Improving the Management of Adverse Filler Events

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Abstract

Poor management of filler-related adverse events can have profound consequences. The use of dermal fillers has potential for serious side effects such as ischemic events that can result in tissue necrosis and even blindness. Early and proper management reduces the risk of long-term negative consequences. Therefore, it is very important that providers have the knowledge and understanding of how to treat these potential complications (Urdiales-Galvez, et al, 2017). Evidence has shown that many filler-related adverse events have been under treated. New literature has been published with improved occlusion protocols that should be implemented in practices who perform these treatments (DeLorenzi, 2017). The creation of a new protocol with immediate provider access would help improve management of filler-related adverse events. The project design consists of clinic-wide practice change to improve the patient care of those who have experienced a filler related adverse event. Findings showed that although there was a limitation with the timeframe allotted after protocol implementation, there was a more-timely resolution of adverse events and an improvement in patient satisfaction.

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Dermal fillers are used widely in fields such as medical aesthetics, plastic surgery, cosmetic dermatology, and more. These fields are expanding as aesthetic medicine dominates a greater portion of the practice as more patients seek out non-surgically, minimally invasive procedures to enhance quality of life. Due to the novelty of aesthetic medicine and these treatments, adverse events are being encountered and treated for the first time. In comparison to other fields of medicine, protocols are in place to manage adverse events to allow for a rapid recovery and optimal patient outcomes.

Dermal filler is one of the most common non-invasive medical aesthetic procedures. Some of the goals of dermal filler treatment include addressing volume deficiency, softening the appearance of scars or wrinkles, facial sculpting or contouring, and augmentation of facial features (Ballin, et al, 2015). Dermal filler treatment runs the risk of adverse events ranging from filler appearance irregularity, to blindness caused by retinal artery occlusion. Both experienced and non-experienced practitioners will be administering dermal fillers in a variety of outpatient facilities. Even experienced injectors may not be familiar with interventions for all adverse events.

The training process of hospital nurses varies greatly from those in medical aesthetics. For traditional nursing, a year of residency, internship, or some type of new graduate program is provided for new nurses to understand how to perform duties as a bedside nurse. In medical aesthetics, a practitioner would be hired into a facility offering medical aesthetic-based procedures, and the extent of training is completely up to those who hire the practitioner. Sometimes, practitioners are hired after taking a day class for injectables, and are expected to handle all patient needs in a practice with one training. Practitioners who strive to achieve the

best outcomes for their patients must research on their own to ensure the most up-to-date best practices are being used. Occlusion protocols have changed in 2017 with hyaluronidase being used to flood ischemic tissue (DeLorenzi, 2017); however, there are providers who have yet to be updated with these standards. There are several adverse events that call for management protocols to be compiled to improve the practice of aesthetic medicine. Clinical protocols are important to ensure a formal pathway is taken with criteria to provide a specific algorithm to care for a specific condition (Prasad, et al, 2010).

Dermal filler is the focus of this project due to how common and frequently it is injected, which tends to contribute to a high portion of adverse events requiring intervention. Doctoral prepared nurses embrace the responsibility of establishing evidence-based interventions within their workplace. A written protocol for all practitioners administering dermal fillers would improve patient outcomes, decrease severity of adverse event with proper intervention, and decrease the time it takes to recover from adverse event. This displays leadership within the field of medical aesthetics and nursing by providing support and safety measures to all of those performing dermal filler treatments, including nurses and nurse practitioners.

Background

Dermal filler first became United States (U.S.) Food and Drug Administration (FDA) approved in the early 2000s. Back then, pharmaceutical company representatives without a medical degree would teach medical providers how to administer dermal fillers. Neither the medical providers learning nor the representatives teaching knew about adverse events at that time. As the total amount of filler procedures being performed increased, more adverse events were discovered. Practitioners learned how to treat adverse events through experience and medical knowledge. There is no scholarly documentation to support this because neither

pharmaceutical companies nor providers who performed these procedures over ten years ago like to offer up information that states these procedures were being performed without adequate training or testing.

To this day, in training sessions where dermal filler injection techniques are taught, treatment methods for adverse filler events are not taught. Esthetic Skin Institute training courses offer introductory filler courses which focus on achieving optimal outcomes with dermal fillers, but lack in-depth coverage of complication management (Esthetic Skin Institute, n.d.). More classes sharing intervention techniques and studies sharing evidence-based treatment are slowly being offered; however, these classes are expensive with limited availability. An example of this is a safety with dermal fillers lecture which includes coverage of topics such as blindness, necrosis, delayed onset nodules, and more (Goodman, Shamban, n.d.). Many providers share their protocols over social media, or stay up to date with intervention methods through research. An example of how knowledge of best practices has changed is through a Facebook comment in a group called 'Advanced Aesthetic Injectors Circle' where a group member says, "I've been injecting for 14 years and only started aspirating around five years ago. Scary to think of all the injections I've done thinking I was safe" (Castellon, 2019, Facebook comment). Aspirating is a technique used to ensure an artery is not being cannulated to prevent filler from causing an occlusion, and what this practitioner may not know about is the physician pushback of safety of aspiration. In a 2018 study published by Journal of Cosmetic Dermatology, 33% true-positive aspirations were performed while 38% false negatives were performed (Van Loghem, et al, 2018). Aspiration is being relied upon by injectors as a safety indication, when there is a 38% chance that the injection is still not safe. This is only one

example of how dermal filler best practices must be kept updated in a protocol able to be referenced.

The popularity of dermal filler treatment increased dramatically in more recent years. A statistical example of this is shown by the 650,000 filler treatment performed in 2000 compared to the greater than 2.4 million performed in 2015 (Rayess, et al, 2018). There are approximately 160 products available from over 50 companies. Indications include filling of wrinkles and folds and correcting tissue loss (Funt & Pavicic, 2013).

Filler injections were initiated after 1995, and as of 2015 reached a total of about 2.4 million procedures. The first type of filler was injectable collagen, which lasted about two months, with adverse events including, "bruising, detectable implant on palpation, lumpiness, minor asymmetries" (Solomon, et al, 2012, Results section, para.1). After that came the introduction of hyaluronic acid based dermal fillers in 2003, which remains the highest and most commonly used dermal filler, nearly quadrupling the total amount of all other types of filler in the market (Cutis, 2018).

An explanation of adverse events with different types of dermal fillers over time can be reviewed. Hyaluronic acid-based fillers are associated with a low rate of adverse events, which is estimated to be about one to four out of every ten-thousand procedures (Cutis, 2018); It is also important to consider with hyaluronic acid-based fillers that newer technology has allowed for the creation of vycross hyaluronic acid-based fillers (Arsiwala, 2015). These vycross fillers have high viscosity and low molecular weight that allow them to last longer and make them easy to inject. On the other hand, they can also be more difficult to dissolve. It has been said that vycross followed the three-year learning curve for the discovery and implementation of the dermal filler type, and adverse events evens out after the dermal filler is better understood (Cutis,

2018). With this analysis over a thirty-four-year time period, there is a plateau effect of dermal filler adverse events that can be overcome with further innovation (Cutis, 2018).

Adverse events of dermal fillers have been studied extensively through the time period since they have been introduced. In the last five years, there are 1098 articles including dermal filler technologies in the United States (U.S.) National Library of Medicine National Institutes of Health. The pharmaceutical companies who create the fillers also investigate dermal filler adverse events to increase safety profiles of their products. For example, Allergan holds their own clinical and safety trials (Allergan, 2016). Unfortunately, there are no studies performed on the success rate of protocols or interventions for adverse events, likely because the spread of evidence-based interventions in medical aesthetics has not been streamlined.

Problem Statement

As the science of medical aesthetics advances, practitioner interventions should advance as well. Nurses and nurse practitioners are heavily involved in administration of dermal fillers, and neglecting to address this as a skill in nursing fails to acknowledge nursing as a dynamic field, responsive to changes in society and culture. More advanced practice nurses are choosing medical aesthetics as their specialty, which reflects its popularity in society. A nurse writes about nursing being responsive to societal and gender norms in health care (Cardillo, 2011).

