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Review

Efficacy and unintended consequences of hard-stop alerts in electronic health record systems: a systematic review

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ABSTRACT

Objective: Clinical decision support (CDS) hard-stop alerts—those in which the user is either prevented from taking an action altogether or allowed to proceed only with the external override of a third party—are increasingly common but can be problematic. To understand their appropriate application, we asked 3 key questions: (1) To what extent are hard-stop alerts effective in improving patient health and healthcare delivery outcomes? (2) What are the adverse events and unintended consequences of hard-stop alerts? (3) How do hard-stop alerts compare to soft-stop alerts?

Methods and Materials: Studies evaluating computerized hard-stop alerts in healthcare settings were identified from biomedical and computer science databases, gray literature sites, reference lists, and reviews. Articles were extracted for process outcomes, health outcomes, unintended consequences, user experience, and technical details.

Results: Of 32 studies, 15 evaluated health outcomes, 16 process outcomes only, 10 user experience, and 4 compared hard and soft stops. Seventy-nine percent showed improvement in health outcomes and 88% in process outcomes. Studies reporting good user experience cited heavy user involvement and iterative design. Eleven studies reported on unintended consequences including avoidance of hard-stopped workflow, increased alert frequency, and delay to care. Hard stops were superior to soft stops in 3 of 4 studies.

Conclusions: Hard stops can be effective and powerful tools in the CDS armamentarium, but they must be implemented judiciously with continuous user feedback informing rapid, iterative design. Investigators must report on associated health outcomes and unintended consequences when implementing IT solutions to clinical problems.

Key words: hard-stop alert, decision support systems, clinical, medical order entry systems, decision support techniques, alert fatigue

OBJECTIVE

Background and significance

As usage of electronic health records (EHRs) and computerized physician order entry (CPOE) have increased in the era of meaningful use from 23.9% of office physicians in 2005 to 86.9% in 2015,[1] use of clinical decision support (CDS) in the form of alerts has increased exponentially. An alert—an automatic warning message meant to communicate essential information to the clinician using an EHR—is now generated for 6% to 8% of all orders entered into an EHR by providers.[2,3] Each of these alerts represents an intention to provide useful information to the clinician, shape clinician behavior, and positively impact patient safety and outcomes.

However, the utility of these warnings is attenuated by unintended consequences such as alert fatigue (clinicians' tendency to ignore repeated alerts) and distraction, especially in an environment where alert volume is high, and many alerts are clinically irrelevant. In fact, 90% to 95% of alerts are overridden,[2–4] and this phenomenon has been identified as a cause of several high-profile errors.[5,6]

Efforts at minimizing alert fatigue have included tiering alerts by importance and titrating the degree of interaction required by the clinician accordingly.[7] Three different alert categories have arisen from these efforts: hard stops, soft stops, and passive alerts. We define hard-stop alerts as those in which the user is either prevented from taking an action altogether or allowed to proceed only with the external override of a third party. Soft-stop alerts are those in which the user is allowed to proceed against the recommendations presented in the alert as long as an active acknowledgement reason is entered. A passive alert is one in which information is presented but does not interrupt the user workflow and does not require any interaction on the part of the user.

In the context of alert fatigue, hard-stop alerts would appear to prevent the kind of dangerous overrides that result in harm to the patient. They can be an appealing option when compared to soft stops and passive alerts for this reason, but they can have unintended consequences, such as delays to the delivery of appropriate therapy.[8]

To inform the appropriate application of alerts, we sought to characterize the risks and benefits of hard stops by asking 3 key questions: (1) To what extent are hard-stop CDS alerts in EHRs effective in improving patient health and healthcare delivery outcomes? (2) What are the unintended consequences and adverse events of computerized hard-stop alerts? (3) How do hard-stop alerts compare to soft-stop alerts in efficacy and unintended consequences?

MATERIALS AND METHODS

To address these questions, we performed a systematic review of the biomedical literature. This systematic review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines.[9] A formal protocol was developed and submitted to PROSPERO registry of systematic reviews prior to commencing the review (CRD42017057262).

Data sources and searches

We began by performing a simple search on PubMed for the term "hard stop." Of the 38 studies returned, 21 pertained to alerts in the EHR. A full-text review was performed on these studies extracting the definition of "hard stop" from each. There was near, but not universal, consensus on the definition of hard stop in the papers we reviewed. Twenty-one papers used the term "hard stop" or "hard-stop" in the context of CDS. For 16 of these, the definition was similar: hard-stop alerts are automatic warning messages meant to communicate essential information to the clinician using an EHR that either prevent the user from taking an action altogether or allow the user to proceed only with the external override of a third party.[7,10–24] For 3 of the remaining studies, the definition was most consistent with what we have termed a soft stop—an automatic warning message meant to provide information that may change the clinician's course of action but can be ignored or overridden with only minimal action (such as clicking an acknowledgement reason).[24–26] In the final 2 studies, the term "hard stop" was used but not defined.[27,28] Definitions extracted from the papers can be found in Supplementary Appendix B. From these studies and others in the domain of CDS alerts, a consensus definition of hard stop was developed along with definitions for soft-stop alerts and passive alerts.

