Creation of a Risk Statement for Dry Needling for use during Informed Consent to Improve Patient Decision Making

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ABSTRACT

Background: Physical Therapists in the United States can perform Dry Needling (DN) in most states with the legal requirement for the therapist to obtain written and/or verbal informed consent (IC). When consenting patients to DN treatment, it is necessary to inform patients of potential risks of harms. In cases where risks are disclosed as part of IC, patients have potentially shown poor recall which calls into question how best this type of information should be presented.

Purpose: To develop a risk of harm statement that can be used on an IC form for DN in both the clinic and research settings to improve patient autonomy and decision making.

Research Design and Methods: The Delphi study involved three rounds of questionnaires to gain expert consensus for inclusion of AEs for IC. Inclusion criteria for DN experts included: (1) >= 5 years practice performing DN and one of the following secondary criteria: (a) Certification in DN, (b) Completion of a manual therapy fellowship that included DN training, or (c) >= 1 publication involving the use of DN. Participants rated their level of agreement using a 4-point Likert scale. Consensus was defined as >= 80% agreement or >=70% and < 80% agreement with Median >= 3, Interquartile Range <= 1, and Standard Deviation <= 1. A Nominal Group Technique (NGT) methodology was used to achieve consensus among participants to identify what needs to be included in a risk of harm statement to allow patients understand the true risks. Participants included: policy experts, legal experts, DN experts, and patients who received DN. The NGT session consisted of 5 rounds of idea generation and final consensus voting which lasted for 2 hours. Consensus for inclusion of ideas was defined as >= 80% agreement following 2 rounds of voting.

Analysis: In both studies, median, Interquartile range (IQR), standard deviation, and percent agreement (combined “strongly agree” and “agree” responses) were calculated. A Wilcoxon rank-sum test was used to evaluate the consistency and stability of responses between questionnaire responses. Statistical significance was defined as $P < 0.05$. Kendall’s coefficient of concordance (w) was calculated in each round to determine agreement between participants. Readability analysis included: Flesch-Kincaid grade level, Flesch Reading Ease Score, and sentences.

Results: Thirty-Nine DN experts were included in the Delphi Study and five participants were recruited in the NGT study (N=1 legal expert, N=1 policy expert, N=2 DN experts, and N=1 patient). Fourteen AEs identified for inclusion on a risk of harm statement: bleeding, diaphoresis, fatigue, pain during/after, pneumothorax, soreness, bruising, dizziness/lightheadedness, drowsiness, superficial hematoma under skin, skin redness, neurological symptoms, syncope, and temporary increase in symptoms. Each AE was categorized by the experts where 93.6% agreed with the definitions for both severity and likelihood. In the NGT, participants identified 27 elements for IC, 22 of which reached final consensus. The elements pertaining to a risk of harm statement included being able to order the risks that can occur and to stratify the severity and likelihood of each risk.

Conclusion: A final risk of harm statement was generated for inclusion on IC for DN. The final risk of harm statement was 20 sentences long, was written at a 7th grade reading level, contained an ordered list of risks by severity and likelihood of occurrence, and had a Flesch Reading Ease Score of 65.0.

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But Jesus looked at them and said, "With men *it is* impossible, but not with God; for with God all things are possible." (Mark 10:27).

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Chapter 1: Introduction

1.1 Background

Dry Needling (DN) has become an increasingly popular intervention for the treatment of a variety of neuro-musculoskeletal conditions. The application of DN involves insertion of monofilament or acupuncture needles, which could result in non-therapeutic adverse events (AEs). In states where DN has been approved for use as an intervention, regulations have been developed to provide guidance in the safe application of DN. Although there is variation in the requirements for DN, many of the states require informed consent (IC) for the use of DN, despite heterogeneity in the requirements. One of the required elements for IC includes disclosing to the patient the potential risks and benefits. Current studies suggest there is a lack of disclosure of risks prior to performing medical interventions[1–4]. Since risk disclosure is an element of IC, there has been debate on whether individuals are adequately informed regarding medical procedures. In addition, studies have shown that current IC forms are often lengthy and complex which makes it difficult for individuals to make informed decisions regarding their medical care or participation in clinical research trials[5–10]. To date, there is no consensus on what information should be included in a risk statement related to DN application.

Chapter 1 highlights the current problem and need to determine the elements and framework for creating a shortened, concise risk of harm statement that can be used on IC forms for DN.

1.2 Statement of Problem

Dry Needling (DN) refers to "a procedure that requires the insertion of thin monofilament needles without the use of an injectate into muscles, ligaments, tendons, subcutaneous fascia, and scar tissue"[11]. DN can be traced back to the 1940's. In the mid 1970's the introduction of acupuncture needles into practice became a driving force in the developing interest of incorporating DN into the clinic, even though both techniques are distinctly different. Once DN was established, healthcare professionals have enthusiastically incorporated DN into the clinical setting and have described it as a "cheap, easy to learn, low risk, and minimally invasive" therapy that can be combines well with other modalities[12]. Over the past 10 years, many studies have examined the application of DN to numerous pathological conditions, such as: temporomandibular joint dysfunction (TMD)[13,14], post-stroke[15–17], plantar heel pain or plantar fasciitis[18,19], osteoarthritis[20–23], headache[24–29], fibromyalgia[30,31], neck and shoulder pain[32–39], lateral epicondylagia[40], back pain[41], and hallux valgus[42]. Additional studies were conducted to identify the effects of DN. DN has been shown to: improve spasticity and range of motion (ROM)[43], improve flexibility of muscles[44–46], myofascial trigger point pain[47–50], scar tissue[51], and neuromuscular control[52,53]. Since DN can be applied across different pathological conditions, there has been an increasing number of healthcare professionals becoming trained and certified in DN. This has led to the increased use of DN in the clinical setting with a need to continue to produce high quality research regarding the development of practice guidelines. As with any intervention technique, there is a need to further understand the risks associated with such an intervention to allow for improved clinical decision making.

To date, there has been limited research that has examined the adverse events (AE) of DN which has led to a call for further studies in this area[54,55]. Additionally, there has been no consensus among experts in how these AEs should be classified. A scoping review found that there was a general lack of standardized AE reporting and documentation which makes the relative risk of DN unclear[56]. For DN to be applied safely in a clinical setting there continues to be an increased need to understand the AE's associated with DN. This would allow patients to make decisions regarding their own care and participation in research studies.

Enhancing patient choice is a central theme of medical ethics and law[57–59]. Informed Consent (IC) can be defined as

"The process by which a researcher/physician sensitizes a patient/participant about the nature of the study/research and what the patient/participant is supposed to go through (interventions and data collection) during the study/research, in their vernacular language that is non-technical and fully understandable by the patient/participant, in order to help them to participate with their complete willingness and without any coercion"[60].

The current process of obtaining IC typically involves: explanation of the IC to the participant, reading of the consent form by the participant, investigator answering questions posed by participant, participant signs and dates the form, investigator signs and dates the form, participant receives a copy of the form, and another copy of the form is filed at the trial site[61]. Informed consent is the legal process used to promote patient autonomy while concepts of shared decision making (SDM) is a widely promoted ethical approach[57]. The development of IC

was formed through different strands of theory and practice over the years. These ideas include: Autonomy, Medical Experimentation, Legal Developments, and Rejection of Physician Paternalism[62]. As IC has become more developed over the years, the shift from this paternalistic model has driven more towards promoting patient autonomy with decision making. Autonomy refers to an individual who chooses and makes major life decisions on their own rather than allowing other individuals to dictate their choices. In the case of IC, the patient has the right to make an informed decision regarding their participation in research or medical treatment. One of the important elements of IC is the disclosure of risks involved with an intervention[63]. SDM is a process where clinicians and patients work together to develop a treatment plan to help patients achieve health-related goals and to determine which approach would be best in achieving those goals[64]. Shared Decision Making strengthens IC by emphasizing understanding and helping to prioritize different medical interventions based on the patients values and experiences[65]. Empowerment of the patient is important in healthcare and can lead to improvements in overall quality of patient care and outcomes. Both guidelines and IC are important components to help perpetuate shared decision making that can lead to improvements in patient-centered care.

Dry Needling has been defined by a Task Force that was created by the Federation of State Boards of Physical Therapy (FSBPT) as “a skilled intervention performed by a physical therapist using filiform needles to penetrate the skin and/or underlying tissues to affect change in body structures and functions for the evaluation and management of neuromusculoskeletal conditions, pain, movement

impairments, and disability".[66]. Throughout recent years, a great deal of studies have focused on DN to deactivate myofascial trigger points. However, there has been some support being gathered for increasing the scope of DN applications to other target tissues such as tendons, ligaments, and scar tissue.

As DN interest continues to expand, there is a need to understand the risks related to the use of DN. Understanding the risks associated with DN will allow for improvements in clinical decision making regarding its application in the clinic. Studies have identified the frequency and occurrences of potential AE's that are associated with DN[54,55,67]. However, these studies have not shown a consistent strategy and methodology for how the reported AEs should be classified. To attempt to address this problem, studies have attempted to categorize and define the types of AE's that can be associated with DN, as well as AE's that occurred because of DN. A clinical commentary utilized classifications and definitions for AE's based on previously used definitions in prior studies[67]. This study had a severity classification system that uses 3 levels: mild/minor, significant, serious. Other studies have utilized different terminology such as: major, moderate, and minor[68]. Without consensus among experts as to how to classify AE's, it is difficult for AE's to be effectively reported and communicated to the patient.

1.2.1 Specific Aim 1

Based upon AE's identified by expert DN clinicians, which AEs associated with DN should be included for use in generation of a risk statement on an IC form?

1.2.2 Specific Aim 2

When constructing a risk statement for use on an IC form, what elements should be used to allow for creation of a concise, informative, and well-structured statement that can be applied in the clinical or research setting?

1.3 Background and Significance

Dry Needling (DN) has continued to see a significant increase in usage in the clinic over the past 20 years. Since its inception, the application of DN now contains research involving its application to a variety of conditions and medical diagnoses. The increased use of DN techniques in the clinic creates a growing need to understand better the adverse events (AE) to allow patients the opportunity to make informed clinical decisions regarding its use as a treatment intervention. The discussion of risks is paramount for IC to occur[63]. Despite risk being an important element, individuals may not be adequately informed about this area. Patients may struggle with readability of informed consent based on literacy levels and the information written which can lead to poor memory recall regarding major risks disclosed during the IC process[4,69]. The overall length and complexity of IC forms has continued to increase over the years, calling into question how these forms can be modified to improve readability and understanding[7,9,10]. An important consideration is finding a balance between providing patients too much information regarding risks that can be extremely unlikely and potential misunderstandings[70].

Identifying ways in which to better facilitate the construction of shortened, concise IC forms to improve patient decision making is necessary. Evidence does offer suggestions for improving IC form structure by creating templated forms using easy to understand language[71,72]. The construction of templated statements that

convey disclosure of risks would provide a beneficial step in improving the overall readability of IC forms.

1.4 Scope of the Investigation

To allow for a larger and more diverse participant sample size and to improve the generalizability of results, the studies were conducted virtually using electronic platforms for data collection. The virtual format also negated the need for specific sites and locations. In each of the studies, the anticipated number of subjects were recruited based on clearly defined inclusion criteria. Initially, the criteria for “expert” was modified from 7 years of clinical practice performing DN to 5 years in consideration that DN training programs have started to become more prevalent in the last 10 years. Additionally, either experts needed to be certified in DN, have completed a manual therapy fellowship that included DN training, or had more than 1 publication involving the use of DN. Recruitment of individuals occurred through professional networks with encouragement to “snowball” invitations to other potential candidates. To have accomplished this project, several electronic resources were required to facilitate data collection and participation in the studies. The use of online platforms were used for data collection and included: SurveyMonkey, Microsoft Zoom, IBM SPSS, and Microsoft Word. The data collection process was expected to take up to 6 months for completion of both studies.

1.5 Definition of Terms

Adverse Event = “any ill-effect, no matter how small, that is unintended and non-therapeutic”[73].

Mild Severity = “short duration up to a few hours, reversible, and cause minimal inconvenience to the patient”[74].

Significant Severity = “require some medical intervention and/or will interfere with a patient's activities. May persist for days or weeks”[74].

Serious Severity = “require hospitalization or prolong an existing hospitalization, cause a permanent or significant disability, or are life-threatening and may result in death. May persist for days or weeks”[74].

Common Probability = “1-10%”[75].

Uncommon Probability = “0.1-1%”[75].

Rare Probability = “0.01-0.1%”[75].

Very Rare Probability = “<0.01%”[75].

Delphi Technique = “a structured technique to modulate a group communication process effectively in allowing a group of individuals, as a whole, to deal with a complex problem”[76].

Nominal Group Technique = “a highly structured face-to-face group interaction, which empowers participants by providing an opportunity to have their voices heard and opinions considered by other members”[77].

1.6 Summary

Informed Consent can be defined as:

"The process by which a researcher/physician sensitizes a patient/participant about the nature of the study/research and what the patient/participant is supposed to go through (interventions and data collection) during the study/research, in their vernacular language that is non-technical and fully understandable by the patient/participant, in order to help them to participate with their complete willingness and without any coercion"[60].

In the case of IC, it is recognized that the patient/participant has the right to make an informed decision regarding their participation in research or medical treatment. As IC has become more developed over the years, there has been a shift from the traditional paternalistic model of decision making to enhancing patient autonomy.

A specific purpose of the IC process is to allow patients to make informed decisions regarding their healthcare and participation in research studies. An important element of IC involves the disclosure of potential risks associated with an intervention[63]. A common fallacy that remains in society is that there is a "quest for zero risk". The minimizing of risk and defining what "acceptable risk" would entail for the patient encompasses part of the shared decision making process[78]. In the discussion of risks, it is recommended that risks be communicated in the following manner: general risks, risks specific to the procedure, and the risks of having no treatment and alternatives. With patient safety being a primary focus of healthcare, full implementation of the IC process is needed.

Despite risk being an important element, individuals may not be adequately informed about this area[1]. When risk disclosure does occur, patients struggle with

the format of the IC form due to the length, level of complexity, and overall readability of the document[4,69]. Studies have shown that there has been an increase in the overall length of IC documents which has called into question whether the length and complexity of these documents has compromised an individual's ability to understand and evaluate the information[79]. Research-related consent forms can contain information that is complex in regards to study procedures, legal terminology, and unfamiliar medical and research terminology[80,81]. Length and complexity of these forms have been indicated as a possible factor for reduced trial participation in research studies[82]. This has led to a call to improve readability of IC documents to be written in plain language that is easy to understand so that individuals can make a more informed choice. An important consideration is finding a balance between providing patients too much information regarding risks that can be extremely unlikely and potential misunderstandings[70].

There have been studies conducted that have examined ways to improve the overall format of IC forms to facilitate better comprehension and understanding by the patient. These studies offer suggestions which can include: avoiding duplication of information and the use of appendices to provide more detailed supplemental information[83]. Other studies recommend the creation of IC templates that have a lower reading level and have a more consistent structure[71,72]. The use of these templated forms demonstrated increased adoption rate in usage with patients providing increased positive feedback regarding their level of understandability. Since DN treatment involves the insertion of fine needles into

the skin, there are inherent risks that can be associated with the treatment[49,54,67,84]. Currently, there is no established guidelines or framework for how a risk statement should be constructed to allow for adequate disclosure of risks associated with DN.

Chapter 2: Literature Review

2.1 Introduction

Dry Needling (DN) has continued to see a significant increase in usage in the clinic over the past 20 years. Originally, DN was utilized more sparingly in patients who were experiencing pain over areas of tenderness. Since its inception, the application of DN now contains research involving its application to a variety of pathological conditions and medical diagnoses.

The increased use of DN techniques in the clinic creates a growing need of understanding the adverse events (AE) to allow patients the opportunity to make informed clinical decisions regarding its use as a treatment intervention. There have been studies that attempted identification of AE's associated with DN, but to date, those studies cite a lack of consensus over how to classify and document the AE's[56]. Without a consensus methodological approach to classifying AE's in DN, there are inaccuracies in the ability to translate this important information into clinical application and practice. Additionally, the process of informed consent (IC) requires disclosure of potential risks associated which can help an individual make a more informed decision regarding treatment options. The purpose of Chapter 2 was to provide a thorough review of the literature with respect to identification of AE's associated with needling and the identification of how AEs were categorized by consensus in other intervention studies. In addition, there are two sections that have been added to better understand DN and its role in clinical application: overview of DN and the IC process. The overview of DN section will provide important information related to the history of DN, physiological effects of DN, DN techniques, current education standards for training in DN, and clinical applications

of DN. The clinical decision-making section provides information related to the process of IC as it relates in both the clinical and research settings.

2.2 Overview of Informed Consent

The foundation of evaluating risks and benefits follows along the traditional Hippocratic Oath: “I will follow that method of treatment which according to my ability and judgment, I consider for the benefit of my patient and abstain from whatever is harmful.”[85]. The basis for evaluating whether an intervention is appropriate for a patient is to assess the potential risks and benefits. For this to occur, a clinician needs to be able to make sound decisions based on available evidence. This section highlights some of the important elements and concepts related to the Informed Consent (IC) Process, including a brief history and evolution of IC in the modern clinic and research setting.

2.2.2 Basic Principles and Elements of Informed Consent

Informed Consent can be defined as “the process by which a researcher/physician sensitizes a patient/participant about the nature of the study/research and what the patient/participant is supposed to go through (interventions and data collection) during the study/research, in their vernacular language that is non-technical and fully understandable by the patient/participant, in order to help them to participate with their complete willingness and without any coercion”[60].

Elements that are required to be included on an IC form include:

1. Nature and purpose of the study
2. Duration of participant participation
3. Procedures to be followed
4. Foreseeable risks or discomforts
5. Investigational product may not have an intended effect
6. If a placebo is present that it will not have an effect
7. Any benefits or payment
8. Alternative procedures available
9. Defining how confidentiality will be maintained
10. Clinical treatment schedule
11. Policy for compensation for participation
12. Contact information for Investigators
13. Participant responsibilities in participating
14. Participation is voluntary
15. Situations where a participant can be removed without consent
16. The consequences of a participant withdrawing from a study
17. If any new findings occur which can affect the participant's willingness to continue, they should be informed
18. Communicating that a treatment can involve potential risks
19. Additional costs to the participant because of participating
20. Name of participant, date of birth, address, qualification, occupation, annual income, name/age/address/contact number of a designated individual if death should occur.

The discussion of risks is paramount for IC to occur[63]. In the discussion of risks, it is recommended that risks be communicated in the following manner: general risks, risks specific to the procedure, and the risks of having no treatment and alternatives. With patient safety being a primary focus of healthcare, full implementation of the IC process is needed. The process of IC has been described as more than just a patient signing a legal document and should focus more on communication with the patient. The current process of obtaining IC typically involves: explanation of the IC to the participant, reading of the consent by the participant, investigator answers questions posed by participant, participant signs and dates the form, investigator signs and dates the form, participant receives a copy of the form, and another copy of the form is filed at the trial site[61]. In the end, the root of IC is to protect the autonomous choices of the patient or research subject.

2.2.3 Evolution of the Informed Consent Form

One of the important elements of IC is the disclosure of risks involved with an intervention. A common fallacy that remains in society is that there is a "quest for zero risk". Despite risk being an important element, individuals may not be adequately informed about this area. Vikas et al[1] examined the level of information provided to a patient prior to surgery, and found that 34% of patients reported they were informed of the risks of the surgery. Additionally, 100% of the consent forms used in the study stated that the patient had been informed about the procedure despite only 34% saying they were informed of the risks. Some reasons for this

discrepancy may include preoperative anxiety and language barrier which may lead to a lack of information regarding risks which may be disturbing for the patient to hear[86]. Sivanadarajah et al[69] cited that patients may struggle with readability of IC based on literacy levels and the information written. Woods et al[87] identified possible barriers to IC from the perspective of doctors which can include: “lack of time, inexperience of clinicians, and patient factors such as reluctance”. Wei Bai et al[4] performed an observational study to determine whether patients would remember the risks associated with an interscalene brachial plexus block immediately following an IC discussion. In the study, 12% of the participants recalled all nine true risks with participants correctly identifying a mean of six risks. This indicates that patients demonstrated poor immediate memory recall of major risks and that the validity of the IC process may be undermined.

As IC has continued to evolve over the years, research studies have examined the application of IC within practice. Studies have shown that there has been an increase in the overall length of IC documents. This has called into question whether the length and complexity of these documents has compromised the ability for individuals to evaluate the information. An observer in one study noted “[Consent forms] are growing in length and complexity, becoming ever more intimidating, and perhaps inhibiting rather than enhancing participants’ understanding. Participants may not even read them, much less understand them.”[79]. Research-related consent forms can contain information that is complex in regards to study procedures, legal terminology, and unfamiliar medical and research terminology[80,81]. Length and complexity of these forms have been

indicated as a possible factor for reduced trial participation in research studies[82]. The recommended grade reading level for consent forms is a 6th to 8th grade reading level or lower[80]. This has led to a call to improve the readability of IC documents to be written with more easily understood wording so that individuals can make a more informed choice. The recent revision to the Common Rule requires that consent be "in language understandable by the subject" and further mandates that "IC must be organized in such a way that facilitates comprehension"[88]. Health literacy is also important in improving the readability of IC forms and involves elimination of jargon with words that are easier to understand[89–91]. The formatting of the IC form also makes a difference and includes use of large fonts and text bolding. Despite these suggestions, few IC forms follow these recommendations.

There are examples in the literature that have assessed trends in IC form development over the years. In the case of oncology trials, Berger et al concluded that the length of IC documents for oncological trials has increased from 1987 to 2007. Berger found that the mean length of IC documents increased from 338 to 1,087 words and the number of basic components increased from 7 to 14[7]. Berger concluded that the increasing length and complexity of these documents demands increasingly competent readers and may prohibit true IC. Emanuel et al[10] also found a similar trend when examining COVID-19 vaccine trial IC documents. Emanuel found that the mean page count of IC documents was 21.8 pages, and the mean word count was 8,333. Emanuel calculated that if an individual read at 240 words per minute, it would take a mean time of 34.7 minutes to read the IC

document[10]. The overall reading level of the documents was higher than a 9th grade level which is higher than the recommended grade 6 to 8[92]. Emanuel concluded that consent forms are lengthy and complex, and that Federal guidance has been insufficient to create a shorter and easier to understand document. Ennis and Wykes[9] also examined whether IC documents had become more complex and lengthier over time. Ennis and Wykes found that information sheets have increased from an average of 1,333 words in 2003 to 1,714 words in 2013[9]. Of the studies examined, those involving dementia and intellectual disabilities were easier to read compared to pharmacological or device intervention that were the longer and more complex. The mean reading level for the studies was grade 10 and increased to grade 13 for more complex sections. Documents that are longer in length are also less likely to be read. Ennis and Wykes[9] concluded that researchers would benefit from guidance by ethics committees on improving writing to balance the legal aspect with the participants ability to understand the research study.

As the growing body of evidence continues to show the progressively longer and more difficult to read IC documents, there have been studies conducted to determine how best to shorten these forms. Corneli et al[83] conducted a study that explored evidence-based strategies to shorten IC forms that can be used in research. In the study, 95% of research stakeholders agreed that IC forms were too long and 96% agreed that IC forms should be shorter, as long as essential information is retained[93]. The suggested methods for reducing the length of these forms involves the use of three strategies. Strategy 1 involved grouping information

by frequency to reduce the risk of duplication particularly when breaking down which procedures would occur at specific visits. Strategy 2 involved the use of appendices where more detailed supplemental information could be stored. This would allow for more detailed information to be stored for individuals who want to access it without compromising the main body of the IC form. Strategy 3 involved avoiding the supplication of side effects and risks. Hadden et al[72] conducted a readability assessment of IRB approved informed consent documents from 2013 to 2015. The study found that the mean readability was at a 10th grade level[72]. The study implemented strategies to improve readability of IRB approved consent forms and to measure impact over a 1 year time period. The implementation of a clear, understandable IC template showed a 49% adoption rate with a mean readability of 7th grade. Of those that used the template to develop an IC form, 90% were in the recommended readability range compared to only 12% in the group that did not use the template. This demonstrated that the development of a template could help to improve consistency and structure of IC documents over time. Zimmerman et al[71] conducted a pilot study that sought to create an easy to read IC form that can be used as a model for the use of plain language. In the study, a plastic surgery IC form was assessed using language comprehension software and then was modified using shortened sentences and simplified words. The form was then reassessed with the same software and then provided to 160 adult volunteers to assess the form's readability and degree of difficulty. The first analysis showed the document was at a grade level of higher education and after revision the grade level was reduced to grade 4-6. Seventy-Eight percent of

participants rated the revised consent form as “Entirely Understandable” and 16.1% found the form “Partly Understandable”. There were strong correlations with younger age and University level education in being able to fully understand the form. Hitchcock et al[94] conducted a focus group based study to assess the consent form used for genome-wide sequencing. In the study, 2 consent forms were used: one 12 pages and an abbreviated 7-page form that contained 45% fewer words with the removal of more detailed explanations. The focus groups had an opportunity to see both versions of the consent form. The parent participants mentioned that the length of the form was a barrier to understanding information presented. The parents recommended the form be written easy to understand language and have an option for more detailed explanations. A further recommendation was made to include an appendix for supplementary information that may be important for decision making but not crucial for consent. This would allow for the creation of a simplified form with an appendix to satisfy the desire for less information. A last recommendation included the use of bullet points for key pieces of information.

2.3 Overview of Dry Needling

The use of DN has continued to emerge as an area of increased study and application since its development in the 1940’s. To better understand the etiology of potential AE’s associated with DN, it is important to understand the theoretical basis for DN, its physiological effects, and the techniques for how DN can be applied. Since DN involves the use of fine filiform needles that are inserted into

selected areas of the body, safe application of DN requires the therapist to have a good working knowledge of human anatomy, be properly trained in application, and understand how to appropriately identify patients who can benefit from the use of DN. Many of the AE's that are classified as "severe" or "major" in the literature argue that some could be preventable if the therapist applying the needling had sufficient and adequate training. To better understand DN and its application, the following sections will provide a foundation for the evolution of DN, it's physiological effects, techniques for applying DN, DN scope of practice, and DN education programs.

2.3.1 History of Dry Needling and Acupuncture

There has been debate over the years regarding the potential relationships between DN and acupuncture. In essence, both appear similar in the sense that filiform needles are used to penetrate the skin and both techniques can be used for the treatment of various medical conditions. According to Fan et al[95,96] many experts believe that DN is a form of acupuncture that has been reframed in Western theoretical principles and research. This opinion is formulated on the fact that both DN and acupuncture use the same needles, stimulating points, needling techniques, and involves the same biological mechanisms[97]. In fact, there is a prevalent belief among many experts that DN is a form of trigger point needling, which was recognized by the World Health Organization (WHO) as a form of acupuncture. Dr Ma, a leading expert on both acupuncture and DN counters this argument and states that DN has no relationship to acupuncture and was

developed by Physical Therapists (PT) themselves. Despite the ongoing debate, an increasing number of healthcare professionals are currently using DN.

Dry needling is an intervention that involves insertion of needles into tender points of the body without the use of a substance. Legge conducted a literature review to illustrate the evolution of the practice and theoretical basis of DN[98]. The preceding history is derived extensively from the work of Legge who provided a detailed chronological history of DN.

Dry needling and trigger point theory developed during the utilization of injections of anesthetics to help treat musculoskeletal conditions. The link between tender muscle nodules and tight muscle bands to pain was not understood well until the twentieth century. Dr Janet Travell and colleagues described "trigger points" as tender points in muscles in 1942[99]. Dr David Simons and Dr. Travell both became highly associated with the concepts of myofascial trigger points. A myofascial trigger point is described as a "hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band". When the tender spot is pressed upon, it can cause referred pain, motor dysfunction, and autonomic phenomena[100]. A 1941 publication by Brav and Sigmond claimed that needling without injection of a substance could help in relieving pain[101]. In the study, 62 patients presented with low back pain and without any underlying visceral disease. Three treatment groups were established: the 1st group was injected with 1% novacaine, the 2nd group was injected with normal saline solution, and the 3rd group received insertion of a hypodermic needle with no substance injection. Although the novacaine group produced the best outcome, the group that did not

receive any injection was a close second, which demonstrated the possibility that needling without injectate could be beneficial. The early use of the term “dry needling” was in a paper published by Paulett in 1947 where it was demonstrated that injection with procaine, saline, and DN all provided relief from pain among 25 cases of low back pain without evidence of organic disease[102]. Paulett also described a jab of pain that caused a reflex spasm when inserted into the muscle, which may be analogous to a local twitch response. Travell and Rinzler produced a publication that suggested intensive afferent stimulation that resulted from a trigger point created pain sensations that can mimic visceral and autonomic phenomena and even cause referred pain[103]. Travell and Rinzler also provided a series of illustrations that demonstrated the referral patterns from 38 muscles that can be utilized for diagnosis and location of muscle trigger points. The paper also went on to suggest that DN might be beneficial for treating myofascial trigger points. In the 1960’s, trigger points were well established in literature and common in general practice, but the usual course of treatment still involved the injection of anesthetics for pain relief. There was an increase of interest in utilizing acupuncture for the treatment of pain. A study conducted by Ghia et al[104] was the first to compare acupuncture versus DN at tender points. The study concluded that both were effective, and that the location of the needling may not have mattered. A study by Melzack[105] also attempted to compare the locations used for acupuncture points versus those utilized at identified trigger points and claimed that there was a high degree of correlation. In the 1970’s, a divergence began to occur between acupuncture and DN. Chan Gunn examined the prevalence of

tender points in different conditions[106,107]. Gunn developed an approach to DN that combined aspects of acupuncture with tender point models which he called “intramuscular stimulation”. Karel Lewit published a paper that highly contributed to the development of DN in 1979[108]. In this case series paper, the following observations from Lewit were made: the effect of technique depended on intensity at the point and the accuracy of the needling, tender points in scars/ligaments/periosteal insertions were all used in the study, both acupuncture and hypodermic needles were used in the study with the finding that acupuncture needles caused less bleeding and bruising and appeared to be safer. The ambiguity and poor separation of concepts established with DN and acupuncture continued throughout the 1970’s and 1980’s. Studies done during this time period often cited the treatment as “acupuncture” or utilized needles of acupuncture to perform needling treatments. The first manual for DN that descriptions of techniques for specific conditions was developed by Gunn in 1989 based on the intramuscular stimulation system of DN[109]. In 1989, the work of Peter Baldry who was a physician who had an interest in acupuncture, attempted to further connect trigger point theory with Chinese acupuncture theory[110]. Baldry had suggested that despite acupuncture needles becoming widely used for DN applications, the theory and techniques of DN varied from those used in the practice of acupuncture. At this point, DN linked more closely with trigger point theory and manual therapy rather than acupuncture. Throughout the 1980’s and 1990’s there was only modest interest in the use of DN with few publications and research studies. A surge of interest in DN occurred during the years of 2000 to 2013. Increased

interest in DN spread worldwide and began to involve medical, physiotherapy, chiropractic, and osteopathic professions. With the increased interest in DN worldwide, there was also a surge in DN training courses that were being offered around the world. The cause for this increased interest is described by Legge: the ability to perform DN using acupuncture needles which are not highly regulated; the ease in which DN can be taught using a hybrid model; the work of Travell and Simons provided an abundance of clinically useful information; Gunn and Baldry's manuals provided treatment and diagnostic instruction for DN; the growing evidence that supports the use of DN for myofascial trigger points; and the potential of success for treating severe chronic tender point cases. The findings of reviews related to the use of DN for painful musculoskeletal conditions has supported its possible use, however the evidence does continue to remain unclear in some cases. There have been several styles of DN that have been described which may produce different results (most refer to the depth of needle insertion). As an example, the use of superficial DN requires need insertion that does not extend to the trigger point and may be only millimeters deep[111]. Deep needling seeks to infiltrate the trigger point which could produce a desirable local twitch response[112,113]. Based in the application of the DN technique, different outcomes and results may occur. Throughout recent years, a great deal of studies have focused on DN to deactivate myofascial trigger points. However, there has been some support being gathered for increasing the scope of DN applications to other target tissues such as tendons, ligaments, and scar tissue. In the end, DN has

been described as a “cheap, easy to learn, low risk, and minimally invasive”[114] form of therapy that can be utilized alongside other treatment strategies.