Treating adverse events are within the nurse and nurse practitioner's scope of practice. If severe enough, patients experiencing dermal filler adverse events may present in emergency rooms and urgent care. Patient recovery directly depends on the practitioner's ability to manage an adverse event. Some adverse events are easy to address, while other require more skill and knowledge. All adverse events have evidence-based intervention to be applied, but practitioners would need to recall this information. The lack of evidence-based practices supports the lack of

adverse event protocol in medical aesthetics. This can be an issue when new nurses enter this field without experience or knowledge. This is also an issue for experienced nurses who must continue to self-educate since evidence-based practices change since the beginning of dermal filler implementation over ten years ago.

A protocol to manage adverse events of dermal fillers would keep these patients out of urgent cares and emergency departments and would be effectively handled in the outpatient clinic where the injection was performed. With the application of a dermal filler adverse event protocol, other leaders in the field can follow to create well researched protocols for other procedures and adverse event management. By increasing access to dermal filler adverse event protocols, it, "provides key elements to help clinicians who are starting to use dermal fillers to employ standard procedures and to understand how best to prevent potential complications of the treatment" (Urdiales-Galvez, et al, 2017, Conclusions section, para. 1).

Purpose Statement

Patient safety and the advancement of medical aesthetics are two important objectives for this specialty to address. Through the creation and implementation of a protocol available for all practitioners delivering dermal filler treatment, both of these goals can be achieved. The goal is to provide information in the format of a protocol for safe management of adverse events with dermal fillers. This will also reduce transfer of patients to acute care facilities, which is caused by practitioner lack of knowledge in dermal filler treatment. This can be achieved and measured on a timeframe of one month to allow for education of the protocol, implementation, and evaluation.

Dermal fillers can be valuable if used with the appropriate demographics. Managing symptoms of the aging face with volume expansion increases the quality of life (Urdiales-

Galves, et al, 2018). The safety profile of dermal fillers is favored because of the low risk of adverse event. This is considered to be why adverse events were not particularly prevalent a decade ago when dermal fillers were not being used as frequently. As their effectiveness and versatility became acknowledged, the amount of use increased exponentially. In efforts of promoting safety in medical aesthetics, "the importance of careful patient selection, through informed product choice, to vigilant procedural planning" (Heydenrych, et al, 2018, Conclusion section, para.1), will be demonstrated through the creation and implementation of a protocol for filler adverse events.

Project Question

In a PICOT format, the population target is nurses, nurse practitioners, and other practitioners injecting dermal fillers and managing complications. The intervention is the creation of a protocol and implementation. The comparison is being made to outcomes when practicing with a protocol versus practicing without. The outcome is to decrease time to recovery and increase patient satisfaction on a numerical scale. The time frame would be measured after one month of protocol implementation.

Will the development and implementation of a dermal filler protocol in a medical aesthetic outpatient clinic improve the timeliness of management of adverse event and reduce the transfer of patients to another facility for treatment within the timeframe of the DNP project? This can be answered by conducting quality improvement initiative after implementation of protocol.

Project Objectives

The following objectives will be completed within the timeframe of this DNP project.

- Develop a dermal filler adverse event protocol

- Educate the providers in an outpatient medical aesthetic clinic to the protocol
- Measure the providers' knowledge and skills through a pre and post competency check
- Reduce transferring patients to another facility and treatment delays by 50%
- Improve patient satisfaction scores by 10%

The first objective will be to decrease the time it takes for patients with adverse filler events to make a full recovery. The intention behind measuring the time to patient recovery is to shorten the duration of adverse event, adding to emotional trauma from a possible injury to the appearance of the face. Shortening the duration to treatment is not the goal, but to implement the correct intervention through reference of a protocol will shorten the time the adverse event takes to recover. This also limits the amount of emotional trauma the patient has to go through. The second objective will increase patient satisfaction ratings on a numerical scale after an adverse event. The third objective will increase the number of patients a practitioner sees who have satisfactory (seven out of ten or above) ratings after adverse event.

Search Terms

First, PubMed database was checked for similar review. Second, Cumulative Index to Nursing and Allied Health Literature (CINAHL) was searched along with Cochrane and MEDLINE complete. Search terms included: 'emergency protocols' and 'dermal filler protocol' or 'dermal filler protocol implementation,' or 'emergency protocol implementation,' or 'dermal filler adverse events' or 'adverse event protocols' or 'medical aesthetic adverse event.' At first, no restrictions were applied, but as the available studies were reviewed, prioritization was given

to high value content and more recent content. Search limitations included only articles in English and peer-reviewed. Since medical aesthetics is a more novel field, date limitations were not applied, but priority was given to more recent articles if content was useful. Sixteen articles were found in CINAHL, nine articles in MEDLINE complete, one in Cochrane, and twenty-eight in Pubmed. Eleven articles were chosen to use in this literature review. Not all of the articles available were used due to the ability of the literature to be applied being limited. Abstracts were reviewed to ensure content was appropriate. Articles were included when information to support or reject feasibility for protocol implementation of adverse event protocol was found.

Review of Literature

Over the past three decades, dermal fillers have been increasing in amount of treatments due to the favorability of the safety profile in achieving restoration of volume in the face. Over two and a half million dermal filler procedures were performed in 2015 (Chandawarkar, 2018). From the time dermal fillers have been introduced to now, the rate of adverse events has ranged from less than one in every ten thousand to less than four in every ten thousand (Chandawarkar, 2018). These numbers only account for what is reported to the FDA. One report from a group of dermatologists found their cases of vascular compromise to happen at a rate of five out of every ten thousand (Beleznay, et al, 2014). This proves that the reported number of adverse events is not consistent with the number of adverse events that actually occur in clinical practice. Dermal fillers are not only administered by physicians, but also by nurse practitioners, physician assistants, and other practitioners such as registered nurses. The ability of these providers to provide time-sensitive, appropriate management of adverse events depends on the amount of studying they do to keep up to date with best practices.

Working with guidelines, protocols, and procedures results in optimization of patient care, because they are based on current evidence and experience (Kobo-Greenhut, et al, 2014). Key concepts in this review include protocol implementation, management of adverse filler events, and patient outcomes following adverse events. The current literature on protocols in management of adverse filler events displays patterns, gaps, and relationships in support of the need of further research for protocols in outpatient medical aesthetic practices.

Patterns and Gaps

One pattern in current literature demonstrates the lack, or gap, of available research of best practices to improve patient outcomes in managing adverse events. The most recent protocol for management of one adverse event, vascular occlusion, proves its efficacy by stating that the author has not had signs of secondary healing with the new protocol. The author states that prior protocol resulted in blistering and dermal scarring, which are signs that the occlusion caused atrophy or necrosis. With the new protocol, treatment resulted in complete resolution of ischemia with no scabbing, scarring, or other secondary efforts of healing (DeLorenzi, 2017). The author did not report how many patients healed this way, or if this finding was congruent with other attempts of implementation outside of the author's patients. For this to be considered effective, research should be conducted in a controlled setting and the same finding should be replicated. This supports the finding of an in-office, referenceable protocol where the outcomes are assessed for efficacy of protocol measures. No other authors have published similar findings. This was posted two years ago, and article publication process can take many years.

Another similar pattern is the availability of recommended protocols by a group of physicians. A literature review filtered through articles to find best practices in managing complications of dermal fillers. The goal of this article was to formulate recommendations and

issues useful for clinical management of dermal fillers. It added in its conclusion that establishing action protocols for emergencies would reduce the extent of adverse outcome (Urdiales-Galvez, et al, 2018). There is a gap in this literature review that proves the efficacy of these recommendations through literature. It cannot be concluded that establishment of protocols would reduce the extent of adverse events because the recommended protocol has not been reviewed for efficacy.