Using these studies and associated references, a search strategy was developed in collaboration with our institution's librarian (AH) to identify all hypothesis-testing and qualitative studies in the domain of hard-stop alerts. The Yale MeSH Analyzer was used to identify key Medical Subject Headings (MeSH) in the MEDLINE database.[29] Important free-text search terms included "hard stop," "mandatory," and "forcing functions." These, combined with index terms relevant to computerized CDS, were used to examine the following databases: MEDLINE (Ovid), MEDLINE In-Process (Ovid), EMBASE (Ovid), The Cochrane Library (Wiley), Web of Science, and Engineering Village. Gray literature was searched and the following relevant websites examined: National Institute for Health and Care Excellence (NICE), EMIS, Vision, and SystemOne. Finally, the database search was enhanced by a review of reference lists from relevant articles. No date limits or language restrictions were used. All searches were performed by a professional librarian, initially conducted on March 9, 2017, and updated on December 9, 2017. Full search strategies are available in Supplementary Appendix A.

Study selection

We identified 826 studies using our search strategy (excluding duplicates). All titles and abstracts were screened in duplicate by 3 reviewers (EP, MS, RS). All discrepancies were resolved by discussion requiring consensus from both reviewers. One-hundred-fourteen full-text articles were then reviewed in duplicate (EP, MS) and all discrepancies resolved in a similar manner. Thirty-two articles were included in the review. The screening process is illustrated in Figure 1 and was performed using Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia).

We included experimental and observational studies reporting quantitative measures of the impact of hard-stop alerts or qualitative analysis of the experience of hard-stop alerts. We required that the hard stop be embedded within a software program utilized in a healthcare setting. Studies in which the hard stop was one small component of a much larger intervention and not evaluated directly were excluded. In cases in which the description of the intervention was insufficient to categorize as a hard stop, soft stop, or passive alert, the authors were contacted for further clarification.

Data extraction, quality assessment, and analysis

Data were extracted into a web-based spreadsheet (Google Sheets, Google, Mountain View, CA) and references managed using a web-based reference manager (Paperpile, Paperpile LLC, Vienna, Austria). Data were extracted in full by one reviewer (EP) with
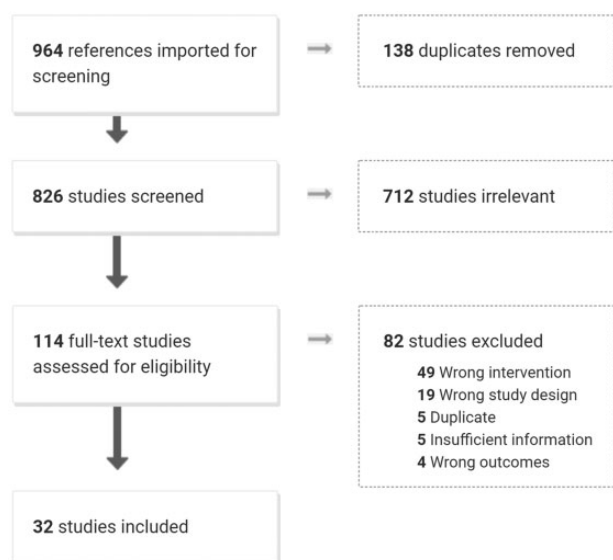
Figure 1. Flow of information through the different phases of the systematic review.

confirmation by a second reviewer (MS). All discrepancies were resolved by discussion. Extracted information included hard stop definitions, synonyms, and technical specifics, including the software program used, hard-stop alert trigger, alert message text, and the process required to resolve the alert. We also extracted study design, time period, sample size, and clinical domain of the intervention as well as process outcomes, patient health and healthcare delivery outcomes, adverse events and unintended consequences, and the user experience reported in each study.

We assessed methodological quality using the Downs and Black Checklist for both randomized and nonrandomized studies.[30] Downs and Black Checklist scores were further categorized into excellent, good, fair, and poor.[31] The heterogeneous character and overall low quality of the studies precluded formal meta-analyses.

RESULTS

Definitions
Of the 32 studies included in the review, 11 used the term "hard stop."[7,8,12,13,15–20,23] Terms used by other studies to describe the same concept included "mandatory," "obligatory," "compulsory," or "required." Some studies described the action of the system such as "must be entered into the system before" or "trigger the system to not allow" without using a specific term.

