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Developing And Implementing A Quality Assurance Strategy For Electroconvulsive Therapy

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DEVELOPING AND IMPLEMENTING A QUALITY ASSURANCE STRATEGY FOR ELECTROCONVULSIVE THERAPY

by

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ABSTRACT

The literature provides scant guidance in effective quality assurance strategies concerning the use of electroconvulsive therapy (ECT) for the treatment of psychiatric conditions. Numerous guidelines are published that provide guidance in the delivery of care, however, little has been done to determine how a program or facility might ensure compliance to best practice for safety, tolerability, and efficacy in performing ECT. The objective of this project was to create a quality assurance strategy specific to ECT. Determining standards for quality care and clarifying facility policy were key outcomes in establishing an effective quality assurance strategy. An audit tool was developed utilizing quality criteria derived from a systematic review of ECT practice guidelines, peer review and facility policy. All ECT procedures occurring over a two month time period of May-June 2017 were retrospectively audited and compared against target compliance rates set for the facility's ECT program. Facility policy was adapted to reflect quality standards and audit findings were used to inform possible practice change initiatives, create benchmarks for continuous quality monitoring and were integrated into regular hospital quality meetings. Clarification on standards of care and the use of clinical auditing in ECT was an effective starting point in the development of a quality assurance strategy. Audit findings were successfully integrated into the hospital's overall quality program and recognition of practice compliance informed areas for future quality development and policy revision in this small community-based hospital in the

southeastern United States. This project sets the foundation for a quality assurance strategy that can be used to help monitor procedural safety and guide future improvement efforts in delivering ECT. While just the first step in creating meaningful quality improvement, setting clear standards and identifying areas of greatest clinical need was a crucial beginning for this hospital's growing program.

Keywords: electroconvulsive therapy, quality assurance, audit

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LIST OF ABBREVIATIONS

APA ..... American Psychiatric Association

ECT ..... Electroconvulsive Therapy

ECTAS ..... Electroconvulsive Therapy Accreditation Service

HABC ..... Health Authorities of British Columbia

ISEN ..... International Society for ECT and Neurostimulation

SEAN ..... Scottish ECT Accreditation Network

CHAPTER 1

PROJECT DESCRIPTION

INTRODUCTION

Quality assurance is imperative in today's healthcare landscape. One of the most influential frameworks regarding healthcare quality was introduced through the Institute of Medicine (IOM) in "Crossing the Quality Chasm" (2001) which asserted that quality healthcare should be: safe, effective, patient-centered, timely, efficient, equitable and endorse the concept of placing quality efforts at the forefront of healthcare development in the United States. Finding ways to ensure compliance to established evidence-based standards of care is a critical first step in this endeavor. However, at present there is little ascribed direction to establish these goals in delivering electroconvulsive therapy (ECT), leaving effective quality assurance difficult to attain.

ECT is a procedure conducted under general anesthesia with the purpose of using a small electric current to produce a brief, controlled seizure within the brain. The anticipated results are symptomatic relief from a variety of psychiatric and medical illnesses (Mayo Clinic, 2017; NAMI, n.d.). Payne and Prudic (2009) outline the theoretical underpinnings for the origins of ECT, which trace back as early as the 16th century, as camphor was given to induce seizures in order to "cure lunacy". Later in 1938, Italian scientists Carletti and Bini adapted induction by applying electricity directly to the human scalp with noted success in treating psychotic symptoms. ECT was introduced into the United States in 1940 by Renato Almansi and David Impastato at Columbus Hospital in Manhattan, eventually becoming a mainstay of treatment in the

1940s and 1950s (Payne & Prudic, 2009). One cannot discuss the historical evolution of ECT without addressing some of the misuses and traumas related to its early use, which have resulted in an ongoing stigma that still plagues the treatment today. This stigma relates to abuses in the past, fear of the unknown, and concerns regarding the extent of memory loss associated with ECT (Kellner, 2012). One of the most commonly cited pieces of media depicting ECT, *One Flew Over the Cuckoo's Nest* (written by Ken Kersey in 1962 and later adapted to film in 1973), shows the procedure being used punitively to treat a characterological flaw without the use of anesthesia or muscle relaxation (Payne & Prudic, 2009). While ECT can still be associated with some degree of cognitive impairment, ECT has been refined since its adoption into practice in 1938. These changes can be seen in the transition from sine wave form energy to brief and ultra-brief pulse waveform energy, known to produce significantly less cognitive impairment (Sackeim et. al, 2007; Swartz, 2009). Additional changes to technique have included improvements in tolerability from the use of general anesthesia and muscle relaxation as well as improved understanding of how stimulus strength (in relation to seizure threshold), number of treatments, and frequency of treatments influence outcomes (Payne & Prudic, 2009). Electrode placement has offered hopes of even further limiting cognitive impairment. Ongoing research supports unilateral electrode placement in reducing cognitive impairment without losing overall efficacy, as compared to traditional bitemporal approaches (Kellner, Tobias & Wiegand, 2010; Semkovska et. al, 2016).

Difficulty in pinpointing the precise mechanism of action has also limited the adoption of widespread ECT use. Established physiological effects include increases in inhibitory neurotransmitters, decreases in excitatory neurotransmitters, increases in

cerebral blood flow during ECT followed by hypometabolism after treatment, neurogenesis to the hippocampus, decreases in cortisol levels after a course of ECT, upregulation of brain derived neurotrophic factor (BDNF), and at least transitory effects in several hormones (prolactin, thyrotropin, oxytocin, vasopressin, and glucocorticoids) (Payne & Prudic, 2009). Despite all advances, certain risks and side effect profiles are still associated with ECT and impact its overall use including cognitive impairment, headache, nausea, and muscle soreness (Mayo Clinic, 2017). Cognitive impairments can further be broken down into more specific disturbances in transient postictal disorientation, anterograde amnesia, short-term retrograde amnesia, and retrograde memory loss in varying degrees (Payne & Prudic, 2009). Despite potential risks, ECT is an effective treatment when used responsibly. Today, the American Psychiatric Association (2001) recognizes several primary indications for ECT including major depression, mania, and schizophrenia disorders. Secondary diagnostic indications are also outlined including other psychiatric disorders as justified by case-by-case indications, mental disorders due to medical conditions (including catatonic and delirium states), and medical conditions (such as Parkinson's disease, neuroleptic malignant syndrome, and intractable seizure disorders). Annually, about 100,000 patients in the United States receive ECT (Abrams, 2002) and an estimated 1 million worldwide receive ECT (Prudic, Olfson, & Sackeim, 2001). These aged estimates highlight serious research paucity in updated usage data. To date, ECT remains the most effective and reliable treatment available for severe depression, even when compared to antidepressant medications (Husein et. al, 2004; Liansby, 2007). ECT is considered a first-line treatment in situations requiring a robust or definitive response, when the risks of ECT

are less than those posed by other treatments, when there has been a poor medication response, when a patient has had prior success with ECT, or even with patient preference (APA, 2001). ECT is a well-established and highly effective treatment in psychiatry, due in no small part to extensive study geared towards refinement of technique and study of efficacy. However, quality assurance efforts related to implementation of the procedure remain largely underdeveloped. Prior literature concerning quality in ECT has focused on large-scale analysis of national trends or impacts of accreditation processes without supplying practical, tangible recommendations for how to implement quality interventions on smaller or program-specific scales, particularly within the United States. Despite the variations found across ECT practice (Leiknes, Schweder, & Høie, 2012), there is a general agreement among clinicians that ECT should be outcome focused. Developing specific and consistent quality standards that can be used to monitor patient safety and program compliance is a crucial step towards ensuring best practice for safety, tolerability, and efficacy of ECT. Consistent quality standards also represent a crucial step towards eliminating the ongoing stigma surrounding this procedure. As Kellner (2012) proposes, education combined with the insistence of high performance standards in ECT may be the best strategy to reduce the long-occurring stigma surrounding ECT. Defining "quality assurance" is an important starting point. In terms of this project, quality assurance will be defined as "all actions taken to establish, protect, promote, and improve the quality of healthcare" (Donabedian, 2003, p.xxiii). Additionally, "quality assurance" refers to "a broad spectrum of evaluation activities aimed at ensuring compliance with minimum quality standards" (HRSA, 2011). The aim of developing an

effective quality assurance protocol is to demonstrate that Aiken Regional Medical Center's ECT service fulfills or exceeds a minimal set of requirements.

Treatment resistant depression represents a significant burden in terms of disability and community expense. As of 2017, depression became the leading cause of disability both in the US and worldwide affecting an estimated 14.8 million adults in the United States and 300 million globally (WHO, 2017; NIMH, 2017). Approximately 7% of the United States population has depression in any given year (SAMHSA, 2017). Without carefully developing a quality assurance model by which to monitor ECT procedures, clinicians not only risk patient safety and poor outcomes, but also potentially propagate stigma and limit the usefulness of this very important technique as healthcare delivery changes into a more quality data-driven environment. As Avedis Donabedian, one of the most prolific authors regarding healthcare quality imparted, "Quality monitoring can be thought of as the eyes and ears of the system of healthcare. Without it, we do not know where we are or where we are going" (2003, p.xxvii).

PROBLEM STATEMENT AND SIGNIFICANCE

Clinical governance can be seen as a systematic approach to the improvement of patient safety and the maintenance of health care quality. Attainment of clinical governance can only be assured when patient care is systematically reviewed and compared with clear criteria in order to establish areas of improvement for the patient, team, and the clinical service (NICE, 2002). Aiken Regional's ECT program is not practicing its own clinical governance until criteria can be established through the use of evidence-based guidelines. Prior to this project, Aiken Regional's only quality assurance

efforts include a once-monthly chart audit conducted on a single ECT procedure. To measure compliance with established protocols, the facility was using an audit tool designed to evaluate general surgery procedures. As a result, areas of ECT delivery that might significantly impact safety were left unexamined while areas that had little or no impact on ECT (e.g., sterility, draping, site-marking, documentation of blood loss and specimen removal) were routinely examined. The process therefore had little impact on assuring quality or assisting staff and providers in recognizing areas for improvement in the ECT program. Through the lens of clinical guidelines, quality measure techniques such as procedural auditing can assist in identifying whether best practice is being followed and every effort is being made to raise continuously the standards for care (Patel, Hacking, Bailey & Warner, 2010). Patel, Hacking, Baily & Warner (2010, p. 32) affirm that ECT is a "domain of practice that must be subjected to regular and rigorous audit." Despite the variations found within ECT practice, recommendations embrace that ECT services should adopt quality assurance practices. The Health Authorities of British Columbia (HABC) (Mental Health Evaluation and Community Consultation Unit, 2002) recommend that each hospital providing ECT audit patient and family education materials, appropriate clinical care, monitoring of ECT as a therapy and privileging of physicians performing ECT. The ECT Accreditation Service (ECTAS) (Royal College of Psychiatrists, 2016) suggests that the ECT team take an active role in audit and quality assurance. An argument for a quality assurance program is outlined by the American Psychiatric Association (APA, 2011) to monitor ECT procedure performance and address any identified deficits. Aiken Regional's implementation of monitoring quality in its ECT program presents a few opportunities including: better outcomes, improved patient

satisfaction and tolerability, improved reimbursement, and ultimately greater ECT utilization. Correcting this clinical problem will keep patients safer and will further legitimize ECT's place as a quality-driven clinical service in this community-based hospital. The purpose of this project was to develop a strategy for monitoring quality assurance by establishing best practice standards for concepts involved in electroconvulsive therapy procedures including: indications, consent processes, assessment and preparation of patients, anesthetic practice, administration, recovery, monitoring, and documentation. Establishing a guideline will allow for the adoption and implementation of quality measures by which to guide Aiken Regional's ECT program and enhance the ability to perform future quality improvement projects. The product of this project is the development of a quality assurance strategy, using a procedural auditing tool, that has been adapted for use in Aiken Regional Medical Center's ECT program with aims to promote and improve compliance to recognized best practice standards. This allows refinement and replacement of previously used, less specific quality assurance efforts already in place that were written to address general surgery patients. In addition, facility policies pertaining to ECT practice were adapted accordingly to ensure uniformity. Prior to this initiative, the facility had a policy to guide ECT procedures. This policy provided directives as to who can perform ECT and anesthesia services, specific guidelines for treating minors with ECT, and general instructions for performing ECT. Lacking however, were quality assurance protocols and more specific outlines for performing care including: frequency of consent for anesthesia and ECT, delegation for what staff perform necessary tasks, parameters for required preprocedural testing, and specific documentation requirements. Through my role as

ECT Coordinator at Aiken Regional, I had both prime access and the interdisciplinary networking capabilities to implement a quality assurance project that accommodates multiple facets of care to tackle this very important clinical problem.

PICOT STATEMENT

When exploring practice-based research, it is often helpful to frame a clinical question in a way that guides and organizes important concepts for careful analysis. The PICOT format allows the clinician to separate individual elements of a proposed clinical concept into: population (P), intervention (I), comparison (C), outcome (O), and time duration (T) (Riva, Malik, Burnie, Endicott & Busse, 2012). In this evidence-based quality assurance project, the PICOT question was: In the electroconvulsive therapy program at Aiken Regional Medical Centers (P), does development and implementation of a quality assurance program through procedural auditing (I) improve recognition of compliance with clinical guideline recommendations (O) more effectively than general surgical auditing (C) over a 2-month time period (T)?

