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Medical Spas: Ensuring Compliance and Patient Safety

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Walden University
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Abstract

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MS, South University, 2016

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Project Submitted in Partial Fulfillment

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Abstract

Nonsurgical aesthetic procedures continue to grow in popularity; however, evidence-based clinical practice guidelines that can assist providers when performing aesthetic treatments are lacking. This gap in practice can result in the increased prevalence of side effects from treatments that can compromise patient safety and result in increased litigation. The goal of this project was the development of a clinical practice guideline (CPG) that can be used by aesthetic providers to standardize care when performing nonsurgical aesthetic procedures that can ultimately improve provider knowledge, which would improve patient safety. This CPG sought to answer the practice-focused question involving whether the development of a CPG for aesthetic providers can increase their knowledge about delivering safe and consistent patient care. The Appraisal of Guidelines for Research & Evaluation (AGREE) II instrument was the guiding framework used to develop and appraise the CPG once it was developed. Based on the AGREE II CPG evaluation criteria, an expert review panel consisting of six professionals from the medical spa industry analyzed the CPG using the AGREE II appraisal tool. Feedback from the expert panel was used to modify the draft version of this CPG before completing and presenting the final draft. The expert panel recommended the CPG for future incorporation and use at the project site. By incorporating and using this CPG, aesthetic treatments can be standardized to help improve patient safety, reduce adverse events, and improve patient outcomes, which can positively impact social change at the project site as well as practice sites locally, nationally, and globally.

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Dedication

This project is dedicated to the hard-working men and women of the nursing field across the world. This project is dedicated to you whether you are working in aesthetics or other care unit. Let us all keep working to advance our nursing practice and enlighten our knowledge of the known and the unknown.

Acknowledgments

I would like to thank the staff of Walden University for their support during my tenure in the program. I would also like to particularly thank Dr. Barbara Barrett for her support as my project mentor and instructor as well as my other committee members, Dr. Barbara Lee Gross and Dr. Faisal Hassan Aboul-Enein. I want to acknowledge the American Med Spa Association (AmSpa) for providing the references on the rules and regulations of aesthetics practice. A special thanks to my friends and family who have always pushed me to do extraordinary things, especially as they could not get the attention they deserved during my studies. To you, I am eternally grateful.

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Section 1: Nature of the Project

Introduction

Options and prevalence of nonsurgical aesthetic procedures continue to rise nationwide. With that rise, there is also an increase in the prevalence of botched procedures by inexperienced providers and those who do not follow safety guidelines set by state nursing and medical boards. There is also a lack of clear and up-to-date safety and legal guidelines governing nonsurgical aesthetic procedures. Inexperienced providers and lack of clear and concise guidelines and adherence to existing guidelines present challenges for the med-spa industry, providers, and patients. The goal of the project was to develop a clinical practice guideline (CPG) that can assist healthcare providers at a local med spa to safely and effectively perform nonsurgical aesthetic procedures. This project supports regulatory compliance, enhances provider practice, and improves patient outcomes and safety, which ultimately improves care practices in the field of aesthetics. In doing so, the CPG improves patient outcomes and helps prevent or reduce legal ramifications associated with healthcare providers' noncompliance with their respective regulatory state licensing boards, with implications for positive social change.

Problem Statement

As advancements in nonsurgical medical aesthetics procedures continue to evolve, state and federal policies providing clear and up-to-date safety and legal guidelines for such procedures performed at medical spas by registered nurses (RNs), nurse practitioners (NPs), physician assistants (PAs), and physicians are limited or lacking. Botched procedures are being performed nationwide, resulting in irreversible

damages such as dermal burns, scarring, and even blindness, which often result from medical spa providers not following state guidelines (American Med Spa Association [AMSPA], 2018). As more people come forward with complications resulting from nonsurgical procedures performed by improperly trained providers, increased exposure through the media has resulted. As the publics' awareness about more cases like these increases, state regulatory agencies have increased enforcement of state guidelines violations (AMSPA, 2018). Many medical spas and operators have faced legal ramifications due to a lack of proper supervision of medical treatments and improperly trained personnel (Goldberg, 2018). Noncompliance with state and federal laws and professional scope of practice compromise patient safety and increase litigation potential.

The Medical Board of California (MBOC) and California Board of Nursing (CBON) require that an initial good faith exam (GFE) be performed and documented by a physician or an APRN (advanced practice registered nurse) (AMSPA, 2018). Physicians may delegate APRNs to perform the initial medical clearance GFE of a patient prior to the patient undergoing an aesthetic procedure (AMSPA, 2020; MBOC, 2020). The AMSPA (2018) said 37% of respondents to a survey related to the GFE admitted either the GFE was not being performed or that the physician, PA, or NP was not the one performing the initial exam. However, there are currently no guidelines for aesthetic providers regarding specifics of the GFE, also known as the medical clearance assessment, and postprocedural follow-up and evaluation for any future medical treatment that may be performed (AMSPA, 2018). The common belief among aesthetic providers is that they are complying with laws and regulations as long as they document

and detail procedures that were performed and patient outcomes. While some providers may admit to verbally reassessing patients before any medical procedure, this information is not documented in formal medical charts. This is also the case at the intended project site.

For inexperienced medical spa owners, current laws are ambiguous in terms of what exactly constitutes physician supervision and delegation for RNs and NPs. This has led to inconsistencies in care that have compromised patient safety and care outcomes. This CPG improves patient and provider safety by ensuring that patients' medical history is reviewed prior to each aesthetic treatment and provides an easy-to-use checklist to support the approach. This checklist allows the health care provider to know if all necessary steps were taken prior to providing treatment or if further action is needed. Developing a practice process that incorporates a medical history review and the completion of a preprocedural checklist during every patient visit improves patient care, patient safety, and nursing practice.

Purpose Statement

Through a review of literature, individual cases of wrongdoing, past and current lack of care oversight, and inadequate training were identified in this project. Customarily, patients receive medical clearance by their primary care physician (PCP) before a scheduled surgery that usually includes tests like blood work and an electrocardiogram (EKG) (Keshavan & Swamy, 2016). Although the procedures at medical spas are considered nonsurgical, similar protocols can be established to guide clinicians and standardize care practices. Medical spa providers must be mindful that the

majority of medical spa procedures being performed are medical treatments and hence should be governed by laws and regulations of standard procedures (SPs) to support compliance with their respective scope of practice (AMSPA, 2020). While healthcare professionals may perceive patient evaluations prior to any medical procedure as common sense, the consistent performance of such evaluations in the medical spa industry due to a lack of procedure protocols and/or lack of knowledge or experience regarding procedures being performed is questionable (AMSPA, 2018). At the intended project site, there is a lack of standardized care practice protocols that can assist staff in providing safe patient care and compliance with current national and state regulations and state scope of practice guidelines, resulting in a gap in practice. This DNP project was focused on the development of a CPG that can assist practitioners in providing safe and consistent care to reduce the practice gap. The project's practice-focused question for this project was: Can the development of a CPG for aesthetic providers increase their knowledge about delivering safe and consistent patient care? The ultimate goals of practice protocols are to provide patients with safe and standardized care, prevent unwanted complications, and avoid legal ramifications (Adatto & Byrd, 2017). This practice protocol can standardize care, increase provider knowledge, and improve patient outcomes, which can positively impact patient outcomes.

Nature of the Doctoral Project

Due to limited literature about the nonsurgical aesthetic field, the AMSPA was established to help guide medical spa organizations and clinicians. As the leading source for policies and procedures in the medical spa industry, the AMSPA's staff agreed to

support the proposed clinical project by providing information that would aid in the development of this project.

A review of literature was conducted to support the clinical practice problem and guideline development using the Walden University Library to search various databases (CINAHL, ERIC, MEDLINE, PubMed, and BioMed Central). Search terms included: *AGREE II*, *best practice*, *clinical practice guidelines*, *Melnyk and Fineout-Overholt rating system of hierarchy of evidence*, *theory in aesthetics*, *rules and regulations*, *medical spas in California*, *lawsuits with med spas*, *California med spa laws*, *California Board of Nursing*, *California Board of Medicine*, *good-faith exam*, *trouble for med spas*, *patient safety*, *safety in aesthetics*, *aesthetic dermatology*, *cosmetic dermatology*, *best practice*, *physician supervision*, *adverse events in aesthetics*, and *medical procedures by nurses.* As an additional source of reference, the AMSPA provided updated information relevant to laws and regulations of medical spas in the state of California.

This clinical practice project was focused on developing a CPG for the medical spa facility at the project site. Approval to conduct this project at the practice site was provided by the administrator and physician owner of the med spa. The Walden University Manual for Clinical Practice Guideline Development was used to support this project. I communicated with the site owner/physician, and a plan was established with measurable and attainable goals as identified in Walden University's CPG project manual. The guideline was developed using The Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II), which involves developing scope and purpose, stakeholder involvement, rigor or development, clarity of presentation, applicability, and

editorial independence. The AGREE II gives researchers guidance on the recommended context of a high quality CPG and has been used for many years by CPG developers. An expert review panel was formed to review the CPG. The expert panel consisted of one physician owner, the general manager, one PA, one NP, and two RNs. The expert panel was educated regarding the AGREE II instrument and its use. The panel was provided 2 weeks to review the CPG and provide feedback. After review by the panel, the CPG was scored according to AGREE II scoring instructions and revised due to panel feedback.

Evidence collected to support this CPG was organized and graded by the Melnyk and Fineout-Overholt rating system (MFRS) of hierarchy of evidence. The MFRS is a reference tool for researchers to grade the quality of evidence they are using to support their proposed project development. During the development of this CPG, the latest evidence-based literature was incorporated. The hierarchy of evidence rating systems helped me to determine the level of evidence of literature ranging from level I –VII with level I being of highest quality.

Significance

Stakeholders impacted by this doctoral project were the employees and the administrator/owner of the medical spa facility located in the western region of the United States. The facility employees impacted by this project were RNs, NPs, PAs, general management, and one physician. The administrator and physician owner of the medical spa supported this doctoral project. The administrator agreed that this doctoral project when disseminated can fill the current clinical practice gap at the med spa and can

assist employees in terms of following state guidelines. This project can improve patient outcomes while potentially reducing the chance of legal ramifications.

