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Pediatric Wound Care: What Can We Learn From A Systematic Review Of The Literature? Using A Systematic Review And A Clinical Consensus Group To Assess The Quality And Content Of Systematic Reviews Focusing On Pediatric Wound Care. Then Providing And Analytical Outline For Creation Of Pediatric Wound Care Guidelines For Evidence Based Clinical Practice

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PEDIATRIC WOUND CARE: WHAT CAN WE LEARN FROM A SYSTEMATIC REVIEW OF THE LITERATURE?

USING A SYSTEMATIC REVIEW AND A CLINICAL CONSENSUS GROUP TO ASSESS THE QUALITY AND CONTENT OF SYSTEMATIC REVIEWS FOCUSING ON PEDIATRIC WOUND CARE. THEN PROVIDING AND ANALYTICAL OUTLINE FOR CREATION OF PEDIATRIC WOUND CARE GUIDELINES FOR EVIDENCE BASED CLINICAL PRACTICE.

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Background: Wound care practices for neonatal and pediatric patients including the category of products, specific products within each category, and length of application of the products have created lack of standardized evidence-based guidelines for treatments in clinical practices. This dissertation addresses this concern by encompassing three crucial steps in developing evidence-based clinical guidelines for wound care specialists. Using a three-paper method, an expert consensus group was formed, a systematic review of reviews completed and a process for creating clinical decision trees created. Methods: Criteria for selection of the consensus group members included: 1) Research graduate active in Pediatric Wound Care research, 2) Board certified Physicians actively practicing in their aforementioned pediatric general surgery or pediatric plastic surgery subspecialty, and 3) Wound Ostomy Care Nurse actively practicing in Pediatric wound care. An adapted questionnaire was created to address eligibility criteria, information sources, systematic review database search strategy, study selection criteria including keywords, the clinical consensus group's experience with clinical

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guideline development, and finally other clinically significant domains that the evidence should be evaluated for. Using domains identified, a systematic review of reviews was completed. PRISMA and AMSTAR were used to assess quality of reporting and quality of the evidence. Results and Conclusions: The consensus group members polled have been proficient in pediatric wound care for several years with the majority of the members practicing for more than 10 years within a hospital setting. Duration and lengths of discussion meetings whether in person or via electronic interface as well as how data collected was reviewed and analyzed, i.e. in person face to face or via conference call, was the driving force in establishing search domains. The articles found in the domain search identified themselves differently, with some identifying themselves as a systematic review, literature review, meta-analysis, or a combination of the two. It was determined that no true "gold standard" for assessing systematic reviews exists. Because this is the first systematic review of systematic reviews in wound care specifically, SRs of SRs in other healthcare related fields were relied upon.

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Pediatric Wound Care Background

Rationale

Nearly six million people, from adults to children, suffer from chronic wounds every year. With more than 1.25 million burns in the Unites States annually and 6.5 million chronic skin ulcers caused by pressure, venous stasis, or diabetes mellitus, it is no wonder why advanced wound healing has become a topic of ongoing research and debate [Sood et al].

The pediatric management of wound care in the United States is a growing concern among the few wound care clinics across the country. The increasing complexity of medical and surgical treatment plans used for the pediatric population has resulted in a population of significant risk for complications such as non-healing surgical wounds, pressure ulcers, and moisture associated skin damage. Wound care practices for the neonatal and pediatric patients including the category of products, specific products within each category, and length of application of the products have created lack of standardized evidence-based guidelines for treatments in clinical practices. Factors that have resulted in this variability in the practice gap include provider experience with the products, product availability, provider preference, or a small number of published clinical guidelines based on expert opinion.

Understanding wound healing at multiple levels—biochemical, physiologic, cellular and molecular provides the provider with a framework for basing clinical decisions aimed at optimizing the healing response [Chhabra et al]. Treating pediatric wounds requires a much different approach than tending to wounds in adults, which adds further complexity to the decision-making process for providers regarding wound care in these populations. Proper treatment of wounds and the type of dressings, including topical healing agents, has been at

the center of systematic reviews since before the turn of the century as standard operating procedures for the treatment management of wounds vary from clinic to clinic. Using advanced wound treatments including debridement, negative pressure therapy, ointment-impregnated dressings, and skin grafting are key to healing chronic wounds such as pressure ulcers, surgical wounds, epidermal stripping, intravenous extravasation injuries, and moisture-associated skin damage wounds.

Wound Management Issues in Pediatrics

The weak point of evidence on the clinical efficacy of proper dressing criteria is reportedly related to the low strength of research and database efficiency. Despite rapid advances in medical and nursing care of pediatric patients and the increasingly complex level of care provided, there has been limited formal assessment of the prevalence, type, and management of wounds in this population. Four basic phases are considered when healing complex wounds: coagulation and hemostasis, inflammation, proliferation and repair, and wound maturation and remodeling. Current research reveals that hospitalized pediatric populations are at significant risk for the development of these complex wounds [King, et al]. Multisite studies of tertiary-care children's hospitals revealed 43% of patients had a wound associated with a surgical incision, 16% of patients developed diaper dermatitis and 6% of patients were thought to be at risk for developing pressure ulcers. Of the patients who developed pressure ulcers, 66% were found to be facility associated. Among the children discharged from the hospitals and receiving home health care, 17% of children still had the chronic wound and relied heavily on provider knowledge and consensus for the most

appropriate standard of care. Pressure ulcers and open surgical wounds among this pediatric population often were cleansed with hydrogen peroxide, household soap, or povidone-iodine – 44% were treated with dry gauze and 19% with normal saline dampened gauze; however, more than 90% of the home care nurses interviewed for this study described the pediatric wound care as appropriate [Baharestani 2007].

Importance of Understanding Advanced Wound Care

Unfortunately, published clinical guidelines for the evaluation and management of wounds in pediatric populations is limited, and none of these guidelines have undergone rigorous assessment. Wound care practices and the selection of wound care product usage currently reflects the provider's experience with and knowledge of wound care management [King, et al]. Not only is it imperative to understand the advanced treatment of wounds, it's also important to understand the cost analysis of clinician time and financial resources required to administer the proper treatment protocol. The annual cost of caring for chronic wounds in the United States approaches US $25 billion. The wound management market is estimated to reach a value of US $4.4 billion in 2019 from US $3.1 billion in 2012. Practitioners can mitigate excessive resource utilization by selecting the optimal wound dressings for patients [Dabiri et al].

To negate the high costs of wound management, some patients have resorted to traditional, natural wound care for home health care. Despite recent advances in wound care products, traditional therapies based on natural origin compounds, such as plant extracts, honey, and larvae, are interesting alternatives. These therapies offer new possibilities for the

treatment of skin diseases, enhancing access to healthcare, and allowing overcoming some limitations associated to the modern products and therapies, such as the high costs, the long manufacturing times, and the increase in the bacterial resistance [Pereira et al].

The focus of these papers is to use a Clinical consensus group to identify appropriate search terms and databases that will be used for a systematic review of systematic reviews (SR). The SR of SRs will be displayed and reported, exploring the strengths and limitations of pediatric wound care management strategies and reporting approaches aimed at improving wound care management in hospitals and within home health care. Finally, I will be developing an analytical tool, with the partnership of the clinical consensus group, to determine how to best create evidence-based decision trees.

Paper 1 – Paper 1 Pediatric Wound Care: Using a clinical consensus group to ensure content assessment for a systematic review of literature.

Aims:

1) Identified international thought leaders following stakeholder mapping and convene consensus body
2) Identified key search terms and databases for systematic review of systematic review
3) Determined the domains that were clinically significant to include in reporting the evidence of the systematic review

Paper 2 – Use of systematic review results to develop policy for Pediatric Wound Care using an evidence-based approach.

Aims: Utilize the results of the systematic review to:

1) Explore the strengths and limitations of wound care management strategies aimed at improving wound management

2) Determine the strengths and limitations of reporting approaches used for pediatric wound care strategies aimed at improving wound management using the Prisma and Amstar 2 guidelines for qualitative analysis.

Paper 3 - Provide analytical outline for creation of draft decision trees for evidence based clinical practice.

Aims: Utilize the results of the systematic review of systematic reviews and the consensus group to:

1) Provide analytical outline for creation of draft decision trees for evidence based clinical practice guidelines

JOURNAL ARTICLE

Title of Journal Article - Pediatric Wound Care: Using a Clinical Consensus Group to Ensure Content Assessment for a Systematic Review of Literature.

Name of Journal Proposed for Article Submission - Advisor

Background

The pediatric management of wound care in the United States is a growing concern among the few wound care clinics across the country. The increasing complexity of medical and surgical treatment plans used for the pediatric population has resulted in a population of significant risk for complications such as non-healing surgical wounds, pressure ulcers, and moisture associated skin damage. Wound care practices for the neonatal and pediatric patients including the category of products, specific products within each category, and length of application of the products have created lack of standardized evidence-based guidelines for treatments in clinical practices. Factors that have resulted in this variability in the practice gap include provider experience with the products, product availability, provider preference, or a small number of published clinical guidelines based on expert opinion.[1-3]

Treating pediatric wounds requires a much different approach than tending to wounds in adults, which adds further complexity to the decision-making process for providers regarding wound care in these populations.[3,4] Understanding wound healing at multiple levels—biochemical, physiologic, cellular and molecular provides the provider with a framework for basing clinical decisions aimed at optimizing the healing response.[5] Using advanced wound treatments including debridement, negative pressure therapy, ointment-

impregnated dressings, and skin grafting are key to healing chronic wounds such as pressure ulcers, surgical wounds, epidermal stripping, intravenous extravasation injuries, and moisture-associated skin damage wounds.

Proper treatment of wounds and the type of dressings, including topical healing agents, has been at the center of systematic reviews since before the turn of the century as standard operating procedures (SOPs) for the treatment management of wounds vary from institution to institution. Systematic reviews (SRs) can be a useful tool when the data collected adequately pertains to the population of interest in generating SOPs. In our case, it is pediatrics. With the quality of systematic reviews being dependent on existing literature, it is important to recognize the need to assess content and quality of the current SRs in publication in relation to the development of pediatric wound management guidelines.

Wound Management Issues in Pediatrics

The weak point of evidence on the clinical efficacy of proper dressing criteria is reportedly related to the low strength of research and database efficiency. Despite rapid advances in medical and nursing care of pediatric patients and the increasingly complex level of care provided, there has been limited formal assessment of the prevalence, type, and management of wounds in this population. Four basic phases are considered when healing complex wounds: coagulation and hemostasis, inflammation, proliferation and repair, and wound maturation and remodeling. Current research reveals that hospitalized pediatric populations are at significant risk for the development of these complex wounds.[3] Multisite studies of tertiary-care children's hospitals revealed 43% of patients had a wound associated

with a surgical incision, 16% of patients developed diaper dermatitis and 6% of patients were thought to be at risk for developing pressure ulcers. Of the patients who developed pressure ulcers, 66% were found to be facility associated. Among the children discharged from the hospitals and receiving home health care, 17% of children still had the chronic wound and relied heavily on provider knowledge and consensus for the most appropriate standard of care. Pressure ulcers and open surgical wounds among this pediatric population often were cleansed with hydrogen peroxide, household soap, or povidone-iodine – 44% were treated with dry gauze and 19% with normal saline dampened gauze; however, more than 90% of the home care nurses interviewed for this study described the pediatric wound care as appropriate.[6]

Importance of Understanding Advanced Wound Care

Unfortunately, published clinical guidelines for the evaluation and management of wounds in pediatric populations is limited. Wound care practices and the selection of wound care product usage currently reflects the provider's experience with and knowledge of wound care management.[1,3] Not only is it imperative to understand the advanced treatment of wounds, it's also important to understand the cost analysis of clinician time and financial resources required to administer the proper treatment protocol. Nearly six million people, from adults to children, suffer from chronic wounds every year. With more than 1.25 million burns in the Unites States annually and 6.5 million chronic skin ulcers caused by pressure, venous stasis, or diabetes mellitus, it is no wonder why advanced wound healing has become a topic of ongoing research and debate.[7] The annual cost of caring for chronic wounds in the United States approaches US $25 billion. The wound management market is estimated to reach a value

of US $4.4 billion in 2019 from US $3.1 billion in 2012. Practitioners can mitigate excessive resource utilization by selecting the optimal wound dressings for patients.[8]

The use of evidence-based practice in wound care is essential in achieving better patient outcomes and has the potential to reduce hospital wound care costs.[9] Clinical Consensus Statements (CCS) are at the forefront of driving clinical decision-making process in other fields of medicine; whereas, evidence-based guidelines for wound care management have been lacking for the last 20 years.