Description of the evidence
The evidentiary table (Table 1) outlines the characteristics of the included studies and their outcomes. Of the 32 included studies, 3 were randomized controlled trials,[8,50,52] 3 retrospective cohort studies,[7,18,36] 18 pre-post studies,[12,13,15,16,19,20,33,35,37,39–49] and 5 time series studies.[17,23,32,34,38] Six were conducted before 2010[7,32,39,41,48,49] and 12 within the past 3 years.[12,15,16,18,33–36,38,46,47,50] The majority (n = 29) were conducted in the United States, with the remaining conducted in Taiwan (n = 1),[13] Korea (n = 1),[48] and Israel (n = 1).[41] Most (n = 26) were conducted in the hospital setting at single-institution, academic medical centers. Two

were conducted at a Veterans Affairs hospital[35,43] and 4 in a multi-practice primary care setting.[15,41,44,49]

Fourteen studies targeted inpatient medicine,[7,8,12,13,16,18,23,32,34,37,40,45–48] 4 emergency medicine,[20,38,39,43] 5 primary care,[13,41,44,49,51] 3 anesthesia,[17,36,52] and 2 pediatrics[23,33] with the remainder targeting diverse specialties. Common clinical topics included venous thromboembolism (VTE) prophylaxis (n = 4),[37,40,45,47] drug-drug or drug-allergy interactions (n = 4),[7,8,49,53] reducing low-yield imaging (n = 3),[44,50,51] and use of pulmonary CT angiography (CTA) for pulmonary embolism (n = 2).[38,43]

Overall, study quality was low. Seven were of poor quality, 17 of fair quality, 8 of good quality, and none of excellent quality.

Types of hard stops
There were 2 types of hard stops identified among the interventions. Interruptive (pop-up) alerts and inline hard stops on data entry fields. For interruptive alerts, a dialog box pops up, interrupting the user workflow to communicate a message and requiring interaction before the workflow can proceed. For inline alerts, the message displays within the window in which the user is working, and no additional steps are needed to continue working in the task other than completing the required documentation. Twenty-three of the 32 studies evaluated interruptive alerts[7,8,12,13,15–20,23,32,33,37,39–41,44,45,47–50] and 9 evaluated inline alerts.[23,32,34–36,38,42,43,49] Technical specifics for each group are available in Supplementary Appendices C and D, respectively.

For interruptive alerts, the most common alert trigger was order placement for the medication or test that was the CDS target. In 2 cases, the alert was fired on discharge order initiation: 1 when the purpose of the CDS was to increase HIV screening in the ED[33] and the other to increase completion of an asthma action plan prior to discharge from the hospital.[23] One study fired the alert on EHR login to attempt to improve appropriate re-evaluation of restraint orders[39] and another upon opening the patient chart to increase blood pressure documentation.[41] Two studies fired the alert on attempt to close the chart: 1 to increase postpartum depression screening[15] and the other to increase anesthesia adverse event reporting.[17] Seven of the studies allowed the alert to be overridden by contacting an external third party such as a pharmacist or radiologist with whom the case could be discussed and who had the ability to enter the order successfully if approved.[8,12,16,18,33,44,51] The remaining 16 did not allow for any override mechanism.

Inline alerts were primarily used to increase documentation in orders (n = 3),[38,42,43] flowsheets (n = 2),[32,36] and notes (n = 4).[23,34,35,49] In all cases, the order could not be signed or flowsheet/note closed until documentation was complete. In no cases was there a mechanism for override other than abandoning the task altogether. For the majority of these alerts, documentation was focused on things that are likely to be assessed in routine practice but were poorly documented, such as anesthesia case start time and pain assessment. In 2 cases, alerts attempted to more actively guide clinical decision making by requiring providers to enter a Well's score within a CTA order[38] or requiring providers to enter a mobility order for intensive care unit (ICU) patients.[42]

Effect on patient health and healthcare delivery outcomes
Of the 32 studies, 15 evaluated patient health or healthcare delivery outcomes, and 11 showed improvement in those outcomes