FRAMEWORK

According to Avedis Donabedian (2003), quality assurance activities can be divided into two parts: system design/resources and performance monitoring/readjustment. Performance monitoring was the focus this project. Within performance monitoring, it is possible to obtain information about the level of quality within health care and use resultant interpretations to protect and improve quality. There are many frameworks used to accomplish effective performance monitoring. The

Institute for Healthcare Improvement (IHI, 2017) recommends clinical audit using the Plan-Do-Study-Act (PDSA) framework as a strategy for quality development action. The clinical audit cycle provides a measurement of performance against predefined criteria. In order to establish this predefined criterion, an audit tool featuring best practices was derived from the study and culmination of various evidence-based guidelines related to ECT practice, aligned with staff input and existing hospital policy. Performance can be compared to the standards repeatedly until the standard is either achieved or until a new standard is formulated. As described by Gillam & Siriwardena (2013), the clinical cycle is a continuous process consisting of four distinct stages:

1. Define criteria and set standards.

This phase is met by identifying the area of necessary improvement. In this case, the area of interest relates to Aiken Regional's ECT compliance with best practice guidelines regulatory guidelines, and hospital policy. The criteria used to monitor performance should be clear with explicit statements that define elements of care to be measured. It is also suggested that a goal level of compliance be set for each criterion (e.g. 80% or 100% compliance).

2. Monitor Performance.

Monitoring of performance should be done in a consistent manner using the same set of criteria for each encounter. The development and implementation of a tool for this purpose will provide criteria that can be applied uniformly to review ECT procedures.

3. Identify divergences.

This phase allows the clinician opportunity to compare actual performance to the previously set criteria or standards. In addition, it can be determined to what extent differences exist between criteria and practice.

4. Change Practice.

In referencing divergent practice patterns, recommendations can be made to target improved compliance. Use of an action plan is recommended. Recommendations should include what area of change is necessary, by whom, and by what time frame.

The clinical audit cycle allows for continuous quality improvement through a concise series of steps. The audit is easily repeated in later quality cycles and allows for follow-up to previously realized deficiencies while allowing visibility for other areas that may need improvement (Gillam & Siriwardena, 2013). This framework (Figure 1.1) provides a simple, yet effective, framework under which to approach procedural auditing for ECT at Aiken Regional Medical Centers.

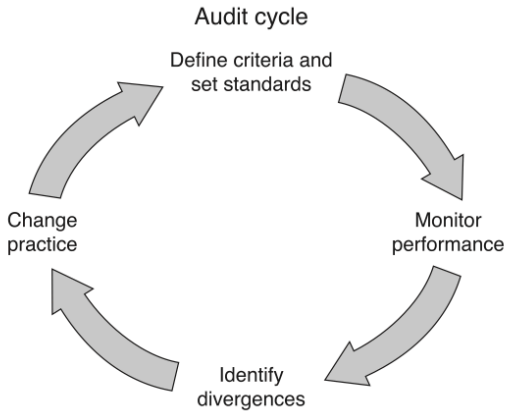

Figure 1.1 Clinical Audit Cycle (Gillam & Siriwardena, 2013)

LITERATURE REVIEW

The concept of auditing and feedback as a means of promoting quality assurance is common in healthcare. The literature search related to this technique included review of online databases including CINAHL Complete, PubMed Medline, Joanna Briggs Institute, Cochrane Library, and the *Journal of ECT*. Search terms included "electroconvulsive therapy," "audit," "quality," "compliance," and "audit and feedback" in varying combinations. Search limits included: being available in English, publication within 10 years, and free full-text availability. Results not closely related to the intervention of auditing were eliminated. An obvious scarcity of evidence exists regarding auditing interventions directed specifically towards ECT delivery, with only three articles recognized to meet criteria. However, many articles involved the use of auditing in other procedural and nonprocedural settings.

Table 1.1 Literature Review Search Results

Database	**"electro-convulsive therapy", "audit"**	**"electro-convulsive therapy", "quality"**	**"electro convulsive therapy", "compliance"**	**"audit", "procedure"**	**"audit", "compliance"**	**"audit and feedback"**
CINAHL Complete	5 results	33 results	9 results	230 results	894 results	237 results
PubMed Medline	18 results	174 results	20 results	776 results	1076 results	524 results
Joanna Briggs Institute	0 results	0 results	0 results	0 results	0 results	24 results

Cochrane Library	0 results	7 results	8 results	3 results	5 results	7 results
Journal of ECT	5 results	7 results	0 results	2 results	0 results	0 results
*Results reported met the requirements for being published within the last 10 years, published in English, and available in full-text format.						

Evaluation of the strength and level of evidence was completed using the framework presented by Newhouse, Dearholt, Poe, Pugh, and White (2015) through the *Johns Hopkins Nursing Evidence-based Practice Rating Scale*. Through this scale, evidence can be graded based on levels ranging from Level 1 (experimental study/randomized controlled trial or meta-analysis of randomized controlled trials) to Level 4 (opinion of individual expert based on non-research evidence). Considering both quality and level of evidence allowed for a more critical and controlled review of available evidence in the literature review process.

ANALYSIS OF EVIDENCE

Several high quality sources were available including a comprehensive Cochrane review was conducted in 2012 (Ivers et. al) which analyzed 140 randomized trials where audit and feedback was considered the core intervention. Audit and feedback were found to generally lead to small but potentially important improvements in professional practice. The efficacy was found to be dependent on elements such as baseline performance and the delivery of feedback. Greater effect was noted when health professionals were not performing well at baseline, when the person responsible for audit and feedback was a supervisor or colleague, when the intervention was provided

more than once, and when feedback included clear targets and action plans. A supplement to the Cochrane Review was completed in 2014 (Ivers et. al) which provided a systematic review to determine if new randomized trials have added to knowledge regarding audit and feedback. While the review confirmed that audit and feedback can effectively improve quality of care, there was little evidence of progress noted since the initial Cochrane Review. Reviewers did note that non-physician providers seemed to show more improvement as a result of feedback. Problematically, there are still vague details provided by research regarding the effective elements of feedback. Another high quality source included the meta-analysis completed by Hysong & Hysong (2009), which reviewed 19 randomized studies on the impact of audit and feedback. Results found a modest but significant effect and concluded that audit and feedback was a reasonably effective tool for changing provider behavior and quality of care. Specific suggestions for performance included frequent delivery of feedback and delivery in writing.

Studies that specifically addressed ECT care had limited quality and often had small sample sizes. Ulhaq, Nnatu, Kelly & Sooky (2011) completed a baseline service audit to determine compliance to National Institute for Health and Care Excellence guidelines at John Connolly Clinic in London. A tool created based solely on NICE criteria was used to positively identify areas for ECT practice improvement and highlight the need for role clarity and improved documentation. This study was small but successfully utilized methodology similar to that of this project. Another study by Onalaja, Sultana, Afghan, & Coupe (2008) used auditing and feedback to evaluate an inpatient program's compliance to an "ECT care pathway" also compiled from National

Institute for Health and Care Excellence guidelines but with additional Royal College ECT Accreditation standards. The authors advocated for the use of a care pathway in delivery of ECT to monitor variance and assure good practice in the use of ECT. Lastly, Lamont, Brunero, Barclay & Wijeratne (2011) evaluated an ECT service at a general hospital in Sydney, Australia using the 2007 Royal Australian and New Zealand College of Psychiatrists standards and cited auditing as essential for quality improvement processes. These studies did not address the long-term effects or outcome changes that might have been impacted nor were randomization and control groups used.

As ECT is often completed within surgery suites or managed by surgery staff, it was important that studies were included considering the utility of audit and feedback within the surgical or procedural environment. A systematic review (Maruthappu, Trehan, Barnett-Vanes, McCulloch & Carty, 2015) looked at how feedback impacted surgical outcome data. Feedback was found to have a powerful effect on surgical outcomes and indicators of surgical performance, although not all studies were randomized and a limited number of studies were included. Lewis et. al (2015) addressed providing head and neck surgeons individualized feedback and found that periodic assessment of performance and outcomes led to improved surgical quality outcomes and reduced surgical variability. Authors concluded that audit and feedback was an effective means of improving surgical quality, particularly by improving compliance with specific processes. Documentation compliance also seemed particularly pertinent to the clinical question. Onerheim, Racette, Jacques & Gagnon (2008) reviewed the effect of audit and feedback on pathology reports in breast cancer surgery, finding a notable improvement in the quality of reports after surveillance. The quality of referral letters in primary care

also found use in implementing an audit and feedback intervention, which used a scored checklist to improve documentation standards (Corwin & Bolter, 2014).

Knaup, Koesters, Schoefer, Becker & Puschner (2009) completed a meta-analysis of 12 controlled (not always randomized) studies that addressed the implications for specialist mental healthcare. Feedback interventions used in mostly outpatient settings in the United States and United Kingdom showed a small but statistically significant effect on short-term outcomes but lacked long-term sustained effects. Kristensen & Hounsgaard (2014) described the audit and feedback as useful in retrospective, systematic monitoring, and evaluations of daily practice within stroke rehabilitation care, particularly when standardized assessment tools and repeated feedback were used. Audit and feedback also improved nurse practitioner adherence to clinical practice guidelines regarding cancer pain treatment, particularly in improving documentation of care (Dulko, Hertz, Julien, Beck & Mooney, 2010). Additionally, audit and feedback were used in effectively reducing severe postpartum hemorrhages (Dupont et. al, 2011) and improving compliance to blood transfusion bundles (Bogert et. al, 2016). Dupont et. al (2011) highlighted the usefulness of institutional support, allowing participation to be included as work time, respect for the facilitator, consideration for every participant, objective assessment through a standardized form, focus on decision-making processes rather than individual mistakes, and conclusions expressed in terms of improvement strategies. Additionally, Bogert et. al (2016) found that timely individual feedback was more effective than team level feedback and that when the feedback was discontinued, compliance rates dropped.

While there is clear variability in how powerful the effect of auditing and resultant feedback can be based on nuances in delivery and practice settings, there is little doubt that it has at least a small to moderate positive effect on care. More study is needed to further develop evidence about the use of audit specific to delivery of ECT and how outcomes of care might be improved. Additionally, there was a consistent lack of evidence noted throughout the literature review on how feedback efforts might be organized or delivered to optimize improvement and what elements of delivery were critical for the intervention to be successful.

STRENGTH OF EVIDENCE

Evidence used to support the intervention of audit with feedback varied in its strength. Several high-quality sources were considered, including meta-analyses and systematic reviews of randomized controlled trials. Additionally, many articles using quasi-experimental means or level 2 studies with either no control or poor control for variables were included. The articles regarding use of auditing techniques specifically towards ECT were of limited strength, with no randomized control trials or level 1 evidence found. Due to the limited literature base regarding quality practices in ECT, this was not unexpected. Higher-quality studies did not address ECT specifically, making some level of extrapolation unavoidable. There was consistency throughout described results, finding a small to moderate positive impact from the use of audit and feedback. The use of auditing as a means of assuring quality in healthcare was deemed an effective evidenced-based strategy and its application to the performance of ECT

was a reasonable departure based on the literature review and its extensive application to healthcare quality.

GUIDELINE REVIEW

The concept of quality assurance within ECT has historical context involving numerous experts, agencies, and accrediting organizations. While no current guideline on ECT administration is necessarily uniformly followed internationally, each guideline offers insight on how ECT quality should be determined and reflect some of the chronological changes in the management of ECT care. In 1978 the first ECT clinical recommendations were published by the American Psychiatric Association Task Force on ECT and were later revised in 1990 and 2001 (APA, 2001). Other countries including the United Kingdom, Australia, Scotland, and New Zealand have each published their own guidelines offering additional recommendations. Accreditation based on adherence to guidelines has been a point of contention, leading to the ECT Accreditation Service by the Royal College of Psychiatrists and the Scottish ECT Accreditation Network (Chan et. al, 2012). Currently, no such ECT-specific accreditation process exists for providers in the United States. Several guidelines were compared for this project in order to outline what essential elements of safe and effective ECT care might be. Guidelines reviewed included: American Psychiatric Association Task Force Report (APA, 2001), Royal College ECT Accreditation Standards (Royal College of Psychiatrists, 2016), ECT Recommendations for Health Authorities of British Columbia (Mental Health Evaluation and Community Consultation Unit, 2002), and Scottish ECT Accreditation Network

Standards (Scottish ECT Accreditation Network, 2010). Table 1.2 details the resultant audit tool that was drafted.

As the largest organization of ECT providers, International Society for ECT and Neurostimulation (ISEN), provides members with a directory. Using this list, efforts were made to contact other ECT programs in the United States to determine prior attempts other facilities used to measure and document the quality of their ECT programs. While response was limited in receiving actual tools used in practice, a few program coordinators were willing to share general criteria used in their programs for procedural quality auditing. However, it seems prudent to note that out of 11 programs that responded to requests for contact, only two reported any quality assurance processes in place. Influence from other providers of ECT already engaging in quality efforts were used in compiling appropriate aspects of care for the auditing tool and to compare the various approaches to procedural auditing.