Clinical Consensus Statements and Expert Groups

Clinical consensus statements reflect opinions drafted by content experts for which consensus is sought using explicit methodology to identify areas of agreement and disagreement. A CCS is most applicable to situations where the evidence base is insufficient for a clinical practice guideline (CPG) but for which significant practice variations and quality improvement opportunities exist.[10] This CCS is based on the views of subject expect panelists who actively treat pediatric patients in the field of wound care. The outcomes of this type of CCS are to 1) identify domains of expert consensus regarding the costs associated with a wound care product and the treatment of the wound, the duration of the wound treatment, the ease of performing the wound treatment on pediatric patients, the accessibility of the product in the health care industry, the available storage of the product, and the length of time pertaining to applying the product or treatment to the wound; 2) identify the indications for surgical intervention on different types of wounds; 3) perioperative management of the wound, and 4) to review the expected outcomes of the review. The core result of a CCS is derived from

an adapted Delphi method survey. The Delphi method is a systematic, iterative approach to identifying consensus without face-to-face interaction.[10]

Clinical decision-making for the creation of CPG is defined as the process of gathering information to enable clinicians to make a judgement about a course of action.[9] There are currently only a limited number of published clinical guidelines for the evaluation and management of wounds in the neonatal and pediatric populations. To date, none of these have undergone the rigorous assessment required for the generation of evidence-based guidelines. As such, wound care practices and selection of wound care products tend to reflect provider experience and preference. Only three qualitative studies published over the last 20 years have described clinical decision-making in wound care.[9] Luker and Kenrick (1992) found that decisions were informed by knowledge, based either on research, practice underpinned by experience, or commonsense.[11] Ideally, a clinical guideline should be developed to assist practitioners faced with infants and children with different types of wounds, and to allow these practitioners to make an informed decision on the proper treatment.

Developing Guideline Development Groups

Identifying stakeholders involves identifying all the groups whose activities would be covered by the guideline or who have other legitimate reasons for having an input into the process. This is important to ensure adequate discussion of the evidence (or its absence) when developing the recommendations in the guideline. When presented with the same evidence a single specialty group will reach different conclusions than a multidisciplinary group—the specialty group will be systematically biased in favor of performing procedures in which it has

a vested interest.[12,13] Ideally the group should have at least six but no more than 12-15 members; too few members limits adequate discussion and too many members makes effective functioning of the group difficult.[14]

Consensus groups are increasingly being used to develop clinical guidelines which define key aspects of the quality of health care, particularly appropriate indications for interventions. Given the resources required to identify all relevant primary studies, many guidelines rely on systematic reviews that were either previously published or created de novo by guideline developers. Systematic reviews can aid in guideline development because they involve searching for, selecting, critically appraising, and summarizing the results of primary research. Most systematic reviews rely substantially on the foundational understanding of the researcher on the topic of discussion.

The five steps of guideline development include 1) Identifying and refining the subject area is the first step in developing a guideline 2) Convening and running guideline development groups is the next step 3) On the basis of systematic reviews, the group assesses the evidence about the clinical question or condition 4) This evidence is then translated into a recommendation within a clinical practice guideline 5)The last step in guideline development is external review of the guideline. The focus of the paper will be identifying a consensus group to ensure appropriate clinical expertise for the systematic review. The goal of this study is to obtain consensus among experts about pediatric wound care who will be proficient in the field of pediatric wound care. The goal of this guideline development group will be to produce recommendations in the light of the evidence or in the absence of, i.e. the systematic review table to be created for future considerations.

Methods

Formation of the Expert Consensus Group

Our goal was to recruit a multidisciplinary team that will consist of board-certified Pediatric Plastic and Pediatric General Surgeons that are active in the International Society of Pediatric Wound Care (ISPEW). The goals of the International Society of Pediatric Wound Care (ISPeW) are to 1) set global standards for the assessment and treatment of pediatric wounds of varying etiologies; 2) provide a forum for international, interprofessional collaboration among healthcare professionals, researchers, educators and industry leaders dedicated to the care of pediatric wounds; 3) promote and support clinical research focused on the prevention, assessment and treatment of pediatric wounds; 4) collaborate with wound care organizations worldwide on pediatric wound care issues; and 5) provide evidence based pediatric wound care education to healthcare professionals, parents and lay caregivers.

The President of ISPEW was contacted and the details of the projects were discussed. Criteria for selection of the consensus group members included: 1) Research graduate active in Pediatric Wound Care research, 2) Board certified Physicians actively practicing in their aforementioned pediatric general surgery or pediatric plastic surgery subspecialty, and 3) Wound Ostomy Care Nurse actively practicing in Pediatric wound care. The President selected 6 individuals (2 from each category) and emailed them inquiring about their interest in participating in the research study. (Demographics included in the results section) All recruited individuals were emailed and agreed to participate after a detailed description of the research project was explained.

Creation of a web-based questionnaire

An adapted questionnaire was created for this study using the Clinician Guideline Determinants Questionnaire, which is a comprehensive, validated instrument that addresses multiple potential determinants specific to guideline use from a clinician perspective[15]. The Questionnaire can be used at multiple time points in the guideline development cycle to assess determinants of the use of new, updated, or adapted guidelines and before and after interventions to assess their impact on the determinants of guideline use[15]. For this study, the adapted questionnaire was created to address Eligibility Criteria, Information sources, systematic review database search strategy, study selection criteria including keywords, the clinical consensus group's experience with clinical guideline development, and finally other clinically significant domains that the evidence should be evaluated for. Domains were created and the consensus group was polled to determine if the evidence should be displayed using certain criteria. Additional domains that can be considered include applicability of the evidence to the population of interest (its generalizability), costs, knowledge of the healthcare system, and beliefs and values of the panelists. These additional domains were extracted from pediatric wound care clinics in which patients voiced and experienced these concerns throughout their treatments. In the adapted survey used for this study, search domains included types of wounds treated by each of the consensus group members such as pressure ulcers, surgical wounds, epidermal stripping, etc. The conducted survey was then used to derive the most crucial information recorded at each of the members' practices and institutions pertaining to the listed types of wounds treated.

Data Collection and Analysis

Survey Monkey was used to create an online instrument with 16 questions ranging from demographic related questions, Systematic Review details, and domain inquiries (see Appendix 1). Responses were downloaded from Survey Monkey for descriptive analysis.

Results

The results from the survey monkey created online yielded the recorded data shown in Figure 1 and Figure 2. Each of the polled consensus group members provided the number of years in their current role within their respective institutions and the length of experience with pediatric wound care management.

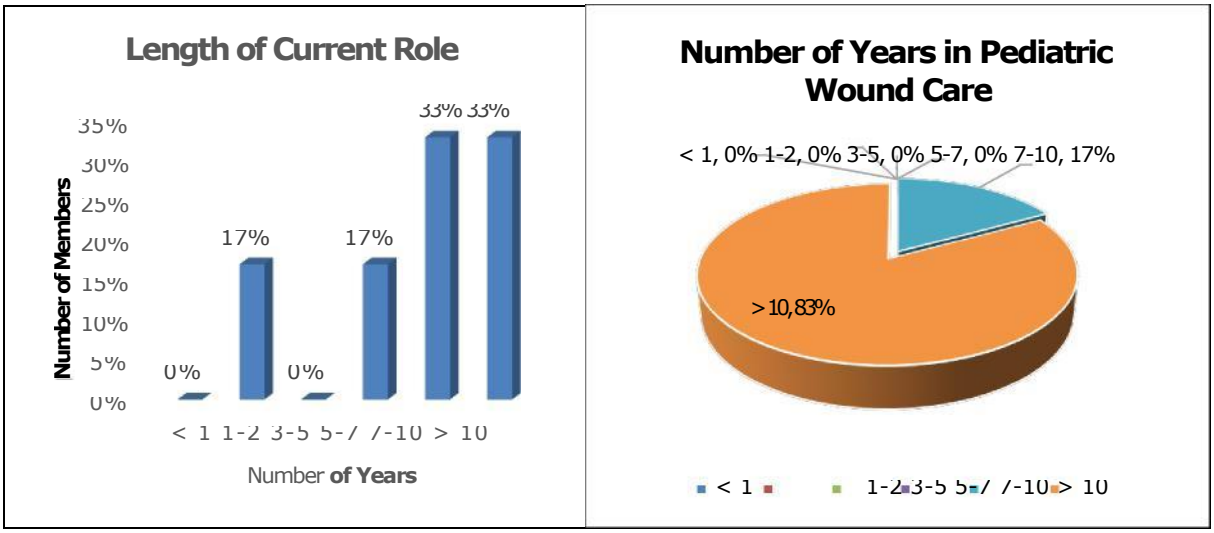


Figure 1. Shown is the length of the current role of each of the consensus group members.

Figure 2. Shown is the number of years each of the consensus group members has spent in pediatric wound care.

As a secondary part of the survey, each of the consensus group members was asked to provide the type of communication experienced during their participation with previous clinical consensus statement development groups. The type of communication was suggested and confirmed by each of the members, and the data recorded in Table 1.

Type of Communication	**Number of Responses**	**Percentage Value**
In-Person Meetings	5	83%
Conference Call Meetings	4	67%
Email Communication	5	83%
No Participation in Guideline Development	0	0%
Other	0	0%

Table 1. Shown are the types of recorded communications used during this survey and other reviewed surveys.

The final pieces of pertinent information recorded during the conducted survey of the consensus group members would be the driving force behind future systematic reviews and future research interests. The recorded data in Table 2 and Table 3 were used to create search domains for future systematic reviews based on the more crucial information on which each of the consensus group members concentrate within each of their practices and institutions.

Type of Wounds Treated	**Number of Responses**	**Percentage Value**
Pressure Ulcers	5	83%
Surgical	5	83%

Intravenous Extravasation Injuries	5	83%
Epidermal Stripping	5	83%
Moisture-associated Skin Damage	5	83%
Advanced Wound Therapy Treatments	5	83%

Table 2. Shown are the types of wounds treated by each of the consensus group members.

Clinical Decision-making Domains	**Number of Responses**	**Percentage Value**
Costs of Product/Treatment	5	83%
Duration of Treatment	6	83%
Ease of Applying Product/Performing Treatment	6	83%
Accessibility of Product	4	83%
Storage of Product	3	83%
Length of Time to Apply Product/Perform Treatment	5	83%

Table 3. Shown are the search domains for future systematic reviews each of the consensus group members found to be most crucial to their practices and institutions.

Discussion

As seen from the literature review and conducted surveys, there remains only a limited number of published clinical guidelines for the evaluation and management of wounds in the neonatal and pediatric populations, and consensus groups are increasingly being used to develop clinical guidelines for future wound care management. Questionnaires are a commonly used approach for identifying determinants because they are relatively inexpensive, reach a large audience, and convenient for busy health care professionals, particularly when

administered online. Although guideline developers lack the resources and capacity to themselves develop and validate determinant questionnaires, the need for a validated guideline determinants questionnaire is widespread.[15]

As shown from the survey, the consensus group members polled have been proficient in pediatric wound care for several years with the majority of the members practicing for more than 10 years within a hospital setting. These survey results are consistent with other conducted surveys given to consensus groups of previous wound care studies where the majority of the polled members are leaders in their field and have all previously played a vital role in clinical guideline development consensus groups.

