Establishing a Standardized Facial Cosmetic Pre-Injection Safety

Tool: The ACIST

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Abstract

In the past twenty years, the American population has seen an increased demand for non-surgical minimally invasive facial rejuvenation solutions for the ageing process. However, this widespread and increased demand for cosmetic injections brings a greater propensity for complications and adverse events. Choosing suitable patients for dermal fillers is essential, as is concrete knowledge of the factors related to adverse events; however, there was no standardized tool to facilitate this process. The Joint Commission's Universal Safety checklist tools have been integrated into hospital surgical operating rooms and ambulatory outpatient settings across America and have successfully reduced errors in patient safety and outcomes. This paper establishes the importance of integrating a standardized pre-injection safety tool (the Assessment Cosmetic Injection Safety Tool, ACIST) into the cosmetic practice to decrease the incidence of adverse events associated with dermal fillers and to achieve optimal patient satisfaction and outcomes. The ACIST was designed from evidence-based literature, piloted at a southern U.S. urban cosmetic practice, finalized based on feedback from the pilot, and disseminated to cosmetic nurse injectors.

Keywords: dermal fillers, facial injections, facial rejuvenation, complications, treatment

Establishing a Standardized Facial Cosmetic Pre-Injection Safety Tool: The ACIST

For the past two decades, non-surgical cosmetic injections for facial enhancements and rejuvenation have increased by 313% among

American men and women between the ages of 20 and 70 (American Society of Plastic Surgeons [ASPS], 2018). In 2005, when many of these
procedures were in their infancy, looked at as off-label or as concepts only, and administered primarily by plastic surgeons (ASPS, 2018), 3.8 million
procedures were performed (ASPS, 2005). In contrast, in 2017 (twelve years later), 15.7 million minimally invasive cosmetic procedures were
performed by plastic surgeons and registered nurses (ASPS, 2018). Consequently, in 2005, approximately 1.71% of the U.S. adult population (1 out
of every 58) received cosmetic injections, compared with 6.23% (1 out of 16) in 2017. The increasing demand for cosmetic injection procedures has
created an ever-growing marketplace for new injectable products and innovative injection techniques, which, unfortunately, leads to an increased risk
of cosmetic injectable complications (Abduljabbar & Basendwh, 2016; Funt & Pavicic, 2015; Ibrahim, Overman, Arndt, & Dover, 2018; Kirkpatrick
& Foroglou, 2016; Uridiales-Galvez et al., 2017).

Problem Statement

Non-surgical dermal soft tissue fillers and neuromodulators are used to fill facial volume loss and wrinkles caused by a decrease in collagen production and a reduced elasticity of the aging skin. Cosmetic dermal soft tissue filler injections plump up facial volume and neuromodulators relax facial muscles, both of which produce a more youthful appearance. Neuromodulators and dermal soft-tissue cosmetic injection procedures are non-surgical in administration and have a high rate of patient outcome satisfaction (Liu, Beynet, & Gharavi, 2019). The non-surgical administration and treatment procedure is quick and causes little to no loss of work hours. Despite the benefits of cosmetic injections, there is a degree of risk.

All cosmetic soft tissue filler and neuromodulator injections have related risks such as immediate post-procedure superficial swelling, pain, redness, and bruising at the site of the injection (Funt & Pavicic, 2015; Graivier et al., 2018; Kirkpatrick & Foroglou, 2016; Urdiales-Galvez et al., 2018). However, delayed onset responses, such as broadened swelling, nodule formation, dermal eruptions, or excessive bruising, are thought to be

an immunologic response and typically present anywhere from two weeks to a year post-injection (Bhojani-Lynch, 2017; Funt & Pavicic, 2015; Ibrahim et al., 2018). In late-onset delayed complications, characteristic foreign body granulomas can form, which are thought to be hypersensitive immune reactions and difficult to treat (Beleznay, Carruthers, Carruthers, Mummert, & Humphrey, 2015; Bhojani-Lynch, 2017; Curi, Cardoso, Curra, Koga, & Benini, 2015; Funt & Pavicic, 2015; Ibrahim et al., 2018). There is no concrete data on the incidence of these adverse events due to the lack of a central reporting structure (Graivier et al., 2018).

Previous injections, certain diseases and disease states, and some medications could potentially predispose cosmetic injection patients to adverse events, including inflammatory lumps, bumps, nodules, and granulomas, as well as an acute stage of infection (Bhojani-Lynch, 2017; De Boulle & Heydenrych, 2015; Funt & Pavicic, 2015). Therefore, it is imperative for the injector to know the patient's medical and social history, including medications, previous injections, prior facial surgery, infections, or trauma (Bhojani-Lynch, 2017; De Boulle & Heydenrych, 2015). Knowing what warning factors would warrant caution for further nursing action or medical director counsel, and knowing when to avoid cosmetic injections altogether, is crucial for patient safety (De Boulle & Heydenrych, 2015; Funt & Pavicic, 2015; Urdiales-Galvez et al., 2018).

There are 23 different dermal soft tissue fillers available on the market today (Abduljabbar & Basendwh, 2016; Funt & Pavicic, 2015), all of which have differing property profiles and associated risks, making deciphering and retaining the information difficult, and increasing the possibility of mistakes and poor decisions. Without a resource to guide nurse injectors through the procedure property profiles and risks, he or she may be unaware of a combination of risk factors present in the patient, or unaware of the procedure's risk profile, or both. If the procedure is ultimately performed under these circumstances, patient safety can be compromised, and adverse events can occur (Kirkpatrick & Foroglou, 2016). Most adverse events can be avoided with a comprehensive patient assessment and safety checklist.

The Institute of Medicine (IOM) called for health care leaders to focus on improving patient safety and patient outcomes (Aspolen, Corrigan, Wolcott, & Erickson, 2003). Important concerns and primary goals of the advanced practice nurse leader align with the IOM and Joint

Commission's view on patient safety and include best practices for patient-centered quality nursing and health care, patient safety, positive outcomes, patient satisfaction, and preventing harm (Pipe, Fitzpatrick, Doucette, Cotton, & Arnow, 2016).

Safety checklist tools improve communication, increase patient safety, and decrease complications (Pugel, Simianu, Flum, & Patchen Dellinger, 2015). According to Schelkun (2014), "surgical safety checklists have contributed to a global decrease in morbidity and mortality after surgical procedures" (para. 1). Schelkun (2014) also found that even the simplest safety checklist decreased adverse events in the surgical arena, and it "did not require a costly, high-tech solution but rather a simple, almost 'no cost' attitude and procedural change in the operating theater" (para. 1). Although safety tools are not failsafe for the complete prevention of adverse events, consistent and correct usage of checklists is a key component in ensuring patient safety (Pugel et al., 2015, p. 1). Thus, standardized safety checklists produced by authoritative organizations are prevalent among nurses.

The Association of periOperative Registered Nurses (AORN) developed an all-inclusive standardized surgical safety checklist, which integrates safety tenets from the Joint Commission and the World Health Organization to reduce the incidence of errors and adverse events and increase positive communication throughout the surgical arena (Sadler, 2014). The Executive Director for the AORN, Linda Groah, provides further insight for patient safety and states, "the surgery checklist serves as a reminder of all the processes that are important for every patient, during every procedure, every time" (Sadler, 2014, p. 1). Similarly, the Institute for Safety in Office-Based Surgery (ISOBS) has a standardized safety checklist for Office-Based Surgery. However, while the IOM and the Joint Commission both stress the importance of patient safety, until now there have been no universal safety standards for cosmetic injection administration and no standard of care in assessment for the facial cosmetic injection patient population.

Until now, there has been no standardized assessment for injection patients. The patient selection process and the recognition of warning factors for potential adverse events is critical for patient safety and should be established during the pre-injection nurse-patient consultation interview. The standardized Assessment Cosmetic Injection Safety Tool (ACIST) has been developed specifically for this patient interview.

PICOT Question

The American culture places a noteworthy emphasis on health, wellness, and self-improvement. Both women and men continually seek ways to look and feel their best by making healthy food choices, participating in various forms of physical fitness (Quach et al., 2017), maintaining a youthful appearance, and preventing the signs of facial ageing through non-surgical cosmetic injections. Demand for non-surgical cosmetic injections has experienced a 12% upsurge in the past decade in America (ASPS, 2018). Cosmetic nurses who administer minimally invasive cosmetic injections are greatly concerned about patient safety. Many, but not all, cosmetic nurse injectors are board-certified and highly competent.

