Improving the Management of Adverse Filler Effects

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Background

- Dermal filler first became United States (U.S.) Food and Drug Administration (FDA) approved in the early 2000s. Practitioners learned how to treat adverse events through experience and medical knowledge. However, this lacks scholarly documentation due to the absence of 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.

Problem

- Nurses and nurse practitioners are heavily involved in the administration of dermal fillers. Neglecting to address this as a skill in nursing fails to recognize nursing as a dynamic field, one that is responsive to changes in society and culture.
- 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.
- Other leaders in the field can follow to create well researched protocols for other procedures and adverse event management.
- Increasing the access to these protocols provides for a better understanding of how to prevent potential treatment complications.

Purpose Statement

- Patient safety and the advancement of medical aesthetics can be achieved through the creation and implementation of a protocol available for all practitioners delivering dermal filler treatment.
- 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 resulting from practitioner lack of knowledge in dermal filler treatment.

Project Question

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?

Project Objectives

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 will 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.

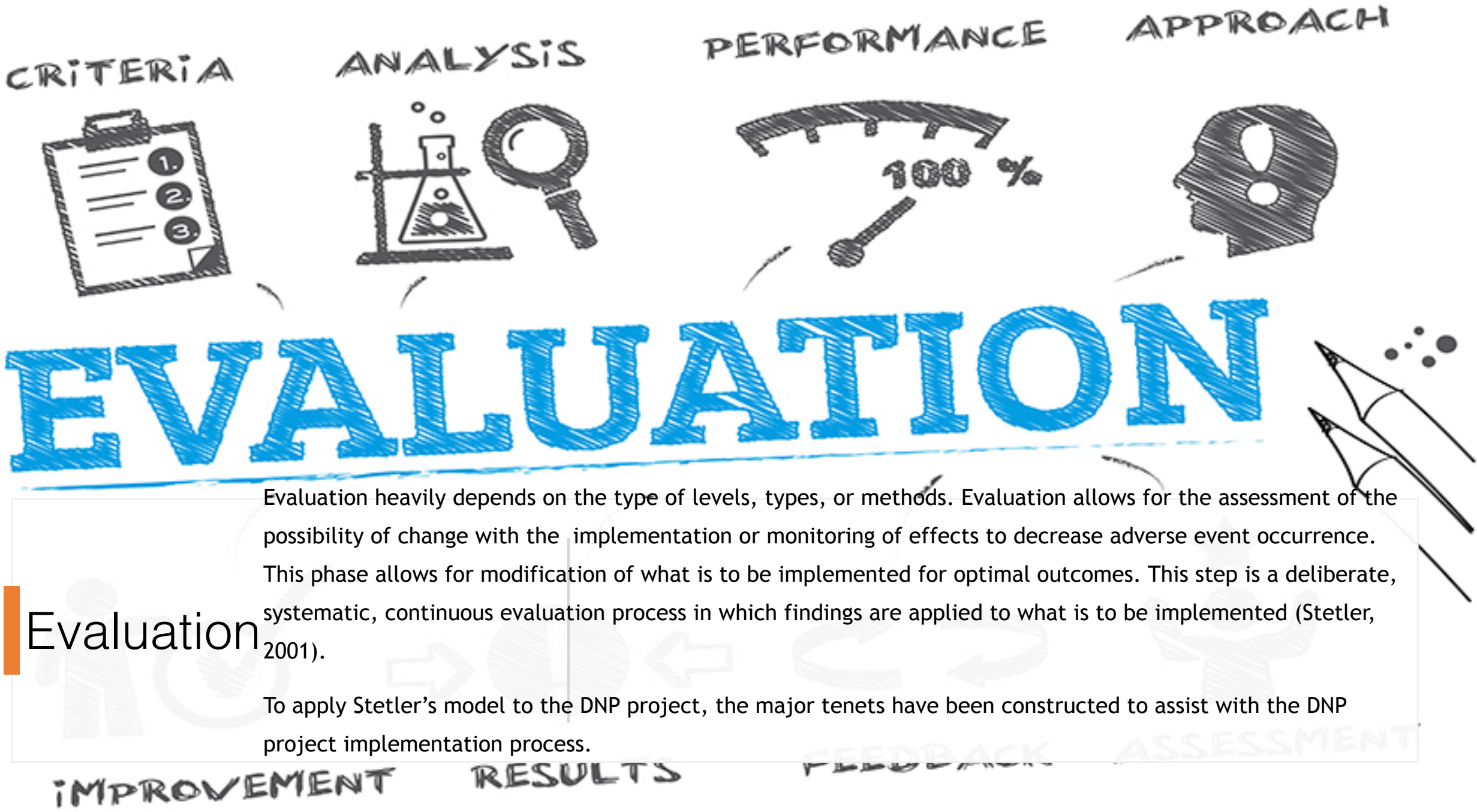
Study Methods

Study methods will be reviewed and explained for relevance to the topic of protocol implementation for dermal filler adverse events.