Throughout this study, previous clinical guideline development projects have recorded several key pieces of information pertaining to decisions concerning the domains of wound care management and which have been the most crucial for successful treatment and overall patient satisfaction. These domains have shown to be driven by various methods of focus during the survey process in both our study and previously reviewed studies in literature including duration and lengths of discussion meetings whether in person or via electronic interface as well as how data collected was reviewed and analyzed, i.e. in person face to face or via conference call.

The resulting focuses from the survey process will play a vital role in determining the precise domains necessary to complete the systematic review process required for a consensus-based clinical guideline development protocol in pediatric wound care. With the addition of a full systematic review of recently reviewed literature, wound care treatments, procedures and

products will be further analyzed and compared to provide one of the most up-to-date evaluations in pediatric wound care management.

Conclusion

The goal of this study is to obtain consensus among experts about pediatric wound care. Through the use of this Consensus group and conducted surveys, we were able to identify a more complete systematic review process, as well as identify additional domains that are important in clinical practice. These results revealed true clinical insight into databases, search terms, and domains that provide the most impact to pediatric wound care. The next steps will to conduct the Systematic review and use the clinical consensus group to develop clinical guidelines for standardization of treatment plans for the pediatric wound patient.

REFERENCES

1. Boyar, V. Issues in Pediatric Wound Care. Wound Management & Prevention. 2019; 61(1):10.
2. Black KD, Cico SJ, Caglar D. Wound Management. Pediatrics in Review. 2015; 36(5): 207-216.
3. King A, Stellar J, Blevins A, Shah K. Dressings and Products in Pediatric Wound Care. Advances in Wound Care. 2014; 3(4): 324-334.
4. McCord S, Levy ML. Practical Guide to Pediatric Wound Care. Semin Plast Surg. 2006; 20(3): 192-199.
5. Chhabra N, Kaur A, Gupta N. Wound Healing Concepts in Clinical Practice of OMFS. J Maxillofac Oral Surg. 2017; 16(4): 403–423. DOI 10.1007/s12663-016-0880-z.
6. Baharestani MM. An overview of neonatal and pediatric wound care knowledge and considerations. Ostomy Wound Management, 2007; 53(6): 34-36, 38, 40 passim.
7. Sood A, Granick MS, Tomaselli NL. Wound Dressing and Comparative Effectiveness Data. Advances in Wound Care. 2014; 3(8): 511-529. DOI: 10.1089/wound.2012.0401.
8. Dabiri G, Damstetter E, Phillips T. Choosing a Wound Dressing Based on Common Wound Characteristics. Advances in Wound Care. 2016; 5(1): 32-41. DOI: 10.1089/wound.2014.0586.
9. Gillespie BM, Chaboyer W, John WS, Morley N, Nieuwenhoven P. Health professionals' decision making in wound management: a grounded theory. JAN: Original Research: Empirical Research-Qualitative. 2014; 4: 1238-1248.

10. Rosenfeld RM, Nnacheta LC, Corrigan MD. Clinical Consensus Statement Development Manual. Otolaryngology–Head and Neck Surgery. 2015; 153(2S): S1–S14. DOI: 10.1177/0194599815601394.

11. Luker KA, Kenrick M. An exploratory study of the sources of influence on the clinical decisions of community nurses. Journal of Advanced Nursing, 1992; 17: 457466.

12. Kahan JP, Park RE, Leape LL, Bernstein SJ, Hilborne LH, Parker L, et al. Variations by specialty in physician ratings of the appropriateness and necessity of indications for procedures. Med Care. 1996; 34: 512-23.

13. Coulter I, Adams A, Shekelle P. Impact of varying panel membership on ratings of appropriateness in consensus panels: a comparison of a multi- and single disciplinary panel. Health Serv Res, 1995; 30(4): 577-591.

14. Schmeer K. Stakeholder Analysis Guidelines.Bethesda.USA, Abt Associates, 1999.

15. Gagliardi AR, Armstrong MJ, Bernhardsson S, Fleuren M, Hernandez HP, Vernooij RWM, Willson M, Guidelines International Network Implementation Working Group. The Clinician Guideline Determinants Questionnaire was developed and validated to support tailored implementation planning. Journal of Clinical Epidemiology. 2019; 113: 129-136. DOI: org/10.1016/j.jclinepi.2019.05.024.

16. Boulkedid R, Abdoul H, Loustau M, Sibony O, Alberti C. Using and Reporting the Delphi Method for Selecting Healthcare Quality Indicators: A Systematic Review. PLoS ONE. 2011; 6(6): e20476. DOI:10.1371/journal.pone.0020476.

17. O'Meara S, Cullum N, Majid M, Sheldon T. Systematic Reviews of Wound Care Management: Antimicrobial Agents for Chronic Wounds; Diabetic Foot Ulceration. Health Technol Assess. 2000; 4(21): 1-237.

Title of Journal Article - Assessing Quality and Content of Systematic Reviews in Pediatric Wound Care

Name of Journal Proposed for Article Submission - Advances in Wound Care

Background

Treating pediatric wounds requires a considerably different approach than tending to wounds in adults, which adds further complexity to the decision-making process for providers regarding wound care in these populations.[1] Understanding wound healing at multiple levels—biochemical, physiologic, cellular and molecular--provides the provider with a framework for basing clinical decisions aimed at optimizing the healing response. Using advanced wound treatments including debridement, negative pressure therapy, ointment-impregnated dressings, and skin grafting are key to healing chronic wounds such as pressure ulcers, surgical wounds, epidermal stripping, intravenous extravasation injuries, and moisture-associated skin damage wounds.[1] Proper treatment of wounds and the type of dressings, including topical healing agents, has been at the center of systematic reviews since before the turn of the century as standard operating procedures (SOPs) for the treatment and management of wounds vary from institution to institution. Systematic reviews (SRs) can be a useful tool when the data collected adequately pertains to the population of interest in generating SOPs. In this case, the pediatric population. Unfortunately, published clinical guidelines for the evaluation and management of wounds in pediatric populations is limited. Wound care practices and the selection of wound care product usage currently reflects the provider's experience with and knowledge of wound care management.[2,3] Not only is it imperative to understand the advanced treatment of wounds,

it's also important to understand the cost analysis of clinician time and financial resources required to administer the proper treatment protocol. The use of evidence-based practice in wound care is essential in achieving better patient outcomes and has the potential to reduce hospital wound care costs.[4] The purpose of this article is to objectively quantify the number of systematic reviews available on pediatric wound care and assess the quality of the existing studies within those systematic reviews. Our aim is to address several aspects of pediatric wound care, including: the number of existing reviews that are relevant to wound care decision-making, the aims of these existing systematic reviews and if existing reviews have addressed the validated domains from clinical experts and practitioners.

Methods

Our systematic review process was guided by a clinical consensus group made up of expert clinicians in the field of pediatric wound care [Paper 1]. Briefly, clinicians were surveyed to determine the search terms, databases, and domains that would be included in this systematic review. The domains reviewed were validated from the clinical consensus group and will allow us to determine how many of the systematic reviews' report evidence in a format to address clinically related domains. These domains included cost of the product, duration of the treatment, ease of applying the product, accessibility of the product/treatment, storage of the product, length of time to apply or perform the treatment and pain associated with the treatment. This systematic review followed the publishing guidelines as set forth by PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). (See Appendix XX). The PRISMA system is an evidence-based minimum set of items for reporting in systematic

reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.[5]

Eligibility Criteria

Published systematic reviews printed in the English language from the past decade (1/1/2009-12/31/2019) were the primary eligibility criteria. Reviews had to include at least one paper in their analysis with pediatric ages 0-17 years in their population. The reviews could include or originate from any country. In addition, articles that conducted reviews in a systemized way, with or without quantitative analysis were also included.

Search Strategy

A comprehensive review was conducted using PubMed (NLM), Academic Search Complete (EbscoHOST), Cochrane and MEDLINE databases. The wound type search terms were “pressure ulcers”, “pressure injuries”, “surgical wounds”, “epidermal stripping”, “intravenous extravasation injuries”, “moisture-associated skin damage” and “advanced wound therapy”. Each wound type term was searched separately through databases based on inclusion criteria. When possible, advanced filters were used and applied to efficiently facilitate search results. For example, in Academic Search Complete, “systematic review” was checked and years of publication was specified.

Screening

Literature results displaying titles only were then exported into a Word document for review and compiled. A single reviewer then excluded articles by title and abstract, when necessary.

Study Extraction and Selection

Screened articles were then compiled into a single Excel workbook at which time two reviewers (SH and RK) determined what to include or exclude. Discrepancies were then discussed and finalized between the two reviewers. Articles considered for inclusion were then divided between the two reviewers to assess. A list of excluded citations from both the screening step and the full text review step will be available from the author. See Figure 1 for the article selection flow chart.

Quality Assessment

There is currently no standardized methodology of assessing the quality of systematic reviews of systematic reviews. Assessment was conducted per the recommendations of Smith et al.[6] and Bigby et al.[7] using PRISMA and AMSTAR checklist per included review. Both authors administered the checklist simultaneously for three articles to ensure interrater reliability. There were no discrepancies. The remaining articles were then divided, reviewed and scored separately by each reviewer. Risk of bias and heterogeneity within the reviews were then discussed to be included narratively (Table 2).

Consensus Group Domains

Two domain checklists were created in an Excel file. In domain checklist A, the first author recorded whether or not the reviews included any of the domains in their primary or secondary outcomes. Domain checklist B contained information pertaining to the articles within the reviews addressed the domains (Table 3).

Results

Four hundred and ten records were identified between all databases. Of these, 77 focused on pressure ulcers/injuries, 310 on surgical wounds, 3 on IV infiltration/extravasation and 20 were on advanced wound care therapy. No articles were found on epidermal stripping or moisture-associated skin damage, and after duplicate articles were removed, 403 were screened. We excluded 292 articles for the following reasons: 1) they did not include a pediatric population; and 2) they were not systematic reviews or the articles did not address wounds or wound treatment. Because inclusion criteria were not explicitly apparent in the article titles, a secondary process was conducted by the authors reviewing abstracts of the 111 abstracts to identify the **P**atient population, the **I**ntervention, the alternative in **C**omparison, and the **O**utcome (PICO) or inclusion criteria of the reviews. If the information was not apparent in the abstract, the full text was reviewed. An additional 103 articles were excluded in this process. Only 8 articles remained and were assessed for methodological quality and content (Fig 1). Due to scope and heterogeneity, quantitative meta-analysis could not be conducted.

Characteristics

Characteristics of included reviews are displayed in Table 1. Four articles identified themselves as systematic reviews and meta-analysis.[8-11] Two of the articles were integrative reviews that followed PRISMA statement[12,13], and one article was a systematic review without meta-analysis. The final article identified as a literature review only. A majority of the reviews (5/8) were aimed towards pressure ulcers/injuries and were not randomized control trial focused. These focused more on assessing risk, prevalence, and bundle implementation. The other three reviews focused on surgical (including burns) and aimed to assess quality of conventional or randomized trials. Two reviews included mostly randomized control trials[9,11], whereas the remaining six were compiled of mostly other types of articles such as retrospective observational studies and quality improvement. Of the three reviews that included both pediatric and adult populations, 15 out of 48 studies included pediatric focus.[8,11] Exact age and mean of conglomerate pediatric population could not be calculated considering not all reviews reported age details. All but one review, Ferreira et al.[12], reported methodology of quality assessment.

