THE UTILIZATION OF CLOSE OBSERVATION IN ACUTE PSYCHIATRIC INPATIENTS

By

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Abstract

Close observation is a psychiatric interventional method implemented for individuals who are displaying self-injurious or aggressive behaviors. This is a widely used intervention within the field of mental health Close observation is also regulated by The Joint Commission and the Centers of Medicare and Medicaid Services for accreditation purposes. A review of the current literature was conducted and revealed that frequently psychiatric patients are placed on inappropriate levels of close observation, that revisions to the close observation policy/practice improve both psychiatric patients and staff safety outcomes, and can overall decrease hospital costs associated with observation intervention. The purpose of this project was to examine the utilization of close observation at an adult psychiatric in-patient facility in Anchorage, Alaska. The Plan Do Study Act model was used as an organizational framework to guide this project. The methodology of the project involved reviewing inpatient psychiatric records, to generate the project's data for analysis under a process that was monitored by Alaska Psychiatric Institute's risk management department. Subsequently, the principal investigator organized and statistically analyzed the collected data using the Chi Square method of statistical analysis. The Chi Square statistical method analyzed the differences between the various levels of close observation, self-injurious and aggressive behaviors. The results of the statistical analysis support recommendations to revise the current close observation protocol and practice at Alaska Psychiatric Institute. The evidence generated was used as a forerunner to revise policy that was aimed at improving the utilization of close observation. The project results were disseminated to API via presentation to key stakeholders. The project was catalogued at the University of Alaska Anchorage per protocol.

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Chapter One: Overview of the Problem

Close observation is a mental health interventional method employed by trained staff members of a psychiatric facility to directly monitor a patient who has been identified as a high risk for self-harm or aggressive behavior. Patients, who are determined to be an imminent risk of harm to themselves or others, are placed into a mandatory observational status that involves increased close observation or one-to-one monitoring. The rationale behind this method of intervention is close monitoring or one-to-one observational status creates or ensures a safe environment for the patients, staff and other residents of the institution. The process of isolation and observation is mandated by multiple regulatory agencies including the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and the Centers for Medicare and Medicaid Services (CMS). Due to the significant restriction of the patient's privacy this intervention is primarily used in an in-patient setting. (National Action Alliance, 2016)

The purpose of this project is to evaluate the utilization of close observation in an in-patient psychiatric facility for patients at increased risk for self-injurious or aggressive behaviors and revise existing close observation policy. Revised policy will incorporate themes identified in the literature review and promote improved patient safety while in observational status. This chapter includes background information surrounding this issue, current practice guidelines, and identifies the research question guiding this project.

Background

This project will focus on the utilization of close observation to prevent self-injurious and aggressive behaviors. The Center for Disease Control and Prevention (2017) report that suicide is the second leading cause of death for individuals between the age of 10 and 34, and the fourth

leading cause of death for individuals between the ages of 35 and 54. The authors noted that Alaska has one of the highest suicide rates in the country.

Close observation and one-to-one observation are interventional methods used throughout the United States in inpatient psychiatric institutions. These institutions, which employ close observation or one-to-one monitoring, must follow nationally set guidelines and standards of care. The Joint Commission (2017) recommends the implementation of one-to-one observation for patients who present with or threaten suicidal ideation, and requires that all patients who meet DSM-V criteria for suicidal ideation be placed on one-to-one continuous observation, be observable through 360-degree viewing, and have continuously monitored video of the patient. The continuous monitored video must be observed by a qualified staff member who can provide immediate response/intervention if indicated. Furthermore, organizations that employ one-to-one or observational methods must have a defined policy in place that addresses the use of close observation within the institution. (The Joint Commission, 2017).

In addition to the Joint Commission's standards of care, there are also existing statewide standards and governmental guidelines for both accreditation and reimbursement purposes surrounding close observation. Furthermore, various local psychiatric institutions have developed their own standards of care or policies surrounding the implementation of close observation.

One such participating facility is the Alaska Psychiatric Institute (API) who has implemented guidelines around the practice of close observation based on incorporating the Close Observation Status Scale (COSS). See Figure 1.

The close observation status scale is comprised of a four-tiered scale where each tier or level determines the requirements for a specific observation method. All levels of observation

within the COSS require staff to record the patient's location in 15-minute intervals on a chart. The lowest level of observation on this scale is routine Q15 minute checks. This lowest level on the COSS does not require one-to-one monitoring and patient's behaviors can be documented by psychiatric nursing assistants. The first degree is the next level on this scale. This level does not require one-to-one observation, but it does require documentation by a registered nurse. The next level, second degree, requires one-to-one observation as well as documentation by a registered nurse. The highest level on this scale, third degree, mandates two-to-one observation with documentation by a registered nurse.

Recently, API's implementation of and policy surrounding the use of close observation for their at-risk psychiatric inpatients was reviewed by an Alaskan state governmental official - an ombudsman. The ombudsman's role is to investigate any grievances related to public agencies within the state of Alaska. The Alaska Ombudsman Report (2019) published the findings of their investigation regarding API's use of the COSS and concluded, "Close observation is required whenever Alaska Psychiatric Institute determines a patient requires additional observation and monitoring due to potential harm to that patient or others." (p. 50-51). The report noted that there were 125-226 patient days requiring one-to-one monitoring and 0-31 patient days requiring two-to-one monitoring. This increased acuity directly results in increased staffing demands of 2,321 staffing days. This created a tremendous financial burden and increased demand for API's resources. (Alaska Ombudsman Report, 2019).

Clinical Significance

One to one observation and close monitoring create both clinical and administrative concerns within institutions, states, and national settings that employ this specific method of observation. Clinical concerns that surround close observational practices includes patient safety,

patient outcomes, and workplace violence. The administrative concerns are related to staffing, financing (or cost), and allocation of hospital resources. The scope of both these concerns are two-fold for API as they affect the facility as well as the patients. Close observation affects API as a facility by affecting policy, procedures, and compliance with regulatory standards. For API's patients there are safety concerns that exist when they are placed under close observation status. Concerns related to safety also extend to API staff members responsible for maintaining close observation as they are at risk for injuries inflicted from the patients due to aggressive and suicidal behaviors.

A variety of outcomes have been identified involving the implementation of close observation and these include: safety/risk management, unsatisfactory patient outcomes, unsatisfactory staff and organizational outcomes, financial concerns, quality concerns such as efficiency, effectiveness, timeliness, equity, and patient centeredness, as well as a need for evidence-based validation for current practice.

Review of the literature related to close observation supports that its implementation can mitigate suicidal behaviors. However, this literature review had conflicting conclusions regarding close observations ability to prevent suicidal behavior. Kim et al. (2010) found that close observation did not directly reduce suicide, although it did exert a protective effect. The authors found there was no statistically significant association between close observation and reduced suicide risk. However, a follow-up analysis did reveal a potentially protective effect from the implementation of close observation. The protective benefit is postulated to arise from early intervention during self-injurious behaviors.

Current Clinical Problem

Self-injurious and suicidal behaviors are very complex problems that require multiple evidence-based solutions and interventions. At API, patients placed on close observation continue to engage in self-injurious and aggressive behaviors despite being in a close observation situation. Current literature supports the use of close observation for suicidal and aggressive patients, and provides evidence to support continued evaluation of the utilization of close observation. Hunt et al. (2010) noted that tighter control of ward exits and more intense observation of patients during the early days of admission are two interventions that might prevent suicide amongst in-patients.

The Alaska Psychiatric Institute (API) utilizes the Close Observation Status Scale (COSS) to support its policies and procedures surrounding the implementation of close observation. As mentioned previously the COSS is a scale that encompasses four degrees of observation.

The lowest degree involves routine 15-minute checks with behaviors documented by psychiatric nursing assistants. The next level of observation is referred to as “first degree” and requires Q15 minute staff checks by a registered nurse. The next level of observation is referred to as “second degree”. This level requires constant one-to-one observation of the patient by staff. This degree contains various specifications such as requiring one-to-one staff to be in the same room with the patient, be within arm’s length of the patient, and must maintain continuous line of sight with the patient. “Third degree” level is the highest level of observation performed and requires a staffing ratio of two-to-one. This highest level of observation also incorporates the same specifiers as the second-degree level to include maintaining a distance of arm’s length of the patient and continuous line of sight monitoring. Figure 1 explains the various COSS levels.

Figure 1

Close Observation Status Scale

Level of Observation	Supervision	Documentation	Specifiers
Q15 minute check	Q15 minute checks	Psychiatric Nursing Assistant (PNA)	None
First Degree	Q15 minute checks	Registered Nurse	None
Second Degree	1:1 constant	Registered Nurse	Same room as patient, within arm's length, or continuous line of sight.
Third Degree	2:1 constant	Registered Nurse	Same room as patient, within arm's length, or continuous line of sight.

Per API policy all patients are initially placed on either first, second, or third-degree COSS when admitted. Following observation and evaluation the initial level is either increased or decreased. Most patients are decreased to routine 15-minute checks within the first 72 hours. However, some patients require increased observation.

Per the 2019 Alaska Ombudsman report API was not meeting the guidelines set by the COSS and missed checking on their patient within the time requirements delineated by COSS. Furthermore, patients placed on increased COSS degree of observation continued to have self-injurious and aggressive behaviors. The increase in self-injurious and aggressive behaviors directly results in poor patient outcomes, increased work place injuries to staff, increases staffing demands, and high utilization of hospital resources. This clearly identifies why there is a need for improvement and revisions in close observation policy at API.

A project exploring the utilization of close observation at API was needed to determine the appropriate use of hospital resources, and to investigate the proposed protective benefits to both patients and staff. Stakeholders directly involved in this project include staff at API and

adult psychiatric in-patients who were placed at API for care and management. Indirectly affected by this project's outcomes are friends and family of inpatients impacted by hospitalization, and community organizations that are responsible for continued outpatient therapy of discharged inpatients. The data generated through this project was used to determine whether utilization of close observation promoted increased patient and staff safety outcomes and whether improved application through policy reform of close observation provides better allocation of hospital resources and staffing. The outcome of this project was utilized to generate evidence that either supported or refuted current practice methods and provided statistical evidence to support possible policy revision.

Question Guiding Inquiry

A PICOT question is a systematic approach to developing an answerable research question. PICOT questions have five parts that examine a distinct part of the research question. (Melnyk & Fineout-Overholt, 2019). These parts include the **p**opulation that will be studied, the **i**ntervention being implemented or examined, the **c**omparison groups, the **o**utcome that will be measured, and the **t**ime frame utilized in the research project.

The elements of the PICOT question involved in this project are the following: Population- Adult acute psychiatric in-patients; Intervention- Close observation; Comparison- Increased degree of close observation compared to routine 15-minute checks; Outcomes- Patient safety outcomes to include self-injurious or aggressive behaviors as documented on Unusual Occurrence Reports (UOR); Time- Three-month record review.

The question formulated by the elements of PICOT is: In adult acute psychiatric in-patients, how are self-injurious and aggressive behavior outcomes related when comparing

increased degree of close observation to current practice (routine checks every 15-minutes) during a three-month record review.

This PICOT question addresses both a system and a population focus by examining close observation as it relates to patient and staff safety outcomes. This question also addresses the systems surrounding the process of close observation utilized at Alaska Psychiatric Institute. This research question was answered by collecting data via a record review process, analyzing the data using appropriate statistical methods, and evaluating the results for significance prior to policy revision recommendation. By utilizing the number of generated Unusual Occurrence Reports (UOR) as an indirect or proxy indicator of self-injurious or aggressive behaviors, this research will systematically categorize behaviors and generate concrete, objective data for decision-making.

The outcomes of this project will positively impact nursing practice and the overall healthcare system at API. The outcomes identified by this project were specific to patient and staff safety outcomes, attainable through a record review process, measurable using statistical analysis, realistic within the organization (API), and had a time frame consistent with graduation requirements for completion.

Conclusion

Current policy on the utilization of close observation is problematic and fails to meet patient needs around safety and positive outcomes. Furthermore, the Alaska Ombudsman Report (2019) identified inconsistencies between close observation and patient safety. Despite regulatory requirements on close observation outlined by The Joint Commission, adult psychiatric in-patients continue to have self-injurious and aggressive behaviors while hospitalized. Current literature supports the use of close observation for suicidal and aggressive

patients, and provides evidence to support continued evaluation of the utilization of close observation. Kim et al. (2010) found that increased close observation exerted a potentially protective effect ($p = .08$). Hunt et al. (2010) noted that interventions that may prevent suicide amongst in-patients included more intensive observation of patients during the early days of admission. This project will evaluate the effectiveness of varying degrees of close observation and the results will be used to improve patient safety, healthcare outcomes, and utilization of hospital resources. The results of this project will have implications for administrative policies and patient interventions.

Chapter Two: Review of the Literature

Reviewing the literature regarding the utilization of close observation in a psychiatric in-patient setting during the first few days of admission is imperative to fully understand the magnitude of this subject. Chapter Two will provide an in-depth review of the existing literature involving close observation. This chapter identifies research strategies and article selection criteria. It discusses the evaluation process including evidence organization and article appraisal. It reviews how data were synthesized and identifies the themes extrapolated through the synthesis process. Limitations to this review are recognized and discussed.

Methodology

The literature was searched using databases provided through the University of Alaska Anchorage Consortium Library. Databases included the Cumulative Index of Nursing and Allied Health Literature (CINAHL) and PubMed. Individual literature was evaluated using the Rapid Critical Appraisal adopted by Melnyk and Fineout-Overholt (2019). The data was then organized into an evidence spreadsheet and then refined into a synthesis spreadsheet.

Search Strategy

Research articles were found using the following two databases: CINAHL and PubMed. A total of 14 articles were retrieved for this review. Twelve articles were retrieved from CINAHL and two articles from PubMed.

CINAHL was searched using the following search terms to collect relevant articles: "(Close observation) AND (violence OR aggression)", "(Close observation) AND (Self-injury" OR "self-injurious" OR "suicide)', "(suicide prevention) AND (observation)". Limiters included: English language, peer reviewed, adult, and inpatient. These search queries yielded 31, 20, and 32 results respectively for a total of 83 articles. Duplicate articles were removed and decreased

total results to 62. Forty-nine articles were excluded because close observation was not a measurable variable. The other articles were excluded due to their focus on predictive factors related to suicide, effectiveness of staff-based intervention on suicide prevention, risk assessments, or were instrument validation studies. This decreased the number of articles to 12.

PubMed was searched using the following search term: "(violence) AND (observation)" "(suicide prevention) AND (observation)". This yielded a total of 1646 results. The following limiters were applied: Meta-analysis and reviews, English language, and adult age group. This decreased the results to eight articles. Three of the eight articles were excluded because they involved using close observation during medication-based interventions. Three of the articles were excluded because they included demographic and diagnostic information related to individuals who completed suicide but did not measure close observation. This decreased the number of articles to two.

The remaining 14 articles were further evaluated. One article was excluded due to being an expert opinion. Expert opinion represents the lowest level of evidence and there is no instrument to critically appraise expert opinions. Three articles were excluded due to being abstract only without the capability of retrieving the full text electronically. This reduced the total number of articles included in the literature search to ten.