Table 1.2 Revised Audit Criteria

Preprocedure	
Indication for ECT Documented by Psychiatrist	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by Joint Commission standards.
H&P Documented/Updated by Psychiatrist within the Last 30 Days	• Recommended by APA, HABC, SEAN, and ECTAS. • Frequency required by Joint Commission standards.
Medication List Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Medication Changes Reviewed	• Recommended by APA, HABC, SEAN, and ECTAS.
Allergies Documented	• Recommended by HABC and ECTAS.
Preanesthesia Evaluation Documented by Anesthesiologist	• Recommended by APA, HABC, and ECTAS.

	• Required by Joint Commission standards. • Consistent with input from peer quality program collaboration.
CBC, CMP Documented Within 6 Months, Unless Prescribed Diuretics (1 Month), or in ESRD (Day of Procedure)	• CBC, CMP cited as commonly used by APA and HABC. • Frequency established through anesthesia staff collaboration.
EKG Documented Within 6 Months	• Cited as commonly used by APA and HABC. • Frequency established through anesthesia staff collaboration.
Urine Pregnancy Obtained if 15-57 and No Prior Tubal Ligation or Hysterectomy	• Identified as useful by APA and ECTAS. • Criteria established through anesthesia staff collaboration.
Informed Consent Performed and Documented Within Calendar Month	• Recommended by APA, HACB, SEAN, and ECTAS. • Required by facility policy and Joint Commission standards. • Frequency established by ECT staff input. • Based on input from peer quality program collaboration.
NPO Status Confirmed and Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Baseline and Discharge Vital Signs Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Pain Assessed and Documented Pre and Postprocedure	• Required by facility policy.
Blood Glucose Measured in Diabetic Patients Prior to Procedure	• Recommended by APA, HABC and SEAN. • Required by facility policy.
Preprocedure Medications Given Per MD Orders	• Based on ECT staff input.
Orientation Status Documented Pre and Postprocedure	• Recommended by APA, HABC, and ECTAS.
Outcome Measurement Tool Completed for Indication	• Recommended by APA, HABC, and ECTAS. • Required by facility policy.
Intraprocedure	
Preprocedure Time Out Documented	• Recommended by SEAN. • Required by Joint Commission standards and facility policy. • Consistent with input from peer quality

	program collaboration.
Anesthetic and Muscle Relaxer Dosing Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Electrode Placement Documented	• Recommended by APA, HABC and ECTAS.
Stimulus Settings Documented	• Recommended by APA, HABC and ECTAS.
Motor and EEG Seizure Lengths Recorded	• Recommended by APA, HABC and ECTAS. • Required by facility policy.
Postprocedure	
IV Discontinue Time Documented	• Based on ECT staff input.
Fluid Administration Totals Documented	• Based on ECT staff input.
Postoperative Anesthesia Assessment Documented and Signed	• Recommended by APA, HABC, and ECTAS. • Required by Joint Commission standards. • Consistent with input from peer quality program collaboration.
Procedure Note from Performing Physician Documented	• Required by Joint Commission standards. • Based on input from peer quality program collaboration.
Written Discharge Directions Signed for by Patient/Family Member/Caregiver if Outpatient	• Required by facility policy.
Discharge Time Documented	• Required by facility policy.
Presence of Dental Injury from Procedure	• Record of adverse events/injuries recommended by APA, HABC, SEAN, and ECTAS. • Consistent with input from peer quality program collaboration.
Unplanned Medical Admission	• Record of adverse events/injuries recommended by APA, HABC, SEAN, and ECTAS. • Consistent with input from peer quality program collaboration.

PROJECT DESIGN

This project design is the creation of a quality improvement strategy specific to the delivery of ECT. This aim was accomplished through several methodologies

including: identifying the present need for a quality assurance program, careful review of facility policy, contact with peer ECT programs, a literature review of quality strategies and quality assurance within ECT and collaboration with staff within the ECT program at Aiken Regional Medical Centers. Aiken Regional is a small community-based hospital in the southeastern United States. The 245-bed hospital features both inpatient and outpatient surgical services and has an on campus 62-bed acute psychiatric stabilization unit. The average patient census for this program over the last 12 months has been 58 treatments per month, ranging from 24-69, treating primarily outpatients with recurrent major depressive disorder or bipolar disorder. In the year 2016, 467 total procedures were performed. ECT services at this location are provided to both inpatients and outpatients based on physician referral for services. ECT procedures are conducted in the surgical services area, with preprocedural preparations taking place in the outpatient surgery suite and the procedures themselves taking place in the post anesthesia care unit. At this facility, the ECT program is still fairly new and has only been in operation since early 2014. Details of ECT remain largely unknown to staff and administration. This lack of awareness has resulted in relative inattention regarding ECT, particularly in the development of quality assurance strategies.

Ultimately, a framework was adopted to guide quality assurance efforts through the use of the PDSA cycle. Retrospective chart auditing served as mechanism by which to objectively measure quality in Aiken Regional's performance of ECT. The success of this project was measured qualitatively through its impact on staff, policy, and care processes.

Comparing the impacts of the newly adopted quality assurance strategy to prior strategies helped provide insight on overall effectiveness and guide directions for future use.

BENEFITS

This project was justified by its aim at improved patient outcomes by laying the groundwork for future quality improvement efforts and enabling future compliance monitoring with standards. While adherence to established clinical recommendations is a desired feature of any clinical procedure, helping to assure the success of external oversight through organizations such as The Joint Commission is a necessity for the overall success of an organization. This quality assurance strategy was created in consideration of Joint Commission standards and will help this program maintain accreditation. Financially, providing evidence-based care with appropriate documentation is key in receiving full reimbursement for services as well as protecting the facility and providers from litigious error. Lastly, achieving status as a quality-driven ECT service helps to promote improved utilization and ensures that patients receive safe, tolerable and effective ECT delivery. Development of a quality assurance program is associated with little direct cost to the facility but presents broad opportunities for expansion, financial gain and long-term longevity for an ECT program that serves the mental health needs of its community.

FEASIBILITY

Assessing organizational readiness is a key ingredient to any successful quality assurance method. Readiness applies not only to the researcher but to all levels of the

institution and its leaders. Within this state of readiness, all must accept the importance of quality assurance and agree that quality care is worth the effort, time, and costs. The potential costs for this project lie in paid time resources for educating staff regarding guideline standards and paid time resources for the ECT Coordinator in conducting ongoing auditing, presenting results, and eventually formulating action plans to correct deficits. These costs would be seemingly offset not only by possible improved reimbursements, but also in the development of the program as a whole through increased utilization. Ensuring that the procedural auditing technique is comprehensive yet practical for regular use will assist with long-term sustainability. The audit tool and process must be brief and easily transferable between users. Another aspect of this project that promoted feasibility included the novelty of the Aiken Regional ECT program (established in 2014), which fosters motivation amongst leadership at the organization to find ways to promote sustainability of the program by providing additional revenue for the hospital. Key stakeholders in this project are the treating psychiatrists, Dr. Peter Rosenquist and Dr. Vaughn McCall, who are dedicated to evidence-based medicine and both have strong research backgrounds. Anesthesia director, Dr. Sandy Ulmer, will serve as advisor for standards and performance related to anesthesia administration. Additionally, the directors of quality and surgical services for Aiken Regional Medical Centers play a central role in reviewing quality assurance efforts and outcomes, giving input to policy and practice changes, and ensuring that quality efforts continue as a long-term effort and are integrated into program culture. The nurses that provide preprocedural and postprocedural care are perhaps the most critical determinants of success. They will ultimately determine the success of compliance to

established quality guidelines and will determine how effectively change can be implemented. Competencies are another critical component of feasibility. It is imperative that the ECT Coordinator (the leader of quality efforts) be versed in available guidelines published regarding ECT and effectively monitor the ongoing compliance with quality standards. Competency could be bolstered by seeking the assistance of quality professionals within the organization who have had prior experience in directing such projects. In addition, it is important to seek out peers in the field of ECT, particularly in older well-established programs, regarding their own experiences with quality assurance efforts. Despite the numerous strengths of this project, limitations still exist. The ECT program for Aiken Regional Medical Centers is essentially managed by one registered nurse or ECT Coordinator. This limits the availability of ancillary staff to assist with data collection, education, and auditing procedures. While the scope of ECT research has improved greatly over time and more information has been obtained regarding ways to improve outcomes for patients, there are still areas where recommendations are vague and lack a clear direction based on firm evidence.

METHODS

This quality assurance initiative was completed over a 6-month time frame and followed a series of steps guided by the Plan-Do-Study-Act (PDSA) framework by defining criteria and setting standards, monitoring performance, identifying divergences, and lastly changing practice. The PDSA framework allows for continuous quality improvement through a concise series of steps and is easily repeated in later quality cycles. Additionally, this process allows for follow-up to previously realized deficiencies

while allowing visibility for other areas that may need improvement. Using the PDSA clinical audit framework, a quality strategy was formulated through the following steps:

1. A checklist-type audit tool was developed based on clinical guidelines as noted above combined with staff input, facility policy and peer ECT program recommendations. These recommendations were informed by a careful comparison of existing care guidelines as referenced above including: American Psychiatric Association, Royal College of Psychiatrists, Scottish ECT Accreditation Network and ECT Recommendations for Health Authorities of British Columbia. The guideline review helped to determine what elements of care were important for the measurement of quality in designing an effective audit tool. The project was reviewed by the University of South Carolina IRB and was determined to be exempt from human subjects oversight. Once a draft of the audit tool was created, an interprofessional ECT task force was convened to review the tool and discuss barriers to implementation. In this facility, the ECT Coordinator is responsible for directing all quality assurance efforts and providing leadership regarding resultant practice changes. The ECT Coordinator is best situated to perform regular clinical audits and to direct the ECT Task Force initiatives. Piloting of the tool was approved by the facility quality director.
2. A pilot audit was performed for 10 procedures to determine the practicality and ease of use of the tool. The audit tool was then tested by another RN not directly involved in the ECT program to determine transferability. Making criteria as specific as possible promoted consistency of results between audit users. Adjustments were made based on identified barriers. Some of these changes included: adding more

specific time frames to preprocedural testing parameters, specifying consent frequency and adding urine pregnancy testing parameters.

3. Staff who worked regularly with ECT (including both nurses and physicians) were given a copy of the ECT audit tool and educated regarding the new quality improvement process prior to initiation. This allowed an opportunity to address any questions regarding current procedural processes or documentation.
4. Audits were conducted once monthly by the ECT Coordinator (BSN) targeting all procedures that occurred over the previous month through retrospective chart review. Every procedure was reviewed for the first two months, with a plan to reduce future auditing to approximately 10% of monthly procedures. It was critical that the auditing process review a representative sample of cases such as: inpatient, outpatient, acute course, maintenance, and a variety of diagnoses. A formal written review of audit findings was presented to ECT staff members including direct care staff, providing psychiatrist, director of quality, and director of surgical services.
5. Results from monthly audits were analyzed and outcomes were thoroughly described. Considerations for possible practice changes were based on areas of concern and compliance rates were compared against target goals. The new quality audit process was critiqued by staff to determine if it was still feasible and met the program's clinical needs.
6. In the future, staff will be updated regarding recognized deficits through individualized meetings and additional ECT Task Force meetings as necessary. The ECT Coordinator, who takes responsibility for ECT quality assurance efforts, should direct these meetings and review previous audit benchmarks so that accountability for

performance can be encouraged. The results were integrated into the hospital's regular quality committee meeting in order to create a sustainable and integrated quality assurance protocol. Policy changes were suggested to better align with audit criteria and available guidelines. The ECT coordinator will collaborate with facility administration to assure consistency between ECT policies and procedures and quality assurance documents.

PROTECTION OF HUMAN SUBJECTS

An application for IRB review was submitted to the University of South Carolina review panel. Since there was neither identifiable patient data collected nor any direct interaction with patients, an exemption letter was granted (Appendix C). While privacy of patients is of utmost importance, no additional clearance was necessary as the ECT Coordinator is already authorized access to needed clinical data and has full capacity to be present during ECT procedures. Every effort should be employed to prevent the use of patient identifiers in audit use; these identifiers will be substituted by the use of medical record numbers. No identifying information was included in the audit process.

EVALUATION PLAN

Key outcomes for the evaluation of this project include providing clearly defined quality assurance criteria informed by evidence-based literature that can guide facility policy and ECT delivery. Amendments to facility policy will be made to align with evidence-based quality standards. Especially important, will be consideration of the impact this quality assurance strategy has on staff and on facility policy directing ECT.

The implementation of clinical auditing may reveal possible practice deficits to discuss and explore in the future. Auditing will be achieved through the use of a tool that has been created specifically for the Aiken Regional Medical Centers ECT program, using a collection of criteria compiled from previously discussed evidence-based practice guidelines, peer input, and hospital policy. Quantifiably measurable outcomes of this project will be identified through comparison of procedural compliance with the newly developed audit tool quality criteria. While not in the scope of this project, the challenges identified can be addressed and reevaluated once a sufficient action plan has been developed and implemented. The practical use and transferability of the audit tool will require examination and review by facility staff. Completion of a comprehensive audit of ECT procedures conducted over a two-month interval will allow for further testing of the utility of the audit tool and will be useful in gauging its application within this facility setting. While simply noting deficits is unlikely to create meaningful change, the results of this initial analysis will be vital to setting in motion a PDSA cycle for continued quality improvement.