Quality Assessment

AMSTAR and PRISMA checklist results are displayed in tables 3 and 4 respectively. Although there may not be a way to summarize the checklists for overall quality of the reviews, the authors intend to provide a one-stop reference for researchers in further evaluating the trends and methodology applied. All articles consisted of at least 5 of the 11 AMSTAR conditions, with the Ferreira et al.[12] having the least number of conditions. Jackson et al.[8]

comprised the most conditions while lacking a list of excluded references. AMSTAR conditions 5 (included and excluded references) and 10 (discussion of publication bias) were primarily not included in each of the reviews. In addressing the PRISMA assessment, all reviews included conditions 3 (rationale), 9 (methods study selection), 10 (data collection process), 17 (results study selection), and 26 (conclusions). The reviews that consisted of most PRISMA conditions were systematic reviews and meta-analyses, including those published in the Cochrane database.[8-11]

Domains

In reviewing the domains that were reviewed in each of the systematic reviews, the cost of the product was addressed in two reviews. Three articles addressed duration of the treatment, one addressed the ease of applying, two addressed the length of time to apply/perform the treatment, one review addressed pain association, and no reviews addressed accessibility of the product or its storage. In some cases, the articles still met all inclusion criteria; yet the authors deemed the reviews not applicable to certain domains; therefore, they were not reported (Table 3). Although the objectives of included reviews did not focus on the consensus group's domains, a supplementary table was created (Table 4) to present instances where articles or studies within the 8 included reviews discussed the consensus group domains.

Figure 3. PRISMA Flow Diagram

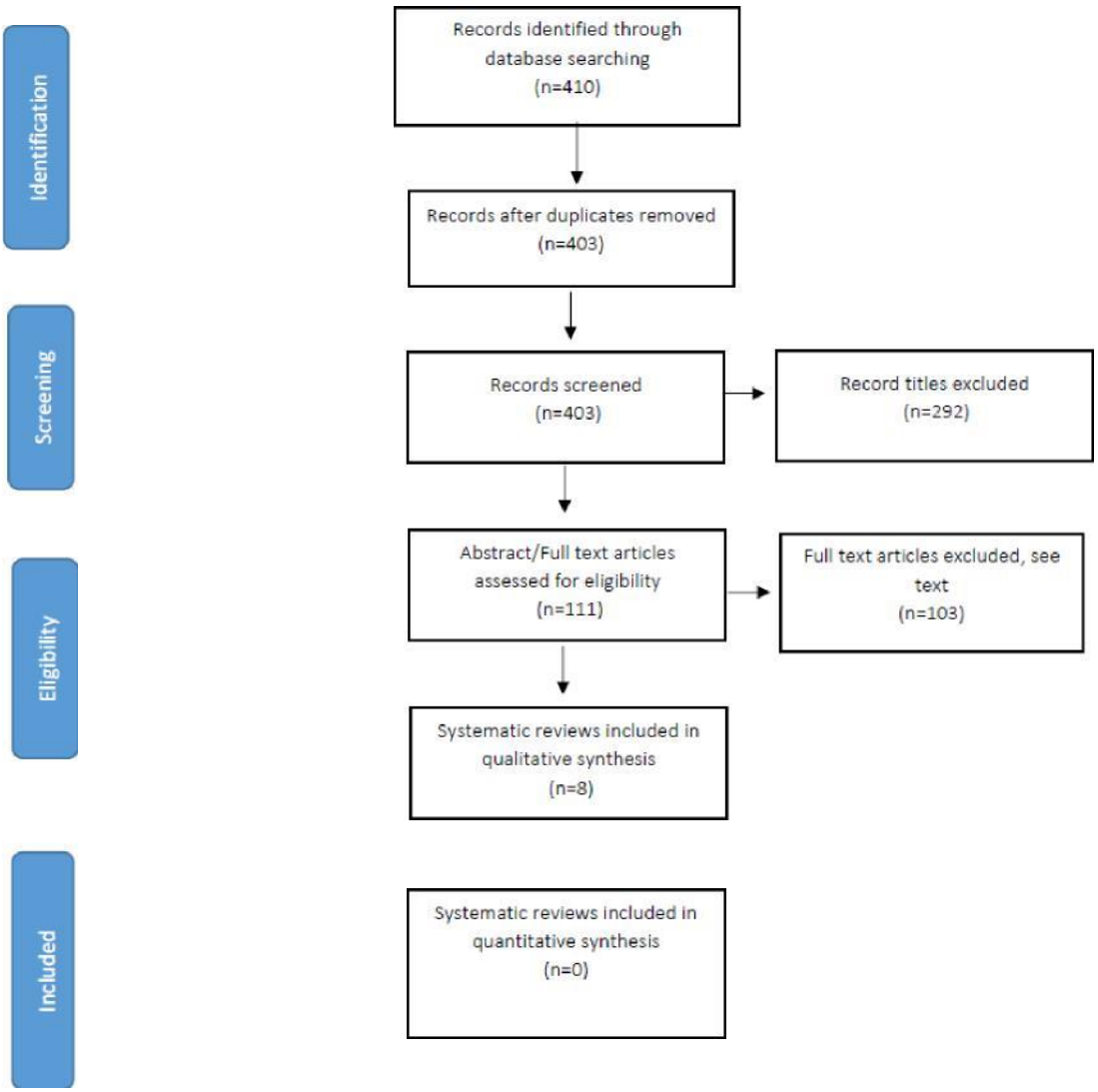


Table 4. Characteristics of Included Systematic Reviews

Author	Kottner et al. (2013)	Kottner et al. (2010)	Ferreira et al. (2018)	Jackson et al (2019)	Courtwright et al. (2016)	Martin et al. (2018)	Jull et al. (2015)	Breederveld et al. (2014)
Aim	PU/PI Risk Scales	PU/PI incidence and prevalence	Instruments about the care of PU/PIs	Observational Studies reporting medical device related PI's	Care bundle methodology to reduce HAPUs and Barriers to implement bundles	Efficacy of tissue glue in pediatric circumcision	To assess the effects of honey compared with alternative wound dressings and topical treatments on the healing of acute (e.g. burns, lacerations) and/or chronic (e.g. venous ulcers) wounds.	To determine the effects of rhGH on the healing rate of burn wounds and donor sites in people with burns
Review Type	Systematic review	Literature review	Integrative Review (following PRISMA)	Systematic Review and Meta-analysis	Integrative Review (following PRISMA)	Systematic Review and Meta-analysis	Systematic Review and Meta-analysis	Systematic Review and Meta-analysis
Wound Type	PU's/ PI's	PU's/ PI's	PU's/ PI's		PU's/ PI's	Surgical	Burns, ulcers	Burns
Population	Pediatric	Pediatric	Pediatric	PU's/ PI's	Pediatric/ Neonate	Pediatric	Adult and Pediatric	Adult and Pediatric
Pediatric population	Range 0-18 yrs.	Mean 7 yrs	Age NR (18/32)	Adult and Pediatric Mean 5.9 yrs. (3/9)	NR	NR	Age NR (6/26)	Range 1-18yrs (6/13)
Population Size (Articles)	15	19	32		7	15	26	13
RCT	0	0	0	29	1	6	24	13
NRCT	0	0	0	0	2	0	2	0
Other	15	19	32	9	4	9	NA	0
Quality Assessment	QUADAS	STROBE	None	0 New-Castle Ottawa	Melnyk and Fineout-Overholt	Cochrane, NOS, AMSTAR	Cochrane GRADE	GRADE
Conclusion	Poor quality, inconclusive results due to limitations and dearth evidence	Scarce empirical evidence, quality improvement in reporting prevalence needed	Valid and reliable instruments exist to asses PIs in Ped population	Mod to High quality, low risk of bias, suggestive that device- related PIs are significant	Low quality, very hetero. Scarce evidence on use of bundle. No evidence on efficacy of bundle	Quality not reported, Low risk of bias, Tissue Glue valid alternative	Any evidence for differences in the effects of hone is of low or very low quality and does not form a robust	Low quality limited evidence, risk of bias-rhGH results in more rapid healing for large burns, reduce LoS, increased risk

	public health issue	basis for decision making	of hyperglycemia

Table 5. Quality Assessment

AMSTAR Checklist Results

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2019)	Courtwrigh t et al (2016)	Martin et al (2018)	Jull et al (2015)	Breederveld et al (2014)
1	Y	Y	Y	Y	Y	Y	Y	Y
2	Y	Y	Y	Y	Y	Y	Y	Y
3	Y	Y	Y	Y	Y	Y	Y	Y
4	N	Y	Y	Y	N	N	N	Y
5	N	N	N	N	Y	N	Y	Y
6	Y	Y	N	Y	Y	N	N	N
7	Y	Y	Y	Y	Y	Y	Y	Y
8	Y	Y	N	Y	Y	Y	Y	Y
9	Y	Y	N	Y	Y	Y	Y	Y
10	N	N	N	Y	N	Y	Y	N
11	Y	Y	N	Y	Y	N	Y	Y

PRISMA Checklist Results

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2019)	Courtwright et al (2016)	Martin et al (2018)	Jull et al (2015)	Breederveld et al (2014)
1	Y	N	N	Y	N	Y	Y	Y
2	N	N	N	N	N	N	N	N
3	Y	Y	Y	Y	Y	Y	Y	Y
4	Y	Y	N	N	Y	Y	Y	Y
5	N	N	N	Y	N	Y	N	N
6	Y	Y	Y	Y	Y	Y	N	Y
7	Y	Y	Y	Y	Y	Y	Y	Y
8	N	N	Y	Y	N	Y	Y	Y
9	Y	Y	Y	Y	Y	Y	Y	Y
10	Y	Y	Y	Y	Y	Y	Y	Y
11	N	Y	Y	Y	Y	Y	Y	N
12	N	N	N	Y	N	N	Y	Y
13	Y	N	N	Y	N	Y	Y	Y
14	Y	Y	N	Y	N	Y	Y	Y
15	N	N	N	Y	N	Y	Y	Y

16	N	Y	N	Y	N	Y	N	Y
17	Y	Y	Y	Y	Y	Y	Y	Y
18	N	Y	N	N	Y	Y	N	Y
19	N	N	N	N	N	N	Y	Y
20	N	N	N	N	N	Y	Y	Y
21	N	N	N	Y	N	Y	Y	Y
22	N	N	N	Y	N	Y	Y	Y
23	N	Y	N	Y	N	Y	N	Y
24	N	Y	Y	Y	Y	Y	Y	Y
25	N	Y	Y	Y	Y	Y	Y	Y
26	Y	Y	Y	Y	Y	Y	Y	Y
27	Y	Y	N	N	Y	N	Y	Y

Table 6. Domains of Included Systematic Reviews

A. Did Objectives of SRs Address Consensus Group Domains?

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2019)	Courtwright et al (2016)	Martin et al (2018)	Jull et al (2015)	Breederveld et al (2014)
Cost of Product	NA	No	No	No	NA	Yes	Yes	No
Duration of treatment	NA	No	No	No	NA	Yes	Yes	Yes
Ease of Applying	NA	No	No	No	Yes	No	No	No
Accessibility of Product	NA	No	No	No	NA	No	No	No
Storage	NA	No	No	No	NA	No	No	No
Length of Time to apply/perform	NA	No	No	No	Yes	Yes	No	No
Pain Association	NA	No	NA	No	NA	Yes	No	No

B. Did Articles in SR Address Consensus Group Domains?

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2019)	Courtwright et al (2016)	Martin et al (2018)	Jull et al (2015)	Breederveld et al (2014)
Cost of Product	NA	No	No	No	NA	Yes	Yes	No
Duration of treatment	NA	No	Yes	No	NA	Yes	Yes	Yes
Ease of Applying	NA	No	Yes	No	Yes	Yes	No	No
Accessibility of Product	NA	No	Yes	No	NA	No	No	No
Storage	NA	No	No	No	NA	No	No	No
Length of Time to apply/perform	NA	No	Yes	No	Yes	Yes	No	No
Pain Association	NA	No	NA	No	NA	Yes	No	No

Discussion

Characteristics of the Studies

Several key aspects of the reviews were noted when reviewing the results. The articles identify themselves differently, with some identifying themselves as a systematic review, literature review, meta-analysis, or a combination of two. Many of the clinical trials did not include exact ages of the population studied. All of the studies had varying levels of aims that ranged from assessing risk factors, to identifying validated instruments, to a focus on product efficacy. Expectedly, conclusions of studies varied, therefore, hindering linear assessment.