Walden University (2018) defined positive social change as "a deliberate process of creating and applying ideas, strategies, and actions to promote the worth, dignity, and development of individuals, communities, organizations, institutions, cultures, and societies" (para. 2). This DNP project focused on developing a CPG to streamline care in a med spa setting and promote patient safety by reducing patient complications, improving patient outcomes, and ultimately preventing legal ramifications. This CPG can promote compliance with state and federal guidelines for med spa clinicians, ultimately improving patient safety and protecting clinicians, hence promoting positive social change. This CPG also benefits RNs, NPs, PAs, physicians, and medical spa organizations at the local, state, and national levels, and most importantly, patients at large.

Summary

Developing a CPG for aesthetic procedures assists clinicians in performing standardized procedures by improving patient outcomes while protecting and enhancing patient and clinician safety. This project can fill the gap in practice related to lack of available guidelines for clinicians to support improving patient care outcomes and safety during nonsurgical cosmetic procedures. As more nurses fill the needed demand for nurse injector positions, the field of aesthetics can continue to grow. This project allows nurses to positively impact social change through the advancement of evidence-based care. The

project aligns with the AMSPA's policies and procedures related to aesthetic nonsurgical interventions in medical spas.

Section 2: Background and Context

Introduction

In the field of nonsurgical aesthetics, procedures primarily performed at medical spas lack clear and up-to-date guidelines on safety protocols and scope-of-practice for RNs, nonphysician providers, and physicians. This CPG provides a tool for such providers to have when performing nonsurgical aesthetic procedures to help improve patient safety while ensuring compliance with state and federal guidelines. The practice-focused question for this project was: Can the development of a CPG for aesthetic providers increase their knowledge about delivering safe and consistent patient care? By following the CPG, healthcare providers can provide safer care and help reduce or prevent legal ramifications. In developing this CPG, concepts, models, and theories that inform and support evidence are discussed in this section. I also synthesized primary writings and clarified terms that may have multiple meanings pertaining to the CPG. This section also includes a summary of local evidence and context of the problem and relevance of the CPG to nursing practice. The role of the DNP student is also discussed.

Concepts, Models, and Theories

This CPG was developed using the AGREE II instrument, one of the most commonly used guideline appraisal tools for CPG development and evaluation. In developing this CPG, it was critical to analyze evidence in a review of literature and grade such evidence accordingly. The evidence was graded using the MFRS of hierarchy of evidence, which also allowed for prioritizing relevance of evidence in terms of the development of the CPG. To support the successful implementation of the CPG, the

theoretical domains framework (TDF) was included in the project and is also recommended to help guide clinicians after this project has been completedwhen implementing the changes. Implementation of this CPG using the TDF will support the recommendations to assist in the facilitation of the CPG. The TDF encourages CPG developers to analyze anticipated behavior changes of end-users to help determine how to better apply or disseminate the CPG. With every change project, it is expected that some level of resistance to change may exist, which further reinforces the importance of the TDF in anticipating such change before implementation. While many researchers may argue that common sense works just as well as theory when applying a CPG, more relevant studies have suggested that CPGs that included a guided theory had a higher chance of implementation success compared to those implemented without a guided theory (Taylor et al., 2014).

AGREE II

The AGREE II instrument is quantitative and allows researchers to develop cost-effective high quality CPGs. The AGREE II details various factors that comprise an appropriate high-quality CPG. Researchers can use the AGREE II as a checklist to ensure they have fulfilled requirements of guideline development, which involves scope and purpose, stakeholder involvement, rigor or development, clarity of presentation, applicability, and editorial independence (Seto et al., 2017). Regarding rigor, the AGREE II details and evaluates systematic methods used to obtain evidence supporting the CPG and evaluates whether or not the CPG was first reviewed by an expert panel prior to its implementation or application to pilot studies (see Table 1).

Table 1

Framework to Develop the CPG

AGREE II Model
Domain 1. Scope and Purpose
1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patient, public, etc.) to whom the guideline is meant to apply is specifically described.
Domain 2. Stakeholder Involvement
4. The guideline development group includes individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.
Domain 3. Rigor of Development
7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strength and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.
Domain 4. Clarity of Presentation
15. The recommendations are specific and unambiguous
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.
Domain 5. Applicability
18. The guideline describes facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and/or auditing criteria.

Domain 6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guideline development group members have been recorded and addressed.

Note. From "Appraisal of Guidelines for Research and Evaluation II," by The AGREE Research Trust, 2013, pp. 6–8. Reprinted with permission.

MFRS Hierarchy of Evidence

Using the MFRS hierarchy of evidence, researchers are able to perform a rapid critical appraisal of current evidence to determine level of evidence, quality of conducted research, and usefulness to practice. In this project, a study evaluation table (see Appendix A) was developed to divide hierarchy of evidence and answer applicable questions. The MFRS was used to determine the appropriate level of evidence for every resource used in the CPG development (see Table 2).

Table 2

MFRS Rating System

Evidence Type	Level of Evidence
Systematic review or meta-analysis	Level I
Randomized controlled trial	Level II
Controlled trial without randomization	Level III
Case-control or cohort study	Level IV
Systematic review of qualitative or descriptive studies	Level V
Qualitative or descriptive study	Level VI
Expert opinion or consensus	Level VII

Note. From "Evidence-Based Practice in Nursing and Health Care: A Guide to Best Practice," by Melnyk and Fineout-Overholt, 2011, p. 12. Reprinted with permission.

TDF

To help improve the successful development of the CPG, the TDF was applied when teaching the expert panel about the content of the CPG and its significance. The TDF was originally developed to evaluate influences on the behavior of medical professionals going through change interventions in their specific organizations. When attempting to change behavior, it is vital to understand and anticipate desired changes in behavior (Atkins et al., 2017). Behavior scientists and researchers developed the TDF to reduce unsuccessful implementation of change through a theoretical approach. Although

this CPG has not yet been disseminated, it is expected that including the TDF enhanced the CPG and its AGREE II rating by the expert panel.

Definition of Terms

Throughout this CPG project, multiple terms are used, some of which may also be used interchangeably. Project terms defined:

Clinician: A healthcare individual who is licensed to provide medical aesthetic treatments in their respective state.

Good faith exam (GFE): Initial medical history review and examination of a patient that can only be performed by physicians or nonphysician providers.

Healthcare Provider: A healthcare individual who is licensed to provide medical aesthetic treatments in their respective state.

Injector: A healthcare individual who is licensed to provide medical aesthetic treatments in their respective state.

Med spa: A medical spa usually positioned outside of a traditional physician's medical office. It provides medical services and is owned and operated by a healthcare provider licensed to practice medicine in their respective state.

Non-physician provider: Licensed nurse practitioners and physician assistants.

Mini GFE: Title given for the CPG form proposed for use by all injectors in aesthetics prior to providing aesthetic treatments.

Nurse injector: RNs and NPs working in the aesthetic field.

Relevance to Nursing Practice

Existing Scholarship and Research

In synthesizing the literature, Rossi et al. (2019) said there were increased adverse events involving nonsurgical cosmetic treatments performed by nonphysician providers and RNs, as compared to physician providers. In the study survey, the most common procedures received by participants included neuromodulator injections for wrinkles and injectable dermal fillers, which are the top two procedures performed at the intended site for this CPG project. Adverse events involving discoloration occurred at a greater rate with nonphysician providers (43.5%; $N = 23$) compared to physician providers (14.8%; $N = 27$). Dermal burns also occurred more frequently with nonphysician providers (34.8%) compared to physician providers (7.4%). Providers in the aesthetic industry are aware that dermal burns are possible side effects or complications from treatments such as chemical peels, laser hair removal, intense pulse light (IPL), and other laser devices for dermal treatments and not injectable neuromodulators and dermal fillers. Because dermal burns are not likely to result from injectable treatments, the higher percentage of adverse events from procedures as presented in Rossi et al. (2019) may not correlate to procedures actually provided by nonphysician clinicians. Training and experience in such procedures can significantly differentiate a good from a better injector. As it pertains to this CPG, it is vital that RNs remain cognizant of state guidelines and contact physicians if and when complications occur, which should be a standardized procedure and can be incorporated as a practice standard.

While collecting appropriate patient medical history before performing nonsurgical aesthetic procedures is a responsibility of all injectors, that information, if collected, is not being documented in the patient's medical chart. This leads to lack of proof that this examination was done. More importantly, the lack of documentation leaves open the question of whether the best evidence-based patient care was performed. While state boards of nursing across the nation agree regarding requirements and documentation of GFEs for new clients entering a med spa, there seems to be a generalized assumption in the aesthetic field that no further medical history review is needed for up to 1 year for these patients. Hence, at the local site, only the initial GFE evaluation is documented annually, regardless of the number of follow-up visits the client may return to receive various cosmetic treatments thereafter. The patient is not asked about his or her medical history, additional medications, or changes in skin before future appointments after that annual GFE. From an added safety perspective, I found it important to document that I reviewed patients' medical history for any changes prior to every patient visit. The CPG aims to address this consistent lack of documentation and medical history review that appears to be occurring due to a lack of knowledge by healthcare providers and administrative staff about the importance of documentation as well as a lack of appropriate CPGs. Werschler et al. (2015) shared that if patients answer yes to any dermatological conditions such as previous skin cancers, psoriasis, eczema, or acne, that yes answer usually warrants further discussion with the patient to help prevent complications associated with aesthetic procedures, particularly with the use of energy-based devices.

Current state guidelines leave many ambiguities in terms of interpretation, leaving inexperienced injectors at risk of legal ramifications while reducing the safety of their patients. Ann and Wicklin (2020) offered that respondents working in the field of aesthetics rated a med spa to be more prone to adverse events than a traditional physicians' office. Of the respondents, 95.8% believed that regulations should be stricter, while 84.3% admitted they would like more support and information from medical societies related to medical spas.