2.3.2 Physiological Effects of Dry Needling Application

Cagnie et al[115] performed a literature review in an attempt to better understand what effects and mechanisms of action could be attributed to DN. A great deal of this section will include the work of Cagnie et al and will review important principles related to DN effects. There have been various treatment effects that have been credited to the use of DN: a decrease in pain, decreases in muscle tension, improvements in range of motion, improvements in muscle strength, and improved coordination.

The exact mechanisms of DN are still being studied. DN can involve the use of more than one needle. The movement of the needle, varying depths of needle insertion, and force amount can lead to a local twitch response (LTR). A LTR refers to an “involuntary spinal reflex” that results in a contraction of affected muscle fibers (It is believed DN is more effective when a LTR is elicited[112]). Deeper penetration of the needle can affect: skin, fascia, and muscle layers compared to superficial which affects only the skin and some superficial dermal layers. In terms of needle depth, deeper penetration had a better analgesic effect compared to superficial[116]. Effects of DN involve different aspects of trigger point pathophysiology: the taut muscle band, ischemia and hypoxia, peripheral and central sensitization. Since myofascial trigger points are typically the target for treatment, the pathophysiology of these points is an important to understand.

Gerwin et al and Simons et al[100,117] were credited with forming the hypothesis of trigger point formation. In their hypothesis it is suggested that “the first phase of trigger point formation consists of “development of a taut band” as a result of abnormal endplate potential caused by excessive acetylcholine (ACh) release”. This results in sustained sarcomere contractions, which can cause local ischemia and hypoxia. Also, vasoactive and allogenic substances are released that can sensitize peripheral nociceptors and can cause central sensitization and referral of pain. The insertion of a needle at a motor endplate can increase discharges that immediately reduce ACh stores, decreasing the level of spontaneous electrical activity (SEA). Another mechanism involves mechanical needling activation near the endplate which would cause muscle fiber discharge to elicit a LTR that can alter the length of the muscle and simulate mechanoreceptors. In terms of blood flow effect, the most plausible model of effect is release of vasoactive substances which leads to vasodilation in small vessels that results in increased blood flow. The small tears prompts the body’s natural defenses to operate, causing nutrient-rich blood to move to the site and helping to boost tissue repair[118]. There is still discrepancy in the literature as to whether the increased blood flow effects are restricted to the area of needling or can extend remotely to other nearby areas.

When inserting the needle, three types of physiological mechanisms occur: mechanical, neurophysiological, and chemical effects. For mechanical effects, insertion of the needle may cause a “localized stretch to contracted cytoskeletal structures”, which can allow untangling of myosin filaments to allow a muscle to resume its resting length. In addition, rotation of the needle after insertion can

cause a winding of connective tissue which can stimulate group II fibers to activate the gate control system which would lead to a reduction in pain[119]. For neurophysiological effects, superficial nerves can be stimulated for up to 72 hours and prolonged stimulation may cause an opioid mediated pain suppression[120]. Another explored neurophysiological effect can derive from activation of serotonergic and noradrenergic descending inhibitory systems, which could lead to the blocking of pain signals coming from the dorsal horn. In terms of peripheral sensitization, studies showed that a single DN session produced a short-term analgesic effect at peripheral sites. In terms of central sensitization, DN may stimulate large, myelinated muscle fibers indirectly by causing the release of inflammatory mediators. This may result in afferent signals which could activate supraspinal and higher centers involved with the processing of pain. Segmental inhibition can occur with a rapid thrust of the needle into a trigger point that would elicit a LTR that stimulates sensory afferent proprioceptive input into the spinal cord. This afferent information would block the noxious information being relayed through nociceptors. When it comes to central effects of DN, the research is limited in this area. It has been shown that pain following needle insertion combined with electrical stimulation may activate enkephalinergic inhibitory dorsal horn interneurons. It is not well understood whether needle manipulation or electrical stimulation was the result of this effect. The combination of both these techniques has led to the term “electro-acupuncture”. For chemical effects, the use of a needle to elicit a LTR may have an effect on bradykinin and substance P chemical levels[121].

Despite some of the evidence presented, there is still a great need for further studies to explore the DN mechanisms for analgesia. How a therapist performs DN and the techniques they use can be important for the overall therapeutic effect.

2.3.3 Dry Needling Theory and Application as a Treatment Intervention

Unverzagt et al[122] produced a clinical commentary that explored DN intervention for myofascial trigger point pain. Unverzagt explains that the technique of DN is different from acupuncture and is broken down into three models: radicular, spinal segmental and sensitization, and trigger point. The radicular model was developed by Charles Gunn and hypothesizes that "myofascial pain is always the result of neuropathy or radiculopathy". The model is based on the "Law of Denervation" written by Cannon and Rosenbluth that states "the health of innervated structures is dependent upon the unhindered flow of nervous impulses providing a regulatory trophic affect". If a disruption occurs to this flow in the efferent neurons, "an increased irritability to chemical agents develops in the isolated structure or structures, the effect being maximal in the part directly denervated.". Gunn observed that treatment areas are in proximity to muscle motor points, musculotendinous junctions, and that the distribution is myotomal which means that trigger points do not play a significant role. The spinal segmental sensitization model which was developed by Andrew Fischer stated that muscle spasms are responsible for the compression of nerve roots, stenosis of foraminal spaces, and the spraining of the supraspinous ligament. Fischer

contended that the most effective treatment for musculoskeletal pain included: preinjection blocks, dry or wet needling, infiltration of tender spots, somatic blocks, spray and stretcing, and relaxation exercises. The use of a needle with a local anesthetic is needed to achieve longer term relief of pain and tenderness in this model. The last model which is the most frequently used is the trigger point model which involves the targeting of trigger points for the relieving of sensory, motor, and autonomic abnormalities. In this model, the inactivation of trigger points using DN is the quickest and effective way to reduce pain when compared to conventional interventions. The elicitation of a LTR when paired with stretching relaxes actin-myosin bonds in tight bands. Those who advocate for this model believe trigger points should only be a part of a patient's care plan which should also include other strategies such as: stretching, joint mobilizations, neuromuscular re-education, and strengthening.

Safe application of DN requires correct identification of ideal candidates and understanding of the relative and absolute contraindications of DN. Dry needling should not be applied in the following scenarios: "patient with needle phobia, patient who is unable or unwilling to give consent, patient with a history of abnormal reaction to needling or injection, in a medical emergency, patient who is on anticoagulant therapy, or who has thrombocytopenia, and into an area or limb with lymphedema". Relative contraindications include: "abnormal bleeding tendencies, a severely compromised immune system, vascular disease, diabetes mellitus, pregnancy, frail patients, epilepsy, allergy to metals or latex, children, and individuals taking certain prescriptive medications (significant mood-altering

medication, blood thinning agents)". Additional relative contraindications include: "an altered psychological status, anatomic considerations (extreme caution must be taken over the pleura and lungs, blood vessels, nerves, organs, joints, prosthetic implants, implantable electrical devices), needling near a surgical site within four months of the surgical procedure, and a decreased ability to tolerate the procedure". A candidate for DN would include:" a diagnosis that can improve with DN, ability to understand the procedure, ability to effectively communicate their response to treatment, ability to be still during treatment, and ability to give informed consent". Standards of care with DN recommend use of 70% isopropyl alcohol prior to needling with gloves donned. Once the trigger point is identified, a pincer grip technique is used to lift the skin. A high quality, sterile, disposable, solid filament needle is insert directly through the skin, or with the use of a guide tube. The depth of needle penetration depends on engaging of the trigger point. Once the needle penetrates skin, there is variability in techniques that the practitioner may perform. Some examples include utilization of slow, steady, lancing or pistoning motions in and out of the muscle (dynamic needling), leaving of the needle in situ (static needling), or the needle may be rotated several revolutions to draw fascia. If the static technique is utilized, it can be augmented with electrical stimulation to further elicit muscle relaxation and increase in blood circulation. When the needle is withdrawn, tissue should be compressed 5-10 seconds or 30-60 seconds using a cotton swab if bleeding is present.

2.3.4 Scope of Practice and Dry Needling Training

The use a needle to puncture skin in order to reduce pain and improve function has raised questions regarding if this intervention falls within the scope of PT practice. The American Physical Therapy Association (APTA) recognizes DN as a therapeutic intervention provided by or under supervision of a PT. While the APTA states, “DN falls within the practice of physical therapy”, there are some states that believe DN falls outside of the scope of PT practice[55,123]. There are currently 7 states where DN is not approved, 6 states where the DN status is unknown, 2 states with unclear standards, and 35 states where DN is approved. Of the states where DN has been approved, regulations have been set in place that specify the requirements for Physical Therapists who perform DN. Although the requirements vary from state to state, most states do include a requirement that the PT have written consent for each patient and that the consent form should have information regarding the risk and benefits.

As DN continues to become incorporated into practice, there is a need to understand and develop the training requirements that would be needed to safely perform this intervention in the clinic. Ijaz et al[124] conducted a study using extensive document analysis and interviews to construct training requirements for acupuncture-needling physiotherapists and chiropractors in the United States, Canada, and Australia[124]. It should be noted that in this study the use of the terms “acupuncture” and DN were used interchangeably depending on the location of practice. The findings of the study reported that 60% of states in the United States with which PT’s perform DN have no minimum training standards. The World Health Organizations (WHO) recommends a training requirement of 200 hours

minimum. Ijaz et al continues to highlight the international gap in terminology and training requirements that currently exist. Because DN requires the use of carefully placed needle insertion, it is important that the PT performing the DN procedure be adequately trained to minimize risk for AE's and improve overall patient safety. There continues to be contested debate regarding what training is needed to ensure safe clinical application and the need for further studies to develop training requirements.

Safe DN practice requires a specific level of knowledge, skill, and attributes. These include: "appropriate patient selection, creation of a safe and comfortable environment, assessment of one's own capacity to provide the treatment (time constraints, stress, fatigue), safe handling of needles, handling and positioning of the patient, anatomical knowledge, appropriate needle technique (direction and depth), and appropriate monitoring of the patient both during and following treatment"[123]. The Federation of State Boards of Physical Therapy (FSBPT) published a final report on the Analysis of Competencies for DN by Physical Therapists[125]. In this report, DN is defined as "a skilled technique performed by a physical therapist using filiform needles to penetrate the skin and/or underlying tissues to affect change in body structures and functions for the evaluation and management of neuromusculoskeletal conditions, pain, movement impairments, and disability.". The results of the report showed that 86% of knowledge requirements for DN could be acquired during PT entry-level education and 14% of knowledge requirements can be acquired through post-professional education. Additionally, the FSBPT identified that DN is not considered an entry level skill and

recommended that those wishing to pursue DN should participated in advanced training.

Matthews et al[126] followed up this recommendation by exploring DN instruction in entry-level PT education programs. The purpose was to identify which PT programs had integrated DN training into their entry-level curriculum programs and to see how this content was integrated. Of the 75 programs, 40 (53.3%) had integrated DN theory and practice into their programs. The amount of programs that provided DN content was significantly higher for programs located in a state where DN was allowed in the practice act. Programs that did not include DN reported several reasons why including: belief that it is not an entry level skill, not a high priority, lack of qualified staff, not enough time, and perceived lack of scientific evidence. Of the programs that included DN content, twenty-eight (70%) indicated that DN education was integrated into a required course and four (10%) indicated that it was done as an elective. When rating the level of competency of their graduates, twenty-one (52.5%) programs rated their graduates as “not competent”, five (12.5%) rated their graduates as “minimally competent”, and 4 (10%) rated their graduates as “competent”. This study demonstrates the level of variability in training for DN in entry-level programs and continues the debate on whether additional post-graduation training is needed to be competent in DN application[126].

Fan et al[127] published a White Paper that did address some concerns regarding the training and use of DN. In his paper Fan states “DN courses taught in continuing education program typically run 20–30 hours (proposed to increase

to 54 hours in future in some program). This lack of adequate professional training increases the risk of patient injury and can be a threat to public health and safety. Reports of serious injuries associated with DN or acupuncture by PTs are not uncommon. Under current healthcare regulations and system, a patient has no way to know if his or her DN practitioner has sufficient training and what is the risk of being injured when treated by "dry needlers" who received minimal training."[127].

The standardizing of training programs is an important aspect to safe application of DN in the clinic for public safety. As DN continues to expand in its use in the clinic, the need for adequate training programs and guidelines continues to be of importance to reduce the risk for AE's.

2.4 Classification of Adverse Events in Needling Procedures

Since acupuncture involves the use of similar equipment and procedures used in DN, some of the reported AEs in both techniques may be shared. By performing a search of the literature regarding AE's for DN and acupuncture, an initial list can be developed. Current evidence suggests the need for continued studies and standardization of documentation regarding AE's associated with DN[56]. This section highlights important studies that sought to identify the specific AE's that could be experienced.

2.4.1 Adverse Events Experienced in Acupuncture

Acupuncture is a procedure that has been utilized as an integrative or complimentary therapy for pain management. Acupuncture involves insertion of thin needles into a patient's skin at multiple points (sometimes referred to as Ashi

or acupoints). There are no absolute contraindications to acupuncture and the relative contraindications include frailty and febrile illness[128]. Kelly et al[129] conducted a literature review of acupuncture and its clinical application. In their review, they identified mild AE's: "tiredness, local pain, and headache" which occurred in approximately 10% of patients. Significant minor AE's: "severe nausea, fainting, severe or prolonged exacerbation of symptoms, or strong emotional reactions" occurred in 1.3 per 100 treatments. There were no reports of serious events, such as hospitalizations, permanent disability, or death[129]. Witt et al[130] conducted a prospective observational study that included the use of 229,230 patients to assess the safety of acupuncture. In the study, the frequency of AE's were classified according to guidelines of the European Commission "(very common > 1/10, common > 1/100 to < 1/10, uncommon >1/1,000 to <1/100, rare >1/10,000 to <1/1,000, and very rare < 1/10,000)". The AEs were categorized by trained staff using consensus among doctors, acupuncturists, epidemiologists, and psychologists. Of the 229,230 patients recruited for the study, 19,726 (8.6%) reported at least 1 AE. A total of 4,963 (2.2%) of patients had an AE that required further treatment. The common AEs reported were Hematoma (6.1%) and Pain (1.7%). The most predominant AE was bleeding or hematoma which accounted for 58% of all AE's. Adverse events which were caused by negligence or malpractice included: "broken or forgotten needle, pneumothorax, and burns" which accounted for 0.1%[130]. White et al[131] conducted a prospective study of 32,000 consultants to study the AEs of acupuncture as well. In this study, 2,178 AEs were reported in 31,822 consultants. The most common minor AE's that

occurred included: bleeding, needle pain, and aggravation of symptoms. There were 43 significant minor AEs reported of which 13 interfered with daily activities. Apart from one patient who suffered a seizure, there were no other AE's that were classified as serious. Avoidable events that were reported included: "forgotten patients, needles left in patients, cellulitis, and moxa burns"[131]. Ernst et al[132] conducted a multicenter survey using a questionnaire with a checklist of possible AEs, as well as open lines that patients could write in their own statements. The study utilized 409 patients who received a total of 3,535 acupuncture treatments. Of those treatments, there were reported AEs in 402 of them (11.4%). The AEs reported by the patient included: "Small Hemorrhage (2.9%), Hematoma (2.2%), Dizziness (1.0%), Fainting (0.1%), Nausea (0.2%), Other systemic symptoms (2.7%), Pain while needle is in place (0.9%), Pain after needle was removed (0.4%), Other adverse events (2.7%)". The Systemic effects reported included: "Fatigue, Generalized sweating, Feeling of cold, Isolated sweating of hands, Increased peristalsis, Feeling of heat, Tachycardia". Other AE's reported include: "Paresthesia, Worsening of symptoms after removing the needles, Tingling, Headache, Fear, Itching"[132].

Further, Ernst and White[133] conducted a systematic review which focused on the safety of acupuncture and the frequency of reported AE's. In their review, they noted that "minor complications may be more common than previously appreciated with 38% of all patients experiencing some bleeding, 28% reported an AE on at least one occasion, and 45% reported an aggravation of pain". Serious events were reportedly rare with pneumothorax being reported only twice and no

incidences of infection. Although there were no reported life-threatening events, the authors noted that the studies were mainly conducted in hospitals or teaching clinics where standards of training and supervision are better. It is also important to note that there is the potential for variation in these studies as the methodology for defining, identifying, and reporting data differed between studies. In addition, the type of acupuncture varied across studies with some using a Chinese-style acupuncture versus a Japanese-style acupuncture. The review also delineated between avoidable versus unavoidable AE's. Some of the unavoidable AE's included: "hematoma, nausea and vomiting, and aggravation of symptoms". Among the avoidable AE's were "pneumothorax, moxa burns, fainting of the patient while seated, and failure to remove a needle". Although the review was able to confirm that the true incidence of serious complications is low, minor events can potentially lead to serious complications (such as hematoma becoming infected). The reviewers recommended that further studies should involve the use of a standardized methodology that utilizes symptom checklists[133].

Cox et al[134] conducted a systematic review to examine the safety of acupuncture for musculoskeletal disorders. Nine of the 15 studies reported no major AE's. The rate of minor AE's varied across patients depending on the area of treatment. According to the review, the lowest amount of AE's were for patients receiving acupuncture for carpal tunnel syndrome (5%) and the highest amount was reported for patients with nonspecific upper extremity pain (54%). Reported AE's included: "temporary bruising, ecchymosis, transient paresthesia, fainting, dizziness, dyspepsia, anxiety, and exacerbation of symptoms"[134].

Although current literature reviews seem to form a consensus regarding a relative lack of serious AE's associated with acupuncture[135], it should be noted that there is the potential for isolated incidents to occur that could produce serious AE's. Snyder[136] in a case report described a rare AE where a patient received acupuncture treatment while on an international business trip. The therapist had failed to retrieve a needle, resulting in two needle fragments that were located in cervical tissue with one needle that had relocated to within 2 mm of the vertebral artery before being surgically removed[136]. Another case report by Callan et al[137] described a patient who received acupuncture for chronic back and shoulder pain who developed a deep infection following posterior spinal fusion for adolescent idiopathic scoliosis[137]. A final case report example by Karavis et al[138] describes a patient who received acupuncture treatment for acute thoracic and neck pain. The patient had previously received acupuncture treatments for musculoskeletal pain without any AE's reported. Following intense manipulation of the needle, the patient developed acute intense pain that remained even after needle removal.. The patient did not initially accept advice to go to the emergency room until 48 hours after the acupuncture session where a diagnosis of traumatic hemothorax was given to the patient[138].

Although there have been a greater number of studies that examined AEs in acupuncture versus DN, there is a lack of generalizability in the findings of acupuncture studies compared to DN because the education and training of DN clinicians is different than acupuncture.

2.4.2 AEs experienced with DN techniques

Dry needling is a modern treatment designed to ease muscular pain[139]. DN involves inserting a needle through the skin into the area of injury to stimulate a healing response in the area.

Brady et al[54] was one of the first researchers who examined the AE's associated with the application of DN. In her study, a prospective survey was sent to physiotherapists who were trained in the David G Simons Academy (DGSA) in Ireland. In the study, an AE was defined as "any ill-effect, no matter how small, that is unintended and non-therapeutic". Sub-classifications were also utilized in the study to further delineate severity levels using the terms: "significant" and "mild". A "mild" classification is defined as "short-term and non-serious, with no change in function". A "significant classification is defined as "moderate or major AEs, as medium to long-term events that are serious, distressing and may require further treatment.". Trigger-point DN was performed by the physiotherapists who completed the survey and recorded any AEs. Table 2.1 outlines the types of AE's reported in 7,629 treatments with trigger point DN.

Adverse Event	**Reported Cases**	**Number reported per 100 treatments**	**Physiotherapists who reported "none"**
Bleeding	576	7.55	4 (10.25)
Bruising	355	4.65	3 (7.69)
Pain during treatment	230	3.01	9 (23.08)
Pain after treatment	167	2.19	12 (35.9)
Aggravation	67	0.88	22 (56.41)
Drowsiness	20	0.26	32 (82.05)
Feeling faint	17	0.22	28 (71.79)
Headache	11	0.14	31 (79.49)
Nausea	10	0.13	31 (79.49)
Fatigue	3	0.04	37 (94.87)
Emotional	3	0.04	37 (94.87)

Shaky	1	0.01	38 (97.44)
Itching	1	0.01	38 (97.44)
Claustrophobia	1	0.01	38 (97.44)
Numbness	1	0.01	38 (97.44)

Table 1 Adverse Events Reported in Trigger Point Dry Needling

No serious AE's were reported and only 39 respondents were used for data collection, indicating the need for larger size studies[54].

A more recent study by Boyce et al[55] utilized a larger sample size of 420 physical therapists. In this study, AEs were divided into two categories: "minor" and "major". A "minor adverse event" is operationally defined as "short-term, mild, non-serious, and the patient's function remains intact with short-term consequences lasting hours or a few days.". A "major adverse event" is operationally defined as "medium to long-term, moderate to severe events that may require further treatment and can be serious and distressing lasting days or weeks.". Surveys generated in the study were modified from the study of Brady et al. Therapists completed the surveys after performing DN treatments on their patient to report AE's[55]. Table 2.2 and 2.3 outlines minor and major AEs reported during DN.

Event	Number Reported	Percentage per Total Treatments
Bleeding	3288	16.04%
Bruising	1581	7.71%
Pain During	1216	5.93%
Pain After	558	2.72%
Aggravated Symptoms	312	1.52%
Drowsiness	190	0.93%
Feeling Faint	159	0.78%
Headache	133	0.65%
Nausea	94	0.46%

Table 2 Minor Adverse Events Reported with Dry Needling

Event	Number Reported	Percentage per Total Treatments
Prolonged Symptom Aggravation	6	0.03%
Fainting	4	0.02%
Forgotten Needles	3	0.01%
Flu Like Symptoms	2	0.009%
Infection	2	0.009%
Excessive Bleeding	1	0.004%
Lower Limb Weakness	1	0.004%
Numbness	1	0.004%
Total Major Adverse Events	20	0.1%

Table 3 Major Adverse Events Reported with Dry Needling

A clinical commentary by Valdes[67] utilized three categories to classify AE's: mild or minor, significant, and serious which were utilized in a study by MacPherson et al[74]. A "mild" AE is defined as "being of short duration, reversible, and causes minimal inconvenience to the patient". A "significant" AE is defined as "one that requires some medical intervention and/or will interfere with a patient's activities". A "serious" AE is defined as "one that requires hospitalization or prolongs an existing hospitalization, can cause a persistent or significant disability, or are life-threatening or can cause death". Typically, a mild AE will last for a few hours compared to a significant or serious AE, which could persist for days or weeks. Valdes constructed a list of AE's based upon the previous studies of Brady et al[54], MacPherson et al[74], White[140], and Witt et al[130]. Table 2.4 outlines types of dry needling/acupuncture adverse events based on severity and frequency[67,84].

Severity	Mild/Minor	Significant	Serious
Frequency	Common: (1% - 10%)	Uncommon: (0.1% - 1%)	Rare: (0.01% – 0.1%)

	• Bleeding • Bruising • Pain – during/aft • Dizziness • Temporary symp aggravation • Nausea • Sweating • Fatigue	• Prolonged Pai • Excessive blee or bruising • Nerve Injury • Headache • Vomiting • Forgotten nee • Seizures • Extreme Fatigu • Severe Emotio Reactions	• Pneumothorax/Hemothorax • Other organ puncture • Infection • Broken Needle • Cardiac Tamponade

Table 4 Dry Needling/Acupuncture Adverse Events by Severity and Frequency

Valdes reaffirmed that there are still considerable debates on how to systematically categorize AE's and that further research needs to improve consistency in how AEs are reported to help reduce the potential for accidents.

Gattie et al[141] surveyed 865 physiotherapist in the US through special interest groups. The study found that over half of the clinics (55%) performed DN with varied levels of training being reported. Respondents reported that minor AEs associated with DN treatments were common and the estimated level of occurrence was 39.6%. In comparison, major adverse events were rare and typically did not require emergency care. Gattie et al suggests that further research is needed to quantify the risks of DN[141].

These studies form the foundation of a broad view of generalized AE's that can occur with the application of DN. It should be noted that there are several studies that have reported AE's when looking at more specific applications of DN. A prospective study by Uygur et al[142] studied the effectiveness of DN for patients with lateral epicondylitis. The study involved random allocation of 110 patients to

two groups: one that received DN and the other that utilized ibuprofen with a forearm brace. In all, 93 patients were analyzed over the course of three weeks and 6-month time intervals. Out of 51 patients assigned to the DN group, three patients had complications (5.8%) total. Of the three, two high levels of pain during the intervention and another hand an episode of local hemmorhage[142]. Infection is a relatively rare, but serious AE that could potentially result from the application of DN. Both Kim et al and Steentjes et a[143,144]l published a case study describing the occurrence of an infection following DN application to a 16 year old teenager following a knee injury and to a 57 year old who was 7 months post-op from a hip replacement[143,144]. McManus and Cleary[145] conducted a case report regarding a 27-year-old secretary who presented to the outpatient orthopedic department after having attended physiotherapy where she received DN and deep tissue massage for shoulder pain. The patient reported that the needles were inserted on the lateral aspect of the arm, at the level of the middle and distal third of the left humerus. Upon insertion of the needle, the patient reported spasms and subsequent wrist drop. Electromyogram (EMG) was performed and revealed neuropraxia of her left radial nerve[145]. Pneumothorax is a potentially rare and serious AE that can occur with the use of DN. Cummings et al and Patel et al[146,147] both describe a patient case scenario where pneumothorax was demonstrated as an AE following the application of DN. Both studies describe the symptoms experienced by the patient following DN. Although hematomas have been reported as an AE with DN, there are case studies that have been published that highlight where hematomas developed close to the spine. One such case was reported by

Lee et al[148] which identified a 58-year-old female who presented with quadriparesis and neck pain. Magnetic Resonance Imaging (MRI) revealed that the patient had a hyperintense mass at the C2-T2 level of the spine which was diagnosed as an epidural hematoma. Berrigan et al[149] described a similar case and highlighted the need for caution when performing DN near the spine. Additionally, a randomized control trial conducted by Mejuto-Vazquez et al[150] examined the effects of trigger DN on range of motion and cervical pain in patients who have acute mechanical neck pain. Pain using an 11-point numeric scale and pressure pain thresholds were indicated as primary outcome measures. Secondary outcome measures included cervical range of motion. This study did include a section on AE's where patients reported any AE's they experienced after needling and during 1-week follow-up. Of the nine patients who underwent DN intervention, eight reported upper trapezius muscle soreness with no increase in pain that resolved spontaneously in 24 to 36 hours. No other serious AEs were reported in the study. An AE was defined as "sequelae of medium-term duration of any symptom perceived as distressing and unacceptable to the patient and requiring further treatment."[150]. Gonzalez-Perez[151] conducted a randomized single center clinical trial that examined the application of DN to trigger points located in the lateral pterygoid muscle for myofascial pain and temporomandibular dysfunction. Pain using the visual analog scale and the range of mandibular movements associated with opening of the mouth were included as the main outcome measures. The authors did collect information regarding type and frequency of AE's during each

visit for the 24 patients in the DN group. The authors reported that there were no serious AE's experienced in the DN group[151].

