PROTOCOL TITLE

Capability, capacity, and culture change: Building confidence and competence in nurses to prevent, recognise, and respond to clinically deteriorating patients in mental health units.

(Short Title: CUBIC Project)

PROTOCOL VERSION AND DATE

Version 1, 28 August 2017

LIST OF INVESTIGATORS AND PARTICIPATING INSTITUTIONS

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GLOSSARY OF TERMS

Between the Flags: The Between the Flags Program was implemented in NSW public hospitals to improve early recognition and response to clinical deterioration and thereby reduce potentially preventable deaths and serious adverse events in patients who receive their care.

Clinical deterioration: For the purpose of this proposal, a clinically-deteriorating patient is defined as one who moves from one physiological or mental state to a worse state which increases their risk of morbidity, disability or death

Clinical review: Part of an escalation protocol to respond to a deteriorating patient, who has been observed to have abnormal physiological measurements or other deteriorating which required care to be escalated and further clinical review by a nurse in charge or medical officer.

Medical Emergency Team: The MET provides a 24-hour service which rapidly responds to MET calls, initiated by staff when MET calling criteria / Rapid Response calling criteria are recognised.

Physiological status: The condition or state of the body or bodily functions.

Productive Mental Health Ward: Focuses on improving systems, processes, and environments to help clinical staff spend more time on client care, thereby improving both safety and efficiency.

Safety Assessment Code (SAC): Numerical score that rates incidents affecting patient or security incidents. The score is based on the consequence of that incident and the likelihood of its recurrence. The SAC Matrix assists in calculating the score, which guides the level of incident investigation or review that is undertaken.

Vital signs: At a minimum, should include the measurement of respiratory rate, oxygen saturation, heart rate, blood pressure, temperature and level of consciousness.

ABBREVIATIONS

HETI	Health Education Training Institute
IMMS	Incident Information Management System
MET	Medical Emergency Team
MHN	Mental Health Nurse
SAC	Safety Assessment Code
SMI	Severe mental illness

SYNOPSIS

Failure to recognise and appropriately respond to clinical deterioration in patients admitted to mental health units has been highlighted as a significant factor in a number of adverse events within these settings. Reasons for this are multifactorial but likely related to the relative infrequency of acute physiological deterioration in mental health settings, for example, deterioration in cardiovascular and respiratory function, evidenced by changes in blood pressure and respiratory rate. As a consequence, staff lack experience in recognising signs of physiological deterioration and responding effectively. Evidence also suggests staff commonly undertake observations from a distance (for example, shining a torch through a window during the night while undertaking observation rounds) and on the basis of appearances only (as opposed to what has been learned through direct engagement with a patient). This is reflected in medical records and during verbal handover with comments such as 'patient appears settled', 'patient appears to be resting' and 'no change observed'. These actions by staff have been implicated in and heighten the failure to detect clinically-deteriorating patients. Further, evidence suggests managing physiological deterioration in mental health settings is often suboptimal due to poor communication between multiple healthcare providers from more than one team, and across different locations. In the proposed study setting, 32% of Medical Emergency Team (MET) calls (due to clinical deterioration of patients) result in the transfer of patients to critical care, with some of these patients dying. In most cases, earlier recognition of deterioration could have prevented these outcomes.

RATIONALE / BACKGROUND

A substantial body of literature spanning more than 30 years clearly demonstrates that early recognition of and response to clinical deterioration not only minimises adverse outcomes, but the number of interventions required to stabilise patients who do deteriorate (Franklin & Mathew, 1994). As a consequence, significant effort has been directed toward developing tools, resources and competency-based training programs (e.g. HETI eLearning modules) to improve recognition and response to deteriorating patients in acute inpatient settings.

In contrast, there is an absence of not only research, but resources or training to support nurses to recognise and respond to clinically-deteriorating patients in acute mental health settings (Sands et al., 2017). While the reasons for this gap are unclear, it appears three factors have contributed to the current situation: (i) the focus on acute physiological deterioration (commonly evidenced by abnormal vital signs) and the explicit omission of deterioration in mental state from the National Safety and Quality Health Service Standards (specifically Standard 9—Recognising and Responding to Clinical Deterioration in Acute Health Care) (Craze et al., 2014); (ii) the lack of an agreed definition as to what constitutes a deteriorating patient with common definitions of clinical deterioration traditionally based on abnormal vital signs,(Jones, Mitchell, Hillman, & Story, 2013) an approach that fails to take into account other important patient and organisational factors, and (iii) different use of terminology, with mental health clinicians using terms such as 'risk' and 'change' as opposed to 'deterioration'.