Shallwani et al. (2019) said the use of the AGREE II instrument to appraise current CPGs related to the benefits of physical activity in cancer patients was instrumental in their study. Using the AGREE II to measure the quality of each domain in their CPG, Shallwani et al. (2019) were able to identify that their CPG was lacking in the domain of applicability. Using the AGREE II instrument, healthcare providers can also identify where their CPGs maybe lacking to help improve overall patient outcomes and quality of care.

Standard Practices Used by Accrediting Organizations

Vital to the medical spa industry is understanding the scope of practice of each profession and tailoring policies and procedures to comply with those scopes of practices. The MBOC and the CBON both operate under state guidelines that indicate the scope of practice for nurses and physicians.

According to the California Nurse Practice Act (CNPA) Section 2725 (b, 4), in providing nursing care or overlapping functions between physicians and RNs in organized health care systems, the RN is responsible for: Observation of signs and

symptoms of illness, reactions to treatment, general behavior, or general physical condition, and determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures (Nurse Practice Act, 2021).

The MBOC said that physician supervision is required when specific procedures are being performed but does not clearly identify to what extent. Instead, the MBOC requires that NPs and RNs operate under a formally written standardized procedure (SP) agreement that is developed between the physician and the nurse, not the medical spa institution. Both the MBOC (Title 16, CCR Section 1379) and the CBON (Title 16, California Code of Regulations (CCR) section 1474) have jointly agreed on the requirements for these SPs. Section 1474 (7) requires SPs to: "Specify the scope of supervision required for performance of standardized procedure functions, for example, telephone contact with the physician" (MBOC, 2020, p. 2). Furthermore, Section 1474 (2) requires the SPs to "Specify which standardized procedure functions registered nurses may perform and under what circumstances" (MBOC, 2020, p.2).

Other Approaches Used For Medical Clearance

In further researching literature on safety protocols for aesthetic procedures, the articles that exist refer specifically to the initial GFE with a total disregard to the discussion of any future pre-procedure examinations, which confirms the significant gap in the existing literature. More importantly, existing literature does not link the adverse

events of nonsurgical procedures to the lack of pre-procedural health history examination; however, the literature has linked these adverse events with surgical procedures. Kim et al. (2015) argued that the majority of surgical adverse events are directly related to errors occurring before or after the procedure and not during it. Furthermore, Kim et al. (2015) emphasized that failures or breakdowns in communication within and amongst the surgical team, patients, and their families were key factors that may have been eliminated with pre-procedural health histories. Chhabra et al. (2019) and Kim et al. (2015) said that interventions such as the World Health Organization's (WHO) pre-operative checklist and Reason's Swiss Cheese Model (RSCM) have helped prevent or reduce surgical adverse events. The WHO pre-operative checklist focuses on four areas of improvement including safety, and the prevention of surgical site infections. According to Chhabara et al. (2019) operating room employees are given a checklist consisting of questions that guide the surgeon and assists staff on what steps to take prior to anesthesia and skin incision, as well as after surgery. This CPG also provides clinicians with a checklist to use prior to performing nonsurgical treatments. Using the RSCM, accidents and mistakes in surgery were significantly reduced as it helped prevent one error from becoming prolonged throughout the surgical process. In short, a process is completed in a particular order before moving forward, hence preventing errors from prematurely advancing in the process. This CPG also has similar attributes to help limit the number of errors made by aesthetic providers in an effort to standardize pre-procedure protocols. This CPG requires providers to answer specific questions before they can move on to the next question.

Advances to Nursing Practice

The CPG aligns with the American Association of Colleges of Nursing DNP Essentials by advancing nursing practice, empowering nurses to provide evidence-based practice, while ensuring patient safety of the highest level in the field of aesthetics (Garritano et al., 2016). With implementation, the CPG aims to streamline and standardize provider practice, improve patient safety, and reduce the legal ramifications for injectors. The development of a CPG such as this by an NP can advance nursing practice by providing a quality evidence-based project that can easily be implemented by nurses and other providers practicing in the field of aesthetics. As more aesthetic patients present to the local med spa with complaints of bleeding and bruising resulting from aesthetic procedures, the CPG can guide current and future injectors on the steps necessary to break the cycle of reviewing a patient's medical history once per year but rather review the medical history prior to every aesthetic procedure. The CPG requires injectors to screen patients for medications and medical history that may place patients at a higher risk of bleeding or bruising during aesthetic procedures.

Local Background and Context

It is important that injectors review and use the guidelines developed from other specialties, which can be customized for the aesthetic nonsurgical field. To help improve provider knowledge, improve patient outcomes and safety, and reduce adverse events, the CPG helps to fill this gap in the literature and practice. Kim et al. (2015) believes that while errors may always occur, as a change agent, it is essential to reinforce a change such as the CPG to help eliminate the tolerance of unsafe practice and align providers

with safer practices. At the local site, a once-yearly GFE is being performed and documented by a physician or non-physician provider prior to a patient's initial medical treatment. The problem that exists at the local site is that providers are not performing a review of the patient's medical history prior to performing every aesthetic procedure. Additionally, if an injector asks certain patient questions or performs a medical history review prior to treatment, it was not being documented. A known practice reality is that a patient's medical history may change from one day to the next; hence, the reliance on a once-yearly GFE by a health care provider may not be of value to a patient seeking treatment throughout the year. More importantly, healthcare providers practicing according to their respective licensures, would be assessing and evaluating the patient's medical history prior to each surgical and nonsurgical event to look for possible contraindications to treatment. While multiple med spa settings could be practicing the same bad habits, injectors could help break this cycle by implementing a practice protocol or this CPG at their respective practice site. A review of a patient's medical history and pre-procedural instructions before a medical treatment has been shown to reduce adverse events and side effects (Chhabra et al., 2019; Kim et al., 2015; Werschler et al., 2015).

The estimated time it takes a clinician to perform a mini-GFE for a patient is about 30-60 seconds, as long as no potential adverse contraindications were identified needing further explanation. A significant component of the CPG requires clinicians to document whether or not an initial GFE had ever been performed, which is mandated nation-wide. Other steps in the CPG ensure that clinicians educate their patients about

measures to reduce the risk of bleeding and bruising by avoiding certain commonly used substances prior to their next appointment. The CPG will also include substances to avoid, including non-steroidal anti-inflammatories (NSAIDs), alcohol, and some herbal supplements like gingko biloba, folic acid, turmeric, and fish oil.

The local project site is a med spa located in the Western region of the United States. The staff includes three medical assistants (MA), four receptionists, two NPs, one PA, one general manager, one human resources manager, three RNs, and one medical doctor (MD). Of the 16 employees, seven are licensed and able to provide aesthetic medical treatments (RNs, NPs, & MD). Currently, none of these injectors use a written CPG or similar protocol as a guide when providing medical treatments. At the project site, the organization's vision is to provide quality aesthetic procedures at affordable prices that are less than the current average prices in the surrounding area. This vision is geared towards giving individuals, who may not have otherwise had the finances, the opportunity to obtain aesthetic procedures, alleviating the financial difference through providing care to a higher volume of patients. The spa operates six days per week with an average of nine hours per day. The organization services an average of about 100 patients per week that present for medical aesthetic services.

Role of the DNP Student

As a DNP student, I served as the developer and project manager of this CPG. I am a registered family nurse practitioner (FNP) with over 10 years of experience in the healthcare field and 4 years of experience in nonsurgical aesthetic treatments. I received my Bachelors in Science of Nursing (BSN) from Wayne State University in Detroit, MI

in 2010 and my Master of Science in Nursing (MSN) from South University in Novi, MI in 2016. I have extensive experience and hold certifications in performing many aesthetic procedures such as laser treatments, the injections of dermal fillers, botulinum toxins, platelet-rich plasma, deoxycholic acid, and many others for the treatment of fine lines, wrinkles, fat pads, and volume loss. As an experienced leader in the field of aesthetic services at the project site, I am aware of the need to standardize the treatment process for aesthetic procedures. My experiences afforded me the ability to develop a CPG, and I attained full support of the organization's administrators, staff, and other end-users. I moved from Detroit, Michigan in late 2018 to the Western region of the United States primarily because of my passion and love for the field of aesthetic. My passion and leadership position at the project site may be construed as a bias; however, that bias affords me the opportunity to make positive social change in generating and translating the much-needed evidence into practice, especially where patient outcomes and safety are a concern. Compared to the Eastern part of the nation, the West provided a more significant chance and opportunity to advance my aesthetic skills through exposure to the latest and greatest in aesthetic devices and procedures in a rapidly growing field. This experience has laid the foundation for my growth and reputation as an expert in aesthetic procedures.

Summary

Having the reputation, credentials, and experience in aesthetic procedures further supported my ability to recognize the existing practice gap and the need for this CPG. Providers at the local project site continue to perform aesthetic procedures based on

routine habits with limited information on safety and the respective state board regulations. As a trusted tool in research and guideline development, the AGREE II tool was used to evaluate the guideline from multiple perspectives. Developing this CPG has helped improve the knowledge of injectors in aesthetics, which can translate to providing safer treatments to patients. If implemented, the CPG can help standardize aesthetic procedures, build cultural confidence in the improved safety protocols of aesthetic treatments, and improve overall patient outcomes. Furthermore, the MFRS of hierarchy of evidence was used to analyze and evaluate the latest evidence that was used in the project in regard to relevance and strength. While there are existing guidelines for surgical treatments, the nonsurgical field lacks evidence and guidelines that can be used to support nonsurgical procedures. Hence, reviewing and analyzing surgical guidelines influenced and assisted me in the development of this CPG for nonsurgical procedures. Incorporating the mini GFE as a component of the CPG may also help build a trusting relationship between the injector and the patient, especially when time is taken to explain that the reason for the mini GFE is to ensure a higher level of safety before treatments. In a very busy med spa such as the local project site, time is of the essence, but safety must always come first, safety that the implementation of the CPG will significantly improve. While the CPG is an adjunct guideline, it is not to be considered a replacement to the initial GFE that is required to be completed by a physician or non-physician provider. Further analysis and synthesis of evidence will be discussed to justify the need and provide more comprehensive support for this CPG project and its application in practice.

