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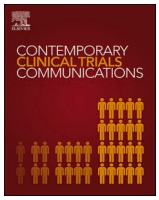

Comparing the Safety Action Feedback and Engagement (SAFE) Loop with an established incident reporting system: Study protocol for a pragmatic cluster randomized controlled trial

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ABSTRACT

Background: Incident reporting is widely used in hospitals to improve patient safety, but current reporting systems do not function optimally. The utility of incident reports is limited because hospital staff may not know what to report, may fear retaliation, and may doubt whether administrators will review reports and respond effectively.

Methods: This is a clustered randomized controlled trial of the Safety Action Feedback and Engagement (SAFE) Loop, an intervention designed to transform hospital incident reporting systems into effective tools for improving patient safety. The SAFE Loop has six key attributes: obtaining nurses' input about which safety problems to prioritize on their unit; focusing on learning about selected high-priority events; training nurses to write more informative event reports; prompting nurses to report high-priority events; integrating information about events from multiple sources; and providing feedback to nurses on findings and mitigation plans. The study will focus on medication errors and randomize 20 nursing units at a large academic/community hospital in Los Angeles. Outcomes include: (1) incident reporting practices (rates of high-priority reports, contributing factors described in reports), (2) nurses' attitudes toward incident reporting, and (3) rates of high-priority events. Quantitative analyses will compare changes in outcomes pre- and post-implementation between the intervention and control nursing units, and qualitative analyses will explore nurses' experiences with implementation.

Conclusion: If effective, SAFE Loop will have several benefits: increasing nurses' engagement with reporting, producing more informative reports, enabling safety leaders to understand problems, designing system-based solutions more effectively, and lowering rates of high-priority patient safety events.

1. Introduction

Despite decades of effort by policymakers, hospitals, and clinicians, medication errors still contribute to numerous patient deaths and injuries in hospitals each year [1]. In other high-risk industries such as aviation, voluntary incident reporting is a widely used and effective technique through which frontline personnel describe events—particularly near misses and hazardous conditions—so that safety officers can learn from them [2]. In such industries, personnel who witness the incidents write narrative descriptions that reveal critical details including contributing factors, and then organizations analyze the narratives, conduct follow-up investigations, provide feedback to front-line personnel, and ultimately modify systems to reduce the likelihood of future incidents [3].

Voluntary incident reporting systems have existed in U.S. hospitals

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ADE	Adverse Drug Event
DSM	Data and Safety Monitor
HFACS	Human Factors Analysis and Classification System
ICC	Intra-Cluster Correlation
IRB	Institutional Review Board
ISMP	Institute for Safe Medication Practices
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
PSO	Patient Safety Organization
SAFE	Safety Action Feedback and Engagement
SD	Standard Deviation
US	United States

for over 50 years [4], but they have been less effective at improving safety than reporting systems in other industries, in three major ways. First, although nurses believe reporting is a professional responsibility, have a patient-centered role in care that facilitates detection of safety events, and file the vast majority of incident reports, they are often uncertain about which non-adverse events to report and seldom receive feedback about how incident reports and follow-up reviews are used [5–9]. Second, hospitals receive thousands of reports each year, but most reports address low-risk problems and provide little information on contributing work-system factors (underlying factors in the work environment that lead to errors and near misses) [4,10–12]. Third, nurses often doubt whether hospital leaders will investigate reported incidents, use them to improve systems of care, cause reprisal for the reporter, and inform reporters and other nurses about such actions. Follow-up varies among different hospitals and hospital departments, and no optimal procedures for following up have been described.

By addressing these three shortcomings, this project seeks to transform hospitals' existing voluntary incident reporting systems into effective tools for improving patient safety. In this pragmatic cluster randomized controlled trial (RCT), we propose to compare the hospital's existing incident reporting system (i.e., usual practice) with the Safety Action and Feedback Engagement (SAFE) Loop, a novel intervention that engages frontline nurses to select and report target medication events and works with them to develop mitigation strategies. We define a "target medication event" as a high-priority event selected by a nursing unit that will be the focus of the SAFE Loop intervention on that unit.

