

BMJ Open Study protocol for the ACT response pilot intervention: development, implementation and evaluation of a systems-based Agitation Code Team (ACT) in the emergency department

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ABSTRACT

Introduction Emergency department (ED) visits for behavioural conditions are rising, with 1.7 million associated episodes of patient agitation occurring annually in acute care settings. When de-escalation techniques fail during agitation management, patients are subject to use of physical restraints and sedatives, which are associated with up to 37% risk of hypotension, apnoea and physical injuries. At the same time, ED staff report workplace violence due to physical assaults during agitation events. We recently developed a theoretical framework to characterise ED agitation, which identified teamwork as a critical component to reduce harm. Currently, no structured team response protocol for ED agitation addressing both patient and staff safety exists.

Methods and analysis Our proposed study aims to develop and implement the agitation code team (ACT) response intervention, which will consist of a standardised, structured process with defined health worker roles/responsibilities, work processes and clinical protocols. First, we will develop the ACT response intervention in a two-step design loop; conceptual design will engage users in the creation of the prototype, and iterative refinement will occur through in situ simulated agitated patient encounters in the ED to assess and improve the design. Next, we will pilot the intervention in the clinical environment and use a controlled interrupted time series design to evaluate its effect on our primary outcome of patient restraint use. The intervention will be considered efficacious if we effectively lower the rate of restraint use over a 6-month period.

Ethics and dissemination Ethical approval by the Yale University Human Investigation Committee was obtained in 2019 (HIC #2000025113). Results will be disseminated through peer-reviewed publications and presentations at scientific meetings for each phase of the study. If this pilot is successful, we plan to formally integrate the ACT response intervention into clinical workflows at all EDs within our entire health system.

INTRODUCTION

Emergency department (ED) visits for behavioural conditions are common and

Strengths and limitations of this study

- This work will use a human factors systems approach to develop a pragmatic, structured team-based protocol with defined health worker roles/responsibilities and work processes.
- Our approach to investigating agitation and workplace violence in the emergency department simultaneously addresses and balances patient and staff safety.
- We will use quantifiable outcomes of safety for patients and healthcare workers to demonstrate measurable decreases in restraint/sedative use and frequency of assaults as a result of our intervention.
- We will employ a controlled interrupted times series design to evaluate our intervention since randomisation is not possible in this single site study, which may be subject to geopolitical or institutional factors unique to our clinical environment.
- Variable compliance and adoption of the new protocol may be a potential limitation, which we will mitigate through administrative buy-in and use of staff champions.

rising rapidly, with one in eight visits related to mental health and substance use disorders.¹ The most severe of these visits are associated with symptoms of acute agitation, which manifest as excessive psychomotor activity leading to violent and disruptive behaviour in patients.² Agitation events occur 1.7 million times a year in emergency settings.³ Treatment and management of these acute agitation episodes are complex and pose potential safety threats for both patients themselves and ED staff caring for them. Although physical restraints are commonly used in the ED setting, physical trauma, respiratory depression, and asphyxiation leading

to cardiac arrest are well-documented risks of restraint placement.^{4–6} Serious adverse effects can also result from sedative use, including a systematic review reporting up to 37% of cases complicated by respiratory compromise, QT prolongation, paradoxical increase in agitation, and death.⁷ Concurrently, staff are increasingly subject to workplace violence during agitation management, with the ED identified as one of the highest risk healthcare environments.⁸ A recent meta-analysis identified a pooled incidence of 36 workplace violence events for every 10,000 ED patients.⁹ One in five healthcare professionals experienced workplace physical violence perpetrated by patients or visitors worldwide annually.¹⁰ Studies have consistently demonstrated missed workdays and burnout from exposure to violent incidents.¹¹