Section 3: Collection and Analysis of Evidence

Introduction

With the rapid growth and prevalence of nonsurgical aesthetic treatments, more RNs than ever have made their career in the field of aesthetics. An increase in aesthetic treatments has also facilitated the growth of various options, products, and machines that are readily available at many local medical spas. While there is no unique governing body or state board specific to aesthetics, RNs, NPs, and physicians must always practice according to their respective licensing boards and guidelines.

Unfortunately, with the rapid growth of the aesthetic field, state and federal guidelines continue to be lacking with respect to safety and scope of practice for aesthetic injectors. Consequently, botched procedures and adverse events from such procedures are also rising (AMSPA, 2018). In fact, the lack of supervision of medical treatments by physicians, as well as lack of training of injectors, has been the primary cause of legal ramifications due to adverse events for patients undergoing such treatments.

The purpose of this DNP project was to develop a CPG that would help improve knowledge of aesthetic injectors and standardize the treatment process prior to providing medical treatments for patients. Evidence-based CPGs have become a foundation in research, bridging the gap between literature on best policy, local context, and patient choice. Adatto and Byrd (2017) said that the Institute of Medicine (IOM) defined a CPG as a recommendation tool to help practitioners in clinically based patient decision-making after a systematic review of literature and evidence has been completed. Kredo et al.

(2016) supports the purposes of CPGs to standardize variations in practice, help improve measurable quality care, and reduce adverse events.

Practice-Focused Question

While patients' medical history and preprocedural instructions may be reviewed verbally at the local project site, the lack of formal documentation prior to procedures is lacking. Injectors have become dependent on a once-yearly GFE, even though patients may receive varying treatments throughout the year. More importantly, patients' medical history and active medications may change more often than annually, requiring further investigation and review by the injector before each medical aesthetic treatment (De Boulle & Heydenrych, 2015).

The practice-focused question for this project is: Can the development of a CPG for aesthetic providers increase their knowledge about delivering safe and consistent patient care? In reviewing the literature, evidence on protocols and guidelines particular to nonsurgical aesthetic procedures was limited. However, evidence and guidelines exist in the field of medical aesthetic surgery and dermatology, where such procedures are also performed. The AMSPA has many published articles on rules, laws, and regulations pertaining to nonsurgical aesthetic procedures. AMSPA (2018) has reported that liability for physicians and nonphysician providers in aesthetics continues to rise as more nonsurgical aesthetic procedures are developed. This CPG can help to improve care outcomes and safety and reduces injectors' liability by adding official documentation to patients' medical record that a mini GFE was documented prior to treatment.

Sources of Evidence

My search for evidence revealed 205 related academic journal articles and publications. Of these 205 articles, I selected 31 that aligned with the DNP project. I used the following keywords in my search: *AGREE II*, *best practice*, *clinical practice guidelines*, *Melnyk and Fineout-Overholt rating system of hierarchy of evidence*, *theory in aesthetics*, *rules and regulations*, *medical spas in California*, *lawsuits with med spas*, *California med spa laws*, *California Board of Nursing*, *California Board of Medicine*, *good-faith exam*, *trouble for med spas*, *patient safety*, *safety in aesthetics*, *aesthetic dermatology*, *cosmetic dermatology*, *best practice*, *physician supervision*, *adverse events in aesthetics*, and *medical procedures by nurses*. Along with the Walden University Library, the following databases were used: CINAHL, ERIC, PubMed, Medline, and BioMed Central.

Evidence collected for this CPG project was appraised using the MFRS hierarchy of evidence rating system. The evidence selected for this CPG was rated and organized in Appendix A. In searching literature, only information that was evidence-based, recent, and relevant to the CPG was chosen. Chosen literature involved lack of protocols and regulations in the aesthetic field and prevalence of adverse events in med spas as well as lack of guidelines. Furthermore, I also focused on addressing patient safety, prevalence of adverse events due to aesthetic procedures, and trends involving why such adverse events were occurring according to current literature.

Evidence Generated for the Doctoral Project

In this section, I provide information about evidence that was generated for this CPG project. This section includes information about participants, procedures, and protections that supported the development of this evidence-based CPG.

Participants

Participants included an expert panel that consisted of individuals who have extensive experience in the field of aesthetics practice. Their feedback was instrumental during the final development of the CPG. This expert panel was made up of six members, including one attending physician owner, one general manager, one PA, one NP, and two RNs.

Procedures

The CPG was developed after the Walden University Institutional Review Board (IRB) approved the project. After approval by the Walden University IRB (#06-23-21-1021061), the CPG was developed using the following steps:

- Appraise evidence collected from the literature search.
- Synthesize evidence.
- Develop the guideline/recommendations.
- Identify an expert panel.
- The expert panel reviews the guideline using the AGREE II instrument to validate the content.
- The expert panel scores the AGREE II Instrument.
- Revise the guideline based on recommendations.

- Identify groups of stakeholders and end users.
- Present the revised guideline to end users, /key stakeholders, and /local experts and discuss to validate content and ensure usability.
- Develop a final report.
- Disseminate the final report to key stakeholders.

The AGREE II model was used to develop this CPG for aesthetic procedures. The CPG was presented to an expert panel for feedback with detailed instructions on its use. To evaluate the CPG, the expert panel was asked to rate various items from each domain of the AGREE II on a four-point scale: strongly agree (1), agree (2), disagree (3), and strongly disagree (4). The expert panel members used the AGREE II questionnaire to appraise the EBP guideline, using the AGREE II six quality domains (see Table 3).

Table 3

Questionnaire for the CPG Using the Six Domains of AGREE II

	1 Strongly Agree	*2* Agree	*3* Disagree	4 Strongly Disagree
Domain 1: Scope & Purpose The population (patient, public, etc.) to whom the guideline is meant to apply is specifically described.	O	O	O	O
Domain 2: Stakeholders' Involvement The target users of the guideline are clearly defined.	O	O	O	O
Domain 3: Rigor of Development Systematic methods were used to search for evidence.	O	O	O	O
Domain 4: Clarity of Presentation The recommendations are specific and unambiguous.	O	O	O	O
Domain 5: Applicability The guideline provides advice and/or tools on how the recommendations can be put into practice.	O	O	O	O
Domain 6: Editorial Independence The views of the funding body have not influenced the content of the guideline.	O	O	O	O

Note. From "AGREE II: Advancing Guideline Development, Reporting and Evaluation in Healthcare," by the AGREE Research Trust (2010). Reprinted with permission.

Protections

The development of this CPG involved searching and synthesizing evidence and did not involve patients. An expert panel comprised of administrative personnel reviewed and provided feedback and recommendations on the guideline. Based on recommendations, the CPG was revised and finalized. Names of expert panel members using the AGREE II tool questionnaire were not required to support the confidentiality of

evaluation results from the expert panel members. The name of the CPG implementation site was also not included in the final report. Permission to conduct this project was obtained from the Walden University IRB (#06-23-21-1021061), and the IRB approval criteria were maintained.

Analysis and Synthesis

The CPG was evaluated and graded using the AGREE II tool questionnaire (see Table 3) after review by the expert panel. Each related article used to support the development of this CPG was appraised and graded using the MFRS of hierarchy of evidence and organized in a table (see Appendix A). Because of the limited availability peer-reviewed articles on efficacy of safety protocols in the field of nonsurgical aesthetic treatments, peer-reviewed articles involving the associated fields of dermatology and cosmetic surgery were also used to support the CPG. The limited number of peer-reviewed articles was one of the driving forces for the development of this CPG. Information to support the development of this CPG was also garnered from professional organizations and professional licensing boards. The development of the CPG, evaluation by the expert panel, recommendations from the expert panel, and final CPG report are discussed in Section 4.

Summary

To date, there is no CPG focused on standardizing care that can lead to enhancing patient care outcomes and patient and provider safety that can be used to guide aesthetic injectors prior to the delivery of nonsurgical aesthetic procedures. The development of this evidence-based CPG is the first of its kind to provide guidance for injectors when

performing aesthetic procedures. The CPG will help to fill this gap in practice and available literature in the field of aesthetics. This project was presented to an expert panel comprised of members who were experienced in the nonsurgical aesthetic field. Changes to the CPG were made according to feedback from this panel.

Section 4: Findings and Recommendations

Introduction

This doctoral project focused on establishing a CPG to improve provider knowledge and practice, through providing guidance to aesthetic providers when performing nonsurgical procedures. At the local practicum site, nurses and other aesthetic providers lack evidence-based guidelines to help them review safety protocols before performing aesthetic procedures for patients presenting to the clinic. To date, this project serves as the first of its kind in the field of nonsurgical aesthetics, with a focus to help fill the existing gap in literature and practice as an evidence-based safety-oriented practice guideline to streamline aesthetic services. The lack of standardization in practice resulted in the practice gap that led to undesired patient outcomes that resulted from aesthetic procedures, which compromised patient safety and increased litigation risks for aesthetic providers.

While annual GFEs are currently being performed at the practice site, there was no documentation that aesthetic providers were screening and documenting reviews of patients' medical history before every aesthetic procedure after that initial GFE. Reviewing patients' medical history before any medical treatment helps reduce adverse events and side effects of treatments (Chhabra et al., 2019; Kim et al., 2015). The practice-focused question for this DNP project asked: Can the development of a CPG for aesthetic providers increase their knowledge about delivering safe and consistent patient care?

The purpose of this project was to address the practice-focused question by creating this evidence-based CPG to help guide nurses and other aesthetic injectors in streamlining the screening process of patients before performing any aesthetic procedure. The CPG can help improve provider knowledge while bridging the gap in practice and improving patient safety. Kredo et al. (2016) supports the use of CPGs and shared that CPGs had become a foundation in practice, helping to guide evidence-based policy. Furthermore, literature highlighted the importance of such CPGs in standardizing variations in practice while also helping to improve the quality of care.