Further studies that identified AE's with DN have done so as a secondary outcome. Most of these studies looked at the effectively of DN compared to other interventions for specific patient problems and complaints. During these studies, the authors did include some AE's experienced from the patients. Brennan et al[152] conducted a study that examined DN versus cortisone injection for treatment of greater trochanteric pain syndrome. In the study, the authors compared the treatments looking at pain and function as the primary and secondary outcome variables. The authors included a section on AE's and reported that none of the 43 patients in the study reported an AE. However, the authors explained the following: "The typical side effects associated with needle penetration/injection, such as temporary pain, bruising, and posttreatment soreness, were not documented as AE's."[152]. Other studies that looked at AE's secondarily found that there were no serious AE's that occurred as a result of DN application[153,154], suggesting that DN is a relatively safe technique that can be performed.

A clinical commentary by Kearns et al[155] discussed the need for adequate screening of patients who potentially receive DN interventions. The commentary highlights the need for understanding of risk factors, comorbidities, DN techniques that are utilized, and potential AE's that can occur. As a way to classify potential AE's, the author breaks down considerations and AE's according to comorbidities and target tissue to gain a better understanding of the benefit-risk ratio for more specific applications[155]. Kearns concluded that:

“Most clinical decisions regarding patient care, including DN, require clinical reasoning where it is essential that physical therapists use the patient history to establish and test hypotheses related to potential DN AE. Physical therapists are responsible to recognize and weigh the risks to benefits ratio for each patient and to do whatever is reasonable to minimize risks and enhance the benefits associated with DN intervention using their clinical reasoning skills.”

Although the emphasis for this section involved understanding, not only what AEs are associated with DN, but also how they are categorized, Kearns brings up a very good point that AE’s can be avoidable and minimized if proper clinical reasoning is utilized. This implies that although there is a risk of AE’s with DN, there are other factors and variables that could contribute to the overall frequencies and occurrences of these AE’s. It is important for clinicians who perform DN to be adequately trained and to utilize appropriate clinical reasoning when screening patients.

Reporting bias may lead to overestimating potential benefits of an intervention[156] and underestimating potential AEs[157–159]. There are different types of reporting bias that can exist and include: “publication bias (non-publication or publication based on direction of results), time lag bias (rapid or delayed publication of findings), location bias (publication in journals with different levels of access), language bias (publication in a particular language), and outcome reporting bias (selective reporting of some outcomes but not others)”[160]. Studies suggest that reporting bias is not uncommon[161]. Parsons et al[162] found that 62% of reviews lacked any mention of AE’s in their protocol and 35% of PROSPERO-

registered systematic reviews had differences in outcome reporting between the protocol and publication[162]. Saini et al[163] reported a similar occurrence with 86% of reviews in the Cochrane cohort not including data from the main harm outcome of each review for all studies that were eligible. The single primary harm outcome was inadequately reported in 76% of the studies[163]. Reporting bias can skew risk–benefit ratio of treatments, misinform medical professionals and policymakers, and result in uniformed and poor medical decisions[161]. Evidence remains limited regarding the methods that are used when selecting AEs for reporting and whether this contributes to reporting bias. This calls into question ways in which studies can be conducted to help eliminate reporting bias and avoid underestimating of potential AE's[164]. There is a need to consider that some of the reported AEs in the literature may not be complete.

2.5 Methodological Approaches to Performing a Delphi Technique

The Delphi study technique is "a well-established approach to answering research questions through the identification of consensus view across subject experts"[165]; including AE reporting[166–169]. These studies provide a good framework for future studies that can help to classify and categorize AEs across a variety of other intervention strategies. In addition to expert consensus, there are examples of Delphi studies being utilized to better understand how AEs should be classified based on the perspective of the patient. Understanding both the expert and patient perspectives allow for a better consensus in appropriately identifying AE's. This section highlights important information regarding application of the Delphi

methodology. To date, there are no studies that have utilized a Delphi methodology to gain consensus on important AE's that should be included in IC.

Carnes et al[68] conducted a Modified Delphi Consensus study, which examined ways to define AEs in manual therapy. The aim of the overall study was to seek expert consensus definitions for AEs in relation to manual therapy with a modified Delphi technique. The Delphi study involved use of a questionnaire survey in three rounds until agreement or consensus is established among a group of experts. In the study, consensus was defined as >74% agreement citing that the range of consensus used in similar studies was 66%[170] up to 83%[171]. The questionnaire for the study was developed using a focus group that consisted of a chiropractor, an osteopath, a general practitioner, and a physiotherapist. The group generated a listing of AEs for the initial content of the first-round questionnaire. The participants in the study were experts that included: health researchers, secondary care clinicians, pharmacists, general practitioners, and international researchers. There were no specific criteria for who was considered an "expert" in this study other than the individuals were drawn from those who published in the field of manual therapy and may include individuals who attended the United Kingdom General Osteopathic Council Conference in 2008. The first-round questionnaire sought opinion on constructs used to define "major", "moderate", and "minor" AE's. Each construct was made into a bipolar statement and used a six-point numerical rating scale (1 = Distressing to 6 = Not distressing) to rank importance of each statement as a "minor", "moderate", and "major" AE. Participants were asked to use the numerical scale to rate where a "minor",

"moderate", and "major" AE would lie along the continuum[68]. The second round presented the results to the group and asked members to further define those areas where consensus was not achieved in round one. The group participants were also asked to classify a list of 36 potential AEs into "minor", "moderate", "major", and "not adverse". A description of each term was drawn from round one consensus[68]. Round three was designed to seek additional consensus and opinion regarding AE's. Group participants also had an opportunity to free text feedback issues regarding AE's or the questionnaire[68]. Based upon the results tabulated from all three rounds of questionnaires, Carnes et al was able to establish a pragmatic definition of each of the categories of AE's. A "major" AE is seen as "medium to long term, moderate to severe and unacceptable; they normally require further treatment and are serious and distressing". A "moderate" AE is similar to "major" but only moderate in severity. A "mild" and "not adverse" event is" short and mild, they are non-serious, the patient's function remains intact, they are transient/reversible and no treatment alterations are required"[68].

Carlesso et al[172] conducted an exploratory qualitative analysis of AEs in manual therapy from a patient's perspective to gain further insight into how AE's can be categorized. In this study, 13 patients who were receiving manual therapy from a healthcare professional in Ontario Canada were utilized and underwent a semi-structured interview. The interview guide was constructed by using evidence and consulting with methodological experts. The interviews were taped, and data analysis was performed independently using thematic content analysis. An important finding of the study revealed that patients defined "mild", "moderate", and

"major" AEs by pain and symptom severity, functional impact, and duration. The patient perspective for AE's can differ from previously proposed frameworks and underlines the need to consider the patient perspective when defining such events[172]. Carlesso et al[173] followed up on this study in 2013 where she conducted a cross-sectional survey of patients who were receiving manual physiotherapy in Canada. The survey included different questions regarding symptoms that patients identified as either: adverse, casually associated with treatment, and the impact of contextual factors. The objective was to identify the occurrence of AEs in manual therapy and evaluate predictors of the incidence rate of AE's identified by patients who received manual therapy. A total of 324 respondents were utilized in this study. The results from the study attempted to capture how the patient's felt AE's should be categorized, as well as, what events occurred after manual therapy and whether the patient felt that the event should be considered adverse[173].

Funabashi et al[174] proposed a protocol for an international e-Delphi study to determine expert consensus regarding the severity classification for AE's associated with spinal and peripheral joint manipulation. The use of an e-Delphi (electronic) allows for experts to be approached globally without limits to certain participant groups. The study format calls for three rounds of questionnaires. The protocol does identify eligibility criteria that will be utilized in the study. The protocol identifies an "expert" as an adult individual who possesses a high level of understanding in patient safety and AEs related to spinal manipulation and peripheral mobilization. For researchers, an expert should have ≥ 2 peer reviewed publications related to safety or AE's. For clinicians, ≥ 7 years of clinical practice

performing spinal manipulation[174]. Target sample population was set for 30-73 which is the number in previous Delphi consensus studies with the aim of defining intervention AE's and complications[68,175,176]. The objectives for Round 1 included the collection of demographics and to generation of statements on the definition and severity classifications for AE's related to spinal manipulation and peripheral joint mobilization. The round one questionnaire contained open-ended questions and asked participants to identify their current understanding of AE's and their severity classification. The objectives of Round 2 evaluated consensus of statements from Round 1 and identified the findings of a review that examined AE definitions and their severity classification following spinal manipulation or peripheral mobilization. The authors extracted definition and classification of AE's following their review that were used for Round 2 questionnaire development. A 5-point Likert scale was utilized to rate their level of agreement with statements generated where 1=strongly disagree and 5=strongly agree[177]. An open text box would be included for each statement to allow for participants to add any additional comments. The objective of Round 3 is to further evaluate the statements regarding AE definitions and their severity classification following spinal manipulation and peripheral mobilization. The Round 3 questionnaire included feedback from Round 2 to allow for participant reflection. In round 3, participants will be asked to rate their agreement with the statements achieving consensus from round 2 using the same 5-point Likert scale. A free text box would be provided to clarify statements, but the generation of new statements was not encouraged. Any participants were allowed to complete a current round even if they did not

complete a previous round. Each round lasted 6 weeks to allow adequate response time. The definitions of consensus, agreement, and stability were provided in the study for each round. Data analysis involved three areas: Consensus (extent to which the group shared the same opinion), Agreement (measure of inter-rater agreement where the rating of one expert predicted the rating of another), and Stability (consistency of responses between rounds). In Round 2, consensus was defined as Median ≥ 3.5, IQR ≤ 1.5, and Percent agreement (percent of those responding with "Agree" or "Strongly Agree") ≥ 60%. Agreement was identified through Kendall's coefficient of concordance with (p< 0.05). In Round 3, Consensus was defined as Median ≥ 3.5, IQR ≤ 1, and Percent Agreement ≥ 70%. Agreement was identified through Kendall's coefficient of concordance with (p< 0.05). Stability was tested using a Wilcoxon rank-sum test to compare round 2 and 3 results (p< 0.05)[174].

Kranenburg et al[175] conducted a three-round Delphi study to obtain consensus agreement on a classification system of AE's following cervical spinal manipulation. In the study, participants were selected from three groups: medical specialists, manual physical therapists, and patients. A total of 30 participants were included in the study (10 from each group). Inclusion criteria for manual physical therapists included graduation from an accredited Orthopedic Manual Therapy organization. Each round allowed for 21 days for participants to respond using an online survey tool called SurveyMonkey, with survey reminders being sent out at 10, 17, and 20 days. In this study, strong consensus was defined as ≥ 75%, Mild Consensus as 60-74%, and no consensus as 0-59%. The objectives for

Round 1 focused on forming an inventory of all possible AE's following cervical spine manipulation and to reach a consensus on either a three or four categorical AE classification system. Experts were asked to select one of two categorical classification systems based on the definitions established by Carnes et al: not, minor, moderate, major[68]. The objectives of Round 2 were to obtain an agreement on the influence of the length of time using time units defined previously by Carnes et al (hours, days, weeks). The objectives for Round 3 were to validate answers from Round 2[175].

2.6 Methodological Approaches to Conducting a Nominal Group Technique

The Nominal Group Technique (NGT) approach was first described in the 1960's as a way to enhance group-decision making in social psychological research[178]. The purpose of the NGT is to "generate information in response to an issue that can be prioritized through group discussion"[179]. NGT is" a formal consensus development method based on structured group discussion; the method prevents individual participants from controlling the discussion and ensures all groups members have the opportunity to share their suggestions and opinions"[180]. The NGT is particularly useful where participants are likely to have diverse views on a subject or where limited research evidence is available[77]. A modified form of the NGT has been recently used in literature, referred to as a virtual nominal group technique (vNGT). The following sections describe studies that have utilized the vNGT protocol. The use of a vNGT protocol provides for multiple benefits which include: the participation of participants from

geographically distant locations[181], reducing the burden of travel costs and expenses, and high levels of acceptability among participants[182]. To date, identification of important elements needed to construct a risk statement for IC have not been examined using NGT methodology.

2.6.1 Logistical Considerations for Set-Up of a Nominal Group Study

Studies that utilize the NGT methodology have done so either by using a standardized face-to-face in-person meeting[183–187] or using a modified vNGT protocol that can be conducted in an online format[188–191]. Virtual study protocols utilized software such as Microsoft Teams, Cisco WebEx, and Microsoft Zoom to conduct their online NGT. Participant identification in studies were varied and often contained multiple groups of stakeholders which resulted in multiple inclusion criteria characteristics. Ideally, a maximum of seven participants has been recommended while group sizes of 2-14 have been used in nominal group research[77,192]. Participation in an NGT involves the use of a highly structured meeting that can feature one or two questions, which are sent to participants in advance. The time needed to complete a nominal group technique varies, and depends on group size, how many questions are asked, and the type of participants involved. Usually one question can take 2 hours and 2 questions can take up to 4 hours[193,194]. Studies often provided participants with an e-booklet that could contain information such as: scoping literature review, context statement, questions to be posed in the study, and guidance on the NGT process.

2.6.2 Format of Rounds in a Nominal Group Study

The NGT process typically involves 5 steps: Introduction and Explanation, Silent Idea Generation, Sharing Ideas, Group Discussion, and Voting/Ranking[179]. Stage 1 offers an introduction, which details the vNGT process and allowed for questions or clarifications to occur. Stage 2 would allow for 15 minutes of silent idea generation where participants silently wrote down their ideas to the questions posed. In this stage, participants would not be allowed to have contact with anyone. Stage 3 involves a "round robin" process where each participant offered a single idea in turn until all ideas were exhausted. The ideas generated were recorded by a second researcher. All ideas documented would be placed on a live document that was visible to all members in real time through screen sharing. Stage 4 involved a clarification stage, which allowed for discussion of each idea generated amongst participants. Stage 5 involves individual scoring/ranking from the recorded ideas.

2.6.3 Data Analysis from a Nominal Group Study

Obtaining consensus in NGT studies has been done through a variation of methods that may include: score ranking[77] or rating by using a Likert Scale[195]. The use of re-ranking and allowing participants to revise their original thoughts can also be implemented either during a meeting or through a secondary survey[196]. An example of Likert Scale use included a 9-point scale rating from not important/do not agree (1) to important/strongly agree (9). Consensus was defined as >=75% response in the score range of 7-9[187]. No further re-rating was conducted in this

example. An example of a ranking system included participants voting for their top 3 ideas based on importance, allocating 3 points to their most preferred idea, 2 points to their next preference, and 1 point to their third. If a participant did not rank an idea, it was given a score of “0”. The scores for each ideas were totaled an calculated to identify the top 3 ideas[184].

Chapter 3: Manuscript #1 – Delphi Study

Identifying which Adverse Events Associated with Dry Needling Should be Included for Informed Consent: A Modified e-Delphi Study

Category: Research Paper

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ABSTRACT

Objective: Dry needling (DN) uses a monofilament needle to reduce pain and is performed by several healthcare professions. Due to the invasive needle puncture, adverse events (AE) have been associated with DN. It is unclear, which AEs should be included in a risk statement for Informed Consent (IC). The purpose of this study was to identify which AEs should be included in a risk statement for IC through expert consensus.

Methods: A three-round e-Delphi study was undertaken using a panel of DN experts. Expert inclusion criteria included: (1) ≥ 5 years practice performing DN and one of the following secondary criteria: (a) Certification in DN, (b) Completion of a manual therapy fellowship that included DN training, or (c) ≥ 1 publication involving the use of DN. Participants rated their level of agreement using a 4-point Likert scale. Consensus was defined as ≥ 80% agreement or ≥70% and < 80% agreement with Median ≥ 3, Interquartile Range ≤ 1, and Standard Deviation <= 1.

Results: Of the 39 eligible participants, 34 (87.2%) completed Round 1, 31 (79.5%) completed Round 2, and 30 (76.9%) completed Round 3. A total of 14 (28%) AE's achieved final consensus in round 3 for inclusion on IC. Kendall's Coefficient (*w*) of agreement for round 2 was 0.213 and improved to 0.349 after round 3. Wilcoxon rank tests revealed statistically significant changes for 12 of the 50 AE's.

Conclusion: Consensus was attained for 14 AEs for inclusion on IC. The AE's identified can be used for development of a shorter, more concise IC risk statement. 93.6% of experts agreed with definitions for how AEs should be classified.

Impact: The design of this study helps provide a framework that can be used across multiple interventions cross healthcare professions for the development of a risk statement for IC.

INTRODUCTION

Dry needling (DN) is a minimally invasive intervention using a fine monofilament needle to penetrate symptomatic soft tissue to reduce pain and disability[1]. Over the past 10 years, there have been a great deal of studies that examined the effects and application of DN across varying conditions[2–12]. Potential adverse events (AEs) may occur during the application of DN. An AE is defined as "any ill-effect, no matter how small, that is unintended and non-therapeutic"[13]. Documented AEs associated with DN range from minor incidences like bruising, discomfort, to more severe events including infection, pneumothorax, excessive bleeding, cardiac tamponade, broken needle, fainting, numbness, and organ punture[14–17]. Risks can vary based on the type of DN performed impacting the depth, patient characteristics, or the skillset of the clinician. While some AEs identified in literature may be preventable, some are not. When consenting patients to DN treatment, it is necessary to inform patients of potential risks to make decisions regarding their healthcare or participation in clinical research.

It is legal for Physical Therapists to perform DN in most states. Moreover, there is a legal requirement for the therapist to obtain written and/or verbal informed consent (IC). Informed consent is defined as, "a process by which the treating healthcare provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment."[18]. Three fundamental criteria are needed for IC: the patient must be: competent, adequately informed, and not coerced. One of the required statements that needs included for IC, as established in Federal Code Title 42 Tag A-0238 §482.24(c)(2)(v) is "that the procedure, including the anticipated benefits, material

risks and alternative therapies, was explained to the patient or their legal representative". In some states, a specified minimum standard for satisfying IC includes a written document signed by the patient that clearly states these minimum requirements: risk and benefits of DN, the Physical Therapists level of training and education, and that the patient is not receiving acupuncture[19]. The Federation of State Board of Physical Therapy (FSBPT) identified elements of knowledge that therapists who practice DN must know to provide safe and effective practice when applying DN. Two of these elements include knowledge of IC and AE's[20]. Despite the importance of IC, patients may not be adequately informed of risks prior to receiving a medical treatment[21], even though patients want to know of major complications that could occur[22]. In cases where risks are disclosed as part of IC, patients have potentially shown poor recall, which also calls into question how best this type of information should be presented[23]. The thoroughness of the IC process can fluctuate based up on the complexity of the intervention or individual patient factors. Thus, there is lack of uniformity and consensus on the degree of information that should be presented to the patient while discussing consent. Evidence suggests that current IC forms are too long in length and need to be made shorter if important information is retained[24]. Long IC documents make it more difficult to find pertinent information and can negatively impact a participants understanding of research[25]. Evidence has also shown that shorter IC forms can be effective leading to an effort to produce shorter and more concise statements[26].

The Delphi process uses a sequence of structured questionnaires to identify and build consensus particularly in the absence of complete information and when expert opinion is needed to provide a framework for practice [27]. Delphi studies have been used in

relation to AEs to identify risk factors or events that cause the AE[28–30], development of treatment and safety protocols[31–33], and taxonomy/classification systems to develop standardized methods for documenting AE's[34–36]. No studies have sought to identify necessary AE's that should be included on an IC risk statement with the goal of providing a more shortened, structured, and explicit statement for use in clinic or research. The aim of this e-study was to identify important AEs associated with DN that should be included in a risk statement for IC to improve patient decision making regarding their health or clinical research participation.

METHODS

Study Participants

Ethics approval for this study (2022-117) was provided by the Youngstown State Institutional Review Board. This study was also registered on clinicaltrials.gov (NCT05300815). Eligible experts were identified using the following inclusion criteria: (1) Must have ≥ 5 years of clinical practice performing DN and one of the following secondary criteria: (a) certification in DN, (b) completion of a manual therapy fellowship that included DN training, or (c) ≥ 1 publication involving the use of DN. Eligible participants were identified through existing professional networks and social media/internet-based searching. Potential participants were invited to participate by an author or via their professional network connection. Recruitment was maximized by encouraging identified experts to snowball the invitation with other potential expert participants, including calls for expressions of interest on social media and professional organizations and networks.

Study Design

A modified electronic Delphi (e-Delphi) method was used to achieve consensus among experts through completion of sequential questionnaires that were refined by participant feedback to obtain a convergence of opinion and eventual consensus[35]. Questionnaire items were formulated by the study executive committee which consisted of the primary investigator (EI) and a DN expert with ≥ 10 years of experience (DG). All data collection for this study was conducted through SurveyMonkey. Participants provided consent for participation and whether they met the criteria for inclusion in this study. If the participant answered "yes" to both, they were then asked to complete a demographic form, along with providing an email for future communication. Following completion of the form, the participant was officially enrolled in the study. If an individual did not provide IC, meet the inclusion criteria, or did not complete the demographic form, they were excluded from participation in the study. The Delphi process is outlined in Figure 1.

Round 1

Participants were asked the following question: "List all potential AE's that could be experienced with the application of a DN intervention". In this study, an AE was defined as: "any ill-effect, no matter how small, that is unintended and non-therapeutic"[13]. Participants were provided with open free-text boxes to list up to 50 AE's if they desired. Round 1 remained open for 2 months to allow for recruitment of 30 to 73 participants which is the recommended amount for achieving consensus[35]. Participants who did not initially complete Round 1 were provided with reminder emails.

Round 2

A condensed list of AEs was constructed by removing duplicate entries and identifying common themes of AEs from Round 1. The condensed list of AEs were classified using terminology from previous studies related to the severity level[37] and probability of occurence[38] by the study executive committee. Current literature has established a lack of standardization in AE documentation and categorization, making it difficult to properly classify each AE[39]. In cases where no research evidence was found, expert opinion was used to classify AEs. In cases where EI and DG did not agree on the AE or its classification, a third party (KL) was utilized to settle the dispute.

The questionnaire of Round 2 consisted of multiple questions which included:

1. A question asking whether participants agreed with the use of a classification system for defining AEs (Response of "yes" or "no"). The classification system defined each AE according to severity and probability. Severity definitions included: "Mild" (short duration up to a few hours, reversible, and cause minimal inconvenience to the patient), "Significant" (require some medical intervention and/or will interfere with a patient's activities. May persist for days or weeks), and "Serious" (require hospitalization or prolong an existing hospitalization, cause a permanent or significant disability, or are life-threatening and may result in death. May persist for days or weeks)[37]. Probability definitions included: "Common" (1-10%), "Uncommon" (0.1-1%), "Rare" (0.01-0.1%), and "Very Rare" (< 0.01%)[38]. If participants responded "no" to this question, a free-text box was provided for feedback.

2. A series of 3 questions for each AE identified from Round 1:

A. A question regarding the level of agreement on whether the AE should be included for IC. The response used a 4-point Likert scale (strongly disagree "1", disagree "2", agree "3", strongly agree "4").

B. An optional question that allowed participants to provide a severity level for AE if they did not agree with the previously used rating.

C. An optional question allowing participants to provide a probability level for AE if they did not agree with the previously used rating.

Round 2 remained open for 3 weeks with email reminders sent at 1-week intervals and a final email 24-48 hours from the final closing date. Participants who did not participate in round 1 were invited to participate in round 2.

Round 3

A week after the completion of Round 2, participants were invited to complete the Round 3 questionnaire. In Round 3, classification questions were removed, leaving only the IC inclusion questions. In addition, the results of the IC inclusion questions from Round 2 were provided to participants who were asked to rate their agreement on whether the AE should be included for IC. No free-text options were provided in Round 3. Round 3 remained open for 3 weeks with email reminders sent at 1-week intervals and a final email 24-48 hours from final closing date. Participants who did not participate in rounds 1 or 2 were invited to participate in round 3.

Definition of Consensus

Definitions for consensus and agreement in the literature are conflicting and report varying methods for achieving concensus[40–42]. Consensus criteria developed for this study utilized multiple methods established in other Delphi studies to enhance rigor. Consensus for each item was determined by a combination of the percentage agreement (PA), interquartile range (IQR), and standard deviation (SD), and Median. PA was defined as the percentage of responses that either were "agree" or "strongly agree".

The measurement of consensus in this study was first determined by examining the PA. If the PA was ≥ 80%, consensus would be achieved[43]. If the percent agreement was ≥ 70% and < 80%, the following additional criteria must be met to achieve consensus:

1. IQR ≤ 1: IQR lies within one unit of the median.
2. Median ≥ 3: central tendency of response is "agree".
3. SD < 1.0: homogeneity in the participant responses.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics Version 28.0 for Windows (IBM Corp, USA) at the conclusion of each round. The open-ended list of AEs generated from round 1 was analyzed thematically. Demographic and Likert data responses were analyzed using descriptive statistics. The median, IQR were calculated for each AE. The categories "strongly agree" and "agree" were combined to compute the PA. The variability in responses was measured by using SD. Regardless of the level of consensus obtained in Round 2, all AEs were re-introduced into Round 3 for the question regarding agreement of inclusion for IC. Additionally, Kendall's coefficient of concordance (*w*) was calculated during Round 2 and 3 to determine agreement between experts on AEs for inclusion on IC,

as well as, for severity and probability classification of AE's. A Wilcoxon rank-sum test was used in Round 3 to evaluate the consistency and stability of responses between Round 2 and 3 when assessing whether an AE should be included on IC. Statistical significance was defined as $P < 0.05$.

RESULTS

A consensus of AEs for inclusion on IC was achieved following three rounds. Figure 2 represents a flow diagram of the Delphi process, including participation at each round. This study was administered March to July of 2022.

Recruitment was completed prior to Round 1. A total of 60 individuals responded to this study. Of those 60, one did not provide IC and another 12 did not meet the inclusion criteria. Those who met inclusion criteria and provided IC were 48. An additional 9 were excluded due to not completing the initial demographic form. A total of 39 participants were deemed eligible for this study. Of the 39 eligible participants, 34 (87.2%) completed Round 1, 31 (79.5%) completed Round 2, and 30 (76.9%) completed Round 3. Of the 39, a total of 28 (71.4%) completed all three rounds. A response rate for overall e-mail invitations could not be calculated due to the use of snowball recruitment. Round 1 was extended an additional 5 weeks to allow for recruitment of experts. Many of the participants were from the United States and received their training through Integrative Dry Needling (IDN). The demographic characteristics for all 39 participants are presented in Table 5.

Following round 1, a list of 190 AEs associated with DN were identified by participants. Duplicate entries were removed, and the list was further condensed by identifying common themes. A final condensed list of 50 AE's was constructed for use in

round 2. Each of the AE's were classified by severity and probability of occurrence. This final list is presented in Table 6.

Following round 2, the median, IQR, PA, and SD were calculated for AE's identified for possible inclusion on IC. From the AE list, 30% (15/50) met consensus for inclusion on IC. Kendall's Coefficient (*w*) of agreement for these items was 0.213 ($p < 0.001$). These results are presented in Table 7 and 8. Of the 31 participants, 29 (93.6%) agreed with the use of proposed definitions for classifying the AE's. The 2 (6.4%) who did not agree, provided further feedback. In addition, one participant provided feedback regarding the AE list generated from Round 1. The feedback from these participants is presented in Table 9. Prior to round 3, participant responses to the classification of each AE were examined and the majority response was used to reclassify the AE. Of the 50 AEs, only 2 (4%) were modified by the participants: "Large Vessel Puncture" was changed from "Rare" probability to "Very Rare" and "Seizures" was changed from "Uncommon" probability to "Very Rare". The majority response for the severity and probability occurrence for each AE is presented in Table 10. Kendall's Coefficient (*w*) of agreement for severity of AE was 0.818 ($p < 0.001$) and 0.738 ($p < 0.001$) for probability.

The median, IQR, PA, and SD for round 3 were presented alongside round 2 results in Tables 7 and 8 for AE's identified for inclusion on IC. A total of 14 (28%) AE's achieved final consensus in round 3 for inclusion on IC. Kendall's Coefficient (*w*) of agreement for these items was 0.349 ($p < 0.001$). These results are presented in Tables 7 and 8. "Allergic Reaction to the Needle (itching, pins, and needles)", "Local Infection", and "Nerve Injury (Peripheral)" were 3 AE's initially reaching consensus for inclusion during round 2 but were excluded after round 3. "Soreness" and "Superficial Hematoma

under the skin" did not achieve consensus for inclusion after round 2 but were included in round 3. A Wilcoxon rank sum test was performed between round 2 and 3 responses for inclusion of AEs for informed consent and is provided in Tables 7 and 8.

DISCUSSION

The purpose of this study was to generate expert consensus to identify AE's that would be most beneficial to include in creating a structured IC document risk statement. Consensus was achieved for 14 of the 50 AE's (28%) for inclusion on IC. This list can be used to generate a risk statement that aligns with the goals of creating a shorter, more concise statement. Levels of agreement based on Kendall's coefficient improved from 0.213 in round 2 to 0.349 in round 3 but was still considered "Fair Agreement"[44]. Stability of responses between rounds 2 and 3 were measured using the Wilcoxon Rank Sum Test and demonstrated statistically significant response changes for only 12 (24%) of the AE's: Fatigue, Bruising, Blood Borne Transmission, Hypotension, Local Infection, Migraine, Seizure, Temporary Increase in Symptoms, Organ Puncture, Subdural or Epidural Hematoma, Worsening of Health Condition, and Systemic Infection. This would indicate that after viewing results from round 2, experts did not have a changing opinion for many of the AEs presented.

A study by Corneli et al. used evidence-based strategies for shortening consent forms in clinical research. In this study, 95% of stakeholders agreed that IC forms are too long and 96% agreed or strongly agreed that IC forms should be made shorter if essential information is retained. Relating to the length of content area on IC, discussion of risks was identified as the 2nd longest area next to procedures. Stakeholders recommended that

the overall length for communication of risks should be between 83-87 sentences in total length[24]. Condensing important statements such as risks using a shorter, more concise, and targeted format to optimize patient decision making is a great need. In addition, the development of a more standardized and structured IC process may improve quality of care[45].

