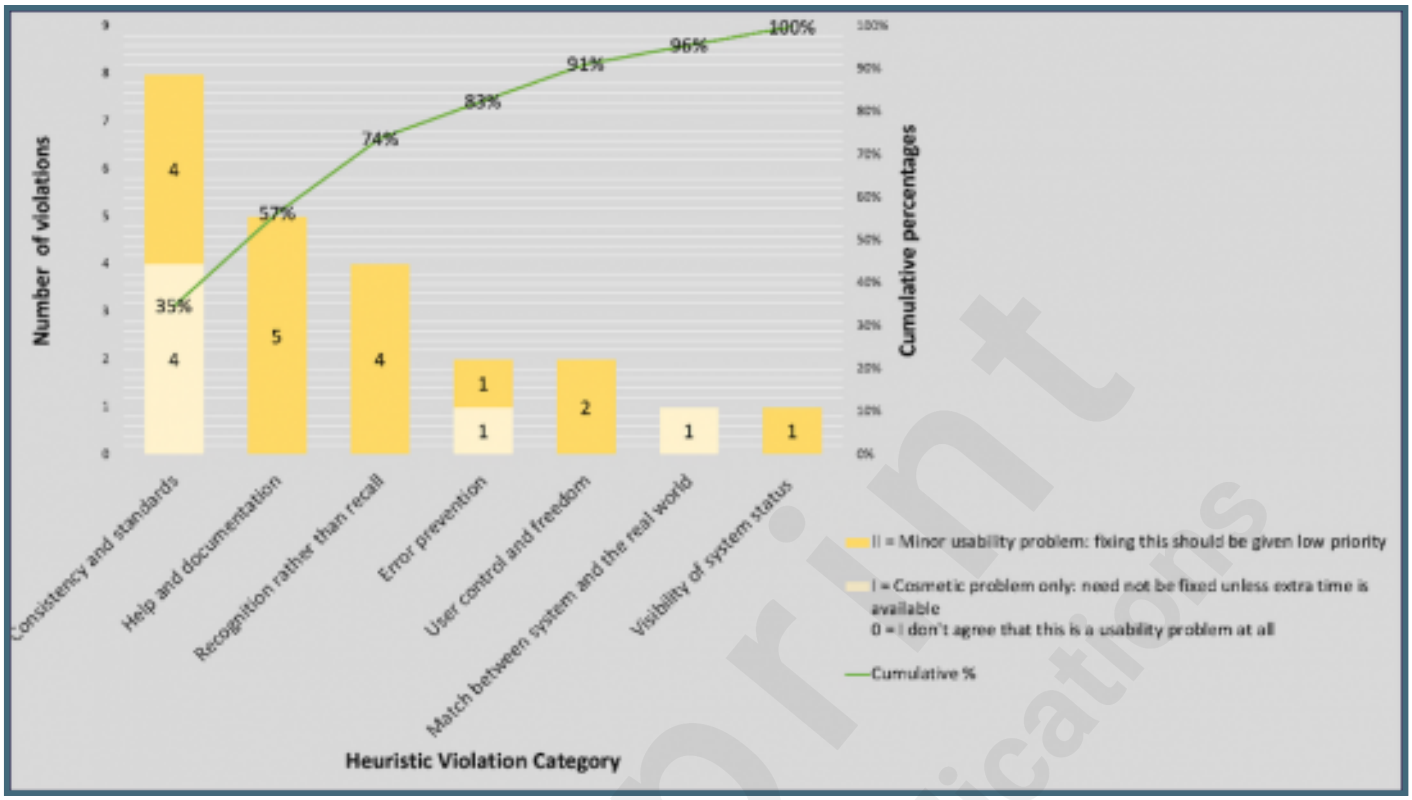
Description of seven alerts in TBI-CDSS.



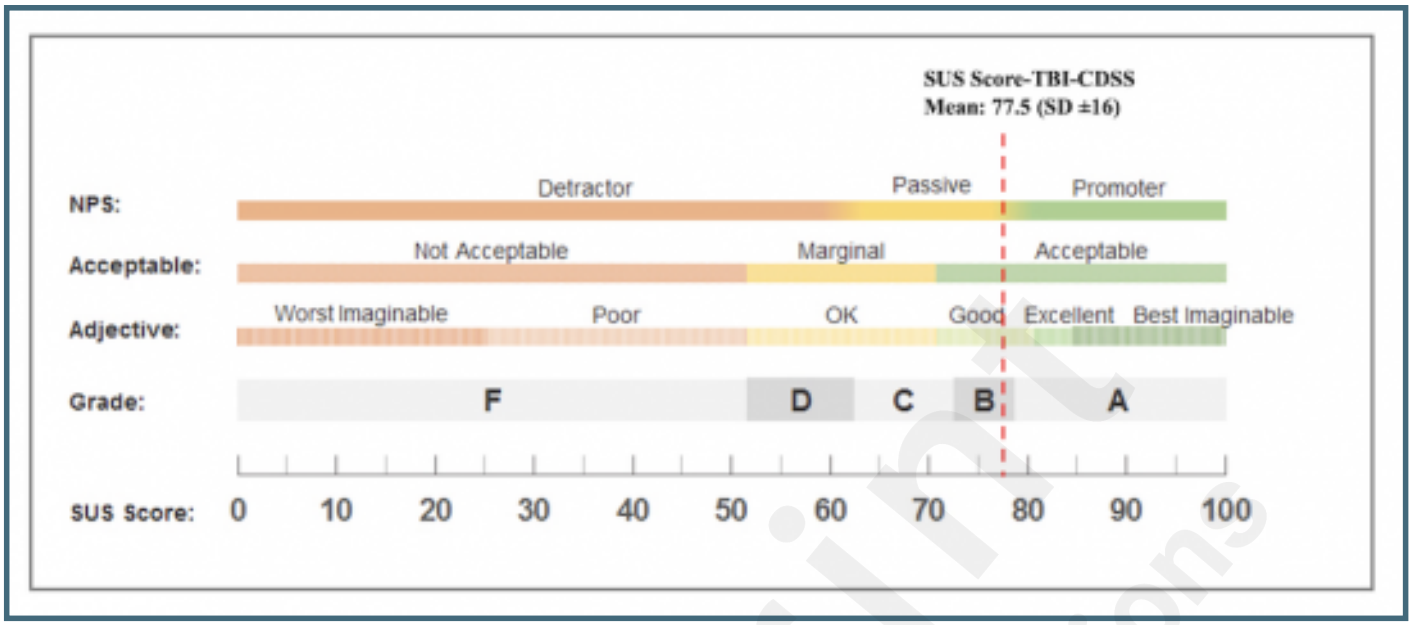
The seven heuristic principles violated.