Cianco displays another protocol recommendation that has been concluded to avoid necrotic tissue. It is stated that the protocols of early infiltration of hyaluronidase of 40 units per square centimeter, corticosteroids, anti-aggregation therapy, antibiotics, and more avoided necrotic tissue in his patients (Ciancio, et al, 2019). There are no other recordings of this management recommendation being followed in other cases. The number of patients seen by one provider is extremely limited compared to the number of patients treated with dermal filler nationally. This method has not been repeatedly tested to ensure necrotic tissue would not persist with this protocol, and therefore cannot be validated. A best practice should not be referred to if it cannot be replicated in other circumstances, such as other patients in other clinics.

Importance of Assessment of Protocols

Recommended protocols need to be evaluated for efficacy so they can be validated. If a best practice is being referred to as a protocol and cannot be replicated in other cases, it cannot be supported as a protocol. Protocols must be evidence-based involving the best recommendations of published guidelines (Thomas, 2015). A protocol should be able to be replicated so another investigator can arrive at the same conclusions (Sakka & Al-Jundi, 2016).

Current management

Medical aesthetic clinics need to have a policy and procedure manual in place to be in compliance with regulations. This includes treatment indications, contraindications, warnings, precautions, injection techniques, and documentation (Brennan, 2015). This helps ensure appropriate procedural guidelines. A protocol or procedure manual has never been explored for appropriate management of adverse events. Since there is no governing board for medical aesthetics, management of adverse events is completely up to the individual who performed treatment. Recommendations have been published in journals, for example, an article from the department of plastic surgery in Mount Sinai Hospital in New York states the aesthetic physician should have a detailed understanding of ways to prevent and avoid potential complications (Funt & Pavicic, 2015).

Relationships

A strong relationship between protocols and decreased adverse events is demonstrated through the literature in healthcare. Surgical checklists are associated with decreased complications, deaths, and infections, and clinical pathways reduced in-hospital complications (Zegers, et al, 2016). These protocols are examples of interventions applied to prevent adverse events. Anesthesiologist John Eichorn identified that anesthesia has become so safe due to implementation of prevention strategies, but in the event of intraoperative accident, few practitioners have experience dealing with adverse events (Eichorn, n.d.). This also holds true for medical aesthetics. The first adverse event protocol was published in The Journal of Clinical Anesthesia in 1993 (Eichorn, n.d.). Since then anesthesia-related deaths declined from two out of every ten thousand to one per every two-hundred to three-hundred thousand anesthetics

administered. Success of adverse event protocols have not been performed due to the low availability of adverse events and lack of adverse event reporting.

Study Methods

Study methods will be reviewed and explained for relevance to the topic of protocol implementation for dermal filler adverse events. Article by Beleznay, et al, in 2014 gathered information by using their twelve cases of vascular compromise over a ten-year period. This is relevant to supporting the issue that greater volume of adverse events needs to be assessed. Eichorn outlines the creation of an adverse event protocol in anesthesiology. The history of the issue and plan was detailed. This supports the effort to prepare organized resources to respond to accidents to limit injury. A systematic review by Zegers, et al, (2016) reviewed sixty systematic reviews to reduce adverse events in hospitals. The conclusion of identifying a need to focus on high-quality research standards to identify the interventions that impact patient safety supports the need for the same concept in medical aesthetics. The methodology is important to support study selection in this literature review. Funt and Pavicic (2013) reviewed reports of dermal filler complications in medical literature. The methodology of this study was based on the evidence provided by various publications and author experience. Basing a conclusion on someone's experience lacks validity. Cianco, et al (2018) does not provide an outlined methodology, but provides information on two patient cases that followed a specific protocol. This information can be useful in identifying protocols applied to adverse events with dermal filler. DeLorenzi (2017) does not provide methodology, but states that his findings come from his experience. This supports the need for protocol implementation and review so that evidence-based practice can be identified to be effective over a greater volume of adverse events.

Significance

Medical aesthetics has been adopted in the field of nursing as advanced practice nurses provide aesthetic procedures. The profession of nursing values minimizing harm, and the implementation of adverse event protocol to support a standardized evidence-based practice. The topic of protocol implementation in dermal filler adverse events is needed because there are no high-volume studies available in the body of knowledge to prove the efficacy of best-practices. Medical aesthetics cannot advance if what is currently recommended as a best-practice has not been applied, reviewed, and refined.

Conclusion

Adverse events have proven to not be reported to the FDA as much as they are found in clinical practice, as reported by physician-published research. The management of adverse events can be supported with referenceable protocols as they have the potential to decrease the severity of adverse events and decrease the time it takes to make a full recovery. The implementation and assessment of referenceable protocols should be supported in this project due to the lack of research on best practices to prove efficacy. In addition to this, the lack of a referenceable protocol to prove the validity and efficacy of evidence-based practices supports the need for this project. Lastly, the ties between protocols and decreased adverse events displayed in anesthesia supports the need for referenceable protocols to use for adverse events with dermal fillers.

Theoretical Framework

The Stetler model of evidence-based practice can be applied and used to provide framework for implementing the DNP project. It is useful for aiding practitioners in developing standards or policies by informing program planning and implementation. It is assumed in this

model that a formal organization may or may not be involved in ones' use of research (Stetler, 2001). It is also assumed that lack of knowledge or skill can inhibit effective use of research or evidence-informed practice. It is important that the knowledge of available resources is understood to be used in this case. It is also important to be able to appraise research. This model was first introduced as the Stetler/Marram Model of Research Utilization (1976), but was later changed to the Stetler Model of Research Utilization (1994). This was again changed to the Stetler Model of Evidence-Based Practice (2001), and consists of the five phases of research use. Cheryl B. Stetler is responsible for the refinement of the model to be used with evidence-based practice.

Implementation Science

The Stetler model of evidence-based practice will assist in implementation of proposed methods. There are five phases to be applied. The goals of the phases are to facilitate critical thinking about the application of research, use evidence in daily practice, and decrease human errors in decision making. This model can be directly applied to the DNP project because the project itself has goals to implement evidence-based practice, and decrease human errors by using a protocol. A recent study used the Stetler model in efforts to identify models for evidence implementation (2018, Camargo, et al). The diagram of the model can be referenced in appendix A.

Historical Development of the Theory

Stetler and Marram first created the Stetler/Marram Model of Research Utilization in 1976. The goal of this model was to help with the application of research findings to practitioners, as compared to an organizational level. This was made due to the emergence of the concept of research utilization in the 1970s. The original model began with traditional research

critique. If the research was weak, it was to be stopped. If it was strong, the findings could be stated. If the statement of findings could be related to substantiating evidence, fit the appropriate setting, was feasible, and set as a basis for practice, it could move on to the next step (Stetler, 2001). The next step consisted of three options: Non-application, cognitive application, or action application. Non-application would lead to stopping the use of research. Action application proved to be evidence for change, a catalyst for evaluation, and model for behavior. In the 1992, evidence-based practice emerged as a new concept and challenged research utilization (Stetler, 2001). The model's further refinement allowed it to be applicable to practitioners and organizational levels.

Stetler became a consultant of evidence-based practice, which allowed her to explain the relationship between research utilization and evidence-based practice. Starting with research, the critique and use of techniques applied to research allowed for the application as an evidence-based practice. Evidence-based practice can emergence as an intermediate result of research utilization, or as an application of external or internal evidence in practice as a routine. This led to the outcomes of evidence-based practice impacting providers or units as well as patients and families (Stetler, 2001).

Major assumptions of the theory help guide understanding of how it should be utilized. Direct organizational involvement may be present in the form of policies or provisions of resources to be used. Organizations may not always be involved, especially when many innovations occur. At times, organizational involvement is crucial for planned change, but it may not be needed for every case. Another major assumption is that research provides us with variable information. Intervention characteristics affect the likelihood of events, but do not often determine outcomes. The final application of findings depends on the skilled practitioner.

Lastly, competencies are expected in basic research, research utilization, prescriptive models, inferential statistics, raw data analysis, and critical thinking skills. These competencies are expected to be able to translate findings to practice (Stetler, 1994). The updated model can be found in appendix A.