In the context of clinical deterioration in patients admitted to mental health settings, a definition that allows for deterioration in physiological status, and/or deterioration in mental state should be considered. For the purpose of this proposal, a clinically-deteriorating patient is defined as one who moves from one physiological or mental state to a worse state which increases their risk of morbidity, disability or death(Jones et al., 2013) and indicates the need for closer observation,

clinical review (or more frequent review) and for the introduction, change or 'up-scaling' of therapeutic interventions.(Craze et al., 2014)

Failure to recognise and appropriately respond to clinical deterioration in patients admitted to mental health units has been highlighted as a significant factor in a number of adverse events within these settings. Reasons for this are multifactorial but likely related to the relative infrequency of acute physiological deterioration in mental health settings and hence, staff lacking experience in recognising signs of physiological deterioration and responding effectively. Staff undertaking observations from a distance and on the basis of appearances only (as opposed to what has been learned through direct engagement with a patient) are commonly reflected in medical records and during verbal handover with comments such as 'patient appears settled', 'patient appears to be resting' and 'no change observed'. These actions by staff have been implicated in and heighten the failure to detect clinically-deteriorating patients. Further evidence suggests managing physiological deterioration in mental health settings is often suboptimal due to poor communication between multiple healthcare providers from more than one team, and across different locations.

Perhaps the most challenging factor contributing to failure to recognise physiological deterioration in patients with mental illness is resistant or negative attitudes from clinicians who regard their role as exclusively attending to patient's mental well-being and do not see the physical care of patients as part of their role. A number of studies have reported mental health nurses (MHNs) lack confidence in undertaking physical health assessments and care including cardiopulmonary resuscitation and undertaking neurological observations (Ward, 2005). In an Australian study undertaken at a large, teaching hospital in Queensland, MHNs utilised significantly fewer clinical skills (*M* = 6.3, 95% CI = 4.5, 8.7) compared to surgical (*M* = 14.2, 95% CI = 12.2, 16.4) and medical nurses (M = 12.1, 95% CI = 10.3, 14.1)(Osborne, Douglas, Reid, Jones, & Gardner, 2015) suggesting MHNs may lack the requisite knowledge and practice skills to attend to the physical health care needs of patients in acute healthcare settings.

Documentation of physical health assessments has also been shown to be poor with one study finding more than half the case notes audited were missing physical nursing assessments, and even basic observations such as recording a blood pressure on admission were only undertaken in 57% of case notes (Howard & Gamble, 2011). Even with adequate documentation, failure to identify deteriorating patients can occur because there is a lack of tracking systems such as "Between the Flags" and technology including wireless monitoring that could assist with early recognition of a deteriorating patient.

Evidence also suggests lack of organisational supports and poor leadership may contribute to poor team culture, distress and burnout and reduced commitment to professional standards(Craze et al., 2014) which in turn contributes to failure to prevent, recognise and respond to clinical deterioration. This is reflected in poor safety cultures in mental health settings. In an online survey of the attitudes towards patient safety of the public health workforce in the state of South Australia, Gallego and colleagues(Gallego, Westbrook, Dunn, & Braithwaite, 2012) reported staff in mental health services were among those with more negative safety cultures.

Culture change is imperative in supporting Nurse Leaders and Nurses to reframe and adapt existing cultural norms, goals, objectives, leadership styles, values and motivations, their approaches to change and problem solving, and their attitudes within the context of changes to clinical practices in patient observation, assessment and escalation of clinical deterioration.

AIMS

The aim of this study is to evaluate the effectiveness of a positive workplace culture program designed to develop effective workplace cultures and nursing leadership within adult inpatient mental health units. This culture change program aims to (i) ensure the delivery of compassionate, safe, patient-centred care through the early recognition of, and response to, clinical deterioration and (ii) build on the work undertaken as part of the Productive Mental Health ward by increasing the amount of time nursing staff spend engaging with patients.

