Pharmacists in behaviours of concern (Pharma-BOC1): A randomised controlled trial of emergency medicine pharmacists in Behaviours Of Concern response teams

A Randomised Controlled Trial of Emergency Medicine pharmacists in BOC calls versus standard care

INVESTIGATORS

Carl Luckhoff
Biswadev Mitra
Michael Dooley
Shaun Baxter
Rebecca Hope

De Villiers Smit
Peter A. Cameron
Cristina Roman

ABSTRACT

Introduction:

Caring for patients with behavioural concerns in the Emergency Department (ED) is a common occurrence. Violence and aggression, are often a consequence of patients in acute distress who react unfavourably to a restrictive, unfamiliar and often re-traumatising hospital environment.

Strategies to mitigate risks include verbal de-escalation, scoring systems to help clinicians recognise early escalation in risk of violence, standardised guidelines (including therapeutic medications) and the Behaviour of Concern (BOC) notification calls in which multidisciplinary teams respond to patients with aggressive behaviour.

Aim:

The aim of this project is to test the feasibility of the addition of the Emergency pharmacist to a multidisciplinary BOC response team.

Participants:

All patients being received after a “Behaviour of Concern” (BOC) call, initially assessed in the BOC room during Emergency pharmacist working hours.

Methods:

This will be a pilot un-blinded randomised controlled trial comparing EM pharmacist attendance at BOC calls versus standard care.

Outcomes:

It is expected that the pharmacist will provide additional resources for adherence to the guidelines, reducing subsequent distress and agitation.

BACKGROUND

Caring for patients with behavioural concerns in the Emergency Department (ED) is a common occurrence. Violence and aggression, self-harm, absconding, and assault are often a consequence of patients in acute distress who react unfavourably to a restrictive, unfamiliar and often re-traumatising hospital environment. The causes of aggression are usually multifactorial and include characteristics and severity of mental illness, the rules and limitations of the environment, past experience, waiting times to see clinical staff, comorbidities such as underlying psychiatric illness or are facilitated by exposure to alcohol and other drugs such as methamphetamines. These behaviours pose threats to patients, visitors, and staff who must be protected from harm.

Strategies to mitigate risks include verbal de-escalation, the use of scoring systems (eg. Broset Violence Checklist) to help clinicians recognise early escalation in risk of violence, standardised guidelines (including therapeutic medications or chemical restraint) and the Behaviour of Concern (BOC) notification calls in which multidisciplinary teams respond to patients with, or who have the potential for aggressive behaviour. The BOC call out process is triggered when a person’s behaviour meets a set of pre-specified criteria.1 Subsequent escalation of behaviour may also utilise similar Code Grey or Code Black multidisciplinary response calls, depending on the level of aggression.

The first option for management of violence or aggression in the emergency department (ED) is through verbal de-escalation. However, this can be unsuccessful, particularly in the setting of exposure to alcohol and other drugs. In such circumstances restrictive interventions may be employed to defuse volatile behaviour and prevent harm.

Restrictive interventions include the use of mechanical restraint and chemical restraint, and should only be used when absolutely necessary to prevent imminent and serious harm to the patient and/or others. Acknowledging that restrictive interventions may compromise patient autonomy, their use is legislatively regulated.1

Uncertainty in the current evidence exists to guide the correct use of medications for chemical restraint and treatment in the setting of aggression in the ED. Outcome measures vary and methods used to report sedation are often not consistent across the studies. Despite this, guidelines have been developed with the aim of standardised care, providing clinicians with safe medication choices when required, and encouraging early intervention for distressed and agitated patients. Early treatment of patients on arrival may reduce subsequent Code Grey or Code Black responses for patients in the ED, which can have downstream benefits for patients, visitors and staff. Despite the above strategies compliance with guidelines is often low and at The Alfred Emergency & Trauma Centre (E&TC) occurred in 35% of cases (departmental audit, unpublished).