Data Evaluation

Literature was evaluated by identifying each articles' conceptual framework, research design, sample, setting, major variables, measurement of variables, data analysis, study findings, level of evidence, and critical appraisal score. These components were identified and organized into a spreadsheet. See Appendix A.

Appraisal scores were generated using the Rapid Critical Appraisal adopted by Melnyk and Fineout-Overholt (2019). See Appendix D. Appraised studies included: meta-analysis, systematic reviews, cohort studies, case studies, and descriptive studies.

Critical Appraisal

Articles were critically appraised based on research design. Meta-analysis and systematic reviews were appraised using nine yes/no/unknown responses examining the validity of the reviewed results, relevancy to psychiatric population, and clinical benefit of treatment. Evidence based practice articles were evaluated using 15 yes/no/unknown responses for credibility and applicability to psychiatric patients. Cohort and case studies were appraised using ten yes/no/unknown responses for validity, magnitude of results, and generalizability of the results to this review. Descriptive studies were evaluated using 29 yes/no/unknown items related to validity, credibility, and relevancy to psychiatric population. See Appendix D.

Synthesis Strategy

The data generated by the literature review was synthesized through categorizing, ordering, and summarizing each research article and placing each study's conclusion into a synthesis chart. The individual studies were also categorized by determining the level of evidence based on the hierarchy of evidence according to Melnyk and Fineout-Overholt (2018). This hierarchy of evidence incorporates six levels of evidentiary strength based on the rankings of highest to lowest level of evidence-based research design. The highest level of evidence, Level 1, includes meta-analysis and systematic review. Level II evidence includes randomized control trials (RTC) and is considered high strength evidence. Level III includes controlled cohort studies and is considered medium strength evidence. Level IV includes uncontrolled cohort studies and is considered medium strength evidence. Level V includes case studies, case

series, qualitative and descriptive studies, evidence base practice implementations, and quality improvement projects. This level of evidence is considered low strength but may be applicable to a specific project or study. Level VI is the lowest level of evidence and includes expert opinions.

The studies that were analyzed were ranked in order according to the proportionate number of yes responses using the Rapid Critical Appraisal instrument. A percentage of yes to no responses was used because appraisal instruments contained varying number of questions and using a percentage makes them comparable.

The studies were summarized based on their overall research findings and recommendations. The articles were then further synthesized into an evidentiary spreadsheet. This spreadsheet was generated to assist in organizing and logically presenting the findings of the conducted literature review. This analysis provided grouped summaries based on the level of evidence and the strength of the articles. The evidentiary spreadsheet allows readers to quickly look at the spreadsheet to figure out what each level of evidence recommends based on the overall strength of the articles. See Appendix B.

Evaluation

Literature was evaluated by identifying each articles' conceptual framework, research design, sample, setting, major variables, measurement of variables, data analysis, study findings, level of evidence and critical appraisal score. Some articles had multiple research designs, sample sizes, and data analyses.

The conceptual frameworks of the studies in this review included descriptive and practical analysis, exploratory, and working hypothesis. The research designs of these studies included both qualitative and quantitative methods. Data collection methods within these studies ranged from an individual focus to a vast record review or sample size. Sample sizes of these

studies ranged from one participant to 887,859 charts. The major variables identified through the literature review and critical appraisal process were close observation and number of suicides and suicidal behavior. Data collection for these studies was overwhelmingly conducted through a record review process and the data accumulated was analyzed through inferential statistics. Level of evidence for each study was identified, appraised, and assigned. Appraisal scores were calculated and ranged from 78%-93% which assisted with the systematic evaluation of these studies. All of these various components were identified and organized into a spreadsheet. See Appendix A.

Synthesis

The data obtained from the literature review was categorized, ordered, and summarized into a synthesis chart. The studies were categorized by level of evidence determined according to Melnyk and Fineout-Overholt (2018).

The appraised Level I evidence included three meta-analyses with quality ratings between 89% and 78%. The meta-analysis conducted by Sakinofsky (2014) and Huisman et al (2010) suggested that there is a need to review or make intervention studies that relate to suicide. Both of these studies concluded that it is possible to reduce suicide risk by having a safe environment, optimizing patient visibility, supervising patients appropriately, careful assessment, and adequate clinical treatment. The third Level 1 evidence by Tingle (2019), suggested that patients admitted to inpatient mental health units were subject to inadequate and inappropriate observation processes. Recommendations drawn from all three meta-analysis included the themes that suicide risk can be reduced through close observation, psychiatric patients are often placed on inappropriate levels of observation, and that all relevant staff ought to undergo specific training in close observation.

No level II evidence was appraised. Considering the nature of close observation and the relation to patient safety it is not surprising that no randomized control trials were found during this literature review process. It would be unethical to knowingly neglect patients at risk for suicide for a research study. (American Nurses Association, 2015).

The appraised Level III evidence included two research studies that employed controlled cohort studies and had quality ratings of 90% and 80%. Kim et al (2010) study on close observation suggested that there is a potentially protective effect from the implementation process of close observation. Heyman and Lombardo's (1995) hallmark study suggested that there is a general lack of knowledge regarding the cost of close observation. Both of these studies, despite their fifteen-year time difference, came to the same conclusion that a decrease in the number and duration of one-to-one observation directly parallels the need for staff education programs.

No Level IV evidence was retrieved during the literature search. As a result, no Level IV evidence was appraised or included in the synthesis spreadsheet.

The appraised Level V evidence included five articles which had quality ratings between 93% and 80%. The Alaska Ombudsman (2019) report and Haney (2019) suggested that facilities should have policies, procedures, training, and monitoring systems in place to ensure patient safety through the use of close observation and one-to-one monitoring. Hunt et al (2010) suggested that close observation can potentially prevent suicidal behaviors amongst in-patients. Jayaram, Sporney and Perticone (2010) recommended increased use of one-to-one observation instead of only using 15-minute checks. Lepiešová et al (2015) reported a significantly ($p < .001$) higher number of violent patients in psychiatric settings than other healthcare settings. They recommended the use of close observation to mitigate violence toward staff and other patients.

Only one Level VI evidence research study was identified and appraised through the literature review process. This article by Captain (2006) was excluded due to a lack of a critical appraisal strategy by Melnyk and Fineout-Overholt for expert opinions. Furthermore, Level VI evidence represents the lowest level of evidence, and was not applicable to this project.

The process of synthesizing research articles and their findings led to the creation of a synthesis spreadsheet. See Appendix B. From this synthesis process three themes were identified that were relevant to close observation.

Theme I. Patients are frequently placed on inappropriate levels/ degree of close observation.

Theme II. Close observation cannot prevent suicide but it can limit injury caused by self-injurious behaviors. Observers are able to intervene quicker, and thereby decrease the negative consequences of these behaviors such as hypoxia and tissue damage.

Theme III. The cost and duration of one-to-one observation can be reduced. Some of the articles discussed the financial burden that close observation placed on staffing and hospital resources.

Limitations

One limitation to this literature review was the inability for the highest level of research, random control trials, to ever be conducted because it would involve unethical situations related to safety. The American Nurses Association *Code of Ethics for Nurses* (2015) states that nurses need to provide high quality care to their patients. Randomized control trials that would possibly test various levels of observation may lead to self-injurious or aggressive behaviors.

In addition, much of the current literature available on this topic is limited to older studies. The retrieved articles ranged in publication year from 1995 to 2019. The availability of

more recent articles would have hopefully provided stronger evidence for clinical change and more relevant suggestions for policy change. Furthermore, search strategies and limiters only allowed for English articles to be included in this review.

Conclusion

This chapter discussed the current state of the literature on close observation. CINAHL and PubMed were searched and a total of 14 relevant articles were found. This number was refined to ten after evaluation and appraisal. Literature was evaluated by identifying each articles' conceptual framework, research design, sample, setting, major variables, measurement of variables, data analysis, study findings, level of evidence, and critical appraisal score. Articles were appraised using the Rapid Critical Appraisal developed by Melnyk and Fineout-Overholt (2019). Data weas synthesized by categorizing, ordering, and summarizing each research article and their studies findings. Through this synthesis process three themes were identified.

The first theme is the identification of a discrepancy between the level of observation required by a patient, and the level of observation implemented. The second theme was that close observation cannot prevent suicide but it can limit injury caused by self-injurious behaviors. The third theme identified is the cost and duration of one-to-one observation can be reduced.

There are two major limitations to this literature review. Randomized control trials are impeded by ethical standards to provide high-quality care. Another limitation was the availability of recent literature. Research studies for this project ranged in publication years from 1995 to 2019. Furthermore, search strategies used and inclusion/exclusion criteria limited the number of articles that were included in this review.

Chapter 3: Organizational Framework

This project was guided by the organizational framework of continuous quality improvement using the Plan, Do, Study, Act model (PDSA). This framework seeks to continuously improve quality, care, and patient outcomes. (Department of Children & Family Services, 2019). The PDSA model was chosen because this project evaluated processes and outcomes related to the use of close observation. Furthermore, Alaska Psychiatric Institute utilizes the framework developed by the PDSA model for its quality improvement projects, and the facility is familiar with this organizational approach to project development. This chapter will provide background information on the PDSA model and explain how this organizational framework guided this project.

Continuous Quality Improvement

Quality improvement in healthcare is a patient centered philosophy that is driven by evidence-based research. Utilizing quality improvement ideals in health care help to create and develop new interventions that can be implemented and revised based on feedback. New data is generated through evidence-based research and can be used to guide policy and practice revisions. By examining available data related to the current practice of close observation of psychiatric patients at Alaska Psychiatric Institute, and supported by the literature review conducted, improvement in the safety outcomes of these particular groups of patients are expected. Furthermore, staff at API should derive benefits by improving overall safety policies and procedures surrounding close observation.

The key elements of continuous quality improvement are driven by stakeholder accountability and ensuring that individual tasks are completed, data derived from record review, and feedback provided by patients and staff. The key elements of continuous quality

improvement are reflected in and helped guide this project. All stakeholders at API to include administration and floor staff are held accountable for maintaining both the patients' safety while hospitalized and staff safety while on duty. All the data accumulated from the literature review combined with the projects generated data provided evidence for recommendations for policy revisions and protocols related to close observation. This mechanism of feedback allows for the process of evidence-based research to begin anew. For quality improvement projects to be successful they require input from all stakeholders to build teamwork. They also develop group goals while simultaneously reviewing the group progress focused on the one goal of improved safety outcomes. (Department of Children & Family Services, 2019). These key elements of a quality improvement project contribute to the internal needs and benefits of an organization while providing external benefits seen in the broader community.

In regards to API the internal benefits of quality improvement project include: improved staff and leadership accountability, improved staff morale, and improved delivery of services. Some of the external benefits derived from a quality improvement project in regards to the broader organization and community include: decreased violence, decreased exposure to traumatic experiences, and injury due to a lack of appropriate behavioral observation. Furthermore, an organizational framework based on continuous quality improvement model allows for the development of creative and innovative solutions that improve patient safety outcomes and goals. The goals of this continuous quality improvement project were centered on ensuring a safe environment, providing a high quality of services, meeting standards and regulations identified by the Joint Commission and CMS, and to assist API in revising programs and services to meet facility goals consistent with patient safety.

There are several models for continuous quality improvement in the literature. They all share consistent activities related to identifying the problem, developing improvements strategies, and evaluating effectiveness. The Plan, Do, Study, Act (PDSA) model of quality improvement was chosen for this project. The PDSA model is a quality improvement model that is comprised of a four-step circular process consistent with evidence-based practice that critically investigates process and outcomes. (Hughes, 2008).

Plan, Do, Study, Act

The Plan, Do, Study, Act model was made popular by Dr. Edward Deming in 1950. (Hughes, 2008). He utilized this model to effect change in a business setting, but it has since been adapted to the healthcare setting. Furthermore, it is widely used by the Institute of Medicine (Hughes, 2008). This model critically investigates processes and outcomes specific to facility need. It has been utilized to search for common causes of variation within facilities/practice and identifies systematic solutions for improvement. The PDSA model is driven by data, uses feedback, and it can be implemented to affect long-term approaches to patient care.

The PDSA model has been implemented for a variety of practice settings and has resulted in sustainable change. Knudsen et al. (2019) found that 98% of the 120 quality improvement projects they evaluated reported improvement using the Plan, Do, Study Act model.

McGowan and Reid (2018) investigated improving a patient feedback system for older adults on a medical rehabilitation ward. They found that the Plan, Do, Study Act model was effective at measuring outcomes and improving systematic processes within the facility. Their revised policy on patient feedback offered a tailored approach to capturing the adult experience of health care, and the results of their study were also used for making practice improvements.

Coury et al. (2017) implemented improved colon cancer screening protocols in a clinic setting. They found that understanding how the Plan, Do, Study, Act model can be applied to practice change helped their facility integrate evidence-based interventions into their routine care processes.

Plan, Do, Study, Act at API

Continuous quality improvement development and implementation involves multiple stakeholders from various departments at Alaska Psychiatric Institute. The application of a quality improvement project will rely heavily on the quality improvement department and the Licensed Independent Practitioners within API. Furthermore, as new close observation policies are developed and implemented, the efficacy will impact all API's agency staff, from nursing assistants to the chief of psychiatry. The steps incorporated by the PDSA model were applied to develop the framework for this quality improvement projects and are described below.

Step 1. "Plan" by establishing objectives and requirements for the desired results. This step has two parts. The first part of the "Plan" step was completed by conducting a literature review and identifying consistent themes for the improvement of close observation policies as well as reviewing The Alaska Ombudsman Report (2019) identified deficiencies in current practice at Alaska Psychiatric Institute. The second part involved meeting with API's Quality Improvement department as well as some of the License Independent Practitioners to discuss their insight and opinions toward changes to the current close observation policy and procedure implemented at API.

Step 2. "Do" required implementing each component identified in the planning phase and gathering the data to see how effective the change can be. This "Do" step included collecting data related to self-injurious and aggressive behaviors for patients who were placed on close

observation status at API. The data collection process occurred through the Risk Management department and involved reviewing the Unusual Occurrence Reports (UOR) that were generated between January and March of 2020. The principal investigator then identified relationships between close observation and self-injurious/aggressive behaviors through data collection and organization.

Step 3. "Study" is the analysis of data by conducting a statistical analysis. This data analysis will either identify significance - or lack of - between the various levels of close observation and self-injurious/aggressive behaviors. "Study" component of this model will also help identify areas of specific practice improvement. Evaluating and applying the data analysis results provided direct evidence for policy revision and practice change.

Step 4. "Act" or adjust the quality improvement process by identifying key areas of improvement and repeating this process if necessary. This "Act" step included revising existing close observation policy to reflect changes identified by data analysis. This revised policy will be submitted to the Quality Improvement department at Alaska Psychiatric Institute for review and possible permanent change. The "Act" of disseminating the results will also include updating the License Independent Practitioners concerning the impact and possible changes to their current practice of close observation. After dissemination of the outcomes has occurred it can be repeated based on any newly acquired feedback obtained from the quality improvement project results and from the Licensed Independent Practitioners input and responses.