Expert consensus panels have derived recommendations regarding the management of agitation and prevention of workplace violence in the ED.³ However, limited work exists to translate these recommendations into pragmatic interventions that consider both patient and health worker safety.⁸ Using a rigorous, systematic approach to address this critical issue, our team recently proposed a novel framework for ED agitation management based on mixed-methods analysis of staff data.¹² Our framework identified factors and potential targets for intervention coalescing at five interrelated levels of care delivery: patient, staff, healthcare team, unit environment, and health system. Most importantly, we found that workplace violence and agitation management needed to be considered concurrently as integrated concepts to balance patient safety with prevention of assaults on staff for any potential interventions to be effective.¹³

Structured and coordinated teamwork has long been established as valuable to improving patient safety, with significant reductions in morbidity and clinical errors.¹⁴ However, a standardised team approach has not been traditionally used in emergency psychiatry, despite the elevated risk to physical safety.^{15 16} Healthcare facilities commonly purchase proprietary programmes for agitation management, including the Nonviolent Crisis Intervention used at our institution,¹⁷ which focus on training for one-on-one interactions between an individual staff member and the patient. In our previous qualitative studies of ED agitation, we observed that the primary gaps in safety resulted from teamwork challenges that were rarely addressed by these commercial products.^{12 18} De-escalation attempts were often more successful when

communication and trust-building occurred between colleagues. On the other hand, professional hierarchy and disparate goals of agitation care created tension and disagreement in treatment plans, leading to increased safety threats. Experts have also recognised this and proposed a structured team approach for ED agitation, comparable to those designed for trauma and cardiac arrest.^{16 19} To test this approach, we piloted novel team-based simulations for ED agitation to demonstrate feasibility in a team-based approach to agitation management.^{20 21} Our interprofessional scenarios brought hospital security, ED nurses and emergency physicians together in a simulated clinical encounter. As a result of these simulations, staff participants expressed interest in a team-based protocol for ED agitation and felt that it would improve both patient and staff safety.

Health safety experts are increasingly adopting a human factors systems approach to analyse and redesign healthcare delivery.²² This approach considers complex, high-pressure industries like healthcare as a set of interrelated elements in a work system, including worker(s), tasks, tools/technologies, physical environment, and organisational conditions to achieve desired safety outcomes.²³ While this human factors systems approach has frequently been applied to patient safety in the healthcare setting, it has recently been recognised as applicable in examining workplace safety as well.²⁴ We were previously successful in applying the guiding principles from this approach to derive our systems-based framework for ED agitation.¹² Experts in human factors employ user-centred design, direct observations, simulations, and focus groups to improve critical decision making and workflow.^{25 26} These techniques will successfully uncover the complex clinical decisions made during agitation management to create a team-based protocol that maximises safety under fluctuating work conditions and potential physical danger.

Rationale and aims of study

Our study aims to develop and pilot the Agitation Code Team (ACT) response intervention, which will consist of a standardised, structured process with defined health worker roles/responsibilities, work processes, and clinical protocols. By using a human factors systems approach, the ACT intervention will simultaneously address and balance patient and staff safety in the ED through two aims: (1) to develop the ACT prototype in a two-step loop of conceptual design and iterative refinement and (2) to pilot and evaluate the ACT response intervention for efficacy in the ED.

METHODS AND ANALYSIS

Overview

The ACT response intervention study will occur in two phases (figure 1). Phase I aims to create the ACT response intervention that integrates with clinical workflow and supports health worker task performance, and phase II aims to pilot the ACT response intervention to

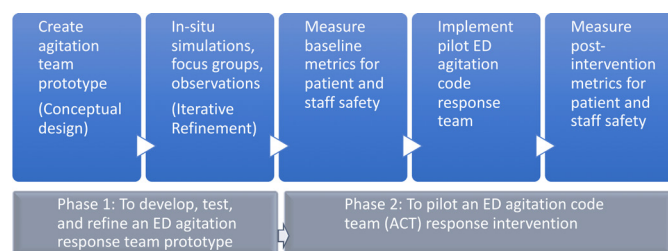


Figure 1 Overview and steps for each phase of ACT response intervention study. ED, emergency department.