With the rise in cosmetic injections, nurse injectors have been seeing more adverse events, including hypersensitivity reactions and, even more seriously, biofilm and cosmetic injection complications (Abduljabbar & Basendwh, 2016; Artzi, Loizides, Verner, & Landau, 2016; Beleznay et al., 2015; Curi et al., 2015; Funt & Pavicic, 2015; Uridiales-Galvez et al., 2017). Many adverse events result in minor swelling and occasional bruising at the injection site; however, more complex and unfavorable outcomes such as granulomas, nodules, and biofilms can also occur (Bhojani-Lynch, 2017; Graivier et al., 2018; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018). With a comprehensive assessment and evaluation, proper patient selection, and the use of the ACIST, adverse events could be decreased or avoided (De Boulle & Heydenrych, 2015; Uridiales-Galvez et al., 2017; H. Wood, personal communication, January 17, 2018; G. Obi, personal communication, January 17, 2018).

With optimal patient outcomes and safety in mind, the ACIST (Appendix B) identifies a cosmetic patient's predisposition for adverse events as indicated by the number of warning boxes checked. Depending on the total number of warning boxes, the nurse injector should follow a course of

nursing action, seek medical direction, or not administer the cosmetic injection, thus keeping patient safety at the forefront of patient care and decreasing the incidence of adverse events.

The cosmetic injector has the responsibility to optimize patient safety in the cosmetic arena and reduce adverse events of filler injections. In this project, the question was posed: (P) In non-surgical patients seeking facial cosmetic rejuvenation (more specifically, facial enhancements) with cosmetic injectables, (I) does using a pre-injection safety tool (C) compared to not using the pre-injection safety tool (O) delay or avoid cosmetic injectables and decrease adverse events (T) over a ten-week time frame?

Doctor of Nursing Practice (DNP) nurse leaders strive to advance quality care in all patient populations and have the education to successfully implement changes for optimal patient safety in the health care arena. The DNP is the ideal change agent to develop and implement a safety checklist tool to ensure optimal patient safety for the cosmetic injection patient population.

Conceptual and Theoretical Framework

To institute a standardized safety tool into the cosmetic injection arena, an organizational change was implemented. The process of organizational change demonstrates changing or moving from a comfortable and known state to one of uncertainty or unfamiliarity (Hussain et al., 2018). Kurt Lewin's Change Theory, which was developed in the late 1940s, is still applicable to the present day and is widely used in nursing for quality and patient improvements in care (Hussain et al., 2018; Wojciechowski, Pearsall, Murphy, & French, 2016). Due to its broad applicability and appeal to nursing, Lewin's change theory was utilized in the DNP project.

Lewin's theory is a three-step model of linear change. Lewin's theory integrates three concepts: unfreeze, change, and refreeze, which are all applicable to this project's organizational strategies and framework (Wojciechowski et al., 2016). The change replaced outdated thinking and assessment with current and updated reasoning for an optimal change to deliver patient safety.

The first step of Lewin's change theory is unfreeze, where an awareness of the problem allows people to remove old patterns of doing. For this project's purpose, the unfreeze step made it possible for the cosmetic injection specialist to let go of outdated medical history intake forms. The second step of Lewin's theory is to change the old pattern or to move it in a different direction. For this project, the second step used the ACIST. The third step in Lewin's change theory is refreeze the new integration, which stabilized the organization change (Wojciechowski et al., 2016). For the project, the third step of change was to standardize the ACIST into the cosmetic injection specialists' armamentarium. Utilizing Kurt Lewin's change theory to implement the ACIST created a new and improved approach to address and identify potential adverse events in the cosmetic patient population.

Synthesis of the Literature

Methods

With the PICOT question in mind, a literature search was employed using the databases of PubMed, Ovid, and Google Scholar with the keywords of dermal fillers, facial injections, facial rejuvenation, complications, and treatment. Search results were limited to the English language with publication dates between 2013 and 2018. A total of 55 articles were found; however, not all were pertinent to the review criteria. Further information was gleaned from articles but was excluded based on the relevance of the cosmetic injectable and adverse events. Finally, 11 articles were chosen based on how well the topic related to dermal filler, adverse events, and the injector's technique. Articles were also selected based on the inclusion of facial anatomy, medical history assessment, patient selection, injection procedure care and post treatment, as well as complications and the practice recommendations.

Similarities

All 11 articles shared expert insights focused on dermal fillers, adverse events, treatments, and prevention. All articles claimed that non-surgical, minimally invasive dermal fillers are elective injection treatments that have become increasingly popular choices over traditional surgical

procedures. They further agreed that the increase in cosmetic procedures has also increased the potential for adverse events (Abduljabbar & Basendwh, 2016; Artzi et al., 2016; Beleznay et al., 2015; Bhojani-Lynch, 2017; Curi et al., 2015; De Boulle & Heydenrych, 2015; Funt & Pavicic, 2015; Graivier et al., 2018; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017). All agreed that dermal filler complications such as redness, bruising, and swelling at the site of the injection, which appear within a few hours to a few days post injection, are minor and temporary. Additionally, all 11 articles agreed that delayed onset adverse events that present with warmth, redness, swelling, tenderness, or pain along the injection site and that feel hard are highly likely due to hypersensitivity reactions that could appear anywhere from one to thirteen months post injection (Abduljabbar & Basendwh, 2016; Artzi et al., 2016; Beleznay et al., 2015; Bhojani-Lynch, 2017; Curi et al., 2015; De Boulle & Heydenrych, 2015; Funt & Pavicic, 2015; Graivier et al., 2018; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017). Further, all agreed that knowledge of product, injector technique, procedural cleansing, and comprehensive patient assessment are critical in infection prevention. Many articles referenced that sterile technique or using a chlorhexidine face cleanse is optimally essential when preparing the face for filler administration and that no injections should be administered to people with active infections, as this would potentiate abscess, nodule, or even granuloma formation, which could become a virulent biofilm (Abduljabbar & Basendwh, 2016; Artzi et al., 2016; Beleznay et al., 2015; Bhojani-Lynch, 2017; Curi et al., 2015; Funt & Pavicic, 2015; Graivier et al., 2018).

Dominant similarities throughout all articles revealed that all dermal fillers have the potential to cause adverse reactions. Auspiciously, most adverse events, like swelling, redness, and bruising, are minor, only temporary, and usually disappear within a week. Selecting patients, performing a comprehensive medical assessment, having knowledge of facial anatomy and the product to be injected, and employing proper injection technique are important considerations that can help to decrease the incidence of adverse events (Abduljabbar & Basendwh, 2016; Artzi et al., 2016; Beleznay et al., 2015; Bhojani-Lynch, 2017; Curi et al., 2015; De Boulle & Heydenrych, 2015; Funt & Pavicic, 2015; Graivier et al., 2018; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017). Finally, authors advocated that established dermal filler guidelines or a uniform

tool would help to decrease infections, but nothing had been instituted at the time of writing (Abduljabbar & Basendwh, 2016; De Boulle & Heydenrych, 2015; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018; and Uridiales-Galvez et al., 2017).

Differences

While not many articles disagreed in their findings, a few differences were noted. Beleznay et al., (2015) and Graivier et al., (2018) found it to be essential that the injector has an astute awareness of the triggers and causes of dermal filler adverse events, as well as having a medically directed, approved protocol in place. Both Beleznay et al., (2015) and De Boulle & Heydenrych (2015) found that the more volume of filler one receives, the greater the potential for an adverse event, including layering different filler products. In addition, Beleznay et al., (2015) and De Boulle & Heydenrych (2015) found that simultaneously combining two or more different filler products in the same area could set up an environment suitable for bacteria formation due to the varying filler properties. Due to the common nature of dermal fillers, adverse events, and complications, along with the consensus of need for patient suitability, comprehensive history assessment, and prudent treatment, there were no controversies found in the body of evidence.

Practice Recommendations

The body of evidence and its strength is presented in Appendix C. Literature supported, and authors advocated, that established dermal filler guidelines, or a uniform tool would help to decrease infections. Thus far, no instrument has been instituted in the cosmetic injection arena (Abduljabbar & Basendwh, 2016; De Boulle & Heydenrych, 2015; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018; and Uridiales-Galvez et al., 2017). In addition, in order to prevent complications, ensure proper treatment, and provide safe care options for adverse events, expert recommendations for cosmetic injection practice derived from the literature include the following practices before, during, and after the procedure:

1. <u>Prevention of adverse events and complications before the procedure:</u> Appropriate patient selection and, more importantly, not treating unsuitable patients is a critical component in the assessment and cosmetic plan to avoid dermal filler adverse events (De Boulle &

Heydenrych, 2015; Funt & Pavicic, 2015; Graivier et al., 2018; Ibrahim et al., 2018). To select patients and match them to appropriate products requires product knowledge and awareness of patients' medical and social histories. To avoid selecting patients with potential for adverse events additionally requires competent familiarity with warning indicators related to complications (Abduljabbar & Basendwh, 2016; Curi et al., 2015; De Boulle & Heydenrych, 2015; Graivier et al., 2018; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017). As prior to this project, there was no general form of a standardized process for the prevention of potential treatment complications (Abduljabbar & Basendwh, 2016; Graivier et al., 2018; Ibrahim et al., 2018; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017), injectors were advised to be scrupulous with patient selection, be cognizant of patients' underlying medical conditions, and be familiar with treatment protocols and procedures that decrease the occurrence of an adverse event.