Applicability of Theory to Current Practice

Stetler's model is applicable to current practice as the need for research implementation to practice is needed. One example of this model applied to both practitioner and organization levels includes its use as a framework to support utilization in practice at Brigham & Womens' Hospital in Boston (Aikawa, et al, 2017). It has also been used in education in a graduate course at Johns Hopkins University in personal communication (Ashley & Hanson, 1994). In 2001, the Stetler model was used to create an evidence-based procedure involving the maintenance of central venous catheters (Broughton, et al). It has also been used for staff development with preceptors in nursing (Romp, 2009). A more recent study used the Stetler model to identify models for evidence implementation (2018, Camargo, et al). It is understood that this model is applicable to implementing research or evidence-based practice to daily practice.

Major Tenets

Major tenets within the model include preparation, validation, comparative evaluation, application, and evaluation (Stetler, 2001). These are drawn from Stetler's five phases from her most recently updated model (2001). These phases are used to guide the implementation process to formulate evidence-based research to apply towards practice. This model is a series of critical-thinking steps that overcome barriers to utilization of research findings.

Phase one focuses on preparation. In phase one, the purpose of the evidence is to be identified. Identifying the purpose allows for application to the later phases in the model. Phase

two is validation. The credibility of findings and qualifiers are assessed. In this phase, findings may be rejected based on credibility. Relevant details should be summarized and reflected relative to the issue at hand. Phase three includes evaluating and comparing findings. From this, the research can be used, additional information may be gathered, or information may be rejected. Phase four is the translation or application phase. Formal dissemination and change strategies are planned. Phase five is the evaluation phase, where expected outcomes are to be clarified (Stetler, 2001).

Preparation

The preparatory phase focuses on the purpose or significance of research. It should be considered that both external and internal factors can influence findings of research. When thinking critically, these considerations help the user be conscious in selecting the research to be selected. While summarized in other articles, this is best described in Stetler's update in the Nursing Outlook Journal in 2001. Whether nursing research or research outside of nursing is being reviewed, users should differentiate the sources of information (Stetler, 2001).

Validation

Validation phase is used as a utilization focused approach as compared to research critique with the most up to date refinements. This is aligned with the model's purpose of applying research to practice. With this in mind, the findings are appraised more so than the study itself. The findings are then critiqued for applicability to be used in daily activities. The caveats and qualifiers of study findings should be weighed for such applicability (Stetler, 2001).

Comparative Evaluation

Findings should be evaluated against other published findings. While experts may be able to form the base of a study, it is more likely that multiple studies would be reviewed and

compiled. This phase focuses on identifying, organizing, and integrating information from many studies (Stetler, 2001). After synthesis of findings occur, the strength of the presenting information is to be judged. In this phase, the findings are then decided to be used, or decided not to be used. Use of findings indicates acceptance while not using findings indicates rejection of findings (Stetler, 2001).

Application

This phase outlines how to apply information to practice. The type of finding is concluded, as well as the method and level of use. When plans for use include organizational change, behavioral change in the targeted group may be necessary to explore (Stetler, 2001).

Evaluation

Evaluation heavily depends on the type of levels, types, or methods. Evaluation allows for the assessment of the possibility of change with implementation, or monitoring of effects to decrease adverse event occurrence. This phase allows for modification of what is to be implemented for optimal outcomes. This step is a deliberate, systematic, continuous evaluation process in which findings are applied to what is to be implemented (Stetler, 2001).

Theory Application to the DNP Project

Stetler's model is informative in guiding this DNP project. The goal of the DNP project is to apply evidence-based practice as a policy in the practice of adverse event management with dermal fillers in medical aesthetics. As explained by Stetler, these actions directly impact practitioners or units as well as patients. The Stetler model has been summarized to be a model focusing on individual practitioners. This is also the goal of the DNP project as a leadership project. To apply Stetler's model to the DNP project, the major tenets have been constructed to assist with the DNP project implementation process.

Preparation

Preparation of the literature on best practices of adverse dermal filler events would be gathered. They would be sorted through for accuracy and sorted based on application to adverse event. Influential factors such as who is writing it, who is funding the study, and when it was performed will be considered. In this phase, the purpose of the gathered articles would be defined.

Validation

In this phase, a utilization-focused critique & synopsis is to be performed. If the critique of the adverse dermal filler event study is identified, it can then be accepted or rejected. Rejection would cause the study to not be used further. Acceptance would allow the literature to move forward through the next phase. If accepted, the findings will be synthesized and evaluated for future use.

Comparative Evaluation

In comparative evaluation, knowledge of medical aesthetics is important to understand how literature would be applied. If a finding does not fit the setting of medical aesthetics, is not feasible to the practice, cannot be used in current practice, or does not have substantiating evidence, it will not be used. If the findings are applicable, they can be used or considered in future steps.

Application

Application consists of two steps where the type of findings and level or method of use is confirmed, and then the findings can be used. In a medical aesthetic clinic, the findings regarding adverse dermal event management can be applied formally or informally. Formal use

requires the design of the evidence-based document to be in place, including a change plan and evaluation plan.

Evaluation

Dynamic evaluation includes identifying the goals, obtain evidence and outcomes for comparison, and use such evidence to achieve goals. Evaluation can be conducted on success of outcomes after implementation of dermal filler adverse event management practices.

Project Design

The project design will be a clinic wide practice change, which is guided by a quality improvement approach. Defined by the American Academy of Family Physicians (AAFP), quality improvement consists of specific measures. Establishing a culture of quality in the practice will be performed by implementing the Dermal Filler Adverse Event Protocol. The project is the creation of a protocol to manage adverse events that sometimes occur with the injection of dermal fillers. The goal of quality improvement is to cause measurable improvement in patient care of a specific group (Health Resources and Services Administration, 2011). The populations to be affected are the providers at the clinic. The providers at the clinic consist of both nurses, who hold a minimum of a registered nurse license, and advanced practice nursing licenses, such as nurse practitioners. The nursing experience of the providers also varies from over one year to over fifteen years.

Project variables are identified based as factors that impact the project. The dependent variable is the protocol that is designed to be referenced in the event of an adverse response. The independent variables are the provider's compliance with that protocol, the pre and post competency check, how many patients are transferred to other facilities, and satisfaction scores of patients. Satisfaction depends on how well patient care is managed. The purpose of the

project implementation is to improve staff education to provide timely, evidence-based care when patients are experiencing dermal filler complications. This in turn will improve patient satisfaction.

Qualitative data is made from observations, such as satisfaction rates, levels of education, and patient outcomes (Bhatia, 2018). Data will be collected in the form of a pre and post educational test, measuring protocol compliance via retrospective chart reviews, and measuring the pre and post implementation patient satisfaction scores. Content analysis may be successful because in an assessment of performance, patient and provider feedback can be screened for underlying themes (Mailman School of Public Health, 2014).

Population of Interest, Setting, Stakeholders, & Recruitment Methods

Population of Interest

The population of interest has been determined to be the registered nurses (RN) and nurse practitioners (NP) who perform dermal filler procedures and who manage adverse events if they should occur. Those nurses who are included as participants in this project are the RNs and NPs who are employed at the practice site, have completed orientation, completed the necessary training, and hold the required credentials. Those who will be excluded include ancillary staff, such as office managers and staff managers who do not perform these procedures in the clinic. Also excluded are those who are not employed by the practice site, such as consultants, vendors, or nurses who did not complete the necessary training. There are three NPs and three RNs at the practice site who meet the criteria for participation.

Setting

The setting in which the protocol will be implemented is a free-standing medical aesthetics clinic. The clinic is located in Southern California and opened in 2011. There are one

to four nurses of varying degrees performing procedures, treating, and consulting with patients daily. Anywhere from one to four nurses may be scheduled per day. There is a director of nursing and a nurse manager on staff. The practice is open Monday through Saturday, from nine in the morning to seven thirty in the evening. Permission and full support to conduct the project within the clinic has been obtained (See Appendix B).

The clientele of this clinic consists of men and women ranging from ages eighteen to over eighty. The volume of patients ranges from fifty to one hundred patients daily. The procedures offered by the providers of this clinic consist of Botox, fillers, laser skin treatments, chemical peels, laser hair removal, and body contouring.