- The 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.
- 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.
- Cianco, et al (2018) does not provide an outlined methodology, but instead provides information on two patient cases that followed a specific protocol, which can be useful in identifying protocols applied to adverse events with dermal filler.
    - 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.
- 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.

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 hinking 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.



Evaluation

Evaluation heavily depends on the type of levels, types, or methods. Evaluation allows for the assessment of the possibility of change with the 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).

To apply Stetler's model to the DNP project, the major tenets have been constructed to assist with the DNP project implementation process.

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 n 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.

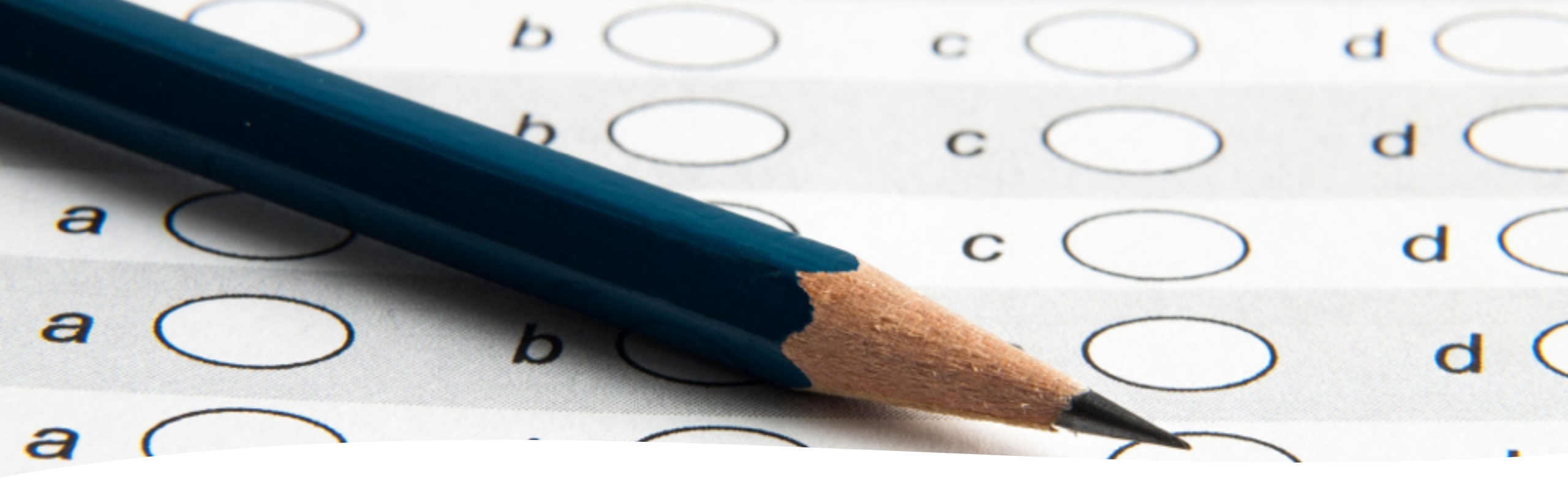
Recruitment Methods

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. 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.

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. 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.

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.

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.