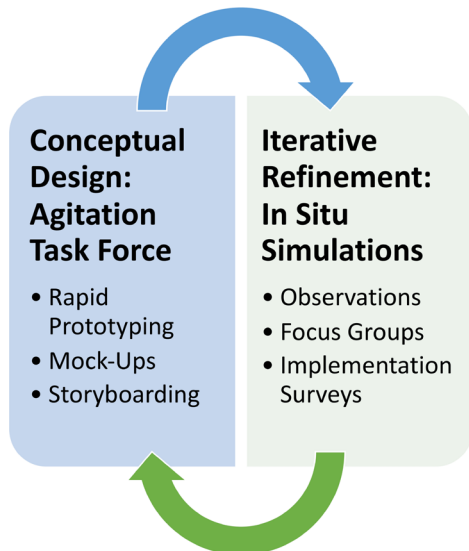


Figure 2 Iterative two-step user-centred design process for development of ACT response prototype.

determine its impact on safety outcomes for patients and staff members in the clinical environment. Results from this investigation will derive a systems-based, data-driven intervention that minimises harm during ED agitation management.

Patient and public involvement

There were no funds or time allocated for patient and public involvement so we were unable to involve patients. However, we have invited patient advocates to help us develop our dissemination strategy.

Phase I: development and refinement of ACT response prototype

This phase will occur via an iterative two-step user-centred design²⁷ process (figure 2) to develop and refine the ACT response prototype: (1) conceptual design to create a model team response structure and protocol, and (2) iterative refinement via in situ simulated agitated patient encounters with a live standardised participant (SP). Through buy-in from hospital stakeholders and clinical staff, we have created a newly-formed inter-professional agitation task force consisting of staff liaisons and representatives from patient safety, social work, legal,

emergency psychiatry, protective services and ED leadership. Teamwork factors in agitation management¹² as well as existing guidelines for managing ED agitation³ will be vetted through the agitation task force to create a model of ACT. Next, in situ simulations will test the developing ACT prototype in the clinical environment. Results from this testing phase will be inputted back into conceptual design for the agitation task force to improve the prototype for further testing in another iterative round of iterative refinement. The process will adapt and improve ACT while assimilating within the ED system until it is ready for clinical implementation.

Conceptual design

We will first integrate our previously identified teamwork factors¹² into existing knowledge regarding management of ED agitation to create an initial framework of the ACT response prototype. We will base the constructs for this template (table 1) on results from Project (BETA) Best practices in Evaluation and Treatment of Agitation,³ a series of landmark publications describing expert consensus guidelines for best practices in evaluation and treatment of agitation. Next, we will implement conceptual design with the agitation task force to create a formal approach for ACT with a detailed set of roles/responsibilities and clinical protocols. We anticipate that ACT membership will be ad hoc in nature, with individuals from each participating profession fluctuating between different agitation encounters, shifts and times of the day depending on staffing and workflow needs of the ED as a whole. However, defined structures with specified workflow for each individual role of the ACT response will be dictated by the prototype to facilitate team effectiveness. This conceptual design process²⁷ will consist of techniques used by leading design thinking firms, including brainstorming, rapid prototype development, physical and graphical mock-ups of the ACT protocol, and storyboarding.²⁸ These techniques incorporate user and stakeholder input through early and consistent engagement of the agitation task force in the design process, thus building buy-in and facilitating customisation of the design based on multiple perspectives, needs and preferences. In addition, members of the agitation task force who serve in hospital administrative roles will ensure

Table 1 Proposed constructs for initial template of ACT response prototype	
Construct	Potential guidelines and measures
Medical Evaluation and Triage	Agitation scale(s); laboratory tests and diagnostic imaging; protocols for transfer/treatment; inclusion/exclusion criteria of patient classes.
Team structure and protocol	Personnel and professions to be included; roles/responsibilities of individual members; documentation/electronic health record (EHR) interface; staffing and environmental logistics.
Avoidance of restraint and coercion	Thresholds/indications for use of coercion; types/routes/frequencies/doses of sedatives; strategies/domains of behavioural techniques/seclusion/de-escalation.
Incorporation of existing relevant programmes	Staff training; modification of physical space/security; improve/change reporting mechanisms; worksite analysis; limitations of visitors/patient volume.

integration of ACT into existing workplace safety policies and procedures of our health system that may influence agitation management in the ED.