2. SETTING, INTERVENTION, and TRIAL DESIGN

2.1. Setting

The study is taking place across 20 nursing units at Cedars-Sinai Medical Center, a hybrid academic/community hospital embedded in a learning healthcare system in urban Los Angeles, California. The medical center has 915 licensed beds, and there are more than 90,000 emergency department visits and 55,000 inpatient admissions each year. In 2015, the discharge payor mix was 42.9% Medicare, 12.6% Medicaid, 42.3% private insurance, and 2.1% other payors [13]. Approximately 1980 nurses provide 294,470 patient-days of care per year. Cedars Sinai Medical Center has achieved Six consecutive Magnet Nursing designations from the American Nurses Credentialing Center (ANCC).

2.1.1. Usual practice for incident reporting

At baseline, to manage patient safety and quality, Cedars-Sinai Medical Center uses the RLDatix platform (Datix Limited, London, United Kingdom) to submit, track, and follow-up on patient safety incident reports. All staff have access to submit incident reports, though most events are submitted by nurses. Reporting is entirely voluntary. The institution has education modules on the incident reporting process available for staff but training is not mandatory. Each event report includes structured data fields (e.g., the medication involved, route of administration, level of harm perceived by reporter) as well as a free-text narrative area where the reporter is asked to describe what occurred. These reports are received by nursing unit leaders and medical center patient safety staff, including the chief patient safety officer as well as nursing and pharmacy leaders. In 2021, staff submitted more than 5000 incident reports related to medication safety. Most of the reported incidents involved near misses or no-harm events.

2.2. Study participants

2.2.1. Nursing units

The study includes 34 acute care areas within Cedars-Sinai Medical Center, which are grouped together into 20 nursing units by virtue of sharing the same nursing unit manager. The study will include general medical and surgical floor units (which included monitored and unmonitored beds), intensive care units (there are no dedicated "step-down" units), and the emergency department due to similarities in workflows, activities, and patient populations. Each of the 20 nursing units has been randomized to either the intervention or control arm. Outpatient clinics, operating/procedure rooms, post-anesthesia care, and diagnostic and therapeutic services are excluded from the study due to their distinct workflows, activities, and patient populations.

2.2.2. Nurses

All 1980 nurses working on the 20 nursing units are eligible to participate in the study. All nurses on intervention units will be exposed to the intervention, whereas nurses on control units will continue to practice usual care and will be expected to continue to report medication safety events using the existing incident reporting system. Nurses working >50% time on a given nursing unit will be invited to complete surveys about attitudes toward incident reporting. The intervention did not distinguish nurses according to their degrees or experience. All nurses on acute care units at this hospital are Registered Nurses (RNs); 93% have a baccalaureate or higher degree in nursing and 81% have specialty certification.

2.2.3. Patients

Patients receiving care in an eligible nursing unit will also be eligible for inclusion in the study. While patients will not participate directly, their electronic health records will be reviewed to measure rates of target medication events.

2.3. SAFE loop intervention

2.3.1. Intervention components

The SAFE Loop has six key attributes: (1) obtaining input from frontline nursing staff and unit leaders on which safety problems are priorities; (2) focusing on one target medication event selected by each nursing unit; (3) training nurses to write reports that communicate more information about contributing factors; (4) stimulating nurses to report target medication events for a designated period; (5) following investigative procedures to integrate information from internal and external sources to develop mitigation plans; and (6) providing feedback to nurses about safety problems and mitigation plans.

See Fig. 1 for a diagram of the SAFE Loop intervention, and Table 1 for a timeline of study activities for the intervention units.

During the intervention period, the SAFE Loop team will collaborate with frontline nurses and unit managers to collect information about target medication events by reviewing event reports, discussing events during nursing huddles, and reviewing peer-reviewed and gray literature identified in consultation with a medical librarian. The SAFE Loop

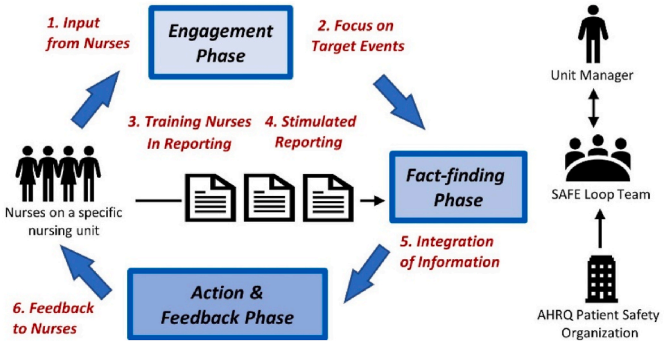

Fig. 1. Six key attributes designed to maximize the effectiveness of reporting.

team will also confer with the Institute for Safe Medication Practices, an Agency for Healthcare Research and Quality (AHRQ) Patient Safety Organization (PSO), about potential sources of information on causes and mitigation strategies for each type of target event. The team will integrate information sources to develop a comprehensive understanding of target events occurring within the medical center and how other institutions have approached similar events.