Quality Assessment

When assessing the quality of the studies, it was determined that no true "gold standard" for assessing systematic reviews exists. Because this is the first systematic review of systematic reviews in wound care specifically, SRs of SRs in other healthcare related fields

were relied upon. There have been modified versions of AMSTAR (AMSTAR-2 and R-AMSTAR) used.[14-16] AMSTAR-2 was created to have 16 questions focusing on randomized versus non-randomized healthcare interventions,[14] and R-AMSTAR was modified to quantify each of the 11 conditions with a rated scale of 1 to 4. Due to their lack of traditional usage, AMSTAR-2 and R-AMSTAR were not utilized for this systematic review assessment to maintain integrity. Regardless of the assessment version, all reviews seemed to conclude that there is generally poor quality of evidence due to reporting methodology limitations and scarcity of literature. Utilizing both AMSTAR and PRISMA provided assurance in validating the assessment strategy in the sense that there was consistency seen across both checklists. It was expected that most Cochrane publications would contain higher checklists in PRISMA, considering that several items in methods and results are paralleled on addressing meta-analysis conduct. This supports the lower PRISMA scoring of integrative reviews that reportedly followed PRISMA guidelines.

Domains

The expert consensus group was assembled to establish the important domain information pediatric wound experts found crucial to extract from the literature search. After review of the systematic reviews, we determined that very few articles discussed the desired domains neither in the description of their objectives (table 1) nor within the written content of the review (table 2). Some reasons for this lack of information may include varying levels of research priorities amongst the scientific community, the lack of priority for a cost savings approach to wound care, etc.

Limitations

Despite our best efforts, there were several limitations that were noted. For example, eligibility criteria used discrete terms, therefore, we may have missed other reviews that had varying phrases or terminology. In addition, we excluded all non-English publications. Our search strategy, as discussed in Methods section, while not all inclusive, was validated and deemed appropriate by the clinical consensus group. Our search only included pediatric systematic review of systematic reviews, which limited our search total to eight studies. In reviewing the studies, it was difficult to discern exact or mean age of the pediatric population in the various studies. A lack of "gold standard" quality assessment tool prevented linear comparison. We feel that the heterogeneity of the selected studies limited the breadth of the study results.

Conclusion

This is the first article to summarize the systematic review literature on pediatric wound care intended to shed light on the extent of quality and content of the work used to make critical decisions and guidelines. The breadth of work done has been widely influential in the decision-making process of wound care. Even though there is not necessarily a lack of expressing the need for more literature and research, there seems to be a lack in direction, uniformity and methodology in carrying out high quality research and publications. With patience and tenacity, rigorous efforts must be undertaken in order to achieve publications worthy of influencing critical decision-making processes in pediatric wound care.

REFERENCES

1. Bernabe, K.Q., Desmarais, T.J., Keller, M.S. Management of Traumatic Wounds and a Novel Approach to Delivering Wound Care in Children. Advances in Wound Care 2014; 3(4). DOI: 10.1089/wound.2013.0465.
2. Baharestani MM: An overview of neonatal and pediatric wound care knowledge and considerations. Ostomy Wound Manage 2007; 53: 34.
3. Noonan C, Quigley S, and Curley MA: Skin integrity in hospitalized infants and children: a prevalence survey. J Pediatr Nurs 2006; 21: 445.
4. Werdin F, Tennenhaus M, Schaller H, Rennekampff H. Evidence-based Management Strategies for Treatment of Chronic Wounds. Eplasty. 2009; 9: e19.
5. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, et al. The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration. Ann Intern Med. 2009; 151(4).
6. Smith, V., Devane, D., Begley, C.M. et al. Methodology in conducting a systematic review of systematic reviews of healthcare interventions. BMC Med Res Methodol. 2011; 11(15). https://doi.org/10.1186/1471-2288-11-15.
7. Bigby M, Williams H. Appraising Systematic Reviews and Meta-analyses. Arch Dermatol. 2003;139(6): 795-798. DOI:10.1001/archderm.139.6.795.
8. Jackson D, Sarki AM, Betteridge R, Brooke J. Medical device-related pressure ulcers: A systematic review and meta-analysis. Int J Nurs Stud. 2019; 92: 109–120. DOI:10.1016/j.ijnurstu.2019.02.006.

9. Martin A, Nataraja RM, Kimber C, Pacilli M. The Use of Tissue Glue for Circumcision in Children: Systematic Review and Meta-analysis. Urology. 2018; 115: 21–28. DOI:10.1016/j.urology.2018.01.022.
10. Jull AB, Cullum N, Dumville JC, Westby MJ, Deshpande S, Walker N. Honey as a topical treatment for wounds. Cochrane Database Syst Rev. 2015; (3): CD005083. DOI:10.1002/14651858.CD005083.pub4.
11. Breederveld RS, Tuinebreijer WE. Recombinant human growth hormone for treating burns and donor sites. Cochrane Database Syst Rev. 2014; (9): CD008990. DOI:10.1002/14651858.CD008990.pub3.
12. Ferreira et al (2018)
13. Courtwright SE, Mastro KA, Preuster C, et al. Reducing hospital-acquired pressure ulcers using bundle methodology in pediatric and neonatal patients receiving extracorporeal membrane oxygenation therapy: An integrative review and call to action. J Spec Pediatr Nurs. 2017; 22(4). DOI:10.1111/jspn.12188.
14. Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017; 358: j4008. DOI:10.1136/bmj.j4008.
15. Kung J, Chiappelli F, Cajulis OO, et al. From Systematic Reviews to Clinical Recommendations for Evidence-Based Health Care: Validation of Revised Assessment of Multiple Systematic Reviews (R-AMSTAR) for Grading of Clinical Relevance. Open Dent J. 2010; 4: 84–91. DOI:10.2174/1874210601004020084.

16. Corry M, While A, Neenan K, Smith V. A systematic review of systematic reviews on interventions for caregivers of people with chronic conditions. J Adv Nurs. 2015; 71(4): 718–734. DOI:10.1111/jan.12523.

Title of Journal Article - Analytical Outline for the Creation of Guidelines for Evidence Based Clinical Practice

Name of Journal Proposed for Article Submission - Advisor

Purpose

The purpose of this paper will be to define the steps required to take the evidence gained from our systematic review and consensus group statement and apply it to clinical practice through the development of a clinical decision tree.

Background

The Expert Consensus Panel

In 2019, a multidisciplinary team of board certified Pediatric Plastic and Pediatric General Surgeons that are active in the International Society of Pediatric Wound Care (ISPEW) was created to form our expert consensus panel to address, via survey, critical variables of pediatric wound care guideline development such as information sources, systematic review database search strategies, study selection criteria including keywords, the clinical consensus group's experience with clinical guideline development, and finally other clinically significant domains that the evidence should be evaluated for.

Group decision-making is often a cognitive, collaborative process. In the context of guideline development, it results in the formulation of a recommendation for or against an intervention and in the determination of the recommendation's strength, both on the basis of the available scientific evidence and of various other factors.[1] The decision-making process used to formulate recommendations relies heavily on logic and reasoning. It is informed by

systematic reviews of the evidence and uses an explicit framework to delineate the various factors that should be considered. This process should involve experts with diverse perspectives, experiences and knowledge. Decisions are never attributed to any one individual, but to the entire guideline development group.[1]

For each guideline development group, the decision-making approach to be followed during guideline development must be defined. This is a key process that must be transparently communicated to all guideline development group members and well documented. A clear, agreed-upon approach to decision-making allows guideline development group members to have explicit and reasonable expectations and to engage in a respectful and productive process. It also ensures that all members understand the procedures to be followed and are given the opportunity to participate so that the biases that may affect the decision-making process are avoided or minimized. Ultimately this will result in a high-quality, more credible guideline.[1] The methods of guideline development should ensure that treating patients according to the guidelines will achieve the outcomes that are desired.[2]

Criteria for selection of the consensus group members included: 1) Research graduate active in Pediatric Wound Care research, 2) Board certified Physicians actively practicing in their aforementioned pediatric general surgery or pediatric plastic surgery subspecialty, and 3) Wound Ostomy Care Nurse actively practicing in Pediatric wound care. The President selected 6 individuals (2 from each category) and emailed them inquiring about their interest in participating in the research study. (Demographics included in the results section) All recruited individuals were emailed and agreed to participate after a detailed description of the research project was explained.

This multidisciplinary team of consensus group experts was assembled to create a clinical consensus statement based upon evidence in clinical practice. Clinical consensus statements (CCS) reflect opinions drafted by content experts for which consensus is sought using explicit methodology to identify areas of agreement and disagreement. The outcomes of this type of CCS included 1) identifying domains of expert consensus regarding the costs associated with a wound care product and the treatment of the wound, the duration of the wound treatment, the ease of performing the wound treatment on pediatric patients, the accessibility of the product in the health care industry, the available storage of the product, and the length of time pertaining to applying the product or treatment to the wound; 2) identifying the indications for surgical intervention on different types of wounds; 3) perioperative management of the wound, and 4) reviewing the expected outcomes of the review.[3]

Evidence Based Guidelines for Policy

Evidence-based guidelines, also called clinical practice guidelines, "are systematically developed statements to assist clinicians and patient decisions about appropriate health care for specific clinical circumstances".[4] These guidelines are widely developed tools, that improve the quality of care.[5] There is, however, significant research that shows guidelines relevant to a multitude of conditions, clinicians, and settings are underused, resulting in suboptimal health service design and delivery of patient and health system outcomes.[6-8] Research shows that guidelines tailored to address preidentified determinants are more likely to improve professional practice compared with either no intervention or simple dissemination

of guidelines, underscoring the imperative to optimize implementation by pre-identifying determinants.[9]

The topic for guideline development will usually need to be refined before the evidence can be assessed in order to answer exact questions. The usual way of refining the topic is by a dialogue among clinicians, patients, and the potential users or evaluators of the guideline. Discussions about the scope of the guideline will also take place within the guideline development panel. If the topic is not refined, the clinical condition or question may be too broad in scope. For example, a guideline on the management of diabetes could cover primary, secondary, and tertiary care elements of management and also multiple aspects of management, such as screening, diagnosis, dietary management, drug therapy, risk factor management, or indications for referral to a consultant. Though all of these could legitimately be dealt with in a guideline, the task of developing such a guideline would be considerable; therefore a group needs to be clear which areas are and are not within the scope of their activities. It is possible to develop guidelines that are both broad in scope and evidence based, but to do so usually requires considerable time and money, both of which are frequently underestimated by inexperienced developers of evidence based clinical practice guidelines.

Texas Children's Hospital Wound Care Management

At Texas Children's Hospital, Wound, Ostomy and Continence (WOC) Services are provided to patients of all ages. Common diagnoses requiring consultation include but are not limited to abscess, pressure ulcers, skin conditions (graft versus host disease (GVHD), Steven-Johnson's syndrome, Epidermolysis bullosa, dermatitis), and complications arising from

medical and vascular access devices. Procedures performed include nursing or provider assessment, dressing changes, application of negative pressure wound therapy, ostomy care (marking, pre and post op teaching, pouching), fistula and gastrostomy tube and continence management. Pre-operative teaching, discharge education and follow up is provided as appropriate for each condition.

As a national leader in pediatric healthcare and a system dedicated to providing quality care to patients and families, Texas Children's must enhance our current care delivery model. The goal our approach to wound, ostomy, and continence care by establishing a Pediatric Wound Care Center of Excellence to provide access to care for all patients within our system and to better serve our community.