Stakeholders

There are two important stakeholders at this practice, including the lead NP (who acts as nurse manager), and the director of nursing. All individuals involved with implementing the protocol are considered stakeholders. There are no corporate partnerships. The plan for establishing rapport included arranging a meeting with the nurses to debrief and align the goals of the facility and goals of the DNP project. The plan for establishing and maintaining a rapport with the stakeholders included arranging a meeting to brief them of the goals of the project and to report the progress. The rapport was established by talking about hopes, expectations, past experiences, first impressions, valued attributes, and actionable opportunities with these stakeholders (Dang, Westbrook, et al, 2017). Meetings can be performed monthly to discuss the progress of the project. All stakeholders will be invited to these meetings. I will collaborate with the staff in the development of the protocol to ensure buy in, transparency, and scholarly practice. Patients are also considered secondary stakeholders since the project will affect the care they receive.

Recruitment Methods

The project is a clinic wide practice change; therefore, all providers are mandated to participate in this project. There is no monetary compensation or special treatment for participation. Participation in this project is not a condition of employment. Employment will not be influenced by participation; therefore, based on the inclusion criteria the project lead is using a convenience sample. Providers identify that this protocol can help increase their success with patients in improving management of adverse events, therefore recruitment methods are not necessary. Participants' data will be kept private by assigning a letter to each provider. These letters will only be known by the project lead. The results of the tests and chart audit will be stored on a password protected computer that is only accessed by the project lead. There will be no advertisements or incentives to participate in the project.

Patient charts will be audited to determine provider compliance with the protocol. The charts will be chosen by the date the patients were seen. Charts to be included in the audit will be those with documented adverse events. Mild complications can be seen daily. Chart audits will be performed for patients seen four weeks prior to implementation and those patients seen four weeks during implementation to determine provider compliance. Any changes that will need to be made will also be identified through auditing charts.

Tools

Protocol

The protocol will be the only tool used for education (See Appendix C). The protocol is a compilation of steps to take during an adverse event. It will be used both as a reference during adverse events and as an educational tool prior to implementation. It is color coded for prompt identification in emergent events.

Provider Knowledge Test

The one tool to be used to assess competency of nurses will be a ten-question test based on the education provided in the protocol (See Appendix D). The questions are all multiple-choice. Multiple choice questions can be scored objectively (Farooqui, et al, 2018). The purpose of the protocol is to be a reference in emergency situations when knowledge cannot always be relied upon. This test will be used to measure knowledge in managing dermal filler complications. No return demonstration will be necessary. All questions must be answered correctly for a passing score. If a provider fails, a review will be performed to reinforce the material.

Content Validity Index

A content validity index (CVI) will be performed by the project team to rate the tools utilized in this project for validation. The content validity index scale is used by the content experts to determine the validity of the test questions based on the protocol. They will rate the test questions on a scale of one to four. One is defined as not relevant, two defined as somewhat relevant, three defined as quite relevant, and four defined as highly relevant (Beck & Polit, 2006). This has also been used in other published studies, such as the one written by Zamanzadeh, et al, in 2015. In this project, this scale demonstrates appropriate content validity (Zamanzadeh, et al, 2015). The final score of four was calculated using a defined equation (See Appendix E). This score concludes the test questions are highly relevant and valid.

Chart Audit Tool

The audit tool will be used to gather data on nursing compliance with the protocol, as well as patient satisfaction scores (See Appendix F). Patient satisfaction is sent to the project site by email through a survey so no medical charts will need to be referenced. No data will be

placed on the audit tool to measure the objective. The audit tool will measure the compliance of the participants. The information obtained from the chart include patient complaint, filler used, devices used during treatment (cannula or needle), specific adverse event, time passed since filler treatment, and interventions used. No patient identifiers will be extracted to comply with Health Insurance Portability and Accountability Act (HIPAA). One month of surveys will be gathered for the four weeks prior to project implementation.

Survey

The survey is texted to patients after an appointment. This is the current practice of the business. They have the opportunity to rate their appointment from one to five stars. After submitting, the scores are sent to our database via nexhealth, our office software. There is a copy of the text sent to patients attached (see Appendix G). This survey is currently integrated into the practice of this clinic. The project lead will have access to the results of this satisfaction survey, which will be collected to measure the patient satisfaction objective.

Data Collection Procedures

Provider Knowledge Test

Data will be collected from the pre and post-tests from the providers. The scores will be inputted in the statistical package for social sciences (SPSS) software where the project lead will analyze the data. Pre-test will be administered immediately prior to the education. The post-test will be administered after the four weeks of implementation to allow for absorption of the material.

Audit Tool

A retrospective chart audit will be performed prior to implementation of the protocol. The audit will capture the components of the audit tool described above from the charts of

patients seen in the clinic four weeks prior to protocol implementation. To measure if the protocol was effective in improving patient care, data will be collected from the charts of patients seen during the implementation phase. The data collected will be inputted into SPSS system using a code book. The project lead will then be able to apply statistical testing recommended by the statistician to analyze and interpret the results. No personal health information is being extracted. The data retrieved after implementation will be collected to compare against what was retrieved pre-implementation. This type of data collection is a textual or content analysis and is best used in official or organizational views on a topic, such as managing adverse events with dermal filler (Paradis, et al, 2016). The patient satisfaction scores will be extracted from the database retaining the scores during any given period of time. To measure if the protocol was effective in increasing satisfaction rates with management of adverse events, data will be collected during and after the implementation phase. Patient transfer scores will also be extracted from the chart audit. This should be detailed in the chart if transfer took place. This will be used to measure if patient transfers have decreased with protocol implementation. The project lead will apply testing recommended by the statistician to analyze and interpret the results.

Patient Satisfaction Survey

The results from the texted patient satisfaction survey will be collected retrospectively of the four weeks prior to implementation and again after implementation of this project. The scores before and after implementation will be compared and analyzed utilizing appropriate statistical testing. This will measure the objective of improving patient satisfaction with care.

Project Timeline

The intervention identified is protocol implementation. At least one month minimum will be needed to execute. The project topic was identified in July of 2019. Foundational development was created, such as establishing topic purpose, theoretical framework, and performing literature review. These took place over four months from July to November of 2019. November 2019 through February 2020 is the timeframe used to design this project. Designing the project included taking a quality improvement approach. Identification of the population of interest, setting, and stakeholders was completed. The project lead created tools to be utilized during implementation and discussed how the data will be collected. Approval for implementation will be provided by the end of February 2020. Implementation of the project will occur in March of 2020. Below is an implementation timeline to be utilized in the DNP project III beginning March 2020. Participants are the nursing staff at the clinic. Since this is a clinic wide practice change, participation is mandatory.

Implementation Timeline

Weeks	Activities
Week 1	Gather all educational tools to use in educational session Email participants to remind them of educational session Arrange room for educational session Begin retrospective pre-implementation chart audit
Week 2	Provide education to the staff Administer pre-test Monitor staff members once a week to ensure compliance and provide support
Week 3	Meet with all staff members once a week to provide support and ensure compliance
Week 4	Meet with all staff members once a week to provide support and ensure compliance

Week 5	Implementation completed Administer post-test Begin compilation of data collected
Week 6	Perform post-implementation chart audit Review total data and analyze findings

Ethics/Human Subjects Protection

Actions will be taken during project implementation to protect the privacy of the participants and patients. These include assessing needs and resources, establishing a strong ethical foundation, implementing a culture of integrity, and focusing on values (Ethics & Compliance Initiative, 2019). Equitable selection of participants will be maintained, as all participants are included. Human subjects will be protected by maintaining concepts of autonomy, non-maleficence, beneficence, and justice. A DNP project determination form will be completed to ascertain if Institutional Review Board (IRB) review is required. Benefits to participants may include improved management of adverse events. No compensation is provided. Participation is not considered a condition of employment. Privacy will be maintained through use of electronic medical records and hiding pertinent participant identifiers. HIPAA guidelines will be followed to ensure privacy will be kept for patients. No patient personal identification or health information will be collected. Values will be assigned for every nurse to keep personal information private and the codes will be kept on a computer only able to be accessed by myself.