For medication safety events other than the Target Events, nurses will be encouraged to submit event reports as per usual practice.

2.3.2. Implementation

To facilitate SAFE Loop implementation across the 10 intervention units, one physician or nurse champion will be selected to act as a liaison between the nursing unit and the research team. This unit champion will meet periodically with nursing leaders for their unit to help select a target medication event; attend nursing unit huddles on a weekly basis; and ensure that SAFE Loop is included on huddle agendas. The champions will work with a medical librarian to conduct literature reviews related to their unit's target event, perform mini-interviews with frontline nurses, and work with unit leaders and research team leaders to develop diagrams of contributing factors and plans to reduce the occurrence of unit-specific target medication events.

2.4. Trial design

Randomization: This pragmatic cluster randomized controlled trial divides eligible nursing units into intervention and control groups (usual practice for incident reporting) in a one-to-one ratio. Randomization has been done in 5 blocks to assure the similarities of the nursing units, with 4 nursing units per block that are matched on type of unit (e.g., medical unit, ICU, surgical unit, etc.), patient population, size of the nursing unit, and other factors (Appendix Table 1). A random number generator was used to randomly assign the four nursing units within each of the five randomization blocks to one of four study groups, reflecting two arms (intervention and control) and two periods of time (sequential implementation). Allocation to intervention or control groups will be concealed from researchers and nursing unit leaders until the time the intervention begins on a given unit. Research staff involved in data collection will be blinded to which nurses (and patients) are assigned to which group.

Timeline: The intervention will be implemented in two time-based waves, with each wave's intervention period lasting 6 months. The decision to implement in waves was made to maximize the feasibility of conducting study procedures effectively across all units. Data will be collected to characterize study endpoints during baseline, intervention, and follow-on periods for each unit. See Table 2 for an overview of study design for the entire study period.

3. Quantitative analyses

3.1. Endpoint definitions

3.1.1. Incident reporting practices

The two primary endpoints of this project relate to incident reporting practices: 1) The rate at which nurses report high-priority medication incidents; and 2) the number of contributing factors described per report. For the first primary endpoint, we will calculate the rate per 1000 patient-days of submitted incident reports addressing the unit-specific target medication event. Because ten nursing units will participate in the intervention arm, we will have a total of 10 target medication events in our sample. For the second primary endpoint, we will characterize and count system and patient factors. To count and characterize contributing system factors, we will use the Human Factors Analysis and Classification System for Healthcare (HFACS-Healthcare), which contains 21 categories of system factors within four tiers [12,15]. To count and characterize patient factors, we will use categories from prior work [4]. For each event report, we will classify level of harm using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Medication Error Index [16,17], and we will classify preventability by adapting a pre-existing scale [18].

3.1.2. Nurses' attitudes toward incident reporting

A secondary endpoint for the study is nurses' attitudes toward incident reporting. To measure this, we will administer two composite measures from the AHRQ Hospital Survey on Patient Safety (SOPS)

Table 1
Timeline depicting individual nursing unit involvement in the 3 phases of the SAFE Loop intervention.

Week→	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	…	24
Engagement Phase																					
1.Input from nurses																					
2. Focus on target events																					
Fact-finding Phase																					
3. Train nurses in reporting																					
4. Stimulated reporting					1	2	3	4	5	6	7	8	9	10	11	12				…	
5. Integration of information																				…	
Action & Feedback Phase																					
6. Feedback to nurses																					
Implement, sustain																				…	…

Table 2
Study design, including study arms and measurement Periods.