Conclusion

Continuous quality improvement models have been successfully used since the 1950s. They have contributed too effective and sustainable practice changes, have provided the framework for multiple evidence-based quality improvement projects, and can be implemented

in a variety of practice settings to include business and healthcare. The specific quality improvement model implemented for this project was the Plan, Do, Study, Act model. The "Plan" step involved establishing objectives, goals and desired outcomes for improving close observation. The "Do" step involved reviewing, organizing, and analyzing the data collected. The "Study" step of this model involved analyzing the data to determine significance and provide direct evidence for policy revision and practice change. The "Act" step involved revising current close observation policy and identifying further areas of improvement. This four-step model is cyclical and encourages continuous quality improvement.

Chapter 4: Design and Methods

Research design and methods can have an impact on the outcome of a project. Identifying these elements will assist in accurately and consistently acquiring data, analyzing data, and drawing conclusions. Chapter Four identifies the design and methods that were used for this project, discuss the setting and population involved in the project, the planned intervention, and the intended practice change. Furthermore, discussion of the data collection and organization process, the data analysis process, cost benefits, and ethical considerations will occur.

Design

The overall approach to the design of this project utilized a continuous quality improvement process based on reviewing existing records. This pragmatic trial sought to identify relationships amongst the various levels of close observation. (Toulany, McQuillan, Thull-Freedman, & Margolis, 2013). The control condition was routine 15-minute observation. The other measurable variables were the various level of observation associated with close observation and any self-injurious or aggressive behaviors that occurred during the patient's observational period. A systematic process for data collection and organization using existing record reviews was conducted. The data acquired was provided through the Risk Management department at API. No protected health information was contained, and all the data collected was de-identified to align with both UAA and API IRB requirements. To ensure that health information was protected, the gathered data was stored electronically in a secured file that limited access and was password accessible only. The Risk Management department at API and the principal investigator were the only individuals with access to this file.

This project occurred at Alaska Psychiatric Institute (API), which is a state run psychiatric in-patient facility with an official capacity of 80 beds located in Anchorage, Alaska.

API offers a variety of services and acts as an extension of the court system. The majority of patients are admitted to API on either *ex parte* court orders or Title 12 court orders. (Alaska Ombudsman, 2019). However, API is neither a jail nor a prison and operates through the Division of Behavioral Health rather than the Department of Corrections.

Patients with an *ex parte* order are admitted for 72 hours for observation. Following this observation period, health care providers must decide to either discharge the patient, allow the patient to remain at the hospital voluntarily, or file for a 30-day involuntary commitment for treatment. A Title 12 is an order for competency evaluation and/or restoration to stand trial. These patients are admitted to a specific unit (Taku) within the hospital and have different programming and groups.

The facility consists of five units named Susitna, Katmai, Chilkat, Taku, and Denali. Susitna is an adult admitting unit that has 26 beds. Katmai is also an adult admitting unit that has 24 beds. Chilkat was designed to be a 10-bed adolescent admitting unit. However, this unit can be converted to an adult population in order to meet the needs of the hospital. Taku is an adult forensic 10-bed unit for competency evaluation and restoration. The final unit, Denali, is a 10-bed unit used for acute or long-term patients. This unit is currently not in use due to inadequate hospital staffing. (Alaska Ombudsman, 2019). De-identified data from all units that received admissions will be included in this project.

API consists of multidisciplinary teams and departments that are related to patient care. These various departments include medical, nursing, social work, psychology, clinical services, and administrative. Administration is responsible for developing and enforcing policies related to close observation. The Administration department determines and controls who has access to patient records, what requirements for close observation are required, and they are the final

decision maker for the facility policy approval. Medical is responsible for ordering close observation, implementing the close observation process, assessing the effectiveness of close observation and will be directly affected by changes and any revisions to API's close observation policy and procedure. (E. Steeves, personal communication, 2019). The Nursing department is responsible for implementing all orders initiated for close observation. Despite the specific spheres or roles of responsibility, all staff and all departments within API are responsible for maintaining patient safety and ensuring good patient outcomes during observational status. (Alaska Ombudsman, 2019).

Facilitators and Barriers

The most significant facilitating method in this project was the use of communication. It was imperative to maintain open communication with the hospital's administration, the various departments within API, the Quality Improvement department and individual providers. Without communication and teamwork throughout this project the ability to implement, acquire, organize and disseminate the results would not be possible. Furthermore, by working with the Quality Improvement department ensured that practice changes would be implemented. The Quality Improvement department was identified as the best strategy for gaining acceptance by API, which would ultimately lead to a smoother acceptance of recommended practice change. Another facilitating factor for this project was the identification of key stakeholders throughout API's various departments. These key stakeholders supported the projects goals and outcomes, maintained open communication and help the dissemination of the project's results.

The largest barrier to this project was acceptance of the revised policy by API. The Alaska Psychiatric Institute has a right not to implement new close observation policy, and psychiatric providers have a right not to utilize new close observation recommendations. (E.

Steeves, personal communication, 2019). The best way to overcome this barrier was to conduct appropriate data collection, organization, analysis, and to provide clear evidence that supports the proposed policy revisions. Furthermore, working with stakeholders throughout this process will leverage stronger support for practice change.

Another barrier was the restrictions implemented due to the novel coronavirus, COVID-19. COVID-19 caused disruptions in communication with select stakeholder as many employees transitioned to working remotely. Disruptions and delays in communication led to revision to the timeline of this project. Project completion was pushed back to the Fall 2020 semester.

Intervention/Practice Change

The planned practice change was a revision to API's current close observation policy. The conducted literature review developed the themes that patients have been frequently placed on inappropriate degrees of close observation and that close observation cannot prevent suicide but can decrease its occurrence. Furthermore, the literature review also highlighted that close observation can limit injury caused by self-injurious behaviors. A revision of current policy can help mitigate these deficiencies and improve overall patient safety outcomes. (Melnyk & Fineout-Overholt, 2018).

The principal investigator worked with the quality improvement department hoping that statistical analysis of the data would justify and be the forerunner for policy revision. The statistical analysis revealed that there was not a statistical significance between routine 15-minute checks and first-degree close observation. However, even though statistical analysis did not find significance the conclusion did highlight that either method of observation does not have an advantage over the other. In response to this finding a policy was developed that merged these two levels of observation together. This policy recommendation alone streamlines time,

decreases staff requirements, and overall decreases costs associated with close observation. If data analysis had illustrated that there was no statistical significance between second degree and third-degree close observation then, a policy reconciling these levels of close observation would be recommended.

Quality improvement design involving policy revision has been utilized in similar quality improvement projects. Speroff and O'Connor (2004) stated, "Stable or chronic processes are candidates for quasi-experimental designs and quality improvement." (p. 30). API's close observation process is both stable and chronic in nature. The stability of API close observation exists because every patient must have an order for a level of observation. Close observation is chronic in nature because this intervention is mandatory and must remain in place in order to meet current state and federal standards of care set by the State of Alaska and the Joint Commission.

Revisions to current close observation policy and procedure must first be accepted by API administration in order to be utilized and implemented by providers. There must be a persuasive presentation to administration that showcases best practices from a current literature review and the results of the data analysis from this project. Without strong evidence that the practice change will benefit patients, the policies are not likely to be approved by API. (E. Steeves, personal communication, 2019). Speroff and O'Connor (2004) further state in their article that the use of any statistical technique provides more convincing evidence for quality improvement changes as opposed to anecdotal evidence.

The only area where revision is limited despite the occurrence of statistical significance is the removal of second degree or one-to-one observation. Second-degree observation policy may

be altered but it cannot be removed. This is due to regulatory requirements from CMS and The Joint Commission.

Measures

To measure the outcome of this DNP project, data was collected through the Risk Management department utilizing a chart review of psychiatric inpatients. Raw de-identified data was collected that identified the occurrences of both self-injurious and aggressive behaviors was then organized by the principal investigator into an Excel spreadsheet designed specifically for this data. Both self-injurious and aggressive behaviors warrant the generation of an Unusual Occurrence Report (UOR). Each UOR represents an occurrence of either behavior and the same patient may have multiple UORs generated during their hospitalization. These UORs identify which behavior necessitated the generation of the report. These reports can also include unusual medical occurrences, facility deficits, safety concerns, injury, security failures, and hazards. However, these specific occurrences will be excluded if they do not contain or are secondary to self-injurious or aggressive behaviors. The UOR was then connected to the level of close observation associated with that report and specific behaviors. The Risk Management department was responsible for this process to successfully shield any exposure to protected personal health information. A total of 471 UORs were retrieved, but only 154 articles met inclusion criteria.

The benefit of using existing inpatient psychiatric records is that no apparent risk exists to the patient in terms of safety or physical wellness. Furthermore, by extrapolating data from records provided an objective source of quantitative data. The data collected from the UORs was organized into an Excel spreadsheet, Figure 2.

Figure 2

Data Collection Spreadsheet

	Level of observation	Self-injurious behaviors	Aggressive behavior
1			
2			
3			
…			

Data Collection

Data was collected through Risk Management via existing psychiatric inpatient records. The Quality Improvement staff at API provided oversight for the data collected. Patients were not recruited for this project not required as all data was collected through record review process. The only stakeholders involved in the data collection process for this project was Risk Management, more specifically, the director of the quality improvement department. They both verbally agreed to assist with the data collection. (E. Steeves, personal communication, 2019). Healthcare providers would only be recruited/involved once the data has been organized, analyzed, and policy revisions were made and approved by API. All records from patients admitted during a three-month period between January 2020 and March 2020 were included. De-identified raw data was organized into an Excel spreadsheet, Figure 3.

Figure 3

Data Organization Spreadsheet

	Routine 15-minute checks	First Degree	Second Degree /1:1	Third Degree / 2:1	Total
Total # of Self-injurious behaviors					
Total # of Aggressive behaviors					
Total					

The inpatient chart review process and the data collected from that process were exclusively conducted by the Risk Management team who are under the direct supervision of the Quality Assurance and Process Improvement (QAPI) department. The director of QAPI granted permission for this project to occur and was apprised during both the process of data collection and of the results after data analysis had occurred. (E. Steeves, personal communication, 2019). In addition to individual UOR reports, aggregated data was also made available in the form of Excel spreadsheets that were used to organize and categorize the de-identified data. See figure 2 and Figure 3.

Data Analysis

A portion of the effectiveness of this project rested on the evaluation of the generated evidence to support or revise current existing policy. Evidence for policy change was based on statistical analyses of the current close observation protocols and their effect on patient self-injurious and aggressive behaviors. If policy revisions are approved, then future follow-up research can investigate long-term consequences of policy change.

Patient demographic information was not collected nor required for this project. The only data collected focused on the total number of occurrences that were recorded via the UOSs and the level of observation incorporated during the behavior incident. The primary outcome measurement was gathered through the systematic process of reviewing existing policy at API and generating evidence via data collection, organization, and analysis. This evidence was then used to evaluate the effectiveness of each level of close observation to prevent harmful patient outcomes. Evidence generated through the statistical analysis of the data collected was the forerunner for recommendations and revisions to existing policy surrounding close observational status.

Descriptive and inferential statistics were applied to analyze the collected de-identified data. The process of statistical analysis began by identifying the total number of self-injurious and aggressive behaviors. A total of 28 records pertained to self-injurious behaviors while 126 records pertained to aggressive behaviors were included in this analysis. Then, a Chi Square was calculated to examine if any significance between the four levels of observation and behaviors occurred. The Chi Square statistically describes the relationship between the level of close observation and the number of self-injurious and aggressive behaviors exists or not.

Cost Benefit Analysis & Budget

The cost of this DNP project was very low, especially when considering the potential benefits. There will be little cost to API for this project because the project included a review of already existing records to acquire data. Aa small financial expense occurred through the use of printing documents including the cost of paper and printer toner; these specific expenses were kindly absorbed by API. There could be a cost associated with statistical analysis if a statistician was recruited. Fortunately, that was not required for this project. There was a higher cost

associated with the time required to complete this project. DNP project requires a total of three, two credit courses consisting of 60 clinical hours per course. Data collection, analysis, and report preparation will require approximately 180 hours from the project director. With an hourly rate of $60.00, the estimated cost of the project director's effort will be $10,800. Please refer to Figure 4.

It is difficult to monetize the benefits to API because there are non-monetary benefits such as employee retention and safety that is hard to quantify and labor expenses will vary. The potential costs savings to API occur by decreasing staffing required for close observation if pending revisions to close observation policies are accepted. It costs approximately $400/day (using the hourly rate of a psychiatric nursing assistant at $16.66/hour X 24hours) to provide a patient with one-to-one close observation for 24hours if following set protocol. If staffing is unavailable for close observation the facility is required by law and accreditation standards to mandate employees or seek volunteers to work overtime. Overtime pay can raise the staffing costs to over $600/day. Furthermore, if patients require two-to-one staffing, then the cost estimation can double to over $1200/day. Any revisions to the current policies that improve observation length of time or alter number of observations required has the potential to mitigate this expense. Furthermore, the cost to train employees for the application of close observation is approximately $10,000 per employee in regard to training and orientation required to be an observed for close observation. (E. Steeves, personal communication, 2019). Retaining experienced employees can be a significant cost benefit generated by this project through revisions to close observation policy geared to improve the overall process surrounding close observation. Furthermore, by retaining existing employees the high cost of recruiting, selecting, training, and orienting new employees is not required and thus becomes saved money. Also, by

preventing or limiting self-injurious and aggressive behaviors by the patients will directly decrease emergency room visits and their associated costs. It is further surmised that by decreasing emergency room visits by decreasing injuries experienced by patients and staff an estimated $614 per emergency room visit can be saved. (Primera, 2014). See Figure 4.

Figure 4

Cost Benefit Analysis

Cost/ Expense	Estimated benefit or saving
Labor to conduct project	(180 hours of project) * ($60/hour) = $10,800
Misc supplies (flashdrive, paper, toner, etc) < $100	Facilitates secure information exchange
Statistician < $100	Facilitates accuracy of data and analysis
$614/ emergency room visit.	Increased patient/staff safety.
Staff training costs approximately $10,000/ employee.	Increased staff retention.
Labor costs for implementing COSS	As much as $1200/day

In summary, this project has the potential to benefit API financially by decreasing staffing costs (limit training numbers required and staff ratios), retaining employees (improved satisfaction), and overall may decrease injuries experienced during observational status by cutting down on expensive emergency room visits. This is a labor-intensive project through data collection and policy revision, but low in cost in terms of financial resources that are required to complete this project. API has potential to reap tremendous amount of financial savings if close observation protocol can be revised to decrease the need for superfluous close observation and help retain staff. Furthermore, patients and staff will have a safer environment to reside and work in with the potential decreased emergency room visits.

Timeline

The timeline for this project was approximately seven months. Proposal defense occurred at the start of the Spring 2020 semester. Following proposal defense IRB was completed. Then,

data collection began immediately. After data collection ended data organization and categorization began. Next, data analysis occurred. Once the data was analyzed and the results were evaluated the process of policy revision began. Once a new policy was developed it was submitted to API. API required time to review the new policy recommendations and decide whether or not they would be incorporated into their current practice. It was during time that the final write-up of this project began. Following the completion of the final write-up a formal project defense will occur. Final project defense will then occur during the Fall 2020 semester. See Figure 5 below.