Sources of Evidence and Analytical Strategies

Sources of evidence were obtained using online databases to search for problems in the aesthetic field relating to lack of practice guidelines for aesthetic procedures. In searching for evidence through the Walden University Library, CINAHL, ERIC, PubMed, Medline, and Bio-MedCentral databases were used. I also focused on evidence related to patient safety during aesthetic procedures and protocols for improving such safety in the fields of dermatology and plastic surgery. Established safety measures from the field of dermatology and plastic surgery were incorporated into this CPG. The evidence I used in developing this guideline was appraised using the MFRS hierarchy of evidence rating system. As previously identified, expert panel members were individually educated about AGREE II criteria via a written introductory statement and instructions (see Appendix B). A summary that included the purpose of the CPG was provided to the expert panel. Of the six expert panel members, five were also end users.

Findings and Implications

The expert panel evaluated the CPG using AGREE II evaluation survey criteria. Based on their evaluation, survey responses from the expert panel revealed support for the guideline and a high interest in instituting the guideline at the local practicum site. The expert panel's high evaluation scores of this CPG were due to the strength and completeness of the project. Comments and suggestions made by some of the expert panel members indicated the importance and need for such a project at the local practicum site:

- Domain 1 - Scope and Practice: All six reviewers strongly agreed that the CPG accurately and clearly described the population for whom the guideline is intended.
- Domain 2 - Stakeholders' Involvement: All six reviewers strongly agreed that the CPG clearly defined the intended target users. The expert panel included professionals involving all intended users of the CPG (two RNs, one NP, one PA, and one MD) to ensure their involvement in the development, review, and approval of this CPG.
- Domain 3 - Rigor of Development: All six reviewers agreed that the CPG was developed using systematic methods to search for incorporated evidence. This confirmed the reviewers' unified support of criteria used to search for evidence.
- Domain 4 - Clarity of Presentation: Five members of the expert panel strongly agreed that components of the CPG were clearly presented, One

reviewer disagreed and provided feedback that grammatical errors needed to be revised. This recommendation was embraced and addressed. Future researchers can modify expert panel information to clarify that grammar, while not part of the evaluation process rating when using the AGREE II questionnaire, was important to the guideline's content and clarity and was also appreciated. If grammatical issues impact the clarity of the CPG, the CPG developer should be contacted immediately to resolve content feedback.

- Domain 5 - Applicability: Four out of six reviewers strongly agreed regarding the applicability of the CPG. One reviewer added that the CPG provides advice and tools on how recommendations can be put into practice. One reviewer disagreed and provided feedback that grammatical errors needed revision. This feedback was embraced and addressed like noted in domain 4.
- Domain 6 - Editorial Independence: All six reviewers strongly agreed that there was no funding involved in this project; therefore, there was no influence on the content of the CPG, and editorial independence was maintained.

Table 4 includes the expert panel's evaluation scores of this CPG based on AGREE II evaluation criteria. Figure 1 shows a bar-graph representation of results.

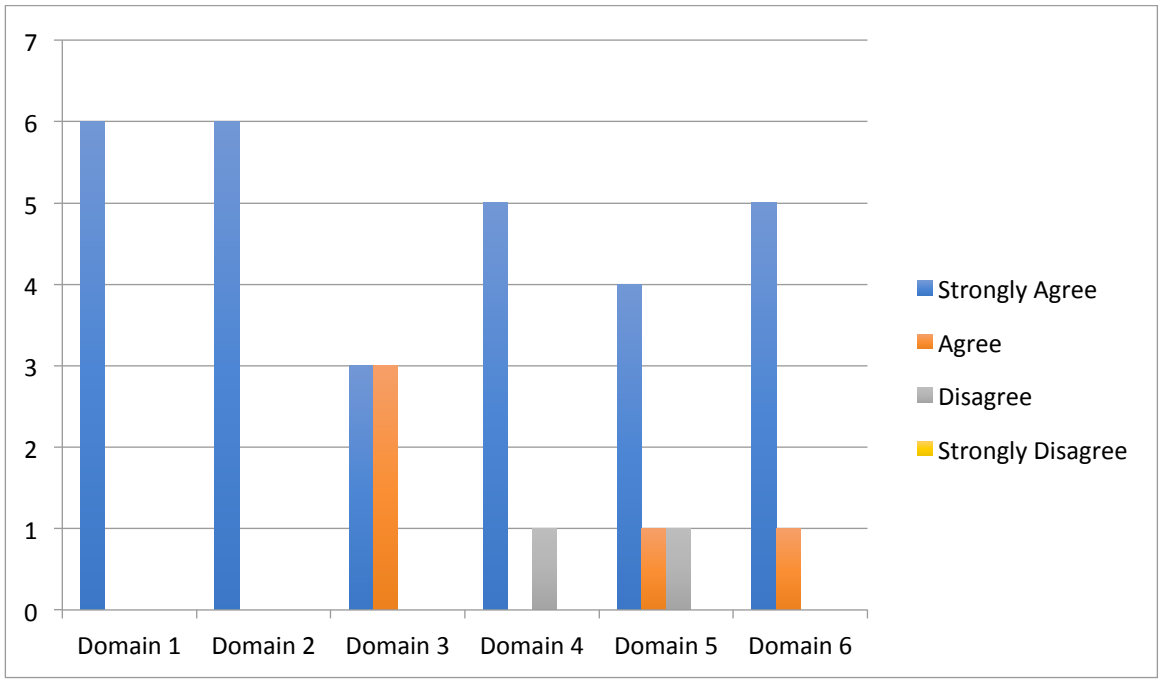
Table 4

Results of the AGREE II Questionnaire for EBP CPG Development

Domains	Strongly Agree	Agree	Disagree	Strongly Disagree
Domain 1: Scope & Purpose	6	0	0	0
Domain 2: Stakeholders' Involvement	6	0	0	0
Domain 3: Rigor of Development	3	3	0	0
Domain 4: Clarity of Presentation	5	0	1	0
Domain 5: Applicability	4	1	1	0
Domain 6: Editorial Independence	5	1	0	0

Figure 1

Visual Representation of Expert Panel Questionnaire Results



Unanticipated Outcomes

As a part of this DNP project, the CPG was developed with the intention to implement it at the practicum site. However, due to limited time and the transition of the practicum site's method of documentation from paper charting to electronic charting via electronic medical record (EMR) software, it was not possible to develop and implement the guideline simultaneously. Nonetheless, project site administrators plan to implement this CPG after the completion of this DNP project and in the near future.

Only one expert panel member rated Domains 4 and 5 as "Disagree" as shown in Table 1 and commented that these domains "need grammatical revisions." Statistically, this evaluation response is considered an outlier compared to median results of the evaluation by other expert panel members. This suggests that ratings on these two domains were due to grammatical errors; there was no comment that the rating was based on the content of the guideline in these domains. Grammar while not a criterion of the AGREE II evaluation tool, is an expectation to support content and clarity. Nonetheless, evaluation decisions by other panel members supported domains 4 and 5. After reviewing the expert panel's evaluation results, the CPG was reviewed and revised. All recommended changes were made, including any that related to grammar that remained. Due to the unanticipated outcome relating to grammar, changes to instructions provided to future expert panel evaluators can be made regarding immediate notification of the project leader about grammatical concerns, especially if the grammatical concerns impact the clarity of the CPG's content and clarity of content. The project leader's contact information should be highlighted as a part of the CPG's instruction, as it was for this

CPG. Reiterating that panelists focus on content, structure, and clarity of information presented in the CPG per the AGREE II tool as a part of instructions could also add clarity to the evaluation process.

Individual Implications

More information is needed in the aesthetic field to help guide injectors. CPGs such as this are needed to help inform healthcare provider practice. The project findings align with this DNP project's aim to support healthcare providers working in the aesthetic field. The time it takes an individual injector to complete the mini GFE is about one minute. This additional effort by injectors helps to improve their knowledge of the patient's medical history and possible contraindications to treatment, as well as patient outcomes. Incorporating this CPG, which includes this additional mini GFE step, can furnish providers with a safe evidence-based care protocol to use as a guide when providing aesthetic treatments.

Community Implications

The literature stressed the association of lack of protocols available to aesthetic providers and the impact on poor patient outcomes, resulting in increasing litigation risks. Using the developed CPG, medical facilities offering nonsurgical medical aesthetic treatments can benefit from incorporating a standardized care process that can provide a safer approach to care for patients. Furthermore, incorporating this CPG can help improve injector knowledge about practice safety and proper federal protocols, which can improve patient outcomes and have a positive impact on the aesthetic community.

Institutional Implications

There is a gap in proper and consistent clinical practice at the local project site, including the lack of a CPG to support treatment administration and documentation. A documented review of patients' medical history prior to providing each aesthetic treatment was not found in medical records. While medical records reflected that annual GFEs were being documented, there was no guideline in place that required assessment of patients' medical history prior to each patient procedure. This CPG will help reduce and/or eliminate that gap in practice to ensure that aesthetic providers deliver standardized care that can result in safer patient care. Once the CPG is implemented, the institution's administrators can communicate changed and improved practice standards that can increase level of safety for patients seeking care there.

System Implications

Nonsurgical aesthetic procedures such as neurotoxins and dermal fillers at med spas are considered medical treatments, and as such, are regulated by state medical board (MBOC, 2020). Individuals such as RNs and NPs must ensure that they are following guidelines set by boards of nursing in their respective states, in addition to what particular institutions may impose. Using the developed CPG, injectors can have a standardized practice process requiring that GFEs are completed at least once annually, and mini GFEs are completed prior to every subsequent procedure. Once the CPG is implemented at the project site, the organization can incorporate this CPG at other partner med spas, providing a system-wide practice standard.

Implications for Positive Social Change

This CPG can serve as a system-wide standardized practice approach for the project site, other associated sites, and aesthetic institutions nationally and globally. This CPG can prevent aesthetic providers from experiencing unnecessary practice and procedural issues that can result in the need to halt procedures and institute resolutions. Standardized aesthetic treatments can help improve patient safety, reduce adverse events, and improve patient outcomes. Positive social change can be achieved through the application of a standardized practice protocol like this CPG at the project site system-wide, locally, nationally, and globally.