The overarching aim of this project is to test the feasibility of the addition of the EM pharmacist to a multidisciplinary BOC response team. It is expected that there will be an improvement in the effective treatment of patients with acute distress and agitation, reducing the need for repeated dosing of medications and improvement in the experience of both patients and staff in the ED.

In the last decade Emergency Medicine pharmacists have begun to establish themselves as necessary members of the ED clinical team.2 Beyond the traditional roles of medication history taking and discharge medication counselling, their expertise is significantly expanding. EM pharmacists practising in the ED are associated with a reduction in medication errors, increased identification and reporting of adverse drug reactions, identification of medication related problems and early consideration of existing home medications on admission to hospital.3 Increasing evidence suggests EM pharmacists can also improve time to prescription and administration of medications when added to multidisciplinary acute response teams such as Code stroke, Sepsis calls and Trauma Calls.4-6

With the growth of EM pharmacy services globally and the recognised expertise of pharmacists in medication use and safety there is potential for pharmacists to also have a benefit when added to a multidisciplinary BOC response team.

HYPOTHESIS

The addition of an EM pharmacist to the BOC team will result in:

1. A reduction in subsequent Code Grey and/or Code Black response calls in the ED following initial presentation and management
2. Improved treatment with medications according to established local guidelines
3. Improved practice in preemptive prescription of medications that alleviate anxiety
4. Enable early prescribing and delivery of medications, reducing cognitive load on clinicians

Methods

This will be a pilot un-blinded randomised controlled trial comparing EM pharmacist attendance at BOC calls versus standard care.

#### Setting

This study will be conducted at an adult major referral hospital in metropolitan Melbourne, Victoria, Australia with an annual attendance of approximately 70,000 patients. The hospital provides state services for major trauma, burns, haemophilia, cystic fibrosis, heart and lung transplants, HIV, adult haematological malignancies.

The Emergency and Trauma Centre (E&TC) is staffed by Emergency Physicians and Emergency Psychiatric clinicians 24 hours a day. There is additional support from a dedicated Emergency Psychiatrist between the hours of 8am-12pm Monday to Friday.

Selection of Participants

Notification (BOC calls) either pre-arrival or on patient arrival to ED are activated 24 hours a day where patients are assessed by community mental health clinicians, Ambulance Victoria team members, or the police as requiring urgent assessment and treatment to manage acute aggression, agitation and/or distress. Reception of BOC calls is delivered by a multidisciplinary team which includes the ED nurse in charge of the shift, ED registrar or consultant, a member(s) of the security team, an ED clinical nurse, and a clinician from the Emergency Psychiatry Service.

A simple randomisation technique using a computer generated sequence will be used to randomise patients who are received in the ED using a BOC call to the intervention or standard care arm.

During EM pharmacist working hours (Monday-Friday 7am-9pm), the designated pharmacist available to attend a BOC call selects the next envelope in sequence that corresponds to either the intervention or control arm.

#### Eligible patients

* All patients being received after a “Behaviour of Concern” (BOC) call, initially assessed in the BOC room
* During EM pharmacist working hours (7am-9pm Monday to Friday)

#### Exclusion criteria

* BOC call for patients already in the ED, apart from in the Waiting Room
* Patients less than 18 years and greater than 65 years
* Patients not requiring medication for treatment or restrictive intervention

#### Intervention

Attendance of a BOC call on arrival by an EM pharmacist in addition to the multidisciplinary team. Specific responsibilities in the team will be to facilitate medication decision making after consultation with the medical team leader on previous allergies, known past medical history and current medications; prescribe and draw up medications where required for administration by a nurse, and obtain an accurate and efficient medication history on patient arrival, where possible. A medication treatment plan will be prescribed using both regular and as required medications. The use of chemical restraint will be minimised according to local guidelines and in accordance with the Mental Health and Wellbeing Act 2022. The EM pharmacist will also expedite prescribing and administration of other medications including home medications, nicotine replacement therapy, opioid agonist treatment and alcohol related withdrawal. Prescribing of medications by the EM pharmacist will occur prior to medication administration, directly into electronic medical records, utilising the Partnered Pharmacist Medication charting model (PPMC) previously evaluated.7