Figure 5

Project Timeline

Task	PDSA	Time to complete	Estimated date of completion
Proposal defense and IRB	Plan	7 weeks	4/13/20
Data organization and analysis	Do	4 weeks	5/11/20
Policy revision	Study	2 weeks	5/25/20
Policy submission	Study	2 weeks	6/8/20
Decision to implement policy	Act	1 week	6/15/20
Final project write-up	Act	6 weeks	7/27/20
Final project defense	Act	1 weeks	8/3/20 – 11/19/20

Ethical Considerations and Protection of Human Subjects

This project included reviewing existing records and was considered a very low risk of harm to participants. The risks associated with exposing both protected health information and

personal identifiable information was mitigated by involving the Risk Management department to conduct the data collection and by incorporating the use of de-identified data. Personal identifiable information was not collected nor recorded by the principal investigator and was instead handled by the Risk Management department. Specifically, the data that was handled by the principal investigator did not include names or any personal identifiers, medical numbers, visit numbers, and patient diagnoses. Furthermore, demographic information such as age, race, or gender was not collected nor required for this project. Despite having minimal risk to participants there still remained a high potential for benefits to API.

The benefits of this project are associated with maximizing efficiency of close observation protocol. This project produced results that directly benefited the facility by streamlining policies to reflect the needs of the hospital and promote staff and patient safety. These specific policy recommendations benefit API by decreasing unnecessary staff use, decreasing training numbers, and increasing employee retention. Patients will experience the benefits of policy change through safer observation policies and protocols.

By using a record review process, as opposed to preemptively implementing changes to close observation practice or policies, patients were not exposed to any potentially dangerous circumstances or situations. To further prevent harm an application was submitted through the Institutional Review Board (IRB) at UAA and through the API process regulations board to ensure patient safety. The principal investigator only had access to de-identified raw data. Data was handled and stored using secure technology including encrypted flash drives password protected computers and limited access from other members at API. Furthermore, the principal investigator maintains up to date Collaborative Institutional Training Initiative (CITI) certification used to demonstrate competency with the principles of human subject research.

Additionally, the Health Insurance Portability and Accountability Act (HIPPA) provided guidance related to the standards of care and protection of patients' health information.

Conclusion

Chapter Four examined the design and methods of this project and described how this project will address the clinical problem. This chapter discussed the various aspects of this project to include the project's design, setting, population, facilitators and barriers encountered, interventions, measurement of data, data collection methods, data analysis, cost risk and benefits, established timeline, and finally discussed ethical considerations associated with this project.

Chapter 5: Implementation Process and Procedures

The implementation of a project is a complex process that involves great preparation and attention to detail to ensure successful project outcomes. Chapter Five will identify the steps taken to implement this project plan. It will discuss the processes used in implementation, the barriers and challenges to implementation, and other considerations that altered the implementation plan or caused adaptions during the implementation phase. This chapter will reflect a foundation, synthesis, and application of knowledge.

Plans and Steps

The first step in implementation was acquiring approval to conduct the project at API. Approval was obtained by meeting with key stakeholders, reviewing the project design and methods with these key stakeholders and ensuring that existing API policy was being met. First, meeting with stakeholders began with discussing the project with the director of Quality Assurance and Process Improvement. Next, the principal investigator met with the Risk Management department to discuss data collection methods, various ways to ensure privacy of data and any other concerns they might have with chart review, patient privacy and the overall DNP project. The principal investigator then met with Information Technology employees to ensure that the feasibility of data collection and organization could be accomplished with the existing facilities technology and databases.

Per policy the principal investigator met with the Director of Clinical Services who is the President of the Academic Integrity Committee. See Appendix I. After garnering his approval, the proposal was presented to medical staff. The medical staff, including the Chief of Psychiatry, approved the project and documented the approval in meeting minutes. See Appendix E.

Occurring concurrently was submission of Human Subject Research Determination and application to the Institutional Review Board (IRB) at UAA. The IRB at UAA determined that this project should be classified as a quality improvement project and was determined to be non-human subject research. API was informed of this decision and data collection was allowed to commence.

The next step was data collection and organization of the obtained data. The Risk Management department collected data in order to mitigate unnecessary exposure of protected health information. Data was then organized by the principal investigator through summation of the total number of occurrences of self-injurious and aggressive behaviors in relation to the level of observation. Organized data was inputted and stored into Microsoft Excel version 16.01 Statistical analysis was conducted using Statistical Products and Service Solutions (SPSS).

Data was analyzed using the Chi Square statistical method and these results are discussed in more depth in Chapter 6. The results of the statistical analysis were then used to draw conclusions that were incorporated as a primary source of evidence and a forerunner for policy revisions.

Policy was revised to reflect the statistical evidence generated from the Chi Square statistical application. Revisions to existing policy reflected the significance between self-injurious and aggressive behaviors compared to the level of observation that was generated through application of the Chi Square statistical method. Policy revisions were brought to the QAPI department and to the medical board at API for review. Recommendations and revisions to current policy will be discussed at greater length in Chapter 7.

Processes Used in Implementation

The process of this project closely followed the Plan, Do, Study, Act model outlined in Chapter 3. (Hughes, 2008). The "Plan" step was completed by conducting a literature review, identifying consistent themes for the improvement of close observation policies and procedures, and by reviewing existing policy related to close observation at API. Planning also involved meeting with several different key departments at API including Quality Improvement, Risk Management, medical staff, and key staff members.

The "Do" step included data collection and organization. Data collection occurred through Risk Management and involved reviewing Unusual Occurrence Reports. Data organization was completed by the principal investigator and involved calculating the total number of self-injurious and aggressive behaviors as a function of level of observation.

The "Study" step included data analysis. Data analysis using Chi Square was used to identify whether a lack of significance existed between self-injurious and aggressive behaviors as it relates to level of observation. This step generated the evidence that was then used a forerunner for policy revision.

The "Act" step utilized the results of data analysis to provide direct evidence for policy revision and practice change. This step included revising the current close observation policy. The revised policy was disseminated via email to the QAPI department and discussed with medical staff during weekly medical staff meeting. After departmental review, this process can be repeated based on individual feedback from each department.

This model promotes sustainability because it is cyclical in nature. The "Act" step allows the investigator to review the outcomes of change, and identify opportunities for continuous

quality improvement. In this DNP project sustainability is achieved by either policy approval or identification of further inquiry.

There were barriers to the steps outlined above. This process was complicated due to the uncertainty of this project being human subject research versus quality improvement. Furthermore, IRB was concerned of the risk of using a vulnerable population, and the potential exposure of protected health information.

Barriers and Challenges

There were barriers to the implementation of this project. Barriers included defining this project as quality improvement or research, organizational culture, the risk of using a vulnerable population, and the potential exposure of protected health information.

Determining if this project was quality improvement or research prevented the start of data collection, organization, and analysis by approximately six weeks. This barrier was overcome through a series of applications and communication with the IRB at UAA. The IRB determined that this is a quality improvement project and qualifies as non-human subject research.

Another barrier to this project was organizational culture. API has a right to not implement new close observation policy, and psychiatric providers have a right to not utilize new close observation recommendations. It was imperative to have open communication with hospital administration throughout this project to demonstrate the utility of the data and the resulting recommendation to change practice. Working with quality improvement to ensure that practice changes can be implemented was the best strategy for acceptance by the facility. Furthermore, working with a key stakeholder throughout this process provided stronger support for practice change. (Melnyk & Fineout-Overholt, 2015).

The risk surrounding involving a vulnerable patient population in a quality improvement project and the potential of exposure to protected health information were mitigated by using a controlled record review and abiding by scope and standards outlined by the American Nurses Association (2015). However, the IRB at UAA required information attesting to the de-identification of data involved in this project. This also prevented the onset of data collection. This barrier was overcome by having the Risk Management department collect data instead of the principal investigator.

One of the anticipated challenges was data analysis. The expected statistical calculation involved with this project was an ANOVA. However, collected data did not meet the assumptions of parametric statistics, and the non-parametric equivalent Chi Square was used. To mitigate this challenge consultation with a statistician occurred. This ensured the utility of organized data and the appropriate corresponding statistical test.

Alterations to Methods

There were alterations to the original project design. Alterations to this project were made as barriers were encountered. The timeline of project implementation was revised following the delay caused by IRB determination. The timeline also required revisions to the expected time for data collection.

The original project design included the principal investigator collecting identifiable patient data in order to connect level of observation and occurrence of self-injurious and aggressive behaviors. This process unnecessarily exposed protected health information to the principal investigator. It was recommended that Risk Management de-identify the data under the direction of the Director of Quality Assurance and Process Improvement. The principal

investigator was then provided raw de-identified data that required organization before it could be utilized in statistical analysis.

Alterations to data analysis also occurred. Data was expected to be parametric in nature. After data was collected and organized it was determined that the data did not meet parametric assumption. The non-parametric equivalent, chi square, was utilized for data analysis.

Conclusion

The implementation of this project was an intricate process that followed an organizational framework established in Chapter 3 and methods established in Chapter 4. The Risk Management department at API and not the principal investigator collected the raw de-identified data. The raw de-identified data was provided to the principal investigator as protected patient health information. Next, the principal investigator organized and analyzed the de-identified data using the chi square method of statistical analysis. The evidence generated by this statistical analysis was used as a forerunner for policy revision and followed the Plan, Do, Study, Act model for continuous quality improvement. (Hughes, 2008).

The implementation of this quality improvement project had many unanticipated challenges and barriers. These challenges and barriers were recognized and alternative solutions and adaptions were identified and implemented. Outcome measures for this project were clearly identified and presented to executive leadership at API early on in this project.

Chapter 6: Results

The results of this project represent the assimilation of knowledge from the literature review as well as information generated through statistical analysis. Chapter Six will identify the outcome measures of this project. It will also discuss sample size, the various elements of data organization, analysis, and the results of the statistical analysis used in this project.

Outcome Measures

The primary outcome measure of this project was the systematic process of reviewing existing policy and generating evidence used to evaluate the utilization of close observation. Evidence was then used as a forerunner for recommendations and revisions to policy.

Statistical analysis using Chi Square was used to evaluate the significance of the utilization of close observation across all levels. The evidence generated included the possibility of producing support for current practice standards as well as support for future policy revision. Regardless, generated evidence and conclusions were disseminated to the key stakeholders at API and recommendations and revisions to close observation policy were provided.

Outcomes were presented to key stakeholders at API. This included executive leadership, QAPI, and medical staff. Stakeholders were given time to process the new recommendations and revisions as well as ask any questions regarding the purposed changes. Common questions included methods of data analysis and financial implications of practice change. The results of data analysis are presented below.

Sample Size

The director of Quality Assurance and Process Improvement reported that between 150-400 UORs are submitted each month (E. Steeves, personal communication, 2019). A three-month record review from January 2020 to March 2020 was chosen due to the number of UORs

submitted and completed on time. Steeves estimated that this time period would adequately capture the volume of data needed for analysis and would adequately represent the close observation frequency used at API. The three-month review also represented the first quarter of 2020 and was a good representative sample for API psychiatric inpatient population. Additionally, the timeline for project completion facilitated the collection and analyzing of a representative sample rather than a population driven or random sample.

A total of 471 UORs occurred during this three-month time frame. A total of 124 records were excluded because they did not pertain to self-injurious or aggressive behaviors e.g. falls, contraband, medical, inappropriate body exposure, med refusal, unspecified allegations, property damage, elopement, and security failure. A total of 193 UORs were excluded because they did not specify the precipitating behavior that resulted in the brief manual restraint, mechanical restraint, seclusion, or "unsafe behavior". A total of 154 entries remained and were included in data analysis.

A total of 28 of these records pertained to self-injurious behaviors while 126 pertained to aggressive behaviors. Aggressive behaviors included verbal, physical, and sexual. Physical aggression includes physical contact as well as attempts at physical contact. Sexual aggression includes sexual contact as well as attempts at sexual contact.

Results of Data Organization

Table 1 presents the organization of collected data.

Table 1

Total Number of Behaviors at Each Level of Observation

	Self-Injurious	Aggressive	Total
Routine 15-minute checks / Q15	8	42	50
First Degree	15	26	41
Second Degree /1:1	5	54	59
Third Degree / 2:1	0	4	4

Determinations for Data Analysis

The originally proposed statistical calculation was an Analysis of Variance (ANOVA). However, the data did not meet parametric assumptions including evenly distributed data (bell curve) and the data was nominal and ordinal (not ratio or interval). The non-parametric alternative test, Chi Square (X^2) test of associations/independence, was used to analyze for significant differences between self-injurious and aggressive behaviors across all levels of observation. This value confirms or denies any significance or associations between all levels of the dependent variable based on the data.

The number of events that occurred while on third-degree COSS were less than the expected count. Data related to third-degree COSS was included in a second and third-degree COSS column in order to meet testing assumptions. It was appropriate to condense second-degree and third-degree observational data because in practice, these two levels of observation may fluctuate based on clinical judgment and safety. Furthermore, there are no accrediting requirements for API to maintain both a second-degree and third-degree observational level.

Results of Data Analysis

The Chi Square (X^2) test has both a null hypothesis and an alternative hypothesis. The null hypothesis (H0) was the following: There is no difference between (independent) self-injurious and aggressive behaviors and (dependent) level of observation. The alternative hypothesis (H1) was the following: There is a difference between self-injurious and aggressive behaviors and level of observation.

The results of this statistical test show that the chi square value was less than the critical *p* value. Therefore, we reject the null hypothesis, and there is a significant difference between self-injurious and aggressive behaviors and level of observation. X^2 (2, N = 154) = 13.94, p = .001. Figure 6 presents the results generated by SPSS.