Group	½ Year 1		Year 2				Year 3			
1	Baseline	b	**SAFE Loop**	f	i	Follow-on				
2	Baseline	b	Control	f		Follow-on				
3				Baseline	b		**SAFE Loop**	f	i	Follow-on
4				Baseline	b		Control	f		Follow-on
Light green = baseline measurement periods for Aims 1 & 3										
Orange = baseline (b) and follow-up (f) survey deployments for Aim 2										
Dark blue = SAFE Loop arm										
Medium blue = control arm										
Yellow = qualitative interviews (i) on implementation and follow-on period										
Dark green = follow-on period for Aim 3										

Culture™, Version 2.0 (English) [14]. AHRQ developed the survey in 2004 to assess the perspectives of frontline providers and staff on patient safety, error, and event reporting. The two composite measures we plan to use are directly relevant to incident reporting and likely to be responsive to system-level changes: "Communication About Error" (3 items) and "Reporting Patient Safety Events" (2 items). We will also include one item from SOPS on Response to Error category, an item from SOPS on the number of events reported, two newly developed items on confidence in reporting (when to report, what to include), and a new item on how many minutes were spent during the most recent incident report submission.

3.1.3. Rate of target medication events

An additional secondary endpoint is the rate of target medication events detected by triggered review of electronic health record data. We will identify whether each event meets criteria as a target medication event for the applicable nursing unit (yes/no). For each event identified, we will characterize preventability, severity/harm, medication class (e.g., cardiovascular, diabetes, etc.), and route of administration (intravenous, oral, etc.) as done in prior studies [19–22]. We will classify any errors by stage in medication use process (ordering, dispensing, administering, monitoring), profession(s) involved (physician, pharmacist, nurse, other), and error types (allergy, drug-disease interaction, drug-drug interaction, drug-lab interaction, duplicate therapy, therapeutic omission, concentration, duration, route/dosage form, dose/-frequency/rate, wrong medication, wrong patient, wrong timing, incomplete order) [1].

3.1.4. Nursing unit-level characteristics

We will obtain the number of nurses assigned to each nursing unit total and >50% time, the proportion of nurses who are travel/registry nurses, nursing turnover rates on the unit, and the ratio of nursing unit administrators (associate directors, assistant nurse managers) and clinical nurse educators per nurse on the unit.

3.2. Data sources and data collection

Data sources will include: incident reports filed at the level of the nursing unit (primary endpoints); surveys of nurses delivered via REDCap; and electronic health records for patients cared for on nursing units.

3.2.1. Incident reporting practices

We will obtain incident reports from the hospital's reporting system that relate to medication safety events on participating nursing units during the study period. Analysts with clinical experience and training in HFACS-Healthcare will manually review incident reports related to medication safety for each unit. Pairs of analysts will independently judge whether each incident matches one of the definitions of target medication events, extract information related to the above measures, and then meet to discuss and reach consensus. A human factors expert (TC) will adjudicate any ties. As part of training, analysts will practice on at least 30 sample reports, consulting with each other and the human factors expert until scores are consistent. To evaluate reliability of data collection on incident reporting practices, we will calculate Cohen's Kappa for 10% of records.

3.2.2. Nurses' attitudes toward incident reporting

We will administer pre- and post-intervention surveys to 1980 eligible nurses on intervention and control nursing units. To identify eligible nurses, we will obtain staffing databases including names, email addresses, title/position, percent effort, dates of work on the unit, and work schedule. The survey will be delivered via REDCap using a weblink embedded in an email.

3.2.3. Rate of target medication events

To identify target medication events on nursing units (including events not reported by staff), we will randomly sample electronic health records for 1520 hospitalizations divided equally between intervention/control groups and baseline/follow-on periods. To detect events, we will use the Trigger Tool method that has been defined by the Institute for Healthcare Improvement and widely used by patient safety researchers [19–25]. It involves two stages: 1) nurses will systematically screen the sample of electronic health records to identify pre-specified "triggers" (clues that a medication safety event occurred) and write synopses of possible events; and 2) physicians will review synopses to confirm and classify them. Pre-specified triggers include the use of medications that can counteract other medications (e.g., naloxone), abnormal lab results (e.g., serum glucose <50 mg/dL), clinical events (e.g., rash), abrupt cessations of medication, and transfers to a higher level of care [26]. To increase our ability to detect potential adverse drug events, we will add an additional "trigger": events in the Epic-based electronic health record "iVent" database, where pharmacists routinely record changes to medication orders made to address medication errors before they reach patients. iVent reports are distinct from voluntary incident reports. For all triggered event reviews, two research nurses will perform initial screenings, blinded to study arm. Next, two physicians will independently review each synopsis, employing a standardized rating form, and then meet to discuss responses. Discrepancies will be resolved by consensus, involving a third physician to break ties.