- 2. <u>Prevention of adverse events and complications and ensuring proper patient treatment during the procedure</u> requires a thorough understanding of facial anatomy, good injection technique, proper cleansing of the instruments and facial injection site, and product knowledge (Abduljabbar & Basendwh. 2016; Beleznay et al., 2015; De Boulle & Heydenrych, 2015; Graivier et al., 2018).
- 3. Provision of safe care options in the event of adverse events and complications after the procedure: injectors should have a good command of the indications and symptoms of complications and adverse events, understand protocols and procedures of complication management, and know when to seek medical direction should the patient experience an adverse event. Early identification of adverse events and swift intervention can critically decrease the incidence of adverse events with dermal fillers (De Boulle & Heydenrych, 2015; Funt & Pavicic, 2015; Graivier et al., 2018; Uridiales-Galvez et al., 2017).

To facilitate implementation of these recommendations, the patient's record should include detailed documentation related to medical and social history, consent forms, and cosmetic plan, including type and name of product, placement, volume, injection technique used, before and after photos, and instructions (De Boulle & Heydenrych, 2015; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017).

Project Design

The project was a quality improvement design that assessed the current state of aesthetic nursing with emphasis on the increased adverse events with cosmetic dermal fillers. Through scientific discovery, it was concluded that there was no universal pre-injection assessment form in the cosmetic arena. With that knowledge, a problem statement was identified, and a needs assessment and Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis were conducted. The strategic planning for the change project began.

The strategy of the DNP Project was to assess the environment of the cosmetic population from the micro to macro level, and through that lens, the core purpose of the intended project was identified. The problem statement was declared, and the plan included a clinical practice change. Formulated through translational science and the synthesis of scientific literature, the universal assessment form known as the Assessment Cosmetic Injection Safety Tool (ACIST) was developed and established to effectively decrease the potential for adverse events with cosmetic injectables. The project setting, stakeholders, and participants were also identified, secured, and engaged throughout the entire project.

The project, a quality improvement action, created an organizational change for cosmetic nurse injectors to revise or update their current methods of patient assessment. By using the ACIST, identification of significant medical and social factors and pertinent warning indicators decreased potential adverse events for cosmetic dermal fillers injections and gave way to high-quality patient care and safety (Lyle-Edrosolo & Waxman, 2016).

The ACIST questions were formulated through translational science and the synthesis of literature. The tool was successfully piloted at a southern U.S. urban cosmetic practice, and data was gathered from the implementation and finalized based on the pilot feedback. The ACIST was then disseminated as a downloadable web resource for domestic and international cosmetic injectors.

Development of the Assessment Cosmetic Injection Safety Tool (ACIST)

Questions and data

The ACIST (Appendix B) is divided into three distinct headings:

- Medical and Social History Validation
- Adverse Event Risks and Limitations
- Warning Indicators and instructions for the number of checked boxes.

Tool Design

Succinct checklist assessment forms such as the AORN (2018) comprehensive safety tool and the Joint Commission (2018) Speak Up universal surgery protocol concisely express effective thoughts, reflect and increase communication, critical thinking, significant learning, motivation, and success (Hasturk & Dogan, 2016). Therefore, the ACIST was created for use in cosmetic practices as a standardized medical and social history assessment form to promote patient safety.

The three headings and subtopics of the ACIST were based on the synthesis of literature and created a straightforward awareness of the potential for dermal filler adverse events, indicated by the tool's number of checked warning boxes. Depending on the number of checked boxes, the ACIST guides actions for optimal patient safety and recommends either further nursing exploration, medical director consultation, or a delay or avoidance of the cosmetic injections to decrease the potential for adverse events.

If 1-3 boxes were checked, the patient's risk for adverse events is low and the only nursing action is to further discuss the patient's history to determine if the filler procedure is safe to continue. If four or more boxes were checked, the risk is intermediate for potential adverse events, and the next course of action is to explore and discuss the checked issues with the Medical Director prior to injection treatment. However, the risk for adverse events is high and postponement of the dermal filers are strongly recommended if any of the following were checked:

• Flu shot within the last two weeks;

- Dental cleaning or dental work within the last two weeks or scheduled within the next two weeks following injection;
- Active skin infections such as active bacterial, viral, body, or blood infections;
- Active herpes simplex;
- Undiagnosed or unstable autoimmune disorders;
- Steroid usage or other immunosuppressive treatments within two weeks of the cosmetic injections such as Remicade for Rheumatoid arthritis, or methotrexate; or
- Any current or recent upper respiratory tract or sinus infections.

Testing the ACIST

The standardized ACIST was piloted with an office-based cosmetic nurse injector at a southern U.S. urban cosmetic practice. For those patients requesting facial injections with dermal fillers, the ACIST was utilized as the patient's medical and social history intake form. Prior to the administration of any cosmetic facial injections, the nurse injector evaluated and assessed the completed ACIST form to determine the patient's potential for dermal filler adverse events. Based on the findings of the tool, the appropriate cosmetic injection treatment plan was ascertained.

Project Setting

The ACIST was piloted at a southern U.S. urban cosmetic practice. The practice is owned and operated by a national expert and focuses on facial enhancements only. The one-provider nurse practitioner practice employs a total of six team members. The clientele includes both men and women ages 22 through 76 years of age (H. Wood, personal communication, October 12, 2018). The owner, managers, employees, and patient clients are all stakeholders who work cohesively together to ensure best treatments, optimal outcomes, and patient safety for the cosmetic population. The practice is financially sound, professionally interconnected in the local business community, and is poised to grow.

The purpose, practice values, and goals of the southern U. S. urban cosmetic practice are:

Mission: Using the most advanced and safest non-surgical rejuvenation techniques to enhance the self

Vision: To be the top leader in patient experience, outcomes, and facial aesthetic knowledge (H. Wood, personal communication, October 12, 2018).

The practice was established in 2017. The cosmetic injector and entire staff value both high-quality patient care and aesthetic safety, have great passion for the art and science of facial aesthetics, and appreciate the popularity of minimally invasive rejuvenation procedures (ASPS, 2018). The practice's leadership style is inspirational and supportive, and people-and performance-oriented. It is well managed, efficient in its daily productivity, flexible to accommodate patients' needs, and is a natural calm and caring environment that offers innovative treatments for facial rejuvenation. The practice involves its staff in decision making and problem solving, integrating a team-oriented work environment.

The owner/administrator/injection specialist has over 13 years of experience in the field of Aesthetic Nursing, is a nationally recognized cosmetic injection trainer and nurse expert, a role model who exhibits integrity daily, and is ethical in all facets of patient care and nursing practice. She was eager to integrate the ACIST at her practice to standardize and streamline patient assessment and selection, stay at the forefront of medical best practices, and optimize patient safety. The medical director of the practice is a double Board-Certified Facial Plastic Surgeon.

Tandem to the cosmetic practice's mission, vision, and commitment to high-quality patient safety and optimal outcomes, the ACIST aligned well with the organizational need to be the top leader in the cosmetic industry. Use of the ACIST aided in patient safety through the identification of warning factors and stopped inadvisable injections before a potential adverse event could occur.

As the ACIST is a much-needed tool in the realm of the cosmetic facial injection arena (De Boulle & Heydenrych, 2015; Urdiales-Galvez et al., 2018; Uridiales-Galvez et al., 2017), the short-term objective of the project was to pilot the ACIST in the cosmetic practice to test how easily the cosmetic nurse injector could integrate the safety tool into the practice and discover how useful the tool was in identifying the warning factors that

reduce adverse events. The long-term objective was to make the ACIST available for all cosmetic injectors to use to decrease the potential for adverse events and to increase the ability of the injector to interpret patient safety warnings, optimize patient outcomes, and to identify best practices for cosmetic facial injections.

Risks and unintended consequences were minimal for the project. Although the intent is to standardize the cosmetic injection safety tool, there may be some cosmetic nurses who are unaware of the tool, do not use the tool, do not use it correctly or consistently, do not interpret the warning factors appropriately, or who use the tool, but it does not lead to any reduced adverse events.

The Participants

There were 100 patients seeking facial enhancements with dermal fillers that partook in the ten-week pilot at the southern U. S. urban cosmetic practice. Throughout the ten-week period, one nurse injector and two medical assistants used the ACIST to assess potential warning factors for each of the 100 patients. The tool was in the form of a separate document placed on top of the patient intake form and had no patient identification information or any way to link it back to the individual patient. After the patient consultation, these documents were collected in an envelope folder and placed in a locked file in the injector's office. There was no direct contact with patients by this author. Therefore, no identifiable data regarding the patient was collected.