Table 1. Evidentiary table

| Study	Quality	Intervention			Process Outcomes				Patient Health/Healthcare Delivery Outcomes				Unintended/ Adverse Events		User Experience
Author, year / Targeted behavior	Downs and Black score(cat)	Type	Trigger/Setting	Third Party Over-ride	Measured	Baseline	Goal	Outcome (*p<0.05)	Measured	Baseline	Goal	Outcome (*p<0.05)	Measured	Events Discussed	Discussed Good/Neutral/Poor
Bails et al.[32], 2008 Medication reconciliation	12 (P)	interruptive	order (any)		reconciliation completed	50%	◄	95%							✓ neutral
Balasuriya et al.[33], 2017 Reduction of adverse drug events	16 (F)	interruptive	order (med)	✓	order modified	34.2%	◄	92.70%						increased alerts	
Ban et al.[34], 2017 Procedural supervision documentation	16 (F)	inline	note (procedure)		documentation completed	62.8%	◄	99.8%*							✓ good
Bansal et al.[35], 2016 Intent of chemotherapy documentation	11 (P)	inline	note (outpatient visit)		documentation completed	74.11%	◄	80%							✓ poor
David et al.[36], 2016 Documentation of key anesthesia case features	14 (F)	inline	flowsheet (anesthesia case)		documentation completed	95.6%	◄	100%							
Galanter et al.[37], 2010 VTE prophylaxis	21 (G)	interruptive	order (any)						✓ prophylaxis received / VTE rate	25.9% / 0.51%	◄ / ▶	36.8%* / 0.43%	✓	no increased bleeding	
Geeting et al.[38], 2016 Appropriate pulmonary CTA use	20 (G)	inline	order (pulmonary CTA)		appropriateness of CTA	58%	◄	76%*	✓ diagnosis of PE	0.44%	◄	0.38%			✓ poor
Griffey et al.[39], 2009 Physical restraint orders	17 (F)	interruptive	EHR login		median time to renewal / mean # orders/patient	189 min / 1.46	▶ / ◄	133 min* / 2.34*	✓ median time in restraint	235 min	▶	130 min		no events reported	
Haut et al.[40], 2012 VTE prophylaxis	18 (F)	interruptive	order set		risk stratification documentation	3.0%	◄	97.8%*	✓ prophylaxis received / DVT rate / preventable VTE rate	66.2% / 2.25% / 1.00%	◄ / ▶ / ▶	84.4%* / 0.25%* / 0.17%*			✓ neutral
Helmons et al.[12], 2015 Inpatient formulary non-adherence	15 (F)	interruptive	order (med)	✓	nonadherence rate	3.5%	▶	1.2%*							
Heymann et al.[41], 2005 Blood pressure documentation	11 (P)	interruptive	open patient chart		bp documentation	40.6%	◄	58.5%*							
Hildreth et al.[42], 2010 ICU mobility	17 (F)	inline	order set		mobility orders / mobility achieved	58% / 22%	◄ / ◄	82%* / 80%*	✓ multiple			X no change	✓	no events reported	

(continued)

Table 1. continued

Study	Quality	Intervention			Process Outcomes				Patient Health/Healthcare Delivery Outcomes				Unintended/Adverse Events		User Experience
Author, year Targeted behavior	Downs and Black[a] score(cat)	Type	Trigger/Setting	Third Party Over-ride	Measured	Baseline	Goal	Outcome ($*p<0.05$)	Measured	Baseline	Goal	Outcome ($*p<0.05$)	Measured	Events Discussed	Discussed Good/Neutral/Poor
Hoo et al.[43]**, 2011** Appropriate pulmonary CTA use	17 (F)	inline	order (pulmonary CTA)	✓					✓ pulmonary CTA yield	3.1%	◀	16.5%*			
Hsu et al.[13]**, 2014** Inappropriate pill splitting	20 (G)	interruptive	quantity in order (med)		✓ warning rate	0.61%	▶	0.16%*							
Ip et al.[44]**, 2014** Inappropriate lumbar-spine MRI for low-back pain	21 (G)	interruptive	order (lumbar-spine MRI)	✓	✓ guideline adherence	78%	◀	96%*	✓ visits w/ lumbar-spine MRI visits w/ any MRI	5.3% 6.5%	▶ ▶	3.7%* 4.5%*			
Khoury et al.[45]**, 2014** VTE prophylaxis	13 (P)	interruptive	order (any)						✓ prophylaxis received prophylaxis within 24h VTE rate	73% 73% 2%	◀ ◀ ▶	90%* 93%* 0.5%			
Larson et al.[46]**, 2016** Red blood cell transfusions	16 (F)	interruptive	pharmacy approval						✓ transfusion rate estimated cost savings	84%	▶	76%* $700k/yr			
Lau et al.[47]**, 2015** VTE prophylaxis	15 (F)	interruptive	order set						✓ prophylaxis received racial disparity	55-70% 6-14%	◀ ▶	82-85%* 1-4%*			
Loudon et al.[15]**, 2016** Post-partum depression screening	12 (P)	interruptive	close patient chart	✓	✓ screening rate	58%	◀	99.5%							
Nikolic et al.[16]**, 2017** Stool studies after hospital day 3	16 (F)	interruptive	order (stool culture, GC-EIA, O&P)	✓					✓ # stool O&P # GC-EIA # stool cultures estimated cost savings	129 47 249	▶ ▶ ▶	46* 27 106* $8k	✓	decrease in bacterial detected	
Park et al.[48]**, 2008** Drug hypersensitivity reporting	13 (P)	interruptive	not noted		✓ past reaction reporting rate	0.23%	◀	0.78%	✓ rate of reactions from known allergen	15%	▶	1%			
Paterno et al.[7]**, 2009** Drug-drug interaction alerts	17 (F)	interruptive	order (med)		✓ compliance (not tiered vs tiered) compliance (soft vs hard)	34% 29%	◀ ◀	100%* 100%							✓ good
Peterfreund et al.[17]**, 2011** Anesthesia adverse event reporting	12 (P)	interruptive	close anesthesia case		✓ number events captured	132	◀	213*							✓ good