Classification of Adverse Events

Classification of AE's were examined in round 2. Current literature lacks a standardized methodology for the documentation of AE's in DN, making it difficult to provide information for use in decision making[39]. Delphi studies have been published that sought to create a taxonomy and classification system of AE's[34–36]. Such studies provide a basis for application in clinical and research settings to further develop a standardized approach for documenting AE's. One such application is the ability to analyze the risks associated with an AE. The definitions used in our study allow for the creation of a risk matrix for ranking of the AE's that can be used for IC. The definitions correspond to two recommended variables to identify risk level: probability/likelihood of harm and severity of harm[46]. Valdes used these variables when classifying AEs associated with DN based on severity and probability. These definitions were presented in round 2 and allowed for participants to identify whether they agreed or disagreed with the classification system used[16,17]. In the study, 93.6% (n = 29) of participants agreed with this system for classifying AE's which provides for a possible standardized approach that can be utilized in future studies for documenting AE's. In round 2, participants were asked how they would rate severity and probability of each AE generated from round 1. This suggests that

experts generally agree on how each of these events should be classified. The 6.4% who did not agree with the classification felt that either only 2 severity levels were needed (Serious and Mild) or that the Mild timeline should be modified from a few hours to up to 48 hours to account for delayed onset of muscle soreness (DOMS). Another area of disagreement was conveyed from one participant regarding the AE list generated. In the participant statements, they indicated that "Organ Puncture" could have various degrees of severity based upon the organ being punctured (spleen vs kidney) and that many of the responses could be further condensed into a general autonomic response category. When examining the literature, there is an acupuncture study by Witt et al that contained categories for AEs, but still contained separate listing of individual AE's[47]. Additionally, the AE's used in this study attempted to match headings used in previous studies for DN[14–16].

Strengths

This is the first study attempting to identify AE's that should be included in a risk statement for IC using Delphi methodology. The findings of this study can be used to develop a risk statement for IC to help improve decision making regarding participation with DN intervention. Previous Delphi studies with the aim of defining intervention AEs and complications typically achieved consensus with responses between 30 to 73[35]. Thus, 39 participants were deemed sufficient for achieving consensus. Larger sample sizes could potentially provide diminishing returns regarding the validity of findings[48]. A ≥ 71.8% response rate was achieved across all three rounds. This response rate was consistent with recommended literature values that indicate a response rate of ≥ 70% is sufficient for stability of responses across Delphi studies[49].

Identifying criteria for expertise in DN practice is difficult since no criteria currently exists. In general, an "expert" is defined as "a person who is very knowledgeable about or skillful in a particular area"[50]. A lack of clarity on how to define an "expert" has resulted in a wide range of definitions throughout Delphi studies[50]. This study used multiple elements from a previously published protocol to define an "expert"[35]. Years of experience practicing DN for inclusion in this Delphi was initially set at least 7 years. Due to the difficulty finding participants with greater than 7 years of experience since the use of DN for most clinicians is fairly new, we changed this requirement to greater than 5 years. Many participants reported 5-6 years of experience in DN (69.2%).

Consensus, agreement, and stability were assessed using standardized a-priori definitions and criteria from established protocols[35,51]. The lack of consistency on what "consensus" should be defined as makes it imperative for researchers to provide clear reporting of the standards for consensus. Many Delphi studies use either a ≥ 70% or ≥ 80% agreement in responses as a sole criterion for inclusion[36,52,53], while others use the median, IQR, or SD as additional tools for defining consensus[54]. We used a combination of criteria from other Delphi studies to improve the rigor with consensus being defined as either ≥ 80% agreement or ≥ 70% and < 80% agreement with Median ≥ 3, IQR ≤ 1, and SD ≤ 1.

Limitations

This study did have some limitations. First, we used snowball recruitment through professional networks and emails among potential experts. As a result, there is the potential that participants may have knowledge of others who participated in the study to which absolute anonymity could not be ensured. Second, although attempts were made to

open recruitment internationally, many participants were located within the United States (97.4%). Additionally, expert participants were strictly Physical Therapists who met the expert criteria. This could lead to limitations in generalizability of the findings. It is possible that healthcare professionals outside physical therapy and in the international community may have varying opinions that were not adequately represented. Future studies should include a wider range of healthcare professions on a more international level. Expert opinion also represents low level evidence with potential for bias. The lack of standardization in documenting and reporting AE's in DN has also made it difficult to provide accurate information regarding AE probability and severity. Such documentation would provide useful information in identifying AE's that should be included for IC. Additionally, the ability to classify AEs was identified as a helpful element in developing informed consent for patients[55]. There may be individual risks based on medical or surgical histories not identified through this Delphi that clinicians may still consider.

CONCLUSION

The design of this study helps provide a future framework that can be used across multiple interventions and healthcare professions for the development of a risk statement for IC. Delphi consensus was attained for 14 AE's that participants agreed should be included for IC. The AE's identified can be used for development of a shorter, more concise IC risk statement. 93.6% of experts agreed with definitions for how AEs should be classified which may help with developing a standardized system for documenting AE's. Participants were able to provide opinions regarding classification of AEs to allow for improved risk analysis to improve patient decision making.

Conflicts of Interest: David Griswold is an instructor for Integrative Dry Needling who provides continuing education courses on the topic of dry needling.

REFERENCES

1. Kalichman L, Vulfsons S. Dry needling in the management of musculoskeletal pain. *J Am Board Fam Med*. 2010;23(5):640-646. doi:10.3122/jabfm.2010.05.090296

2. Boyles R, Fowler R, Ramsey D, Burrows E. Effectiveness of trigger point dry needling for multiple body regions: a systematic review. *J Man Manip Ther*. 2015;23(5):276-293. doi:10.1179/2042618615Y.0000000014

3. Bynum R, Garcia O, Herbst E, et al. Effects of Dry Needling on Spasticity and Range of Motion: A Systematic Review. *Am J Occup Ther*. 2021;75(1):7501205030p1-7501205030p13. doi:10.5014/ajot.2021.041798

4. France S, Bown J, Nowosilskyj M, Mott M, Rand S, Walters J. Evidence for the use of dry needling and physiotherapy in the management of cervicogenic or tension-type headache: A systematic review. *Cephalalgia*. 2014;34(12):994-1003. doi:10.1177/0333102414523847

5. Kietrys DM, Palombaro KM, Azzaretto E, et al. Effectiveness of dry needling for upper-quarter myofascial pain: a systematic review and meta-analysis. *J Orthop Sports Phys Ther*. 2013;43(9):620-634. doi:10.2519/jospt.2013.4668

6. Liu L, Huang QM, Liu QG, et al. Evidence for Dry Needling in the Management of Myofascial Trigger Points Associated With Low Back Pain: A Systematic Review and Meta-Analysis. *Arch Phys Med Rehabil*. 2018;99(1):144-152.e2. doi:10.1016/j.apmr.2017.06.008

7. Llurda-Almuzara L, Labata-Lezaun N, Meca-Rivera T, et al. Is Dry Needling Effective for the Management of Plantar Heel Pain or Plantar Fasciitis? An Updated Systematic Review and Meta-Analysis. *Pain Med*. 2021;22(7):1630-1641. doi:10.1093/pm/pnab114

8. Navarro-Santana MJ, Sanchez-Infante J, Fernández-de-Las-Peñas C, Cleland JA, Martín-Casas P, Plaza-Manzano G. Effectiveness of Dry Needling for Myofascial Trigger Points Associated with Neck Pain Symptoms: An Updated Systematic Review and Meta-Analysis. *J Clin Med*. 2020;9(10):E3300. doi:10.3390/jcm9103300

9. Pourahmadi M, Dommerholt J, Fernández-de-Las-Peñas C, et al. Dry Needling for the Treatment of Tension-Type, Cervicogenic, or Migraine Headaches: A Systematic Review and Meta-Analysis. *Phys Ther*. 2021;101(5):pzab068. doi:10.1093/ptj/pzab068

10. Ughreja RA, Prem V. Effectiveness of dry needling techniques in patients with knee osteoarthritis: A systematic review and meta-analysis. *J Bodyw Mov Ther*. 2021;27:328-338. doi:10.1016/j.jbmt.2021.02.015

11. Valencia-Chulián R, Heredia-Rizo AM, Moral-Munoz JA, Lucena-Anton D, Luque-Moreno C. Dry needling for the management of spasticity, pain, and range of movement in adults after stroke: A systematic review. *Complement Ther Med*. 2020;52:102515. doi:10.1016/j.ctim.2020.102515

12. Vier C, Almeida MB de, Neves ML, Santos ARSD, Bracht MA. The effectiveness of dry needling for patients with orofacial pain associated with temporomandibular dysfunction: a systematic review and meta-analysis. *Braz J Phys Ther*. 2019;23(1):3-11. doi:10.1016/j.bjpt.2018.08.008

13. White A, Hayhoe S, Ernst E. Survey of Adverse Events following Acupuncture. *Acupunct Med*. 1997;15(2):67-70. doi:10.1136/aim.15.2.67

14. Boyce D, Wempe H, Campbell C, et al. ADVERSE EVENTS ASSOCIATED WITH THERAPEUTIC DRY NEEDLING. *Int J Sports Phys Ther*. 2020;15(1):103-113.

15. Brady S, McEvoy J, Dommerholt J, Doody C. Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists. *J Man Manip Ther*. 2014;22(3):134-140. doi:10.1179/2042618613Y.0000000044

16. Valdes VR. Dry Needling in Physical Therapy Practice: Adverse Events Part 1: Types and Frequency of Adverse Events. *Orthopedic Physical Therapy Pratice*. 2021;33(1):34-39.

17. Valdes VR. Dry Needling in Physical Therapy Practice: Adverse Events Part 2: Serious Adverse Events. *Orthopaedic Physical Therapy Practice*. 2021;33(2):96-100.

18. Cocanour CS. Informed consent-It's more than a signature on a piece of paper. *Am J Surg*. 2017;214(6):993-997. doi:10.1016/j.amjsurg.2017.09.015

19. State Training Guidelines. Published August 26, 2017. Accessed July 19, 2022. https://www.masterdryneedling.com/state-training-guidelines/

20. DryNeedlingFinalReport_20150812.pdf. Accessed June 28, 2022. https://www.fsbpt.org/Portals/0/documents/free-resources/DryNeedlingFinalReport_20150812.pdf

21. Vikas H, Kini A, Sharma N, Gowda NR, Gupta A. How informed is the informed consent? *J Family Med Prim Care*. 2021;10(6):2299-2303. doi:10.4103/jfmpc.jfmpc_2393_20

22. Sandiford NA, Mahendra M, Wickramarachchi L, Back D, Bansal M. Informed Consent in Patients Undergoing Primary Hip and Knee Arthroplasty: What Do Patients Want to Know? *Cureus*. 12(6):e8457. doi:10.7759/cureus.8457

23. Bai JW, Abdallah FWW, Cohn M, Ladowski S, Madhusudan P, Brull R. Say what? Patients have poor immediate memory of major risks of interscalene block disclosed during the informed consent discussion. *Reg Anesth Pain Med*. Published online August 23, 2019:rapm-2019-100858. doi:10.1136/rapm-2019-100858

24. Corneli AL, Namey E, Mueller MP, et al. Evidence-based strategies for shortening informed consent forms in clinical research. *J Empir Res Hum Res Ethics*. 2017;12(1):14-25. doi:10.1177/1556264616682550

25. Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? *J Clin Oncol*. 2007;25(9):e13-14. doi:10.1200/JCO.2006.10.3341

26. Enama ME, Hu Z, Gordon I, et al. Randomization to standard and concise informed consent forms: development of evidence-based consent practices. *Contemp Clin Trials*. 2012;33(5):895-902. doi:10.1016/j.cct.2012.04.005

27. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs*. 2000;32(4):1008-1015.

28. Shi C, Zhang Y, Li C, Li P, Zhu H. Using the Delphi Method to Identify Risk Factors Contributing to Adverse Events in Residential Aged Care Facilities. *Risk Manag Healthc Policy*. 2020;13:523-537. doi:10.2147/RMHP.S243929

29. Nanji KC, Roberto SA, Morley MG, Bayes J. Preventing Adverse Events in Cataract Surgery: Recommendations From a Massachusetts Expert Panel. *Anesth Analg*. 2018;126(5):1537-1547. doi:10.1213/ANE.0000000000002529

30. Hunt R, B Lazebnik L, C Marakhouski Y, et al. International Consensus on Guiding Recommendations for Management of Patients with Nonsteroidal Antiinflammatory Drugs Induced Gastropathy-ICON-G. *Euroasian J Hepatogastroenterol*. 2018;8(2):148-160. doi:10.5005/jp-journals-10018-1281

31. Toscano Guzmán MD, Galván Banqueri M, Otero MJ, Alfaro Lara ER, Casajus Lagranja P, Santos Ramos B. Development of a Trigger Tool to Identify Adverse Drug Events in Elderly Patients With Multimorbidity. *J Patient Saf*. 2021;17(6):e475-e482. doi:10.1097/PTS.0000000000000389

32. Johnson DA, Katz PO, Armstrong D, et al. The Safety of Appropriate Use of Over-the-Counter Proton Pump Inhibitors: An Evidence-Based Review and Delphi Consensus. *Drugs*. 2017;77(5):547-561. doi:10.1007/s40265-017-0712-6

33. Baletic N, Riggs J, Lebovic G, Petrosoniak A, Dumas RP, Nolan B. Introducing the Safety Threats and Adverse events in Trauma (STAT) taxonomy: standardized classification system for evaluating safety during trauma resuscitation. *Eur J Trauma Emerg Surg*. Published online June 7, 2022. doi:10.1007/s00068-022-02007-9

34. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *Man Ther*. 2010;15(1):2-6. doi:10.1016/j.math.2009.02.003

35. Funabashi M, Pohlman KA, Gorrell LM, Salsbury SA, Bergna A, Heneghan NR. Expert consensus on a standardised definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilisation: protocol for an international e-Delphi study. *BMJ Open*. 2021;11(11):e050219. doi:10.1136/bmjopen-2021-050219

36. Nolan B, Petrosoniak A, Hicks CM, Cripps MW, Dumas RP. Defining adverse events during trauma resuscitation: a modified RAND Delphi study. *Trauma Surg Acute Care Open*. 2021;6(1):e000805. doi:10.1136/tsaco-2021-000805

37. MacPherson H, Thomas K, Walters S, Fitter M. A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists. *Acupunct Med*. 2001;19(2):93-102. doi:10.1136/aim.19.2.93

38. smpc_guideline_rev2_en_0.pdf. Accessed June 28, 2022. https://health.ec.europa.eu/system/files/2016-11/smpc_guideline_rev2_en_0.pdf

39. Kearns GA, Brismée JM, Riley SP, Wang-Price S, Denninger T, Vugrin M. Lack of standardization in dry needling dosage and adverse event documentation limits outcome and safety reports: a scoping review of randomized clinical trials. *J Man Manip Ther*. Published online May 23, 2022:1-12. doi:10.1080/10669817.2022.2077516

40. von der Gracht HA. Consensus measurement in Delphi studies: Review and implications for future quality assurance. *Technological Forecasting and Social Change*. 2012;79(8):1525-1536. doi:10.1016/j.techfore.2012.04.013

41. Niederberger M, Köberich S, members of the DeWiss Network. Coming to consensus: the Delphi technique. *European Journal of Cardiovascular Nursing*. 2021;20(7):692-695. doi:10.1093/eurjcn/zvab059

42. de Villiers MR, de Villiers PJT, Kent AP. The Delphi technique in health sciences education research. *Medical Teacher*. 2005;27(7):639-643. doi:10.1080/13611260500069947

43. Jorm AF. Using the Delphi expert consensus method in mental health research. *Aust N Z J Psychiatry*. 2015;49(10):887-897. doi:10.1177/0004867415600891

44. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33(1):159-174.

45. Lin YK, Chen CW, Lee WC, et al. Development and pilot testing of an informed consent video for patients with limb trauma prior to debridement surgery using a modified Delphi technique. *BMC Med Ethics*. 2017;18(1):67. doi:10.1186/s12910-017-0228-3

46. Pascarella G, Rossi M, Montella E, et al. Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables. *Risk Manag Healthc Policy*. 2021;14:2897-2911. doi:10.2147/RMHP.S309098

47. Witt CM, Pach D, Brinkhaus B, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. *Forsch Komplementmed*. 2009;16(2):91-97. doi:10.1159/000209315

48. Vogel C, Zwolinsky S, Griffiths C, Hobbs M, Henderson E, Wilkins E. A Delphi study to build consensus on the definition and use of big data in obesity research. *Int J Obes*. 2019;43(12):2573-2586. doi:10.1038/s41366-018-0313-9

49. Keeney S, McKenna H, Hasson F. *The Delphi Technique in Nursing and Health Research*. John Wiley & Sons; 2011.

50. Baker J, Lovell K, Harris N. How expert are the experts? An exploration of the concept of "expert" within Delphi panel techniques. *Nurse Researcher (through 2013)*. 2006;14(1):59-70.

51. Price J, Rushton A, Tyros V, Heneghan NR. Consensus on the exercise and dosage variables of an exercise training programme for chronic non-specific neck pain: protocol for an international e-Delphi study. *BMJ Open*. 2020;10(5):e037656. doi:10.1136/bmjopen-2020-037656

52. Bartsch KM, Baumgart C, Freiwald J, et al. Expert Consensus on the Contraindications and Cautions of Foam Rolling-An International Delphi Study. *J Clin Med*. 2021;10(22):5360. doi:10.3390/jcm10225360

53. Robinson SM, Walker BF, Brown RM. Which adverse events should be reported in an emergency department? A Delphi study. *Eur J Emerg Med*. 2017;24(2):108-113. doi:10.1097/MEJ.0000000000000308

54. Osman T, Lew E, Sng BL, Dabas R, Griva K, Car J. Delphi consensus on the American Society of Anesthesiologists' physical status classification in an Asian tertiary women's hospital. *Korean J Anesthesiol*. 2022;75(2):168-177. doi:10.4097/kja.21426

55. Dommerholt J, Fernández-de-las-Peñas C. *Trigger Point Dry Needling E-Book: An Evidence and Clinical-Based Approach*. Elsevier Health Sciences; 2013.

Table 5. Participant Characteristics

Demographic Characteristic	n	%	Demographic Characteristic	n	%
Sex			*Patients seen for Dry Needling (per week)*		
Male	21	53.8	0	1	2.6
Female	18	46.2	1-4	6	15.4
Ethnicity			5-9	11	28.2
White or Caucasian	35	89.7	10-14	10	25.6
Hispanic or Latino	3	7.7	15-19	2	5.1
Asian or Asian American	1	2.6	20+	9	23.1
Country			*Dry Needling Style*		
United States	38	97.4	Trigger Point Dry Needling	32	
Spain	1	2.6	Dry Needling with E-Stim	28	
Terminal Degree			Superficial Dry Needling	15	
Bachelor of Science (BS)	4	10.3	Spinal Segmental Sensitization	17	
Master of Science (MS)	5	12.8	Peri-Neural Needling	12	
Doctorate of Physical Therapy (DPT)	23	59.0	Western Medical Acupuncture	3	
Doctor of Philosophy (PhD)	4	10.3	*Received Dry Needling as a Patient*		
Doctor of Science (DSc)	2	5.1	Yes	32	82.1
Doctor of Education (EdD)	1	2.6	No	7	17.9
Setting			*Resource for Dry Needling Training*		
Outpatient Clinic	17	43.6	Integrative Dry Needling	28	
Private Practice Owner	15	38.5	Dr Ma	2	
Academic/Research	6	15.4	Myopain Seminar	3	
Hospital	1	2.6	Frank Gargano	1	
Physical Therapy Experience			Kinetacore	5	
5-9	8	20.5	Spanish University	1	
10-14	10	25.6	James Dunning	3	
15-19	6	15.4	AAMT	1	
20+	15	38.5	Acupuncture Association	1	
Dry Needling Experience			American Dry Needling Institute	2	
5-6	27	69.2	*Scholarly Products*		
7-10	4	10.3	0	21	53.8
11-14	5	12.8	1-4	11	28.2
15+	3	7.7	5-9	1	2.6
Dry Needling Training Prior to Graduation			10+	6	15.4
Yes	3	7.7			
No	36	92.3			

Table 6. Final Adverse Event List from Round 1

Adverse Event	Probability	Severity	Adverse Event	Probability	Severity
Bleeding	Common	Mild	Skin Irritation (Redness)	Rare	Significant
Diaphoresis	Common	Mild	Loss of Bladder Control	Very Rare	Significant
Fatigue	Common	Mild	Migraine	Rare	Significant
Headache	Uncommon	Significant	Muscle Spasm	Rare	Mild
Nausea	Common	Mild	Nerve Injury (Peripheral)	Uncommon	Significant
Pain During/After	Common	Mild	Neurological Symptoms (numbness/tingling/motor control)	Rare	Serious
Pneumothorax	Rare	Serious	Seizure	Uncommon	Significant
Soreness	Uncommon	Significant	Shortness of Breath	Rare	Serious
Allergic Reaction to the Needle (itching, pins and needles)	Rare	Mild	Sympathetic "flush"	Very Rare	Mild
Large Blood Vessel Puncture	Very Rare	Serious	Syncope/Fainting	Rare	Serious
Broken Needle	Rare	Serious	Temporary Increase in Symptoms	Common	Mild
Bruising	Common	Mild	Trypanophobia	Very Rare	Mild
Cardiac Tamponade	Rare	Serious	Vomiting	Uncommon	Significant
Compartment syndrome	Very Rare	Serious	Excessive bleeding/bruising	Uncommon	Significant
Muscle Cramping	Rare	Mild	Organ Puncture (liver, kidney, spleen)	Rare	Serious
Bloodborne Transmission	Very Rare	Significant	Excessive duration of	Rare	Significant

			normal discomfort		
Dizziness/Lightheadedness	Common	Mild	Rash	Rare	Mild
Drowsiness	Uncommon	Mild	Tachycardia	Rare	Serious
Emotional Response (crying, laughing, anxiety)	Uncommon	Significant	Worsening of condition	Rare	Significant
Forgotten Needles	Uncommon	Significant	Pre-Syncope	Rare	Serious
Superficial Hematoma under skin	Uncommon	Significant	Excessive Referred or Radiating Pain	Rare	Significant
Hypersensitivity	Rare	Significant	Excessive Muscle Soreness/Aching	Rare	Significant
Hypertension	Rare	Serious	Subdural or Epidural Hematoma	Rare	Serious
Hypotension	Rare	Serious	Systemic Infection	Very Rare	Serious
Local Infection	Rare	Serious	Central Nervous System Traumatic Injury	Very Rare	Serious

Table 7. Adverse Events for Inclusion on Informed Consent

	Round 2				Round 3					
Adverse Event	**Median**	**IQR[a]**	**PA[b]**	**SD[c]**	**Median**	**IQR**	**PA**	**SD**	**WQR[d]**	**Outcome[e]**
Bleeding	4	1	93.5	0.63	4	1	96.7	0.48	0.26	Yes
Diaphoresis	3	1	80.6	0.79	3	0	80.0	0.53	0.20	Yes
Fatigue	3	0	80.6	0.66	3	1	76.7	0.53	0.03*	Yes
Headache	3	1	64.5	0.78	3	1	50.0	0.57	0.32	No
Nausea	3	1	64.5	0.92	3	1	63.3	0.61	0.28	No
Pain During/After	3	1	96.8	0.67	3	1	96.7	0.49	0.13	Yes
Pneumothorax	4	1	93.5	0.72	4	0	93.3	0.81	0.34	Yes
Soreness	3	2	67.7	0.97	3	1	86.7	0.68	0.48	Yes
Allergic Reaction to the Needle (itching, pins and needles)	3	1	74.2	0.72	3	1	66.7	0.77	0.18	No
Large Blood Vessel Puncture	3	1	58.1	0.86	3	1	56.7	0.73	0.23	No
Broken Needle	3	1	58.1	0.93	3	1	53.3	0.74	0.79	No
Bruising	3	1	100	0.50	3	1	100	0.46	0.03*	Yes
Cardiac Tamponade	2	1	48.4	0.95	2	1	43.3	0.71	0.83	No
Compartment syndrome	2	1	38.7	0.97	2	0	16.7	0.71	0.15	No
Muscle Cramping	3	1	61.3	0.82	3	1	60.0	0.50	0.50	No
Bloodborne Transmission	3	2	67.7	0.91	3	1	50.0	0.78	0.04*	No
Dizziness/Light headedness	3	0	93.5	0.52	3	0	90.0	0.53	0.32	Yes
Drowsiness	3	0	80.6	0.72	3	0	83.3	0.53	0.47	Yes
Emotional Response (crying, laughing, anxiety)	3	1	54.8	0.77	2	1	43.3	0.61	0.64	No
Forgotten Needles	2	1	48.4	0.89	2	1	26.7	0.74	0.13	No
Superficial Hematoma under skin	3	1	64.5	0.73	3	1	73.3	0.49	0.78	Yes

Hypersensitivity	3	1	54.8	0.56	2	1	48.3	0.57	0.41	No
Hypertension	2	1	45.2	0.88	2	0	13.8	0.46	0.07	No
Hypotension	3	1	58.1	0.86	2	1	31.0	0.47	0.01*	No
Local Infection	3	1	71.0	0.90	3	1	65.5	0.63	0.05*	No

a Interquartile Range

b Percent Agreement consisting of the sum of “Agree” and “Strongly Agree” responses

c Standard Deviation

d Wilcoxon Rank Sum Test

e Consensus defined by >= 80% agreement or 70-79.9% agreement with Median >= 3, IQR <= 1, and SD <= 1

Table 8. Adverse Events for Inclusion on Informed Consent

	Round 2				Round 3					
Adverse Event	**Median**	**IQR[a]**	**PA[b]**	**SD[c]**	**Median**	**IQR**	**PA**	**SD**	**WQR[d]**	**Outcome[e]**
Skin Irritation (Redness)	3	0	83.9	0.71	3	0	82.8	0.44	0.17	Yes
Loss of Bladder Control	2	1	41.9	0.92	2	1	13.8	0.80	0.06	No
Migraine	3	1	64.5	0.67	2	1	48.3	0.68	0.02*	No
Muscle Spasm	3	1	67.7	0.72	3	1	69.0	0.47	0.61	No
Nerve Injury (Peripheral)	3	1	71	0.90	3	1	69.0	0.55	0.18	No
Neurological Symptoms (numbness/ tingling)	3	1	74.2	0.68	3	1	75.9	0.53	0.61	Yes
Seizure	2	1	45.2	0.84	2	1	20.7	0.78	0.07*	No
Shortness of Breath	3	1	54.8	0.66	2	1	34.5	0.54	0.09	No
Sympathetic "flush"	3	1	54.8	0.77	2	1	44.8	0.78	0.42	No
Syncope/Fainting	3	0	83.9	0.58	3	0	86.2	0.59	0.53	Yes
Temporary Increase in Symptoms	3	1	87.1	0.64	3	0	86.2	0.59	0.03*	Yes
Trypanophobia	2	1	45.2	0.95	2	1	27.6	0.77	0.16	No
Vomiting	2	1	30.0	0.83	2	0	17.2	0.63	0.09	No
Excessive bleeding/bruising	3	1	56.7	0.68	3	1	51.7	0.51	0.80	No
Organ Puncture	3	1	66.7	0.87	3	1	55.2	0.69	0.020*	No
Excessive duration of normal discomfort	3	1	61.3	0.70	2	1	43.3	0.57	0.08	No
Rash	2	1	51.6	0.72	2	1	33.3	0.64	0.09	No
Tachycardia	2	1	48.4	0.93	2	1	36.7	0.55	0.32	No

Worsening of condition	3	1	53.3	0.82	2	1	37.9	0.76	0.01*	No
Pre-Syncope	3	1	61.3	0.76	3	1	69.0	0.55	0.78	No
Excessive Referred or Radiating Pain	3	1	58.1	0.75	2	1	43.3	0.57	0.12	No
Excessive Muscle Soreness/Aching	3	1	54.8	0.85	3	1	50.0	0.51	0.61	No
Subdural or Epidural Hematoma	3	1	54.8	0.81	2	1	27.6	0.89	0.03*	No
Systemic Infection	3	1	67.7	0.81	2	1	41.4	0.83	0.01*	No
Central Nervous System Traumatic Injury	2	1	51.6	0.99	2	2	27.6	0.80	0.07	No

a Interquartile Range

b Percent Agreement consisting of the sum of "Agree" and "Strongly Agree" responses

c Standard Deviation

d Wilcoxon Rank Sum Test

e Consensus defined by $\geq$ 80% agreement or >70 and <80% agreement with Median ≥ 3, IQR ≤ 1, and SD ≤ 1

Table 9. Feedback received during Round 2 from Participants

Feedback regarding Categorization of Adverse Events		
Do you agree with the above definitions for how adverse events are classified in the literature?	Yes (29) 93.6%[a]	No (2) 6.4%
Feedback from Participants	"I am unsure of the term "Adverse Event". There are "Responses" to dry needling. "Mild" responses are not necessarily adverse, such as bruising, bleeding, soreness, etc., which can last a few days. I do not believe a "Significant" category is necessary. Mild and Serious, I agree with."	"Mild timeline should be modified from a few hours to up to 48 hours. I consider DOMS a mild side effect."
Feedback regarding Adverse Event List		
Feedback from Participants	"the question regarding organ puncture includes the liver, spleen, and kidney. I find this somewhat problematic, because puncturing a kidney is not a problem whatsoever, and I would rate puncturing a kidney as mild as it does not require any medical attention. However, puncturing the spleen can be potentially life threatening."	"many of the stated adverse events can be summarized as autonomic responses. Personally, I would prefer to bundle many of the noted adverse events into one category and not create a seemingly endless list of possible autonomic responses."