Plan for Analysis/Evaluation

A statistician was consulted for appropriate analysis tests to be run. A paired t-test will be used to measure percentage correct on pre and post-test to measure competency to prove the assumption that the protocol increases provider knowledge. This test is appropriate since it tests

differences in scores at two different times after an intervention (Pallant, 2016, p.278). A Mann-Whitney test will be used to measure times of adverse events before and after protocol implementation to prove the assumption of decreased timespan of adverse events after protocol implementation. This is appropriate because Mann-Whitney tests are used to test for differences between two groups, before implementation and after (Pallant, 2016, p.534). A chi-square test will be used to measure patient transfers before and after protocol implementation to prove the assumption of decreased patient transfers. This test is appropriate to prove a negative correlative relationship between transfers and protocol implementation (Pallant, 2016, p.274). A Wilcoxon-Signed Rank test will be used to measure satisfaction rates before and after. This test is appropriate to measure a change of scores in two different periods of time (Pallant, 2016, p.542).

Implications for Nursing

Project results may impact the field of medical aesthetics, in which nurses participate, to decrease severity of adverse events by managing them in more effective manners by the use of the protocol. Key concepts in the literature review included protocol implementation, management of adverse filler events, and patient outcomes following adverse events. Not only will nurses or other levels of practitioners be able to manage adverse events more efficiently, but patients may also benefit from these direct outcomes. Current literature outlines adverse events being managed by knowledge in medical aesthetics while hospitals have referenceable protocols (Prasad, et al, 2010). The project provided can address this issue by creating and implementing a Dermal Filler Adverse Event Protocol. This will impact the nursing profession by supporting quality improvement measures lead by nurses in a specialty field. A doctoral prepared nurse demonstrates leadership in exceling the nursing field by implementing an evidence-based nurse led protocol.

Data Analysis

Pre and Post-Test Competency

A paired t-test was used to measure percentage correct on pre and post-test to measure provider competency to prove the assumption that training and the use of a protocol increases provider knowledge. The paired t-test is an appropriate statistical test to utilize since it tests differences in scores at two different times after an intervention (Pallant, 2016, p.278).

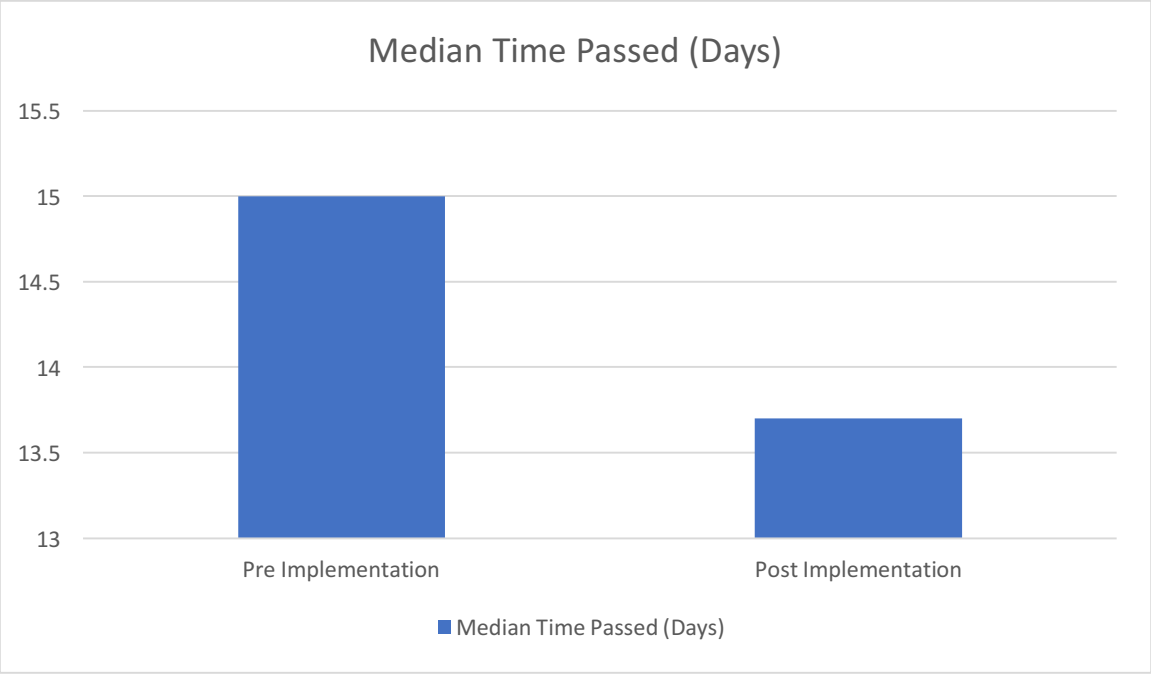
A paired-samples t-test was conducted to evaluate the impact of the intervention on providers' scores on the pre and post-test. There was no statistically significant difference in scores from Time 1 ($M = 10$, $SD = .000$) to Time 2 ($M = 10$, $SD = .000$), $t(6) = .000$, $p < .001$ (two-tailed). This result shows the providers are knowledgeable and competent to correctly answer the test questions.

Times of Adverse Events

A Mann-Whitney test was used to measure times of adverse events before and after protocol implementation to prove the assumption of decreased timespan of adverse events after

protocol implementation. This is appropriate because Mann-Whitney tests are used to test for differences between two groups, before implementation and after (Pallant, 2016, p.534).

A Mann-Whitney U Test revealed no significant difference in the time of adverse events before protocol (Md = 15, n =8) and after protocol (Md = 13.7, n = 3), U = 85.5, z = –1.44, p = .26, r = -.02. This means, the time difference was not proven to be statistically different by standards of the Mann-Whitney U Test.



Patient Transfers

A chi-square test was used to measure patient transfers before and after protocol implementation to prove the assumption of decreased patient transfers. This test is appropriate to prove a negative correlative relationship between transfers and protocol implementation (Pallant, 2016, p.274).

A chi-square test for independence (with Yates' Continuity Correction) indicated no significant association between patient transfers and protocol implementation, $\chi 2$ (1, n = 28) =

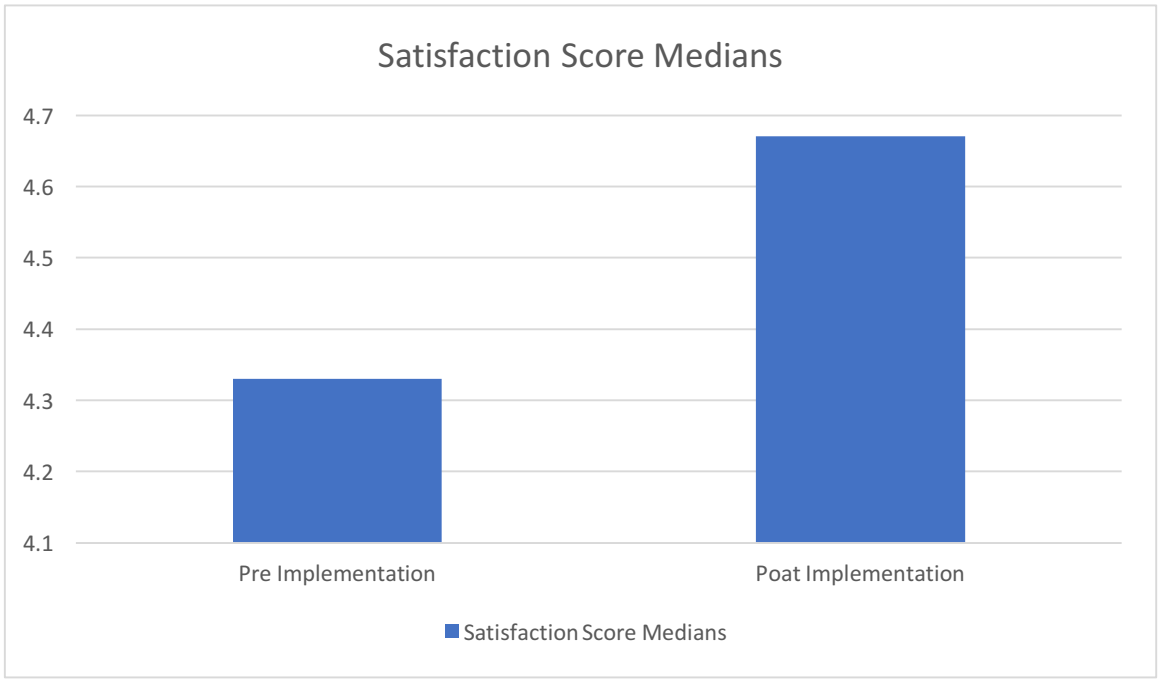
.54, p = .46, phi = –.27. The phi value has an effect between medium and small, indicating association strength.