Quality

A five-item pre-survey (Appendix D) was administered to the nurse injector via electronic mail prior to the ACIST implementation at the practice. The survey captured how the practice's cosmetic patient was assessed prior to injections, how potential adverse events were identified, how many medical consultations occurred over the past year, and the number of injections delayed or avoided. A five-item post-survey (Appendix E) with an additional query regarding the ease of using the ACIST and how using the ACIST changed the practice methods of patient assessment was again administered to the same nurse injector ten weeks later.

The ACIST, which had no patient identifiers on the document, was a planned organizational change that was implemented with intake forms of all patients seeking dermal fillers. The documents are stored securely in a locked file in the cosmetic injector's office, and in accordance with Ferris State University's Institutional Review Board (IRB) policy, the documents will remain locked for three years.

Ethics and Human Subjects Protection

Ethics and professional behavior standards in a non-surgical medical practice are essential. The nurse injector at the pilot location practice had an ethical responsibility to the business, staff, and patients. She is also the owner and administrator of the practice, and as such, is the primary figure to promote and demonstrate the mission, vision, and core values of the practice to the staff and all who enter. The owner/administrator is the authority of the practice and responsible for safeguarding and maintaining the ethical standards between the staff, patients, and business, and continually assimilating honest nursing practice, respect, and the safety of the cosmetic patient population.

Other ethical characteristics relevant to this project that the nurse injector demonstrated included the responsibility to be professional and to use integrity, transparency, and truthfulness to respectfully problem solve, make principled decisions, and respect patients and their privacy (the tool has no patient identifiers). The nurse injector had the responsibility to promote, advocate, and protect the health of patients and maintain optimal patient care and safety (Aitamaa, Leino-Kilpi, Iltanen, & Suhonen, 2016).

Pursuant to human subject protection, The Ferris State University Doctor of Nursing Practice program requires students to apply to the IRB for approval prior to implementing the project. Therefore, the IRB process was followed by this author in accordance to the degree requirements. However, because this was a quality improvement project and no human research subjects were involved, the IRB review and decision were exempt. Therefore, the project proposal was reviewed and approved by this author's DNP committee. The project then proceeded without pause.

Budget

Adhering to a budget was essential to show accountability to the project. The budget was a financial guide that illustrated the expected actions and resources that were needed to provide efficient and effective results and reach the targeted goal of a successful change project. A baseline or foundational budget was needed to provide an anticipation of project costs. The following information includes the proposed budget for the ACIST. The tool itself was developed by this author.

Expenses and justification

One trip to the pilot location practice to work with content expert/preceptor for one 40-hour workweek had an estimated roundtrip cost of \$1,680. Nine trips in total were taken to the project's pilot site. These trips consisted of preceptorship; project content construction; and development, implementation, immersion, and evaluation of the ACIST safety tool. The overall total cost was \$10,931.00 (as shown in Table 1).

Table 1

Budget

EXPENSES		REVENUE	
Direct:		N/A	\$0
Travel-flight, hotel, taxes, fees	\$5,928		
Parking	900		
Car mileage	552		
Meals	1,800		
Rental Car	900		

Subtotal (Direct)	\$10,080	
Indirect: (ISPAN)		
Project management	170	
Template Creation	85	
Importing and placing content	85	
Design and layout	213	
Export to other media (PDF)	43	
Updates after initial spec design	255	
Subtotal (Indirect)	\$851	
Total	\$10,931	

This author designed the initial content draft and the final form of the ACIST. Once the implementation and concluding evaluation of the ACIST had been completed, the International Society of Plastic and Aesthetic Nurses (ISPAN; 500 Cummings Center Suite 4400, Beverly, Massachusetts 01915) web team embedded the ACIST into the ISPAN website for cosmetic nurse membership to download and integrate into a patient's medical record. The task process and costs for ISPAN was \$851.00 (as shown in Table 1).

Strengths and Weaknesses

The SWOT analysis was done to primarily to assess the strengths and weaknesses of the pilot location practice prior to the implementation of the ACIST pilot. The strengths of piloting the ACIST at this southern U.S. urban cosmetic practice far outweighed the weaknesses (Appendix F).

The staff at the practice were found to be focused, team-oriented, and cohesive, and they fully supported the significance and importance of the safety tool. The injector is a Board-Certified Women's Health Nurse Practitioner and a Plastic Surgical Nursing Board-Certified aesthetic nurse specialist. The injector is also well experienced with non-surgical cosmetic injection facial enhancements and is a national expert injection trainer. This urban cosmetic practice is located in a growing upper-middle-class community, where the target population of 20- to 70-year-olds seeking non-surgical cosmetic injections for facial enhancements is thriving. Another significant strength is the cash or credit basis for services. All these factors were essential for the implementation and success of the ACIST.

While strengths are important for success, weaknesses are also important to understand. One of the weaknesses considered was patient transparency. It would have been a weakness in the success of the ACIST if the patient did not fully disclose the truth regarding his or her medical state, including past or current diseases, previous facial surgeries, upcoming dental treatments, flu immunization, current infections, or any prior cosmetic filler treatments. Another weakness is if a patient withheld information regarding medications – prescription or otherwise. If the ACIST was not used properly by indication of accurate past medical or social history, warning factors of adverse events would not have been correctly identified.

Project Description

This project was a quality improvement action, which created an organizational change for cosmetic nurse injectors to revise or update their current methods of patient assessment. By using the ACIST, significant medical and social factors and pertinent warning indicators were identified, which decreased the potential for adverse events with cosmetic dermal fillers, and overall gave way to high-quality patient care and safety (Lyle-Edrosolo & Waxman, 2016).

To institute the ACIST, an organizational change was implemented using Kurt Lewin's change theory. Organizational change integrates a changing to or moving from a comfortable and known state to one of uncertainty or unfamiliarity (Wojciechowski et al., 2016). The project change entailed the taking of the pilot site's current patient medical history assessment form and replacing it with the ACIST.

The organizational change follows Lewin's theory, which is a three-step model of linear change. Lewin's theory integrates three concepts: unfreeze, change, and refreeze (Wojciechowski et al., 2016). In more scientific terms, the first step of Lewin's change theory is unfreeze, where an awareness of the problem allows people to remove old patterns of doing. For this project's purpose, the unfreeze step made it possible for the cosmetic injection specialist to let go of the pilot site's "outdated" medical history intake forms. The second step of Lewin's theory is to change the old pattern or to move it in a different direction. For this project, the integration of the ACIST was the second step. The third step in Lewin's change theory is refreeze the new integration - the ACIST, which will then stabilize the organization change (Wojciechowski et al., 2016).

The ACIST was piloted in a southern U.S. cosmetic office, with a cosmetic nurse injector. For those patients requesting facial injections with dermal filler, the ACIST was integrated with their history intake forms, and during the cosmetic injection consultation, each patient was screened using the ACIST for warning signs that could lead to potential adverse events. With optimal patient safety in mind, the ACIST identifies a cosmetic patient's predisposition for adverse events as indicated by the number of warning boxes checked. Depending on the total number of checked waning boxes, the injector followed a course of nursing action, seek medical direction, or not administer the dermal filler injections, all of which kept patient safety at the forefront and decreases the incidence of adverse events.

Unfreeze

The success of the ACIST was based on Kurt Lewin's change theory. Leadership and staff involvement at the cosmetic practice were essential for the effective change.

Leadership is a primary factor for change and integrating Lewin's theory into an organizational change exemplified how important interrelated leadership and the sharing of new knowledge is for unfreezing and letting go of old behaviors (Hussain et al., 2018). The owner at the pilot location practice is a visionary leader who regularly reviews the practice's direction and proficiencies to optimally serve its cosmetic population. The owner understands that non-surgical rejuvenation is a constantly changing environment. To be pertinent in the industry and optimize patient safety and outcomes, the practice (the organization) needs to be in a continual state of motion by keeping up to date with trends, techniques, products, patient safety, and quality standards. This philosophy is equally as critical to implement Lewin's theory into the organizational change at both the unfreeze and change stages. The purpose of unfreeze was to let go of the cosmetic practice's familiar way of gathering patient medical history (a limited, non-comprehensive questionnaire) and to integrate a new form of medical and social history assessment – the ACIST. Implementation of the ACIST took the cosmetic practice into a new direction of patient safety standards.