(continued)

Table 1. continued

| Study — Author, year / Targeted behavior	Quality — Downs and Black[a] score(cat)	Intervention — Type	Intervention — Trigger/Setting	Third Party Over-ride	Process Outcomes — Measured	Baseline	Goal	Outcome (*p < 0.05)	Patient Health/Healthcare Delivery Outcomes — Measured	Baseline	Goal	Outcome (*p < 0.05)	Unintended/Adverse Events — Measured	Events Discussed	User Experience — Discussed Good/Neutral/Poor
Procop et al.[18], 2015 Unnecessary duplicate lab tests	16 (F)	interruptive	order (lab)	✓	effectively averting duplicate orders (soft vs hard)	43.6%	◀	92.3%*	✓ cost savings per alert (soft vs hard)	$3.52	◀	$16.08			✓ good
Rossi et al.[19], 2012 Inappropriate metformin administration in patients at risk for lactic acidosis	19 (G)	interruptive	order (metformin)		inappropriate administration rate	32.6%	▶	8.8%*	✓ lactic acidosis events	0	▶	0		improved glycemic control	
Saigh et al.[49], 2006 Pain assessment	16 (F)	inline	note (outpatient visit)		✓ pain diagnosis rate / pain documentation	42% / 49%	◀ / ◀	36% / 44%							✓ poor
Schnall et al.[20], 2013 ED HIV screening	18 (F)	interruptive	order (discharge)		✓ compliance discharges / compliance admissions	6.4% / 6.0%	◀ / ◀	94.0%* / 44.5%*							
Strom et al.[8], 2010 Inappropriate concurrent TMP-SMX/warfarin administration	21 (G)	interruptive	order (TMP/Sulfa, warfarin)	✓	✓ not reordering alerting med	13.5%	◀	57.2%					✓	4 cases delayed therapy	
Tajmir et al.[50], 2017 Ottawa Ankle Rules adherence	20 (G)	interruptive	order (foot/ankle x-ray)		✓ adherence ankle x-ray / adherence foot x-ray	61.8% / 63.6%	◀ / ◀	92.6%* / 81.0%*	✓ visits w/ ankle x-ray / visits w/ foot x-ray / fractures detected	48.9% / 54.0% / 4.8%	▶ / ▶ / ◀	64.3%* / 54.6%* / 10.1%*		note/CDS discordance	
Vartanians et al.[51], 2010 Low-yield imaging (CT, MRI, Nuclear Medicine)	16 (F)	interruptive	order (imaging)	✓	✓ % studies low-yield / % low-yield abandoned	5.43% / 44.33%	▶ / ▶	1.92%* / 11.45%*							
Wetmore et al.[52], 2014 Pre-anesthetic safety check-list	21 (G)	inline	flowsheet (anesthesia case)		✓ median items completed / median time to med	9.5 / 240s	◀ / ▶	19* / 520.5							
Zipkin et al.[23], 2013 Asthma action plan	17 (F)	interruptive	order (discharge)		✓ plan provided and complete	79%	◀	81%*							✓ good

Abbreviations: bp, blood pressure; CT, computed tomography; CTA, computed tomography angiography; DVT, deep venous thrombosis; ED, emergency department; EHR, electronic health record; GC-EIA, Giardia/Cryptosporidium enzyme immunoassay screen; HIV, human immunodeficiency virus; ICU, intensive care unit; MRI, magnetic resonance imaging; O&P, ova and parasite; PE, pulmonary embolism; TMP-SMX, trimethoprim-sulfamethoxazole; VTE, venous thromboembolism.