DISSEMINATION PLAN

This project will be important for dissemination as it closely relates to two major areas of interest within healthcare. Firstly, this project represents a critical gap of scholarship within the specialized area of electroconvulsive therapy. In the United States, electroconvulsive therapy study and development is represented most heavily by the International Society for ECT and Neurostimulation (ISEN) and the *Journal of ECT*. While not geared specifically towards nursing, both the ISEN and *Journal of ECT* are

multidisciplinary in nature. A manuscript was created for submission based on the criteria specified for "original research" listed by the official *Journal of ECT* website (Chapter 2). Additionally, an abstract will be submitted to the ISEN. ISEN holds a yearly conference with poster and podium presentations that would be a key opportunity for communicating any noteworthy findings that could impact clinical care. Another viable option would be submission to a nursing journal that deals specifically with quality issues such as *Journal of Nursing Care Quality*. Both *Journal of ECT* and *Journal of Nursing Care Quality* are published quarterly. The results of this project were presented to the staff delivering ECT services as well as hospital management through their regular quality management meeting. During this presentation, identified areas for improvement were discussed along with a potential action plan to effectively address the deficits. It is important that the newly established ECT quality assurance efforts become a transparent process, involving several tiers of hospital administration to successfully integrate as a long-term, ongoing project. By becoming a regular feature at the quality management meeting, accountability can be fostered to continue audits regularly as well as provide follow-up regarding improvement projects and subsequent outcomes.

CHAPTER 2

MANUSCRIPT: "DEVELOPING AND IMPLEMENTING A QUALITY ASSURANCE STRATEGY FOR ELECTROCONVULSIVE THERAPY"[1]

[1] Hollingsworth J., Baliko B., McKinney S., and Rosenquist P. To be submitted to *The Journal of ECT*.

Background: The literature provides scant guidance in effective quality assurance strategies concerning the use of electroconvulsive therapy (ECT) for the treatment of psychiatric conditions. Numerous guidelines are published that provide guidance in the delivery of care, however, little has been done to determine how a program or facility might ensure compliance to best practice for safety, tolerability, and efficacy in performing ECT.

Objective: The objective of this project was to create a quality assurance strategy specific to ECT. Determining standards for quality care and clarifying facility policy were key outcomes in establishing an effective quality assurance strategy.

Methods: An audit tool was developed utilizing quality criteria derived from a systematic review of ECT practice guidelines, peer review and facility policy. All ECT procedures occurring over a two month time period of May-June 2017 were retrospectively audited and compared against target compliance rates set for the facility's ECT program. Facility policy was adapted to reflect quality standards and audit findings were used to inform possible practice change initiatives, create benchmarks for continuous quality monitoring and were integrated into regular hospital quality meetings.

Results: Clarification on standards of care and the use of clinical auditing in ECT was an effective starting point in the development of a quality assurance strategy. Audit findings were successfully integrated into the hospital's overall quality program and recognition of practice compliance informed areas for future quality development and policy revision in this small community-based hospital in the southeastern United States.

Conclusion: This project sets the foundation for a quality assurance strategy that can be used to help monitor procedural safety and guide future improvement efforts in delivering ECT. While just the first step in creating meaningful quality improvement, setting clear standards and identifying areas of greatest clinical need was a crucial beginning for this hospital's growing program.

Keywords: electroconvulsive therapy, quality assurance, audit

Quality assurance is imperative in today's healthcare landscape. Finding ways to establish and measure evidence-based standards of care is a critical first step in this endeavor. ECT is a well-established and highly effective treatment in psychiatry, due in no small part to extensive study geared towards refinement of technique and study of efficacy. However, quality assurance efforts related to implementation of the procedure remain largely underdeveloped. Prior literature concerning quality in ECT has focused on large-scale analysis of national trends or impacts of accreditation processes without supplying practical, tangible recommendations for how to implement quality interventions on smaller or program-specific scales, particularly within the United States. Although quality ECT care relies on adherence to evidence-based guidelines, differences among facilities still exist in the adaptation of practice standards in ECT[1].

Despite the variations found across ECT practice, there is a general agreement among clinicians that ECT should be outcome focused. Developing specific and consistent quality standards that can be used to monitor patient safety and program compliance is a crucial step towards ensuring best practice for safety and efficacy of ECT. Standardized documentation of safe and effective care can also potentially reduce

stigma and raise awareness of the usefulness of this very important technique as healthcare delivery changes into a more quality data-driven environment. Through the lens of clinical guidelines, quality measure techniques such as procedural auditing can assist in identifying whether best practice is being followed and facilitate efforts to continuously raise care performance[2].

BACKGROUND AND SIGNIFICANCE

The project was implemented in a small community-based hospital in the southeastern United States. The 245-bed hospital features both inpatient and outpatient surgical services and an on campus 62-bed acute psychiatric stabilization unit. The ECT program was established in 2014 and performed 467 procedures in the year 2016. Prior to this initiative, the facility had a policy to guide ECT procedures. The policy provided directives as to who can perform ECT and anesthesia services, specific guidelines for treating minors with ECT, and general instructions for performing ECT. Lacking however, were quality assurance protocols and more specific outlines for performing care including: frequency of consent for anesthesia and ECT, delegation of care tasks, standards for preprocedural testing, and documentation requirements. To measure compliance with established protocols, the facility was using an audit tool designed to evaluate general surgery procedures. As a result, areas of ECT delivery that might significantly impact safety were left unexamined while areas that had little or no impact on ECT (e.g., sterility, draping, site marking, documentation of blood loss and specimen removal) were routinely examined. The process therefore had little impact on assuring quality or assisting staff and providers to recognize areas for improvement in their ECT

program. The purpose of this project was to develop a quality assurance strategy specific to ECT. It was first necessary to define the criteria that would indicate the degree to which the program fulfilled or exceeded a minimal set of requirements and then devise a means of auditing the procedures. Once the audit process was successfully piloted, it was possible to make recommendations for improvement, revise facility policy, and integrate ECT outcomes into the broader quality assurance efforts of the hospital.

METHODOLOGY REVIEW

The concept of auditing and feedback as a means of promoting quality assurance is common in healthcare. The literature search related to this technique included search of online databases including: CINAHL Complete, PubMed Medline, Joanna Briggs Institute, Cochrane Library, and the *Journal of ECT*. Search terms included "electroconvulsive therapy," "audit," "quality," "compliance," and "audit and feedback" in varying combinations. Search limits included: being available in English, publication within 10 years, and full-text availability. Results not closely related to the intervention of auditing were eliminated. An obvious scarcity of evidence exists regarding auditing interventions directed specifically towards ECT care, with only three articles recognized to meet criteria. Many articles involved the use of auditing in nonprocedural and nonsurgical settings.

Several high quality sources were available including a comprehensive Cochrane review[3] was conducted in 2012, which analyzed 140 randomized trials across medical settings where audit and feedback was considered the core intervention. Audit and feedback were found to generally lead to small but potentially important improvements

in professional practice. Greater effect was noted when health professionals were not performing well at baseline, when the person responsible for audit and feedback was a supervisor or colleague, when the intervention was provided more than once, and included clear targets and action plans. A supplement to the Cochrane Review[4] was completed in 2014, which provided a systematic review to determine if new randomized trials have added to knowledge regarding audit and feedback. While the review confirmed that audit and feedback can effectively improve quality of care, there was little evidence of progress noted since the initial Cochrane Review. Reviewers did note that non-physician providers seemed to show more improvement based on feedback. Problematically, there were inadequate details provided regarding the effective elements of successful feedback. Another high quality source included the meta-analysis completed by Hysong & Hysong[5] which reviewed 19 randomized studies on the impact of audit and feedback. Results found a modest but significant effect and concluded that audit and feedback was a reasonably effective tool for changing provider behavior and quality of care. Specific suggestions for performance included frequent delivery of feedback and delivery in writing.

The studies that specifically addressed ECT care had limited quality and often had small sample sizes. Ulhaq, Nnatu, Kelly & Sooky[6] completed a baseline service audit to determine compliance to NICE guidelines at John Connolly Clinic in London. A tool created based on solely on NICE criteria was used to identify areas for ECT practice improvement and highlighted the need for role clarity and improved documentation. Another study by Onalaja, Sultana, Afghan, & Coupe[7] used auditing and feedback to evaluate an inpatient program's compliance to an "ECT care pathway" also compiled

from National Institute for Health and Care Excellence guidelines but with additional Royal College ECT Accreditation standards. The authors advocated for the use of a care pathway in delivery of ECT to monitor variance to help assure good practice in the use of ECT. Lastly, Lamont, Brunero, Barclay & Wijeratne[8] evaluated an ECT service at a general hospital in Sydney, Australia using 2007 Royal Australian and New Zealand College of Psychiatrists standards and cited auditing as essential for quality improvement processes. These studies did not address the long-term effects or outcome changes that might have been impacted nor were randomization and control groups used.

Methods to ensure documentation compliance also seemed particularly pertinent to the clinical question. Onerheim, Racette, Jacques & Gagnon[9] reviewed the effect of audit and feedback on pathology reports in breast cancer surgery, finding a notable improvement in the quality of documented reports after surveillance. The quality of referral letters in primary care also found utility in implementing an audit and feedback intervention which used a scored checklist to improve documentation standards[10].

Knaup, Koesters, Schoefer, Becker & Puschner[11] completed a meta-analysis of 12 controlled (not always randomized) studies that addressed the implications for specialist mental healthcare. Feedback interventions used in mostly outpatient settings in United States and United Kingdom showed a small but statistically significant effect upon short-term outcomes but sustained effects have not been demonstrated. Kristensen & Hounsgaard[12] described the audit and feedback as useful in retrospective, systematic monitoring, and evaluations of daily practice within stroke rehabilitation care, particularly when standardized assessment tools and repeated feedback were used. Audit and feedback also improved nurse practitioner adherence to clinical practice guidelines

regarding cancer pain treatment, particularly in improving documentation of care[13]. Additionally, audit and feedback was used in effectively reducing severe postpartum hemorrhages[14] and improving compliance to blood transfusion bundles[15]. Dupont et. al[14] highlighted the usefulness of institutional support, allowing participation to be included as work time, respect for the facilitator, consideration for every participant, objective assessment through a standardized form, focus on decision-marking processes rather than individual mistakes, and conclusions expressed in terms of improvement strategies. Additionally, Bogert et. al[15] found that timely individual feedback was more effective than team level feedback and that when the feedback was discontinued, compliance rates dropped.

While there is clear variability in how powerful the effect of auditing and resultant feedback can be based on nuances in delivery and practice settings, the above literature review suggests that audit and feedback creates at least a small to moderate positive effect on care. More study is needed to further develop evidence about the use of audit specific to delivery of ECT and how outcomes of care might be improved. Additionally, there was a consistent lack of evidence noted throughout the literature review on how feedback efforts might be organized or delivered to optimize improvement and what elements of delivery were critical for the intervention to be successful.

GUIDELINE REVIEW

The concept of quality assurance within ECT has historical context involving numerous experts, agencies, and accrediting organizations. While no current guideline

on ECT administration is necessarily followed internationally, each guideline offers insight on how ECT quality should be determined and reflect some of the chronological changes in the management of ECT care. In 1978 the first ECT clinical recommendations were published by the American Psychiatric Association Task Force on ECT and were later revised in 1990 and 2001 (APA, 2001). Other countries including the United Kingdom, Australia, Scotland, and New Zealand have each published their own guidelines offering additional recommendations. Accreditation based on adherence to guidelines has been a point of contention, leading to the ECT Accreditation Service by the Royal College of Psychiatrists and the Scottish ECT Accreditation Network (Chan et. al, 2012). Currently, no such ECT-specific accreditation process exists for providers in the United States. Several guidelines were compared for this project in order to outline what essential elements of safe and effective ECT care might be. Guidelines reviewed included: American Psychiatric Association Task Force Report[16], Royal College ECT Accreditation Standards[17], ECT Recommendations for Health Authorities of British Columbia[18], and Scottish ECT Accreditation Network Standards[19]. Table 2.1 details the resultant audit tool that was drafted.

As the largest organization of ECT providers, International Society for ECT and Neurostimulation (ISEN), provides members with a directory. Using this list, efforts were made to contact other ECT programs in the United States to determine prior attempts other facilities used to measure and document quality of their ECT programs. While response was limited in receiving actual tools used in practice, a few program coordinators were willing to share general criteria used in their programs for procedural quality auditing. However, it seems prudent to note that out of 11 programs that

responded to requests for contact, only two reported any quality assurance processes in place. Influence from other providers of ECT already engaging in quality efforts were used in compiling appropriate aspects of care for the auditing tool and to compare the various approaches to procedural auditing.