Change

The second stage of Lewin's theory demonstrated the change that took place within the organization. The ACIST was integrated as a proactive change in January 2019 at the pilot location practice. Prior to the tool immersion, significant knowledge and information regarding the use of the ACIST and its subsequent determination for patient safety was shared with the owner and staff who implemented the ACIST at the practice. Questions were welcomed and clarifications were supplied. Once the pilot concluded, the ACIST was integrated into the electronic medical record, providing accurate medical and social history intake assessments, greater and more effective work flow and efficiency, improved communications, increased patient care and safety, more apparent warnings of potential adverse events, better cosmetic treatment plans, and an overall reduction in medical errors (Alpert, 2016). The ACIST was used with each cosmetic patient seeking facial rejuvenation enhancements with dermal fillers for the entire ten-week pilot.

Refreeze

The third stage of Lewin's theory is the refreeze stage, where the implementation of the change has already occurred, and the preferred organizational change is maintained. During the refreeze stage, sharing the knowledge and increasing the awareness of the ACIST was paramount to sustaining the change. This was accomplished in April 2019 upon the evaluation and completion of the pilot. Using the feedback from the pilot immersion, the ACIST was further developed in collaboration with the ISPAN Information Technology (IT) team for website integration. The ACIST is now offered to all cosmetic nurses as a standard safety tool through the ISPAN website.

This quality improvement project established, tested, and disseminated a comprehensive medical and social history assessment form (the ACIST) to improve patient safety. The ACIST questions were formulated through translational science and the synthesis of literature. The tool was successfully piloted at a southern U.S. urban cosmetic practice, and data was gathered from the implementation and finalized based on the pilot feedback. The ACIST was then disseminated as a downloadable web resource for domestic and international cosmetic injectors as a proven organizational change to decrease potential adverse events and optimize patient safety.

The project was accomplished through the:

- 1. Development of the ACIST;
- 2. Testing and implementation of the tool; and
- 3. Dissemination and integration of the ACIST into cosmetic practices.

Barriers and Facilitators

Barriers

Although the entire project was highly successful, there were a few barriers experienced during the implementation and immersion phases of the ACIST:

- 1. Time
- 2. Workflow
- 3. Technology Gap
- 4. Tool Name

The urban cosmetic practice where the ACIST was piloted is an extremely busy business. Due to the volume of patients, efficient technology, time, and work productivity are important factors for daily operations. Because the ACIST was piloted as a printed document and not embedded into the electronic medical record, it took more time for the nurse injector to complete the assessment safety tool, thereby slowing the daily work productivity. Therefore, the author arranged for the intake medical assistant to conduct the medical and social history assessment with the patient prior to the injection specialist's review of the ACIST and injection treatment plan. It was expected that the professional patient assessment would still be maintained, and time and workflow would be optimized and sustained without compromising patient safety.

However, despite the initial change of the intake medical assistant completing the ACIST with the patient instead of the nurse injector, time management and workflow remained a concern. Therefore, another change was implemented: upon making an appointment, the front office staff would instruct patients to arrive 10 minutes prior to their appointment time in order to complete the first section of the medical/social history assessment form. This policy was readily accepted as a positive change by the staff and even prompted discussion as to the possibility of having the medical and social history assessment form eventually built into the patient portal for patients to complete online (before the actual appointment).

Having the patients complete the form caused frustration when the patients began asking the front desk staff for clarifications regarding some of the medical and social history questions. The staff were then further instructed on how to help the patients answer the questions more appropriately, which was viewed as an acceptable change.

Another unforeseen barrier was the controversy that came with the negative connotation associated with the initial acronym of the medical and social history assessment form, the Cosmetic Injection Safety Tool (CIST). The more the nurse injector specialist and staff utilized the tool, they started to feel as if CIST related too closely to "cyst" and it was beginning to sound more unpleasant with each use of the tool. This author then changed the name of the safety tool to ACIST, which resonates as "assist." The new name reflected the purpose of the tool more accurately:

**assisting* the injector to identify factors of potential adverse events through the assessment of the medical and social history safety checklist. The new acronym had a much more favorable appeal with the injector and staff.

Facilitators

The primary impetus for the project was to develop a standardized pre-injection safety tool to decrease the potential for adverse dermal filler events. The southern U.S. urban cosmetic practice was essential for the piloting of such a tool. The following facilitators were experienced during the implementation and immersion phases of the ACIST:

- 1. Motivation
- 2. Flexibility
- 3. Constructive Attributes

The primary facilitators of the project were the mutual motivation and support for optimal patient safety. Flexibility and willingness of the injector and staff to acclimate the ACIST into the cosmetic practice were also catalysts. Additional driving forces for the success of the project were the honesty, trustworthiness, adaptability, and sound solutions expressed and shared between the cosmetic practice, staff, and this author, all of which greatly enhanced the value of the ACIST in decreasing the potential for adverse events in the dermal filler patient.

Leadership

Once the project was approved and the timeframe established (Appendix G), the organizational change process was successfully implemented at the urban cosmetic practice pilot site for a ten-week testing period from January to April 2019. Providing support, effective communication, and encouragement to the owner and staff was essential to the successful organizational change (Hussain et al., 2018).

The author used transformational leadership with the staff on a continual basis throughout the project immersion and communicated the overall importance of collaborative team efforts in maintaining cosmetic injection patient safety and optimal outcomes. Leadership was sustained through the ongoing communication and daily integration of the ACIST that reinforced the purpose, objectives, and goals of the project. Essential and effective communication and updated clarification provided optimal time management and workflow productivity throughout the project period.

Project Evaluation Results

The planned organizational change was evaluated by a non-experimental pre- and post-survey design used to reveal if the use of the ACIST decreased the potential for adverse events in the cosmetic patient population. The target population for the change was cosmetic injectors and cosmetic patients.

A pre-survey (Appendix D) was given to the injection nurse specialist at the pilot location. It consisted of five questions asking the specialist to describe the current method used in her practice for the cosmetic patient assessment. The questions determined if the patients were cooperative in providing a complete medical and social history, how many interviews resulted in medical consultations, how many potential adverse events were identified, and how many injections were avoided or delayed over the past year at the pilot site.

After the pre-survey was complete, the intervention or behavior change (the ACIST) was implemented at the practice for a ten-week period.

Each patient seeking facial enhancements with cosmetic injectables at the pilot site was individually interviewed using the ACIST and evaluated by

the cosmetic nurse injector prior to the injectable treatment plan. The ACIST paper document was independently located on top of the patient's chart and did not have any name or identifiers associated with it. The pilot site staff were the only individuals who had contact with the patients.

At the five-week mark, a formative evaluation of the effectiveness the ACIST was conducted to provide insight and opportunity to modify any of the warning indicators for adverse events (Sze-Lau, 2016). The evaluation revealed there were no ACIST warning indicators that needed amendment. However, modifications were executed to have the intake nurse conduct the history assessment prior to the nurse injector's review of the ACIST, and the tool name was retitled to a more pleasing acronym.

After the ten-week period of the ACIST immersion, the same injection specialist completed the post-survey (Appendix E), which described her experience while using the tool. The post-survey questions determined if the patients were cooperative and provided a complete medical and social history, how many interviews resulted in medical consultations, how many potential adverse events were identified, and how many injections were avoided or delayed within the ten weeks, and an additional question asked how using the ACIST had changed the injection specialist's practice.

Once the post-survey was complete, each of the completed ACISTs that were used over the ten weeks were reviewed, and the number of cases flagged by the injection specialist, such as those requiring additional nursing action, the number of medical director consultations, and the number of delayed or avoided treatment injections, was counted and assessed.

In all, there were 100 tools that were used and completed during the implementation of the change process. Out of those 100, 32% of patients required additional nursing action of further discussion of the medical and social histories, and 68% required medical director consultations. Of that 68% requiring medical director intervention, 4% had recommended indications to delay or avoid cosmetic treatment injections (as shown in Figure 1).

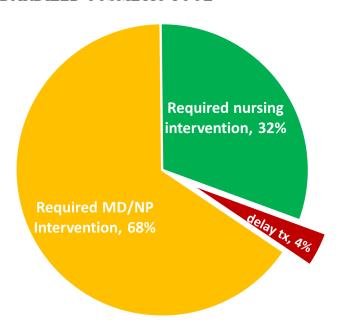


Figure 1. ACIST Project Evaluation Results

- 32% = 1-3 Checked Boxes on the ACIST indicates the patient is at a low risk for a potential adverse event. Nursing action includes more exploration and discussion of stated history prior to Cosmetic Injection Treatment.
- 68% = 4+ Checked Boxes on the ACIST indicates intermediate risk potential for adverse event. Consult with Medical Director before initiating Cosmetic Injection Treatment Plan.