3.2.4. Nursing unit-level characteristics

We will obtain staffing databases for each nursing unit.

3.3. Analytic plan and sample size

3.3.1. Incident reporting practices

Hypotheses: We hypothesize that nurses on intervention units will file more incident reports addressing the target medication event per patient-day compared to nurses on control units, and that reports on intervention units will contain a greater number of contributing factors per report.

Statistical Analyses: We will compare changes over time between study arms for: a) rate of incident reports per 1000 patient-days; and b) number of contributing factors per report. Multivariable Poisson regression models will be fitted with response variables as a) number of reports per patient, with offset given by the length of stay divided by 1000; and b) number of system plus patient factors per report. For both models, the main hypothesis is whether there is an interaction between study arm and time period (baseline, post-intervention). Nursing units will be divided between two implementation steps, creating the possibility of an implementation trend. Therefore, a three-way interaction among study arm, time period, and implementation step (Step 1: Groups 1 and 2, Step 2: Groups 3 and 4) will be tested. If this is statistically significant, results will be presented separately for each implementation step. Otherwise, implementation step will be an additive effect. Random effects will describe nursing units and models will adjust for demographics, Elixhauser comorbidity index, and primary payer. All hypotheses will be two-sided at 5% significance level. Calculations will be performed in R-package, version 4.0.5 [27].

Sample Size: The study is powered to detect differences in the two primary endpoints between intervention and control units. Prior to beginning the study, baseline reporting practices led to 2.26 incident reports per 1000 patient-days (665 reports/294,470), and the expected baseline number of system plus human factors is 0.70 per report based on prior published studies [4].

Appendix Table 2 presents the minimum detectable differences in outcomes as functions of the between-cluster coefficient of variation (CV) and the presence or absence of implementation trend, using two-sided t-tests for Poisson rates with 80% power at 5% significance level. These differences would be meaningful to safety leaders, reflecting >35% increases in reporting rates and enhanced detection of the multiple contributing factors that are typically involved in every error.

3.3.2. Nurses' attitudes toward incident reporting

Hypotheses: We hypothesize that nurses' attitudes toward incident reporting will improve more between the baseline and follow-on periods for intervention units compared to control units.

Statistical Analysis: We will compare changes over time between study arms for the two composite measures from the Hospital Survey on Patient Safety. Multivariable regression models with normal errors will be fitted for survey endpoints. We will adjust for nurse characteristics, including: years worked in this hospital, years worked in current nursing unit, and hours worked per week. We will perform subgroup analyses by years of experience in current profession because experience has been associated with medication error rates. We will calculate nurse survey response rates, examine respondent characteristics (years worked in current profession, hospital, and current nursing unit and hours worked per week), and describe outcome measures (overall scores and composite measures) during each study period, stratified by study arm. To evaluate the two selected composite measures' internal consistency, we will calculate Cronbach's α using data from baseline survey. To assess construct validity and convergent validity, respectively, we will evaluate associations (Pearson correlation coefficients) between scores on the composite measures and incident reporting rates at the nursing unit level. To assess responsiveness, we will compare scores from baseline and follow-up surveys among nurses in the SAFE Loop arm (paired t-tests).

3.3.3. Rate of target medication events

Hypotheses: We hypothesize that the number of target events detected by triggers will be lower on intervention units compared with control units.

Statistical Analyses: We will compare changes over time between study arms for rates of a) target medication events per 1000 patient-days and b) harmful target medication events per 1000 patient-days. Multivariable Poisson models will be fitted with response variable as the number of a) target medication events and b) harmful medication events, with offset the length of stay divided by 1000 days. Model covariates will include patient demographics, biological sex, Elixhauser comorbidity index, and insurance payer. Furthermore, we will calculate rates of preventable adverse drug events (ADEs) and potential ADEs per 1000 patient-days. We will also describe the severity of the events, medication classes, errors, clinicians involved, and stages in drug therapy.

3.3.4. Nursing unit-level characteristics

We will assess the adequacy of randomization by comparing characteristics between intervention and control nursing units.