Figure 6

Results from SPSS

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided) p value
Pearson Chi-Square	13.940[a]	2	.001
Likelihood Ratio	13.288	2	.001
Linear-by-Linear Association	1.717	1	.190
N of Valid Cases	154		

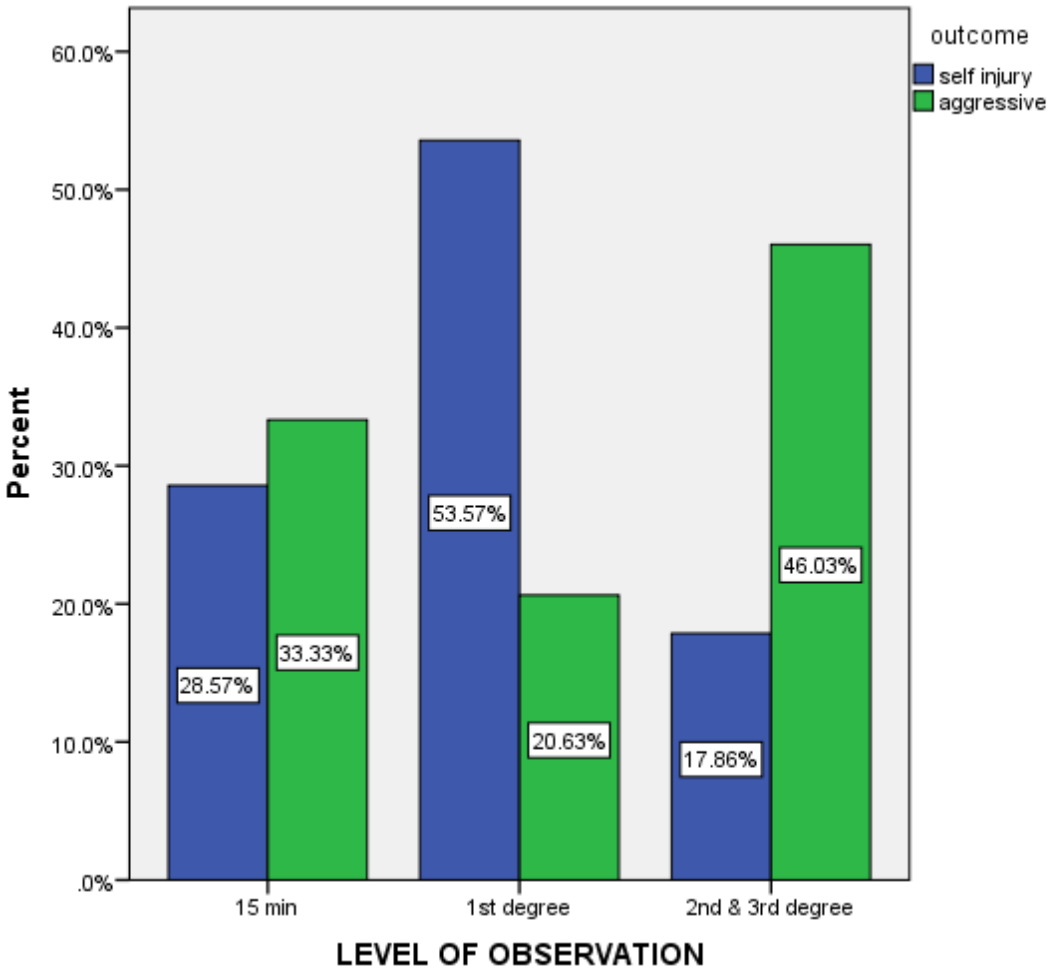
a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.45.

The data was further analyzed to examine frequency of self-injurious and aggressive behaviors at the various levels of observation. This analysis showed that patients on routine 15-minute checks have similar occurrence of self-injurious and aggressive behaviors. However, on first-degree and second-degree observations there were observable differences. On first-degree

observation there appears to be a higher frequency of self-injurious behaviors, while on second-degree observation there appears to be a higher occurrence of aggressive behaviors. See Figure 7 below.

Figure 7

Percentage of Behaviors Occurring at Level of Observation



In summary, the results of this statistical analysis illustrated that there was a significant relationship that existed between level of observation conducted and occurrence of self-injurious or aggressive behavior. Further analysis revealed similar frequency of self-injurious and aggressive behaviors while on routine 15-minute checks.

Conclusion

Data was organized and analyzed using the non-parametric statistic chi-square. The results of this analysis showed statistical significance existed between level of observation and self-injurious/ aggressive behaviors exhibited. X^2 (2, N = 154) = 13.94, p = .001. Therefore, we reject the null hypothesis and there is a difference between self-injurious and aggressive behaviors as a function of level of observation.

Despite not being the first choice for statistical analysis, chi square was an appropriate test to generate evidence for policy revisions. Future analysis that utilizes interval or ratio data may indicate the use of ANOVA. The results were statistically and clinically significant. These results have implications related to policy revisions. Based on themes derived from the literature review clinically significant results indicated that levels of observation can be consolidated to more appropriately utilize close observation.

The result of this analysis was used as evidence to revise close observation policy at API. The implication of these policy revisions will be further discussed in Chapter 7.

Chapter 7: DNP Essentials, Implications, & Limitations

The Doctor of Nursing Practice (DNP) is a terminal degree in the field of nursing. It represents a synthesis of knowledge, and the application of that knowledge in a clinical practice setting. Holders of the DNP degree may have different specialties including family nurse practitioners, psychiatric and mental health nurse practitioners, certified registered nurse anesthetist, midwives, and clinical nurse specialist. However, the essentials of the degree must be met regardless of specialty. This chapter will identify each of the DNP essentials outlined by American Association of Colleges of Nursing (2006), and their relevancy to this project. This chapter will also discuss policy revisions as well as the limitations of this project.

DNP Essential I - Scientific Underpinnings for Practice

This essential was incorporated into this project by conducting a review of the literature to identify if the possibility for a quality improvement project existed. This process allowed for the integration of nursing science into nursing practice.

DNP Essential II - Organizational and Systems Leadership for Quality Improvement and Systems Thinking.

This essential was incorporated into this project by meeting with key stakeholders at API and recognizing API as an organization in need of a quality improvement project. Taking a leadership role to develop and implement a project promoted the use of evidence-based research for quality improvement. Systems were developed around recognizing API organizational structure and providing policies that reflect organizational need. This whole process advanced communication skills required to lead quality improvement projects and promotes patient safety initiatives.

DNP Essential III - Clinical Scholarship and Analytical Methods for Evidence-Based Practice

This essential was incorporated into this project by collecting, organizing and analyzing data. This process allowed for the application of the project's findings to develop practice guidelines and improve utilization of close observation through policy.

DNP Essential IV - Information System/ Technology and Patient Care Technology for the Improvement and Transformation of Health Care.

This essential was incorporated into this project by utilizing technology to de-identify data, data collection techniques, the use of Excel spreadsheets, incorporating statistical analysis programs, using password encryption, and working in conjunction with both IT and API. Furthermore, databases available through the Consortium Library at UAA were used to retrieve articles utilized in the literature review of this project.

DNP Essential V - Health Care Policy for Advocacy in Health Care

This essential was incorporated into this project by formulating revisions and recommendations for close observation policy at API. This process demonstrates how leadership in the development and implementation of institutional health policy can occur and drive policy change from within. Recommendations for policy change were based off the statistical analysis and interpretation of the data collected.

DNP Essential VI - Interprofessional Collaboration for Improving Patient and Population Health Outcomes

This essential was incorporated throughout the implementation of this project by working with Quality Assurance, Risk Management, IT, and medical staff. This process allowed for

effective communication, promoted collaboration between all entities involved, and helped to sustain the development and implementation of a scholarly project.

DNP Essential VII - Clinical Prevention and Population Health for Improving the Nation's Health.

This essential was incorporated into this project through the generation of new policy aimed at preventing injury to patients and staff and to evaluate healthcare delivery models with their applicability to quality improvement projects. This essential was reflected by generating recommendations to revise close observation policy in an inpatient psychiatric setting.

DNP Essential VIII - Advancing Nursing Practice

This essential was incorporated into this project by engaging in activity that promoted the role of the advanced practice nurse as a practitioner, interdepartmental liaison, and advocate for policy change. Furthermore, this essential was demonstrated by evaluating a therapeutic intervention using analytical skills and nursing science.

Policy Revision

One main policy revision was generated based on the evidence obtained through statistical analysis. This revision involved combining the standards of Q15 minute checks and first-degree COSS. This revision was supported by the results of the chi square statistical analysis as well as the review of the literature. The literature review identified several themes around close observation. These themes are: patients are frequently placed on incorrect levels of observation, close observation can reduce damages caused by self-injurious and aggressive behaviors, and the cost and duration of one-to-one observation can be reduced. By combining these levels of observation mental health providers are more likely to have a patient placed on the correct level of observation. See Appendix E for policy revisions.

Limitations

One of the limitations of this study is the lack of generalizability. The sample size and records were collected from one agency, API, and are therefore not generalizable elsewhere. Collecting data from multiple agencies would increase the generalizability of the results and would be further recommended for future studies. Furthermore, collecting data from different locations (i.e. other Alaska cities) would also increase the generalizability of the results and provide a more robust picture of psychiatric inpatients within the state of Alaska.

Another limitation is sample size. A three-month record review resulted in a sample size of 154. If a six-month or twelve-month record review was conducted this would provide a larger sample size. A larger sample size may have an impact on the significance of statistical analysis.

Conclusion

The implementation of this project met all the DNP essentials including: scientific underpinnings for practice, organizational leadership for quality improvement, information system and technology for the improvement of health care, clinical scholarship and analytical methods, health care policy, interprofessional collaboration for improving health outcomes, clinical prevention, and advancing nursing practice. Implications and limitations that were encountered in this project were discussed and adaptions were reviewed. Recommendations to policy revisions were provided with justifications for their use. Future implication regarding close observation were discussed, future research studies were suggested, and limitations to generalizability were identified.

Chapter 8: Final Reflection

This chapter will discuss final reflections related to this DNP project. It will include project goals, methods, implementation, significance of results, a reflection, and a summary of learning.

Project Goals

The primary outcome measure of this project was the systematic process of reviewing existing policy, generating evidence through statistical analysis of data, drafting policy revision, and disseminating them to the appropriate stakeholders. The principal investigator was not able to guarantee that revisions were accepted by API. For this reason, the outcome goal remained the process and not final acceptance.

The review of existing policy and data analysis were used to evaluate the utilization of close observation. Statistical evidence was then used as a forerunner for revisions to policy. Generating statistical evidence included the possibility of producing support for current practice as well as support for policy revision. The outcome goal was determined to be the completion of the process instead of relying on the significance of the results.

The evidence was used to make recommendations and revisions to close observation policy. Outcomes were disseminated via presentation of project outcomes to key stakeholders at API to include executive leadership, QAPI, risk management, and medical staff. Stakeholders at each various meeting were given the opportunity to ask questions regarding the purposed policy changes and provide feedback.

Methods

The overall approach to the design of this project was continuous quality improvement utilizing a record review process. (Toulany, McQuillan, Thull-Freedman, & Margolis, 2013).

This methodology has been previously used at API and they are familiar with this type of quality improvement study. The control condition was routine 15-minute observation. The other measurable variables used were the various level of close observation and the occurrence of self-injurious and/or aggressive behaviors. Data collection and organization was a systematic process using record reviews. Data was collected and provided through the Risk Management department and did not contain any protected health information.

The data was then organized and analyzed by the principal investigator into an Excel spreadsheet and analyzed through SPSS using the chi square statistical method. The results derived from data analysis were used as a forerunner for policy revision. Policy revisions that were developed from this quality improvement project were submitted to API's policy committee and executive leadership for review and possible acceptance. They were then sent to the governing body for final approval.

Continuous quality improvement using a record review process proved to be an effective method for this project. The facility already had familiarity with this method, of gathering data and this made the acceptance of this project smoother. Furthermore, the literature review supported this specific method of data collection and its efficacy in a healthcare setting. The literature review also noted that this method of study also provides the possibility for periodic review which is known to promote high quality outcomes in relation to quality improvement projects.

Implementation and Resources

The implementation process of this project closely followed the Plan, Do, Study, Act model outlined in Chapter 3. (Hughes, 2008). The "Plan" step was completed by conducting a literature review that identified themes that surround close observation and possible policy

revisions. Planning of the project involved meeting with several different departments at API and their key stakeholders who include Quality Improvement, Risk Management, and medical staff.

The "Do" step included data collection and organization. Data collection occurred through the Risk Management department and involved reviewing Unusual Occurrence Reports. The principal investigator organized the data into a specifically designed Excel spreadsheet.

The "Study" step included data analysis. Statistical data analysis was conducted to identify if any differences between self-injurious and aggressive behaviors and the level of observation the patient was on at the time of the behavior existed. This analysis resulted in the generation of statistical evidence that was used to influence policy revisions.

The "Act" step utilized the results of data analysis to provide direct evidence for policy revision and practice change. This step included revising the current close observation policy. The revised policy was disseminated to the Quality Improvement department and discussed with medical staff. After dissemination this process can be repeated based on feedback from those entities.

This was an effective framework for this project. This model promotes sustainability because it is cyclical in nature. The "Act" step allows for investigator to review the outcomes of change and identify opportunities for new continuous quality improvement projects.

Significance of Results

The results of this statistical test show that the chi square value was less than the critical *p* value. Therefore, we reject the null hypothesis, and there is a significant difference between self-injurious and aggressive behaviors and level of observation. X^2 (2, N = 154) = 13.94, p = .001.

Chi-square was an appropriate statistical test due to the level of measurement that was captured in data collection. The results of this analysis had utility. The utility of this data was emphasized by revising policy that captured the facility need.

The results of this statistical analysis were applied as evidence as a forerunner for policy revisions. Revisions were made to improve the utilization of close observation at API.

Self-Reflection and Summary of Learning

The Boyer Model of Scholarship (Zaccagnini & White, 2011) delineates four types of scholarship including discovery, integration, application, and teaching. Discovery involves engaging in original research that advances knowledge. Integration involves synthesis of information across disciplines and topics. Application involves using results across disciplines and applying knowledge outside of one's role. Teaching and learning involves systematic study and learning through peer critique and reproducibility by others.

Discovery occurred in this project by generating new knowledge through data analysis and statistical interpretation. Integration occurred by incorporated the use of knowledge across disciplines by collaborating with colleagues for a quality improvement project. This project aided society and professions by addressing problems related to close observation. Application occurred by providing policy revisions that can be utilized outside of the principal investigators role as a primary care provider. Teaching occurred by educating other nurse practitioners on the utilization of close observation.

This process has made me a better practitioner, student, researcher, and advocate for policy change. It has introduced me to the complexities of working with other disciplines in a large health care setting, organizational influences, and the complexities of developing,

implementing, and creating sustainability of a quality improvement project in a healthcare setting.

Conclusion

This quality improvement project explored the utilization of close observation in adult psychiatric inpatients at a facility in Anchorage, Alaska. Chapter one discussed the background of close observation and its application to the state of Alaska and a local facility. Chapter two discussed how literature was searched and then systematically appraised using evidence-based appraisal methods. Chapter three presented the Plan Do Study Act model that was used to create the organizational framework that guided this project. Chapter four discussed the projects design and methods. It identified how each step of the Plan Do Study Act model was executed. Chapter five discussed the implementation process of this project which including data collection, organizational format, and statistical analysis. Chapter six identified the results of data analysis and their relation to the outcomes of this DNP project. Chapter seven discussed the DNP essentials and their application to the project, limitations encountered by the project, and implications for future research based on this project. Chapter eight summarized this project and discussed final reflections.

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List of Figures

Figure 1: Close Observation Status Scale

Close Observation Status Scale

Level of Observation	Supervision	Documentation	Specifiers
Q15 minute check	Q15 minute checks	Psychiatric Nursing Assistant (PNA)	None
First Degree	Q15 minute checks	Registered Nurse	None
Second Degree	1:1 constant	Registered Nurse	Same room as patient, within arm's length, or continuous line of sight.
Third Degree	2:1 constant	Registered Nurse	Same room as patient, within arm's length, or continuous line of sight.