Table 2.1 Revised Audit Criteria

Revised Audit Criteria	
Preprocedure	
Indication for ECT Documented by Psychiatrist	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by Joint Commission standards.
H&P Documented/Updated by Psychiatrist within the Last 30 Days	• Recommended by APA, HABC, SEAN, and ECTAS. • Frequency required by Joint Commission standards.
Medication List Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Medication Changes Reviewed	• Recommended by APA, HABC, SEAN, and ECTAS.
Allergies Documented	• Recommended by HABC and ECTAS.
Preanesthesia Evaluation Documented by Anesthesiologist	• Recommended by APA, HABC, and ECTAS. • Required by Joint Commission standards. • Consistent with input from peer quality program collaboration.
CBC, CMP Documented Within 6 Months, Unless Prescribed Diuretics (1 Month), or in ESRD (Day of Procedure)	• CBC, CMP cited as commonly used by APA and HABC. • Frequency established through anesthesia staff collaboration.
EKG Documented Within 6 Months	• Cited as commonly used by APA and HABC. • Frequency established through anesthesia staff collaboration.
Urine Pregnancy Obtained if 15-57 and No Prior Tubal Ligation or Hysterectomy	• Identified as useful by APA and ECTAS. • Criteria established through

	anesthesia staff collaboration.
Informed Consent Performed and Documented Within Calendar Month	• Recommended by APA, HACB, SEAN, and ECTAS. • Required by facility policy and Joint Commission standards. • Frequency established by ECT staff input. • Based on input from peer quality program collaboration.
NPO Status Confirmed and Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Baseline and Discharge Vital Signs Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Pain Assessed and Documented Pre and Postprocedure	• Required by facility policy.
Blood Glucose Measured in Diabetic Patients Prior to Procedure	• Recommended by APA, HABC and SEAN. • Required by facility policy.
Preprocedure Medications Given Per MD Orders	• Based on ECT staff input.
Orientation Status Documented Pre and Postprocedure	• Recommended by APA, HABC, and ECTAS.
Outcome Measurement Tool Completed for Indication	• Recommended by APA, HABC, and ECTAS. • Required by facility policy.
Intraprocedure	
Preprocedure Time Out Documented	• Recommended by SEAN. • Required by Joint Commission standards and facility policy. • Consistent with input from peer quality program collaboration.
Anesthetic and Muscle Relaxer Dosing Documented	• Recommended by APA, HABC, SEAN, and ECTAS. • Required by facility policy.
Electrode Placement Documented	• Recommended by APA, HABC and ECTAS.
Stimulus Settings Documented	• Recommended by APA, HABC and ECTAS.
Motor and EEG Seizure Lengths Recorded	• Recommended by APA, HABC and ECTAS.

	• Required by facility policy.
Postprocedure	
IV Discontinue Time Documented	• Based on ECT staff input.
Fluid Administration Totals Documented	• Based on ECT staff input.
Postoperative Anesthesia Assessment Documented and Signed	• Recommended by APA, HABC, and ECTAS. • Required by Joint Commission standards. • Consistent with input from peer quality program collaboration.
Procedure Note from Performing Physician Documented	• Required by Joint Commission standards. • Based on input from peer quality program collaboration.
Written Discharge Directions Signed for by Patient/Family Member/Caregiver if Outpatient	• Required by facility policy.
Discharge Time Documented	• Required by facility policy.
Presence of Dental Injury from Procedure	• Record of adverse events/injuries recommended by APA, HABC, SEAN, and ECTAS. • Consistent with input from peer quality program collaboration.
Unplanned Medical Admission	• Record of adverse events/injuries recommended by APA, HABC, SEAN, and ECTAS. • Consistent with input from peer quality program collaboration.

METHODS

This quality initiative was completed over a 6-month time frame and followed a series of steps guided by the Plan-Do-Study-Act (PDSA) framework by defining criteria and setting standards, monitoring performance, identifying divergences, and lastly changing practice. The clinical audit PDSA framework allows for continuous quality improvement through a concise series of steps and is easily repeated in later quality cycles. Additionally, this process allows for follow-up to previously realized deficiencies

while allowing visibility for other areas that may need improvement[20]. Using the PDSA clinical audit framework, a quality strategy was formulated through the following steps:

1. A checklist-type audit tool was developed based on clinical guidelines as noted above combined with staff input, facility policy and peer ECT program recommendations. These recommendations were informed by a careful comparison of existing care guidelines as referenced above including: American Psychiatric Association, Royal College of Psychiatrists, Scottish ECT Accreditation Network and ECT Recommendations for Health Authorities of British Columbia. The guideline review helped to determine what elements of care were important for the measurement of quality in designing an effective audit tool. The project was reviewed by the University of South Carolina IRB and was determined to be exempt from human subjects oversight. Once a draft of the audit tool was created, an interprofessional ECT task force was convened to review the tool and discuss barriers to implementation. Piloting of the tool was approved by the facility quality director.
2. A pilot audit was performed for 10 procedures to determine the practicality and ease of use of the tool. The audit tool was then tested by another RN not directly involved in the ECT program to determine transferability. Making criteria as specific as possible promoted consistency of results between audit users. Adjustments were made based on identified barriers. Some of these changes included: adding more specific time frames to preprocedural testing parameters, specifying consent frequency and adding urine pregnancy testing parameters.
3. Staff who worked regularly with ECT (including both nurses and physicians) were given a copy of the ECT audit tool and educated regarding the new quality

improvement process prior to initiation. This allowed an opportunity to address any questions regarding current procedural processes or documentation.

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5. Results from monthly audits were analyzed and outcomes were thoroughly described. Considerations for possible practice changes were based on areas of concern and compliance rates were compared against target goals. The new quality audit process was critiqued by staff to determine if it was still feasible and met the program's clinical needs.
6. In the future, staff will be updated regarding recognized deficits through individualized meetings and additional ECT Task Force meetings as necessary. The ECT Coordinator, who takes responsibility for ECT quality assurance efforts, should direct these meetings and review previous audit benchmarks so that accountability for performance can be encouraged. The results were integrated into the hospital's quarterly quality committee meeting in order to create a sustainable and integrated quality assurance protocol. Policy changes were suggested to better align with audit criteria and available guidelines. The ECT coordinator will collaborate with facility

administration to assure consistency between ECT policies and procedures and quality assurance documents.

RESULTS

There were strengths and barriers to implementation of this quality assurance strategy. The developed audit tool was more helpful in realizing areas for potential improvement in clinical practice and consistently revealed more practice deficits than the previous general surgery audit. The results were more specific and allowed for easier translation into an action plan for correction. However, the newly developed audit tool did take longer to complete than the general surgery audit largely due to having to locate information from several sources including the electronic record, paper chart, and scanned documents. Each audit took the ECT Coordinator an estimated 15 minutes to complete. The audit also provided clarity on opportunities to enhance the facility ECT policy in accordance to the audit, including: a specified consent frequency, detailing elements of comprehensive procedure documentation, clarifying roles/tasks, specifying parameters for preoperative testing and refining discharge procedures.

While nurses conveyed satisfaction with clarification of expectations surrounding ECT care, a few nurses discussed concern that the criteria were excessive in some areas. For example, the criteria originally called for temperature to be measured in the last set of vital signs prior to discharge. However, nurses noted the temperature is already measured in the first recovery phases after treatment. Simplification of the audit tool included eliminating duplicate tasks revealed by ECT staff review. Additionally, nurses expressed some confusion over which staff were responsible for some tasks, including

administration of the outcome monitoring tools (e.g. PHQ-9) or ensuring the laboratory results were current. The need for role clarification as well as adapting more thoroughly described standards (consistent with the new audit criteria) through policy revision became imperative. A more collaborative relationship formed with the anesthesia staff, who seemed to appreciate being involved in determining care standards and in having the ECT Coordinator assist in ensuring standards were being monitored according to their directives.

Although the focus of this project was the development of an evidence-based strategy for quality assurance in ECT, there were possible practice issues revealed by the audit process. During the comprehensive audit of all ECT procedures performed during the months of May and June 2017 (N=87), there were findings that will require future exploration and discussion including: lack of documentation for post-anesthesia evaluation by the primary anesthesia team, missing elements of postprocedural vital sign documentation, and deficits for the preparation and care of patients noted to be of child-bearing age or diabetic through urine pregnancy testing and blood glucose checks. Many of these deficits had not yet been adequately addressed by the facility policy and were integral in realizing deficits for necessary policy revision.

DISCUSSION

The literature provides scant guidance in effective quality assurance strategies concerning the use of therapy and there was difficulty in obtaining responses from other ECT programs regarding their quality assurance activities. Despite contacting numerous facilities by that included ECT as a treatment option, there was a notable absence of

quality assurance protocols in use. While audit and feedback has been widely used and its effects often show positive impacts on outcomes, its application to ECT required some level of extrapolation. This project does demonstrate that implementing a quality assurance framework is feasible to monitor ongoing procedure quality in the delivery of ECT. This attempt to ensure quality assurance of ECT is just a foundation in the more complex and ongoing needs of ensuring quality within a clinical service. Audit results alone do not represent quality independently without an accompanying action plan, intervention, and reevaluation.

Adding further scope to quality efforts will be important for maturation of quality efforts. While the audits were helpful in establishing more technical features of care, they did not address how providers were serving the subjective needs of patients or how patients experienced care. It is also certainly possible that appropriate documentation of care failed to align with the reality of care actually provided, as criteria were measured retrospectively rather than in real-time or through direct observation. Piloting the audit tool for every procedure during the two month time frame allowed for special patient populations to be captured, such as: inpatient and outpatient procedures, those with chronic medical conditions, those being treated for indications other than depression, and those in both maintenance and acute phase ECT. The ECT clinical coordinator at the hospital site completed the audits and reviewed the data for the project. This increased validity and feasibility as expert insight informed ECT audit strategies. The setting of this project is a small, growing program that has a very distinct process that may not be representative of national ECT care trends or facility policies. Certain standards used in the audit tool are unique to this particular facility and may not be consistent with other

facility policies regarding ECT. As an example, elements of adequate medical workup prior to ECT vary considerably among guidelines and details for frequency of testing for ongoing treatment is largely neglected. Until a more solid stance is ascertained, provider preference will likely dictate these issues. Each patient is unique, requiring patient-centered adaptation based on clinical presentation. However, compliance is still a useful facet of care regardless of the specific standard instituted. Compliance was determined as a dichotomized "met" or "unmet" therefore, if there was a missing element of data, the whole measure was noted as deficit. For example, if all vitals were present except for temperature, the vital sign criterion was noted as "unmet". This decision was made in order to apply clear boundaries to the criteria and was not necessarily mandated by reviewed guidelines. Ultimately, these nuances reflect the importance of tailoring quality efforts to each individual facility as appropriate.

Cognitive monitoring was a consistent recommendation found in guideline review that had yet to be fully integrated into practice at this facility. While a Likert-style assessment of subjective memory function is assessed, no validated tool has been hardwired into policy. Future areas worth considering include: addition of live observation as a additional means of ensuring safe practice and staff competency, assessing patient understanding of their care and consent processes, surveying for patient satisfaction, and implementation of an effective cognitive monitoring protocol through the use of a validated measurement tool.

CONCLUSION

Quality is an increasingly important aspect of providing care, not only in terms of safety, but also in promoting health care system accountability and value of services. Without establishing consensus, evidence-based quality standards for ECT, actual quality is unknown and quality improvement is unattainable. ECT is a highly technical procedure, perfectly amenable to the scrutiny of observation and guidance by clinical standards. This project shows the potential value of examining care provided during ECT by both highlighting areas of achievement and areas requiring future development. While criteria will certainly vary somewhat based on facility policy and provider preferences, it seems prudent that care be measured objectively. Providing quality electroconvulsive therapy to patients is the responsibility of the team as a whole and further ongoing efforts should be made to promote consistent, high-level, guideline-based care. As Coffey[21] contends, a "quality chasm" still exists in ECT care and providing a mechanism for monitoring procedural quality is just one opportunity that exists in closing this gap. A comprehensive quality assurance protocol for the delivery of ECT will combine regular clinical audit and team-based problem solving to address clinical issues. Consistent outcome reviews and system revisions will help promote long-term success. This process is dynamic; helping to ensure that adherence promotes improved outcomes for patients, providers, and the facility.

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CHAPTER 3

RESULTS

RESULTS OF THE QUALITY ASSURANCE PROCESS

There were strengths and barriers to implementation of this quality assurance strategy. The developed audit tool was more helpful in realizing areas for potential improvement in clinical practice and consistently revealed more practice deficits than the previously used general surgery audit. The results were more specific to the delivery of ECT and allowed for easier translation into an action plan for correction. In spite of this, the newly developed audit tool did take longer to complete than the general surgery audit largely due to having to locate information from several sources including the electronic health record, paper chart, and scanned documents. Each audit took the ECT Coordinator an estimated 15 minutes to complete. The audit also provided clarity on opportunities to enhance the facility ECT policy in accordance to the audit, including: a specified consent frequency, detailing elements of comprehensive procedure documentation, clarifying roles/tasks, specifying parameters for preoperative testing and refining discharge procedures. Many elements of care had simply not been addressed in a collaborative manner prior to this project and starting a conversation between the providers, nursing staff, and administration to review these issues was of immeasurable importance.

While nurses conveyed satisfaction with clarification of expectations surrounding ECT care, a few nurses discussed concern that the criteria were excessive in some areas. For example, the criteria originally called for temperature to be measured in the last set of

vital signs prior to discharge. However, nurses noted the temperature is already measured in the first recovery phase after treatment. Simplification of the audit tool included eliminating duplicate tasks revealed by ECT staff review. Additionally, nurses expressed some confusion over which staff were responsible for some tasks, including administration of the outcome monitoring tools (e.g. PHQ-9) or ensuring the medical workup results were current. The need for role clarification as well as adapting more thoroughly described standards (consistent with the new audit criteria) through policy revision became imperative. A more collaborative relationship formed with the anesthesia staff, who seemed to appreciate being involved in determining care standards and in having the ECT Coordinator assist in ensuring standards were being monitored according to their desired directives.