This CPG can also serve as a resource for other medical practices providing aesthetic treatments. For those currently practicing or institutions currently offering care in the field of aesthetic medicine without a CPG, it is my recommendation that a CPG be incorporated to provide a safer and standardized approach to clinical practice that can improve patient outcomes and reduce litigations. I recommend that individuals and institutions conduct their research and consult an attorney familiar with med spa practices prior to adopting and implementing this or any other CPG supporting aesthetic care. Applying a standardized practice protocol like this or other CPGs can further enhance positive social change by supporting aesthetic injectors and providing a safer approach to aesthetic treatments.

Recommendations

It is the responsibility of each licensed professional (RN, NP, PA, MD, DO) to ensure that they are following their respective state licensing board guidelines regardless

of protocols that maybe imposed at any particular med spa agency. This CPG should not be constituted as a replacement to any state regulations on the administration of neurotoxins, dermal fillers, or any other medical aesthetic procedure. However, given the evidence provided and rigor in developing this CPG, it is recommended that the project site take advantage of incorporating a standard of care. This CPG, which is presented in Appendix B, was developed as a standard of care for aesthetic procedures performed at the project site. If instituted at the project site, I also recommend that this CPG be reviewed at least annually to determine if revisions are needed to assure that the guideline continues to meet the needs of the institution, its providers, and patients.

Strengths and Limitations of the Project

Strengths

This CPG was developed using current evidence-based literature to enhance its rigor. An expert panel at the local practice site with many years of experience in the aesthetic field evaluated the CPG using the six domains of the AGREE II guideline evaluation tool. The evaluators provided primarily positive feedback in their evaluations. Despite one member rating two domains as less than “agree”, the rest of the expert panel rated the six domains as either “strongly agree” or “agree”, with the majority of responses coinciding with “strongly agree” as presented earlier in Figure 1. Best related evidence from the fields of medical aesthetic surgery and dermatology were used to help support and develop a CPG that can improve patient outcomes and safety. Resources from the AMSPA were also used to help clarify legal regulations and discussions involving the performance of aesthetic procedures.

Limitations

A significant limitation of this CPG was the lack of existing clinical guidelines in the aesthetic medicine industry. Another limitation was the lack of published evidence in the field of aesthetics to support this guideline. Because of the limited evidence available in aesthetics, evidence was garnered from the fields of aesthetic surgery and dermatology. The DNP project was limited as projects' scope would not include the implementation of the guideline and therefore would not include the measurable data that would arise from the outcome of the guideline's use and the benefit to the project site. Analysis of end-user feedback could have proven useful in future clinical projects, in the development of similar CPGs, and other practice sites. Issues with compliance and user and administrative feedback could not be obtained without implementation, which is also a limitation to this project. While guideline implementation was my original goal for this project, time and other site constraints impaired such an achievement from happening.

Section 5: Dissemination Plan

Although the literature supports significant advancements to nursing knowledge through project developments such as CPGs, lack of dissemination of such CPGs has contributed to the gap between available evidence-based literature and application in clinical practice. Dissemination of CPGs can help fill that gap and increase the prevalence of CPGs in practice. The final CPG will be disseminated to the expert panel and other staff members during a lunch meeting at the practicum site to facilitate end-user discussions with other interested parties prior to site implementation. Once implemented, this CPG will also be incorporated into the organization's standard procedures and protocols manual that is available to all employees at any time for reference.

Another means of disseminating this DNP project is an oral presentation at the Medical Spa Show 2022 hosted by the AMSPA. If approved for presentation, this venue will lead to significant exposure of the CPG and DNP project to some of the world's top aesthetic injectors, as this show is a highly anticipated annual event. A link to this DNP project will be provided to audience members as a resource for future review of the project in more detail. This link will also provide the show and conference audience with an opportunity to print and download the CPG for further review or incorporation into their own aesthetic practices.

Disseminating this DNP project on social media can also help in filling the clinical practice gap. One of the barriers to research implementation that has been relevant in the literature is the lack of a dissemination venue that incorporates feedback loops, or a way of allowing the targeted audience to express their thoughts on any given

project presentation. Social media outlets like Facebook and Instagram allow users to engage in open communication through messages and videos. The CPG will be presented on social media through a PowerPoint video presentation to encourage other aesthetic providers to review and possibly incorporate into their own practices.

This evidence-based CPG can be disseminated to medical clinics that provide nonsurgical aesthetic treatments such as neurotoxins and dermal fillers. Administrators and providers can align the CPG to their respective state guidelines and institutional policies. Although this CPG has incorporated information from regulatory agencies in the state of California, it can be applied to medical spas in any state, regardless of state law, as objectives include streamlining aesthetic services and improving patient outcomes.

Analysis of Self

Conducting a clinical practice project and DNP project findings provided me with tools as a nursing scholar as well as advancing the fields of nursing and aesthetics. The experiences I gained in the development of this DNP project allowed me to become more knowledgeable about the process of change that included factors such as facilitators, barriers, and the importance of stakeholder involvement. Developing this project also allowed me to learn how to better work through organizational channels and reach and identify the relevant audience when seeking support for a change project.

Searching and collecting best evidence and sources of evidence for this DNP project posed a challenge due to the current lack of scholarly resources and relevant information about nonsurgical aesthetic practices. As the aesthetic field continues to evolve, more researchers, clinical project leaders, and innovators are needed to help

develop evidence-based CPGs that provide up-to-date protocols. Another challenge was researching laws and regulations which govern aesthetic treatments. To date, there remains no regulatory body that specifically regulates nonsurgical aesthetic procedures. Currently, nurses and other aesthetic professionals are dependent on vague guidelines, word of mouth, and what is considered to be common practice when providing aesthetic treatments. The future dissemination of this DNP project will help nurses and other aesthetic providers by addressing the importance of being informed, proper training, and providing standardized care when performing aesthetic procedures.

Over the past 4 years, I have had the privilege of working at multiple medical spa clinics in Michigan and California. I have also had the privilege of training with some of the nation's top aesthetic providers, constantly advancing my injection techniques for improved patient outcomes and safety. Working for a growing organization has further contributed to my growth as an aesthetic provider because of the value the organization places on growth and development.

After the DNP project is approved and implemented at the project site and my DNP degree from Walden University has been conferred, I plan to further advance my position with my current employer becoming the head of the aesthetics department responsible for overseeing and training novice injectors. As the head of the aesthetics department, my responsibilities would be to develop policies, procedures, and CPGs, as well as train other injectors about various aesthetic procedures. Supervisory duties also include evaluating aesthetic injectors' performance to ensure proper safety protocols are being followed. As part of my long-term professional goals, I strive to become a public

figure on social media, advocating for safe and consistent treatment and educating other aesthetic providers.

Summary

This DNP project involved developing an evidence-based CPG to fill the gap in practice related to the lack of a CPG for aesthetic injectors at the project site. This CPG provides a streamlined approach when screening patients presenting for nonsurgical aesthetic procedures that can be applied at the project site and other medical facilities that offer nonsurgical aesthetic procedures. The CPG also serves as a simple yet effective tool to assist aesthetic injectors in following a standardized practice guide, which incorporates state and regulatory guidelines that can improve patient outcomes. This CPG can empower new and novice aesthetic injectors to become more knowledgeable about standard rules and regulations of providing safe and standardized nonsurgical aesthetic treatments with an aim to improve patient safety that can serve to reduce legal ramifications.

Implementation of this CPG at a practice site will help standardize patients' documentation and screening processes prior to nonsurgical aesthetic procedures. CPGs such as this have become a standard in clinical practice. By applying this or another evidence-based CPG at their respective practice sites, nurses and other aesthetic professionals can help to streamline the implementation of aesthetic procedures, improve patient outcomes, and positively impact social change.

References

Adatto, B., & Byrd, M. (2017). Legal and regulatory issues in the medical spa industry. *Modern Aesthetics*, 8-10. https://modernaesthetics.com/pdfs/0617_supp2.pdf

American Med Spa Association (2020). Hyaluronic injection pens: What you need to know. https://www.americanmedspa.org/blogpost/1633466/338800/Hyaluronic-Injection-Pens-What-You-Need-to-Know

American Med Spa Association (2018). Medical spa bad press: Coming to terms with compliance. https://www.americanmedspa.org/blogpost/1633466/312413/Medical-Spa-Bad-Press-Coming-to-Terms-with-Compliance

American Med Spa Association (2018). Physician supervision: Keeping the "Medical" in medical spas. https://www.americanmedspa.org/blogpost/1633466/309338/Physician-Supervision-Keeping-the-Medical-in-Medical-Spas

Anderson, B. (2017). Botox-injection parties in homes and a day spa get a nurse and doctor in trouble. https://www.fresnobee.com/news/local/article183973856.html

Ann, S., Wicklin, V. (2020). Study expresses concerns about the safety of medical spas. *Plastic Surgical Nursing, 40*(2), 63-65. https://doi.org/2010.1097/PSN.0000000000000314

Atkins, L., Francis, J., Islam, R., O'Connor, D., Patey, A., Ivers, N., Foy, R., Duncan, E., Colquhoun, H., Grimshaw, J., Lawton, R., Michie, S. (2017). A guide to using the theoretical domains framework of behaviour change to investigate implementation problems. *Implementation Science 12*(77), 1-18. https://doi.org/10.1186/s13012-017-0605-9

Brouwers, M., Kho, M. E., Browman, G. P., Burgers, J. S., Cluzeau, F., Feder G … Zitzelsberger, L. (2010). AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Canadian Medical Association Journal, 182*(18), E839-E842. https://doi.org/10.1503/cmaj.090449

Brownson, R. C., Eyler, A. A., Harris, J. K., Moore, J. B., & Tabak, R. G. (2018). Getting the word out: New approaches for disseminating public health science. *Journal of Public Health Management and Practice, 24*(2), 102-111. https://doi.org/10.1097/PHH.0000000000000673

Chhabra, A., Singh, A., Kuka, P. S., Kaur, H., Kuka, A. S., & Chahal, H. (2019). Role of perioperative surgical safety checklist in reducing morbidity and mortality among patients: An observational study. *Nigerian Journal of Surgery: Official Publication of the Nigerian Surgical Research Society, 25*(2), 192-197. https://doi.org/10.4103/njs.NJS_45_18

Coromelas, A. (2020). *The United States of America v. South Coast MedSpa.* https://www.ada.gov/hiv/

De Boulle, K., & Heydenrych, I. (2015). Patient factors influencing dermal filler

complications: Prevention, assessment, and treatment. *Clinical, Cosmetic and Investigational Dermatology, 8*, 205-214. https://doi.org/10.2147/CCID.S80446

Doniselli, F., Zanardo, M., Manfre´, L., Papini, G., Rovira, A., Sardanelli, F., Sconfienza, L., Arana, E. (2018). A critical appraisal of the quality of low back pain practice guidelines using the AGREE II tool and comparison with previous evaluations: A EuroAIM initiative. *European Spine Journal. 27*. 10.1007/s00586-018-5763-1.