Analysis

Utilization of an Expert Consensus Group

A variety of methods on using a consensus group have been outlined in the literature. Several studies had clinical consensus group members meet face to face during a 2-day period. On day 1, the group discussed each review paper (6 total) and the chairman and discussant identified key issues for further debate. On day 2, the group discussed these key issues to arrive at a consensus view. After the group meetings, the consensus statement was drafted by the chairman and approved by all attendees.[10,11]

Achieving Consensus

A key issue during guideline development, during formulation of recommendations, is acquiring consensus among a diverse group of individuals, often with competing interests and values.[4] The Delphi method Developed in the early 1950s and named after the ancient Greek oracle at Delphi, the Delphi method is a process used to survey and collect the opinions of experts on a particular subject.[12] A key characteristic of the Delphi method is that participants never meet or interact directly. Rather, the process involves the use of structured questionnaires to be filled out individually and anonymously. The goal is to incorporate a large number of viewpoints to obtain, in general, a more reliable estimate of the "real" answer to a question.[3,13] The Delphi method is particularly useful whenever the judgments of experts are needed but time, distance and other factors make it unlikely or impossible for the group to convene in person.[2] Many modifications exist, but the general structure of the Delphi method is as follows:

- A questionnaire is sent (by post or email) to group participants, who individually rate or rank their agreement with specific statements.
- The organizers of the Delphi method collate and summarize the responses and document the preliminary level of group consensus for each item.
- A second questionnaire, displaying the summary response and consensus level, is sent back to the participants, who are then given the opportunity to rerank their initial judgment in light of the group's response. Any respondent who holds an opinion that still differs substantially from that of the group should provide a brief explanation or reason for disagreeing.

■ Steps 2 and 3 are repeated for a third time in light of the emerging pattern of group consensus and reasons for dissent.

The use of evidence in the form of systematic reviews is now considered as a standard internationally for guideline development. However, systematic reviews do not provide any information on how much confidence can be placed on a recommendation made on the basis of the evidence from the systematic review and how applicable it might be in a particular setting and how well it aligns to health systems values and preferences.

The IOM (2011) defined clinical practice guidelines as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Trustworthy guidelines should be based on a systematic evidence review, developed by panel of multidisciplinary experts, provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations.

Developing Practice Guidelines

The five steps to practice guideline development include 1) Identifying and refining the subject area is the first step in developing a guideline 2) Convening and running guideline development groups is the next step 3) On the basis of systematic reviews, the group assesses the evidence about the clinical question or condition 4) This evidence is then translated into a

recommendation within a clinical practice guideline 5)The last step in guideline development is external review of the guideline.

The next step was to create a questionnaire to survey the consensus panel, which is a comprehensive, validated instrument that addresses multiple potential determinants specific to guideline use from a clinician perspective. The questionnaire can be used at multiple time points in the guideline development cycle to assess determinants of the use of new, updated, or adapted guidelines and before and after interventions to assess their impact on the determinants of guideline use.[14] This questionnaire was created to address eligibility criteria, information sources, search strategy, and study selection . Domains were also created and the consensus group was polled to determine if the evidence should be displayed using certain criteria. Domains that can be considered include applicability of the evidence to the population of interest (its generalizability), costs, knowledge of the healthcare system, beliefs and values of the panel. Survey Monkey was used to create the survey which consisted of a total of 16 questions ranging from demographic related questions, systematic review details, and domain inquiries. (Survey is attached as Appendix 1)

Results of the Panel Survey

Each of the expert consensus panelists polled had participated in past clinical guideline development roles. The types of providers in the panel consisted of a clinical specialist in Wound, Ostomy & Continence Care, an advanced nurse practitioner Pediatric Skin and Wound management, a professor of surgery, a director of neonatal wound services, and the Chief

Pediatric Wound Care Surgical Unit, Division of Plastic and Maxillofacial Surgery, Bambino Gesù Children's Hospital, Rome, Italy (MD, PhD).

The initial results from the survey monkey created online yielded the recorded data shown in Graphic 1. Each of the polled consensus group members provided an account of their experience with the clinical guideline formation process during their current and past participation.

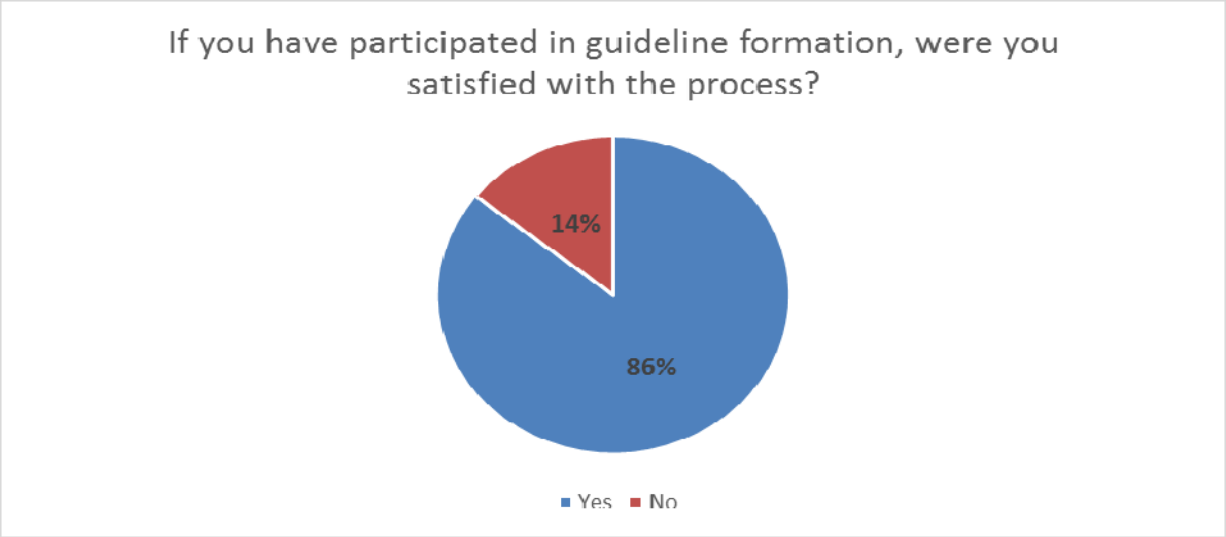


Figure 4. Shown is the satisfaction of each of the consensus group members through the process..

As a secondary part of the survey, each of the consensus group members was asked to provide the type of communication experienced during their participation with previous clinical consensus statement development groups. The type of communication was suggested and confirmed by each of the members, and the data recorded in Table 1.

Types of Communication	Number of Responses	Percentage Value
In-Person Meetings	5	83%
Conference Call Meetings	4	67%
Email Communication	5	83%
No Participation in Guideline Development	0	0%
Other	0	0%

Table 1. Shown are the types of recorded communications used during this survey and other reviewed surveys.

The final pieces of information recorded in the survey were based upon the preferences of the expert consensus group members pertaining to how each member would prefer to conduct future consensus group meetings according to time and technique. The results are shown in Tables 2 and 3.

Type, Length and Frequency of Meetings	Number of Responses	Percentage Value
Longer Meetings, Less Frequency	3	50%
Shorter Meetings, More Frequency	3	50%
Face to Face Meetings Only	3	50%
Communication via Email Only	3	50%
Skype/Telecommunication Meetings Only	3	50%
No Participation in Guideline Formation	0	0%
Other	3	50%

Table 7. Shown are the group member responses regarding the type, length and frequency of meetings.

Type of Response	Number of Responses	Percentage Value
Multiple Face to Face Meetings with All Consensus Group Members to Review Data	2	33%
Receive All Information via Email to Individually Review with One 2-hour Skype or Face to Face Meeting to Discuss Guidelines	3	50%
One Hour Face to Face Meeting to Review Data with a Mock Clinical Guideline Developed by PI, Then to Follow Up via Email to Discuss Edits and Recommendations	3	50%
Other	1	17%

Table 8

Discussion

As seen from the literature review and conducted surveys, there remains only a limited number of published clinical guidelines for the evaluation and management of wounds in the neonatal and pediatric populations, and consensus groups are increasingly being used to develop clinical guidelines for future wound care management. Questionnaires are a commonly used approach for identifying determinants because they are relatively inexpensive, reach a large audience, and convenient for busy health care professionals, particularly when administered online. Although guideline developers lack the resources and capacity to

themselves develop and validate determinant questionnaires, the need for a validated guideline determinants questionnaire is widespread.[14]

As shown from the surveys, the majority of the consensus group members polled have had good experiences participating in guideline development processes, not only in their past experiences but with this current study as well. These survey results are consistent with other conducted surveys given to consensus groups of previous wound care studies where the majority of the polled members are leaders in their field and have all previously played a vital role in clinical guideline development consensus groups.

Throughout this study, we sought to capture with data the preferences of the consensus group members regarding how they would prefer to conduct current and future meetings to decide upon evidence for guideline development. This data has shown to be driven by various methods of communication during the survey process in both our study and previously reviewed studies in literature including duration and lengths of discussion meetings whether in person or via electronic interface as well as how data collected was reviewed and analyzed, i.e. in person face to face or via conference call.

Summary

The goal of this study was to review the clinical guideline development process and apply it to our own study through the use of an expert consensus group and survey process to determine the best actions moving forward for future decision-making. These data results revealed true clinical insight into the preferences of clinicians and providers regarding how the clinical guideline development process has and should be conducted to provide the most impact

to pediatric wound care. This study was proposed to evaluate what shapes the complete clinical guideline decision-making process in variable wound care practices on a national and local scale. Identifying this process to be important to advancing wound care research and clinical practice, particular information and how it was acquired through the use of expert consensus panelists and systematic reviews guided this study through the best course of action necessary to develop the conceptual framework of establishing clinical guidelines. Because decision-making approaches clinicians use may vary depending on subspecialties and the lack of research among wound care related clinical guidelines, evidence based guideline-driven decisions appear largely contextual. Unfortunately, producing systematic reviews with recommendations from expert consensus panelists and disseminating survey results does not naturally bring more awareness and use of evidence in wound care practices. However, it is important the overall concept has been supported by a quantitative analysis to invoke necessary improvements in the field. The current and ongoing research evidence and forward thinking should make evidence-based decision-making possible in pediatric wound care.

REFERENCES

1) WHO handbook for guideline development – 2nd ed. (ISBN 978 92 4 154896 0) © World Health Organization 2014.
2) Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Developing Guidelines. BMJ. 1999; 318(7183): 593–596.
3) Rosenfeld RM, Nnacheta LC, Corrigan MD. Clinical Consensus Statement Development Manual. Otolaryngology–Head and Neck Surgery. 2015; 153(2S): S1–S14. DOI: 10.1177/0194599815601394.
4) Institute of Medicine; 1990, p. 381; 2001, p. 1512
5) Shekelle P, Woolf S, Grimshaw JM, Schunemann HJ, Eccles MP. Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development. Implement Sci. 2012; 7: 62.
6) McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristoforo A, et al. The quality of health care delivered to adults in the United States. N Engl J Med. 2003; 248: 2635-2645.
7) Runciman WB, Hunt TD, Hannaford NA, Hibbert PD, Westbrook JI, Coiera EW, et al. CareTrack: assessing the appropriateness of health care delivery in Australia. Med J Aust, 2012; 197: 100-105.

8) McNamara RL, Chung SC, Jernberg T, Holmes D, Roe M, Timmis A, et al. International comparisons of the management of patients with non-ST segment elevation acute myocardial infarction in the United Kingdom, Sweden, and the United States: the MINAP/NICOR, SWEDEHEART/RIKS-HIA, and ACTION Registry-GWTG/NCDR registries. Int J Cardiol. 2014; 175: 240-247.

9) Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2015; 3: CD005470.

10) Ballenger JC, Davidson JR, Lecrubier Y, Nutt DJ, Baldwin DS, den Boer JA, Kasper S, Shear MK. Consensus statement on panic disorder from the International Consensus Group on Depression and Anxiety. The Journal of Clinical Psychiatry. 1997; 59(Suppl 8): 47-54. PMID: 9707162.

11) Ballenger JC, Davidson JRT, Lecrubier Y, Nutt DJ, Foa EB, Kessler RC, McFarlane AC. Consensus statement on posttraumatic stress disorder from the international consensus group on depression and anxiety. The Journal of Clinical Psychiatry. 2000; 61(Suppl 5): 60–66.