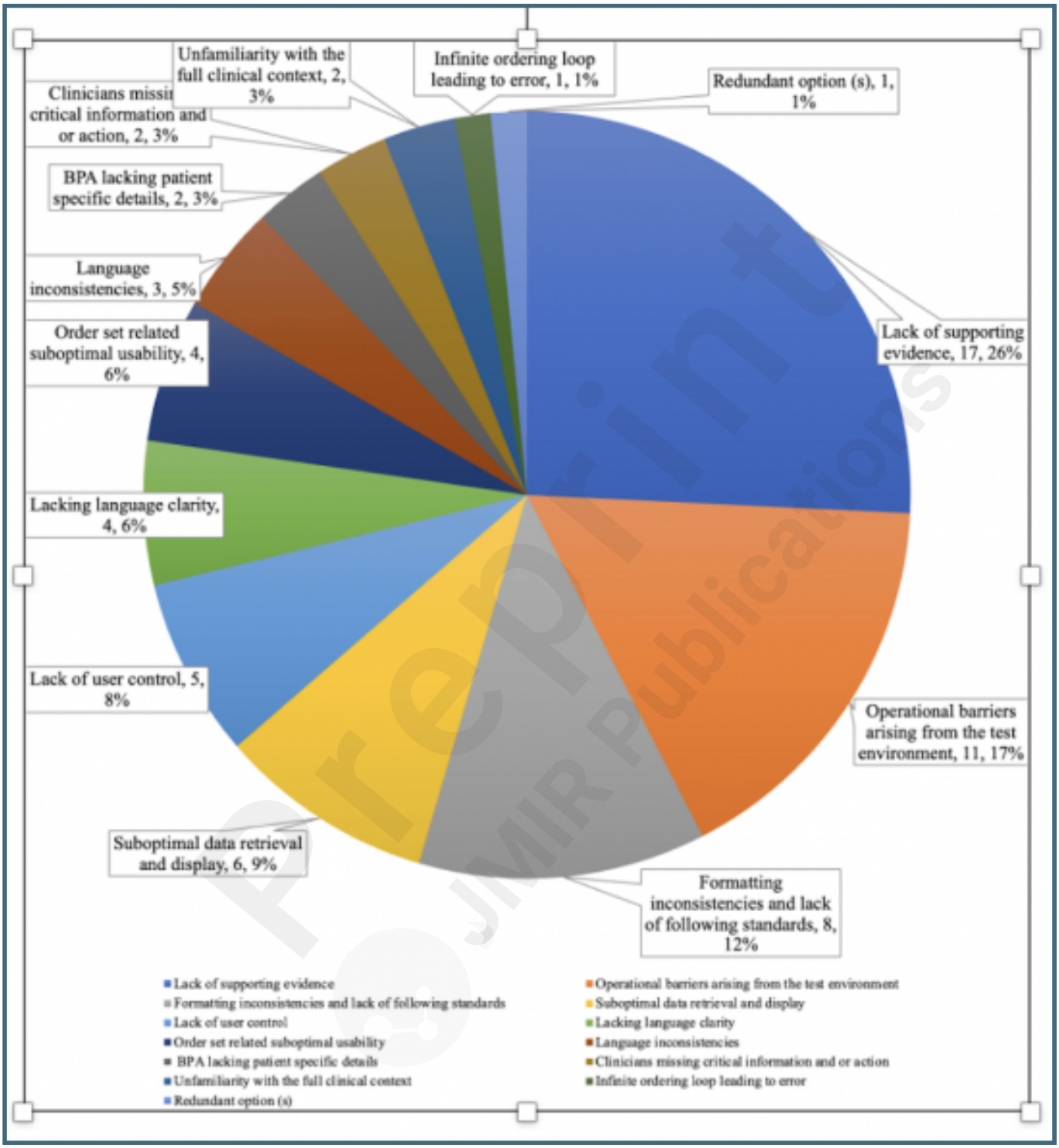
The Pareto chart of Heuristics principles violation and the severity ranking.



Systems usability scale interpreted as an acceptable/ good usability range.



Thematic analysis distribution.



Examples of modifications. Images included with approval from EPIC.

Multimedia Appendixes

Usability issues by theme.
URL: http://asset.jmir.pub/assets/93ba534ea0982f9ea2e951e5e7e7d123.docx