Pharmacist prescribing is not standard practice in most countries and requires additional training. Prescribing via the PPMC model of care requires a pharmacist to have two years of general clinical experience and successfully complete the PPMC credentialing. As part of the model a credentialed pharmacist takes a medication history then has a face-to-face discussion with the medical officer about current medical and medication related problems, following which a medication management plan is agreed upon. The medication management plan is documented in the patients’ medical record and co-signed by the medical officer. Appropriate medications are then prescribed by the pharmacist on the patient’s medication record.

The EM pharmacists attending BOC calls will have at least two years of clinical experience in hospital pharmacy practice and are required to complete formal training prior to involvement. Successful BOC credentialing includes completion of an in-house online BOC module for pharmacists and successful involvement in a BOC callout under supervision by a senior pharmacist, the PPMC credentialing, Therapeutic Drug Monitoring of Aminoglycosides and Vancomycin credentialing, stroke thrombolysis credentialing, sepsis credentialing and Trauma credentialing.4-8

#### Comparator

Current standard practice includes BOC call attendance by a multidisciplinary team without an EM pharmacist. If a patient is randomised to the control arm, the pharmacist will communicate the treatment allocation to the medical team leader and ED nurse in charge. They will be available for consultation if requested by the BOC response team and would also review other patients based on clinical judgement and availability, after a time delay, which is current standard practice. Ongoing education regarding best practice guidelines for management of patients presenting with behaviours of concern in the ED will continue to encourage minimising the use of restrictive interventions. The current guideline on acute medication treatments will be promoted (Appendix 1).

#### Outcomes

The primary outcome will be defined as the proportion of patients that have a subsequent Code Grey and/or Code Black during ED length of stay.

Secondary outcomes will be:

* Treatment with medications according to locally established guidelines will be defined as the proportion of patients who are compliant with all the following criteria:
	+ Selection of medication
	+ Dose of medication
	+ Route of medication
* Time to prescribing and administration of first doses of medications for treatment or chemical restraint
* Proportion of patients who are administered additional doses of medications for treatment or chemical restraint within 60 minutes
* Proportion of patients charted medications by the EM pharmacist in a BOC call
* Medications charted by EM pharmacist in a BOC call
* Proportion of patients requiring mechanical restraint
* Proportion of patients requiring care within a resuscitation cubicle
* ED Length of Stay
* Initial Broset Score on arrival and subsequent Broset scores while in the ED

BOC call in the ED

Exclusions (n):

-Patients already in ED

-Age< 18 or >65 years

Intervention

Control

Included for analysis: Target n= 25

Included for analysis: Target n= 25

Figure 1: Flow Diagram

No medication required

No medication required

SAMPLE SIZE

A local audit of patients initially assessed in the BOC room between July 2022 and June 2023 identified that approximately 11% of patients presenting with acute behavioural disturbance, and meeting criteria for a BOC call out, had a subsequent Code Grey or Code Black response. To test for a reduction in subsequent Code Grey or Code Black response from 10% to 5% using 90% power and an alpha of 0.05 we will require a sample size of 1064 patients. A pilot study of 50 patients will be used to initially determine feasibility of this model of care prior to securing funding for a larger multi-centre study (Pharma-BOC2) with the required power to test the primary outcome.

DATA AND STATISTICAL ANALYSIS

An intention to treat analysis will be undertaken. Continuous data will be summarised using means and standard deviation if near-normally distributed. Medians with interquartile range will be used if data is skewed. Categorical variables will be summarised using proportions. The primary outcome variable will be reported using relative risk (RR) with 95% confidence intervals, and proportions compared using the chi-square test. A p-value of <0.05 will be defined to be statistically significant. All analyses will be performed using Stata v 15.0 (Statacorp, Texas, USA).

ETHICS

A waiver of seeking informed consent will be requested from the Alfred research and ethics committee.