Satisfaction Rates

A Wilcoxon-Signed Rank test was used to measure satisfaction rates before and after. This test is appropriate to measure a change of scores in two different periods of time (Pallant, 2016, p.542).

A Wilcoxon Signed Rank Test revealed no statistically significance in satisfaction rates after protocol implementation, z = –1.61, p < .001. The median score of satisfaction rates increased from pre-implementation (Md = 4.33) to post-implementation (Md =4.67).

In the month of February, there were ninety patients who responded to the surveys. The average rating was 4.33 out of a scale of one to five. After protocol implementation, there were forty-four patients that responded to the survey with an average rating of 4.67.



Discussion and Significance

Summary of Findings

A chart review was performed for the month of February for all dermal filler patients prior to implementation. Out of the one hundred sixty-one charts included in this chart audit, eight charts were found to have adverse events and one was treated for a foreign body granuloma. Seven of the eight adverse events were seen at two weeks post treatment and were treated for surface irregularities. The eighth adverse event was a patient with a foreign body granuloma that presented seven weeks after initial treatment. The chart audit revealed that all treatments were appropriate and in accordance with the previous protocol in place during the pre-implementation phase. The previous protocol produced resolution of adverse events but did not produce those results as timely as they could have been. The new protocol comes from the need to resolve the adverse event in a timely manner, therefore improving patient outcomes and satisfaction. This helps meet the goal of decreased time span of adverse event duration.

The protocol was implemented for the month of March. There were three adverse events after the protocol implementation. Adverse events varied in severity and will be detailed so that connections can be made between the implementation of the protocol and quantity of adverse events. This data analysis is constructed of quantitative data, making this a quantitative data analysis. The data to be analyzed consists of three topics related to the adverse events in the chart, and satisfaction rates reported by the patient in an online system.

Staff Competency

The participants answered 100% of the questions correctly before and after the protocol education was provided. This result suggested that the providers were competent by standards of the protocol to recall foundational knowledge with injectable fillers. The paired t-test proved no

significant difference, which makes sense since the scores were the same before and after. The providers likely received a score of 100% because they had recently attended a Safety with Dermal Fillers educational seminar, which current best practices.

Delay in Treatment Time

The objective was met for a decreased time in duration of adverse events but statistically it was not proven to be significantly different. The time that had passed for the two surface irregularities was exactly two weeks. The standard for follow up appointments is two weeks for this industry (Vedamurthy, et al, 2010). The patient is recommended to notify the clinic if moderate to major adverse events are being experienced; therefore, the patients did not call to report this adverse event since it was considered a mild complication. The patients kept their follow up appointments. The third patient notified the office with concerns that her swelling was not subsiding so she was given an earlier appointment. This explains why time passed with adverse events decreased from pre to post implementation. However, the Mann Whitney U test proved not to be statistically significant. Though not statistically significant, this decrease is as a result of the protocol implementation.

Patient Transfers

There were two patient transfers the month prior to protocol implementation and zero patients transferred following protocol implementation. Though not significantly different by the standards of a chi-square test, the two-patient difference may be contributed to the ability to reference a protocol and respond to an adverse event with optimal timing. The protocol gave the providers a tool to follow to improve outcomes; thus, mitigating the need for patient transfers.

Satisfaction Rates

Satisfaction rates of treatments were measured one a scale of one to five, one being unsatisfactory and five being excellent. The text message/email was sent twenty-four hours after the treatment was provided. The month prior to project implementation, there were 90 patients who responded to the surveys. The average rating was 4.33 out of five. After protocol implementation, there were 44 patients who responded to the survey with an average rating of 4.67. A Wilcoxon-Signed Rank test was used and determined that 95% of messages sent were answered.

Therefore, it is possible to conclude, the time the survey is sent impacts the scores. It was discussed in the summary that three patients had adverse events post implementation. The goal was to increase average satisfaction rates post protocol implementation. The objective was met though the Wilcoxon Signed Rank test did not prove it to be significantly significant.

Adverse Events

There were two patients who experienced mild complications and one patient who experienced moderate complications post protocol implementation. All the patients were treated according to the protocol. The use of the protocol reduced the need for further treatment. The objective was to decrease the number of adverse events post implementation; however.

Significance

The project objectives were met for each factor being measured. Though these results were not proven to be statistically significant, there were minor changes before and after implementation that proved the protocol positively impacted these factors. Since scholarly evidence is limited in the medical aesthetics field, developing evidence-based protocols and performing DNP projects will improve the credibility of nurses who choose this specialty for a career. This DNP project will contribute to the scholarly body of knowledge for this industry.

This project indicates the nurses can be integral participants in policy and protocol development that positively impacts patient care outcomes.

Limitations

Project Design

This project only included participants of a single outpatient office with providers that had significant prior knowledge of handling adverse events. Since it is a single practice the number of patients seen within the specified timeframe is limiting.

Data Recruitment

The amount of data was limited because the project was stopped due to clinic closure to non-emergency treatments due to the Covid-19 pandemic. The abrupt pause of patient returns cut off the possibility of minor adverse events, allowing the three adverse reactions post implementation to be the only adverse events. Any patients with minor adverse events such as minor contour irregularities were likely satisfied enough with their treatment to not seek out follow up, or understand that the follow up may have been a possibility. Some patients may not have been able to identify a minor adverse event on their own.

Another limitation in data recruitment is the patient satisfaction metrics. The patient satisfaction survey is sent to all patients' post-procedure. The survey does not differentiate between patients that had an adverse event compared to those who did not have one. The patient satisfaction rate is measured as a whole. This is a limitation because it is also measuring patients' satisfaction who had treatment and did not experience an adverse event.

Collection Methods

The data was collected through a pre-posttest test, through chart audits, and through a system-generated electronic survey that is sent to patients. The pre-posttest given to the

providers may have reflected less retained knowledge if it were given three weeks after the educational session. The satisfaction survey was sent to all patients who received a treatment and requested an overall satisfaction score of their visit. The survey may have had a different result if it was specific to the satisfaction rate of their filler treatment outcome.

Data Analysis

The analysis of data was limited due to the quantity of post protocol data retrieved. Due to the fact that data was incomplete, the interpretation of this data may not have been as thorough. The office closure, due to the virus, contributed to a partial implementation of this project. The data analysis depends upon the quality and quantity of the data; therefore, the results of this project may also be skewed due to the limited time given after project implementation, which was weeks vs years of data (Cianco et al. 2018).

Dissemination

It would be recommended to distribute this protocol widely among outpatient aesthetic practices in addition to emergency rooms and urgent care clinics. This project will be provided to the American Academy of Emergency Medicine with a request to share the project as a speaker presenter at a future conference. Emergency departments and urgent care centers are not commonly equipped to manage ischemic events or adverse events relating to dermal filler treatments. Guidelines on managing these events will likely help with the early treatment of ischemic events when a patient seeks treatment in an emergency department or urgent care center. The project will also be disseminated to stakeholders, instructors, student colleagues, and the DNP repository.