PARTICIPATING SITES

This will be a multi-site study, conducted across three SWSLHD sites: Mental Health Inpatient Units at Bankstown, Campbelltown, and Liverpool Hospitals. Staff (mental health nurse leaders and nurses) working in the adult inpatient mental health units at these facilities will be eligible to participate.

RESEARCH PLAN / STUDY DESIGN

Study Design / Method

This study will use a four-stage sequential mixed methods study design. Both quantitative (surveys, audit data) and qualitative approaches (individual interviews and focus groups) will be used.

Phase 1: Pre-Positive Workplace Culture Program (0-2 months)

Baseline data collection:

- Staff survey, focus groups, data.
    - Survey (see Appendix A)
        - Staff working in adult inpatient mental health units will be invited to complete a survey. Questions related to (a) demographic and work-related profile; (b) organisational culture assessment (OCAI) and (c) safety attitudes (Safety Attitudes Questionnaire - SAQ) will be included. Open-ended responses will be used to capture initial qualitative data. (See Appendix A).
        - Assessment of knowledge, skills and attitudes related to recognising and responding to clinically deteriorating patients in mental health units. To date, no tool has been identified. The investigators are currently developing a tool which will be submitted once finalised.
    - Focus Groups (see Appendix B)
        - Focus groups (1 for Senior Nurse Leaders across the three participating sites, and 1 for Nurses at each participating site) will be conducted to explore workplace expectations relating to conducting physiological observations in mental health units.
    - Aggregate data on staff absenteeism and retention at a unit level will be collected (no individually identifiable data will be collected). This information will be provided by the Nurse Manager for Workforce.

- Audit data
    - A baseline audit of the assessment, allocation and review of observation levels will be undertaken. A random sample of patients' medical records on each Observation Level will be audited using the Quality Audit Reporting System (QARS) developed by the Clinical Excellence Commission. This provides Local Health Districts with a tool to conduct quality audits to provide evidence for the accreditation process, evaluate performance and initiate relevant action plans. The QARS allows evaluation at LHD, facility or ward levels. Benchmarking against the NSW average and peer groups is also available. Additional data will be extracted from the patient's medical record in relation to (a) risk assessment; (b) the presence of a documented management plan; and (c) involvement of the patient / carer in determining the Observation Level. This information will be provided by the Nursing Executive Officer (Mental Health).
    - A separate audit of patients' medical records who have clinically deteriorated will be audited using Medical Emergency Team (MET) data. Data will be extracted in relation to (a) measurement and documentation of observations; (b) escalation of care; (c) establishment of a rapid response system; and (d) communication about clinical deterioration. This information will be provided by the Nursing Executive Officer (Mental Health).
    - All IIMS and SACs data relating to the clinical deterioration of patients in the study setting will be extracted including both numeric and textual data for the 12 month period prior to the project commencement. This information will be provided by the Nursing Executive Officer (Mental Health) or the Patient Safety Manager.
        - IIMS data reported under the principal incident type of clinical management will be collected for clinical deterioration.
        - All SACs will be collected, including investigation reports.
    - Data related to the use of restraints, seclusion, aggression (to staff and other patients), absconding, and sexual safety will be collected for the 12-month period prior to project commencement. This information will be provided by the Nursing Executive Officer (Mental Health) or the Patient Safety Manager.
        - IIMS data reported under the principal incident type of aggression will be collected for seclusions and restraints.

Phase 2: Positive Workplace Culture Program (3-15 months)

An organisational change consultant will work with nurse leaders and nurses to collectively identify the type and style of strategies that will support them in achieving key objectives. The positive workplace culture program will focus on assisting staff to develop strategic self-awareness of their leadership style, strengths, motivations, drivers, and potential weaknesses particularly in the context of leading and co-creating culture change. Two programs will run concurrently – one for the nurse leaders, which will focus on leadership capability and cultural transformation and a program run 'at the coal face' with Nurses. (See Appendix C). To reiterate, this application is not seeking approval for the positive workplace culture program as attendance at this is mandated.

Phase 3: Post-Positive Workplace Culture Program (16-18 months)

Immediately following the completion of the positive workplace culture program, post-program data will be collected from staff and an audit of patient records undertaken.

- Staff survey, focus groups, data.