Iterative refinement

Once we have created a first draft of the ACT response prototype from the conceptual design phase, we will immediately evaluate the prototype in the clinical environment using simulation techniques. A trained SP acting as an acutely agitated patient will 'arrive' in our ED as an in situ simulated clinical encounter on a biweekly basis to uncover potential systems barriers in usability of the ACT response prototype. Live SPs are frequently employed for in situ simulations that analyse high-stakes human interactions with patients during healthcare delivery.^{29 30} Our prior work demonstrated that SPs created a high level of fidelity and facilitated discussion for staff participating in an agitation simulation.^{12 20} Staff members on clinical duty will act as participants for the sessions. Each simulation will use variations of a base scenario template developed in our previous work.¹² The SP will be trained through prescribed prompts and actions, while staying within defined safety measures for the simulation. Immediately following, we will conduct a focus group with the staff participants through structured debriefing for 30 min. Qualitative data will be collected while observing the in situ simulations and from focus groups during simulation debriefings to feed back to the agitation task force for iterative refinement and modification of the prototype after each session. Guest *et al* have shown that three to five focus groups uncovered >90% of their completed thematic codebooks, respectively.³¹ Thus, we will aim for six to eight simulations held biweekly over a period of 3–4 months. Observations will be made on a qualitative instrument, while debriefings will be guided by open-ended questions relevant to systems elements that affected the simulated encounter. Key constructs of the data collection will reflect elements in the human factors systems approach (table 2)²³ to assist in seamless integration of the team intervention. Participants in the simulations will

also fill out a quantitative survey that asks respondents to rate implementation outcomes for each construct of the ACT response prototype (team, tasks, tools/technology, environment, organisation/process) on a seven-point Likert scale. For each construct, we will also include an open text box field to solicit one area of improvement. We will focus on feasibility as our primary area of interest but will also solicit feedback for the seven areas of implementation outcomes as described by Proctor *et al*³² for mental health interventions.

Phase II: pilot implementation and evaluation of ACT response intervention

This phase will be a prospective quantitative study to measure the effect of the ACT response intervention in reducing restraint use.³³ Given site-wide implementation of our ACT response protocol and the ad hoc nature of team membership in emergency care, randomisation by individual patients or staff members will not be feasible in this study. Thus, we will use a controlled interrupted time series (CITS) design, which is considered one of the strongest quasi-experimental designs when randomisation is not possible.³⁴ Its rigour is derived from its full use of the longitudinal nature of available data and account for preintervention trends through collection at multiple and equally spaced time points before and after an intervention.³⁵ Baseline measurements for safety outcomes will be collected from the electronic health record for a 12-month period before implementation of the ACT intervention. We will budget a transition period of 1 month for the intervention to successfully be adopted into established clinical practice. After implementation, these measurements will be repeated for another 12 months for an internal comparison of safety outcomes. Concurrently, these measurements will also be collected at our community site ED, situated fifteen minutes away, with stable measured rates of agitation events.³⁶ The community site will not receive the ACT response intervention during the study period, thus serving as the control for the interrupted time series analysis.