Figure 2: Data Collection Spreadsheet

Data Collection Spreadsheet

	Level of observation	Self-injurious behaviors	Aggressive behavior
1			
2			
3			
…			

Figure 3: Data Organization Spreadsheet

Data Organization Spreadsheet

	Routine 15-minute checks	First Degree	Second Degree /1:1	Third Degree / 2:1	Total
Total # of Self-injurious behaviors					
Total # of Aggressive behaviors					
Total					

Figure 4: Cost Benefit Analysis

Cost Benefit Analysis

Cost/ Expense	Estimated benefit or saving
Labor to conduct project	(180 hours of project) * ($60/hour) = $10,800
Misc supplies (flashdrive, paper, toner, etc) < $100	Facilitates secure information exchange
Statistician < $100	Facilitates accuracy of data and analysis
$614/ emergency room visit.	Increased patient/staff safety.
Staff training costs approximately $10,000/ employee.	Increased staff retention.
Labor costs for implementing COSS	As much as $1200/day

Figure 5: Project Timeline

Project Timeline

Task	PDSA	Time to complete	Estimated date of completion
Proposal defense and IRB	Plan	7 weeks	4/13/20
Data organization and analysis	Do	4 weeks	5/11/20
Policy revision	Study	2 weeks	5/25/20
Policy submission	Study	2 weeks	6/8/20
Decision to implement policy	Act	1 week	6/15/20
Final project write-up	Act	6 weeks	7/27/20
Final project defense	Act	1 weeks	8/3/20 - 11/19/20

Figure 6: Results from SPSS

Results from SPSS

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided) p value
Pearson Chi-Square	13.940[a]	2	.001
Likelihood Ratio	13.288	2	.001
Linear-by-Linear Association	1.717	1	.190
N of Valid Cases	154		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.45.

Figure 7: Percentage of Behaviors Occurring at Level of Observation

Percentage of Behaviors Occurring at Level of Observation

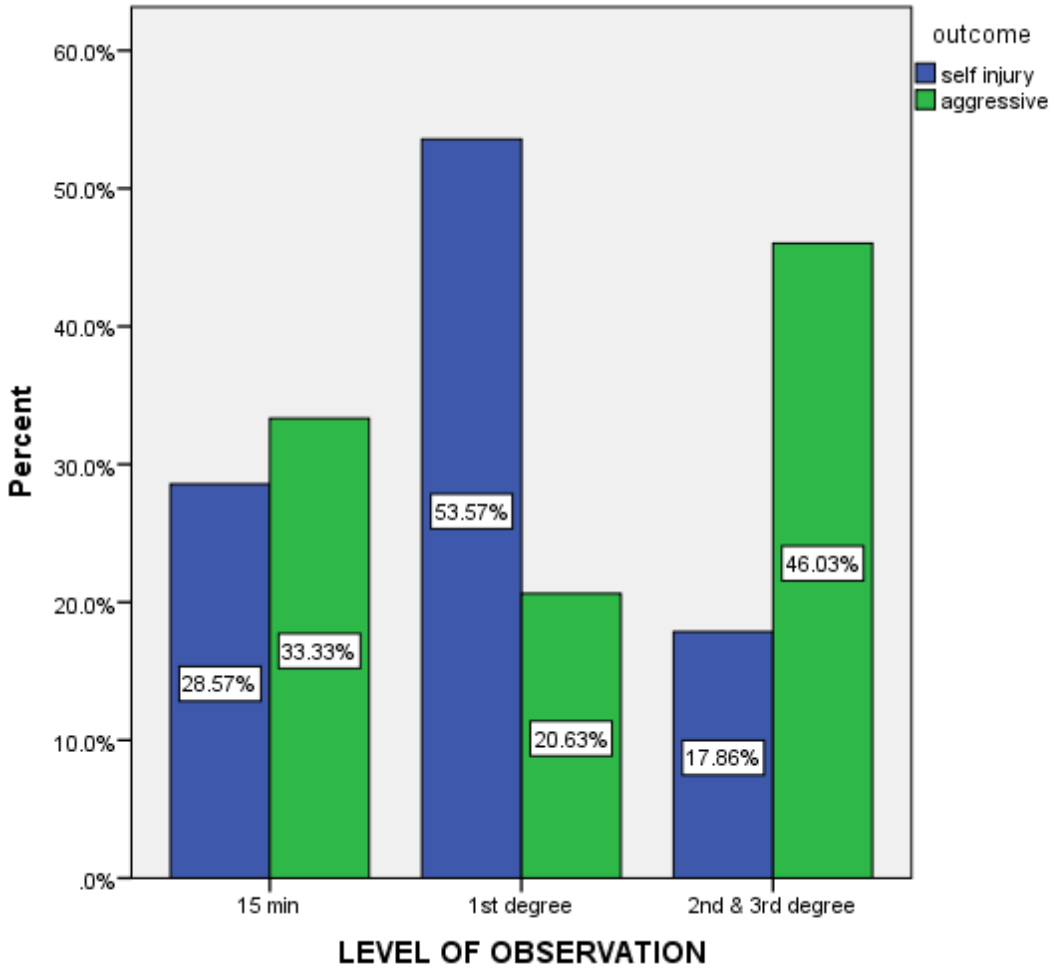

Table 1: Total Number of Behaviors at Each Level of Observation

Table 1

Total Number of Behaviors at Each Level of Observation

	Self-Injurious	Aggressive	Total
Routine 15-minute checks / Q15	8	42	50
First Degree	15	26	41
Second Degree /1:1	5	54	59
Third Degree / 2:1	0	4	4

List of Appendices

Appendix A: Evidence Spreadsheet

Citation	**Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major variables studies and their definitions**	**Measurement of Major Variables**	**Data Analysis**	**Study Finding**	**Appraisal of worth to practice/ strength of the evidence + quality.**
Alaska Ombudsman. (2019). Ombudsman Investigation – Alaska Psychiatric Institute. (API)	Descriptive and Practical analysis	Qualitative and Quantitative	n = 150 COSS patient days; 80 bed facility; United States/ API.	Explanation of current practice and statistics at API.	Number of assaults and suicidal behavior at API; discussion with staff.	Record review and staff interview.	Identified deficits in practice at API.	Level 5 evidence: descriptive and qualitative. Appraisal score 14/15
Captain C. (2006). Is your patient a suicide risk?	Excluded due to lack of appraisal tool for expert opinion and low level of evidence.						If you're initiating one-to-one observation, instruct the observer to stay at least an arm's length away from the patient at all times. An appropriate observer is a staff nurse. who's had special training about how to observe and how to respond.	
Cardell R, & Pitula CR. (1999). Suicidal inpatients' perceptions of therapeutic and nontherapeutic aspects of constant observation.	Excluded abstract only						Findings support the conclusion that constant observation has therapeutic potential. Observers should engage inpatients in actively supportive interventions. However, observers' perceived attitudes and behaviors can cause patients distress, which reaffirms the need for careful supervision of observers.	
Haney, K. (2019). Keeping Psychiatric Patients Safe in our Nation's Emergency Departments.	Descriptive	Case Study	n = 1; 22 year old female; Emergency room.	Case study	Suicide and prevention strategies	Record review.	Organizations should have policies, procedures, training, and monitoring systems in place to ensure these practices and procedures are reliable. Even when most of the safety guidelines are followed, a brief and minor lapse in protocol can result in attempted or completed suicide.	Level 5; Appraisal score 12/15
Heyman EN, & Lombardo BA. (1995). Success stories. Managing costs: the confused,	Controlled cohort study	Quantitative	n = 101; patients requiring one-to-one observation;	IV; Education regarding observation. DV: Number of	Number of one-to-one observation patients and cost of one-to-one observation	Record review	There is a general lack of knowledge regarding the costs of one to ones. Results showed a decrease in number of and duration of one to one	Level 3; Cohort study; Appraisal score is 8/10

agitated, or suicidal patient.			psychiatric in-patients	patients requiring one to one observation.			need. Essentially education decreased utilization costs.	
Huisman A, Pirkis J, Robinson J, Huisman, A., Pirkis, J., & Robinson, J. (2010). Intervention studies in suicide prevention research.	Exploratory	Meta-analysis; Quantitative	n = 1209 abstracts included epidemiology, genetics, intervention, and description of one-to-one patients.	IV: Patients requiring one-to-one observations DV: # of suicidal behaviors	IV: number of abstracts DV: interventions requiring one to one observation	Record review	There is a need for review or make intervention studies that relate to suicide.	Level 1 meta-analysis; Appraisal score is 8/9
Hunt, I. M., Windfuhr, K., Swinson, N., Shaw, J., Appleby, L., & Kapur, N. (2010). Suicide amongst psychiatric in-patients who abscond from the ward: A national clinical survey.	Working hypothesis	Quantitative using a national survey	n = 1,851 cases of suicides; England and Wales	IV: Increased close observation DV: # of suicides.	Number of suicides Inferential statistics using a 2-sided *p* value of < 0.05 was considered statistically significant.	One of the features of pt.s that completed suicide was their level of close observation. Observation level: high or medium: 117 absconders = 31%, $p < 0.001$.	Interventions that may prevent suicide amongst in-patients might include tighter control of ward exits and more intensive observation of patients during the early days of admission. Absconding patients were significantly more likely to have been under a high level of observation.	Level 5 evidence: Descriptive study. Large sample size. 95% confidence interval was used. Appraisal score 12/15
Jayaram G, Sporney H, & Perticone P. (2010). The Utility and Effectiveness of 15-minute Checks in Inpatient Settings.	Working hypothesis	Quantitative; Survey from Duke University, Massachusetts General Hospital, and NewYork-Presbyterian/Weill Cornell Medical Center.	n = 98 hospitals were surveyed from North Carolina, Massachusetts and New York.	IV: Level of observation; DV: Number of suicides	Number of suicidal behaviors. Descriptive statistics.	51 percent were on 15-minute checks or one-on-one observation, and 28 percent had a "no suicide contract" in effect	Recommend that the observation practice of 15-minute checks be eliminated and the use of close observation (one certified observer to one or more patients) be used instead.	Level 5: Descriptive study. Appraisal Score 13/15
Kim, H. M., Eisenberg, D., Ganoczy, D., Hoggatt, K., Austin, K. L., Downing, K., … & Valenstein, M. (2010). Examining the relationship	Working hypothesis	Quantitative; Case–control design	n = 887,859 of suicides; Depression diagnosis, United States Veterans	IV: More intensive monitoring during high-risk treatment periods DV: # of suicides under	Number of suicides	Inferential statistics; Conditional logistic regression models indicated	None of their analysis indicated that closer monitoring of patients had a statistically significant association with reduced suicide risks ($p = 0.29$). However, a follow-up analysis did reveal a potentially protective	Level 3 evidence: Case Controlled. Appraisal score 9/10. Study admits that there may be incorrect information in

between clinical monitoring and suicide risk among patients with depression: Matched case–control study and instrumental variable approaches.			Health Administration	intensive monitoring.		a 0.032 percent decrease in risk (p = .29).	effect from the implementation of close observation (p = 0.08)	VHA database.
Lepiešová, M., Tomagová, M., Bóriková, I., Farský, I., Žiaková, K., & Kurucová, R. (2015). Experience of Nurses with In-Patient Aggression in the Slovak Republic.	Descriptive	Qualitative	n = 1042 nurses with an average of nearly 20 years of experiences	IV: Nurses with experiences with DV:	Verbal and physical aggression	Nurses experiences with violent patients. Correlations included years of experience, age, and clinical disciplines.	All forms of patient aggression presented in the VAPS were proved to be experienced significantly more frequently by nurses working in psychiatric wards, and emergency and intensive care units $p < 0.001$.	Level 5 evidence; Appraisal score is 25/29
Lynch MA, Howard PB, El-Mallakh P, & Mathews JM. (2008). Assessment and management of hospitalized suicidal patients.	Excluded abstract only						Recommendations include assessing suicide risk regularly throughout hospitalization, including on admission, during changes in a patient's mental or physical status, after a change in observation level, and before discharge."	
O'Brien L, & Cole R. (2003). Close-observation areas in acute psychiatric units: a literature review.	Excluded abstract only						This paper examines the literature related to close-observation areas and argues that they are highly demanding of expert psychiatric nursing skills.	
Sakinofsky I. (2014). Preventing suicide among inpatients.	Exploratory	Meta-analysis	n = 2595 references searching Cochrane, PubMed, Web of Knowledge, and Embase.	Search terms included (hospital or inpatient) and suicide.	IV: Number of abstracts DV: Search terms including hospital or in patient and suicide.	Record review. Articles were not systematically appraised.	It is possible to reduce suicide risk on the ward by having a safe environment, optimizing patient visibility, supervising patients appropriately, careful assessment, awareness of and respect for suicide risk, good teamwork and communication, and adequate clinical treatment.	Level 1. Meta-analysis. Appraisal score is 8/9
Tingle, J. (2019). Suicide prevention and patient safety.	Exploratory	Meta-analysis	n = 101 compensation claims. Then 29 mental health in-patients were reviewed	IV: observation level. DV: number of suicidal behaviors.	Suicide prevention strategies	Record review.	Of the 29 patients admitted to inpatient mental health units, almost half were subject to inadequate observation processes (Oates, 2018: 63). In five (17%) claims the observation was not carried out within the prescribed time	Level 1. Meta-analysis. Appraisal score is 7/9

			related to observation.				interval. Patients were often on an inappropriate level of observation. Recommendations included that all relevant staff in every mental health trust should undergo specific training in therapeutic observation.	

Appendix B: Synthesis Spreadsheet

Level of Evidence	Total Number of articles	Overall Quality Rating	Synthesized Findings
Level I	3	89% - 78%.	The appraised Level I evidence included three meta-analyses with quality ratings between 89% and 78%. Two articles at 89% suggest that there is a need to review or make intervention studies that relate to suicide. They suggest that it is possible to reduce suicide risk by having a safe environment, optimizing patient visibility, supervising patients appropriately, careful assessment, and adequate clinical treatment. One article at 78% suggested that patients admitted to inpatient mental health units were subject to inadequate and inappropriate observation processes. Recommendations included that all relevant staff undergo specific training in therapeutic observation.
Level II	NONE	N/A	No level II evidence was appraised. Considering the nature of close observation and its relation to patient safety it is not surprising that no randomized control trials were found. It would be unethical to knowingly neglect patients at risk for suicide.
Level III	2	90%-80%	The appraised Level III evidence included two articles with quality ratings of 90% and 80%. The 90% article suggested that there is a potentially protective effect from the implementation of close observation. The 80% article suggested that there is a general lack of knowledge regarding the cost of close observation. Their results showed a decrease in the number and duration of one-to-one need following staff education programs.
Level IV	NONE	N/A	No Level IV evidence was appraised
Level V	5	93%-80%	The appraised Level V evidence included five articles with quality ratings between 93% and 80%. The 93% article suggested that facilities should have policies, procedures, training, and monitoring systems in place to ensure patient safety through the use of close observation and one-to-one monitoring. Two articles suggested that close observation can potentially prevent suicidal behaviors amongst in-patients. Many of the articles recommended increased use of one-to-one observation instead of only using 15 minute checks. One article reported a significantly ($p < 0.001$) higher amount of violent patients in psychiatric settings than other healthcare settings. They recommend the use of close observation to mitigate violence toward staff and other patients.
Level VI	Excluded	N/A	One expert opinion was identified through the literature search. This article was excluded due to a lack of a critical appraisal strategy.

Appendix C: Alaska Psychiatric Institute COSS Policy

Alaska Psychiatric Institute Policy & Procedure P&P No:		**PC-060-14**
Title: Close Observation Status Scale (COSS)		
Key Words: COSS, 1:1 (One-to-One), Observation, Treatment		
Primary: Medical	**Effective Date: 03/14/19**	**Page 1 of 6**
CEO Signature: *Signature on File*		

PURPOSE

To delineate Alaska Psychiatric Institute's (API) policy for the ordering and performing of close observation for the protection of individual patients and others.