Field, M., & Lohr, K. (1990). Institute of medicine (US) committee to advise the public health service on clinical practice guidelines. Clinical practice guidelines: Directions for a new program. *National Academies Press (US)*. https://pubmed.ncbi.nlm.nih.gov/25144032/

Fineout-Overholt, E., Melnyk, B., Stillwell, S., & Williamson, K. (2010). Evidence-based practice step by step: Critical appraisal of the evidence: Part I. *The American Journal of Nursing, 110(*7), 47-52. https://doi.org/10.1097/01.NAJ.0000383935.22721.9c

Garritano, N., Glazer, G., & Willmarth-Stec, M. (2016). The doctor of nursing practice essentials in action: Using the essentials to build a university-wide automatic external defibrillator program. *The Journal for Nurse Practitioners, 12*(4), e143-e150. https://doi.org/10.1016/j.nurpra.2015.12.003

Goldberg, D. (2018). Medical spa owners face increasing liability risks. *Dermatology Times, 39*(11), 10. https://ezp.waldenulibrary.org/login?qurl=https%3A%2F%2Fsearch.proquest.com %2Fdocview%2F2153564339%3Faccountid=14872

Hoffmann-Esser, W., Siering, U., Neugebauer, E., Brockhaus, A., Lampert, U., & Eikermann, M. (2017). Guideline appraisal with AGREE II: Systematic review of the current evidence on how users handle the 2 overall assessments. *PloS one*, *12*(3), e0174831. https://doi.org/10.1371/journal.pone.0174831

Keshavan, V., & Swamy, C. (2016). Pre-operative laboratory testing: A prospective study on comparison and cost analysis. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5125188/

Kim, F., da Silva, R., Gustafson, D., Nogueira, L., Harlin, T., & Paul, D. (2015). Current issues in patient safety in surgery: A review. *Patient Safety in Surgery, 9*, 26. https://doi.org/10.1186/s13037-015-0067-4

King M. (2017). The management of bruising following nonsurgical cosmetic treatment. *The Journal of Clinical and Aesthetic Dermatology, 10*(2), E1-E4.

Kredo, T., Bernhardsson, S., Machingaidze, S., Young, T., Louw, Q., Ochodo, E., Grimmer, K. (2016). Guide to clinical practice guidelines: The current state of play. *International Journal For Quality in Health Care, 10*(1), 122-128. https://academic.oup.com/intqhc/article/28/1/122/2363781

Medical Board of California. Medical Board. (2020). https://www.mbc.ca.gov/Licensees/Cosmetic_Treatments_FAQ.aspx

Melnyk, B., & Fineout-Overholt, E. (2011). *Evidence-based practice in nursing and health care: A guide to best practice*. Lippincott, Williams & Wilkins

Nurse Practice Act, Ca. Stat. § 2725 (2021).

https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=6.&article=2.

Nursing Practice Act - California Board of Registered Nursing. (2013). http://www.rn.ca.gov/practice/npa.shtml

Rossi, A., Wilson, B., Hibler, B., & Drake, L. (2019). Nonphysician practice of cosmetic dermatology: A patient and physician perspective of outcomes and adverse events. *Dermatologic Surgery: Official Publication for American Society for Dermatologic Surgery 45*(4), 588-597. https://doi.org/10.1097/DSS.0000000000001829

Seto, K., Matsumoto, K., Kitazawa, T., Fujita, S., Hanaoka, S., & Hasegawa, T. (2017). Evaluation of clinical practice guidelines using the AGREE instrument: Comparison between data obtained from AGREE I and AGREE II. *BMC Research Notes, 10*(1), 716. https://doi.org/10.1186/s13104-017-3041-7

Shallwani, S., King, J., Thomas, R., Thevenot, O., De Angelis, G., Aburub, A., & Brosseau, L. (2019). Methodological quality of clinical practice guidelines with physical activity recommendations for people diagnosed with cancer: A systematic critical appraisal using the AGREE II tool. *Plos one, 14*(4), e0214846. https://doi.org/10.1371/journal.pone.0214846

Taylor, N., Lawton, R., Moore, S. Graig, J., Slater, B., Cracknell, A., Wright, J., Mohammed, M. (2014). Collaborating with front-line healthcare

professionals: The clinical and cost effectiveness of a theory based approach to the implementation of a national guideline. *BMC Health Services Research 14*, 648. https://doi.org/10.1186/s12913-014-0648-4

Walden University. (2019). Manual for clinical practice guideline development (CPGD): Doctor of Nursing Practice (DNP) scholarly project. https://drive.google.com/file/d/0B1_8mknkC0j1TWl1eU4xQS1QYVU/view

Walden University. (2019). About Us: Theme & Mission. https://academicguides.waldenu.edu/social-change/mission

Werschler, W., Calkin, J., Laub, D., Mauricio, T., Narurkar, V., & Rich, P. (2015). Aesthetic dermatologic treatments: Consensus from the experts. *The Journal of Clinical and Aesthetic Dermatology, 8*(10), S2-S7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4635431/

Appendix A: Literature Matrix

Authors	Year	Name of Journal or Book	Title	Summary	Evidence Level
Adatto, B., & Byrd, M.	2017	Modern Aesthetics	Legal and regulatory issues in the medical spa industry	National survey of medical spas to collect data about the growth of the industry and legal and regulatory issues. Expert opinion by attorneys who focus their work on legal cases in the medical spa industry.	VII
Ann, S., & Wicklin, V.	2020	Plastic Surgical Nursing	Study expresses concerns about the safety of medical spas	Authors identified that medical spas had a higher incidence of adverse events than a traditional physician's office. Most adverse events occurred due to lack of training or care oversight.	VI
Chhabra, A., Singh, A., Kuka, P., Kaur, H., Kuka, A., & Chahal, H.	2019	Nigerian Journal of Surgery	Role of perioperative surgical safety checklist in reducing morbidity and mortality among patients: An observational study	An observational study that stressed the importance of reviewing a patient's medical history and safety checklist prior to surgery to help reduce adverse events. Concluded that most adverse events occurred because of errors that were overlooked prior to or after surgery.	IV
Goldberg, D.	2018	Dermatology Times	Medspa ownership liabilities	Study stresses the importance of proper training of injectors after finding that many legal ramifications occurred due to lack of training or proper supervision.	IV
Kim, F., Da Silva, R., Gustafson, D., Nogueira, L., Harlin, T., & Paul, D.	2015	Patient Safety in Surgery	Current issues in patient safety in surgery: A review	Qualitative study focused on the importance and need for standardized practice guidelines in surgeries to help	VI

				improve safety and prevent adverse events.	
King, M.	2017	The Journal of Clinical and Aesthetic Dermatology	The management of bruising following nonsurgical cosmetic treatment	Expert knowledge on the prevention and treatment of the number one adverse event of cosmetic treatments, bruising. The authors support the need for pre-treatment evaluations and review of medical history to help prevent adverse events.	VII
Rossi, A., Wilson, B., Hibler, B., & Drake, L.	2019	Dermatologic Surgery	Nonphysician practice of cosmetic dermatology: A patient and physician perspective of outcomes and adverse events.	Patients experienced more adverse events from medical spas outside the traditional physician office, questioning the training and safety protocols in place at medical spas.	IV
Taylor, N., Lawton, R., Moore, S. et al.	2014	BMC Health Services Research	Collaborating with front-line healthcare professionals: The clinical and cost effectiveness of a theory based approach to the implementation of a national guideline	In randomized controlled trial, authors concluded the importance of using the Theoretical Domains Framework in implementing a guideline as compared to the control group.	II
De Boulle, K., & Heydenrych, I.	2015	*Clinical, Cosmetic and Investigational Dermatology*	Patient factors influencing dermal filler complications: Prevention, assessment, and treatment	Importance of medical history review to help improve patient safety and prevent adverse events from cosmetic treatments. Authors discussed medications that may be contraindicated if taken before cosmetic dermal fillers.	VI

Appendix B: Medical Spas: Ensuring Compliance and Patient Safety

Objectives:

1. Standardize the Medical Spa treatment processes.
2. Increase aesthetic injector knowledge and treatment practices about care standards on providing medical treatments for patients.
3. To enhance treatment compliance and patient safety.

Problem Statement -Can the development of a clinical practice guideline (CPG) for aesthetic providers increase their knowledge about delivering safe and consistent patient care?

Target Population - Aesthetic injectors employed (Registered Nurses (RNs), Nurse Practitioners (NPs), Physician Assistants (PAs), and Medical Doctors (MDs).

Guideline Monitoring -The medical assistant is currently responsible for ensuring that all necessary patient forms are completed prior to beginning treatment such as patient consent forms and arbitration agreements. This will be a continuous process, as the injector assistant will ensure that the injector for every patient's physical chart has completed the CPG questionnaire before filing it. Monthly reviews of charts by the MD of the practice will ensure continuous monitoring of guideline compliance.