3.4. Ethics and data safety monitoring

This study was approved by the Institutional Review Board (IRB) at Cedars-Sinai Medical Center. The IRB concluded that the intervention itself is an organizational quality improvement intervention and that the data collection procedures involve minimal risk. Overall, the risks of nurse and patient participation are no greater than they normally encounter during clinical care in the hospital setting. We recruited a single external Data and Safety Monitor (DSM), rather than a full multimember Data and Safety Monitoring Board, based on a prior publication [28] as well as input from the IRB, the University of California Clinical and Translational Science Institute (with which Cedars-Sinai is affiliated), and the funder. The DSM has a background in nursing research, ethics, and service on data and safety monitoring boards, and they have reviewed planned study procedures and data collection instruments. The DSM will also review study results at key interim junctures.

4. Qualitative analyses

If SAFE Loop improves outcomes, understanding how and why it worked will enable the intervention to be improved and adapted across other nursing units at Cedars-Sinai and at other hospitals. Similarly, if the SAFE Loop is ineffective, insights into its limitations will reveal how incident reporting systems and processes could be improved through other types of changes. We will perform a qualitative analysis of implementation informed by the Consolidated Framework for Implementation Research to collect data and report on barriers to and facilitators for implementation [29].

4.1. Recruitment and eligibility

After the intervention is complete for each block of nursing units, we will conduct one-on-one in-person interviews with 10 nursing unit managers and 22 frontline nurses. This sample size will enable us to perform purposive sampling to acquire broad representation by randomization block, study group, and nursing unit. Interviews will occur in locations convenient to interviewees, last approximately 30 min, and be audio recorded (with permission).

4.2. Data collection

We will use a semi-structured interview guide with open-ended questions and follow-up probes to examine several topics, including: fidelity to SAFE Loop as planned, adaptations to SAFE Loop, SAFE Loop "dose" (e.g., did nurses learn about it once or several times?) and "reach"

(e.g., were all nurses on the study units aware?), facilitators/barriers to implementation, mechanisms of action (e.g., did nurses respond to providing input, receiving guidance on how to report, or emphasizing near misses?), exposure to the SAFE Loop in the control arm, and contextual factors that may have moderated its effectiveness. Finally, we will discuss how to adapt the SAFE Loop for ongoing use over the long term and how to enhance its effectiveness.

4.3. Analysis

Interviews will be transcribed from audio recordings, with personal identifiers removed. Trained coders will analyze transcripts in Dedoose using a combination of content-analysis and qualitative inquiry. We will use an iterative process to identify *a priori* themes based on the domains above, and to create *in vivo* themes as they emerge during coding (e.g., specific barriers to implementation). Coders will code each interview independently and then discuss coding discrepancies until consensus is reached. After coding all interviews, we will use the constant comparative method to combine similar themes with limited data under more general themes. In the final step of analysis, we will review Dedoose code reports and develop a summary of key findings.

5. Discussion

5.1. Strengths

To improve the utility of incident reporting systems, safety leaders need to engage with frontline nurses throughout the process of reporting, investigation, and improvement. Events that are common, preventable, and have implications for patient safety should be the highest priority. The systems should emphasize near misses and unsafe conditions to reduce the chance that reporters might be blamed. Reports should provide rich detail on contributing factors, facilitating follow-up investigations. Lastly, reporting systems should provide feedback about the problems identified and communicate the resulting mitigation plans to frontline staff.

5.2. Limitations

We anticipate several barriers to implementation of SAFE Loop. First, successful implementation will require careful coordination with nursing unit leaders and frontline nurses. If situational barriers arise such as staffing shortages or surges in patient volumes, implementation may be adversely affected. However, since we have developed SAFE Loop together with patient safety and nursing leaders, their engagement should help mitigate adverse effects that arise. Second, the SAFE Loop focuses on nurses because they most incident reports. However, physicians or other clinicians may also submit incident reports, and our study will have limited impact on their reports since our focus is on nurses. Third, our study will include the two nursing units that previously pilot tested the SAFE Loop; the prior exposure is unlikely to have residual effects after two years, and any effects would create bias toward null hypotheses. Fourth, we propose to leave the selection of target medication events and plans for mitigating them to the nursing units; therefore, the effect of the intervention on medication error rates detected by trigger tool is hard to predict. Fifth, unmeasured confounding factors may exist at the nursing unit level, such as nurse years of experience, nursing culture, and other factors. The purpose of blocked randomization at the nursing unit level is to balance unmeasured confounding factors. Sixth, we cannot eliminate contamination, such as if float nurses adopt SAFE Loop practices on intervention units and bring them to control units. However, the intervention is deployed at the unit level, and we will exclude nurses who work $\leq$50% time on a unit from the surveys. Seventh, the study will occur in one large hospital with senior leaders who are committed to the project, so generalizability of results will be uncertain; nonetheless, the current study will demonstrate proof of concept.