4% = POSTPONEMENT of the Cosmetic Injection Treatment Plan is to be strongly considered with the following HIGH-RISK indicators for adverse events:

- o Flu shot within last two weeks
- O Dental cleaning or dental work within last 2 weeks or scheduled within two weeks following cosmetic injections
- Active skin infections
- o Any active bacterial, viral, body, or blood infection
- o Active Herpes Simplex (contraindicated especially for perioral or lip injections)
- Undiagnosed or unstable autoimmune disorders
- Steroid or other immunosuppressive treatments within two weeks of cosmetic injections, e.g., Remicade for RA, Methotrexate, Prednisone, etc.
- o Any current or recent (within two weeks) upper respiratory infections or sinus infections

In addition to the post-survey, a summative discussion with the cosmetic injection specialist revealed a positive experience with the overall effectiveness of the ACIST. The tool is now fully integrated into the pilot site's practice and used with every dermal filler patient to decrease the potential for adverse events and optimize patient safety.

Overall, the completed evaluation revealed that the ACIST served as a positive organizational change. It was efficient in identifying indicators that recommended cosmetic injectables should be delayed or avoided, which decreased the potential for adverse events in people seeking non-surgical facial rejuvenation. The ACIST provides high-quality patient safety to the cosmetic patient population.

Validity and Reliability

Surveys are descriptive in design and are widely used methods for data collection in nursing research (Mc Peake, Bateson, & O'Neill, 2014). An overall goal of the survey is to "understand respondent attitude, knowledge and practice at a point in time or to compare changes" (Mc Peake et al., 2014, p. 24). Surveys are user-friendly, flexible, and easy to employ. Surveys offer the opportunity to gather insight into lived experience and interpretive information directly from involved individuals (Coulter, Locock, Ziebland, & Calabrese, 2014).

The pre-and post-survey for this project is a single group, quantitative design that gathered baseline data that assessed "knowledge, attitudes, satisfaction, or skills in single subjects; [where] interventions are typically…behavioral in nature" (Spurlock, 2018, p. 70). The pre-and-post-survey was used to gather borderline quantitative data before the application of the ACIST. Upon completion of the pilot implementation, the data was again collected and assessed for the number of potential decreased adverse events and the number of delayed or avoided cosmetic injections.

Surveys are often used to gather quantitative data. They provide various benefits such as cost efficiency and speed of results over other variations of quantitative designs (Mc Peake et al., 2014). However, the survey design is not without weakness and the internal validity is a threat in that the pre-and post-survey had a potential for bias responses (Mc Peake et al., 2014).

Discussion and Implications for Nursing and Healthcare

The ACIST has successfully answered the PICOT question posed at the beginning of this project: In non-surgical patients seeking facial cosmetic rejuvenation (more specifically, facial enhancements) with cosmetic injectables, does using a pre-injection safety tool compared to not using the pre-injection safety tool delay or avoid cosmetic injectables and decrease adverse events over a ten-week time?

Prior to this project, there were no universal safety checklists for cosmetic injections. However, the ACIST has successfully integrated an organizational change into cosmetic practices and has affected patient safety. Using the ACIST decreases the potential for cosmetic injection adverse events. The ACIST proactively alerts the cosmetic injector to consider further nursing action or to explore treatment options with the counsel of a medical director prior to the administration of dermal fillers. The ACIST advises a delay in cosmetic injections due to high-risk indicators for adverse events.

Using the ACIST is a collective and practical way for cosmetic patients and injectors to comply with medical and social history intake forms.

It is low cost, easily transferable to electronic health records, easy to update, and convenient to use.

Because there are currently no other standard checklists for cosmetic injection safety, the potential for the ACIST to sustain its presence in the non-surgical cosmetic arena is great. The ACIST will serve as an essential component for continuous quality improvements and best practices for cosmetic injection patient safety. The ACIST is user friendly and takes the guesswork out of choosing suitable patients. The ACIST establishes a standard guide to identify warning factors for potential dermal filler adverse events.

The ACIST will keep the injector organized and on task by increasing productivity and workflow, ensuring that all comprehensive information is complete, and empowering better patient care and safety. The universal recognition and identification of the adverse event warning factors will take the guesswork out of the patient assessment and provide a clearer and more comprehensive cosmetic treatment plan, resulting in optimal patient safety and satisfactory outcomes.

The ACIST can be easily integrated into cosmetic nursing practices, and can ideally decrease cosmetic injection adverse events, and influence patient safety and outcomes in the cosmetic patient population.

Recommendation

As evidenced throughout the literature support found in this project, dermal filler adverse events are not common. However, they are real and do happen. There has been no universal or standardized medical and social history form to assess for potential adverse events in the cosmetic injection patient population until the development of the ACIST. While the ACIST is a facial cosmetic pre-injection safety tool that has proven to successfully identify factors to decrease or prevent potential dermal filler adverse events, further study, exploration, and advancement of a standard cosmetic treatment tool or course of action for the serious adverse events that could occur in patients who had unforeseen dermal filler complications is recommended. Having a standard cosmetic complications safety tool in nurse injectors' armamentarium could immediately address adverse events such as tissue necrosis, vascular occlusion, and blindness. Having such a tool would be beneficial for all cosmetic nurse injectors to include in their practices for optimal cosmetic patient safety and best outcomes.

Plans for Dissemination and Sustainability

The ACIST was a change in the patient assessment process that identified warning factors that could potentiate adverse events for the patient seeking facial rejuvenation. It proactively alerts the cosmetic nurse injector to consider further nursing action or to explore treatment options with the counsel of a medical director prior to the administration of dermal fillers. The ACIST also directs strong advisement for delay in the cosmetic injection due to high-risk indicators for adverse events.

Literature supported and authors advocated that established dermal filler guidelines or a uniform tool would help to decrease infections. Prior to this project, no instrument had been instituted (Abduljabbar & Basendwh, 2016; De Boulle & Heydenrych, 2015; Ibrahim et al., 2018; Urdiales-

Galvez et al., 2018; and Uridiales-Galvez et al., 2017). The creation, implementation, and findings of the ACIST successfully answered the call for a standardized tool to decrease the potential for dermal filler adverse events in the cosmetic arena and improve cosmetic patient safety and outcomes.

Central to dissemination and sustainability is the translation of knowledge (Curtis, Fry, Shaban, & Considine, 2016). The dissemination plan for the completed ACIST doctoral project included a public and oral defense presentation. The Ferris State University School of Nursing DNP Committee, nursing faculty, and DNP cohort will be invited to the final presentation of the project results. The project information was presented with an oral presentation consisting of a general overview and summary of the ACIST project, its findings and conclusions, and the intention for its sustainability.

Dissemination also requires reaching the appropriate audience and presenting the findings of the DNP project (Curtis et al., 2016). Therefore, the following forums were chosen:

- The summary of the ACIST project findings and results were discussed with the stakeholders and content expert at the project pilot site upon completion of the 10-week implementation of the ACIST.
- An exclusive abridgment of the ACIST, its efficiency, and its positive results in decreasing the potential for adverse events was presented to the ISPAN stakeholders and leadership at a Board of Directors meeting in Nashville, Tennessee.
- The complete ACIST project, including results, evaluation, and conclusion, will be submitted as a manuscript to the international peer-reviewed *Plastic Surgery Nursing Journal* (PSN).

Curtis et al., (2016) also promotes social media as platforms for dissemination. Thus, in alignment with this method, other dissemination venues will include:

- ACIST launch complete with overview video and ACIST PDF download through the ISPAN website (ww.ispan.org) as a complimentary patient safety resource for ISPAN membership.
- The ACIST was announced to the 1,700 ISPAN members through a member electronic mail blast.
- Upon publication in the PSN, the completed ACIST project was provided through the ISPAN Facebook members-only page, Twitter, and
 Instagram accounts, and will be included in the September 2019 ISPAN electronic newsletter.

Sustainability of the ACIST is an essential component for continuous cosmetic injection improvements and patient safety. Therefore, best practice advancements to the tool will be made on an annual basis through the ISPAN community. Quality improvements and patient safety will be based on the current cosmetic scientific literature and ISPAN membership quality improvement survey evaluations.

Conclusion

In the past twenty years, the demand for cosmetic injections has increased by 313%. People between the ages of 20 to 70 years have increasingly been seeking non-surgical facial enhancements for the ageing process, including facial wrinkles, volume loss, and skin laxity (ASPS, 2018). As cosmetic injectable products rapidly come to market, the demand for them increases accordingly, along with increased chance of adverse events. Cosmetic injectors need to be critically aware of patients' comprehensive social and medical histories to identify warning factors for potential adverse events and complications. Development of the ACIST eliminated paper intake assessment forms and notifies the cosmetic injection specialist of medical and or social complication risks prior to the administration of the cosmetic injection treatment. The ACIST was tested and piloted as an organizational change following Lewin's theory at a southern U. S. urban cosmetic practice. The tool has been integrated into the practice's electronic medical record. The ACIST will identify suitable cosmetic injection patients and expedite workflow, productivity, efficiency, and patient safety, satisfaction, and outcomes by decreasing cosmetic facial injection adverse events.