a Displayed as (n) %

Table 10. Round 2 Majority Response for Classifying Adverse Events

AE[a]	Sev[b]	Prob[c]	AE	Sev	Prob
Bleeding	Mild (100%)	Com[f] (93.5%)	Skin Irritation	Sig (67.7%)	R(80.6%)
Diaphoresis	Mild (100%)	Com (87.1%)	Loss of Bladder Control	Sig (96.8%)	VR(96.8%)
Fatigue	Mild (100%)	Com (77.4%)	Migraine	Sig (96.8%)	R (87.1%)
Headache	Sig[d] (54.8%)	UnC[g] (83.9%)	Muscle Spasm	Mild (96.8%)	R (90.3%)
Nausea	Mild (100%)	UnC (41.9%)	Nerve Injury (Peripheral)	Sig (96.8%)	UnC (41.9%)
Pain During/After	Mild (100%)	Com (93.5%)	Neurological Symptoms	Ser (80.6%)	R (77.4%)
Pneumothorax	Ser[e] (77.4%)	R[h] (61.3%)	Seizure	Sig (90.3%)	VR (45.2%)
Soreness	Mild (54.8%)	UnC (54.8%)	Shortness of Breath	Ser (83.9%)	R (80.6%)
Allergic Reaction to the Needle	Mild (83.9%)	R (74.2%)	Sympathetic "flush"	Mild (96.8%)	VR (83.9%)
Large Blood Vessel Puncture	Ser (77.4%)	VR[i] (90.3%)	Syncope/Fainting	Ser (71%)	R (74.2%)
Broken Needle	Ser (90.3%)	VR (58.1%)	Temporary Increase in Symptoms	Mild (100%)	Com (90.3%)
Bruising	Mild (100%)	Com (93.5%)	Trypanophobia	Mild (100%)	VR (83.9%)
Cardiac Tamponade	Ser (100%)	R (54.8%)	Vomiting	Sig (73.3%)	UnC (53.3%)
Compartment syndrome	Ser (93.5%)	VR (96.8%)	Excessive bleeding/bruising	Sig (90.0%)	UnC (60.0%)
Muscle Cramping	Mild (100%)	R (77.4%)	Organ Puncture	Ser (93.3%)	R (60.0%)
Bloodborne Transmission	Sig (80.6%)	VR (100%)	Excessive duration of normal discomfort	Sig (80.6%)	R (100%)
Dizziness/Lightheadedness	Mild (100%)	Com (64.5%)	Rash	Mild (90.3%)	R (67.7%)
Drowsiness	Mild (100%)	UnC (87.1%)	Tachycardia	Ser (83.9%)	R (67.7%)
Emotional Response	Sig (51.6%)	UnC (77.4%)	Worsening of condition	Sig (100%)	R (86.7%)
Forgotten Needles	Sig (90.3%)	UnC (77.4%)	Pre-Syncope	Ser (67.7%)	R (80.6%)

Superficial Hematoma under skin	Sig (77.4%)	UnC (80.6%)	Excessive Referred or Radiating Pain	Sig (80.6%)	R (87.1%)
Hypersensitivity	Sig (83.9%)	R (83.9%)	Excessive Muscle Soreness/Aching	Sig (67.7%)	R (74.2%)
Hypertension	Ser (83.9%)	R (80.6%)	Subdural or Epidural Hematoma	Ser (90.3%)	R (67.7%)
Hypotension	Ser (77.4%)	R (87.1%)	Systemic Infection	Ser (96.8%)	VR (100%)
Local Infection	Ser (90.3%)	R (61.3%)	Central Nervous System Traumatic Injury	Ser (96.8%)	VR (100%)

a	Adverse Event	f	Common
b	Severity	g	Uncommon
c	Probability	h	Rare
d	Significant	I	Very Rare
e	Serious		

Figure 1. Overview of the Delphi Survey Process

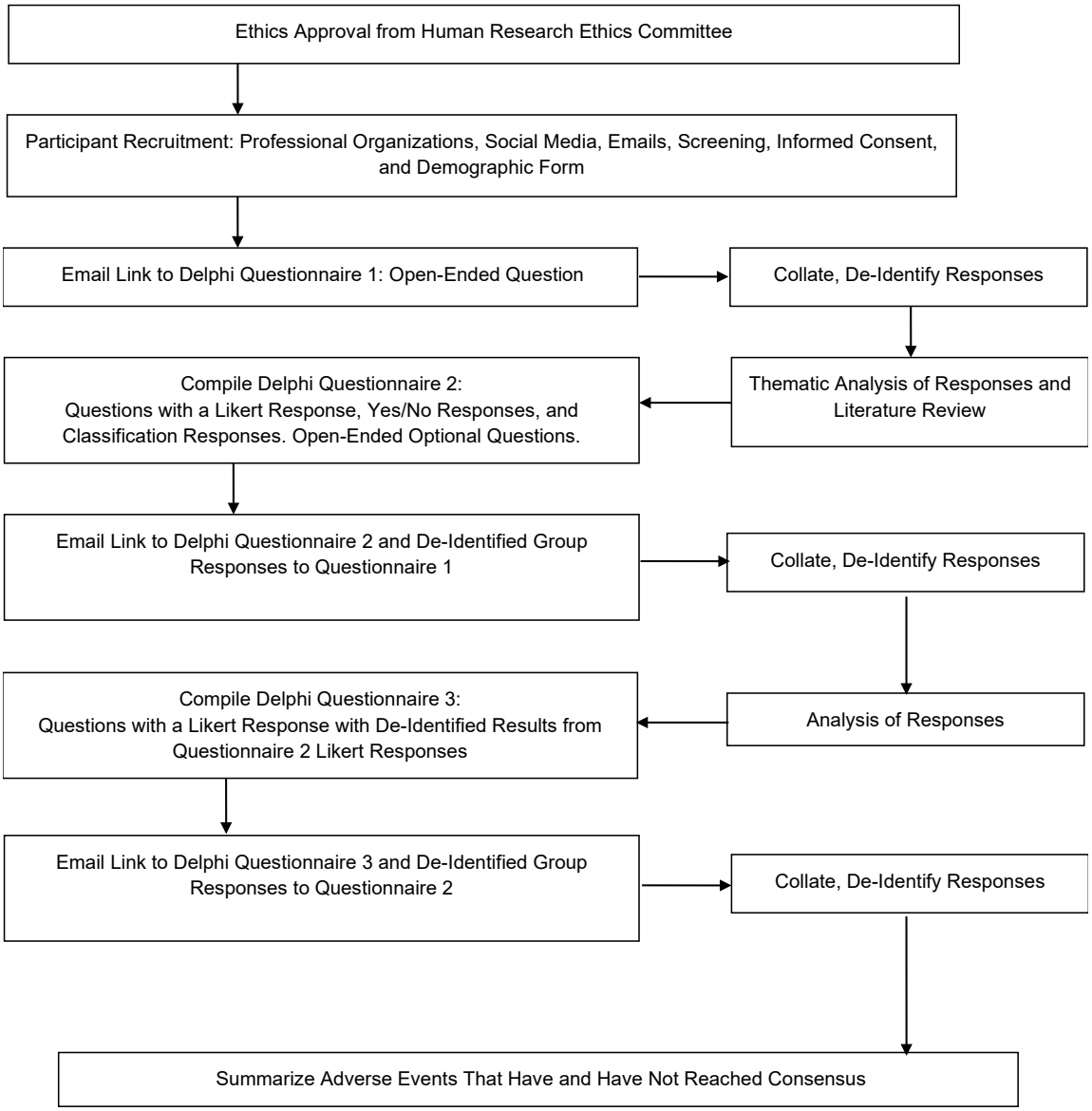
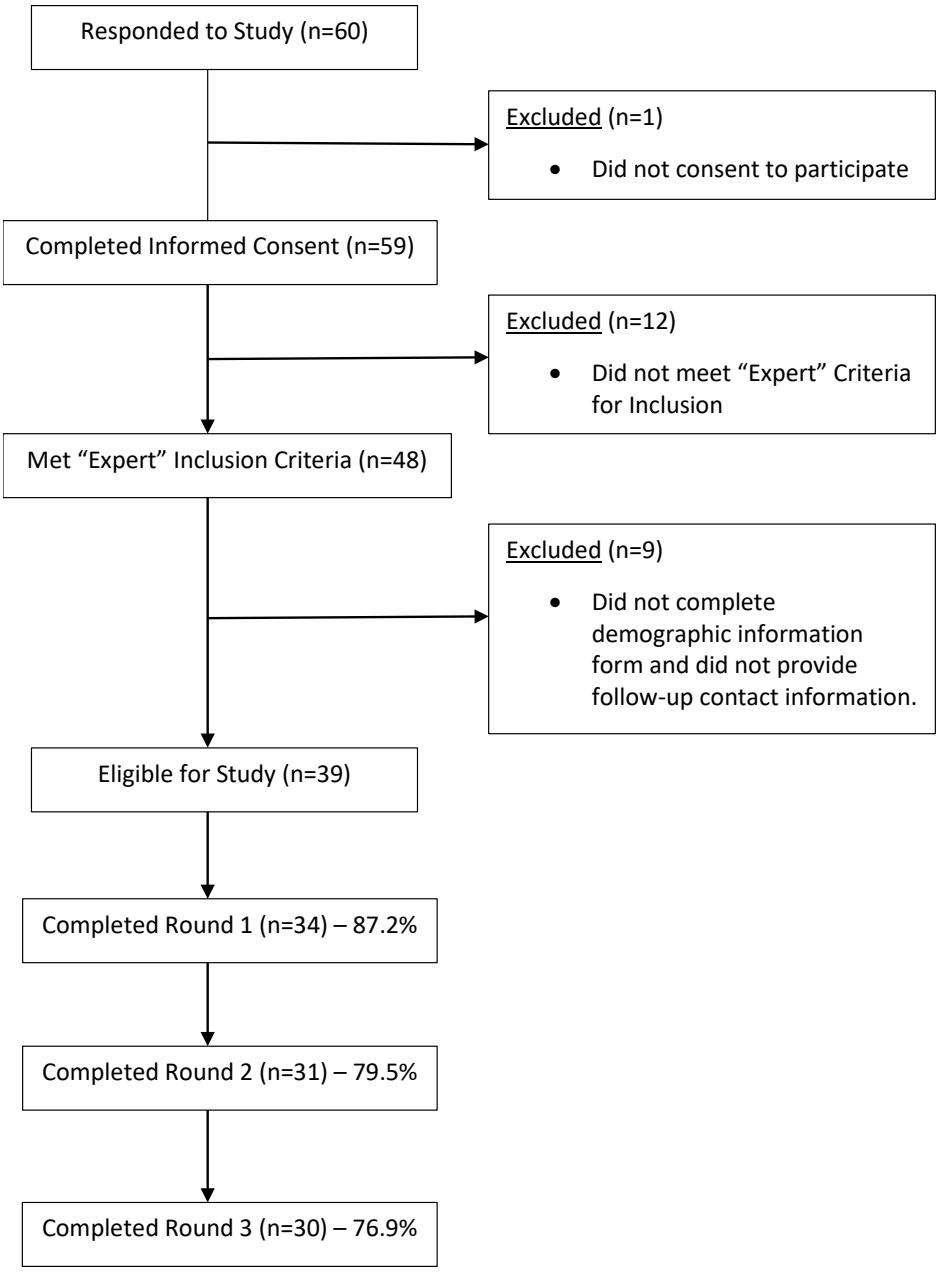


Figure 2. Participant Recruitment Flow Diagram



Chapter 4: Manuscript #2 – Nominal Group Technique Study

Creation of a Risk of Harms Informed Consent Form for Dry Needling: A Nominal Group Technique

Category: Research Paper

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Keywords: nominal group technique, dry needling, informed consent, risk of harm statement

Conflicts of Interest: David Griswold is an instructor for Integrative Dry Needling who provides continuing education courses on the topic of dry needling.

Funding Source: None

Youngstown State IRB Approval #: 2022-173

Clinicaltrials.gov Registration: NCT05560100

DECLARATIONS

Ethics approval and consent to participate

All participants signed an informed consent form prior to participation in the study. The study was approved by the Youngstown State University Institutional Review Board (#2022-173).

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

DG is an instructor for Integrative Dry Needling who provides continuing education courses on the topic of dry needling.

Funding

None

Authors' contributions

EI is the primary investigator and was involved in design, implementation, data collection, data analysis, and manuscript preparation.

DG is a co-investigator and was involved in assistance with design, data collection, and manuscript review/editing.

KL is a co-author and was involved with design and substantial manuscript preparation/editing.

CC is a co-author and was involved in design and substantial manuscript preparation/editing.

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ABSTRACT

Objective: The aim of this study was to identify elements and framework for an Informed Consent (IC) risk of harm statement to improve patient decision-making.

Methods: Eligible participants were identified as one of four groups: legal expert, policy expert, dry needling expert, or patient. A virtual Nominal Group Technique (vNGT) methodology was used to achieve consensus among participants to identify what needs to be on a consent form, how it should be framed, and what it should state so that patients understand the true risks. Participants were provided with an E-booklet, which they were asked to review ten days prior to the virtual session. The vNGT session consisted of 5 rounds of idea generation and final consensus voting which lasted for 2 hours.

Results: Five individuals consented to participate in a virtual nominal group. Of the 27 original ideas, 22 reached consensus including ones specifically related to a risk of harms statement: identifying risks and discomforts, identify different sensations, and using a classification to order risks by severity. Consensus was achieved with percent agreement of $\geq 80\%$. The constructed risk of harm statement had a reading level of grade 7 and provided a list of stratified risks associated with dry needling based on severity and likelihood of occurrence.

Conclusion: The generated risk of harm statement can be incorporated on IC forms that require disclosure of risks in both the clinical and research setting. Additionally, further elements were identified by panel participants regarding defining the framework for an IC form outside of the risk of harm statement. The identified elements can be utilized and developed in future studies for the development of a structured IC form that can be used specifically for dry needling.

BACKGROUND

Dry needling (DN) is a minimally invasive intervention whereby a fine monofilament needle penetrates symptomatic soft-tissue to reduce pain and disability[1]. Physical Therapists in the United States can perform Dry Needling (DN) in most states with the legal requirement for the therapist to obtain written and/or verbal informed consent (IC). The Federation of State Board of Physical Therapy (FSBPT) identified elements of knowledge that therapists who use DN must know to provide safe and effective practice. In some states, the specified minimum standard for satisfying IC includes a written document signed by the patient that clearly outlines these minimum requirements: risk and benefits of DN, the Physical Therapists level of training and education in DN, and that the patient is not receiving acupuncture[2].

Informed consent is defined as, "a process by which the treating healthcare provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment."[3] When consenting patients to DN treatment, it is necessary to inform patients of potential risks of harms. A risk can be referred to as a potential harm or the potential of an action or event to cause harm[4]. Specific risks can be characterized by several dimensions including severity and probability[5]. A harm can be a hurtful or adverse outcome of an action or event that can include physical, psychological, and social harms. Evidence suggests that patients may not be adequately informed of risks prior to receiving a medical treatment[6]. In cases where risks are disclosed as part of IC, patients have potentially shown poor recall which calls into question how best this type of information should be presented[7]. Current trends regarding the length of IC documents, has led to concerns whether the length and

complexity of these documents compromises an individual's ability to understand and evaluate the information[8–13]. Long IC documents make it difficult to find pertinent information negatively impacting a patient understanding of research.

Strategies have been developed to improve readability and decrease length to decrease complexity[14]. The recent revision to the Common Rule requires that consent be "in language understandable by the subject" and further mandates that "IC must be organized in such a way that facilitates comprehension"[15]. Health literacy is also important in improving the readability of IC forms[16–18]. The formatting of the IC forms can also make a difference and includes use of white space, large fonts, and text bolding if needed. Despite these suggestions, few IC forms follow these recommendations[19].

The Nominal Group Technique (NGT) uses a five round meeting format with the purpose of generating information in response to an issue[20]. Nominal Group studies have been used to establish components of programs[21], assessing priorities[22,23], and determining implementation factors for programs[24,25]. Previous studies have examined which adverse events should be included for use in a risks of harm statement for IC for DN[26]. No studies have sought to identify the elements and framework needed for an IC risk of harm statement with the goal of providing a more shortened, structured statement for use in clinic or research. The aim of this study was to identify elements and framework for an IC risk of harm statement to improve patient decision-making regarding health or clinical research participation involving dry needling.

METHODS

Study Participants

Ethics approval for this study (2022-173) was provided by the Youngstown State Institutional Review Board. This study was also registered on clinicaltrials.gov (NCT05560100). Eligible participants were identified as one of four groups: legal expert, policy expert, dry needling expert, and patient. Inclusion criteria for each of these groups is outlined below:

Patient

Must have participated in ≥ 1 session of dry needling treatment and not be a healthcare provider

Dry Needling Experts

(1) Must have ≥ 5 years of clinical practice performing dry needling and at least ONE of the following secondary criteria:

(a) Certification in Dry Needling

(b) Completion of a manual therapy fellowship that included dry needling training

(c) ≥ 1 total scholarly product (poster presentation, author of a peer-reviewed publication) involving the use of dry needling

Legal Expert

An individual who is an attorney and who has had training in health law as evidenced by at least ONE of the following criteria:

(a) Training in health law as evidenced by ONE of the following:

(1) Concentration/Certification in Health Law

(2) L.L.M in health or medical law

(3) SJD in health law

(b) Experience in litigating medical malpractice cases involving failure to obtain

informed consent

(c) Published scholarship on informed consent in an academic journal (≥ 1)

Policy Expert

Must have completed prior coursework that pertains to ethical topics in healthcare and must satisfy at least ONE of the following criteria:

(a) ≥ 5 years of experience in obtaining informed consent or a degree in bioethics

(b) Has served on ethics related committee in a healthcare institution or healthcare society/professional association

(c) Is or has been a member of a state licensing board

(d) Is teaching or has taught an ethics related healthcare class

(e) Is currently or has served as an administrator for a healthcare clinic

Eligible participants were identified through existing professional networks and social media. Potential participants were invited to participate by an author. Recruitment was maximized by encouraging identified experts to snowball the invitation with other potential expert participants, including calls for expressions of interest on social media and professional organizations and networks.

Study Design

A virtual Nominal Group Technique (vNGT) methodology was used to achieve consensus among participants through completion of sequential questionnaires administered as part of a 2-hour virtual meeting to come to consensus on what the elements should be included for a DN risk of harm statement[20,23]. All data collection for

this study was conducted through SurveyMonkey™. Participants provided consent for participation and whether they met the criteria for inclusion in this study. If the participant answered "yes", they were asked to complete a demographic form specific to their group, along with providing an email. Participant eligibility criteria was screened for inclusion.

Study Procedure

Participants were provided with an E-booklet ten days prior to the virtual session. The E-booklet contained information that included: the research question, overview of the vNGT technique, a context statement, a small article providing information on IC, an example of a risk of harm statement generated in an acupuncture study, and common definitions (Appendix H).

During the virtual session, the five-stage NGT process following the protocol by Potter et al[20]. The virtual session was conducted using Microsoft Zoom (Microsoft Corp™, Redmond, WA). The moderator for the session was the study Primary Investigator (EI) and the co-moderator was the co-investigator (DG).

Stage one (Introduction and Explanation): An introduction and welcome to all participants with an explanation of the purpose and procedure. Participants had a chance to ask any initial questions for clarification.

Stage two (Silent Idea Generation): The question was introduced to the participants: "Our goal will be to identify what needs to be on a consent form, how it should be framed, and what it should state so that patients understand the true risks". All participants were asked to create a list of ideas that come to mind when considering the question.

Participants were asked not to consult or discuss ideas with each other. Corresponding chat functions and video were disabled temporarily. A total of 10 minutes was provided.

Stage three (Sharing Ideas): Chat and video were re-enabled, and participants were now invited to share their ideas. The moderator had each participant offer one idea in turn while the ideas were recorded on a document using Microsoft Word (Microsoft Corp™, Redmond, WA) by the co-moderator. This document was shared on the screen so that all participants can see the list in real time. This stage continued until all ideas had been presented. No debate occurred at this stage.

Stage four (Group Discussion): Participants were invited to seek verbal explanation about any ideas that were generated in stage 3. The moderator ensured that each person was able to contribute and that all ideas were discussed. The overall tone of the discussion remained neutral to avoid judgement or criticism. Participants were able to suggest new items for discussion or combining of items to modify the current list. No ideas were eliminated at this stage.

Stage five (Voting): Participants were asked to vote on whether they agreed or disagreed with the idea being used for constructing a risk of harm statement using SurveyMonkey™. The response used a 4-point Likert scale (strongly disagree "1", disagree "2", agree "3", strongly agree "4"). After initial voting, the results were added to the SurveyMonkey™ questionnaire and participants were asked to again re-rate whether they disagreed or agreed with the idea after reflection. Following completion of both questionnaires, the virtual session concluded.

Definition of Consensus

The measurement of consensus in this study was first determined by examining the percent agreement (PA). Percent Agreement was defined as the percentage of responses that either were "agree" or "strongly agree". If the PA was ≥ 80%, consensus would be achieved for inclusion[27].

Statistical Analysis

Data were analyzed using IBM SPSS Statistics Version 28.0 for Windows (IBM Corp™, USA). Demographic and Likert data responses were analyzed using descriptive statistics. The median, Interquartile Range (IQR) were calculated for each item. The categories "strongly agree" and "agree" were combined to compute the PA. The variability in responses was measured by using Standard Deviation (SD). Kendall's coefficient of concordance (*w*) was calculated between initial and final voting to determine agreement between participants ("Slight" 0-0.2, "Fair" 0.21-0.4, "Moderate" 0.41-0.6, "Substantial" 0.61-0.8, "Almost Perfect" 0.81-1.0)[28]. A Wilcoxon rank-sum test was used to evaluate the consistency and stability of responses between first questionnaire and second questionnaire responses. Statistical significance was defined as $P < 0.05$. The generated risk of harm statement was assessed for readability in Microsoft Word (Microsoft Corp™, Redmond, WA) which reported: words, characters, sentences, words per sentence, characters per word, Flesch Reading Ease Score, and Flesch-Kincaid Grade Level.

RESULTS

Seven participants met inclusion criteria for participation in the study. Because of scheduling considerations, five individuals consented to participate. Participant

backgrounds included: legal expert (n=1), policy expert (n=1), DN experts (n=2), and patient (n=1) (Table 11). Data collection occurred on a single day lasting 2 hours.

During stage two, the panel contributed a total of 27 ideas. These ideas were further discussed in the next round to provide clarity (Stage 3) and opportunity for the panel to combine or add any additional ideas or information (Stage 4) (Table 12). Of the 27 original ideas, 22 reached consensus for use in developing an IC template and risk of harm statement (>80% agreement). One idea met consensus during initial voting but was later rejected ("Identify the General Financial Costs Associated with DN"). The median, IQR, PA, and SD for both rounds of voting (Table 13). A Wilcoxon rank sum test was performed between initial and final voting. There were no statistically significant changes identified between corresponding rounds of voting. Kendall's Coefficient (w) of agreement for initial voting was 0.44 ($p < 0.001$) and 0.51 ($p < 0.001$) following final voting.

A final template of the IC form was developed from consensus elements (Figure 3). A risk of harm statement was constructed for use on the templated IC form that contained elements identified by participants (Figure 4). Flesch-Kincaid reading level for the risk of harm statement was 7.3 (7^{th} Grade) and the Flesch Reading Ease Score was 65 (Table 14).

DISCUSSION

The purpose of this study was to generate the elements and framework needed to establish a risk of harm statement that can be used on an IC form for DN. A common theme for the risk of harm statement was the inclusion of ordered risks that could occur

with DN. These elements included: identifying discomforts/pain, identifying risks (pneumothorax, bruising, bleeding, swelling, redness), identifying feelings of unwellness or systemic symptoms (sweating, cold, fatigue, nausea, vertigo), and different sensations (expected feelings, physical feelings). Participants identified the risks be ordered and stratified based on severity and likelihood of occurrence. Many of the specified risks, feelings, and discomforts were identified as ones that should be included in IC for DN in a previous Delphi study[26]. In the Delphi study by Ickert et al, expert consensus was achieved for pneumothorax, bleeding, diaphoresis, fatigue, pain, soreness, bruising, dizziness, drowsiness, superficial hematoma, skin redness, neurological symptoms, syncope, and temporary increase in symptoms. The study also presented a classification of the events used in a commentary of adverse events by Valdes et al[29]. The classification system involved assigning a severity and probability of occurrence to each adverse event using previously established definitions[29]. Since there is no consistency in how risks are documented in the literature for DN, there is a lack of understanding of the true probability and severity that each risk may pose[30]. The Ickert et al study found that 93.6% of experts agreed with the Valdes classification system. Additionally, each risk identified in the study was categorized by experts according to their clinical experience. When compared to the Valdes clinical commentary, 9 of the 14 risks (64.3%) were identified for inclusion on IC. Of the 9 that matched, 8 (88.9%) were identified by severity and probability the same as in the Ickert et al study. The risks used in our study used severity and probability rates for risks that were based on the experience of experts in DN from a previous Delphi.

Despite the focus being on the risk of harm statement, participants also offered ideas regarding the framework for the entire IC template. Examples of IC form template design exist, including one developed by the World Health Organization (WHO). In that template, there are two parts: information sheet and consent certificate. The information sheet contained sections such as: introduction, purpose, intervention description, voluntary participation, selection of individuals, procedures and protocol, description of the process, side effects, risks, benefits, reimbursement, confidentiality, right to refuse, alternatives, and contact information. The certification of consent provided a statement reaffirms the individual had the opportunity to ask questions and that the information was presented to them before signing. In our study, participants described many of these elements as part of the framework for the IC template outside the risk of harm statement. Specific to DN, participants identified 21 of 22 (95.5%) elements that were mentioned directly or indirectly in comparison to the WHO IC template. Despite these elements, it is important to consider that each state may have additional IC requirements that clinicians may need to include.

Recall risks is a key element of understanding and remains one of the most widely accepted measures of comprehension in informed consent[31]. This was also identified by participants as important when constructing the risk of harm statement. Corneli et al. identified that the discussion of risks was the 2nd longest area next to study procedures on an IC form and accounted for up to 83-87 sentences in length when examining 4 different IC forms[32]. Duplication of risks was implicated as a cause for increased IC form length and experts suggested that condensing the list of foreseeable risks is a strategy that can help reduce length and complexity of IC forms. Our strategy of using a condensed list of

risks identified by experts in the Ickert et al study provides a means for offering a shorter, more condense list when constructing the risk of harm statement. The Flesch-Kincaid Score presents a score as a United States grade level to allow for judging of the readability level of books and texts. Risk of harm statement received a Flesch-Kincaid Grade Level Score of 7.3, corresponding to a 7th grade reading level. Most ethics committees recommend a reading level less than 8th grade[34]. A Flesch Reading Ease Score (FRES) was also calculated. The FRES indicates the level of difficulty when reading written material. The FRES for the generated risk of harm statement was 65.0 which corresponds to "Plain English. Easily understood by 13 to 15 year old students"[33]. Twenty sentences were generated in the risk of harm, which is less than the 83-87 total sentence length reported in the Corneli study. These scores indicate that our generated risk of harm statement is short, concise, and is easy to read permitting use across a larger sample of individuals with varying educational backgrounds. There has been one example in the literature of a risk statement that was generated during a research study. The risk statement was generated for acupuncture treatment in a study by Witt et al[35]. The study was a prospective observational study of individuals receiving DN treatment for a variety of conditions. A total of 229,230 treatments were completed with AEs recorded. The AE list was then included in the creation of a risk of harm statement and ranked in order of probability of occurrence. When performing a readability analysis of this generated statement was completed for comparison. The grade level for the risk statement in the Witt study is above the 12th grade level and had a Flesch Reading Ease Score of 28.4. This statement is more difficult to read and requires a higher educational level than our generated statement. In addition, the wording is longer, and the overall

document contains more words than our statement. The generation of our statement utilized a different methodological format than the acupuncture study, allowing to produce a shorter, easier to read statement than what was generated in the Witt study. This illustrates that our methodological approach was better suited in producing a risk of harm statement that can be better applied to an IC form to improve patient comprehension and understanding.

Strengths

The findings of this study allowed for the development of a templated IC form, as well as a structured and concise risk of harm statement for use in both the clinical and research settings. Previous NGT studies that were used in healthcare research were recommended sample sizes between 5 to 9[20]. Thus, 5 participants were deemed sufficient for completion of this study. The protocol utilized in this study was identified by Potter et al for consensus methodology in physiotherapy research[20].

This study used participants with different professional perspectives helping to improve the generalizability and application of the generated risk of harm statement. The perspective of each participant provides improved context for statement generation, on both the consumer end (patient and therapist) and the legal end (legal and policy). This should allow for the construction of a more robust statement that has ability to be applied in both the clinic and research settings.

Limitations

This study did have some limitations. The intent of the study was to identify elements for the framework to construct a risk of harm statement. During the study, ideas generated started to resemble components of an entire IC form instead of just the risk of harm. This led to the formation of a longer list of ideas where some of the ideas were not directly incorporated into the risk of harm statement construction. For purposes of this study, we included these ideas and a possible IC form template that can be elaborated on in future studies. The use of a virtual platform did allow for disabling of communication during round 2 when silent idea generation occurred. However, there is still a possibility that participants could have communicated through alternate forms of communication outside the platform.

CONCLUSION

Consensus was obtained for 22 elements that should be included when designing the framework of an IC form, and more specifically, the risk of harm statement. A shortened, concise risk of harm statement was generated written on a 7th grade reading level. The generated risk of harm statement can be incorporated on IC forms that require disclosure of risks in both the clinical and research setting. This study provides a framework that can be used across multiple interventions and for the construction of a risk of harm statement for use on IC across various health care disciplines. Future studies should focus on applying the generated risk of harm statement in the context of IC documents used for both research and clinical applications. Additionally, further studies may construct structured statements in other identified areas of the IC form template that

was generated in this study. This would allow for the creation of a structured and specific document that can be used for DN.