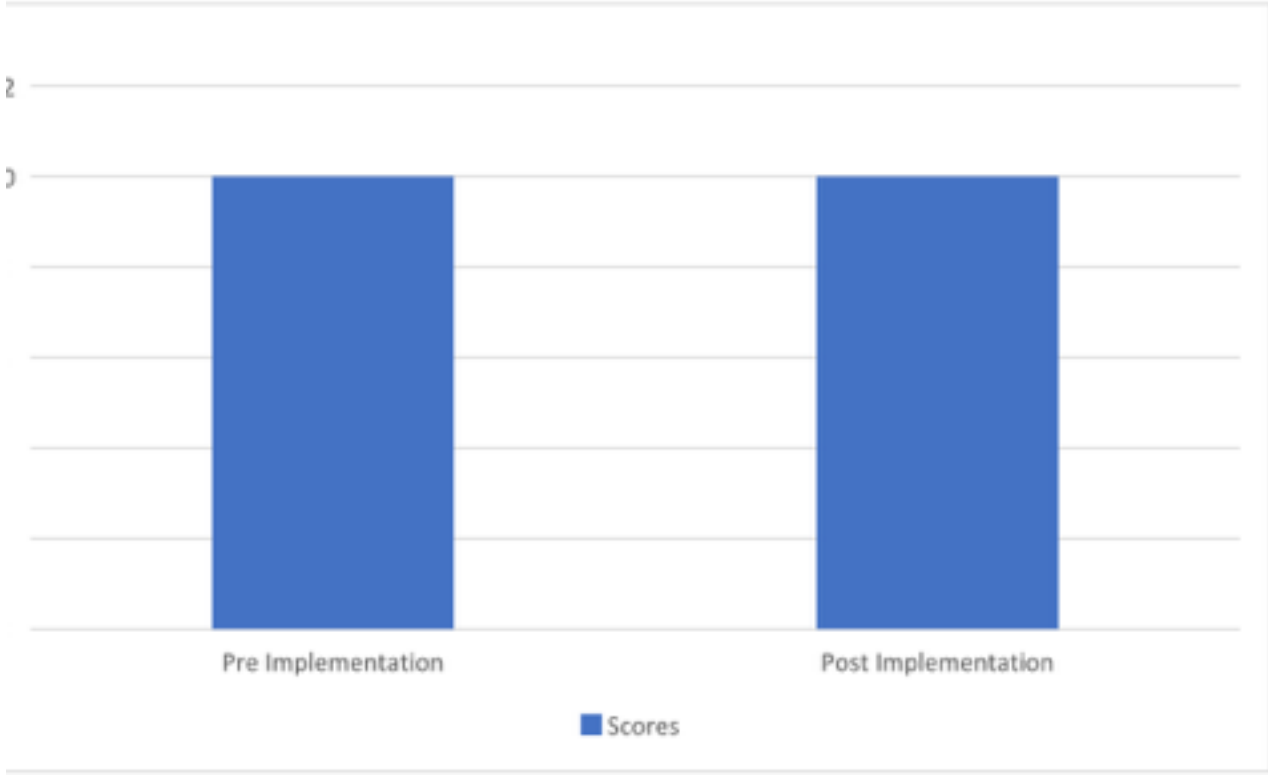
Survey

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.

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 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.