Although the focus of this project was the development of an evidence-based strategy for quality assurance in ECT, there were possible practice issues revealed by the audit process (Table 3.1). During the comprehensive audit of all ECT procedures performed during the months of May and June 2017 (N=87), there were findings that will require future exploration and discussion including: lack of documentation for post-anesthesia evaluation by the primary anesthesia team, missing elements of postprocedural vital sign documentation, and deficits for the preparation and care of patients noted to be of child-bearing age or diabetic through urine pregnancy testing and blood glucose checks. Many of these deficits had not yet been adequately addressed by the facility policy and were integral in pinpointing necessary policy revision to promote future compliance. The quality criteria continued to develop after this initial review, due in large part to continual dialogue with the facility administration and the providers. The

sustained use of auditing practices through the revised quality criteria will be useful in confirming these deficits as part of the larger quality assurance strategy and will guide future activity. It is important to note that the quality standards will likely need even further revision in the future based on evidence-advancement and evolving facility demands.

Table 3.1 Preliminary Audit Findings

May 2017	# of Cases	% Total	Target
H&P Documented/Updated by Psychiatrist within the Last 30 Days	49	100%	100%
Indication for ECT Documented by Psychiatrist	49	94%	100%
Stimulus Settings Documented	49	100%	100%
Motor and EEG Seizure Lengths Recorded	49	100%	100%
Anesthetic and Muscle Relaxer Dosing Documented	49	94%	100%
Procedure Note from Performing Physician Documented	49	100%	100%
Preanesthesia Evaluation Documented by Anesthesiologist	49	100%	100%
Medication List Documented	49	100%	100%
CBC, CMP Documented Within 6 Months, Unless Prescribed Diuretics (1 Month), or in ESRD (Day of Procedure)	49	100%	95%
EKG Documented Within 6 Months	49	92%	95%
Urine Pregnancy Obtained if 15-57 and No Prior Tubal Ligation or Hysterectomy	8	75%	95%
Informed Consent Performed and Documented Within the Calendar Month	49	100%	100%
NPO Status Confirmed and Documented	49	100%	100%
Medication Changes Reviewed	49	100%	100%
Allergies Documented	49	100%	100%
Baseline and Discharge Vital Signs Documented Completely	49	47%	95%
Pain Assessed and Documented Pre and Postprocedure	49	96%	95%
Blood Glucose Measured in Diabetic Patients Pre and Postprocedure	3	0%	95%
Preprocedure Medications Given Per MD Orders	49	100%	100%
Orientation Status Documented Pre and Postprocedure	49	98%	95%
Outcome Measurement Tool Completed for Indication	49	96%	95%
Preprocedure Time Out Documented	49	100%	100%

Electrode Placement Documented	49	100%	100%
IV Discontinue Time Documented	49	98%	95%
Fluid Administration Totals Documented	49	94%	95%
Postoperative Anesthesia Assessment Documented and Signed	49	10%	100%
Written Discharge Directions Signed for by Patient/Family Member/Caregiver if Outpatient	49	86%	95%
Discharge Time Documented	49	92%	95%
Presence of Dental Injury from Procedure	49	0%	0%
Unplanned Medical Admission	49	0%	0%
June 2017	# of Cases	% Total	Target
H&P Documented/Updated by Psychiatrist within the Last 30 Days	38	100%	100%
Indication for ECT Documented by Psychiatrist	38	97%	100%
Stimulus Settings Documented	38	100%	100%
Motor and EEG Seizure Lengths Recorded	38	100%	100%
Anesthetic and Muscle Relaxer Dosing Documented	38	100%	100%
Procedure Note from Performing Physician Documented	38	100%	100%
Preanesthesia Evaluation Documented by Anesthesiologist	38	100%	100%
Medication List Documented	38	100%	100%
CBC, CMP Documented Within 6 Months, Unless Prescribed Diuretics (1 Month), or in ESRD (Day of Procedure)	38	100%	95%
EKG Documented Within 6 Months	38	97%	95%
Urine Pregnancy Obtained if 15-57 and No Prior Tubal Ligation or Hysterectomy	7	86%	95%
Informed Consent Performed and Documented Within the Calendar Month	38	95%	100%
NPO Status Confirmed and Documented	38	100%	100%
Medication Changes Reviewed	38	100%	100%
Allergies Documented	38	100%	100%
Baseline and Discharge Vital Signs Documented Completely	38	71%	95%
Pain Assessed and Documented Pre and Postprocedure	38	97%	95%
Blood Glucose Measured in Diabetic Patients Pre and Postprocedure	5	0%	95%
Preprocedure Medications Given Per MD Orders	38	100%	100%
Orientation Status Documented Pre and Postprocedure	38	100%	95%
Outcome Measurement Tool Completed for Indication	38	87%	95%
Preprocedure Time Out Documented	38	100%	100%
Electrode Placement Documented	38	100%	100%
IV Discontinue Time Documented	38	97%	95%
Fluid Administration Totals Documented	38	95%	95%

Postoperative Anesthesia Assessment Documented and Signed	38	39%	100%
Written Discharge Directions Signed for by Patient/Family Member/Caregiver if Outpatient	38	97%	95%
Discharge Time Documented	38	89%	95%
Presence of Dental Injury from Procedure	38	0%	0%
Unplanned Medical Admission	38	0%	0%

IMPLICATIONS FOR PRACTICE AND POLICY

There seems to be a definitive response to the PICOT question based on the findings of this project; auditing procedures through clearly delineated evidence-based standards improved recognition of compliance with clinical guideline recommendations more effectively than general surgical auditing processes. None of the deficits uncovered by this project had been recognized by the previously used general surgical care audit and meaningful insight was provided for future quality improvement projects. These results demonstrate that clinical monitoring is feasible and useful in the delivery of ECT.

Equally as important, this project highlighted the need for regular review of facility policy to ensure that adequate detail and clarity is provided and that care adheres to the best evidence-based care standards available. Effective written policy and procedures are important safeguards in guiding care and are fundamental in establishing a quality assurance program. Policy should steer standard education and training of ECT staff in order to provide clear directions on the expectations for performance. Regular and methodical critique of policy should continue to guide practice at Aiken Regional Medical Centers.

This quality assurance strategy was accomplished by the successful partnership of the many disciplines involved in the delivery of ECT. Providers, nurses, and administration were able to clarify their expectations for care and desired treatment outcomes. Using a team approach, the audit tool was developed with consideration of many different perspectives with feedback integrated to hone the final outcome. By compelling the team to directly address issues that had long been neglected, this project ultimately improved the flow of communication. Quality was brought the forefront of care and was affirmed as a priority for the ECT program.

The role of the nurse as a champion of quality and change agent was emphasized by this project. While the literature often neglects the recognition of nurses in the delivery of ECT, they serve an indispensible function in the application of evidence-based research, guidance of quality assurance activities, facilitation of interdisciplinary collaboration, and in the delivery of high quality health care services. Nurses are central to the successful delivery of ECT and efforts should be made to promote further research and project development regarding the role of nurses in this specialized field.

DISCUSSION

The literature provides scant guidance in effective quality assurance strategies concerning the use of therapy and there was difficulty in obtaining responses from other ECT programs regarding their quality assurance activities. Contact with numerous facilities that included ECT as a treatment option revealed a notable absence of quality assurance protocols in use. While audit and feedback has been widely used and its effects often show positive impacts on outcomes, its application to ECT required some

level of extrapolation. This project does demonstrate that implementing a quality assurance framework is feasible to monitor ongoing procedure quality in the delivery of ECT. This attempt to ensure quality assurance of ECT delivery is just a foundation in the more complex and ongoing needs of ensuring quality within a clinical service. Audit results alone do not represent quality independently without an accompanying action plan, intervention, and reevaluation.

Adding further scope to quality efforts will be important for maturation of quality efforts. While the audits were helpful in establishing more technical features of care, they did not address how providers were serving the subjective needs of patients or how patients experienced care. It is also certainly possible that appropriate documentation of care failed to align with the reality of care actually provided, as criteria were measured retrospectively rather than in real-time or through direct observation. Piloting the audit tool for every procedure during the two-month time frame allowed for special patient populations to be captured, such as inpatient and outpatient procedures, those with chronic medical conditions, those being treated for indications other than depression, and those in both maintenance and acute phase ECT. The ECT Coordinator at the hospital site completed the audits and reviewed the data for the project. This increased validity and feasibility as expert insight informed ECT audit strategies. The setting of this project is a small, growing program that has a very distinct process that may not be representative of national ECT care trends or facility policies. Certain standards used in the audit tool are unique to this particular facility and may not be consistent with other facility policies regarding ECT. As an example, elements of adequate medical workup prior to ECT vary considerably between guidelines and details for frequency of testing

for ongoing treatment is largely overlooked. Until a more solid stance is ascertained, provider preference will likely dictate these issues. Each patient is unique, requiring patient-centered adaptation based on clinical presentation. Nonetheless, compliance is still a useful facet of care regardless of the specific standard instituted. Compliance was determined as a dichotomized "met" or "unmet" therefore, if there was a missing element of data, the whole measure was noted as deficit. For example, if all vitals were present except for temperature, the vital sign criterion was noted as "unmet". This decision was made in order to apply clear boundaries to the criteria and was not necessarily mandated by reviewed guidelines. Ultimately, these nuances reflect the importance of tailoring quality efforts to each individual facility as appropriate.

FUTURE PROJECTS

This project is just the first step to a comprehensive and effective quality assurance strategy. There are numerous ways in which this facility's quality strategy might be expanded in scope. Cognitive monitoring was a consistent recommendation found in guideline review that had yet to be fully integrated into practice at this facility. While a Likert-style assessment of subjective memory function is assessed at each treatment, no validated tool has been hardwired into policy. As this was a recognized deficit early on, efforts were made to begin the evidence review for possible clinical solutions with intentions to eventually integrate this concept into the procedural audit. The addition of live observation as an additional means of clinical evaluation might further validate that quality measures are actually being met as prescribed. As an example, retrospective documentation that preprocedural timeout has been performed

provides less information than the performance assessment of a live timeout. While this project focused on several objective quality measures, there are critical aspects of care that are subjective in nature including assessment of patients' understanding related to their care and patient satisfaction in rendered services. Just as in other areas of healthcare, patient satisfaction is crucial for success of an ECT service. Feedback from such efforts allows patients to participate firsthand in identifying areas for further development and in enhancing overall experience. This could be easily achieved through supplying patients with ECT-specific patient satisfaction surveys either through the mail or at their last treatment day, allowing for anonymous reporting to the hospital quality department. Additionally, in supporting efforts to increase the electronic storage of healthcare information, supported by the federal government through such initiatives as Meaningful Use, there seems to a prime opportunity in this ECT program to develop more consistency and ease of use by including more elements of ECT care in the electronic health record. This would allow not only for the elimination of extra materials but a reduction in paid-time needed to appropriately keep charts in order or locate documentation from various sources. Finding necessary documentation over time would be easier and less subject to document loss. While this initiative would significant time and financial investment by the hospital, there are some simpler solutions that might adapt the current documentation system. These include creating specific areas in the current paper record to help promote documentation compliance to quality criteria such as urine pregnancy testing results. It will be useful to find a practical method to communicate individual needs for each patient to the nurse or provider administering care. This might be achieved through a risk or special needs communication sticker

located inside the chart. It seems sensible to have a mechanism for identifying special populations, such as diabetics or those requiring additional preprocedural preparation, to serve as a reminder to staff to perform the necessary tasks required for compliance.

DISSEMINATION

Due to the significance of this subject matter and its direct impact on providing effective ECT, an abstract will be submitted to the International Society for ECT and Neurostimulation (ISEN) in December 2017 in hopes of acceptance for poster or podium presentation at the annual conference, which will take place in New York, NY in May 2018. The abstract (Appendix D) was formatted in accordance to standards for submission found on the ISEN website. This conference will be a fundamental site for dissemination, exchange of ideas, and further discussion with other providers of ECT.

CONCLUSION

Quality is an increasingly important aspect of providing care, not only in terms of safety, but also in promoting healthcare system accountability and value of services. Without establishing consensus, evidence-based quality standards for ECT, actual quality is unknown and quality improvement is unattainable. ECT is a highly technical procedure, perfectly amenable to the scrutiny of observation and guidance by clinical standards. This project shows the potential value of examining care provided during ECT by both highlighting areas of achievement and areas requiring future development. While criteria will certainly vary somewhat based on facility policy and provider preferences, it is prudent that care be measured objectively. Providing quality

ECT is the responsibility of the team as a whole and ongoing efforts should be made to promote consistent, high-level, guideline-based care. Continued outcome reviews and system revisions will help promote long-term success. This process is dynamic; helping to ensure that adherence promotes improved outcomes for patients, providers, and the facility. As Coffey (2003) contends, a "quality chasm" still exists in ECT care and providing a mechanism for monitoring procedural quality is just one opportunity to close this gap. A comprehensive quality assurance strategy for the delivery of ECT combines regular clinical audit, collaborative team-based problem solving, a framework to address clinical change, and policy informed by best practice.