Project Sustainability

This project created a sustainable protocol, which can be easily applied for use when there is an adverse filler event. The protocol was created to be easily identified and easily read in case of time sensitive adverse events. The protocol requires little to no financial investment, as it is a collection of evidence-based practices to guide adverse event management. Use of the protocol is efficient and helps provide clarity in managing stressful events. The stakeholders at the clinic will incorporate this protocol as a policy and incorporate this into practice. In addition, it will also incorporate this policy at its' sister facility.

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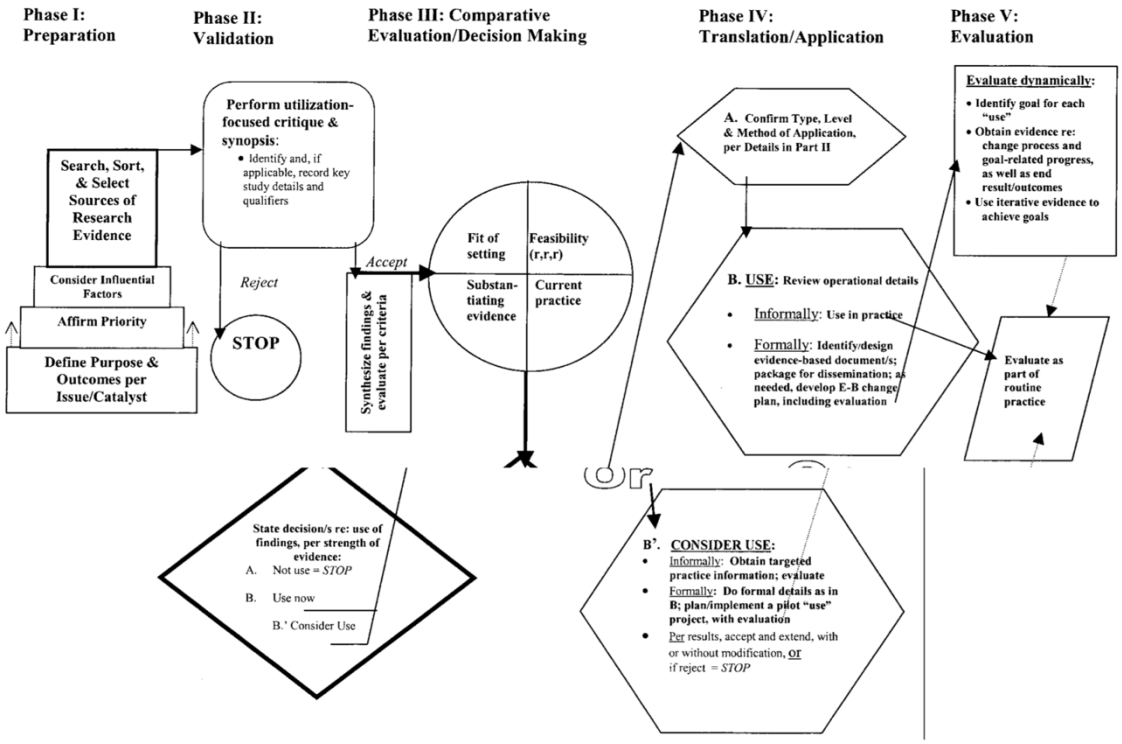
Appendix A

Stetler's Model



Appendix B

Project Site Agreement

Agreement is not needed for Janell Ocampo to use Belle Vie Wellness & Medical Aesthetics as clinical site for DNP project.

Jasmin Carrasco

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Practice Manager

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Belle Vie Wellness & Medical Aesthetics

Appendix C

Protocol

Appendix D

Provider Knowledge Test

Dermal Filler Adverse Event Management Questions

1. **How is a hyaluronic acid-based filler reversed?**

A: with hyaluronidase

Rationale: Hyaluronidases are enzymes (endoglycosidases) that can depolymerise HA, leading to its degradation by hydrolyzing the disaccharides at hexosaminidic β-1through β-4 linkages (King & Convery & Davies, 2018).

2. **How much time can pass until blindness caused by filler is irreversible?**

A: 90 minutes

Rationale: Once the retinal artery has been occluded, there is a window of 60 to 90 minutes before blindness is irreversible (Walker & King, 2018).

3. **What is the Tyndall effect?**

A: Blue color of skin from superficial filler

Rationale: In aesthetics, the Tyndall effect is used to describe the bluish hue that is visible within the skin caused by too superficial placement of hyaluronic acid (HA) filler (King, 2016).

4. **What do you do if you see blanching of the skin while injecting dermal filler?**

   A. Inject 500iu hyaluronidase per region blanched and massage vigorously

   Rationale: For a single region, we recommend starting with a dose of about 500 iu every hour or so, until the ischemia is resolved (until skin color has returned and capillary refill time has returned to normal) (Delorenzi, 2017).

5. **If a patient returns from dermal filler treatment after 2 months and says they have hard nodules, what should be done?**

A: Inject 50-200iu hyaluronidase per region affected

Rationale: Hyaluronidase preparation, dilution, and doses recommended by the panel: 50–200 IU in nodules (Urdiales-Galvez, et al, 2018).

6. **Why is massage used in addressing vascular occlusion?**

A: To promote diffusion and mechanical breakdown

Rationale: Massage the area to promote diffusion and mechanical breakdown (King & Convery & Davies, 2018).

7. **When would a vascular occlusion occur?**

A: Typically instantly, but in rare occasions can take start hours or days later

Rationale: …The Aesthetic Complications Expert group have found many reported cases when the symptoms of ischaemia start several hours or even days later (King & Convery & Davies, 2018).

8. **Why does a delayed occlusion happen?**

A: A particle of filler dislodges in the vessel and floats upstream to occlude a smaller vessel.

Rationale: With this view, partial breakdown of HA is insufficient, because partial breakdown products can still obstruct blood flow (although they may be pushed further downstream by arterial pressure) (Delorenzi, 2017).

9. **How do you perform an intradermal patch test for hyaluronidase allergy?**

A: Inject 4-20 units of hyaluronidase intradermally to the forearm. Check after 30 minutes.

Rationale: An intradermal injection of 4 to 8 units of hyaluronidase in the forearm and observing the results after 30 minutes has been advocated (King & Convery & Davies, 2018).

10. **If a patient is presenting with blanching in two regions, how much hyaluronidase should be administered?**

A: 1000u every hour

Rationale: We present a rough rule of thumb, using the lip, nose, and forehead as dose multipliers, with the standard dose of about 500 iu per area (DeLorenzi, 2017).

Appendix E

Content Validity Index

Item	Expert 1	Expert 2	Expert 3	Mean
1	4	4	4	4
2	4	4	4	4
3	4	4	4	4
4	4	4	4	4
5	4	4	4	4
6	4	4	4	4
7	4	4	4	4
8	4	4	4	4
9	4	4	4	4
10	4	4	4	4

The procedure consists of having experts rate items on a four-point scale of relevance. Then, for each item, the item (CVI) (I-CVI) is computed as the number of experts giving a rating of 3 or 4, divided by the number of experts-the proportion in agreement about relevance.

The content validity index is calculated using the following formula:

CVR = [(E-(N/2)) / (N/2)] with E representing the number of judges who rated the item as Moderately Relevant or Highly Relevant and N being the total number of judges.

The mean total of all of the means was 4 indicating that all of the questions were moderately/highly relevant.

The calculation is as follows:

CVR = [(3-(3/2)) / (3/2)]

CVR = [(3-1.5) /1.5]

CVR = 1.5/1.5

Appendix F

Chart Audit Tool

Provider Number	Patient Initials	Completion of Item
1	A.A	**Patient complaint** Loss of volume in lips
		Filler used Juvederm Ultra Plus
		Device(s) used Cannula
Adverse Event (Y/N) Y		**Adverse event** Contour irregularity
		Time passed with adverse event 2 weeks
		Interventions used Massage and 50iu hyaluronidase

Patient Satisfaction Score (extracted from nexhealth reporting)

1-5

Appendix G

Patient Satisfaction Survey Text

How was your treatment with Belle Vie Wellness & Medical Aesthetics? Reply from 1 to 5, with 5 being the best.