Table 2 Observations and focus group data collection constructs

Construct	Items
Person (patient)	Chief complaint(s), type(s)/nature of aggression, level of agitation.
Team (staff)	Number and profession types, leadership and decision-making structure, communication patterns and interactions between team members, roles/responsibilities and list of actions for all personnel
Tasks	Transfer process between prehospital stretcher and patient bed, type/nature of de-escalation attempts, administration of restraints/sedatives, end outcome(s) of response, patient reassessment.
Tools/technology	Sedative choice/route, type(s) of restraint(s) used, type(s) of stretcher, electronic health record interface.
Physical environment	Time of day, associated visitors/patients, safety threat(s) to staff/patient, ED location of response.
Organisational conditions	Interface with prehospital services, engagement with law enforcement, patient disposition.

ED, emergency department.

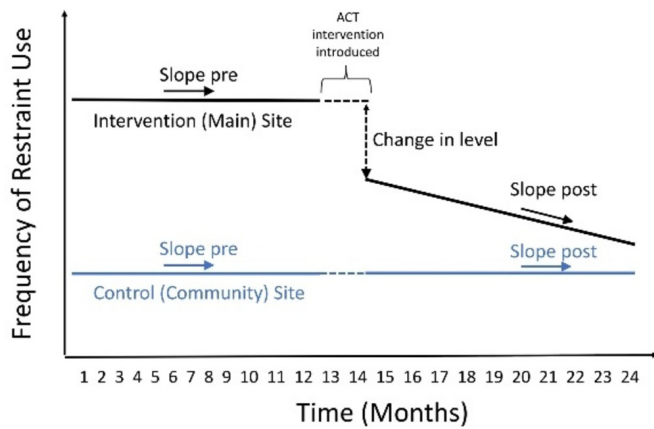


Figure 3 Controlled interrupted time series design. ACT, Agitation Code Team.

Outcomes

As our primary outcome, we will report biweekly and overall rates of physical restraint use for the predefined 12-month periods preintervention/postintervention at our ED (intervention site) and community affiliate ED (control site) as our metric for patient safety. As secondary outcomes, we will report biweekly and overall rates of sedative use and staff injuries for the 12-month periods preintervention/postintervention at both sites. For the primary analysis, we will use a CITS analysis^{33 37} (figure 3) with biweekly measurements of physical restraint/sedative use that occur at the intervention site and control site over the 12-month periods preintervention/postintervention. Using R statistical software (V.3.4.1), we will employ a segmented regression approach using a Poisson Regression (appropriate for modelling rates), assessing the mean restraint use per behavioural health visit and modelling the residuals preintervention and postintervention. Separate models will be constructed for intervention and control sites. Differences in means and slopes between intervention and control groups at baseline, preintervention and postintervention will be included in the segmented regression to adjust for the control.³⁸ Auto-correlation will be assessed using the Breusch-Godfrey test,³⁹ and adjusted for if needed. The CITS analysis will be supported by χ^2 tests between the two periods to determine differences in rates between the preintervention/postintervention phases for the primary outcome. All analyses will involve two-tailed tests of significance and p values < 0.05 will be considered statistically significant. The intervention will be considered efficacious if we effectively lower the rate of physical restraint/sedative use at the intervention site.

In our preliminary studies, we were able to observe 95 restraint events over a 2-month period with RAs stationed in the ED for 30 hours a week in randomised 6 hours blocks, which approximates to 570 restraints in 12 months. It has been suggested that a minimum of 12 data points before intervention and 12 after intervention is sufficient for an CITS design.⁴⁰ We aim to have double the number of data points using biweekly time points for

12 months before and 12 months after the intervention. Thus, we expect to have sufficient data for an CITS, and plan to see a total of 1140 events (570 in each of the preintervention and postintervention phases).

DISCUSSION

Agitation events in the ED lead to both patient and staff safety threats, and there is a pressing need to develop innovative interventions that will have meaningful impact on measurable safety outcomes. Healthcare sector experts have increasingly adopted a human factors systems approach to address safety for patients.²² Our study's innovation lies in its use of a human factors systems approach to improve workflow during agitation management. This approach deliberately places the person(s) in the centre of the system and emphasises that design should focus on users to optimise work performance. This will ensure that our intervention design supports rather than hinders the work required of individuals on the ACT response intervention. Demonstrating feasibility in this type of approach to address workplace violence will provide evidence for using similar methods of systems integration and implementation of workplace safety interventions at other clinical sites.