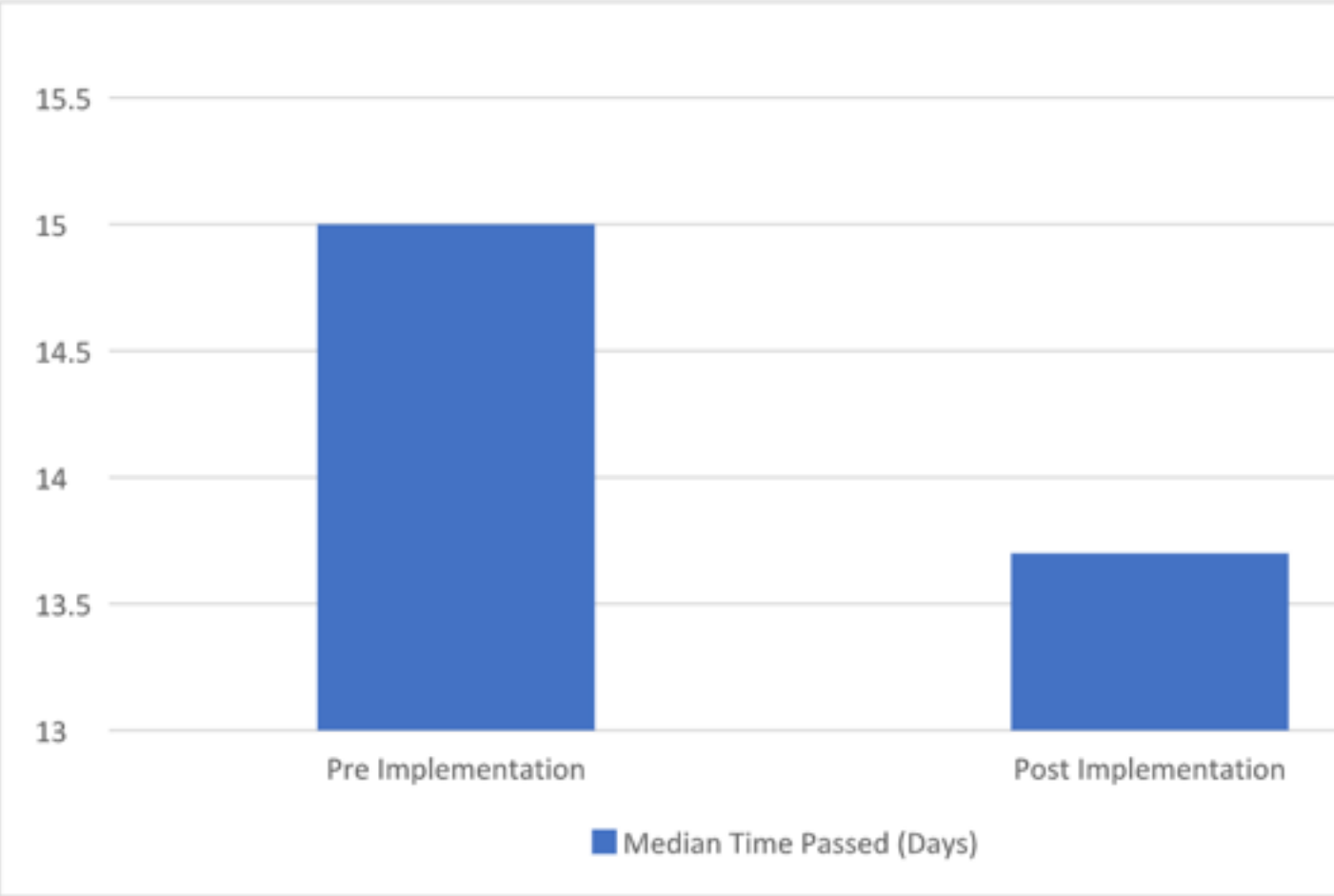
Pre and Post-Test Competency



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).

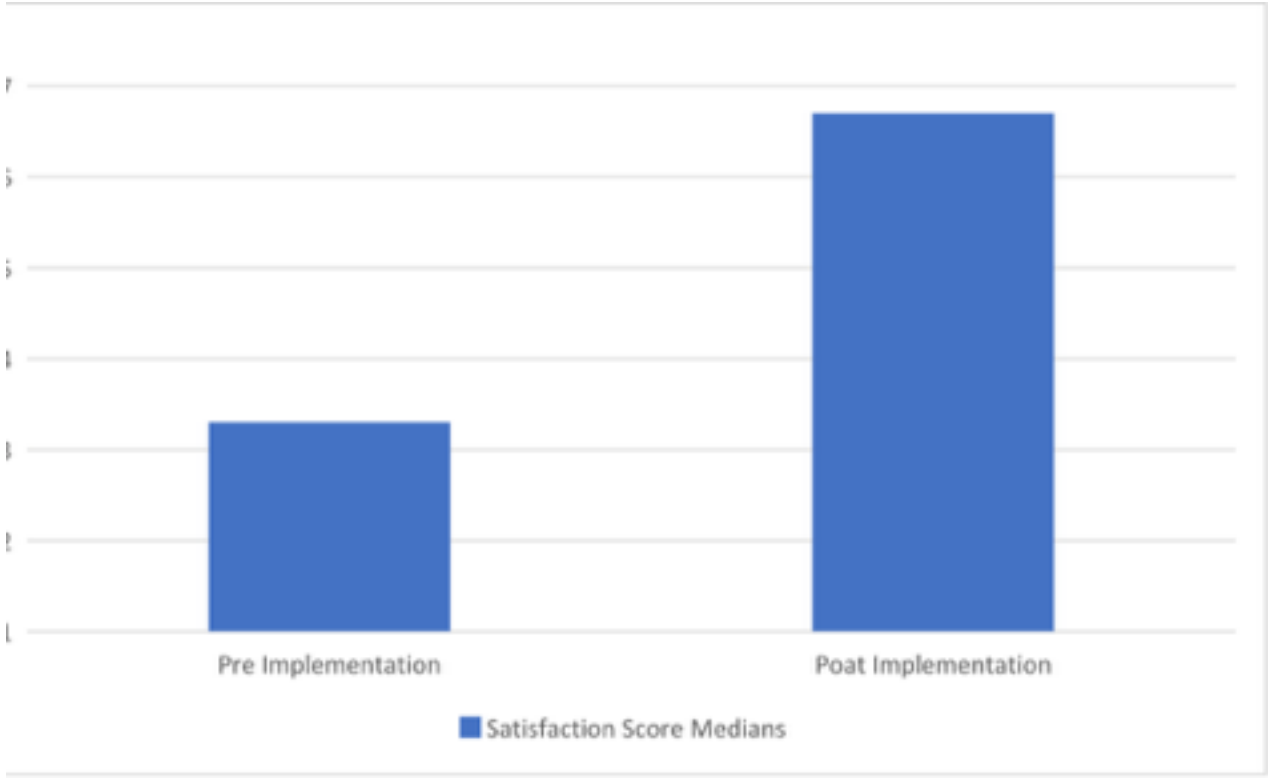
A Mann-Whitney U Test revealed no significant difference in the time of adverse events before protocol (Md = 15, n =8) and after protocol (Md = 13.7, n = 3), U = 85.5, z = -1.44, p = .26, r = -.02. This means, the time difference was not proven to be statistically different by standards of the Mann-Whitney 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, x2 (1, n = 28) = .54, p = .46, phi = –. 27. The phi value has an effect between medium and small, indicating association strength.