Prior to this project, no standardized safety checklists existed in the cosmetic field of injectables. The ACIST created a universal facial cosmetic pre-injection safety tool and is a welcomed answer to the practice of cosmetic injections. The ACIST established the standard change to improve patient suitability, quality, and care, and addressed the safety gap within the cosmetic patient population.

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12/02/2018

Appendix A

Ferris State University School of Nursing Doctor of Nursing Practice Program Proposal Approval

As members of the DNP project committee and department administrator, we certify that we have read this project proposal prepared by: Georgia Elmassian titled: Establishing a Standardized Facial Cosmetic Pre-Injection Safety Tool and approve. Student can move to implementation. Susan Owens, PhD, RN Digitally signed by Susan Owens, PhD, RN DN: cn=Susan Owens, PhD, RN, o=Ferris State University, ou=SON, email=owenss3@ferris.edu, c=US Date: 2018.12.03 11:32.09-05'00' Date: **DNP Faculty Mentor** Name and Position Mentor Date: Name and Position member Date:

Appendix B

Assessment Cosmetic Injection Safety Tool (ACIST)

The ACIST has been removed from this public document. The ACIST can be found in its entirety on the ISPAN website www.ispan.org

Appendix C

Summary of Systematic Reviews (SR)

Citation	Question	Search Strategy	Exclusion Criteria	and Analysis	·	Recommendation/ Implications	Level of Evidence
` '	will complications increase	Pub Med Google Scholar Dermal fillers; Facial rejuvenation; Hyaluronic acid; Complications	55 articles selected and included	complications related to dermal filler injections. Signs and symptoms include:	mild and not permanent. Delayed onset reactions occur weeks to years post filler injections	Thorough knowledge of product, facial anatomy, technique, cleansing, patient medical history, early identification of complications, factors to avoid, and how to manage complications	

Citation	Question	Search Strategy		Data Extraction and Analysis		Recommendation/ Implications	Level of Evidence
Landau, M. (2016). Resistant	developed HA-Vb dermal fillers cause late onset reactions?	Retrospective medical record chart review from four medical centers in the Middle East	28-70 years of age HA-Vb filler (tear	description of reactions to newer HA-Vb fillers Redness Bruising	different products and volume used influence rate of late-onset reactions. Average onset reaction was two	Knowledge of facial anatomy, technique, cleansing, dermal filler properties, judgment of injection limitations, patient history, medication management	

Citation	Question	Search Strategy			·	Recommendation	
			Exclusion Criteria	and Analysis		Implications	Evidence
Beleznay, K., Carruthers, J. D., Carruthers, A., Mummert, M. E., & Humphrey, S. (2015). Delayed- onset nodules secondary to a smooth cohesive 20mg/ml hyaluronic acid filler: Cause and management. Dermatologic Surgery, 41, 929- 939. https://doi.org/10.1 097/DSS.0000000 000000418	use of available fillers increase, adverse events inevitably will increase.	Retrospective chart review over 68 months	treated with HA-V 20-85 years of age February 1, 2009 to September 30, 2014	performed over 68 months using HA- V dermal filler Date and site of injection Date and site of nodule include: Redness Bruising Swelling Pain Warmth Nodules Infection Biofilms Risk factors Immune Treatment	variety of locations with the mid face being most common site of nodule formations Large volume	product, facial	4

Citation	Question	Search Strategy	Inclusion/ Exclusion Criteria	Data Extraction and Analysis	•	Recommendation/ Implications	Level of Evidence
Bhojani-Lynch, T. (2017, December). Late-onset inflammatory response to hyaluronic acid dermal fillers. Plastic and Reconstructive Surgery Global Open, 5(12), pe1532. https://doi.org/10.1097/GOX.0000000000000000001532	popularity of dermal fillers, does a combination of different brands lead to complications?	5 clinical descriptive case studies	treated at different clinics where author was the medical director Late onset inflammatory response occurring at least 3 months	1 Asian woman 2 women present at 4 months with complications post injection 2 women present at 5 months with complications post injection	complications are inflammatory and infectious can be triggered by illness Late onset reactions may appear from weeks to months to over one-year post injection All women had more than one brand filler product	history, prompt identification of triggers, awareness of adverse events, and medication management. Patients should be informed of possible adverse	5

Citation	Question	Search Strategy		Data Extraction and Analysis	<i>•</i>	Recommendation/ Implications	Level of Evidence
			Criteria	·		implications	Evidence
Curi, M. M., Cardoso, C. L., Curra, C., Koga, D., & Benini, M. B. (2015, May). Late-onset adverse reactions related to hyaluronic acid dermal filler for aesthetic soft tissue augmentation. The Journal of Craniofacial Surgery, 26(1), 782-784. https://doi.org/10.1 097/SCS.0000000 000001358	are considered safe, could adverse events show up months to years later?	2 Descriptive clinical studies Key words: Hyaluronic acid dermal filler, Restylane, late-onset adverse reactions, oral manifestation		previous filler injections 1 woman had dental extraction 1 woman received chemotherapy for ovarian cancer Both women presented with oral mucosa involvement Each presented with:	past soft tissue HA injections before their medical treatments 1 woman received filler 12 years previous at the exact site of the delayed late onset symptoms	Knowledge of product, facial anatomy, technique, cleansing, patient medical history is essential, prompt identification of late adverse effects, awareness of medication management.	S

Citation	Question	O	Exclusion	Data Extraction and Analysis	•	Recommendation/ Implications	Level of Evidence
			Criteria				
Heydenrych, I. (2015, April 15).	occur with dermal fillers, but no consensus on best treatments	Medline Search terms: Complications; soft filler complications, Injectable	International group of practicing aesthetic physicians Papers from 2005 were selected (although older papers were personally referenced during discussions)	components of dermal filler patient selection Contraindication and cautions in patient selection Patient expectations must be aware of dermal filler risks Complications present at or near injection site: Redness Bruising Swelling Pain Warmth Nodules Infection Biofilms	an elective process Careful provider attention must be used to avoid complications Patient's comprehensive medical history is essential when providing dermal filler injections Essential to avoid	anatomy, technique, cleansing, sterility, patient medical history is essential, proper patient selection is critical, prompt identification of adverse effects, awareness of medication management, seek trusted advice from colleagues	

Citation	Question	00		Data Extraction	· ·	Recommendation/	
				and Analysis		Implications	Evidence
			Criteria				_
		Descriptive review	_		Different filler	Thorough	5
, (,		of medical	fillers with		.	knowledge of	
,	,	literature			different	product and	
	complications also				properties, risks,	options to prevent	
aesthetics: An	tend to increase.				and injections	or avoid	
overview of			Non-biodegradable		requirements	complications,	
adverse events and			fillers which are	Filler		facial anatomy,	
treatment			more permanent	complications are	All fillers tend to	technique,	
approaches. Plastic			and longer lasting	varied and have	have associated	cleansing, sterility,	
Surgical Nursing				short- and long-	complications	patient medical	
Journal, 36(1), 13-				term durations		history is essential,	
32.					Most	proper patient	
https://doi.org/10.1				Reactions can be	complications are	selection is critical,	
097/PSN.0000000				immediate to	related to injection	prompt	
000000087				delayed for 5 years	technique and	identification of	
				and include:	volume of product	adverse effects,	
				 Redness 		awareness of	
				 Bruising 	Most	planning and	
					complications are	medication	
				• Pain	avoidable with	management	
				• Warmth	appropriate		
				Herpes Virus	knowledge,		
				Nodules	technique, and		
				NodulesInfection	planning		
					_		
				 Biofilms 			

Citation	Question	Search Strategy	Inclusion/ Exclusion	Data Extraction and Analysis		Recommendation/ Implications	Level of Evidence
			Criteria	and many sis			Lviaciice
Graivier, M. H., Bass, L. M., Lorenc, P., Fitzgerald, R., Goldberg, D. J., & Lemperle, G. (2018). Differentiating nonpermanent injectable fillers: Prevention and treatment of filler complications. Aesthetic Surgery Journal, 1-12. https://doi.org/10.1 093/asj/sjy032	dermal fillers increase, complications also tend to increase. Knowledge of prevention and treatment are essential.	Descriptive review of expert opinions in aesthetic medical literature	expert aesthetic physicians	Reactions can be immediate to delayed and include Redness Bruising Swelling Pain Itching Tenderness Rash Nodules	low, but all fillers tend to have associated risks and potential complications Most complications are related to poor patient suitability and inappropriate treatment Most complications are avoidable with appropriate knowledge, technique,	Thorough knowledge of product and treatment options to prevent or avoid complications. Keen awareness of facial anatomy, facial cleansing, injection technique, and patient medical history is essential. Proper patient selection is critical, prompt identification of adverse effects, treatment options, and awareness of planning and medication management	