- Staff Survey. The same measures will be used as described in Phase 1 above.
- Focus Groups (1 for Nursing Leaders across the three participating sites, and 2-3 for Nurses at each participating site) will be undertaken to explore their experiences of the culture change program and its impact on workplace cultures and nursing leadership; whether they believe the program has impacted on the delivery of patient care and their capacity to recognise and respond to clinical deterioration; and whether they feel this has increased the amount of time they are able to spend engaging with patients (see Appendix D).
- Aggregate data on staff absenteeism and retention at a unit level will be collected as described in Phase 1 above.

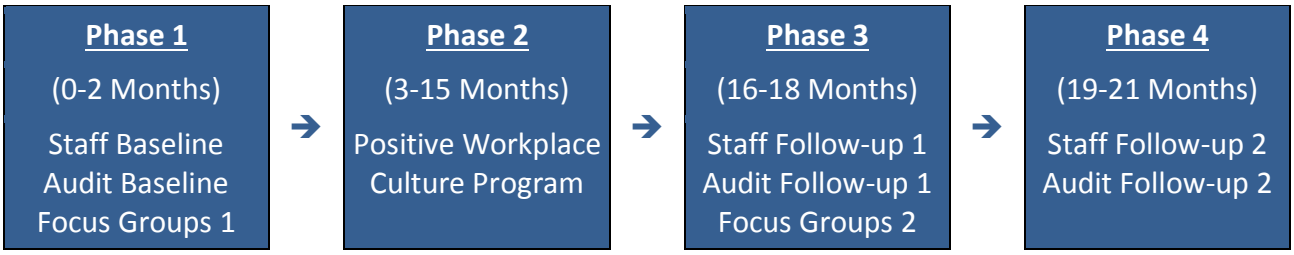
- Audit data will be collected as described in Phase 1 above.

Phase 4: Six month follow-up: (19-21 months)

The purpose of this phase is to assess the sustainability of the positive workplace culture program. Data collection will consist of:

- Staff survey, data.
  - Staff Survey. The same measures will be used as described in Phase 1 above.
  - Data on staff absenteeism and retention at a unit level will be collected as described in Phase 1 above.
- Audit data will be collected as described in Phase 1 above.

Timeline of Data Collection



Recruitment and Selection of Participants

All nursing staff working in the adult inpatient mental health units of the above mentioned facilities will be invited to participate in this study. An email (see Appendix E) will be sent to all Nursing Leaders and Nurses working at the participating sites. A reminder email will be sent to all Nursing Leaders and Nurses (in the interests of anonymity, those who have responded will also be sent the reminder) one week and two weeks after the initial email is sent. Additionally, posters will also be placed on staff noticeboards (see Appendix F).

Inclusion and Exclusion Criteria

All nursing staff (mental health nurse leaders and nurses) working in the adult inpatient mental health units at the abovementioned facilities will be eligible to participate.

Data Collection

Data will be collected in Phases 1, 3, and 4 as described above. The survey questionnaire will include general demographic questions (age, gender, years of experience, highest qualification, etc) and two (2) standardised measures. An investigator-developed scale to measure knowledge, skills and attitudes related to recognising and responding to clinically-deteriorating patients in MH units will be submitted for approval prior to commencement of the study.

Organisational Culture Assessment Instrument (OCAI)

The OCAI tool was developed to quantify organisational culture, however, more importantly, the scores of the OCAI can be used by leaders/managers to gauge the success of organisational change (Suderman, 2012). The approach to data collection of the OCAI is distinctive, in that respondents are offered a series of descriptions of an organisation arranged in six groups or items. Respondents are asked to distribute a total of 100 points for each group of four descriptors according to the similarity with their own organisation. For example, if Descriptor A is somewhat similar, the respondent may give 70 points to A, and distributes the other 30 points to the other 3 alternative descriptors, based on the levels of similarity (Cameron & Quinn, 2011; Jacobs et al., 2013).

Safety Attitudes Questionnaire (SAQ)

A short form version of the SAQ that includes 30 core items and six additional items of interest to senior hospital leaders will be in this study to measure safety climate. The SAQ Short Form assesses six-safety related climate domains including teamwork climate (6 items); job satisfaction (5 items), perceptions of management (6 items); safety climate (7 items); working conditions (4 items); and stress recognition (3 items). Five of the items in the questionnaire are responded to separately for the hospital and ward unit, yielding a total of 41 items. The SAQ Short Form has been used to compare safety climate within and between facilities, and benchmarking data is available to allow organisations to evaluate their own climate data (Soh, Barker, Morello, Dalton, & Brand, 2016). Composite scale reliability for the SAQ was assessed via Raykov's ρ coefficient. The ρ value for the SAQ in this sample was .90, indicating strong reliability of the SAQ.