[a]Downs and Black scores categorized into E for "excellent" (24-28 points), G for "good" (19-23 points), F for "fair" (14-18 points), or P for "poor" (<14 points).[31]

(a) Number of Studies Reporting Outcomes by Category
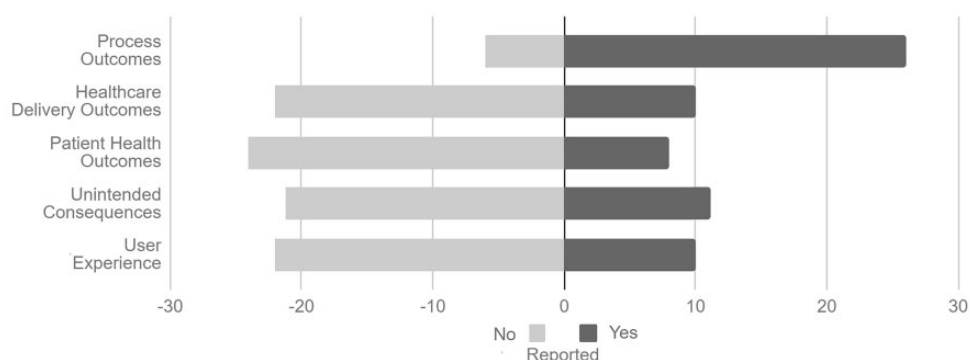
(b) Number of Studies Reporting Improvement in Outcomes
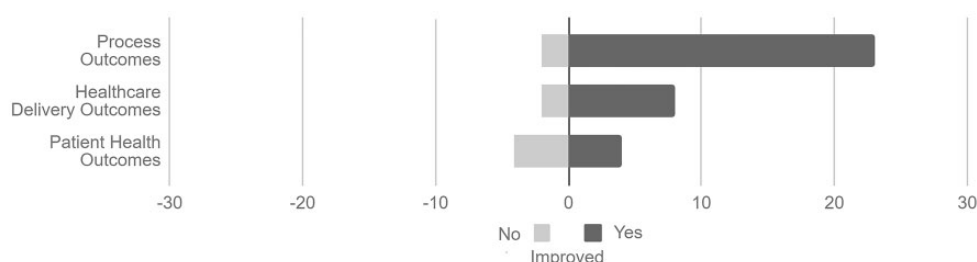
Figure 2. (a) Number of studies reporting outcomes by category. (b) Number of studies reporting improvement in outcomes associated with the hard-stop intervention.

(Figure 2). For patient health outcomes, 4 of 8 studies reported improvement. Haut et al.[40] showed a significant reduction in deep venous thrombosis (DVT) rate and preventable VTE events in trauma patients by embedding a hard-stop VTE risk assessment tool with appropriate prophylaxis orders within the admission order set. Hoo et al.[43] showed an increase in the yield of pulmonary CTA for pulmonary embolism by embedding a mandatory Wells score calculator and conditional D-dimer order into the CTA order process. Park et al.[48] showed a decrease in drug hypersensitivity reactions caused by readministration of a suspected causative agent in response to hard-stop entry of prior drug hypersensitivity reactions on admission. Tajmir et al.[50] showed an increase in detection of clinically significant fractures and an increase in radiographic yield after embedding a mandatory Ottawa Ankle Rules CDS module in the order for plain ankle and foot radiography in the urgent care setting.

In 8 of 10 studies assessing healthcare delivery outcomes such as lab utilization or imaging cost savings, the intervention was associated with improvement as intended. Four studies of interventions to increase rates of appropriate VTE prophylaxis demonstrated improvement after implementation of a hard stop.[37,40,45,47] Ip et al.[44] showed a decrease in percent lower-back pain visits resulting in lumbar-spine MRI in response to a hard-stop risk stratification module with in the MRI order, Larson et al.[46] showed a reduction in transfusion rates after eliminating a hard stop for critical value notification from pharmacy to provider for hemoglobin levels between 7.00 and 7.99, Procop et al.[18] showed cost savings associated with a hard-stop alert preventing duplicate lab orders when compared to a soft-stop alert, and Nikolic et al.[16] showed a reduction in proportion of stool cultures and stool ova/parasite examinations ordered after day 3 of hospitalization and an estimated cost savings in association with a hard-stop alert preventing such orders.

Process measures such as changes in documentation completion rates, order rates, and alert responses were evaluated in 26 studies, and in 16 of these, they were the only outcomes reported.[7,8,12,13,15,17,20,23,32,34–36,41,49,51,52] 24 of these studies reported significant improvement in process measures in association with hard stop implementation.[7,8,12,13,15,17–20,23,32–34,36,38–42,44,48,50–52] Saigh et al.[49] showed no increase in reported pain diagnoses after implementation of a hard-stop pain assessment module for the outpatient encounter note, and Bansal et al.[35] showed no improvement of intent of chemotherapy documentation after placing mandatory fields in the visit note template.