Conflicts of Interest: David Griswold is an instructor for Integrative Dry Needling who provides continuing education courses on the topic of dry needling.

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Additional File 1 (.pdf)

Title: E-Booklet for NGT Study

Description: Contains the E-booklet given to participants prior to participating in the study.

REFERENCES

1. Kalichman L, Vulfsons S. Dry needling in the management of musculoskeletal pain. *J Am Board Fam Med*. 2010;23(5):640-646. doi:10.3122/jabfm.2010.05.090296

2. State Training Guidelines. Published August 26, 2017. Accessed July 19, 2022. https://www.masterdryneedling.com/state-training-guidelines/

3. Cocanour CS. Informed consent-It's more than a signature on a piece of paper. *Am J Surg*. 2017;214(6):993-997. doi:10.1016/j.amjsurg.2017.09.015

4. Field MJ, Behrman RE, Children I of M (US) C on CRI. *Defining, Interpreting, and Applying Concepts of Risk and Benefit in Clinical Research Involving Children*. National Academies Press (US); 2004. Accessed October 13, 2022. https://www.ncbi.nlm.nih.gov/books/NBK25555/

5. Pascarella G, Rossi M, Montella E, et al. Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables. *Risk Manag Healthc Policy*. 2021;14:2897-2911. doi:10.2147/RMHP.S309098

6. Vikas H, Kini A, Sharma N, Gowda NR, Gupta A. How informed is the informed consent? *J Family Med Prim Care*. 2021;10(6):2299-2303. doi:10.4103/jfmpc.jfmpc_2393_20

7. Bai JW, Abdallah FWW, Cohn M, Ladowski S, Madhusudan P, Brull R. Say what? Patients have poor immediate memory of major risks of interscalene block disclosed during the informed consent discussion. *Reg Anesth Pain Med*. Published online August 23, 2019:rapm-2019-100858. doi:10.1136/rapm-2019-100858

8. Berger O, Grønberg BH, Sand K, Kaasa S, Loge JH. The length of consent documents in oncological trials is doubled in twenty years. *Ann Oncol*. 2009;20(2):379-385. doi:10.1093/annonc/mdn623

9. Villamañán E, Ruano M, Fernández-de Uzquiano E, et al. Informed consent in clinical research; Do patients understand what they have signed? *Farm Hosp*. 2016;40(3):209-218. doi:10.7399/fh.2016.40.3.10411

10. Tilch MK, Schranz M, Moringlane A, Theobald M, Hess G. Struggling with extensive informed consent procedures for cancer trials-is there even a benefit for the patients? *Support Care Cancer*. 2022;30(8):6593-6602. doi:10.1007/s00520-022-07063-w

11. Sharp SM. Consent documents for oncology trials: does anybody read these things? *Am J Clin Oncol*. 2004;27(6):570-575. doi:10.1097/01.coc.0000135925.83221.b3

12. Emanuel EJ, Boyle CW. Assessment of Length and Readability of Informed Consent Documents for COVID-19 Vaccine Trials. *JAMA Netw Open*. 2021;4(4):e2110843. doi:10.1001/jamanetworkopen.2021.10843

13. Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? *J Clin Oncol*. 2007;25(9):e13-14. doi:10.1200/JCO.2006.10.3341

14. Enama ME, Hu Z, Gordon I, et al. Randomization to standard and concise informed consent forms: development of evidence-based consent practices. *Contemp Clin Trials*. 2012;33(5):895-902. doi:10.1016/j.cct.2012.04.005

15. Federal Policy for the Protection of Human Subjects. Federal Register. Published January 19, 2017. Accessed August 12, 2022. https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects

16. Kim EJ, Kim SH. Simplification improves understanding of informed consent information in clinical trials regardless of health literacy level. *Clinical Trials*. 2015;12(3):232-236. doi:10.1177/1740774515571139

17. Perrenoud B, Velonaki VS, Bodenmann P, Ramelet AS. The effectiveness of health literacy interventions on the informed consent process of health care users: a

systematic review protocol. *JBI Database System Rev Implement Rep*. 2015;13(10):82-94. doi:10.11124/jbisrir-2015-2304

18. Stunkel L, Benson M, McLellan L, et al. Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form. *IRB*. 2010;32(4):1-9.

19. Manta CJ, Ortiz J, Moulton BW, Sonnad SS. From the Patient Perspective, Consent Forms Fall Short of Providing Information to Guide Decision Making. *J Patient Saf*. 2021;17(3):e149-e154. doi:10.1097/PTS.0000000000000310

20. Potter M, Gordon S, Hamer P. The Nominal Group Technique: A useful consensus methodology in physiotherapy research. *New Zealand Journal of Physiotherapy*. 2004;32.

21. Fisher RJ, Riley-Bennett F, Russell L, et al. Nominal group technique to establish the core components of home-based rehabilitation for survivors of stroke with severe disability. *BMJ Open*. 2021;11(12):e052593. doi:10.1136/bmjopen-2021-052593

22. Keegan D, Heffernan E, McSharry J, Barry T, Masterson S. Identifying priorities for the collection and use of data related to community first response and out-of-hospital cardiac arrest: protocol for a nominal group technique study. *HRB Open Res*. 2021;4:81. doi:10.12688/hrbopenres.13347.2

23. Johnson BJ, Zarnowiecki D, Hutchinson CL, Golley RK. Stakeholder Generated Ideas for Alternative School Food Provision Models in Australia Using the Nominal Group Technique. *Int J Environ Res Public Health*. 2020;17(21):7935. doi:10.3390/ijerph17217935

24. Michel DE, Iqbal A, Faehrmann L, et al. Using an online nominal group technique to determine key implementation factors for COVID-19 vaccination programmes in community pharmacies. *Int J Clin Pharm*. 2021;43(6):1705-1717. doi:10.1007/s11096-021-01335-x

25. Hutchings HA, Rapport FL, Wright S, Doel MA, Clement C, Lewis KE. Nominal Group Technique consultation of a Pulmonary Rehabilitation Programme. *F1000Res*. 2014;3:42. doi:10.12688/f1000research.3-42.v1

26. Ickert E, Griswold DW, Learman K, Cook C. Identifying which Adverse Events Associated with Dry Needling Should be Included For Informed Consent: A Modified e-Delphi Study. *Physiotherapy*. Published online August 2022.

27. Jorm AF. Using the Delphi expert consensus method in mental health research. *Aust N Z J Psychiatry*. 2015;49(10):887-897. doi:10.1177/0004867415600891

28. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33(1):159-174.

29. Valdes VR. Dry Needling in Physical Therapy Practice: Adverse Events Part 1: Types and Frequency of Adverse Events. *Orthopedic Physical Therapy Pratice*. 2021;33(1):34-39.

30. Kearns G, Fernández-De-Las-Peñas C, Brismée JM, Gan J, Doidge J. New perspectives on dry needling following a medical model: are we screening our patients sufficiently? *J Man Manip Ther*. 2019;27(3):172-179. doi:10.1080/10669817.2019.1567011

31. Kinnersley P, Phillips K, Savage K, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database Syst Rev*. 2013;(7):CD009445. doi:10.1002/14651858.CD009445.pub2

32. Corneli AL, Namey E, Mueller MP, et al. Evidence-based strategies for shortening informed consent forms in clinical research. *J Empir Res Hum Res Ethics*. 2017;12(1):14-25. doi:10.1177/1556264616682550

33. Guide to Academic Writing Article - Management - University of Canterbury - New Zealand. Published July 12, 2016. Accessed October 7, 2022. https://web.archive.org/web/20160712094308/http://www.mang.canterbury.ac.nz/writing_guide/writing/flesch.shtml.

34. Pandiya A. Readability and comprehensibility of informed consent forms for clinical trials. *Perspect Clin Res*. 2010;1(3):98-100.

35. Witt CM, Pach D, Brinkhaus B, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. *Forsch Komplementmed*. 2009;16(2):91-97. doi:10.1159/000209315

Table 11. Participant Characteristics

Legal Expert
Age: 30 years old (Sex: Male) *Occupation:* Attorney (Juris Doctorate Degree in 2020, Doctor of Physical Therapy Degree in 2017) *Concentration:* Health Law *Years of Practicing Law:* 1-4 *Cases Litigated Regarding Malpractice:* 1-4 *Scholarly Products Related to Informed Consent in Past 10 Years:* 1-4
Policy Expert
Age: 62 years old (Sex: Male) *Occupation:* Academia/Research (Doctor of Philosophy Degree in 2016) *Experience Obtaining Informed Consent:* 25+ years *Served on an Ethics Committee in a Healthcare Institution or Health Care Society/Professional Association:* Yes *Years Served on Committee:* 20-24 *Scholarly Products Related to Informed Consent in Past 10 Years:* 1-4
Dry Needling Expert #1
Age: 53 years old (Sex: Female) *Occupation:* Outpatient Staff Physical Therapist (Masters Degree in 2017) *Years Experience Working as a Physical Therapist:* 30+ *Years Experience Treating Patients with Dry Needling:* 11-14 *Average Number of Patients Treated Per Week with Dry Needling:* 5-9 *Scholarly Products Related to Dry Needling in Past 10 Years:* 0 *Has Received Dry Needling:* Yes
Dry Needling Expert #2
Age: 55 years old (Sex: Male) *Occupation:* Private Practice (Doctor of Physical Therapy Degree in 2000) *Years Experience Working as a Physical Therapist:* 30+ *Years Experience Treating Patients with Dry Needling:* 15-19 *Average Number of Patients Treated Per Week with Dry Needling*: 20+ *Scholarly Products Related to Dry Needling in Past 10 Years:* 1-4 *Has Received Dry Needling:* Yes
Patient
Age: 67 years old (Sex: Female) *Occupation:* Retired (Master of Science Degree in Metallurgy and Materials Science Engineering) *Times Dry Needling in Past 5 Years:* 25+ *Regions of the Body Dry Needled:* Neck, Trapezius, Sternocleidomastoid, Face, Back, Hips, Arms, and Hands *Had an Adverse Event:* Yes *Adverse Event:* Bruising (Very Minor) *Given Prior Consent to Participate in Medical Procedure or Treatment:* Yes

Table 12. Results from Stage 3 and 4 Idea Generation and Clarification Points

Idea #	Generated Idea Statement	Clarification of Idea
1	Identify the risks for prolonged use of DN	Order the Risks
2	Identify any discomforts or pain (aching, sharp, muscle)	None
3	Identify Pneumothorax Risk	None
4	Ensure Patient Autonomy	Reasonable patient/clinician standard, is autonomy maximized with an expanded document
5	Identify the Benefits of DN	Needed to describe risks (including risk of not receiving Treatment), Cost-benefit analysis of whole Tx, When do risks materialize?
6	Identify Quantity Limits to DN (Risks of too much needling)	None
7	Identify Bruising Risk	None
8	Identify Bleeding, Swelling, and Redness	Stratification of risks, likelihood, severity
9	Identify the General Financial Costs Associated with DN	None
10	Description of Different Sensations with Needling	Physical feelings, Expected feelings (common), Long-term effects, sharp nerve vs twitching
11	Identify that Multiple Treatments can be Required and Consent Covers All Treatments	None
12	Identify General Feelings of Unwellness (Sweating, Cold, Fatigue, Nausea, Vertigo)	None
13	Identify Capacity of Patient to Make Decision	None
14	Identify DN (process, purpose)	None
15	Explanation of the Treatment when Discussing Alternatives (invasive vs non-invasive and what non-pharmacological options are there)	None
16	Identify that DN is different than Acupuncture	None
17	Ensure Document is concise and Clear in an Understandable Language	Clinically usable and friendly, Consent for evaluation vs treatment, Ensure

		document is clinically useful and not burdensome with time
18	Allow for the use of Verbal or Written Consent	None
19	Identify Time to realize when Benefits or Risks Can Occur	Why do I want needles stuck in me?
20	Review of Sanitation Procedures (single-use, gloves, wipes for blood)	None
21	Identify Risks with Pregnancy, Immune System Compromise, Communicable Diseases	Verify blood thinner use, needle allergies, surgical hardware/metal/implants/pacemaker, bleeding disorders, and other allergies
22	Describe Difference Between Hypodermic vs Monofilament Needle	None
23	Ensure a Decision is Voluntarily Made	None
24	Identify Medical Diagnoses for DN Application	None
25	Ensure Adequate Education Provided	Opportunities to ask questions, identify who can answer questions (front desk vs clinician), right to withdraw or refuse treatment
26	Insurance Privacy and Confidentiality with HIPAA Compliance	None
27	Identify Alternatives to DN	Invasive vs Non-invasive

Table 13. Identified Elements for Inclusion in a Risk of Harm Statement

	Round 1				Round 2					
Idea	Median	IQR[a]	PA[b]	SD[c]	Median	IQR	PA	SD	WQR[d]	Outcome[e]
1	3	1	100	0.45	3	1	100	0.45	1.00	Yes
2	4	2	80	0.89	3	1	100	0.45	0.56	Yes
3	4	1	100	0.45	4	0	100	0	0.32	Yes
4	3	1	100	0.45	3	1	100	0.45	1.00	Yes
5	3	2	60	1.00	3	2	60	0.84	0.32	No
6	2	2	40	0.84	2	2	40	0.89	0.16	No
7	3	1	80	0.45	3	0	100	0	0.32	Yes
8	4	1	100	0.55	4	1	100	0.55	1.00	Yes
9	3	1	80	0.45	3	1	60	0.55	0.56	No
10	3	1	100	0.55	3	1	100	0.45	0.56	Yes
11	4	1	100	0.55	4	2	80	0.89	0.32	Yes
12	3	0	100	0	3	0	100	0	1.00	Yes
13	3	1	100	0.55	3	1	100	0.45	0.32	Yes
14	4	1	100	0.45	4	1	100	0.45	1.00	Yes
15	3	1	100	0.45	3	0	100	0	0.32	Yes
16	3	1	100	0.45	3	1	100	0.45	1.00	Yes
17	4	0	100	0	4	1	100	0.45	0.32	Yes
18	3	1	80	0.71	3	1	80	0.45	0.32	Yes
19	3	0	100	0	3	0	100	0	1.00	Yes
20	3	1	60	0.55	3	2	60	0.84	0.32	No
21	3	1	80	0.71	3	1	100	0.45	0.66	Yes
22	3	1	80	0.45	3	1	80	0.45	1.00	Yes
23	4	1	100	0.55	4	1	100	0.45	0.32	Yes
24	2	1	40	0.55	2	1	20	0.45	0.32	No
25	4	1	100	0.45	4	0	100	0	0.32	Yes
26	3	1	80	0.71	3	1	80	0.45	0.32	Yes
27	3	1	100	0.45	3	1	100	0.45	1.00	Yes

a Interquartile Range

b Percent Agreement consisting of the sum of “Agree” and “Strongly Agree” responses

c Standard Deviation

d Wilcoxon Rank Sum Test

e Consensus defined by >= 80% agreement

Table 14. Readability Assessment of Generated Risk of Harm Statement

Count	
Words	357
Sentences	20
Characters	1,936
Averages	
Words per Sentence	12.8
Characters per Word	4.7
Readability	
Flesch-Kincaid Grade Level	7.3
Flesch Reading Ease Score	65.0

Figure 3. Informed Consent Template

I. Overview of Dry Needling
   a. Description of what Dry Needling is
   b. Describe the process and Purpose
   c. Why is it being Proposed
   d. Differences in needle equipment used (monofilament vs hypodermic)
   e. Differentiation from acupuncture

II. Alternatives to Dry Needling

III. Benefits to Dry Needling
   a. How much time to realize benefits

IV. Risk of Harms Statement

V. Specific Patient Scenarios (Safety)
   a. Specifically ask if patient. is on blood thinning med
   b. Needle allergies
   c. Surgical hardware/metal in body/implants/pacemaker
   d. Tissue implants
   e. Blood/bleeding disorders
   f. Any other allergies

VI. HIPAA and Confidentiality

VII. Voluntary Participation Statement/Ability to Withdraw

VIII. Certificate of Consent (written)

IX. Questions and contact information
   a. Providing the patient the opportunity to ask questions
   b. Who is providing the education and answering questions? (front desk versus clinician)
   c. Education that this informed consent covers all subsequent Treatment sessions

Figure 4. Risk of Harm Statement for Informed Consent

Dry needling has some risks that can occur with the treatment. In the hands of a skilled professional, these risks are small, but you should still be aware of them. Certain side-effects may be normal such as "discomfort." Unintended events, or adverse events, could also occur. The most likely adverse events are listed below and can vary from person to person. The adverse events are listed by their level of severity ("Serious", "Significant", and "Mild") and how often it may occur ("Common" <10%, "Uncommon" <1%, and "Rare" < 0.1%). If you have any questions, be sure to ask your healthcare provider.

Adverse Event	Likelihood	Additional Information
Serious Risks (may require hospitalization)		
Collapsed Lung (Pneumothorax)	Rare	Symptoms may include shortness of breath or chest pain that can last for many days to weeks. A more severe lung puncture can require a visit to the hospital.
Fainting (Syncope)	Rare	Symptoms leading to fainting may include warning signs (lightheaded, dizzy, sweating). Let your healthcare provider know if you have any of these symptoms while getting dry needling. People usually recover quickly but a medical exam may be needed if problems occur.
Significant Risks (May continue for days/weeks and can require medical care)		
Bleeding under skin resulting in a bump (Hematoma)	Uncommon	May result in a bruise.
Nerve Injury	Uncommon	May cause temporary numbness, tingling, weakness, or sensation changes. The needles are very small and do not have a cutting edge. The chance for significant tissue trauma is unlikely.
Skin Irritation	Rare	Local redness, small bumps, and itching that may last a few hours. Let your healthcare provider know if you have a metal allergy.
Mild Risks (May cause temporary symptoms and little inconvenience)		
Bleeding (Droplet)	Common	Droplet is quickly cleaned by healthcare provider and may result in a bruise.
Bruising	Common	May last a few days
Sweating (Diaphoresis)	Common	Usually occurs during or after treatment and may last minutes to a few hours
Dizziness	Common	
Fatigue	Common	
Drowsiness	Uncommon	
Temporary Symptom Increase	Common	Usually occurs during or after treatment and may last a few hours up to a few days.
Pain During/After	Common	
Soreness	Uncommon	

Chapter 5: Discussion

5.1 Summary

The purpose of this dissertation was to create a shortened, structured, and concise risk statement used on IC forms for both research and clinical application. The Nominal Group Technique (NGT) provided the initial framework and elements that should be considered when constructing an IC form template and risk of harm statement. The NGT study provided ideas from varying perspectives of experience: a patient who received DN, therapists who treat with DN, legal expert, and a policy expert with experience in IC. Each of these perspectives helped to establish the framework for an IC document and risk statement that would satisfy the legal and ethical requirements of IC. Specific to DN, participants identified 21 of 22 (95.5%) elements that were mentioned directly or indirectly in comparison to the WHO IC template[197]. Although the intended focus of the NGT was to develop the framework specifically for the risk of harm statement, the inclusion of other elements highlights the difficulty in creating such a statement in isolation from other important pieces. Bioethical literature has maintained that any justifiable analysis of IC be rooted in autonomous choice by patients. The main point of IC is to protect and enable meaningful choice[58]. This concept was brought up by the participants who stated, “ensure patient autonomous choice” and “ensure a voluntary decision is made” as important elements. The goal of the risk statement should not be to simply list the risks that can be associated with the procedure, but rather, to provide important information regarding potential risks so that risk management analysis can occur. An individual requires more information beyond the risks in order to

fully analyze each risk involved that would allow for a more informed decision[198]. It is entirely possible that the participants understood that the framework for the risk statement needs to include other information to allow for proper risk analysis. In of itself, the risk statement would not be able to provide this information. This also explains why elements such as: benefits, alternative treatments, and purpose/process of DN were also identified by participants as necessary to include. Although these sections weren't part of the risk statement framework, they work in conjunction with the information provided in the risk statement to improve decision making by the individual.

It is important to also consider that individual states may have additional IC requirements that clinicians need to include. A consistent element identified by the panel of participants was the need to include potential risks, stratification of these risks by severity and probability, as well as what burden the risk may have on an individual's life. It was also suggested that these risks be ordered in terms of greater to least concerning. This laid the groundwork for the Delphi study which sought to examine through expert consensus which AEs associated with DN should be included in the risk statement for IC. Additionally, the Delphi study also sought to gather expert opinion regarding how these AEs should be stratified in terms of severity and probability. Over the last 15 years, there has been an attempt to identify AE's associated with DN[54,55]. These studies may only provide a portion of AE's identified from our Delphi, thus underlying the need for additional studies to identify the true nature of AE's and their occurrence. There is also a lack of standardization and classification of AE's which makes it difficult to thoroughly

document AE's as they occur[56]. Additionally, there is an inherent risk for reporting bias which may lead to the underreporting of AE's. This has been mentioned in a narrative review by McGauran et al[160] in which 50 different interventions were identified as having reporting bias. These examples tend to overestimate efficacy and underestimate safety risks and can result in inappropriate healthcare decisions which can harm patients and misguide future research[160]. The Delphi study becomes even more important in this context to accommodate for these potential gaps in AE reporting and classification. Without proper identification of AE's and their classifications, it would be difficult to construct the risk statement to allow for informed decision making by the patient. Ultimately, the Delphi study was able to provide a list of AEs that expert DN Physical Therapists identified as important for inclusion on IC. In addition, these experts were able to agree (93.6%) on a classification system for both probability and severity of each of the included AE's. This study provided important elements identified in the NGT study and allowed for proper ordering and stratification of the AEs in the generated risk statement. Based upon the results of both studies, an IC form template was produced, along with, a specific risk statement that can be used for DN procedures done in both a clinical and research setting.

Consent forms may not adequately convey knowledge if they are increasingly complex for an individual with a low literacy level[199]. When examining risk information in a study by Manta et al[8], 52% of patients preferred risks be grouped by severity or likelihood. Our generated risk statement sought to present the risk information in a stratified and ordered manner, as well as, at a literacy level

understood by patients with varying levels of education. Most ethics committees recommend a reading grade level of 8th grade or lower[200]. Our risk statement read at a 7th grade reading level and scored a 65.0 on the Flesch Reading Ease Score (FRES). Minimum FRESH scores of 60 for all consent forms could help to protect 85-93% of patients overwhelmed by information that they may not be able to read or understand[69]. In a study by Samadi et al in which 45 IC forms were assessed for readability, the mean FRES was 31.96 and the mean grade reading level was 10.71[201]. The readability scores for our risk statement exceed those found in the Samadi study and allowed for use with a wider range of patients with varying levels of health literacy and education. This template and statement provides all healthcare practitioners who practice DN a structured statement for communicating the risks to their patient.

The benefits to creating this structured, concise risk statement seek to improve patient autonomy and ability to make informed decisions regarding their own care. As society continues to move away from more paternalistic models of healthcare to ones that openly embrace shared decision making and patient autonomy, the need for improving how we communicate with our patients becomes more important. The IC process is one of those areas that was created with the ambition of driving patient autonomy and providing legal and ethical protection of the patients we serve as healthcare providers. It is difficult to justify that we are improving autonomy when our IC forms are becoming longer and more complex for patients to understand. Further, the complexity and length of the forms creates burdensome time constraints on healthcare professionals that can lead to a further

breakdown in the IC process. The variability in how risks are communicated can also affect the patient's ability to analyze the risks effectively when making an informed decision. The construction of the risk statement would eliminate variability and allow healthcare professionals the ability to effectively communicate risk in a time efficient manner. In addition, the construction of a risk matrix that can be used by patients to analyze risks rely on understanding he probability and the severity impact of the risk[202]. Both elements were identified for the AE's that were reported in the risk statement for IC. This allows the patient to make a more informed decision regarding the risk of the event outside of simply knowing the risk exists. This should also improve comprehension of risks and ensure that the patient is adequately informed on a level that they can understand[203,204].

There has been one example in the literature of a risk statement that was generated during a research study. The risk statement was generated for acupuncture treatment in a study by Witt et al[130]. The study was a prospective observational study of individuals receiving DN treatment for a variety of conditions. A total of 229,230 treatments were completed with AEs recorded. The AE list was then included in the creation of a risk of harm statement and ranked in order of probability of occurrence (Figure 5).

When performing a readability analysis of this generated statement was completed to compare to the generated statement for DN (Table 15).

Table 15. Readability Assessment of Acupuncture Risk Statement

Count	
Words	409
Sentences	19
Characters	2,394

Averages	
Words per Sentence	16.5
Characters per Word	6.0
Readability	
Flesch-Kincaid Grade Level	13.4
Flesch Reading Ease Score	28.4

The grade level for this statement is above the 12th grade level and the Flesch Reading Ease Score is 28.4. This statement is more difficult to read and requires a higher educational level than our generated statement. In addition, the wording is longer, and the overall document contains more words than our statement. The generation of our statement utilized a different methodological format than the acupuncture study, allowing to produce a shorter, easier to read statement than what was generated in the Witt study. This illustrates that our methodological approach was better suited in producing a risk of harm statement that can be better applied to an IC form to improve patient comprehension and understanding.

5.2 Limitations

There were limitations identified that should be mentioned. First, to this author's knowledge there have been no studies that have examined specifically which AEs should be included for IC and how the risk of harm statement should be generated. As a result, current methodological protocols did not exist specifically for this type of research study. This required modification of existing protocols to construct a specific research design to answer the question posed which could potentially affect the results obtained in this study. The current

protocols of using a Delphi followed by a Nominal Group Technique (NGT) methodology were adopted for data collection with modifications made to address the specific topic of interest. Great care was taken to adhere to standard protocols for each of these studies. The use of a virtual platform did offer opportunities to reach out to a wider range of potential participants with varying backgrounds. Unfortunately, there is also the risk that participants may communicate with each other using alternate platforms outside of the study. This could potentially produce participation bias where participants may have aligned their answers with those of others. Opportunities for participant bias could have occurred during the Delphi study when participants were completing the questionnaires and during the virtual session in the NGT study during silent idea generation and voting. It is difficult to control for participant bias other than asking participants not to communicate with others during the study. When constructing the list of AEs from the Delphi study it was difficult to determine how best to present the AEs for subsequent voting. The literature was referenced regarding wording AEs in a manner consistent with current research studies. Unfortunately, the lack of many studies that examined AEs associated with DN did not provide a list comprehensive enough to include all the ones identified by the experts. In which case a decision was made on how to thematically organize the generated AE list since no literature reference was found. Further, there is no standardized method from which AE's are documented, particularly in the case of DN. One article did provide a clinical commentary and attempted to classify the AEs by severity and likelihood of occurrence based on a referenced classification system. Unfortunately, many of the AE's identified by the

experts were not classified using this system. As a result, the initial AE list was classified using expert opinion to allow experts to support or refute how the AEs were classified. Additionally, there is a potential to bias to occur as the expert population in the Delphi study may develop an AE list that would not steer individuals away from considering this treatment option. Since all the experts in the Delphi were DN therapists, they may not want to see their choice of AE's negatively impact the willingness of others to accept DN treatment. This could skew the results obtained in the Delphi study. This may also further influence which AE events the experts were wanting patients to have disclosed to them during IC. When translating these AEs into a risk of harm statement, it was important to identify how the framework should be constructed. Although the NGT study did provide some of the elements needed, many of the elements did not pertain specifically to the risk of harm statement and incorporated ideas for other sections of an IC form. This made it difficult to navigate which elements pertained specifically to the risk of harm statement for construction. A more specific question may have provided a more limited list of elements directly related to the risk of harms. The defining of inclusion criteria was difficult in both studies, as the definition of "DN expert", "legal expert", and "policy expert" are not well defined in the literature. The literature showed variations in how an expert was defined, leading to the development of inclusion criteria that were used in similar studies. Additionally, the definitions for consensus are varied in the literature, leading to the merging of different consensus definitions when developing consensus in this study.

5.3 Strengths

Despite the use of both an NGT and Delphi methodology, we were able to obtain adequate recruitment of individuals for both studies based on previous recommendations (30-73 for the Delphi and 5-9 for the NGT). Additionally, we had >= 70% participation across all rounds in the Delphi which is considered the minimum response threshold for stability of responses. The development of a consensus list of AEs by DN experts that can be used on IC helps lead the way into identifying relevant AE's that should be disclosed in developing a risk of harm statement. Given the lack of studies that have examined AEs associated with DN, the Delphi study provides an AE list from the perspective of experts who regularly perform DN. Additionally, a high proportion of experts agreed with the naming system provided for classification of AE's. This provides useful information when considering how AE's can be documented in future studies that examine and report AE's. When constructing the risk of harm statement, the use of a combination panel that consisted of legal experts, policy experts, DN experts, and patients help provide a diverse perspective regarding how the framework should be arranged. This can help construct a statement that satisfies the requirements of IC and improves the generalizability of applying the generated statement in an actual DN IC form. Combined with the AE list generated in the Delphi study, we were able to construct the risk of harm statement in a way that allowed for the AE's to be classified and stratified by severity and likelihood of occurrence. Additionally, the use of readability analysis software can also provide important feedback related to the readability and grade level of our risk of harm statement. The constructed risk of harm statement carried a 7th grade reading level and only used 20 sentences.

This achieves an important goal in developing a concise, readable statement for use on IC. Since the risk of harm statement is identified as the 2nd longest statement on IC, shortening this area can lead to improvements in overall IC form readability and complexity. This allows the risk of harm statement to be integrated in both clinical and research-based applications for IC.