Introduction

As advancements in nonsurgical medical aesthetics procedures continue to evolve, state and federal policies providing clear, up to date, safety and legal guidelines for such procedures performed at medical spas are limited or lacking. The terms physician and MD are used interchangeably in this guideline. The terms NP, PA and non-physician

providers are also used interchangeably in this guideline. As more people come forward with complications resulting from nonsurgical procedures performed by improperly trained providers, state regulatory agencies have begun to increase enforcement of state guidelines violations (AMSPA, 2018). Goldberg (208) said that many medical spas and operators that have faced legal ramifications were due to a lack of proper supervision of medical treatments as well as improperly trained personnel. Non-compliance with state and federal laws and professional scope of practice, compromise patient safety, impact patient outcomes, and increase the potential for litigation.

Part I – Initial Good Faith Exam (GFE)

An initial GFE must be conducted on each patient once they present for services during their first visit. The patient must have an initial GFE completed and documented by a physician or a non-physician provider within the last 365 days for the followup GFE (mini GFE) to be initiated. The initial GFE must be documented and completed per existing organization protocol at least every 365 days.

Part II – Follow up Good Faith Exam (mini GFE)

The mini GFE evaluation form is to be completed for every patient visit by the injector prior to the administration of any aesthetic medical treatment. This mini GFE evaluation applies only to patients who have had an initial GFE performed in the last 365 days.

Clinical Practice Guideline: Improvement of Injector Knowledge and Patient Safety

1. Has the patient had a GFE performed in the last year?	YES: O : Continue to the next question. NO: O : Stop here and perform a GFE per your organization protocol.
2. Does the patient have any bleeding disorders or has the patient taken (NSAIDS), aspirin-containing products, or herbal supplements (ginkgo biloba, folic acid, turmeric, melatonin, garlic, coenzyme Q, cayenne, kava kava, ginger, etc.) in the last 7 days?	YES: O : Please advise the patient on the increased risks for bleeding, bruising, and skin sensitivities that may occur during procedure. Give the patient the options to continue with treatment or to reschedule the service. NO: O : Continue to the next question.
3. Has the patient had any changes in their medical history since the last good faith exam, particularly any new skin conditions or other conditions that may deem to be contraindicated by the injector?	YES: O : If there are questionable contraindications, please contact the physician or non-physician provider to discuss and clarify concerns prior to performing the treatment. NO: O : Continue to the next question
4. Has the patient reviewed, signed, and understands all the pre and post-procedure instructions given to them for the treatment being performed today?	YES: O NO: O : Please review pre and post-procedure instructions with patient for clarity.
Provider Signature: _____	Date: _____

Med Spa Compliance and Safety Guideline Components (Collected from the evidence/literature)	**Recommendation**	**Level of Evidence/Quality Ratings (Melnyk & Fineout-Overholt's hierarchy of evidence rating system)**	**Comments**	**Source of Evidence (Identify Specific literature)**
Part I: Ensure a GFE has been performed. If a GFE has not been performed, the injector must then ensure that a GFE is performed using established organization guidelines.	Always ensure that a GFE has been performed within 365 days prior to providing any medical treatment.	VII / Poor	The Medical Board of California (MBOC) and California Board of Nursing (CBON) require that an initial good faith exam (GFE) be performed and documented by a physician or an APRN.	American Med Spa Association (2018)
Part II: Does the patient have any bleeding disorders and or has taken (non-steroidal anti-inflammatory drugs, aspirin containing products, and or herbal supplements (ginkgo biloba, folic acid, turmeric, melatonin, garlic, coenzyme Q, cayenne, kava kava, ginger, etc.) in the last 7 days?	If the answer is YES, Please advise the patient on the increased risks for bleeding, bruising, and or skin sensitivities that may occur during procedure. Give the patient the option to continue with treatment or to reschedule.	VI / Fair	Importance of medical history review to help improve patient safety and prevent adverse events from cosmetic treatments. Authors discussed medications that may be contraindicate d if taken before cosmetic dermal fillers.	Clinical, Cosmetic and Investigational Dermatology (2015)
Has the patient had any changes in their medical history since the last good faith	If the answer is YES, and if there are questionable contraindications,	IV / Good	An observational study that stressed the	Nigerian Journal of Surgery (2019)

exam, particularly any new skin conditions or other conditions that may deem to be contraindicated by the injector?	please contact the physician or non-physician provider to discuss prior to performing the treatment.		importance of reviewing a patient's medical history and safety checklist prior to surgery to help reduce adverse events. Concluded that most adverse events occurred because of errors that were overlooked prior to or after surgery.	
Has the patient reviewed, signed, and understands all the pre and post instructions given to them for the treatment being performed today?	If the answer is NO, please review pre and post-procedure instructions with patient for clarity.	VII / Poor	Expert knowledge on the prevention and treatment of the number one adverse event of cosmetic treatments, bruising. The authors support the need for pre-treatment evaluations and review of medical history to help prevent adverse events.	The Journal of Clinical and Aesthetic Dermatology (2017)

Rationale Supporting Guideline Questions: Why should we ask these questions?

Question 1: Has the patient had a GFE performed in the last year? If the answer is "Yes", then the injector can continue with the CPG while if the answer is "No", the injector will discontinue the CPG and request that the annual GFE with a physician or non-physician provider be performed with the patient prior to initiating any medical treatment. At the local practicum site, there have been many incidences where an injector would forget to check a patient's file to ensure that a GFE had been previously done and if within the past 365 days. The patient would leave the clinic after receiving a medical treatment, many times performed by an RN. If a nurse injector performs medical treatments without standing orders from a physician or non-physician provider, the nurse could be in violation of both state and federal guidelines for the unlawful practice of medicine (CBON, 2013). For many reasons, this can put the injector's license at risk while leaving the nurse, the medical director, and the med spa organization, open for litigation and impact patient outcomes (AMSPA, 2018).

Question 2: Does the patient have any bleeding disorders and/or has taken non-steroidal anti-inflammatory (NSAIDS) (ibuprofen, Motrin, Advil, Aleve), aspirin containing products, and or herbal supplements (ginkgo biloba, folic acid, turmeric, melatonin, garlic, coenzyme Q, cayenne, kava kava, ginger, etc.) in the last 7 days? If the answer is "Yes", the injector is to educate the patient on this risk and a joint decision between the patient and the provider is made if the patient would like to continue with the procedure or to re-schedule. If the patient has consumed any of these medications within the past 7 days, the procedure can be performed; however, the patient must be informed

that they are at increased risk of possible bruising and or bleeding during the procedure and should be provided the option of re-scheduling their procedure. The use of such products prior to nonsurgical cosmetic treatments has been shown to increase the prevalence of bleeding and contusions during and after treatment. In fact, bruising has been noted as the most common adverse event from dermal filler and botulinum toxin injections. Results showing the prevalence of bruising after such treatments have ranged from 19% to as high as 68% and can last for longer than two weeks. The number one complaint from patient dissatisfaction has been extensive bruising (King, 2017).

Question 3: Has the patient had any changes in their medical history since the last good faith exam, particularly any new skin conditions or other conditions that may deem to be contraindicated by the injector? If the answer is "Yes", the injector will decide whether or not a contraindication exists. If the injector is an RN and there is questionable doubt of possible contraindications, he or she must initiate a telephone consult with the physician or non-physician provider prior to the treatment. Reaching out to the physician or non-physician provider for further evaluation of the patient's medical changes will ensure that the RN is practicing within his/her scope of practice (CBON, 2013).

Question 4: Has the patient reviewed, signed, and indicated understanding of all the pre and post procedure instructions given to him/her for the treatment being performed today? If the answer is "No", it is recommended that these instructions be discussed with the patient prior to administering any treatment so that all questions and concerns are addressed. It is a standard of practice for patients to sign consent forms for treatments as well as sign pre and post-procedure instructions to ensure that any questions

or concerns are addressed prior to the treatment. At the project site, unfortunately these forms are signed for all available treatments from the date of the patient's initial GFE and are not routinely reviewed with the patient prior to any and all of the scheduled treatments thereafter. The American Med Spa Association (AMSPA), reports that 37% of respondents to a survey related to the GFE admitted either the GFE wasn't being performed or, that the physician, PA, or NP was not the one performing the initial exam (Adatto & Byrd, 2017). Prior to administering any medical treatment to a patient, the CPG will provide a guideline-directed process that includes steps for the injector to follow, helping to improve injector knowledge, patient safety, and the prevention of adverse events.

Appendix C: Expert Panel Evaluation

Thank you for your participation in the evaluation of this clinical practice guideline (CPG). Your feedback is critical to the success and further development of this CPG. Please fill out the following questionnaire by choosing one rating for each of the six domains listed below ranging from *strongly agree* to *strongly disagree*.

Questionnaire for the CPG Using the 6 Domains of the AGREE II

	1 Strongly Agree	*2* Agree	*3* Disagree	4 Strongly Disagree
Domain 1: Scope & Purpose The population (patient, public, etc.) to whom the guideline is meant to apply is specifically described.	O	O	O	O
Domain 2: Stakeholders' Involvement The target users of the guideline are clearly defined.	O	O	O	O
Domain 3: Rigor of Development Systematic methods were used to search for evidence.	O	O	O	O
Domain 4: Clarity of Presentation The recommendations are specific and unambiguous	O	O	O	O
Domain 5: Applicability The guideline provides advice and/or tools on how the recommendations can be put into practice.	O	O	O	O
Domain 6: Editorial Independence The views of the funding body have not influenced the content of the guideline.	O	O	O	O

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Appendix D: AGREE II Permission

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February 02, 2021

To Mike Chammout and Walden University,

We, the AGREE Enterprise Research Office, give permission to ***Mike Chammout and his co-authors*** to use the AGREE II tool, in his publication: **"Medical Spas: Ensuring Compliance and Safety."**

This permission provided that the authors properly cite the AGREE II tool in the mentioned article.

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Sincerely,

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