6. Conclusion

If effective, the SAFE Loop will have several benefits: increasing nurses' engagement with reporting, producing more informative reports, enabling safety leaders to understand problems and design system-based solutions more effectively and more efficiently, and lowering rates of medication errors. In turn, receiving feedback about problems and system-based solutions will further improve nurses' perceptions of reporting. In addition to the local benefits to hospitals that implement SAFE Loop, our work will generate secondary benefits at the national level: We will disseminate lessons learned to selected AHRQ Patient Safety Organizations so that they may optimize the use of incident reports in affiliated hospitals to generate solutions that make care safer for patients.

Clinical trial registration

This trial is registered with clinicaltrials.gov under identifier NCT05381441.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix Table 1. Study Nursing Units, Patient Populations, Type, Size, & Allocation to Blocks

	Unit Areas	Typical Patient Population	Type	Nurses	Patient-Days*
Block 1: Larger medical floor units					
A	4SE, 4SW	Adult oncology	Floor	118	22,322
B	5NE, 5NW	Cardiology	Floor	116	21,534
C	5SE, 5SW	Adult medicine, gastroenterology	Floor	103	22,025
D	7SE, 7SW	Adult medicine	Floor	92	22,025
Block 2: Smaller medical floor units and emergency department					
A	6SE, 6SW	Congestive heart failure	Floor	104	18,552
B	ED	Emergency department (ED)	ED	167	19,108
C	3-SCCT	Medicine, congestive heart failure	Floor	50	10,188
D	3NW	Short stay medical	Floor	41	2437
Block 3: Surgical floor units					
A	6NE, 6NW 6ICU	Kidney & liver transplant, cardiac surgery, Post cardiac-catheterization recovery	Floor, ICU	122	21,493
B	7NE, 7NW	Med/surg orthopedics	Floor	106	20,901
C	8SE, 8SW	Med/Surg bariatrics, GI surgery	Floor	100	15,230
D	8NE, 8NW	Neurosurgery, Med/surg spine	Floor	78	15,230
Block 4: Adult intensive care units					
A	4N-SCCT, 6-SCCT	Cardiac ICU, Cardiothoracic surgery ICU	ICU	130	10,711
B	5-SCCT	Surgical and trauma ICU	ICU	91	6381
C	7-SCCT	Respiratory/medical ICU	ICU	69	7085
D	8-SCCT, 4NW	Neurosurgical ICU, Adult stroke/medicine	ICU, Floor	124	17,424
Block 5.1: Obstetric and postpartum units					
A	3NE	Maternal-fetal care (obstetrics)	Floor	123	14,486
B	3SE, 3SW	Post-partum	Floor	115	13,476
Block 5.2: Pediatric units					
C	4S-SCCT, 4NE	Pediatric and congenital cardiac ICU, Pediatrics	ICU, Floor	44	3903
D	4NICU	Neonatal ICU	ICU	87	9959
*Patient-days of care on nursing unit per year. **Total**				1980	294,470

SE Southeast; SW Southwest; NE Northeast; NW Northwest; ED Emergency Department; ICU Intensive Care Unit; SCCT Sapertstein Critical Care Tower.

Appendix Table 2. Minimum Detectable Difference in Outcome

Presence/absence of implementation trend	Between-Cluster Coefficient of Variation			
	0.01	0.05	0.10	0.20
1.1. Incident Reports per 1000 Patient-days				
Yes, trend present	1.241	1.277	1.392	1.851
No, no trend	0.794	0.815	0.877	1.115
1.2. System plus Human Factors per Incident Report				
Yes, trend present	0.471	0.481	0.515	0.651
No, no trend	0.299	0.305	0.322	0.391

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