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APPENDIX A

AUDIT TOOL

Aiken Regional Medical Centers Electroconvulsive Therapy Procedural Audit

Patient FIN: _____

Date of Procedure: _____

Auditor: _____

Date of Audit: _____

Involved Staff: _____

Preprocedure	Compliance		
Indication for ECT Documented by Psychiatrist	YES	NO	N/A
H&P Documented/Updated by Psychiatrist within the Last 30 Days	YES	NO	N/A
Medication List Documented	YES	NO	N/A
Medication Changes Reviewed	YES	NO	N/A
Allergies Documented	YES	NO	N/A

Preanesthesia Evaluation Documented by Anesthesiologist	YES	NO	N/A
CBC, CMP Documented Within 6 Months, Unless Prescribed Diuretics (1 Month), or in ESRD (Day of Procedure)	YES	NO	N/A
EKG Documented Within 6 Months	YES	NO	N/A
Urine Pregnancy Obtained if 15-57 and No Prior Tubal Ligation or Hysterectomy	YES	NO	N/A
Informed Consent Performed and Documented Within Calendar Month	YES	NO	N/A
NPO Status Confirmed and Documented	YES	NO	N/A
Baseline and Discharge Vital Signs Documented	YES	NO	N/A
Pain Assessed and Documented Pre and Postprocedure	YES	NO	N/A
Blood Glucose Measured in Diabetic Patients Pre and Postprocedure	YES	NO	N/A
Preprocedure Medications Given Per MD Orders	YES	NO	N/A
Orientation Status Documented Pre and Postprocedure	YES	NO	N/A
Outcome Measurement Tool Completed for Indication	YES	NO	N/A
Preprocedure Time Out Documented	YES	NO	N/A

Intraprocedure			
Anesthetic and Muscle Relaxer Dosing Documented	YES	NO	N/A
Electrode Placement Documented	YES	NO	N/A
Stimulus Settings Documented	YES	NO	N/A
Motor and EEG Seizure Lengths Recorded	YES	NO	N/A
Postprocedure			
IV Discontinue Time Documented	YES	NO	N/A
Fluid Administration Totals Documented	YES	NO	N/A
Postoperative Anesthesia Assessment Documented and Signed	YES	NO	N/A
Procedure Note from Performing Physician Documented	YES	NO	N/A
Written Discharge Directions Signed for by Patient/Family Member/Caregiver if Outpatient	YES	NO	N/A
Discharge Time Documented	YES	NO	N/A
Presence of Dental Injury from Procedure	YES	NO	N/A
Unplanned Medical Admission	YES	NO	N/A

Notes: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____			

APPENDIX B

EVIDENCE TABLE

STRENGTH of the Evidence	
Level I	Experimental study/randomized controlled trial (RCT) or meta analysis of RCT
Level II	Quasi-experimental study
Level III	Non-experimental study, qualitative study, or meta-synthesis.
Level IV	Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)
Level V	Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience e.g., quality improvement and financial data; clinical expertise, or personal experience)

(Newhouse, Dearholt, Poe, Pugh, &White, 2005)

Reference, Type of study, Evidence Level	**Methods**	**Threats to Validity/ Reliability**	**Findings**	**Conclusions**
Bogert, M., Binnekade, J., Paulus, F., Goossens A., Vroom, M., & Dongelmans, D. (2016). Timely individual audit and feedback significantly improves transfusion bundle compliance-a comparative study. *International Journal For Quality In Health Care*, *28*(5), 601-607. Level 2-Quasiexperimental	-study investigated transfusion bundle compliance between two audit and feedback (A&F) strategies in implementation of a transfusion bundle -conducted in an ICU of a university hospital from May to December 2014 -ICU consisted of two nursing teams containing 63 and 62 nurses -monthly A&F on team level versus a combination of monthly A&F on team level plus timely individual feedback	-conducted in a single hospital in a 'closed-format' ICU, limits the external validity of results -did not measure the quality of the transfusion bundle itself -used bundle checklists to track compliance as recommended by the IHI, could be a discrepancy between actual delivered care and the reported care -bundle compliance was self-reported by nurses	-monthly A&F on team level with timely individual A&F significantly improves bundle compliance during implementation compared to monthly A&F on team level alone -overall effect of compliance during the study period was significantly higher -indicated that when using the combined A&F strategy, nurses are more likely to be compliant to the bundle than when monthly A&F was used alone	-compared to monthly team A&F alone, providing timely individual A&F plus monthly A&F on team level significantly improves the success of implementing a transfusion bundle on the ICU during the implementation period -providing timely individual A&F plus monthly A&F on team level might also be effective for the implementation of other bundles in healthcare
Corwin, P., & Bolter, T. (2014).	-investigated the quality of referrals in a group of	-sample was too small to include a control group not	-feedback improved the quality of	-feedback given to practitioners and nurses can

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
The effects of audit and feedback and electronic referrals on the quality of primary care referral letters. *Journal Of Primary Health Care*, *6*(4), 324-327. Level 2- Quasiexperimental	general practitioners -quality determined using a nine-point checklist; written feedback on referral letter quality was given and referrals reassessed five months later	receiving feedback on their referrals -lengthy letters scored well on the checklist despite potentially being difficult to follow	referral letters in participants whose original referral letters were found to be poor quality -average score for referral letters was 81.496 at baseline, which improved to 86.9% after feedback	improve the quality of referral letters to secondary care
Dulko, D., Hertz, E., Julien, J., Beck, S., & Mooney, K. (2010). Implementation of cancer pain guidelines by acute care nurse practitioners using an audit and feedback strategy. *Journal Of The American Academy Of Nurse Practitioners*, *22*(1), 45-55. Level 2- Quasiexperimental	-study evaluated the effect of an audit and feedback intervention on nurse practitioner implementation of cancer pain clinical practice guidelines and hospitalized patients' self-report of pain and satisfaction -8 NPs and two groups of 96 patients were the sources of data; patients in both groups completed the Brief Pain Inventory-Short Form (BPI-SF) within 24 h of admission and every 48 h until discharge -during audit and feedback NPs received weekly	-conducted on services that were predominately NP managed -did not measure concurrently occurring symptoms or quality of life -did not evaluate pain across time and may not have accounted for a lag time between the intervention and the effect -may have underpowered study to detect differences in pain severity -study period only lasted 3 months, unknown if the results of intervention will	-NP adherence to clinical practice guidelines increased during audit and feedback -pain intensity did not significantly differ between groups; intervention group patients reported significantly less overall pain interference, interference with general activity and sleep -satisfaction with pain relief increased from 68.4% to 95.1% during audit and feedback	-audit and feedback is an effective strategy to promote clinical practice guideline adherence

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
	feedback on pain scores and guideline adherence	persist		
Dupont, C., Deneux-Tharaux, C., Touzet, S., Colin, C., Bouvier-Colle, M., Lansac, J., & ... Piccin, G. (2011). Clinical audit: A useful tool for reducing severe postpartum hemorrhages? *International Journal For Quality In Health Care*, *23*(5), 583-589. Level 2- Quasiexperimental	-study conducted quarterly clinical audit meetings at which a team of reviewers analyzed all cases of severe postpartum hemorrhage; provided feedback on quality of care and where all staff actively participated	-initial audit meeting was part of a research program, the routine use of the audit that followed was a local initiative so the external validity of the results may thus be questionable -not a representative sample, only severe cases used -external factors may have contributed to this decrease -proportion of women at risk decreased over time	-prevalence of severe postpartum hemorrhage declined significantly from 1.52 to 0.96% in the level III hospital and from 2.08 to 0.57% in the level II hospital -proportion of deliveries with severe postpartum hemorrhage that was managed consistently with the guidelines increased for all of its main components	-regular clinical audits of cases severe postpartum hemorrhage were associated with a persistent reduction in the prevalence
Hysong, S., & Hysong, S. J. (2009). Meta-analysis: Audit and feedback features impact effectiveness on care quality. *Medical Care*, *47*(3), 356-363. Level 1-	-analysis completed using studies cited by Jamtvedt's 2006 Cochrane systematic review of audit and feedback, followed by database searches using the Cochrane review's search strategy to identify more	-large number of studies excluded from analysis; small resulting sample size	-519 studies initially identified, 19 met all inclusion criteria -studies were most often excluded due to the lack of a feedback-only arm -audit and feedback has a	-audit and feedback effectiveness is improved when feedback is delivered with specific suggestions for improvement, in writing, given frequently

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
Meta-analysis of RCTs	recent studies -meta-analytic procedures using the Hedges-Olkin method		modest, yet significant positive effect on quality outcomes -providing specific suggestions for improvement, written, and more frequent feedback strengthened this effect, whereas graphical and verbal feedback attenuated this effect	
Ivers N., Jamtvedt G., Flottorp S., Young J.M., Odgaard-Jensen J., French S.D., O'Brien M.A., Johansen M, Grimshaw J., Oxman A.D. (2012). Audit and feedback: Effects on professional practice and healthcare outcomes. Cochrane Database of Systematic Reviews Issue 6. Art. No.: CD000259. Level 1- Systematic Review of RCTs	-study explored the estimate of effect over time; whether new trials have added to knowledge regarding how optimize the effectiveness of audit and feedback -compiled from the Cochrane Central Register of Controlled Trials, MEDLINE, and EMBASE for randomized trials of audit and fee-dback compared to usual care, with objectively measured outcomes assessing compliance with intended professional practice -two reviewers independently	-none recognized	-analyzed 140 studies for this review -total of 108 comparisons from 70 studies compared any intervention in which audit and feedback was a core, essential component to usual care and evaluated effects on professional practice -after excluding studies at high risk of bias, there were 82 comparisons from 49 studies featuring dichotomous outcomes and the weighted median adjusted RD was a 4.3% absolute increase	-audit and feedback generally leads to small but potentially important improvements in professional practice -effectiveness of audit and feedback seems to depend on baseline performance and how the feedback is provided

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
	screened articles and abstracted variables related to the intervention, context, trial methodology -median absolute risk difference in compliance with intended professional practice was determined for each study, and adjusted for baseline performance -meta-regressions were conducted for studies published up to 2002, 2006, and 2010 in which characteristics of the intervention, the recipients, and trial risk of bias were tested as predictors of effect size		in healthcare professionals' compliance with desired practice -across 26 comparisons from 21 studies with continuous outcomes, the weighted median adjusted percent change relative to control was 1.3% -for patient outcomes, the weighted median RD was -0.4% for 12 comparisons from six studies reporting dichotomous outcomes and the weighted median percentage change was 17% for eight comparisons from five studies reporting continuous outcomes -multivariable meta-regression indicated that feedback may be more effective when baseline performance is low, the source is a supervisor or colleague, it is provided more than once, it is delivered in both	

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
			verbal and written formats, and when it includes both explicit targets and an action plan -the effect size varied based on the clinical behavior targeted by the intervention	
Ivers, N. M., Grimshaw, J. M., Jamtvedt, G., Flottorp, S., O'Brien, M. A., French, S. D., & ... Odgaard-Jensen, J. (2014). Growing literature, stagnant science? Systematic review, meta-regression and cumulative analysis of audit and feedback interventions in health care. *JGIM: Journal Of General Internal Medicine*, *29*(11), 1534-1541. Level 1- Systematic Review of RCTs	-study extended the findings of the Cochrane systematic review of audit and feedback on professional practice to explore the estimate of effect over time and examine whether new trials have added to knowledge regarding how optimize the effectiveness of audit and feedback	-many other potential variables, including the clinical topic and context, likely impact the effectiveness of the intervention -co-interventions may interact with the effect modifiers tested in the meta-regressions -reliance upon indirect comparisons and risk of ecological fallacy as relationships identified across studies through meta-regression may not reflect relationships evident within studies	-of the 140 randomized clinical trials (RCTs) included in the Cochrane review, 98 comparisons from 62 studies met the criteria for inclusion -cumulative analysis indicated that the effect size became stable in 2003 after 51 comparisons from 30 trials -cumulative meta-regressions suggested new trials are contributing little further information regarding the impact of common effect modifiers -feedback appears most effective when: delivered by a	-substantial evidence that audit and feedback can effectively improve quality of care but little evidence of progress in the field

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
			supervisor or respected colleague; presented frequently; featuring both specific goals and action-plans; aiming to decrease the targeted behavior; baseline performance is lower; and recipients are non-physicians	
Knaup, C., Koesters, M., Schoefer, D., Becker, T., & Puschner, B. (2009). Effect of feedback of treatment outcome in specialist mental healthcare: Meta-analysis. *The British Journal of Psychiatry*, *195*(1), 15-22. Level 2- Meta-analysis of Controlled Trials	-study reviewed the impact of feedback of outcome to practitioners and/or patients in specialist mental health services -used a systematic search and meta-analysis of controlled trials using outcome management in mental health services published in English or German language	-number of studies these data were drawn from was small and not particularly representative -number of researchers conducting this research is very small and could introduce bias - assessed studies varied considerably with regard to certain patient characteristics, most notably illness severity and comorbid disorders -majority of trials	-twelve studies met inclusion criteria -feedback outcome showed a small but significant positive short-term effect on the mental health of individuals that did not prevail in the long run -subgroup analysis revealed no significant differences regarding feedback modalities -outcome management did	-evidence on the effects of outcome management in mental healthcare is promising -more targeted research is needed in order to identify the effective ingredients of outcome feedback and to assess its cost-effectiveness