Adverse events and unintended consequences

Eleven of the 32 included studies reported on adverse events or unintended consequences associated with hard-stop alerts. In 3 cases, the authors stated that no problems associated with the intervention were reported but did not actively evaluate for adverse events or elaborate further.[18,39,42] Only 2 studies, Galanter et al. and Strom et al., specified health-related adverse events as planned outcomes measures prior to initiation of the study. Galanter et al.[37] evaluated the incidence of major and minor bleeding events after implementation of a hard-stop mandatory VTE risk assessment tool embedded in the admission order set, and an increase was not detected in association with the tool. Strom et al.[8] encountered 4 delays in the delivery of appropriate medical therapy in their randomized controlled trial (RCT) evaluating a hard-stop drug-drug interaction alert for sulfamethoxazole-trimethoprim and warfarin, and the trial was ended early as a result. The remaining 5 studies reported a variety of unintended consequences including an increase in alert frequency,[33] a compensatory increase in specialists' use of lumbar-spine MRI in

response to a hard-stop alert prohibiting lumbar-spine MRI for low back pain without red flags in the primary care,[44] an unexpected improvement in glycemic control in association with a hard-stop alert prohibiting inpatient metformin in patients at risk for lactic acidosis and instead directing providers to an insulin order set,[19] a 1.3% discordance between findings documented in the mandatory CDS tool and those documented in the clinical note,[50] and a decrease in percent of tests positive for enteropathogenic bacteria in patients hospitalized for more than 3 days.[16]

Comparison to soft stops

Four studies directly compared hard-stop alerts to soft-stop alerts. Three out of the 4 studies showed superiority of the hard-stop alert in comparison to the soft-stop alert in achieving the desired process outcome.[7,18,19] The fourth study found that both soft-stop and hard-stop alerts reminding the providers to complete restraint renewal orders improved ordering rates over the alert-free baseline but found no difference between the 2 alert styles in median restraint order renewal time or number of restraint orders.[39] Only 1 study, Procop et al.,[18] directly compared the impact of a hard-stop vs soft-stop alert on a healthcare delivery outcome and showed a significant cost savings using the hard-stop alert over the soft-stop alert to prevent unnecessary duplicate lab orders. No studies compared adverse event rates between the 2 alert styles.

User experience

Ten studies reported on user experience. Among these, 4 studies reported broad provider acceptance of the hard-stop alert and attributed this to comprehensive implementation plans involving user engagement, multiple iterations, and rapid response to feedback.[17,18,23,34] Two additional studies stated their interventions were well accepted with 1 specifying that acceptance was likely tied to low frequency of hard-stop alerts.[7,32] The remaining 3 studies examined inline hard stops on documentation fields and reported poor user reception. After implementation of a hard stop on documentation of chemotherapy intent in a clinical note template, no increase in documentation was shown, and users reported avoiding use of the template because of the hard stops.[35] In Geeting et al.,[38] the authors hypothesized that users falsely inflated the Wells score entered in a mandatory field of a pulmonary CTA order, resulting in improvement in the appropriateness of CTA orders without the expected change in detection rates of pulmonary embolism. Finally, in Saigh et al., the majority of users surveyed felt a mandatory pain assessment tool embedded in their workflow did not change their pain assessment and was difficult to use. Many providers chose the fastest way through the module, even if it produced inaccurate and contradictory clinical documentation to limit time spent in the tool.[49]

DISCUSSION

Main findings

We found that hard stops are often used in clinical practice as a tool to influence provider behavior despite the concerns discussed in the literature around their use.[54,55] Although several prior reviews have more broadly examined the effects of CDS and alerts on a variety of outcomes[56–59] and still other reviews have commented on the use of hard-stop alerts as part of an overall analysis of CDS for a particular clinical question,[11,22] this is the first review to our knowledge that specifically examines the hard-stop modality to answer these key 3 questions:

To what extent are hard-stop CDS alerts in EHRs effective in improving patient health and healthcare delivery outcomes?

In the majority of cases, hard-stop CDS alerts were associated with the desired improvements in process measures but demonstration of improvement in patient health outcomes or healthcare delivery outcomes was less common. This is consistent with what has been shown previously for all categories of CDS alerts.[60] Notably, in more than half the studies, investigators did not report on health outcomes or adverse events associated with the intervention. For those who did, 80% (8 of 10) showed improvement in the desired healthcare delivery outcome such as lab or imaging costs or ordering rate, but only 50% (4 of 8) showed improvement in patient health outcomes such as detection of pulmonary embolism. Patient health and healthcare delivery outcomes are harder to measure, which likely explains the relative paucity of evidence presented in these studies, but more effort needs to be made to include these outcomes in studies, as these are the outcomes that matter most from the perspective of patients, providers, and public health. Based on the evidence presented here, hard-stop alerts appear to be a useful tool in improving healthcare delivery outcomes, but no conclusion can be made about their efficacy in improving patient health outcomes.

What are the adverse effects and unintended consequences of hard-stop electronic alerts?

In agreement with what has now been recognized as an unavoidable part of health information technology,[61] our review showed that unintended consequences do occur in association with hard stops and that these consequences can be either positive or negative, minor or profound. A more complete picture of the consequences specific to hard stops is impossible, given the very limited number of studies that systematically evaluated this area. Recent studies were more likely to incorporate a discussion of unintended consequences likely reflecting increasing awareness of technology-induced error.