The completion of all questionnaires will be anonymous, and a sealed 'drop-box' will be provided for the return of the questionnaires. Prior to staff agreeing to participate, they will be provided with a Participant Information Sheet and then asked to sign a consent form (not attached to the questionnaire). Based on staff numbers across the three sites (n=360), it is expected 150-200 members of staff will complete the questionnaire. It is also expected that 6-8 members of staff will attend each of the focus groups as described above.

Data Analysis

Quantitative data from questionnaires will be entered and analysed using IBM SPSS Statistics for Windows Version 24. Descriptive statistics will be used to summarise the characteristics of participants and aggregate scores, percentages, central tendency and spread of variables will be computed. Continuous data will be expressed as mean, standard deviation (SD) and range. Categorical data will be expressed as median and interquartile range (IQR), and nominal data as frequencies and percentages. Conditional on the results of tests of normality of the SAQ scores, independent *t*-test or the non-parametric equivalence, the Mann-Whitney *U* test, will be used to test for statistical significance, between SAQ score at baseline and the two follow-ups. A *p* value of <0.05 will be considered statistically significant.

Qualitative data from the focus groups will be coded and analysed using QSR NVivo Version 11 (QSR International Pty Ltd, Doncaster, Vic., Australia). An inductive approach to thematic analysis will be undertaken to determine latent themes within the data (Braun and Clarke 2006). Initial codes will be generated for each focus group. These initial codes will then be grouped into main themes and confirmed for both focus groups.

Expected Duration of the Study

The anticipated duration of the study, including data collection and analysis, is approximately 24 months from the date ethics approval is granted (see timeline below).

ETHICAL CONSIDERATIONS

This study will be guided by the National Statement on Ethical Conduct in Human Research. Approval will be sought from the Human Research Ethics Committee of South Western Sydney Local Health District

Risk Considerations

Participants

It is possible that some participants may find some of the material contained in the questionnaires unsettling, or that participating in the focus groups raises new issues. If a participant does become upset or distressed they will be encouraged to contact their health care provider. Alternatively, the participant may prefer assistance in identifying a local counsellor. They will also be provided with the contact details of the Employee Assistance Program (EAP) offered by SWSLHD. The intention of supplying this information is not to decide when participants require counselling, but to inform them of resources available should they choose to access them.

There is a time burden associated with participating in this study. The study questionnaires are estimated to take approximately 30 minutes to complete and it is anticipated the focus groups may take up to one hour. However, completing the questionnaire and participating in the focus groups will take place during work hours, and will therefore not incur any additional time burden.

Professional Reputation of the Institution

There is a possibility that information disclosed by participants may be sensitive, particularly in the context of adverse events involving patients admitted to acute mental health units. Should this information become publicly available it is possible that it would undermine public confidence in the institution and/or staff. As with any discussion involving patients, clinicians have a duty of care to maintain the confidentiality of all patient information and participants will be reminded of this before they agree to participate in the study. Participants will also be asked not to repeat any information discussed during the focus groups.

Informed consent

All participants will be provided with a Participant Information Sheet and Consent Form and informed about the voluntary nature of their participation and the ability to withdraw at any time.

If a participant wishes to withdraw, their wishes will be respected. Signed consent forms will be collected from each participant. Individuals who wish to clarify any information related to this project and their participation will be asked to contact a specified team member. There are no consequences associated with choosing not to participate in this project, and all potential participants will be informed.

Consent will not be sought from patients to access their medical records as there would be an expectation this information would be used for quality improvement purposes. Referring to the National Statement on Ethical Conduct in Human Research (2007), Section 2.3.10:

(a) the research does not carry more than low risk to participants;
(b) the benefits of the research justify any risks;
(c) as we are collecting a random sample of medical records, it is impracticable to obtain consent from all participants;
(d) patients would expect their notes to be audited for quality purposes, therefore there is no known reason they would not consent to participate;
(e) all data collected will be unidentifiable, therefore there is sufficient protection of privacy;
(f) data will be stored in an unidentifiable manner, thereby maintaining confidentiality of all data;
(g) not applicable as this project is primarily concerned with the completeness of the parts of the medical record as outlined above;
(h) not applicable as there is no commercial advantage to this project;
(i) the waiver is not prohibited by State, federal or international law.