SCOPE

This policy applies to all patients, employees, students, interns and contractors at API.

POLICY

If the Licensed Independent Practitioner (LIP) determines that a patient requires additional observation and monitoring due to potential harm to that patient or others, a level of the Close Observation Status Scale (COSS) may be ordered.

INTERPRETATION

Hospital Leadership at API is responsible for interpreting, disseminating and training this policy for staff.

DEFINITIONS – See also P&P INT-005-03 Glossary

Licensed Independent Practitioner (LIP): a Physician (MD/DO), Physician Assistant (PA) or a Nurse Practitioner (ANP) who is providing medical evaluation and management services at API.

OD: Officer of the Day; the on-call LIP.

COSS: Close Observation Status Scale; a system of increased vigilance and monitoring.

1:1 (one-to-one)/ 2nd Degree COSS level of staffing: wherein one patient has one staff member assigned to continuously visually observe them at all times. The assigned staff may talk to other patients during assigned times but must retain their primary attention on the assigned patient.

2:1 (two-to-one): a form of 3rd Degree level of staffing wherein one patient has two staff members assigned to continuously visually observe at all times. The assigned staff will not observe, monitor, or engage other patients during assigned times.

Executive Management Team: Consists of the Director of Psychiatry, the Chief Executive Officer (CEO), Chief Operating Officer (COO) and the Director of Nursing (DON).

PROCEDURE

1.1. Purpose for COSS; Additional observation and monitoring may be required for:

- Assessment of admitted risk in newly patients.
- Danger to Self- Imminent risk of serious self-harm/suicide.
- Danger to Others – Imminent risk of serious harm to others.
- Medical/Needs – Imminent risk of harm due to medical/fall risk.

1.2. On Admission:

1.2.1. To properly assess the patient during the acute admission phase of treatment, upon admission to the hospital, every patient will automatically be placed on 1st Degree level for a minimum of 24 hours from time of

admission, which requires checks every 15 minutes. This must be documented in the patient's Initial Treatment Plan.

1.2.1.1. The admitting LIP will specify risk concerns for this observation, such as alertness to elopement, self-harm, or danger to others, etc.

1.2.2. The order for COSS was reviewed daily by the attending LIP and will remain in effect until discontinued by a LIP order.

1.3. Ordering COSS:

1.3.1. Any staff member who believes a patient may be at an acute risk for elopement, self-harm, or other dangerous or unsafe behavior towards self, others, or property will immediately notify the Unit Charge Nurse.

1.3.2. The Unit Charge Nurse will:

1.3.2.1. Conduct and document a Risk Assessment of the patient and the current unit milieu.

1.3.2.2. The RN will document their assessment on a DAR COSS/Degree Assessment of Risk in the Electronic Health Record (EHR).

1.3.2.3. If it is determined that close observation is warranted, the RN will notify the Unit LIP or OD to recommend a COSS.

1.3.3. The Unit LIP or OD will:

1.3.3.1. Order the appropriate degree of COSS, and

1.3.3.2. Record the reason for the additional needed monitoring to assure the safety of the patient and/or others.

1.3.4. For 2nd Degree COSS (arm's reach), the LIP's order may indicate a

different proximity of staff to the patient (such as 10 feet if COSS is for DTO).

1.3.5. Additional safety provisions may be ordered in accordance with API P&P SC– 030-02.01, Restriction of Patients' Rights (e.g., unit restriction, hospital clothing, finger foods, or 1:1 escort off the unit).

1.3.6. The order for COSS was reviewed daily and documented on by the attending LIP. It will remain in effect until discontinued by an LIP order.

1.3.7. The orders in the EHR are set up so that the LIP has the discretion to order different levels of COSS when the patient is in the milieu or alone in his/her room.

1.3.8. After a LIP discontinues a 3rd Degree or 2nd Degree COSS order, all patients must remain on 1st Degree COSS (15 minute checks noted on the Patient Location Checklist) for a minimum of 24 hours from the time of the discontinuation order.

1.3.9. When there is a plan to discharge a patient on 2nd or 3rd Degree COSS, the LIP will document the reasoning and plan of care. This was reflected in the patient's Master Treatment Plan. There must be Executive Management Team review and approval from the CEO or Director of Psychiatry before discharge.

1.4. <u>Implementation of COSS:</u>

1.4.1. When the COSS order is written, the COSS status will show up on the Status Board in the EHR.

1.4.2. The patient's paper medical record and Kardex was flagged for the degree

of COSS and the justification for the additional monitoring (e.g., suicide or elopement potential, dangerous to self or others, risk of falling, risk of water intoxication).

1.4.3. Unit staff will notify the Nursing Shift Supervisor (NSS) of new orders for COSS.

1.5. Documentation:

1.5.1. Treatment Plan: When a patient is on COSS, the reasoning and plan of care was reflected in the patient's Initial and/or Master Treatment Plan (MTP) as appropriate.

1.5.2. LIP Documentation:

1.5.2.1. The continued need for any COSS was documented by the LIP, at least weekly, in a progress note in the EHR.

1.5.2.2. If the patient is on 2nd or 3rd Degree, the LIP daily will review and document the status and need for continuation in a progress note in the EHR.

1.5.3. Nursing Staff Documentation:

1.5.3.1. The RN will document his/her current assessment using a DAR/COSS/Degree Assessment of Risk. Other staff will document their observations on a DAR/Behavior Note.

1.5.3.2. If the patient is on COSS because of risk to fall, the RN will reassess risk for falls using the Falls Risk Assessment Tool in the EHR. This was done as needed at the discretion of the RN, but no less often than once a week.

1.5.4. The assigned RN will complete an assessment of patient risk:

1.5.4.1. At least once each shift,

1.5.4.2. Whenever significant behavior changes occur, and

1.5.4.3. Each time the degree of observation changes.

1.5.4.4. The RN assessment will include a description of behaviors relating to COSS risk, the patient's mental status, and other factors that may affect the patient's safety.

1.5.5. Assigned observation staff will chart any significant behaviors and/or behavior changes occurring during their shift and report them to the RN.

1.5.6. Observation and engagement checks for patients on any COSS status was noted on the Patient Location Checklist.

1.5.7. When a discipline other than Nursing assumes responsibility for a COSS patient, the assignment is to be specifically noted on the Patient Location Checklist.

1.5.8. During their shift, the NSS will review with the Charge Nurse all 2nd and 3rd Degrees statuses for appropriateness to continue.

1.5.9. List every COSS level ordered within this 24-hour period in the 24-Hour Nursing Summary Report.

1.6. <u>COSS Observation Requirements:</u>

1.6.1. 1st Degree COSS: 15-minute observation and engagement checks, noted on the Patient Location Checklist.

1.6.2. 2nd Degree:

1.6.2.1. 1:1 continuous, strict visual monitoring by assigned staff within

arm's length. Patient bathroom door is to remain locked while on 2nd Degree. When a patient requests to use the bathroom, staff will observe/stand-by with door ajar.

1.6.2.2. The LIP's order may specify the 1:1 staff's decreased proximity to the patient (i.e. 10 feet) in the event of COSS for Danger to Others.

1.6.2.3. The assigned staff must be in the same room as the patient including attending on-unit groups or other activities with the patient. If the LIP order specifies decreased proximity, the assigned staff may be at the patient's doorway of bedroom.

1.6.2.3.1. Staff may talk to other patients but must retain primary attention on the assigned 1:1 patient; and

1.6.2.3.2. No eating, reading, phone use or similar activities allowed while on 1:1. Staff may drink fluid from soft-sided cups (i.e. no soda cans, plastic bottles).

1.6.2.4. Staff may not be assigned to 1:1 for more than 2 hours at a time.

1.6.2.5. If an opposite gender staff member is assigned to the 1:1, it was switched to same gender for observation of toileting and bathing.

1.6.3. 3rd Degree:

1.6.3.1. 2:1 continual, strict visual monitoring by assigned staff within arm's reach must be maintained at all times by both assigned staff members. Patient bathroom door is to remain locked while on 3nd

Degree. When a patient requests to use the bathroom, one staff will observe with the door ajar and the other staff will stand nearby.

1.6.3.2. Decreased proximity may be ordered (i.e. 10 feet) on the event of COSS for Danger to Others.

1.6.3.3. Continuous visual monitoring without any distractions is required for assigned 2:1 staff members. No reading, eating, phone use, or any other patient or staff interactions are allowed. Staff may drink fluid from soft- sided cups (i.e. no soda cans, plastic bottles).

1.6.3.4. Staff may not be assigned to 2:1 for more than 1 hour at a time.

1.6.3.5. If an opposite gender staff member is assigned to the 2:1, it was switched to same gender for observation of toileting and bathing.

Appendix D: Rapid Critical Appraisal Tools

RAPID CRITICAL APPRAISAL OF QUALITATIVE EVIDENCE

1. Are the results of the study valid (trustworthy and credible)?

- a. How were the participants chosen?
- b. How were accuracy and completeness of data assured?
- c. How plausible/believable are the results?
  - i. Are implications of the research stated? Yes No Unknown
    - 1. May new insights increase sensitivity to others needs? Yes No Unknown
    - 2. May understandings enhance situational competence? Yes No Unknown
  - ii. What is the effect on the reader?
    - 1. Are results plausible and believable? Yes No Unknown
    - 2. Is the reader imaginatively drawn into the experience? Yes No Unknown

2. What are the results?

- a. Does the research approach fit the purpose of the study? Yes No Unknown
  - i. Does the researcher identify the study approach? Yes No Unknown
    - 1. Are language and concepts consistent with the approach? Yes No Unknown
    - 2. Are data collection and analysis techniques appropriate? Yes No Unknown
  - ii. Is the significance/importance of the study explicit? Yes No Unknown
    - 1. Does review of the literature support a need for the study? Yes No Unknown
    - 2. Do sample composition and size reflect study needs? Yes No Unknown
  - iii. Is the sampling strategy clear and guided by study needs? Yes No Unknown
    - 1. Does the research control selection of the sample? Yes No Unknown
    - 2. Do sample composition and size reflect study needs? Yes No Unknown
- b. Is the phenomenon (human experience) clearly identified? Yes No Unknown

i. Are the data collection procedures clear? Yes No Unknown
   1. Are sources and means of verifying data explicit? Yes No Unknown
   2. Are researcher roles and activities explained? Yes No Unknown

ii. Are data analysis procedures described? Yes No Unknown
   1. Does analysis guide direction of sampling and when it ends? Yes No Unknown
   2. Are data management processes described? Yes No Unknown

c. What are the reported results (description or interpretation)?
   i. How are specific findings presented?
      1. Is presentation logical, consistent, and easy to follow? Yes No Unknown
      2. Do quotes fit the findings they are intended to illustrate? Yes No Unknown
   ii. How are the overall results presented?
      1. Are meanings derived from data described in context? Yes No Unknown
      2. Does the writing effectively promote understanding? Yes No Unknown

3. Will the results help me in caring for my patients?

a. Are the results relevant to persons in similar situations? Yes No Unknown

b. Are the results relevant to patient values and/or circumstances? Yes No Unknown

c. How may the results be applied in clinical practice? Yes No Unknown

RAPID CRITICAL APPRAISAL OF EVIDENCE BASED GUIDELINES

1. Credibility

a. Who were the guideline developers?

_____

b. Were the developers representative of key stakeholders in this specialty (interdisciplinary)? Yes No Unknown

c. Who funded the guideline development?

_____

d. Were any of the guideline's developers funded researchers of the reviewed studies? Yes No Unknown

e. Did the team have a valid development strategy? Yes No Unknown

f. Was an explicit (how decisions were made), sensible and impartial process used to identify, select, and combine evidence? Yes No Unknown

g. Did its developers carry out a comprehensive, reproducible literature review within the past 12 months of its publication/revision? Yes No Unknown

h. Were all important options and outcomes considered? Yes No Unknown

i. Is each recommendation in the guideline tagged by the level/strength of evidence upon which it is based and linked with the scientific evidence? Yes No Unknown

j. Do the guidelines make explicit recommendations (reflecting value judgments about outcomes)? Yes No Unknown

k. Has the guideline been subjected to peer review and testing? Yes No Unknown

2. Applicability/Generalizability

a. Is the intent of use provided (national, regional, local)? Yes No Unknown

b. Are the recommendations clinically relevant? Yes No Unknown

c. Will the recommendations help me in caring for my patients? Yes No Unknown

d. Are the recommendations practical/feasible (e.g. resources-people and equipment) available? Yes No Unknown

e. Are the recommendations a major variation from current practice? Yes No Unknown

f. Can the outcomes be measured through standard care? Yes No Unknown

RAPID CRITICAL APPRAISAL QUESTIONS FOR COHORT STUDIES

1. Are the results of the study valid?

a. Was there a representative and well defined sample of patients at a similar point in the course of the disease? Yes No Unknown

b. Was follow-up sufficiently long and complete? Yes No Unknown

c. Were objective and unbiased outcome criteria used? Yes No Unknown

d. Did the analysis adjust for important prognostic risk factors and confounding variables? Yes No Unknown

2. What are the results?

a. What is the magnitude of the relationship between predictors (i.e. prognostic indicators) and target outcomes? Yes No Unknown

b. How likely is the outcome event(s) in a specified period of time? Yes No Unknown

c. How precise are the study estimates? Yes No Unknown

3. Will the results help me in caring for my patients?

a. Were the study patients similar to my own? Yes No Unknown

b. Will the results lead directly to selecting or avoiding therapy? Yes No Unknown

c. Are the results useful for reassuring or counseling patients? Yes No Unknown

RAPID CRITICAL APPRAISAL CHECKLIST FOR A RANDOMIZED CLINICAL TRIAL

1. Are the results of the study valid?

a. Were the subjects randomly assigned to the experimental and control groups? Yes No Unknown

b. Was random assignment concealed from the individuals who were first enrolling subjects into the study? Yes No Unknown

c. Were the subjects and providers blind to the study group? Yes No Unknown

d. Were reasons given to explain why subjects did not complete the study? Yes No Unknown

e. Were the follow-up assessments conducted long enough to fully study the effects of the intervention? Yes No Unknown

f. Were the subjects analyzed in the group to which they were randomly assigned? Yes No Unknown

g. Was the control group appropriate? Yes No Unknown

h. Were the instruments used to measure the outcomes valid and reliable? Yes No Unknown

i. Were the subjects in each of the groups similar on demographic and baseline clinical variables? Yes No Unknown

2. What are the results?

a. How large is the intervention or treatment effect (effect size, level of significance)?

_____

b. How precise is the intervention or treatment?

_____

3. Will the results help me in caring for my patients?

a. Were all clinically important outcomes measured? Yes No Unknown

b. What are the risks and benefits of the treatment?

_____

c. Is the treatment feasible in my clinical setting? Yes No Unknown

d. What are my patient's values/family's values and expectations for the outcome that trying to be prevented and the treatment itself?