12) Yousuf MI. Using experts' opinions through Delphi technique. Pract Assess Res Eval. 2007; 12: 1-8. DOI: 10.1016/j.sbspro.2015.03.200.

13) Raine R, Sanderson C, Black N. Developing clinical guidelines: a challenge to current methods. BMJ. 2005; 331: 631. DOI: 10.1136/bmj.331.7517.631.

14) Gagliardia AR, Armstrong M, Bernhardsson S, Fleurend M, Pardo-Hernandez H, Vernooijf RWM, Wilson M. The Clinician Guideline Determinants Questionnaire was

developed and validated to support tailored implementation planning. Guidelines International Network Implementation Working Group.

Dissertation Conclusions

PAPER 1 – SUMMARY

The goal of this study was to obtain consensus among experts about pediatric wound care. Through the use of this Consensus group and conducted survey, we were able to identify a more complete systematic review process, as well as identify additional domains that are important in clinical practice. As shown from the survey, the consensus group members polled have been proficient in pediatric wound care for several years with the majority of the members practicing for more than 10 years within a hospital setting. Throughout this study, previous clinical guideline development projects were reviewed and have recorded several key pieces of information pertaining to decisions concerning the domains of wound care management and which have been the most crucial for successful treatment and overall patient satisfaction. The resulting focuses from the survey process will play a vital role in determining the precise domains necessary to complete the systematic review process required for a consensus-based clinical guideline development protocol in pediatric wound care. These results revealed true clinical insight into databases, search terms, and domains that provide the most impact to pediatric wound care.

PAPER 2 - SUMMARY

This is the first article to summarize the systematic review literature on pediatric wound care intended to shed light on the extent of quality and content of the work used to make critical decisions and guidelines. The breadth of work done has been widely influential in the decision-making process of wound care. Even though there is not necessarily a lack of expressing the need for more literature and research, there seems to be a lack in direction, uniformity and methodology in carrying out high quality research and publications. With patience and tenacity, rigorous efforts must be undertaken in order to achieve publications worthy of influencing critical decision-making processes in pediatric wound care.

PAPER 3 - SUMMARY

The first step proposed is to present the survey results to the expert consensus group to discuss the agreed upon method of communication for the decision-making process. The next step would be to use this method of communication to establish a decision tree based upon the primary domains of clinical practice determined by the results of the consensus group and the systematic review. Upon establishing a evidence based clinical decision tree, the PI will distribute the mock guideline developed to the consensus group for discussion. The developed guideline/guidelines will be utilized to evaluate wound care products for usage in the clinical setting.

LIMITATIONS

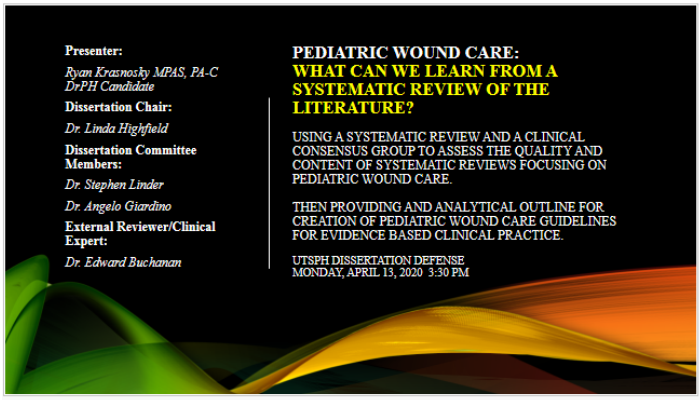
Despite my best efforts, there were several limitations that were noted. Our search strategy, as discussed in Methods section, while not all inclusive, was validated and deemed

appropriate by the clinical consensus group. Eligibility criteria used discrete terms, therefore, I may have missed other reviews that had varying phrases or terminology. I excluded all non-English publications. Our search only included pediatric systematic review of systematic reviews, which limited the search total to eight studies. In reviewing the studies, it was difficult to discern exact or mean age of the pediatric population in the various studies. A lack of "gold standard" quality assessment tool prevented linear comparison. I feel that the heterogeneity of the selected studies limited the breadth of the study results

TEXAS CHILDRENS IMPACT

As a national leader in pediatric healthcare and a system dedicated to providing quality care to patients and families, Texas Children's must enhance our current care delivery model. The goal growing from this dissertation is to inform and update our approach to wound, ostomy, and continence care by establishing a Pediatric Wound Care Center of Excellence to provide access to care for all patients within our system and to better serve our community. Unfortunately, pediatric wound care guidelines do not exist. My goal is to use the systematic review evidence, along with the detailed analytical framework created in this dissertation on how to disseminate the evidence back to the consensus group to guide development of evidence based clinical guidelines. This will include identifying specific types of wounds and conducting evidence based systematic reviews and mapping out the process flow for treatment of each type of wound. This will allow us to serve as a national model/leader for pediatric wound care and publish outcomes in alignment with our academic mission of quality outcomes, education, and research. Developing a pediatric wound care training program with

education tracks for providers and nurses to serve the inpatient and ambulatory areas of the Medical Center campus, and the community aligning with the TCH mission of Education would be the final step.



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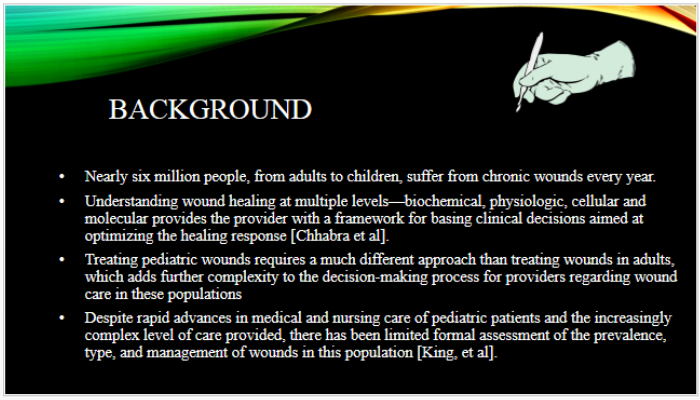

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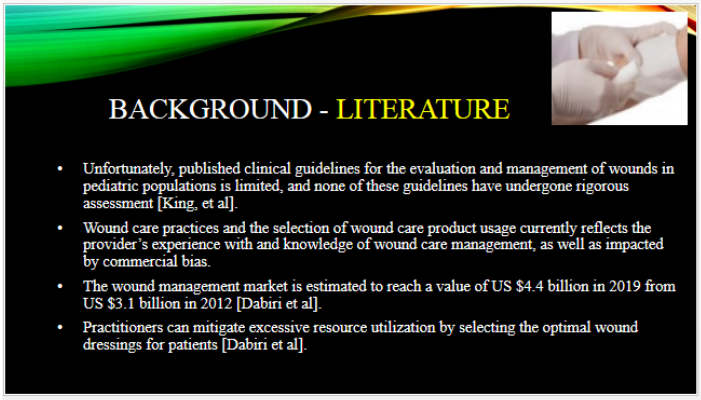

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4

DISSERTATION PROPOSAL – USING THE 3-PAPER METHOD

- Due to the inconsistencies in pediatric wound care management, there is a need to develop evidence based guidelines.

The Focus of these papers was to:

1. Use a clinical consensus group to identify appropriate search terms and databases that were used for a systematic review of systematic reviews.
2. Performed a systematic reviews of pediatric wound care systematic reviews and reported exploring the strengths and limitations of pediatric wound care management strategies and reporting approaches aimed at improving wound care management in hospitals/home healthcare
3. Finally, I developed a proposed analytical tool, with the partnership of the clinical consensus group, to determine how to best create evidence based decision trees.

5

PAPER 1 - STAKEHOLDER MAPPING AND CONTENT ASSESSMENT

Aims - Develop Pediatric Wound Care Consensus Group to:

1. Identified international thought leaders following stakeholder mapping and convene consensus body
2. Identified key search terms for systematic review of systematic review
3. Determined the domains that was clinically significant to include in reporting the evidence of the systematic review

6

PAPER 2 - A SYSTEMATIC REVIEW OF WOUND CARE LITERATURE

Aims - The Systematic Review of Systematic Reviews Was to Evaluate the Pediatric Wound Care Literature to:

1. Explore the strengths and limitations of wound care management strategies aimed at improving wound management
2. Determine the strengths and limitations of reporting approaches used for pediatric wound care strategies aimed at improving wound management using the Prisma and Amstar 2 guidelines for qualitative analysis.

7

PAPER 3 - PROVIDE ANALYTICAL OUTLINE FOR CREATION OF DRAFT DECISION TREES FOR EVIDENCE BASED CLINICAL PRACTICE

Aims - Utilize the Results of the Systematic Review of Systematic Reviews and the Consensus Group to:

1. Provide analytical outline for creation of draft decision trees for evidence based clinical practice guidelines

8

PAPER 1 - USING A CLINICAL CONSENSUS GROUP TO ENSURE CONTENT ASSESSMENT FOR A SYSTEMATIC REVIEW

Methods

Formation of the Expert Consensus Group

Creation of a web-based questionnaire

Data Collection and Analysis

- ***Formation of the Expert Consensus Group*** -recruited a multidisciplinary team that consisted of board-certified Pediatric Plastic and Pediatric General Surgeons, Pediatric Wound and Ostomy Care Nurses (WOCN), and Pediatric Wound Care Research Graduates that are active in the International Society of Pediatric Wound Care (ISPEW).

9

INTERNATIONAL SOCIETY OF PEDIATRIC WOUND CARE (ISPEW)

The Goals of the **International Society of Pediatric Wound Care (ISPeW)** Are to:

(1) Set global standards for the assessment and treatment of pediatric wounds of varying etiologies;

(2) Provide a forum for international, interprofessional collaboration among healthcare professionals, researchers, educators and industry leaders dedicated to the care of pediatric wounds;

(3) Promote and support clinical research focused on the prevention, assessment and treatment of pediatric wounds;

(4) Collaborate with wound care organizations worldwide on pediatric wound care issues; and

(5) Provide evidence based pediatric wound care education to healthcare professionals, parents and lay caregivers.

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PAPER 1 - USING A CLINICAL CONSENSUS GROUP TO ENSURE CONTENT ASSESSMENT FOR A SYSTEMATIC REVIEW

- ***Creation of a Web-based Questionnaire*** - A Survey Monkey survey was created that was used to a establish criteria for inclusive search terms for the systematic review.

- ***Data Collection and Analysis*** - 16 questions ranging from demographic related questions, systematic review details, and domain inquiries. Responses were downloaded from Survey Monkey for descriptive analysis.

11

WEB BASED SURVEY – DELPHI METHOD

- A questionnaire is sent (by post or email) to group participants, who individually rate or rank their agreement with specific statements.
- The organizers of the Delphi method collate and summarize the responses and document the preliminary level of group consensus for each item.
- A second questionnaire, displaying the summary response and consensus level, is sent back to the participants, who are then given the opportunity to rerank their initial judgment in light of the group's response. Any respondent who holds an opinion that still differs substantially from that of the group should provide a brief explanation or reason for disagreeing.
- Steps 2 and 3 are repeated for a third time in light of the emerging pattern of group consensus and reasons for dissent.