Confidentiality and Privacy

Information obtained in the research study will remain confidential and will only be accessible to members of the research team. All data collected from all sources will be de-identified. Generalised results will be submitted for publication to peer reviewed scholarly and scientific journals, and may be presented at relevant health network, national and international conferences. No individuals will be identified.

All collected questionnaire and focus group data will be stored in Excel, SPSS and and / or Word format (as appropriate) in password protected computer files and a password protected server. Audio-recordings will be deleted once transcription has occurred.

Data Storage and Retention

To maintain participants' confidentiality all research data will be stored in a de-identified manner and be kept in a locked filing cabinet in the Centre for Applied Nursing Research. Only those listed in the ethics application will be able to access the data.

Paper documents (such as Participant Information, Consent Forms and hardcopy questionnaires) will be stored in a locked cabinet within a locked room (Principal Investigator's Office) at the Centre for Applied Nursing Research. Computer data (i.e. completed questionnaire data and focus group transcripts) will be de-identified and stored in password-protected files on the Principal Investigator's computer and a copy will be stored on the principal Supervisor's computer in the Centre for Applied Nursing Research. All data will be coded. No individual will be identified in any report or publication arising from this study. After five years all paper copies will be destroyed by

secure shredding or placement in secure bins for destruction and electronic data will destroyed by reformatting to ensure that the data and any pointers in the system are inaccessible.

OUTCOMES AND SIGNIFICANCE

Possible benefits may include a better understanding of approaches for managing self, enhancing workplace resilience, and building effective coping strategies for dealing with complexity, challenge and change. Possible benefits for mental health services include a positive team and workplace culture which will promote the delivery of compassionate, safe, patient centred care.

Outcomes may include changes in staff knowledge, skills and attitudes related to recognising and responding to clinically-deteriorating patients in MH units; reduction of adverse events; reduction in use of restraint and seclusion; reduced incidence of aggression; increased compliance with Observation Policy for Mental Health Inpatient Units and increased engagement time with patients.

TIMELINES / MILESTONES

It is expected that the project will take 24 months to complete from Ethical clearance being granted:

Phase	Description	Month
Phase 1	Pre data collection	0 – 2
Phase 2	Positive Workplace Culture Program	3 – 15
Phase 3	Post-program data collection	16 – 18
Phase 4	Six month follow-up data collection	19 – 21
(Phase) 5	Preparation of final report	22 – 24

PUBLICATION POLICY

Findings will be disseminated at local and state fora. A report detailing the implementation plan, survey tools and other resources developed for the project will be made available to the Nursing and Midwifery Office for distribution to LHD DONMS. If deemed successful, the project team will explore placing the project on the Agency for Clinical Innovation Information Exchange website to share and promote the project and resources with other healthcare institutions across NSW.

Publication and dissemination of research findings will be guided by the Australian Code for the Responsible Conduct of Research and institutional polices. Authorship discussion will occur early in the research process and be reviewed periodically. Findings will be published in peer-reviewed publications, professional forums and presented at national and international conferences. A report and recommendations for service delivery will be made to South Western Sydney Local Health District.

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APPENDICES

The following appendices are attached as separate documents:

Appendix A: Questionnaire

See attached document “CUBIC_Questionnaire_V1_20170823”

Appendix B: Focus Group Question Guide (Baseline)

See attached document “CUBIC_FocusGroupQuestionGuide_Baseline_V1_20170828”

Appendix C: Positive Workplace Culture Program

See attached document “Taylor”

Appendix D: Focus Group Question Guide (Follow-up)

See attached document “CUBIC_FocusGroupQuestionGuide_FollowUp_V1_20170828”

Appendix E: Email Invitation

See attached document “Taylor Made Coaching Solutions Draft Positive Workplace Culture Program Draft 20170828”

Appendix F: Poster

See attached document “CUBIC_Poster_V1_20170828”