How do hard-stop alerts compare to soft-stop alerts in efficacy and unintended consequences?

Although only 4 studies directly compared the 2 alerts styles, hard-stop alerts appear to be superior to soft-stop alerts in achieving the desired process outcomes. This is expected, as hard-stop alerts, by design, allow for only a single course of action. No conclusion can be made about how the 2 alert styles compare when considering patient health, healthcare delivery outcomes, and unintended consequences due to lack of evidence.

Implications

Implications for practice

There is a desire among providers for differentiation of the alert experience based on severity of the alert and agreement that it should be harder to override alerts for critical issues.[53] Such tiering of alerts improves responses to all modalities of alerts.[7] Combined with the demonstrated improvement in process measures associated with hard stops, this review supports a role for hard-stop alerts in the CDS armamentarium. However, because they can be such powerful tools, effectively prohibiting specific actions on the part of the provider, they need to be carefully implemented with diligent assessment of possible harms and continuous user involvement in the design and implementation process. A lack of user testing and iterative design is more likely to lead to unintended consequences and error-prone systems and must be addressed in accordance with the growing body of literature on this topic.[61]

Implications for implementation

Several design characteristics for hard-stop alerts appear to be associated with positive outcomes. These included integrating important clinical decision-making aids, such as recent relevant lab results and specific score or risk calculators,[18,37,40,43,50] triggering the alert at a natural and relevant place in physician workflow,[12,13,18,33,35,43,49] and providing the possibility for a third-party override, such as telephone discussion with a pharmacist or radiologist.[8,12,16,18,33]

Implications for research

As this review demonstrates, there continues to be marked heterogeneity in design, implementation, and evaluation hampering the ability to disseminate these tools and ensure their safe and effective use. Based on the literature presented here, we propose that future research on hard-stop alerts must report on clearly defined patient health outcomes, healthcare delivery outcomes, adverse events, and user experience in addition to any relevant process measures. Publications must include sufficient technical details to allow for replication elsewhere. Screenshots are especially useful in achieving this goal and should be included. Study design also must be strengthened to allow for more robust conclusions to be drawn. Pre-post design may be more realistic in the setting of practical clinical informatics or quality improvement initiatives, but conclusions could be strengthened with the use of cluster randomized trials or stronger quasi-experimental designs, such as an interrupted time-series analysis that accounts for temporal trends by comparison to either a local or national metric.[62] Interventions should be followed out for a long enough period to determine the true impact outside of the novelty effect.[63] Additionally a mixed methods approach—integrating qualitative and quantitative methods—may help better characterize user experience and identify the design features most associated with a successful implementation.[64] Hard-stop alerts are implemented in complex healthcare systems and have the capacity to affect not just the individual patient but all patients receiving care in that system. It is imperative that we approach the study of CDS with the same rigor with which we approach more traditional healthcare interventions. Development of a standard for the reporting of CDS interventions is an important step in achieving this goal.

With more and better designed studies, we may be able to draw conclusions on the clinical topics or clinical actions most and least suited to a hard-stop alert, on the specific design features that are most associated with a successful implementation, such as third-party override or display of clinical calculators/lab results, as well as develop a more specific roadmap for design and implementation. We may also be able to develop a better understanding of how hard-stop alerts fit into the overall alert experience of the clinician and the frequency with which they should be used.

Limitations

The most important limitation to this review is a lack of sufficient high-quality studies examining hard-stop alerts in the EHR as well as marked heterogeneity in the design and setting of the alerts limiting both the strength of the conclusions and generalizability. An additional limitation is the likely existence of significant publication bias. Although we performed a thorough search of the gray literature and included relevant abstracts not published as full articles, it is likely many more alerts are being implemented in clinical practice than are being studied. And of those studied, alerts with positive results are perhaps more likely to be published, potentially biasing the conclusion of this review. Another important limitation was underreporting of patient health and health delivery outcomes, harms, technical implementation details, and user responses. These are especially important in an attempt to judge the utility of the intervention and to replicate implementation of the intervention in new settings.

CONCLUSION

Hard stop can be a useful tool in the CDS armamentarium. Because hard stops are powerful tools, they must be implemented judiciously with continuous user feedback informing rapid, iterative design. Investigators must report on associated health outcomes and harms when implementing IT solutions to clinical problems.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

Conflict of interest statement. None declared.

CONTRIBUTORS

All authors have made substantial contribution to all of the following: (1) the concept or design of the work; or the acquisition, analysis, or interpretation of data for the work; (2) drafting the work or revising it critically for important intellectual content; (3) final approval of the version to be published; and (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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