_____

RAPID CRITICAL APPRAISAL OF SYSTEMATIC REVIEWS OF CLINICAL INTERVENTIONS/TREATMENTS

1. **Are the results of the review valid?**
   a. Are the studies contained in the review randomized controlled trials? Yes No Unknown
   b. Does the review include a detailed description of the search strategy to find all relevant studies? Yes No Unknown
   c. Does the review describe how validity of the individual studies was assessed (e.g. methodological quality, including the use of random assignment to study groups and complete follow-up of the subjects)? Yes No Unknown
   d. Were the results consistent across studies? Yes No Unknown
   e. Were individual patient data or aggregate data used in the analysis? Yes No Unknown
2. **What were the results?**
   a. How large is the intervention or treatment effect (odds ratio, effect size, level of significance)?

      _____

   b. How precise is the intervention or treatment?

      _____
3. **Will the results assist me in caring for my patients?**
   a. Are my patients similar to the ones included in the review? Yes No Unknown
   b. Is it feasible to implement the findings in my practice setting? Yes No Unknown
   c. Were all clinically important outcomes considered, including risks and benefits of treatment? Yes No Unknown
   d. What is my clinical assessment of the patient and are there any contraindications or circumstances that would inhibit me from implementing the treatment? Yes No Unknown
   e. What are my patient's and his/her family's preferences and values about the treatment that is under consideration?

      _____

Appendix E: Alaska Psychiatric Institute IRB Policy

Alaska Psychiatric Institute Policy & Procedure P&P No:		**PRE-010-04.04**
Title: Institutional Review Board		
Key Words: Research, Academic Integrity Committee		
Primary: Medical	**Effective Date: 6/15/2017**	**Page: 1 of 3**
CEO Signature: ***Signature on File***		

PURPOSE

To ensure protection of patients' rights, especially confidentiality, through an institutional review process that evaluates the efficacy of studies, projects and research involving Alaska Psychiatric Institute (API), its patients, and staff.

POLICY

The Academic Integrity Committee, an ad hoc committee, reports to the Medical Executive Committee and Medical Staff through its meeting minutes of activities and recommendations regarding quality improvement projects, student projects, and professional publications involving API, its staff or patients, including work involving retrospective record reviews.

Research conducted by students at API must be approved by the Institutional Review Board (IRB) of the University where the student is enrolled. Research conducted at API also must contribute to the Quality Improvement of the facility.

DEFINITIONS – See also P&P INT-5-3 Glossary

No policy specific definitions.

PROCEDURE

I. ACADEMIC INTEGRITY COMMITTEE MEMBERSHIP

A. Members of the Academic Integrity Committee are qualified by training and experience to review and approve research projects.

1. The Director of Clinical Services serves as Chair.
2. Members are representatives from:
    a. Clinical departments at API as needed to address and evaluate the scope and structure of the research project;
    b. the Hospital Education Department;
    c. the Social Work Department;
    d. the Quality Improvement Department;
    e. The pharmacist (whenever medication issues are involved);
    f. Hospital Support Services (when an aspect of hospital services is involved).

II. RESPONSIBILITIES

A. To ensure patients participating in quality improvement projects, or retrospective records reviews are accorded full patient rights, including protection of patients' confidentiality, and to afford staff similar protections, when appropriate.

B. To assure hospital staff and students training at the hospital have the opportunity to participate in quality improvement projects.

C. To refer all requests for quality improvement projects to the Chair or designee of the Academic Integrity Committee for specific guidelines and further review.

D. To review and authorize investigative quality improvement projects at API, as differentiated from QI Team quality improvement projects, whether originating from intra- or extra-institutional staff, and to ensure compliance with professional and

ethical standards for such studies/research oriented projects and the guidelines for the Academic Integrity Committee. (See attachment for review checklist.)

E. To review all completed projects/studies for compliance with established standards/guidelines before dissemination of resulting report.

III. FREQUENCY OF MEETINGS

A. Meetings are held every other month or on an as needed basis.

IV. MEETING MINUTES AND OTHER RECORDS

A. Minutes are kept on file by the Academic Integrity Chair.

1. Copies of meeting minutes and/or summaries are routed to the Medical Executive Committee, Medical Staff, Governance, departments/services, and individuals, as appropriate.

B. Full and complete records and reports of all projects are maintained by the Clinical Director of all studies/projects, whether published or unpublished.

HISTORY OF REVISIONS

New: 04/22/93.

Revised: 08/10/95; 10/26/00; 10/16/03; 11/02/09; 06/15/17.

Reviewed: 03/06/97; 02/07/07

Appendix F: Revised Alaska Psychiatric Institute COSS Policy

Alaska Psychiatric Institute Policy & Procedure P&P No:		**PC-060-14**
Title: Close Observation Status Scale (COSS)		
Key Words: COSS, 1:1 (One-to-One), Observation, Treatment		
Primary: Medical	**Effective Date: 03/14/19**	**Page 1 of 6**
CEO Signature: *Signature on File*		

PURPOSE

To delineate Alaska Psychiatric Institute's (API) policy for the ordering and performing of close observation for the protection of individual patients and others.

SCOPE

This policy applies to all patients, employees, students, interns and contractors at API.

POLICY

If the Licensed Independent Practitioner (LIP) determines that a patient requires ~~additional~~ observation and monitoring due to potential harm to that patient or others, a level of the Close Observation Status Scale (COSS) ~~may~~ was ordered.

INTERPRETATION

Hospital Leadership at API is responsible for interpreting, disseminating and training this policy for staff.

DEFINITIONS – See also P&P INT-005-03 Glossary

Licensed Independent Practitioner (LIP): a Physician (MD/DO), Physician Assistant (PA) or a Nurse Practitioner (ANP) who is providing medical evaluation and management services at API.

OD: Officer of the Day; the on-call LIP.

COSS: Close Observation Status Scale; a system of increased vigilance and monitoring.

1:1 (one-to-one): 2nd Degree COSS level of staffing wherein one patient has one staff member assigned to continuously visually observe them at all times. The assigned staff may talk to other patients during assigned times but must retain their primary attention on the assigned patient.

2:1 (two-to-one): ~~a form of~~ 3rd Degree COSS level of staffing wherein one patient has two staff members assigned to continuously visually observe at all times. ~~The assigned staff will not observe, monitor, or engage other patients during assigned times.~~ The assigned staff may talk to other patients during assigned times but must retain their primary attention on the assigned patient.

Executive Management Team: Consists of the Director of Psychiatry, the Chief Executive Officer (CEO), Chief Operating Officer (COO) and the Director of Nursing (DON).

PROCEDURE

1.1. Purpose for COSS; Additional observation and monitoring may be required for:

- Assessment of risk in newly admitted patients.
- Danger to Self- Imminent risk of serious self-harm/suicide.
- Danger to Others – Imminent risk of serious harm to others.
- Medical/Needs – Imminent risk of harm due to medical/fall risk.

1.2. On Admission:

1.2.1. To properly assess the patient during the acute admission phase of treatment, upon admission to the hospital, every patient will automatically

be placed on 1st Degree ~~level~~ COSS ~~for a minimum of 24 hours from time of admission,~~ which requires checks every 15 minutes. This must be documented in the patient's Initial Treatment Plan.

1.2.1.1. The admitting LIP will specify risk concerns for this observation, such as alertness to elopement, self-harm, or danger to others, etc.

1.2.2. The order for COSS was reviewed daily by the attending LIP and will remain in effect until discontinued by a LIP order.

1.3. Ordering COSS:

1.3.1. Any staff member who believes a patient may be at an acute risk for elopement, self-harm, or other dangerous or unsafe behavior towards self, others, or property will immediately notify the Unit Charge Nurse.

1.3.2. The Unit Charge Nurse will:

1.3.2.1. Conduct and document a Risk Assessment of the patient and the current unit milieu.

1.3.2.2. The RN will document their assessment on a DAR COSS/Degree Assessment of Risk in the Electronic Health Record (EHR).

1.3.2.3. The RN will instruct any staff member that witnesses a behavior related to the patient's level of observation to document their observations in a DAR Note in the Electronic Health Record (EHR).

1.3.2.4. If it is determined that close observation is warranted, the RN will notify the Unit LIP or OD to recommend a COSS.

1.3.3. The Unit LIP or OD will:

1.3.3.1. Order the appropriate degree of COSS, and

1.3.3.2. Record the reason for the additional needed monitoring to assure the safety of the patient and/or others.

1.3.4. For 2nd Degree COSS ~~(arm's reach),~~ the LIP's order may indicate a different proximity of staff to the patient such as 10 feet if ~~COSS is~~ Danger To Other or within arms' reach for Danger To Self.

1.3.5. Additional safety provisions may be ordered in accordance with API P&P SC– 030-02.01, Restriction of Patients' Rights (e.g., unit restriction, hospital clothing, finger foods, or 1:1 escort off the unit).

1.3.6. The order for COSS was reviewed daily and documented on Progress notes at least weekly by the attending LIP. It will remain in effect until discontinued by an LIP order.

1.3.7. The orders in the EHR are set up so that the LIP has the discretion to order different levels of COSS when the patient is in the milieu or alone in his/her room.

1.3.8. ~~After a LIP discontinues a 3rd Degree or 2nd Degree COSS order, all patients must remain on 1st Degree COSS (15 minute checks noted on the Patient Location Checklist) for a minimum of 24 hours from the time of the discontinuation order.~~ After a LIP discontinues either a 3rd Degree or 2nd Degree COSS order, they was placed on 1st Degree COSS.

1.3.9. When there is a plan to discharge a patient on 2nd or 3rd Degree COSS,

the LIP will document the reasoning and plan of care. This was reflected in the patient's Master Treatment Plan. There must be Executive Management Team review and approval from the CEO or Director of Psychiatry before discharge.

1.4. Implementation of COSS:

1.4.1. When the COSS order is written, the COSS status will show up on the Status Board in the EHR.

1.4.2. The patient's paper medical record and Kardex was flagged for the degree of COSS and the justification for the additional monitoring (e.g., suicide or elopement potential, dangerous to self or others, risk of falling, risk of water intoxication).

1.4.3. Unit staff will notify the Nursing Shift Supervisor (NSS) of new orders for COSS.

1.5. Documentation:

1.5.1. Treatment Plan: When a patient is on COSS, the reasoning and plan of care was reflected in the patient's Initial and/or Master Treatment Plan (MTP) as appropriate.

1.5.2. LIP Documentation:

1.5.2.1. The continued need for any COSS was documented by the LIP, at least weekly, in a progress note in the EHR.

1.5.2.2. If the patient is on 2nd or 3rd Degree COSS, the LIP ~~daily~~ will review and document the status and need for continuation in a progress note in the EHR daily.

1.5.3. Nursing Staff Documentation:

1.5.3.1. The RN will document his/her current assessment using a DAR/COSS/Degree Assessment of Risk. Other staff will document their observations on a DAR Behavior Note.

1.5.3.2. If the patient is on COSS because of risk to fall, the RN will reassess risk for falls using the Falls Risk Assessment Tool in the EHR. This was done as needed at the discretion of the RN, but no less often than once a week.

1.5.4. The assigned RN will complete an assessment of patient risk:

1.5.4.1. At least once each shift if on 2nd or 3rd Degree COSS,

1.5.4.2. Whenever significant behavior changes occur, and

1.5.4.3. Each time the degree of observation changes.

1.5.4.4. The RN assessment will include a description of behaviors relating to COSS risk, the patient's mental status, and other factors that may affect the patient's safety.

1.5.5. Assigned observation staff will chart any significant behaviors and/or behavior changes occurring during their shift in a DAR Behavior Note and report them to the RN.

1.5.6. Observation and engagement checks for patients on any COSS status was noted on the Patient Location Checklist.

1.5.7. When a discipline other than Nursing assumes responsibility for a COSS patient, the assignment is to be specifically noted on the Patient Location Checklist.

1.5.8. During their shift, the NSS will review with the Charge Nurse all 2nd and 3rd Degrees statuses for appropriateness to continue.

1.5.9. List every COSS level ordered within this 24-hour period in the 24-Hour Nursing Summary Report.

1.6. COSS Observation Requirements:

1.6.1. 1st Degree COSS:

1.6.1.1. 15-minute observation and engagement checks, noted on the Patient Location Checklist.

1.6.1.2. Charge Nurse assessments was documented in DAR/COSS/Degree Assessment of Risk.

1.6.1.3. Unit staff observations was documented in DAR Behavior Notes.

1.6.1.4. Patients with a legal status of Ex parte will require assessment and therefore a RN was required to complete documentation.

1.6.1.5. LIP can order assessment of patients on 1st Degree COSS for patient's not on Ex Parte legal status. NSS and Charge Nurse will collaborate to determine who is capable of conducting the assessment.

1.6.2. 2nd Degree:

1.6.2.1. 1:1 continuous, strict visual monitoring by assigned staff. ~~within arm's length. Patient bathroom door is to remain locked while on 2nd Degree.~~ When a patient requests to use the bathroom, staff will observe/stand-by with door ajar.

1.6.2.2. The LIP's order may specify the 1:1 staff's ~~decreased~~ proximity

to the patient (i.e. 10 feet in the event of COSS for Danger to Others or within arm's length in the event of COSS for Danger to Self).

1.6.2.3. The assigned staff must be in the same ~~room~~ proximity as the patient including attending on-unit groups or other activities with the patient. If the LIP order specifies decreased proximity, the assigned staff may be at the patient's doorway of bedroom.

1.6.2.3.1. Staff may talk to other patients but must retain primary attention on the assigned 1:1 patient; and

1.6.2.3.2. No eating, reading, phone use or similar activities allowed while on 1:1. Staff may drink fluid from soft-sided cups (i.e. no soda cans, plastic bottles).

1.6.2.3.3. Staff may not be assigned to 1:1 for more than 2 hours at a time.

1.6.2.4. If an opposite gender staff member is assigned to the 1:1, it was switched to same gender for observation of toileting and bathing.

1.6.3. 3rd Degree:

1.6.3.1. 2:1 continual, strict visual monitoring by assigned staff within arm's reach must be maintained at all times by both assigned staff members. Patient bathroom door is to remain locked while on 3nd Degree. When a patient requests to use the bathroom, one staff will observe with the door ajar and the other staff will stand nearby.

1.6.3.2. Decreased proximity may be ordered (i.e. 10 feet) on the event of COSS for Danger to Others.

1.6.3.3. Continuous visual monitoring without any distractions is required for assigned 2:1 staff members. No reading, eating, phone use, or any other patient or staff interactions are allowed. Staff may drink fluid from soft- sided cups (i.e. no soda cans, plastic bottles).

1.6.3.4. Staff may not be assigned to the same 2:1 patient for more than 1 hour at a time.

1.6.3.5. If an opposite gender staff member is assigned to the 2:1, it was switched to same gender for observation of toileting and bathing.

HISTORY OF REVISIONS

New: 08/31/00.

Revised: 08/27/03; 08/08/06; 09/01/09; 09/10/09; 01/12/11; 06/05/12; 02/11/14; 06/05/14, 04/30/15, 05/24/16, 06/30/16, 06/01/18, 03/14/19

ATTACHMENTS

COSS Guidelines

REFERENCED SOURCES/API P&Ps AND NDPs

SC–030-02.01, Restriction of Patients' Rights, 01/15/19