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

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.

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 data is quantitative, making this a quantitative data analysis.

Staff Competency

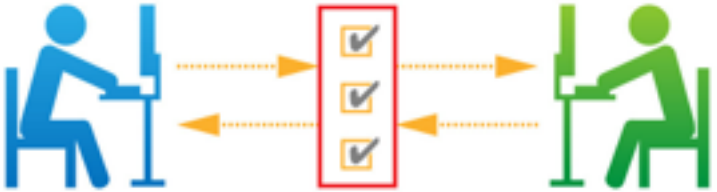
The participants answered 100% of the questions correctly before and after the protocol education was provided. This result suggested that the providers were competent by standards of the protocol to recall foundational knowledge with injectable fillers. The paired t-test proved no significant difference,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

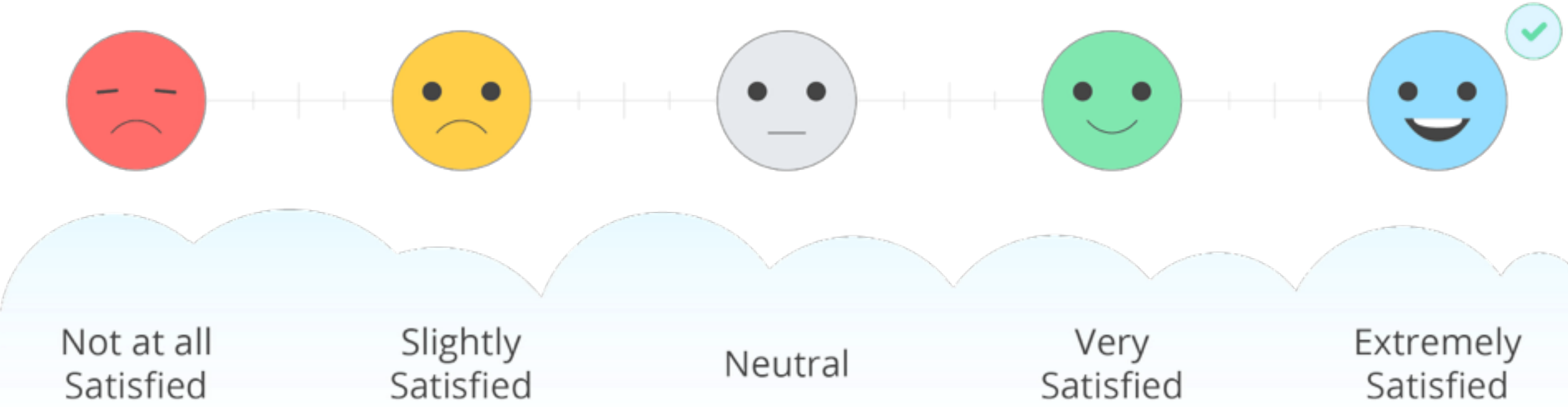
Delay in Treatment Time

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

The 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

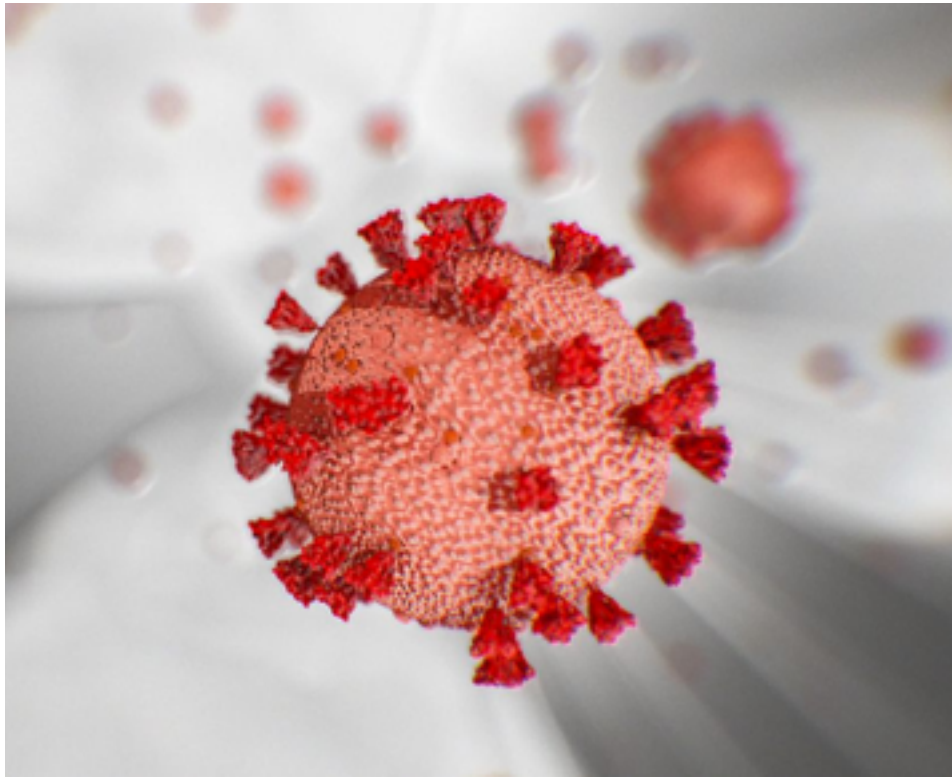
There were two patients who experienced mild complications and one patient who experienced moderate complications post protocol implementation. All the patients were treated according to the protocol. The use of the protocol reduced the need for further treatment. The objective was to decrease the number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

Project Design

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.

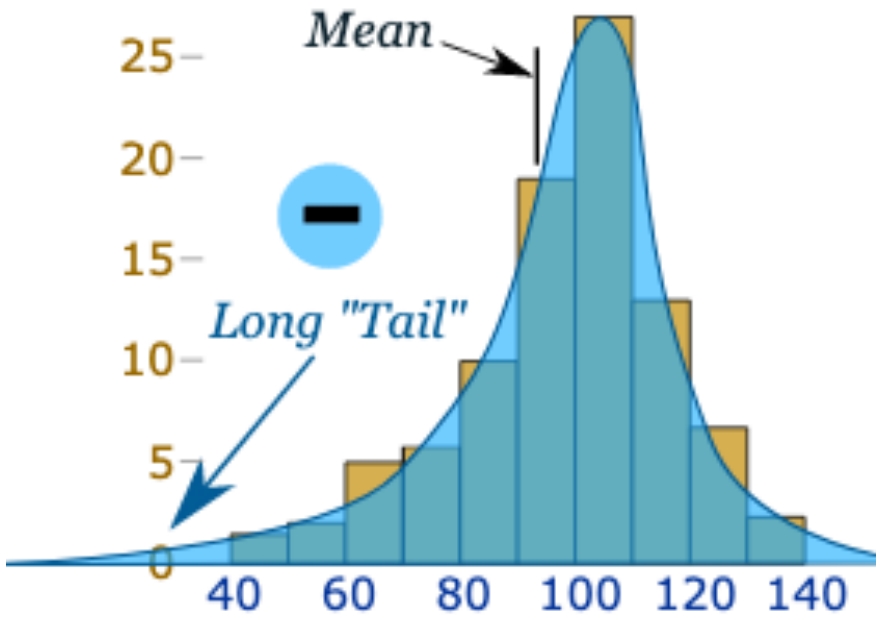
Data Recruitment

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 a 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 the 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).

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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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References

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.

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Belle Vie Wellness & Medical Aesthetics

References

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?**

References

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).

References

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

References

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.