5.4 Future Studies

There are many future studies that can be completed because of these studies. The first is the application of the research methodology to construction of risk of harm statements in other medical procedures and interventions. The established research design could assist in constructing other risk statements for more higher risk or complex procedures. This in turn could help to decrease the complexity and length of IC forms that are used for other medical procedures. The second involves the construction of an entire IC form that is specific to DN, using expert consensus to establish the generation of statements that can be used on the provided IC form template. This will allow for construction of an entire IC form for both clinical and research application. This would also standardize the language and structure of these forms to reduce variability and improve readability for patients to understand. A third application involves the testing of the written risk statement on actual IC forms that utilize DN in both the clinical and research settings. One of the main determinants of understanding the risks of a procedure is the ability of the patient to recall this information. In risk of harm statements that are long, contain complex wording and reading levels, and contain long lists of

risks, patients cannot adequately recall this information. It would be advantageous to test this statement on an IC form to see if patients are able to better recall the risks using this shortened and easy to understand risk of harm statement. This allows for better understanding of whether patients can understand the risks associated with DN using our developed statement. Lastly, a follow-up study could involve taking the constructed risk of harm statement and bringing it back a panel of legal, policy, DN experts, and patients to obtain feedback. This would allow refinement of the generated risk statement and would allow for changes to be made before applying it to an IC form.

5.5 Implications for Practice

The construction of a risk of harm statement is an important element of the IC process and is important for patients to analyze risks. The ability to analyze risks allows the patient to make a more autonomous decision regarding whether they wish to participate in a research study or undergo clinical treatment. As such, it is important that risk of harm statements contain important information regarding potential risks. In addition, these risks need presented for patients to understand the true impact and likelihood of occurrence. For patients to understand the risks, the statement needs to be written at a reading level that facilitates understanding and comprehension. Additionally, the risks described need to concise to avoid unnecessary increases in complexity. Since IC is a legal and ethical obligation in healthcare and research, there is a continued need for development and refinement of shortened, concise documents from which patients can make

informed decisions from. These studies provided a foundational blueprint for developing risk of harm statements that can be applied in both the clinical and research settings.

Appendices

A-D

APPENDIX A

Delphi Demographic Form

1. What is your gender?
A. Female
B. Male
C. Unknown

2. Which option best describes your ethnicity?
A. American Indian or Alaska Native
B. Asian/Native Hawaiian/Other Pacific Islander
C. Black or African American
D. Hispanic or Latina
E. White or Caucasian
F. Other

3. What country do you currently practice in?

_____

4. What is your highest degree of education received?

_____

5. What year did you earn your highest educational degree?

_____

6. What is your primary work setting?
    A. Hospital
    B. Nursing Home
    C. Outpatient Clinic
    D. Private Practice Owner
    E. Home Health
    F. Academic/Research
    G. Other

7. How many years of total experience do you have working as a Physical Therapist?
    A. 1-4
    B. 5-9
    C. 10-14
    D. 15-19
    E. 20-24
    F. 25-29
    G. 30+

8. How many years of clinical experience have you had treating patients with dry needling?
    A. 7-10
    B. 11-14
    C. 15-19
    D. 20-24
    E. 25-29
    F. 30+

9. What is the average number of patients per week that you treated with dry needling ?
    A. 0
    B. 1-4
    C. 5-9
    D. 10-14
    E. 15-19
    F. 20+

10. How many scholarly products (combined total) related to dry needling have you had in the past 10 years? (This includes poster presentations and peer-reviewed publications)
    A. 0
    B. 1-4
    C. 5-9
    D. 10+

11. What dry needling style do you currently utilize or were trained in?

A. Trigger Point Dry Needling
B. Intramuscular Manual Therapy
C. Intramuscular Stimulation
D. Superficial Dry Needling
E. Spinal Segmental Sensitization Model
F. Classic or Traditional Acupuncture
G. Western Medical Acupuncture

12. Where did you receive dry needling training from?

_____

13. Have you received dry needling interventions as a patient?

A. Yes
B. No

APPENDIX B

Nominal Group Technique Demographic Form

General Questions (All Participants)

14. What is your gender?
D. Female
E. Male

15. Which option best describes your ethnicity?
G. American Indian or Alaska Native
H. Asian/Native Hawaiian/Other Pacific Islander
I. Black or African American
J. Hispanic or Latina
K. White or Caucasian
L. Other

16. What is your current age?

_____

17. What is your highest degree of education received?

_____

18. What year did you earn your highest educational degree?

_____

19. What is your primary occupation/work setting?

20. What is your area of expertise?
    a. Dry Needling Expert (Physical Therapist)
    b. Patient
    c. Policy Expert
    d. Legal Expert

A. Dry Needling Expert Additional Questions

1. How many years of total experience do you have working as a Physical Therapist?
    H. 1-4
    I. 5-9
    J. 10-14

K. 15-19
L. 20-24
M. 25-29
N. 30+

2. How many years of clinical experience have you had treating patients with dry needling?
    G. 5-9
    H. 10-14
    I. 15-19
    J. 20-24
    K. 25-29
    L. 30+

3. What is the average number of patients per week that you treated with dry needling ?
    G. 0
    H. 1-4
    I. 5-9
    J. 10-14
    K. 15-19
    L. 20+

4. How many scholarly products (combined total) related to dry needling have you had in the past 10 years? (This includes poster presentations and peer-reviewed publications)
    E. 0
    F. 1-4
    G. 5-9
    H. 10+

5. Have you received dry needling interventions as a patient?

C. Yes
D. No

B. Patient Additional Questions

1. How many times have you received dry needling treatment over the last 5 years?
    A. 1-4
    B. 5-9
    C. 10-14
    D. 15-19
    E. 20-24
    F. 25+

2. What body regions have you had dry needling applied to?

_____

3. Have you had any adverse events “any ill-effect, no matter how small, that is unintended and non-therapeutic”?
   A. Yes
   B. No

4. If you answered yes to question #3, what adverse events/side effects did you experience?

_____

5. Have you ever provided/given informed consent to participate in a medical procedure?
   A. Yes
   B. No

C. Policy Expert Additional Questions

1. How many years of experience do you have in bioethics?
   A. 1-4
   B. 5-9
   C. 10-14
   D. 15-19
   E. 20-24
   F. 25+

2. How many years of experience do you have in obtaining informed consent?
   A. 1-4
   B. 5-9
   C. 10-14
   D. 15-19
   E. 20-24
   F. 25+

3. Do you or have you served on an ethics committee in a healthcare institution or healthcare society/professional association?
   A. Yes
   B. No

4. If you answered “yes” to number 3, please indicate how many years you served on any ethics committees (total).
   A. 1-4
   B. 5-9
   C. 10-14
   D. 15-19
   E. 20-24

F. 25+

5. Are you a member of a state licensing board?
   A. Yes
   B. No

6. If you answered “yes” to number 5, please indicate how many years you served on a state licensing board (total).
   A. 1-4
   B. 5-9
   C. 10-14
   D. 15-19
   E. 20-24
   F. 25+

7. How many scholarly products (combined total) related to informed consent have you had in the past 10 years? (This includes poster presentations and peer-reviewed publications)
   A. 0
   B. 1-4
   C. 5-9
   D. 10+

D. Legal Expert Additional Questions

1. What training did you receive in health law?

_____

2. How many years have you practiced law?
   A. 1-4
   B. 5-9
   C. 10-14
   D. 15-19
   E. 20-24
   F. 25+

3. How many cases have you litigated regarding medical malpractice?
   A. 1-4
   B. 5-9
   C. 10-14
   D. 15-19
   E. 20-24
   F. 25+

4. How many cases have you litigated in the past 5 years related to failure to obtain informed consent?
   A. 0

B. 1-4
C. 5-9
D. 10+

5. How many scholarly products (combined total) related to informed consent have you had in the past 10 years? (This includes poster presentations and peer-reviewed publications)

A. 0
B. 1-4
C. 5-9
D. 10+

APPENDIX C

IRB Approval for Delphi Study

Mar 3, 2022, 9:47:18 AM EST

Edmund Ickert
Grad Health 141214

Re: Exempt - Initial - 2022-117 Defining and Identifying how Adverse Events Associated with Dry Needling Should be Reported During the Informed Consent Process: A Modified e-Delphi Study

Dear Dr. Edmund Ickert:

Youngstown State University Human Subjects Review Board has rendered the decision below for Defining and Identifying how Adverse Events Associated with Dry Needling Should be Reported During the Informed Consent Process: A Modified e-Delphi Study

Decision: Exempt

Selected Category: Category 2.(ii). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Any changes in your research activity should be promptly reported to the Institutional Review Board and may not be initiated without IRB approval except where necessary to eliminate hazard to human subjects. Any unanticipated problems involving risks to subjects should also be promptly
reported to the IRB.

Findings: The researchers are conducting a Delphi study about a medical procedure, the risks, and the cautions communicated about the procedures. The research will be multi-phase (consistent with a Delphi study) and will include the completion of the provided survey items and some basic demographic information.

The IRB would like to extend its best wishes to you in the conduct of this study.

Sincerely,
Youngstown State University Human Subjects Review Board

APPENDIX D

IRB Approval for Nominal Group Technique Study

Jun 30, 2022, 10:39:51 AM EDT

Edmund Ickert
Grad Health 141214

Re: Exempt - Initial - 2022-173 Development of an Informed Consent Statement which Communicates the Risk of Adverse Events Associated with Dry Needling using an Online Nominal Group Technique

Dear Dr. Edmund Ickert:

Youngstown State University Human Subjects Review Board has rendered the decision below for Development of an Informed Consent Statement which Communicates the Risk of Adverse Events Associated with Dry Needling using an Online Nominal Group Technique

Decision: Exempt

Selected Category: Category 2.(ii). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Any changes in your research activity should be promptly reported to the Institutional Review Board and may not be initiated without IRB approval except where necessary to eliminate hazard to human subjects. Any unanticipated problems involving risks to subjects should also be promptly
reported to the IRB.

Findings: The student researcher will conduct online meetings to develop an informed consent risk statement for dry needling that can be used for clinical and research applications. The individuals invited to participate in the study have experience with dry needling. All participants are adults.

The IRB would like to extend its best wishes to you in the conduct of this study.

Sincerely,
Youngstown State University Human Subjects Review Board

BIBLIOGRAPHY

1. Vikas H, Kini A, Sharma N, Gowda NR, Gupta A. How informed is the informed consent? *J Family Med Prim Care*. 2021;10(6):2299-2303. doi:10.4103/jfmpc.jfmpc_2393_20

2. Pucher PH, Johnston MJ, Archer S, et al. Informing the Consent Process for Surgeons: A Survey Study of Patient Preferences, Perceptions, and Risk Tolerance. *J Surg Res*. 2019;235:298-302. doi:10.1016/j.jss.2018.09.046

3. Knifed E, Lipsman N, Mason W, Bernstein M. Patients' perception of the informed consent process for neurooncology clinical trials. *Neuro Oncol*. 2008;10(3):348-354. doi:10.1215/15228517-2008-007

4. Bai JW, Abdallah FWW, Cohn M, Ladowski S, Madhusudan P, Brull R. Say what? Patients have poor immediate memory of major risks of interscalene block disclosed during the informed consent discussion. *Reg Anesth Pain Med*. Published online August 23, 2019:rapm-2019-100858. doi:10.1136/rapm-2019-100858

5. Villamañán E, Ruano M, Fernández-de Uzquiano E, et al. Informed consent in clinical research; Do patients understand what they have signed? *Farm Hosp*. 2016;40(3):209-218. doi:10.7399/fh.2016.40.3.10411

6. Sharp SM. Consent documents for oncology trials: does anybody read these things? *Am J Clin Oncol*. 2004;27(6):570-575. doi:10.1097/01.coc.0000135925.83221.b3

7. Berger O, Grønberg BH, Sand K, Kaasa S, Loge JH. The length of consent documents in oncological trials is doubled in twenty years. *Ann Oncol*. 2009;20(2):379-385. doi:10.1093/annonc/mdn623

8. Manta CJ, Ortiz J, Moulton BW, Sonnad SS. From the Patient Perspective, Consent Forms Fall Short of Providing Information to Guide Decision Making. *J Patient Saf*. 2021;17(3):e149-e154. doi:10.1097/PTS.0000000000000310

9. Ennis L, Wykes T. Sense and readability: participant information sheets for research studies. *Br J Psychiatry*. 2016;208(2):189-194. doi:10.1192/bjp.bp.114.156687

10. Emanuel EJ, Boyle CW. Assessment of Length and Readability of Informed Consent Documents for COVID-19 Vaccine Trials. *JAMA Netw Open*. 2021;4(4):e2110843. doi:10.1001/jamanetworkopen.2021.10843

11. Dunning J, Butts R, Mourad F, Young I, Flannagan S, Perreault T. Dry needling: a literature review with implications for clinical practice guidelines. *Phys Ther Rev*. 2014;19(4):252-265. doi:10.1179/108331913X13844245102034

12. Legge D. A History of Dry Needling. *Journal of Musculoskeletal Pain*. 2014;22(3):301-307. doi:10.3109/10582452.2014.883041

13. Vier C, Almeida MB de, Neves ML, Santos ARSD, Bracht MA. The effectiveness of dry needling for patients with orofacial pain associated with temporomandibular dysfunction: a systematic review and meta-analysis. *Braz J Phys Ther*. 2019;23(1):3-11. doi:10.1016/j.bjpt.2018.08.008

14. Özden MC, Atalay B, Özden AV, Çankaya A, Kolay E, Yıldırım S. Efficacy of dry needling in patients with myofascial temporomandibular disorders related to the masseter muscle. *Cranio*. 2020;38(5):305-311. doi:10.1080/08869634.2018.1526848

15. Ghannadi S, Shariat A, Ansari NN, et al. The Effect of Dry Needling on Lower Limb Dysfunction in Poststroke Survivors. *J Stroke Cerebrovasc Dis*. 2020;29(6):104814. doi:10.1016/j.jstrokecerebrovasdis.2020.104814

16. Sánchez-Mila Z, Salom-Moreno J, Fernández-de-Las-Peñas C. Effects of dry needling on post-stroke spasticity, motor function and stability limits: a randomised clinical trial. *Acupunct Med*. 2018;36(6):358-366. doi:10.1136/acupmed-2017-011568

17. Valencia-Chulián R, Heredia-Rizo AM, Moral-Munoz JA, Lucena-Anton D, Luque-Moreno C. Dry needling for the management of spasticity, pain, and range of movement in adults after stroke: A systematic review. *Complement Ther Med*. 2020;52:102515. doi:10.1016/j.ctim.2020.102515

18. Cotchett MP, Munteanu SE, Landorf KB. Effectiveness of trigger point dry needling for plantar heel pain: a randomized controlled trial. *Phys Ther*. 2014;94(8):1083-1094. doi:10.2522/ptj.20130255

19. Llurda-Almuzara L, Labata-Lezaun N, Meca-Rivera T, et al. Is Dry Needling Effective for the Management of Plantar Heel Pain or Plantar Fasciitis? An Updated Systematic Review and Meta-Analysis. *Pain Med*. 2021;22(7):1630-1641. doi:10.1093/pm/pnab114

20. Ceballos-Laita L, Jiménez-Del-Barrio S, Marín-Zurdo J, et al. Effects of dry needling in HIP muscles in patients with HIP osteoarthritis: A randomized controlled trial. *Musculoskelet Sci Pract*. 2019;43:76-82. doi:10.1016/j.msksp.2019.07.006

21. Ceballos-Laita L, Jiménez-Del-Barrio S, Marín-Zurdo J, et al. Effectiveness of Dry Needling Therapy on Pain, Hip Muscle Strength, and Physical Function in Patients With Hip Osteoarthritis: A Randomized Controlled Trial. *Arch Phys Med Rehabil*. 2021;102(5):959-966. doi:10.1016/j.apmr.2021.01.077

22. Farazdaghi M, Kordi Yoosefinejad A, Abdollahian N, Rahimi M, Motealleh A. Dry needling trigger points around knee and hip joints improves function in

patients with mild to moderate knee osteoarthritis. *J Bodyw Mov Ther*. 2021;27:597-604. doi:10.1016/j.jbmt.2021.04.011

23. Ughreja RA, Prem V. Effectiveness of dry needling techniques in patients with knee osteoarthritis: A systematic review and meta-analysis. *J Bodyw Mov Ther*. 2021;27:328-338. doi:10.1016/j.jbmt.2021.02.015

24. France S, Bown J, Nowosilskyj M, Mott M, Rand S, Walters J. Evidence for the use of dry needling and physiotherapy in the management of cervicogenic or tension-type headache: a systematic review. *Cephalalgia*. 2014;34(12):994-1003. doi:10.1177/0333102414523847

25. Gildir S, Tüzün EH, Eroğlu G, Eker L. A randomized trial of trigger point dry needling versus sham needling for chronic tension-type headache. *Medicine (Baltimore)*. 2019;98(8):e14520. doi:10.1097/MD.0000000000014520

26. Pourahmadi M, Dommerholt J, Fernández-de-Las-Peñas C, et al. Dry Needling for the Treatment of Tension-Type, Cervicogenic, or Migraine Headaches: A Systematic Review and Meta-Analysis. *Phys Ther*. 2021;101(5):pzab068. doi:10.1093/ptj/pzab068

27. Rezaeian T, Mosallanezhad Z, Nourbakhsh MR, Noroozi M, Sajedi F. Effects of Dry Needling Technique Into Trigger Points of the Sternocleidomastoid Muscle in Migraine Headache: A Randomized Controlled Trial. *Am J Phys Med Rehabil*. 2020;99(12):1129-1137. doi:10.1097/PHM.0000000000001504

28. Sedighi A, Nakhostin Ansari N, Naghdi S. Comparison of acute effects of superficial and deep dry needling into trigger points of suboccipital and upper trapezius muscles in patients with cervicogenic headache. *J Bodyw Mov Ther*. 2017;21(4):810-814. doi:10.1016/j.jbmt.2017.01.002

29. Vázquez-Justes D, Yarzábal-Rodríguez R, Doménech-García V, Herrero P, Bellosta-López P. Effectiveness of dry needling for headache: A systematic review. *Neurologia (Engl Ed)*. Published online January 13, 2020:S0213-4853(19)30144-6. doi:10.1016/j.nrl.2019.09.010

30. Casanueva B, Rivas P, Rodero B, Quintial C, Llorca J, González-Gay MA. Short-term improvement following dry needle stimulation of tender points in fibromyalgia. *Rheumatol Int*. 2014;34(6):861-866. doi:10.1007/s00296-013-2759-3

31. Castro Sánchez AM, García López H, Fernández Sánchez M, et al. Improvement in clinical outcomes after dry needling versus myofascial release on pain pressure thresholds, quality of life, fatigue, pain intensity, quality of sleep, anxiety, and depression in patients with fibromyalgia syndrome. *Disabil Rehabil*. 2019;41(19):2235-2246. doi:10.1080/09638288.2018.1461259

32. Navarro-Santana MJ, Gómez-Chiguano GF, Cleland JA, Arias-Buría JL, Fernández-de-Las-Peñas C, Plaza-Manzano G. Effects of Trigger Point Dry Needling for Nontraumatic Shoulder Pain of Musculoskeletal Origin: A Systematic Review and Meta-Analysis. *Phys Ther*. 2021;101(2):pzaa216. doi:10.1093/ptj/pzaa216

33. Arias-Buría JL, Monroy-Acevedo Á, Fernández-de-Las-Peñas C, Gallego-Sendarrubias GM, Ortega-Santiago R, Plaza-Manzano G. Effects of dry needling of active trigger points in the scalene muscles in individuals with mechanical neck pain: a randomized clinical trial. *Acupunct Med*. 2020;38(6):380-387. doi:10.1177/0964528420912254

34. Berger AA, Liu Y, Mosel L, et al. Efficacy of Dry Needling and Acupuncture in the Treatment of Neck Pain. *Anesth Pain Med*. 2021;11(2):e113627. doi:10.5812/aapm.113627

35. Liu L, Huang QM, Liu QG, et al. Effectiveness of dry needling for myofascial trigger points associated with neck and shoulder pain: a systematic review and meta-analysis. *Arch Phys Med Rehabil*. 2015;96(5):944-955. doi:10.1016/j.apmr.2014.12.015

36. Martín-Rodríguez A, Sáez-Olmo E, Pecos-Martín D, Calvo-Lobo C. Effects of dry needling in the sternocleidomastoid muscle on cervical motor control in patients with neck pain: a randomised clinical trial. *Acupunct Med*. 2019;37(3):151-163. doi:10.1177/0964528419843913

37. Murillo C, Treleaven J, Cagnie B, Peral J, Falla D, Lluch E. Effects of dry needling of the obliquus capitis inferior on sensorimotor control and cervical mobility in people with neck pain: A double-blind, randomized sham-controlled trial. *Braz J Phys Ther*. 2021;25(6):826-836. doi:10.1016/j.bjpt.2021.07.005

38. Navarro-Santana MJ, Sanchez-Infante J, Fernández-de-Las-Peñas C, Cleland JA, Martín-Casas P, Plaza-Manzano G. Effectiveness of Dry Needling for Myofascial Trigger Points Associated with Neck Pain Symptoms: An Updated Systematic Review and Meta-Analysis. *J Clin Med*. 2020;9(10):E3300. doi:10.3390/jcm9103300

39. Pecos-Martín D, Montañez-Aguilera FJ, Gallego-Izquierdo T, et al. Effectiveness of dry needling on the lower trapezius in patients with mechanical neck pain: a randomized controlled trial. *Arch Phys Med Rehabil*. 2015;96(5):775-781. doi:10.1016/j.apmr.2014.12.016

40. Navarro-Santana MJ, Sanchez-Infante J, Gómez-Chiguano GF, et al. Effects of trigger point dry needling on lateral epicondylalgia of musculoskeletal origin: a systematic review and meta-analysis. *Clin Rehabil*. 2020;34(11):1327-1340. doi:10.1177/0269215520937468

41. Liu L, Huang QM, Liu QG, et al. Evidence for Dry Needling in the Management of Myofascial Trigger Points Associated With Low Back Pain: A Systematic Review and Meta-Analysis. *Arch Phys Med Rehabil*. 2018;99(1):144-152.e2. doi:10.1016/j.apmr.2017.06.008

42. Kharazmi AS, Okhovatian F, Baghban AA, Mosallanezhad Z, Kojidi MM, Azimi H. Effects of dry needling on symptomatic hallux valgus: A randomized single blind clinical trial. *J Bodyw Mov Ther*. 2020;24(3):246-251. doi:10.1016/j.jbmt.2020.02.016

43. Bynum R, Garcia O, Herbst E, et al. Effects of Dry Needling on Spasticity and Range of Motion: A Systematic Review. *Am J Occup Ther*. 2021;75(1):7501205030p1-7501205030p13. doi:10.5014/ajot.2021.041798

44. Haser C, Stöggl T, Kriner M, et al. Effect of Dry Needling on Thigh Muscle Strength and Hip Flexion in Elite Soccer Players. *Med Sci Sports Exerc*. 2017;49(2):378-383. doi:10.1249/MSS.0000000000001111

45. Alaei P, Nakhostin Ansari N, Naghdi S, Fakhari Z, Komesh S, Dommerholt J. Dry Needling for Hamstring Flexibility: A Single-Blind Randomized Controlled Trial. *J Sport Rehabil*. 2020;30(3):452-457. doi:10.1123/jsr.2020-0111

46. Albin SR, Koppenhaver SL, MacDonald CW, et al. The effect of dry needling on gastrocnemius muscle stiffness and strength in participants with latent trigger points. *J Electromyogr Kinesiol*. 2020;55:102479. doi:10.1016/j.jelekin.2020.102479

47. Sánchez-Infante J, Navarro-Santana MJ, Bravo-Sánchez A, Jiménez-Diaz F, Abián-Vicén J. Is Dry Needling Applied by Physical Therapists Effective for Pain in Musculoskeletal Conditions? A Systematic Review and Meta-Analysis. *Phys Ther*. 2021;101(3):pzab070. doi:10.1093/ptj/pzab070

48. Khan I, Ahmad A, Ahmed A, Sadiq S, Asim HM. Effects of dry needling in lower extremity myofascial trigger points. *J Pak Med Assoc*. 2021;71(11):2596-2603. doi:10.47391/JPMA.01398

49. Boyles R, Fowler R, Ramsey D, Burrows E. Effectiveness of trigger point dry needling for multiple body regions: a systematic review. *J Man Manip Ther*. 2015;23(5):276-293. doi:10.1179/2042618615Y.0000000014

50. Kietrys DM, Palombaro KM, Azzaretto E, et al. Effectiveness of dry needling for upper-quarter myofascial pain: a systematic review and meta-analysis. *J Orthop Sports Phys Ther*. 2013;43(9):620-634. doi:10.2519/jospt.2013.4668

51. Rozenfeld E, Sapoznikov Sebakhutu E, Krieger Y, Kalichman L. Dry needling for scar treatment. *Acupunct Med*. 2020;38(6):435-439. doi:10.1177/0964528420912255

52. Dar G, Hicks GE. The immediate effect of dry needling on multifidus muscles' function in healthy individuals. *J Back Musculoskelet Rehabil*. 2016;29(2):273-278. doi:10.3233/BMR-150624

53. López-González L, Falla D, Lázaro-Navas I, et al. Effects of Dry Needling on Neuromuscular Control of Ankle Stabilizer Muscles and Center of Pressure Displacement in Basketball Players with Chronic Ankle Instability: A Single-Blinded Randomized Controlled Trial. *Int J Environ Res Public Health*. 2021;18(4):2092. doi:10.3390/ijerph18042092

54. Brady S, McEvoy J, Dommerholt J, Doody C. Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists. *J Man Manip Ther*. 2014;22(3):134-140. doi:10.1179/2042618613Y.0000000044

55. Boyce D, Wempe H, Campbell C, et al. ADVERSE EVENTS ASSOCIATED WITH THERAPEUTIC DRY NEEDLING. *Int J Sports Phys Ther*. 2020;15(1):103-113.

56. Kearns GA, Brismée JM, Riley SP, Wang-Price S, Denninger T, Vugrin M. Lack of standardization in dry needling dosage and adverse event documentation limits outcome and safety reports: a scoping review of randomized clinical trials. *J Man Manip Ther*. Published online May 23, 2022:1-12. doi:10.1080/10669817.2022.2077516

57. N. Whitney S, L. McGuire A, B. McCullough L. A Typology of Shared Decision Making, Informed Consent, and Simple Consent. *Annals of Internal Medicine*. Published online January 6, 2004. Accessed February 2, 2022. https://www.acpjournals.org/doi/abs/10.7326/0003-4819-140-1-200401060-00012

58. Beauchamp TL. Informed Consent: Its History, Meaning, and Present Challenges. *Cambridge Quarterly of Healthcare Ethics*. 2011;20(4):515-523. doi:10.1017/S0963180111000259

59. Laine C, Davidoff F. Patient-centered medicine. A professional evolution. *JAMA*. 1996;275(2):152-156.

60. Sil A, Das NK. Informed Consent Process: Foundation of the Researcher-participant Bond. *Indian J Dermatol*. 2017;62(4):380-386. doi:10.4103/ijd.IJD_272_17

61. Chatterjee K, Das NK. Informed Consent in Biomedical Research: Scopes and Challenges. *Indian Dermatol Online J*. 2021;12(4):529-535. doi:10.4103/idoj.IDOJ_83_21

62. Bunch WH. Informed consent. *Clin Orthop Relat Res*. 2000;(378):71-77. doi:10.1097/00003086-200009000-00012

63. Shah P, Thornton I, Turrin D, Hipskind JE. Informed Consent. In: *StatPearls*. StatPearls Publishing; 2022. Accessed June 22, 2022. http://www.ncbi.nlm.nih.gov/books/NBK430827/

64. Sugarman J. Informed Consent, Shared Decision-Making, and Complementary and Alternative Medicine. *The Journal of Law, Medicine & Ethics*. 2003;31(2):247-250. doi:10.1111/j.1748-720X.2003.tb00085.x

65. Childress JF, Childress MD. What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care? *AMA Journal of Ethics*. 2020;22(5):423-429. doi:10.1001/amajethics.2020.423

66. Caramagno J, Adrian L, Mueller, L, Purl, J. *Analysis of Competencies for Dry Needling by Physical Therapists- Final Report*.; 2015.

67. Valdes VR. Dry Needling in Physical Therapy Practice: Adverse Events Part 1: Types and Frequency of Adverse Events. *Orthopedic Physical Therapy Pratice*. 2021;33(1):34-39.

68. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *Man Ther*. 2010;15(1):2-6. doi:10.1016/j.math.2009.02.003

69. Sivanadarajah N, El-Daly I, Mamarelis G, Sohail M, Bates P. Informed consent and the readability of the written consent form. *Ann R Coll Surg Engl*. 2017;99(8):645-649. doi:10.1308/rcsann.2017.0188

70. Rothwell E, Goldenberg A, Johnson E, Riches N, Tarini B, Botkin JR. An Assessment of a Shortened Consent Form for the Storage and Research Use of Residual Newborn Screening Blood Spots. *J Empir Res Hum Res Ethics*. 2017;12(5):335-342. doi:10.1177/1556264617736199

71. Zimmermann A, Pilarska A, Gaworska-Krzemińska A, Jankau J, Cohen MN. Written Informed Consent-Translating into Plain Language. A Pilot Study. *Healthcare (Basel)*. 2021;9(2):232. doi:10.3390/healthcare9020232

72. Hadden KB, Prince LY, Moore TD, James LP, Holland JR, Trudeau CR. Improving readability of informed consents for research at an academic medical institution. *J Clin Trans Sci*. 2017;1(6):361-365. doi:10.1017/cts.2017.312

73. White A, Hayhoe S, Ernst E. Survey of Adverse Events following Acupuncture. *Acupunct Med*. 1997;15(2):67-70. doi:10.1136/aim.15.2.67

74. MacPherson H, Thomas K, Walters S, Fitter M. A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists. *Acupunct Med*. 2001;19(2):93-102. doi:10.1136/aim.19.2.93

75. smpc_guideline_rev2_en_0.pdf. Accessed June 28, 2022. https://health.ec.europa.eu/system/files/2016-11/smpc_guideline_rev2_en_0.pdf

76. Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: How to decide its appropriateness. *World J Methodol*. 2021;11(4):116-129. doi:10.5662/wjm.v11.i4.116

77. McMillan SS, King M, Tully MP. How to use the nominal group and Delphi techniques. *Int J Clin Pharm*. 2016;38(3):655-662. doi:10.1007/s11096-016-0257-x

78. Stahel PF, Douglas IS, VanderHeiden TF, Weckbach S. The history of risk: a review. *World J Emerg Surg*. 2017;12:15. doi:10.1186/s13017-017-0125-6

79. Emanuel EJ, Grady C, Menikoff J. Case Study: Is Longer Always Better? *The Hastings Center Report*. 2008;38(3):10-12.