We believe a waiver to seek informed consent is justifiable due to:

1. Involvement in the research carries no more than low risk
2. the benefits from the research justify any risks of harm associated with not seeking consent
3. it is impracticable to obtain consent (due to eligible subjects being aggressive) additionally, the choice of sedation remains a clinical choice made by clinicians; involving patients in their choice of sedation is sometimes impracticable
4. There is no known or likely reason for thinking that participants would not have consented if they had been asked; there is no deviation from standard clinical practice.
5. there is sufficient protection of their privacy
6. there is an adequate plan to protect the confidentiality of data
7. the possibility of commercial exploitation of derivatives of the data will not deprive the participants of any financial benefits to which they would be entitled
8. the waiver is not prohibited by State, federal, or international law.

Additionally, we contend this intervention carries low risk to patients as if circumstances require, there will be no change to routine practice. Patient details will remain confidential and data will be collated and stored securely, nor is there any obvious commercial application of this research.

Risks and benefits

There is escalating concern regarding occupational violence and aggression in the Emergency Department. It is a situation where the patient, staff and other patients are at risk. The promotion of evidence-based guidelines and efforts to harmonise care is likely to be of benefit for patients and staff.

We believe there is minimal risk to participating in this research project. Clinicians/prescribers have currently available sedation guidelines which outline options, appropriate doses and escalation strategies. There will be no change to the sedation guidelines for this study. In the intervention, it is expected that the pharmacist will provide additional resources for adherence to the guidelines and promote evidence-based prescribing, potentially reducing the need for subsequent re-dosing of medications and reducing subsequent distress and agitation.

Confidentiality

The information collected is for this study only. Information collected will be analysed and published at the end of the study period in a non-identifiable format and disseminated, through conferences and published in peer review journals.

Storage of data

The data will be collated by the chief investigators. Data will be stored securely in a password protected computer. No identifiable data will be collected or stored. Data will be stored for 7 years and destroyed when it is no longer required unless we seek further ethics approval to extend the period.

Use of data for other purposes

Only aggregated non-identifiable data may be used for other projects where ethics approval has been granted.

BUDGET

Nil funding for the pilot study, funding for the multi-centre study will be sought at a later stage.
Study design, ethics application, data analysis and writeup will be performed by the investigators.

References:

1. DHS. Restrictive Interventions Victoria: Victorian Government. Available from: <https://wwwhealthvicgovau/mental-health-and-wellbeing-act-handbook/treatments-and-interventions/restrictive-interventions> 2024.

2. Roman C, Dooley M, Mitra B. Emergency Medicine pharmacy practice in Australia: A national survey. Journal of Pharmacy Practice and Research 2019:1-8.

3. Roman C, Edwards G, Dooley M, Mitra B. Roles of the emergency medicine pharmacist: A systematic review. American Journal of Health-System Pharmacy 2018;75:796-806.

4. Roman C, Cloud G, Dooley M, Mitra B. Involvement of emergency medicine pharmacists in stroke thrombolysis: A cohort study. J Clin Pharm Ther 2021;46:1095-102.

5. Roman CP, Dooley M, Nevill A, et al. Introduction of an emergency medicine pharmacist-led sepsis alert response system in the emergency department: A cohort study. Emerg Med Australas 2023;35:564-71.

6. Roman C, Dooley M, Fitzgerald M, Smit V, Cameron P, Mitra B. Pharmacists in Trauma: a randomised controlled trial of emergency medicine pharmacists in trauma response teams. Emerg Med J 2024.

7. Tong E, Roman C, Mitra B, et al. Partnered pharmacist charting on admission in the General Medical and Emergency Short‐stay Unit–a cluster‐randomised controlled trial in patients with complex medication regimens. Journal of clinical pharmacy and therapeutics 2016;41:414-8.

8. Cairns KA, O'Brien DJW, Corallo CE, Guidone DM, Dooley MJ. Pharmacist-led therapeutic drug monitoring: implementation of a successful credentialing model. J Pharm Prac Res 2017;47:477-82.