In addition, our approach to investigating ED agitation simultaneously addresses and balances patient and staff safety. Our prior work identified a care paradox for ED staff during agitation management, where their altruistic desires and sense of professional duty for this marginalised population clash with self-preservation instincts and fear of being harmed, magnifying their stress load and leading to frustration and burnout.¹⁸ This paradox has not yet been well described, and in fact, the discordance is reflected in the current literature on emergency psychiatry. Separate areas of research exist for staff exposure to workplace violence^{41 42} and agitation management for patients focused on safety profiles of sedatives and restraints,^{7 43 44} and it is unclear how interventions benefiting the safety of one group may impact the other. Several case reports have shown feasibility and anecdotal improvement in staff feelings of safety after implementation of a structured code team response to manage agitation, but the evidence is currently limited by lack of preintervention data and unclear impact on patient-based outcomes.^{45 46} Our ACT response intervention will be one of the first attempts to address patient safety and staff injuries together as one and the same problem, considering healthcare workers and patients together simultaneously as person(s) in a work system with structured measurements for both staff and patient outcomes.²³

However, our study contains some limitations. In phase I, we plan to implement in situ simulations and focus groups in the clinical environment to detect and improve the ACT response prototype, which may be superseded by needs of clinical care and workflow. To mitigate this, we will embed the refinement process within our existing monthly in situ simulation programme at our ED, which

has >90% completion of sessions over the past 2 years. With support from the administrative leadership team, we will also schedule additional staff members on simulation days in case of unanticipated rises in volume or acuity. The development process also lacks direct patient input, which may limit the intervention's improvement on patient experience. Our agitation task force will include our grievance coordinator and patient relations staff to ensure advocacy for patients' rights and autonomy in the ACT response design. In addition, we may encounter potential barriers to implementation of the ACT response intervention in Phase II. A 1-month adjustment period has been budgeted into the timeline to allow for adaptation of the new workflow. In addition, we have developed the study in partnership with administrative leadership team to align with the hospital's strategic goals and ensure staff compliance. Staff champions part of the agitation task force will also serve as early adopters in the culture change process. Finally, our single-site design and lack of randomisation may be limited by geopolitical or institutional factors unique to our clinical environment. Our control site will allow for comparisons of relative trends in planned outcomes of interest to overcome this potential limitation.

In summary, our study approaches agitation management and healthcare workplace violence, both critical and rising issues in the ED, using a human factors systems approach to balance patient and staff safety simultaneously, where no clear standard of care exists and evidence is limited. We hope that a structured ACT response intervention will be successfully embedded within existing work processes to effectively balance staff and patient safety. We initiated the conceptual design step of phase I and plan to complete development by June 2020 in time for pilot implementation in the summer of 2020.

ETHICS AND DISSEMINATION

Ethical approval by the Yale University Human Investigation Committee was obtained in 2019 (HIC #2000025113). All staff participants will provide informed verbal consent prior to being enrolled in the study, and a waiver of consent for patient subjects has been granted. Results will be disseminated through peer-reviewed publications and presentations at international scientific meetings for each phase of the study. If this pilot is successful, we plan to formally integrate the ACT response intervention into processes and clinical workflows at all EDs within our entire health system, which includes eight emergency care sites across the state of Connecticut, USA.

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Contributors AHW, MAA, JMR, CM, TW and SLB designed the study protocol and obtained funding. AHW is responsible for the overall logistical and scientific aspects of the study, data collection and analysis, and draft of this manuscript. AU, AKV, CC, DB, TS and MS provided administrative and logistical support for the study. CTF, AP, JDD and KAY assisted with biostatistical and analytic support for the study design and proposed methods for intervention evaluation. All authors contributed to critical revisions and gave final approval of the manuscript.

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Competing interests None declared.

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