80. Tamariz L, Palacio A, Robert M, Marcus EN. Improving the informed consent process for research subjects with low literacy: a systematic review. *J Gen Intern Med*. 2013;28(1):121-126. doi:10.1007/s11606-012-2133-2

81. Montalvo W, Larson E. Participant comprehension of research for which they volunteer: a systematic review. *J Nurs Scholarsh*. 2014;46(6):423-431. doi:10.1111/jnu.12097

82. O'Hare F, Spark S, Flanagan Z, et al. Impact of informed consent content and length on recruitment of older adults into a community based primary prevention trial. *Contemp Clin Trials Commun*. 2018;11:89-94. doi:10.1016/j.conctc.2018.05.003

83. Corneli AL, Namey E, Mueller MP, et al. Evidence-based strategies for shortening informed consent forms in clinical research. *J Empir Res Hum Res Ethics*. 2017;12(1):14-25. doi:10.1177/1556264616682550

84. Valdes VR. Dry Needling in Physical Therapy Practice: Adverse Events Part 2: Serious Adverse Events. *Orthopaedic Physical Therapy Practice*. 2021;33(2):96-100.

85. Calligaro KD. Do no harm. *Journal of Vascular Surgery*. 2010;51(2):487-493. doi:10.1016/j.jvs.2009.10.106

86. Hanson M, Pitt D. Informed consent for surgery: risk discussion and documentation. *Can J Surg*. 2017;60(1):69-70. doi:10.1503/cjs.004816

87. Wood F, Martin SM, Carson-Stevens A, Elwyn G, Precious E, Kinnersley P. Doctors' perspectives of informed consent for non-emergency surgical

procedures: a qualitative interview study. *Health Expect*. 2016;19(3):751-761. doi:10.1111/hex.12258

88. Federal Policy for the Protection of Human Subjects. Federal Register. Published January 19, 2017. Accessed August 12, 2022. https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects

89. Kim EJ, Kim SH. Simplification improves understanding of informed consent information in clinical trials regardless of health literacy level. *Clinical Trials*. 2015;12(3):232-236. doi:10.1177/1740774515571139

90. Perrenoud B, Velonaki VS, Bodenmann P, Ramelet AS. The effectiveness of health literacy interventions on the informed consent process of health care users: a systematic review protocol. *JBI Database System Rev Implement Rep*. 2015;13(10):82-94. doi:10.11124/jbisrir-2015-2304

91. Stunkel L, Benson M, McLellan L, et al. Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form. *IRB*. 2010;32(4):1-9.

92. Edmunds MR, Barry RJ, Denniston AK. Readability Assessment of Online Ophthalmic Patient Information. *JAMA Ophthalmol*. 2013;131(12):1610. doi:10.1001/jamaophthalmol.2013.5521

93. Corneli AL, Namey E, Mueller MP, et al. Evidence-based strategies for shortening informed consent forms in clinical research. *J Empir Res Hum Res Ethics*. 2017;12(1):14-25. doi:10.1177/1556264616682550

94. Hitchcock EC, Study C, Elliott AM. Shortened consent forms for genome-wide sequencing: Parent and provider perspectives. *Mol Genet Genomic Med*. 2020;8(7):e1254. doi:10.1002/mgg3.1254

95. Fan AY, Xu J, Li YM. Evidence and expert opinions: Dry needling versus acupuncture (I) : The American Alliance for Professional Acupuncture Safety (AAPAS) White Paper 2016. *Chin J Integr Med*. 2017;23(1):3-9. doi:10.1007/s11655-016-2630-y

96. Fan AY, Xu J, Li YM. Evidence and expert opinions: Dry needling versus acupuncture (II) : The American Alliance for Professional Acupuncture Safety (AAPAS) White Paper 2016. *Chin J Integr Med*. 2017;23(2):83-90. doi:10.1007/s11655-017-2800-6

97. Zhou K, Ma Y, Brogan MS. Dry Needling versus Acupuncture: The Ongoing Debate. *Acupunct Med*. 2015;33(6):485-490. doi:10.1136/acupmed-2015-010911

98. Legge D. A History of Dry Needling. *Journal of Musculoskeletal Pain*. 2014;22(3):301-307. doi:10.3109/10582452.2014.883041

99. Travell J, Rinzler S, Herman M. PAIN AND DISABILITY OF THE SHOULDER AND ARM: TREATMENT BY INTRAMUSCULAR INFILTRATION WITH PROCAINE HYDROCHLORIDE. *JAMA*. 1942;120(6):417. doi:10.1001/jama.1942.02830410005002

100. Travell JG, Simons DG. *Myofascial Pain and Dysfunction: The Trigger Point Manual Vol.1, Vol.2, Vol.1, Vol.2,*. Williams & Wilkins; 1992.

101. Brav EA, Sigmond H. The local and regional injection treatment of low back pain and sciatica. *Ann Intern Med*. 1941;15(5):840-852. doi:10.7326/0003-4819-15-5-840

102. Paulett JD. Low back pain. *Lancet*. 1947;2(6469):272-276. doi:10.1016/s0140-6736(47)92037-0

103. Travell J, Rinzler SH. The myofascial genesis of pain. *Postgrad Med*. 1952;11(5):425-434. doi:10.1080/00325481.1952.11694280

104. Ghia JN, Mao W, Toomey TC, Gregg JM. Acupuncture and chronic pain mechanisms. *Pain*. 1976;2(3):285-299. doi:10.1016/0304-3959(76)90006-3

105. Melzack R, Stillwell DM, Fox EJ. Trigger points and acupuncture points for pain: correlations and implications. *Pain*. 1977;3(1):3-23. doi:10.1016/0304-3959(77)90032-X

106. Gunn CC, Milbrandt WE. Tennis elbow and the cervical spine. *Can Med Assoc J*. 1976;114(9):803-809.

107. Gunn CC, Milbrandt WE. Tenderness at motor points. A diagnostic and prognostic aid for low-back injury. *J Bone Joint Surg Am*. 1976;58(6):815-825.

108. Lewit K. The needle effect in the relief of myofascial pain. *Pain*. 1979;6(1):83-90. doi:10.1016/0304-3959(79)90142-8

109. Gunn CC. *Treating Myofascial Pain: Intramuscular Stimulation*. Health Sciences Center for; 1989.

110. *[Myofascial Pain and Fibromyalgia Syndromes: A Clinical Guide to Diagnosis and Management [MYOFASCIAL PAIN AND FIBROMYALGIA SYNDROMES: A CLINICAL GUIDE TO DIAGNOSIS AND MANAGEMENT BY Baldry, P E (Author) Apr-20-2001[MYOFASCIAL PAIN AND FIBROMYALGIA SYNDROMES: A CLINICAL GUIDE TO DIAGNOSIS AND MANAGEMENT [MYOFASCIAL PAIN AND FIBROMYALGIA SYNDROMES: A CLINICAL GUIDE TO DIAGNOSIS AND MANAGEMENT BY BALDRY, P*

E (AUTHOR) APR-20-2001] By Baldry, P E (Author)Apr-20-2001 Hardcover.

111. Baldry P. Superficial versus deep dry needling. *Acupunct Med*. 2002;20(2-3):78-81. doi:10.1136/aim.20.2-3.78

112. Hong CZ. Lidocaine injection versus dry needling to myofascial trigger point. The importance of the local twitch response. *Am J Phys Med Rehabil*. 1994;73(4):256-263. doi:10.1097/00002060-199407000-00006

113. Hsieh YL, Kao MJ, Kuan TS, Chen SM, Chen JT, Hong CZ. Dry needling to a key myofascial trigger point may reduce the irritability of satellite MTrPs. *Am J Phys Med Rehabil*. 2007;86(5):397-403. doi:10.1097/PHM.0b013e31804a554d

114. Kalichman L, Vulfsons S. Dry needling in the management of musculoskeletal pain. *J Am Board Fam Med*. 2010;23(5):640-646. doi:10.3122/jabfm.2010.05.090296

115. Cagnie B, Dewitte V, Barbe T, Timmermans F, Delrue N, Meeus M. Physiologic effects of dry needling. *Curr Pain Headache Rep*. 2013;17(8):348. doi:10.1007/s11916-013-0348-5

116. Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L. Comparison of superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study. *Clin J Pain*. 2002;18(3):149-153. doi:10.1097/00002508-200205000-00003

117. Gerwin RD, Dommerholt J, Shah JP. An expansion of Simons' integrated hypothesis of trigger point formation. *Curr Pain Headache Rep*. 2004;8(6):468-475. doi:10.1007/s11916-004-0069-x

118. What Conditions Can Dry Needling Treat? Endeavor Physical Therapy. Published July 19, 2019. Accessed February 3, 2022. https://www.endeavorrehab.com/2019/07/19/what-conditions-does-dry-needling-treat/

119. Langevin HM, Churchill DL, Cipolla MJ. Mechanical signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. *FASEB J*. 2001;15(12):2275-2282. doi:10.1096/fj.01-0015hyp

120. Baldry P, Yunus MB, Inanici F. *Myofascial Pain and Fibromyalgia Syndromes: A Clinical Guide to Diagnosis and Management*. Churchill Livingstone; 2001.

121. Shah JP, Phillips T, Danoff JV, Gerber LH. A novel microanalytical technique for assaying soft tissue demonstrates significant quantitative biochemical differences in 3 clinically distinct groups: normal, latent, and active. *Archives*

of Physical Medicine and Rehabilitation. 2003;84(9):E4. doi:10.1016/S0003-9993(03)00525-2

122. Unverzagt C, Berglund K, Thomas JJ. DRY NEEDLING FOR MYOFASCIAL TRIGGER POINT PAIN: A CLINICAL COMMENTARY. *Int J Sports Phys Ther*. 2015;10(3):402-418.

123. APTA-DN_ClinicalPracticeEducationalResourcePaper.pdf. Accessed January 26, 2022. https://www.mptalliance.com/wp-content/uploads/2015/12/APTA-DN_ClinicalPracticeEducationalResourcePaper.pdf

124. Ijaz N, Boon H. Evaluating the international standards gap for the use of acupuncture needles by physiotherapists and chiropractors: A policy analysis. Kumar S, ed. *PLoS ONE*. 2019;14(12):e0226601. doi:10.1371/journal.pone.0226601

125. DryNeedlingFinalReport_20150812.pdf. Accessed January 27, 2022. https://www.fsbpt.org/Portals/0/documents/free-resources/DryNeedlingFinalReport_20150812.pdf

126. Matthews L, Ford G, Schenk R, Ross M, Donnelly J. Dry needling curricula in entry-level education programs in the United States for physical therapists. *J Man Manip Ther*. 2021;29(2):83-91. doi:10.1080/10669817.2020.1813471

127. Fan AY, Xu J, Li YM. Evidence and expert opinions: Dry needling versus acupuncture (II) : The American Alliance for Professional Acupuncture Safety (AAPAS) White Paper 2016. *Chin J Integr Med*. 2017;23(2):83-90. doi:10.1007/s11655-017-2800-6

128. Crawford PF, Moss DA, Hawks MK, Snyder MJ. Integrative Medicine: Acupuncture. *FP Essent*. 2021;505:18-22.

129. Kelly RB, Willis J. Acupuncture for Pain. *Am Fam Physician*. 2019;100(2):89-96.

130. Witt CM, Pach D, Brinkhaus B, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. *Forsch Komplementmed*. 2009;16(2):91-97. doi:10.1159/000209315

131. White A, Hayhoe S, Hart A, Ernst E, BMAS and AACP. British Medical Acupuncture Society and Acupuncture Association of Chartered Physiotherapists. Survey of adverse events following acupuncture (SAFA): a prospective study of 32,000 consultations. *Acupunct Med*. 2001;19(2):84-92. doi:10.1136/aim.19.2.84

132. Ernst G, Strzyz H, Hagmeister H. Incidence of adverse effects during acupuncture therapy-a multicentre survey. *Complement Ther Med*. 2003;11(2):93-97. doi:10.1016/s0965-2299(03)00004-9

133. Ernst E, White AR. Prospective studies of the safety of acupuncture: a systematic review. *Am J Med*. 2001;110(6):481-485. doi:10.1016/s0002-9343(01)00651-9

134. Cox J, Varatharajan S, Côté P, Optima Collaboration null. Effectiveness of Acupuncture Therapies to Manage Musculoskeletal Disorders of the Extremities: A Systematic Review. *J Orthop Sports Phys Ther*. 2016;46(6):409-429. doi:10.2519/jospt.2016.6270

135. Farag AM, Malacarne A, Pagni SE, Maloney GE. The effectiveness of acupuncture in the management of persistent regional myofascial head and neck pain: A systematic review and meta-analysis. *Complement Ther Med*. 2020;49:102297. doi:10.1016/j.ctim.2019.102297

136. Snyder DD. Acupuncture gone awry: a case report of a patient who required surgical removal of two single-use filament needles following acupuncture treatment. *J Man Manip Ther*. 2019;27(3):180-184. doi:10.1080/10669817.2019.1608010

137. Callan AK, Bauer JM, Martus JE. Deep Spine Infection After Acupuncture in the Setting of Spinal Instrumentation. *Spine Deform*. 2016;4(2):156-161. doi:10.1016/j.jspd.2015.09.045

138. Karavis MY, Argyra E, Segredos V, Yiallouroy A, Giokas G, Theodosopoulos T. Acupuncture-induced haemothorax: a rare iatrogenic complication of acupuncture. *Acupunct Med*. 2015;33(3):237-241. doi:10.1136/acupmed-2014-010700

139. Dry Needling vs. Acupuncture. Healthline. Published December 5, 2018. Accessed February 3, 2022. https://www.healthline.com/health/dry-needling-vs-acupuncture

140. White A. The Safety of Acupuncture – Evidence from the Uk. *Acupunct Med*. 2006;24(1_suppl):53-57. doi:10.1136/aim.24.Suppl.53

141. Gattie E, Cleland JA, Snodgrass S. A survey of American physical therapists' current practice of dry needling: Practice patterns and adverse events. *Musculoskelet Sci Pract*. 2020;50:102255. doi:10.1016/j.msksp.2020.102255

142. Uygur E, Aktaş B, Özkut A, Erinç S, Yilmazoglu EG. Dry needling in lateral epicondylitis: a prospective controlled study. *Int Orthop*. 2017;41(11):2321-2325. doi:10.1007/s00264-017-3604-1

143. Kim DC, Glenzer S, Johnson A, Nimityongskul P. Deep Infection Following Dry Needling in a Young Athlete: An Underreported Complication of an Increasingly Prevalent Modality: A Case Report. *JBJS Case Connect*. 2018;8(3):e73. doi:10.2106/JBJS.CC.18.00097

144. Steentjes K, de Vries LMA, Ridwan BU, Wijgman AJJ. [Infection of a hip prosthesis after dry needling]. *Ned Tijdschr Geneeskd*. 2016;160:A9364.

145. McManus R, Cleary M. Radial nerve injury following dry needling. *BMJ Case Rep*. 2018;2018:bcr-2017-221302. doi:10.1136/bcr-2017-221302

146. Cummings M, Ross-Marrs R, Gerwin R. Pneumothorax complication of deep dry needling demonstration. *Acupunct Med*. 2014;32(6):517-519. doi:10.1136/acupmed-2014-010659

147. Patel N, Patel M, Poustinchian B. Dry Needling-Induced Pneumothorax. *J Am Osteopath Assoc*. 2019;119(1):59-62. doi:10.7556/jaoa.2019.009

148. Lee JH, Lee H, Jo DJ. An acute cervical epidural hematoma as a complication of dry needling. *Spine (Phila Pa 1976)*. 2011;36(13):E891-893. doi:10.1097/BRS.0b013e3181fc1e38

149. Berrigan WA, Whitehair CL, Zorowitz RD. Acute Spinal Epidural Hematoma as a Complication of Dry Needling: A Case Report. *PM R*. 2019;11(3):313-316. doi:10.1016/j.pmrj.2018.07.009

150. Mejuto-Vázquez MJ, Salom-Moreno J, Ortega-Santiago R, Truyols-Domínguez S, Fernández-de-Las-Peñas C. Short-term changes in neck pain, widespread pressure pain sensitivity, and cervical range of motion after the application of trigger point dry needling in patients with acute mechanical neck pain: a randomized clinical trial. *J Orthop Sports Phys Ther*. 2014;44(4):252-260. doi:10.2519/jospt.2014.5108

151. Gonzalez-Perez LM, Infante-Cossio P, Granados-Nunez M, Urresti-Lopez FJ, Lopez-Martos R, Ruiz-Canela-Mendez P. Deep dry needling of trigger points located in the lateral pterygoid muscle: Efficacy and safety of treatment for management of myofascial pain and temporomandibular dysfunction. *Med Oral Patol Oral Cir Bucal*. 2015;20(3):e326-333. doi:10.4317/medoral.20384

152. Brennan KL, Allen BC, Maldonado YM. Dry Needling Versus Cortisone Injection in the Treatment of Greater Trochanteric Pain Syndrome: A Noninferiority Randomized Clinical Trial. *J Orthop Sports Phys Ther*. 2017;47(4):232-239. doi:10.2519/jospt.2017.6994

153. Ansari NN, Alaei P, Naghdi S, Fakhari Z, Komesh S, Dommerholt J. Immediate Effects of Dry Needling as a Novel Strategy for Hamstring Flexibility: A Single-Blinded Clinical Pilot Study. *J Sport Rehabil*. 2020;29(2):156-161. doi:10.1123/jsr.2018-0013

154. Halle R, Crowell M, Goss D. DRY NEEDLING AND PHYSICAL THERAPY VERSUS PHYSICAL THERAPY ALONE FOLLOWING SHOULDER STABILIZATION REPAIR: A RANDOMIZED CLINICAL TRIAL. *Int J Sports Phys Ther*. 2020;15(1):81-102.

155. Kearns G, Fernández-De-Las-Peñas C, Brismée JM, Gan J, Doidge J. New perspectives on dry needling following a medical model: are we screening our patients sufficiently? *J Man Manip Ther*. 2019;27(3):172-179. doi:10.1080/10669817.2019.1567011

156. Dwan K, Gamble C, Williamson PR, Kirkham JJ, Reporting Bias Group. Systematic review of the empirical evidence of study publication bias and outcome reporting bias - an updated review. *PLoS One*. 2013;8(7):e66844. doi:10.1371/journal.pone.0066844

157. Mayo-Wilson E, Fusco N, Li T, et al. Harms are assessed inconsistently and reported inadequately Part 2: nonsystematic adverse events. *J Clin Epidemiol*. 2019;113:11-19. doi:10.1016/j.jclinepi.2019.04.020

158. Hart B, Lundh A, Bero L. Effect of reporting bias on meta-analyses of drug trials: reanalysis of meta-analyses. *BMJ*. 2012;344:d7202. doi:10.1136/bmj.d7202

159. Golder S, Loke YK, Wright K, Norman G. Reporting of Adverse Events in Published and Unpublished Studies of Health Care Interventions: A Systematic Review. *PLoS Med*. 2016;13(9):e1002127. doi:10.1371/journal.pmed.1002127

160. McGauran N, Wieseler B, Kreis J, Schüler YB, Kölsch H, Kaiser T. Reporting bias in medical research - a narrative review. *Trials*. 2010;11:37. doi:10.1186/1745-6215-11-37

161. Mitra-Majumdar M, Kesselheim AS. Reporting bias in clinical trials: Progress toward transparency and next steps. *PLOS Medicine*. 2022;19(1):e1003894. doi:10.1371/journal.pmed.1003894

162. Parsons R, Golder S, Watt I. More than one-third of systematic reviews did not fully report the adverse events outcome. *Journal of Clinical Epidemiology*. 2019;108:95-101. doi:10.1016/j.jclinepi.2018.12.007

163. Saini P, Loke YK, Gamble C, Altman DG, Williamson PR, Kirkham JJ. Selective reporting bias of harm outcomes within studies: findings from a cohort of systematic reviews. *BMJ*. 2014;349:g6501. doi:10.1136/bmj.g6501

164. Mayo-Wilson E, Fusco N, Hong H, Li T, Canner JK, Dickersin K. Opportunities for selective reporting of harms in randomized clinical trials: Selection criteria for non-systematic adverse events. *Trials*. 2019;20(1):553. doi:10.1186/s13063-019-3581-3

165. Barrett D, Heale R. What are Delphi studies? *Evidence-Based Nursing*. 2020;23(3):68-69. doi:10.1136/ebnurs-2020-103303

166. de Villiers MR, de Villiers PJT, Kent AP. The Delphi technique in health sciences education research. *Medical Teacher*. 2005;27(7):639-643. doi:10.1080/13611260500069947

167. J. Skulmoski G, T. Hartman F, Krahn J. The Delphi Method for Graduate Research. *JITE:Research*. 2007;6:001-021. doi:10.28945/199

168. Niederberger M, Spranger J. Delphi Technique in Health Sciences: A Map. *Front Public Health*. 2020;8:457. doi:10.3389/fpubh.2020.00457

169. Taylor E. We Agree, Don't We? The Delphi Method for Health Environments Research. *HERD*. 2020;13(1):11-23. doi:10.1177/1937586719887709

170. Behrens A, Doyle JJ, Stern L, et al. Dysfunctional tear syndrome: a Delphi approach to treatment recommendations. *Cornea*. 2006;25(8):900-907. doi:10.1097/01.ico.0000214802.40313.fa

171. Armon K, Stephenson T, MacFaul R, Eccleston P, Werneke U. An evidence and consensus based guideline for acute diarrhoea management. *Arch Dis Child*. 2001;85(2):132-142. doi:10.1136/adc.85.2.132

172. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. *Man Ther*. 2011;16(5):440-446. doi:10.1016/j.math.2011.02.001

173. Carlesso LC, MacDermid JC, Santaguida PL, Thabane L. A survey of patient's perceptions of what is "adverse" in manual physiotherapy and predicting who is likely to say so. *J Clin Epidemiol*. 2013;66(10):1184-1191. doi:10.1016/j.jclinepi.2013.05.005

174. Funabashi M, Pohlman KA, Gorrell LM, Salsbury SA, Bergna A, Heneghan NR. Expert consensus on a standardised definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilisation: protocol for an international e-Delphi study. *BMJ Open*. 2021;11(11):e050219. doi:10.1136/bmjopen-2021-050219

175. Kranenburg HA, Lakke SE, Schmitt MA, Van der Schans CP. Adverse events following cervical manipulative therapy: consensus on classification among Dutch medical specialists, manual therapists, and patients. *J Man Manip Ther*. 2017;25(5):279-287. doi:10.1080/10669817.2017.1332556

176. Rosenthal R, Hoffmann H, Clavien PA, Bucher HC, Dell-Kuster S. Definition and Classification of Intraoperative Complications (CLASSIC): Delphi Study and Pilot Evaluation. *World J Surg*. 2015;39(7):1663-1671. doi:10.1007/s00268-015-3003-y

177. Zambaldi M, Beasley I, Rushton A. Return to play criteria after hamstring muscle injury in professional football: a Delphi consensus study. *Br J Sports Med*. 2017;51(16):1221-1226. doi:10.1136/bjsports-2016-097131

178. Van de Ven AH, Delbecq AL. The nominal group as a research instrument for exploratory health studies. *Am J Public Health*. 1972;62(3):337-342.

179. Potter M, Gordon S, Hamer P. The Nominal Group Technique: A useful consensus methodology in physiotherapy research. *New Zealand Journal of Physiotherapy*. 2004;32.

180. Harvey N, Holmes CA. Nominal group technique: an effective method for obtaining group consensus. *Int J Nurs Pract*. 2012;18(2):188-194. doi:10.1111/j.1440-172X.2012.02017.x

181. Sedgwick M, Spiers J. The Use of Videoconferencing as a Medium for the Qualitative Interview. *International Journal of Qualitative Methods*. 2009;8(1):1-11. doi:10.1177/160940690900800101

182. Kulczycki A, Shewchuk RM. Using Internet-based nominal group technique meetings to identify provider strategies for increasing diaphragm use. *J Fam Plann Reprod Health Care*. 2008;34(4):227-231. doi:10.1783/147118908786000550

183. Søndergaard E, Ertmann RK, Reventlow S, Lykke K. Using a modified nominal group technique to develop general practice. *BMC Fam Pract*. 2018;19(1):117. doi:10.1186/s12875-018-0811-9

184. Dorflinger LM, Kulkarni S, Thiessen C, Klarman S, Fraenkel L. Assessing Living Donor Priorities through Nominal Group Technique. *Prog Transplant*. 2018;28(1):29-35. doi:10.1177/1526924817746682

185. Evans N, Hannigan B, Pryjmachuk S, et al. Using the nominal group technique to involve young people in an evidence synthesis which explored 'risk' in inpatient mental healthcare. *Res Involv Engagem*. 2017;3:16. doi:10.1186/s40900-017-0069-8

186. Hutchings HA, Rapport FL, Wright S, Doel MA, Clement C, Lewis KE. Nominal Group Technique consultation of a Pulmonary Rehabilitation Programme. *F1000Res*. 2014;3:42. doi:10.12688/f1000research.3-42.v1

187. Fisher RJ, Riley-Bennett F, Russell L, et al. Nominal group technique to establish the core components of home-based rehabilitation for survivors of stroke with severe disability. *BMJ Open*. 2021;11(12):e052593. doi:10.1136/bmjopen-2021-052593

188. Keegan D, Heffernan E, McSharry J, Barry T, Masterson S. Identifying priorities for the collection and use of data related to community first response

and out-of-hospital cardiac arrest: protocol for a nominal group technique study. *HRB Open Res*. 2021;4:81. doi:10.12688/hrbopenres.13347.2

189. Wilson M, Thavorn K, Hawrysh T, et al. Stakeholder engagement in economic evaluation: Protocol for using the nominal group technique to elicit patient, healthcare provider, and health system stakeholder input in the development of an early economic evaluation model of chimeric antigen receptor T-cell therapy. *BMJ Open*. 2021;11(8):e046707. doi:10.1136/bmjopen-2020-046707

190. Michel DE, Iqbal A, Faehrmann L, et al. Using an online nominal group technique to determine key implementation factors for COVID-19 vaccination programmes in community pharmacies. *Int J Clin Pharm*. 2021;43(6):1705-1717. doi:10.1007/s11096-021-01335-x

191. Johnson BJ, Zarnowiecki D, Hutchinson CL, Golley RK. Stakeholder Generated Ideas for Alternative School Food Provision Models in Australia Using the Nominal Group Technique. *Int J Environ Res Public Health*. 2020;17(21):7935. doi:10.3390/ijerph17217935

192. McMillan SS, Kelly F, Sav A, et al. Using the Nominal Group Technique: how to analyse across multiple groups. *Health Serv Outcomes Res Method*. 2014;14(3):92-108. doi:10.1007/s10742-014-0121-1

193. Bradley F, Schafheutle EI, Willis SC, Noyce PR. Changes to supervision in community pharmacy: pharmacist and pharmacy support staff views. *Health Soc Care Community*. 2013;21(6):644-654. doi:10.1111/hsc.12053

194. Hutchings HA, Rapport FL, Wright S, Doel MA, Wainwright P. Obtaining consensus regarding patient-centred professionalism in community pharmacy: nominal group work activity with professionals, stakeholders and members of the public. *Int J Pharm Pract*. 2010;18(3):149-158.

195. Vella K, Goldfrad C, Rowan K, Bion J, Black N. Use of consensus development to establish national research priorities in critical care. *BMJ*. 2000;320(7240):976-980.

196. Allen J, Dyas J, Jones M. Building consensus in health care: a guide to using the nominal group technique. *Br J Community Nurs*. 2004;9(3):110-114. doi:10.12968/bjcn.2004.9.3.12432

197. Templates for informed consent forms. Accessed October 13, 2022. https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

198. Feld AD. Informed consent: not just for procedures anymore. *Am J Gastroenterol*. 2004;99(6):977-980. doi:10.1111/j.1572-0241.2004.40520.x

199. Lloyd A. The extent of patients' understanding of the risk of treatments. *Qual Health Care*. 2001;10(Suppl 1):i14-i18. doi:10.1136/qhc.0100014..

200. Pandiya A. Readability and comprehensibility of informed consent forms for clinical trials. *Perspect Clin Res*. 2010;1(3):98-100.

201. Samadi A, Asghari F. Readability of informed consent forms in clinical trials conducted in a skin research center. *J Med Ethics Hist Med*. 2016;9:7.

202. Pascarella G, Rossi M, Montella E, et al. Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables. *Risk Manag Healthc Policy*. 2021;14:2897-2911. doi:10.2147/RMHP.S309098

203. Sherlock A, Brownie S. Patients' recollection and understanding of informed consent: a literature review. *ANZ J Surg*. 2014;84(4):207-210. doi:10.1111/ans.12555

204. Weise A, Lühnen J, Bühn S, et al. Development, piloting, and evaluation of an evidence-based informed consent form for total knee arthroplasty (EvAb-Pilot): a protocol for a mixed methods study. *Pilot Feasibility Stud*. 2021;7(1):107. doi:10.1186/s40814-021-00843-x