Citation	Question	Search Strategy	Inclusion/ Exclusion Criteria	Data Extraction and Analysis	<i>•</i>	Recommendation/ Implications	Level of Evidence
Ibrahim, O., Overman, J., Arndt, K. A., & Dover, J. S. (2018, January). Filler nodules: Inflammatory or infectious? A review of biofilms and their implications on clinical practice. Dermatologic Surgery, 44(1), 53-60. http://dx.doi.org/10.1097/DSS.000000 0000001202	cosmetic injections has increased steadily as have complications associated with the dermal fillers. Delayed reactions can become severe and develop into biofilm infections.	Descriptive literature review	Infected nodules associated with dermal filler injections	almost immediately after injection and include: • Redness • Swelling • Rash • Bruising Late and delayed onset reactions:	severity of filler reaction Granulomas have been reported frequently Dental and surgical procedures and trauma influence the formation of biofilms. If not treated properly, biofilms can eventually lead to	biofilms infections are critical, Knowledge of product, facial anatomy, technique, cleansing, sterility, patient medical	

Citation	Question	Search Strategy	Inclusion/	Data Extraction	Key Findings	Recommendation/	Level of
				and Analysis	•	Implications	Evidence
			Criteria				
,		PubMed	References cited in	_		Knowledge of	5
F., Delgado, N. E.,	C 2	English, French,		in composition,	selection of patient		
	P	and Spanish		duration, ease of	is crucial to reduce		
3	number of		reviewed for	5		technique and	
Mira, M., Moreno,		reviewed	relevant reports	administration, and		injection patterns,	
	complications are	Terms used:		potential	The injection	cleansing, sterility,	
	increasing as well.	Complications;		complications	technique and	patient interview,	
Treatment of soft		soft filler	and international		correct choice of	complete patient	
tissue filler		complications;	published		filler is essential	medical history is	
complications:		injectable	guidelines			essential, proper	
Expert consensus		complications;				patient selection is	
recommendations.		dermal fillers	Case reports and		prevention of	critical, informed	
Aesthetic Plastic			summaries of		potential	consent,	
Surgery, 42, 498-			individual		complications	photographs,	
510.			clinicians'			prompt	
https://doi.org/10.1			experience			identification of	
007/s00266-017-						adverse effects,	
1063-0						awareness of	
						medication	
						management	
						Standard	
						assessment tool to	
						streamline	
						injection process	
						and reduce	
						potential	
						complications	

Citation	Question	Search Strategy	Inclusion/		<i>•</i>	Recommendation/	
			Exclusion Criteria	and Analysis		Implications	Evidence
F., Delgado, N. E., Figueiredo, V., Lajo-Plaza, J. V., Mira, M., Ortiz- Marti, F.,	favored cosmetic procedure. This increase has led to a rise in reported complications.	Database, and Google Scholar. English, French and Spanish language articles were reviewed and modified by an expert panel for a descriptive review Search terms: Complications; soft filler complications; injectable complications; dermal fillers; and	filler complications Selected references were also reviewed	Early events occur almost	protocols could be helpful for new practitioners Immediate onset of complications occurs directly after injection and up to 24 hours Early onset is considered 24 hours to four weeks Delayed onset is more than four weeks Advisable to avoid physical work outs	anatomy, technique and injection patterns, cleansing, complete patient medical history, proper patient selection is critical, prompt identification of adverse effects, awareness of medication management and treatment of complications, creation of universal protocols for injection safety	

Appendix D

Pre-Survey Questions

- 1. What do you currently use for patient assessment?
 - We use a questionnaire which includes meds/allergies, h/o¹ autoimmune disorders, previous injection history, previous facial surgery history, recent dental work and recent flu shot.
- 2. Do patients readily disclose all their past medical and social history?

No, they do not. Cosmetic patients consider elective procedures such as facelift/browlift as a non-medical event to report. They do not disclose supplements, hormones or diet drugs unless specifically asked. Often times, they do not want me to know they have been to other injectors, so their previous injection history is inaccurate. I have to make observations of their face while they consult w me, to see if I can identify previous neurotoxin and/or filler injections.

3. How do you identify a potential adverse event?

If someone notes an "allergy" or reaction to a previous injection, it will alert me to ask more questions about that AE^2 . Staying current on issues w new products, being involved in advisory boards, attending conferences allow me to stay on top of what potential AEs could be.

² AE: adverse event

¹ h/o: history of

would have been notified.

- 4. How many medical consultations have you had in the past year?

 Typically, I wait until the specific red flag is resolved, then re-consult with the patient to again make sure they are suitable filler candidates. My years of expert practice and advanced nursing education has greatly influenced how I have been able to medically manage my patient population. Because of these two factors, I have been able to swiftly identify potential AE risks and have been able to make treatment decisions due to my expert knowledge and practice scope. However, if I was a novice injector or one with little experience there would have been multiple occasions where a medical director
- 5. How many cosmetic treatments have been delayed or avoided in your practice over the past year?

I haven't kept record of the exact number. Due to recent colds, infections, teeth cleanings or other circumstances, I postpone 1-4 procedures a month. Again, because of my scope of practice, I am able to medically manage my own patients and make independent decisions whereas other injectors who do not have the advanced education should seek input from their medical director.

Appendix E

Post-Survey Questions

1. How many patients did you assess with the ACIST?

100 patients in total were interviewed with the ACIST from January 28-April 29, 2019

2. Do patients readily disclose all their past medical and social history with ACIST?

Yes, when specifically asked.

3. How many potential adverse events did you identify with ACIST?

32 patients had 1- 3 boxes checked which indicated a low risk for adverse events.
68 patients had 4+ boxes checked which indicated intermediate warnings for the potential of adverse events.

4. How many medical consultations did you identify with ACIST?

I had to have further discussions and clarification of the indicated warning factors for 68 patients. However, being a nurse practitioner, I medically manage my own patients. For all 68 patients, I did the advanced evaluations needed and made the decisions to proceed with the injections or not. Anyone without the advanced education would have had to consult a medical director for those 68 patients.

5. How many cosmetic treatments were delayed or avoided with ACIST?

In accordance with the ACIST recommendations, 4 patients who screened positive for the flu shot, dental procedures, teeth cleaning, and active sinusitis, had their facial injections postponed.

6. How did the ACIST change your practice?

The tool provided me with an organized, comprehensive, and systematic approach for acquiring the much needed and significant medical/social history information of patients which could affect short-and long-term outcomes for dermal filler injections and overall patient safety. The tool was concise, easy to follow, and gathered essential information. The ACIST is now a part of my everyday practice and is used with all patients. Using the tool provides me with the assurance that every filler patient has been properly assessed and screened prior to the injection.

Appendix F

Strengths and Weaknesses Analysis

	SWOT ANALYSIS									
Intern	nal	External								
Strengths	Weaknesses	Opportunities	Threats							
Cohesive staffStaff supports safety tool	 Patients could provide untruths for medical and social history; may not admit current disease states or medications 	Trends showing increasing demands for non-surgical rejuvenation	Growing area for new businesses could bring in non-surgical rejuvenation competition							
 Experienced board-certified injector national industry non-surgical trainer (Allergan and Palette) 	• Fear of truth: patients may not want to admit they have had previous facial surgery or dermal fillers	 Community growth-both housing and business Upper middle-class demographic 	Componion							
Busy location – prime real estate with many businesses in outdoor mall	Safety tool may not be used properly	New businesses in town provide potential for new clients								
New home developments										
Currently no competition										

•	Cash or credit		
•	No insurances		

Appendix G

Project Implementation Timeframe

January 2019

- Pre-survey administered to cosmetic injection nurse specialist
- Leadership provided at pilot site for implementation of the change process project
- Implementation of the ACIST
- Explanation of purpose, objectives, and goals of project, as well as ACIST instructions for use provided to pilot site's staff
- Discussions on the importance of overall patient safety and optimal outcomes for the ACIST
- Clarification of tool questions provided for both injector and staff as needed

February 2019

- Protect immersion and continued integration of ACIST
- Continued support of safety tool importance and change process
- Problem solve and clarify any concerns and issues

March 2019

- Mid-point formative assessment of change process effectiveness and evaluation of completed ACIST's
- Ongoing Project Immersion

April 2019

- Completion of the ACIST implementation
- Post-survey administered to same cosmetic injection nurse specialist

- Initial ACIST data collection and general evaluation
- Summative assessment of ACIST

May 2019

• Collaboration with ISPAN IT web team for ACIST as gold standard of practice

June 2019

- Dissemination of ACIST
- ISPAN launch of ACIST
- Announcement of ACIST via ISPAN electronic mail blast, electronic newsletter, and ISPAN social media platforms: Facebook, Twitter, and Instagram
- ACIST submission to Plastic Surgery Nursing Journal