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
		relied on data from people with rather mild mental illness treated with outpatient psychotherapy -variations in study designs, measurement points had to be pooled in order to be able to examine persistence of effect -feedback was based on patient-reported outcomes whereas it might be worthwhile to also have data obtained from independent raters	not contribute to a reduction of treatment duration	
Kristensen, H., & Hounsgaard, L. (2014). Evaluating the impact of audits and feedback as methods for implementation of evidence in stroke rehabilitation. *British Journal Of Occupational Therapy*, *77*(5), 251-259. Level 3-	-study evaluated audit and feedback as method to increase implementation of evidence in stroke rehabilitation -sample of 22 occupational therapists participated from two Danish hospitals that admitted stroke patients -data collection methods included	-audit method depended on the accuracy of the therapists' medical records and documentation -therapists might have practiced in accordance with the clinical guidelines but failed to report this or over-reported their practice	-daily practice in both settings adapted to the clinical guidelines -implementation of the standardized assessment tools seemed to be the most successful	-effects of audit and feedback profited from the active participation of the therapists, as well as local gatekeepers having formal responsibilities for implementing change -process was strengthened by providing the audits and feedback

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
Qualitative	audits of occupational therapy medical records, documentations of daily practice, and collaborative discussions -active feedback and discussions of the findings took place at a group level in four local clinical audits -daily self-reported recordings and audits were descriptive, audit data were analyzed using descriptive statistics -phenomenological hermeneutical interpretive methodology was used for analyzing qualitative data			more than once -effect of audits and feedback was positively influenced by being in line with current conceptual frameworks, local policies, and values
Lamont, S., Brunero, S., Barclay, C., & Wijeratne, C. (2011). Evaluation of an electroconvulsive therapy service in a general hospital. *International Journal of Mental Health Nursing*, *20*(3), 223-229.	-study discussed the development and characteristics of an ECT service at a teaching hospital in Sydney, Australia -used mixture of methods, including a selective literature review and audit of ECT use -results of the audit	-lack of personal knowledge of patients and treatments, noted as problematic when interpreting or locating data -difficulty to accurately evaluate con-sistency with all aspects of the RANZCP's (2007) guidelines	-significant finding of the audit was that the majority of patients were treated under the New South Wales Mental Health Act -voluntary patients were more likely to have a diagnosis of a depressive disorder, whereas	-study shows that auditing of ECT practices and services by mental health nurses is essential for quality improvement processes -audit highlighted areas of service delivery that should be subject to

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
Level 4- Organizational Experience	were compared with the 2007 revision of the Royal Australian and New Zealand College of Psychiatrists' clinical memorandum on ECT -study examined issues such as the optimal site for ECT delivery, ECT mental health nurse coordinator role, credentialing of psychiatrists, registrar supervision, and the development of an ECT committee	as much information is difficult to locate through retrospective review	involuntary patients were more likely to have a non-mood disorder diagnosis	review and evaluation against professional standards
Lewis, C. M., Monroe, M. M., Roberts, D. B., Hessel, A. C., Lai, S. Y., & Weber, R. S. (2015). An audit and feedback system for effective quality improvement in head and neck surgery: Can we become better surgeons? *Cancer*, *121*(10), 1581-1587. Level 2- Quasiexperimental	-study used an evaluation system for measuring physician performance to determine whether an initial evaluation with surgeon feedback improved subsequent performance -after an evaluation of an initial cohort of procedures surgeons were given risk-adjusted individual feedback; procedures in a post feedback cohort were then assessed	-possible that surgical faculty, after the feedback sessions, became aware that they were being audited and so made changes to improve their performance -total period of data collection (2004-2010) coincided with a growing national awareness about the importance of such performance indicators as the length of stay, blood transfusion rate, and readmission rate -rates of blood transfusion	-factors affecting performance included the surgeon, the procedure's acuity, and patient co-morbidities -mean length of stay significantly decreased for LAPs from 2.1 to 1.5 days and for HAPs from 10.5 to 7 days -incidence of 1 or more negative performance indicators decreased significantly for LAPs from 39.1% to 28.6% and trended downward for	-periodic assessments of performance and outcomes are essential for continual quality improvement -significant decreases in the length of stay and negative performance indicators were seen after feedback -an audit and feedback system may be an effective means of improving quality of care and reducing practice variability within a surgical

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
		unavailable in post feedback cohort -variables collected were categorical and not continuous, unable to statistically evaluate them for outliers	HAPs from 60.9% to 53.5%	department
Maruthappu, M., Trehan, A., Barnett-Vanes, A., McCulloch, P., & Carty, M. (2015). The Impact of Feedback of Surgical Outcome Data on Surgical Performance: A Systematic Review. *World Journal Of Surgery*, *39*(4), 879-889. Level 2- Systemic Review of NRCTs	-study aimed to systematically review the impact of feedback of outcome data to surgeons on their performance -study design included search of MEDLINE, Embase, PsycINFO, AMED and the Cochrane Database of Systematic Reviews -2 reviewers independently reviewed citations using predetermined inclusion and exclusion criteria -42 data-points per	-conducted in different decades, clinical settings, for different procedures, using different methodologies and outcomes, with variability in the educational and techno-logical experience of participating surgeons -studies examined were poorly designed; few delivered feedback interventions in isolation -few studies adequately adjusted outcomes for patient-risk, clustering or the	-search yielded 1,531 citations -7 studies were eligible comprising 18,632 cases or procedures by 52 surgeons -feedback was found to be a powerful method for improving-surgical outcomes or indicators of surgical performance, including reductions in hospital mortality after CABG of 24 % decreases of stroke and mortality following carotid	-literature suggests that feedback can improve surgical performance and outcomes -due to heterogeneity, limited number of studies, and their non-randomized nature it is difficult to draw clear conclusions in regard to the efficacy of feedback and the specific nuances required to optimize the impact of feedback

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
	study were extracted	surgical learning curve, the latter of which may have led to improve-ments in performance over time, regardless of a feedback intervention -lack of randomization in any of the studies, difficult to distinguish the relative impact of feedback -possibility of publication bias; all studies demonstrated that feedback resulted in improvements in performance	endarterectomy -from 5.2 to 2.3 %, improved ovarian cancer resection from 77 to 85 % -reductions in wound infection rates from 14 to 10.3 % -improvements in performance occurred in concert with reduced costs: for hepaticojejunostomy, implementation of feedback was associated with a decrease in overall hospital costs from $24,446 to $20,240 -total cost of carotid endarterectomy and following management decreased from $13,344 to $9548	
Onalaja, D., Sultana, M., Afghan, S., & Coupe, T. (2008).	-study evaluated the effectiveness of a care pathway in the administration of	-small sample size, only considers one	-sixty courses of treatment were reviewed, all were given for severe	-use of a care pathway enhanced aspects of the clinical practice

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
Improving ECT practice with a care pathway: Hits and misses. *International Journal Of Psychiatry In Clinical Practice*, *12*(3), 235-237. Level 3- Quasiexperimental	electroconvulsive therapy (ECT) in a UK psychiatric inpatient unit -used a completed clinical audit cycle of the care pathway and notes variances	facility -does not clearly address the effects of the clinical audit and impacts on clinical outcomes	depressive disorder -consent was recorded for all but one course -clinical assessments were completed for 96% during and 50% after treatment	of ECT, but the overall effect was found inconsistent -ECT was not used to treat schizophrenia -maintenance ECT continues to be used despite NICE guidance on this subject -care pathway ensured regular clinical assessment of patients during their courses of ECT
Onerheim, R., Racette, P., Jacques, A., & Gagnon, R. (2008). Improving the quality of surgical pathology reports for breast cancer: A centralized audit with feedback. *Archives Of Pathology & Laboratory Medicine*, *132*(9), 1428-1431. Level 2- Quasiexperimental	- study evaluated the quality of surgical pathology reports for segmental breast resections for cancer in Quebec hospitals and then reevaluated the same indicators to determine if the first surveillance, with feedback was associated with an improvement in the quality of the reports -a committee of pathologists, after review of the literature, chose 7 diagnostic elements deemed vital to a surgical pathology	-likely that the study contributed to improved reporting and improved quality of care -possible that following the first review of charts, centers were able to begin a process of self-assessment resulting in changes to improve pathology reporting, before the results of the first analysis -quality of surgical pathology reports is topical	-conformity improved from 85.0% in 1999 for the first evaluation to 92.5% in 2003 for the second -6 of the 7 indicators showed an improvement in the level of conformity between the first and second evaluations	-surveillance of quality of surgical pathology reports, with feedback, is significantly associated with an improvement in the quality of reports

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
	report for conservative breast cancer surgery	in the medical literature and in continuing education courses, and these influences cannot be quantified - 2 indicators that showed low conformity rates in the first study, regression to the mean may explain some part of the observed improvement -did not reconfirm the accuracy of the medical archivists' performance in extracting the data in 2003, possibility that an improved performance on their part could have contributed to the findings		
Ulhaq, S., Nnatu, I., Kelly, S., & Sooky, R. (2011). Compliance with ECT NICE guidance by the John Connolly ECT clinic: January 2010-July 2010. *Psychiatria Danubina*, *23*(1), 99-103.	-reviewed current practice at the John Connolly Wing ECT clinic, explored compliance with NICE ECT guidelines -standards used included the ECT TA59 guidelines of 2003 with the updated depression guidance CG90 of	-due to time constraints, data was collected from Rio system only	-total of 14 patients were identified; 6 were male and 8 were female; comprised of 8 inpatients and 6 outpatients -majority of patients had a diagnosis a severe depressive	-audit highlighted the need for sound documentation of practice -audit stressed the need for further clarity regarding the roles and responsibilities of the RMO and their team, and

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
Level 4- Organizational Experience	2009 -retrospective baseline audit was conducted between January 2010 to July 2010 -cases were identified using ECT clinic record; computer Rio notes were reviewed for compliance with NICE guidelines per audit standards -all data was extracted from the case notes on the Rio system; an audit tool was completed for each case -data recorded on the audit tool was entered onto an Excel spreadsheet for analysis		episode -13 patients received bilateral ECT; in one case the first 3 sessions were unilateral and the rest were bilateral due to patient choice -9 patients consented to ECT; 5 lacked capacity to consent and 1 of those was treated under Section 62 of the Mental Health Act -number of treatments ranged from 0-15 with an average number of 7; included 1 patient who did not receive ECT at all due to concerns raised by anesthetist once at the ECT clinic -reasons for stopping ECT included a response being achieved in 5 patients; anesthetic risk in 3; withdrawal of	the ECT team -ECT Care Pathway document was produced to improve compliance with NICE guidance and improve documentation of practice

Reference, Type of study, Evidence Level	Methods	Threats to Validity/ Reliability	Findings	Conclusions
			consent in 2; T6 no longer valid in 1; no reason documented in 3 patients -compliance with NICE guidelines was particularly good regarding the indications for ECT -an adequate trial of treatment was evidenced prior to consideration of ECT -documentation of the risk to benefit ratio amongst the team and with the patient was poor -assessment of the patient after each ECT and ongoing cognitive assessment was poor	

APPENDIX C

LETTER OF IRB EXEMPTION

UNIVERSITY OF
SOUTH CAROLINA

OFFICE OF RESEARCH COMPLIANCE

INSTITUTIONAL REVIEW BOARD FOR HUMAN RESEARCH

DECLARATION of NOT RESEARCH

Jessa Hollingsworth
College of Nursing
1601 Greene Street
Columbia, SC 29208

Re: **Pro00066803**

This is to certify that research study entitled, "***Developing a Quality Assurance Strategy for Electroconvulsive Therapy,"*** was reviewed on **5/2/2017**, by the Office of Research Compliance, which is an administrative office that supports the University of South Carolina Institutional Review Board (USC IRB). The Office of Research Compliance, on behalf of the Institutional Review Board, has determined that the referenced research study is not subject to the Protection of Human Subject Regulations in accordance with the Code of Federal Regulations 45 CFR 46 et. seq.

No further oversight by the USC IRB is required. However, the investigator should inform the Office of Research Compliance prior to making any substantive changes in the research methods, as this may alter the status of the project and require another review.

If you have questions, contact Arlene McWhorter at arlenem@sc.edu or (803) 777-7095.

Sincerely,
Lisa M. Johnson
IRB Assistant Director

APPENDIX D

ABSTRACT FOR DISSEMENATION

Background: The literature provides scant guidance regarding quality assurance strategies in electroconvulsive therapy (ECT). Guidelines are published that provide guidance in the delivery of care, however, little has been done to determine how a facility might ensure compliance to best practice for safety, tolerability, and efficacy.

Objective: The objective of this project was to create a quality assurance strategy specific to ECT. Determining standards for quality care and clarifying facility policy were key outcomes.

Methods: An audit tool was developed utilizing quality criteria derived from review of ECT practice guidelines, peer review and facility policy. All ECT procedures occurring over May-June 2017 were retrospectively audited and compared against target compliance rates. Facility policy was adapted to reflect quality standards and audit findings were used to inform possible practice change initiatives, create benchmarks and were integrated into regular hospital quality meetings.

Results: Clarification on standards of care and the use of clinical auditing in ECT was an effective starting point in the development of a quality assurance strategy. Audit findings were successfully integrated into the hospital's overall quality program and recognition of practice compliance informed future quality development and policy revision.

Conclusion: This project sets the foundation for a quality assurance strategy that can be used to help monitor procedural safety and guide future improvement efforts in delivering ECT. While just the first step in creating meaningful quality improvement, setting clear standards and identifying areas of greatest clinical need was a crucial beginning for this hospital's growing program.

Keywords: electroconvulsive therapy, quality assurance, audit