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RESULTS OF THE SURVEY – DEMOGRAPHICS AND EXPERIENCE

Table 1

Type of Wounds Treated	Number of Responses	Percentage Value
Pressure Ulcers	5	83%
Surgical Wounds	5	83%
Intravenous Extravasation Injuries	5	83%
Epidermal Stripping	5	83%
Moisture-associated Skin Damage	5	83%
Advanced Wound Therapy Treatments	5	83%

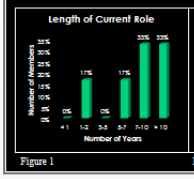

Figure 1

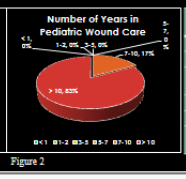

Figure 2

Clinical Decision-making Domains	Number of Responses	Percentage Value
Costs of Product/Treatment	5	83%
Duration of Treatment	6	83%
Ease of Applying Product/Performing Treatment	6	83%
Accessibility of Product	4	83%
Storage of Product	3	83%
Length of Time to Apply Product/Perform Treatment	5	83%

Table 2

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PAPER 1 - SUMMARY

- The goal of this study was to obtain consensus among experts about pediatric wound care. Through the use of this Consensus group and conducted survey, we were able to identify a more complete systematic review process, as well as identify additional domains that are important in clinical practice.
- As shown from the survey, the consensus group members polled have been proficient in pediatric wound care for several years with the majority of the members practicing for more than 10 years within a hospital setting. ***
- Throughout this study, previous clinical guideline development projects were reviewed and have recorded several key pieces of information pertaining to decisions concerning the domains of wound care management and which have been the most crucial for successful treatment and overall patient satisfaction. The resulting focuses from the survey process will play a vital role in determining the precise domains necessary to complete the systematic review process required for a consensus-based clinical guideline development protocol in pediatric wound care.
- These results revealed true clinical insight into databases, search terms, and domains that provide the most impact to pediatric wound care.
- The next steps will be to conduct the Systematic review and use the clinical consensus group to develop and analytical framework for future clinical guidelines for the standardization of treatment plans for the pediatric wound patient.

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PAPER 2 – CONDUCTING THE SYSTEMATIC REVIEW OF SYSTEMATIC REVIEWS FOR PEDIATRIC WOUND CARE

- This study encompasses systematic reviews of wound care products and wound management based upon databases identified from the clinical consensus group.
- All wound care management systematic reviews were analyzed, reviewed and charted to address the weight of evidence using the Primsa guidelines and criteria to evaluate each review.
- The reported evidence was analyzed using Amstar , which is a critical appraisal tool for systematic reviews that include randomized or nonrandomized studies of healthcare interventions, or both.

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PAPER 2 - ASSESSING QUALITY AND CONTENT OF SYSTEMATIC REVIEWS IN PEDIATRIC WOUND CARE

Methods

- ***Establish Eligibility Criteria*** - Published systematic reviews printed in the English language from the past decade (1/1/2009-12/31/2019) were the primary eligibility criteria. Reviews had to include at least one paper in their analysis with pediatric ages 0-17 years in their population. The reviews could include or originate from any country.
- ***Determine Search Strategy*** - A comprehensive review was conducted using PubMed (NLM), Academic Search Complete (EbscoHOST), Cochrane and MEDLINE databases. The wound type search terms were "pressure ulcers", "pressure injuries", "surgical wounds", "epidermal stripping", "intravenous extravasation injuries", "moisture-associated skin damage" and "advanced wound therapy".
- ***Develop Screening Process*** - Literature results displaying titles only were then exported into a Word document for review and compiled. A single reviewer then excluded articles by title and abstract, when necessary.

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PAPER 2 - ASSESSING QUALITY AND CONTENT OF SYSTEMATIC REVIEWS IN PEDIATRIC WOUND CARE

Methods (continued)

- ***Study Extraction and Selection*** - Screened articles were then compiled into a single Excel workbook at which time two reviewers determined what to include or exclude. Discrepancies were then discussed and finalized between the two reviewers. Articles considered for inclusion were then divided between the two reviewers to assess.
- ***Quality Assessment*** - There is currently no standardized methodology of assessing the quality of systematic reviews of systematic reviews. Assessment was conducted per the recommendations of Smith et al.[6] and Bigby et al.[7] using PRISMA and AMSTAR checklist per included review. Both authors administered the checklist simultaneously for three articles to ensure interrater reliability. There were no discrepancies. The remaining articles were then divided, reviewed and scored separately by each reviewer. Risk of bias and heterogeneity within the reviews were then discussed to be included narratively.
- ***Report evidence to address Consensus Group Domains*** - Two domain checklists were created in an Excel file. In domain checklist A, the first author recorded whether or not the reviews included any of the domains in their primary or secondary outcomes. Domain checklist B contained information pertaining to the articles within the reviews addressed the domains.

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PAPER 2 – USE OF PRISMA FLOW DIAGRAM

- The PRISMA system is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses.
- PRISMA focuses on the reporting of reviews evaluating randomized trials but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.[5]

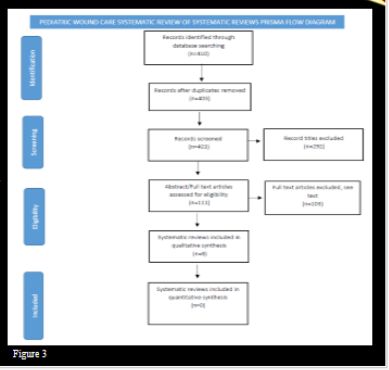

Figure 3

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PAPER 2 – RESULTS OF REVIEWS

- Four hundred and ten records were identified between all databases. Of these, 77 focused on pressure ulcers/injuries, 310 on surgical wounds, 3 on IV infiltration/extravasation and 20 were on advanced wound care therapy. No articles were found on epidermal stripping or moisture-associated skin damage, and after duplicate articles were removed, 403 were screened.
- We excluded 292 articles for the following reasons: 1) they did not include a pediatric population; and 2) they were not systematic reviews or the articles did not address wounds or wound treatment.
- Because inclusion criteria were not explicitly apparent in the article titles, a secondary process was conducted by the authors reviewing abstracts of the 111 abstracts to identify the Patient population, the Intervention, the alternative in Comparison, and the Outcome (PICO) or inclusion criteria of the reviews.
- An additional 103 articles were excluded in this process. Only 8 articles remained and were assessed for methodological quality and content. Due to scope and heterogeneity, quantitative meta-analysis could not be conducted.

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PAPER 2 - AMSTAR 2

Goals of AMSTAR:

(1) To create valid, reliable and useable instruments that would help users differentiate between systematic reviews, focusing on their methodological quality and expert consensus

(2) To facilitate the development of high-quality reviews

Uses of AMSTAR:

(1) To develop and evaluate reviews

(2) To use as a guide to conduct of reviews

(3) To use as an aid to teaching about systematic reviews.

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PAPER 2 – RESULTS OF CHARACTERISTICS

- Four articles identified themselves as systematic reviews and meta-analysis. Two of the articles were integrative reviews that followed PRISMA statement, and one article was a systematic review without meta-analysis. The final article identified as a literature review only.
- A majority of the reviews (5/8) were aimed towards pressure ulcers/injuries and were not randomized control trial focused. These focused more on assessing risk, prevalence, and bundle implementation.
- The other three reviews focused on surgical (including burns) and aimed to assess quality of conventional or randomized trials. Two reviews included mostly randomized control trials, whereas the remaining six were comprised of mostly other types of articles such as retrospective observational studies and quality improvement.
- Of the three reviews that included both pediatric and adult populations, 15 out of 48 studies included pediatric focus. Exact age and mean of conglomerate pediatric population could not be calculated considering not all reviews reported age details.
- Only a few systematic reviews reported clinically significant findings***
- All but one review, Ferreira et al.[12], reported methodology of quality assessment.

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PAPER 2 – RESULTS OF QUALITY ASSESSMENT

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2015)	Courtenright et al (2014)	Martin et al (2016)	Jull et al (2014)	Breadenreid et al (2014)
1	Y	N	N	Y	N	Y	Y	Y
2	N	N	N	N	N	N	N	N
3	Y	Y	Y	Y	Y	Y	Y	Y
4	Y	Y	N	N	Y	Y	Y	Y
5	N	N	N	Y	N	Y	N	N
6	Y	Y	Y	Y	Y	Y	N	Y
7	Y	Y	Y	Y	Y	Y	Y	Y
8	N	N	Y	Y	N	Y	Y	Y
9	Y	Y	Y	Y	Y	Y	Y	Y
10	Y	Y	Y	Y	Y	Y	Y	Y
11	N	Y	Y	Y	Y	Y	Y	N
12	N	N	N	Y	N	N	Y	Y
13	N	N	N	Y	N	Y	Y	Y
14	Y	Y	N	Y	N	Y	Y	Y
15	N	N	N	Y	N	Y	Y	Y
16	N	Y	N	N	Y	Y	N	Y
17	N	Y	Y	Y	Y	Y	Y	Y
18	N	Y	N	N	Y	Y	N	Y
19	N	N	N	N	N	Y	Y	Y
20	N	N	N	N	N	Y	Y	Y
21	N	N	N	Y	N	Y	Y	Y
22	N	N	N	Y	N	Y	Y	Y
23	N	Y	N	Y	N	Y	N	Y
24	N	Y	N	Y	N	Y	Y	Y
25	N	Y	Y	Y	Y	Y	Y	Y
26	Y	Y	Y	Y	Y	Y	Y	Y
27	Y	Y	N	N	Y	N	Y	Y

Table 3

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2015)	Courtenright et al (2014)	Martin et al (2016)	Jull et al (2014)	Breadenreid et al (2014)
1	Y	Y	Y	Y	Y	Y	Y	Y
2	Y	Y	Y	Y	Y	Y	Y	Y
3	Y	Y	Y	Y	Y	Y	Y	Y
4	N	Y	Y	Y	N	N	Y	Y
5	N	N	N	N	Y	Y	N	Y
6	Y	Y	N	Y	Y	N	Y	Y
7	Y	Y	Y	Y	Y	Y	N	N
8	Y	Y	N	Y	Y	Y	Y	Y
9	Y	Y	N	Y	Y	Y	Y	Y
10	N	N	N	Y	N	Y	Y	N
11	Y	Y	N	Y	Y	N	Y	Y

Table 4

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PAPER 2 – RESULTS OF DOMAINS

	Kottner et al (2013)	Kottner et al (2010)	Ferreira et al (2018)	Jackson et al (2015)	Courtenright et al (2014)	Martin et al (2016)	Jull et al (2014)	Breadenreid et al (2014)
Cost of Product	NA	No	No	No	NA	Yes	Yes	No
Duration of treatment	NA	No	Yes	No	NA	Yes	Yes	Yes
Ease of Applying	NA	No	Yes	No	Yes	Yes	No	No
Accessibility of Product	NA	No	Yes	No	NA	No	No	No
Storage	NA	No	No	No	NA	No	No	No
Length of Time to apply/perform	NA	No	Yes	No	Yes	Yes	No	No
Pain Association	NA	No	NA	No	NA	Yes	No	No

Table 5

23

PAPER 2 - DISCUSSIONS

- ***Characteristics of the Studies*** - Several key aspects of the reviews were noted when reviewing the results.
- The articles identify themselves differently, with some identifying themselves as a systematic review, literature review, meta-analysis, or a combination of two.
- Many of the clinical trials did not include exact ages of the population studied.
- All of the studies had varying levels of aims that ranged from assessing risk factors, to identifying validated instruments, to a focus on product efficacy. Expectedly, conclusions of studies varied, therefore, hindering linear assessment.

24

PAPER 2 - DISCUSSIONS

- ***Quality Assessment*** - When assessing the quality of the studies, it was determined that no true "gold standard" for assessing systematic reviews exists.
- Because this is the first systematic review of systematic reviews in wound care specifically, SRs of SRs in other healthcare related fields were relied upon. There have been modified versions of AMSTAR (AMSTAR-2 and R-AMSTAR) used.[14-16] However, due to their lack of traditional usage, AMSTAR-2 and R-AMSTAR were not utilized for this systematic review assessment to maintain integrity. ***
- Regardless of the assessment version, all reviews seemed to conclude that there is generally poor quality of evidence due to reporting methodology limitations and scarcity of literature.
- Utilizing both AMSTAR and PRISMA provided assurance in validating the assessment strategy in the sense that there was consistency seen across both checklists. It was expected that most Cochrane publications would contain higher checklists in PRISMA, considering that several items in methods and results are paralleled on addressing meta-analysis conduct. This supports the lower PRISMA scoring of integrative reviews that reportedly followed PRISMA guidelines.

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PAPER 2 - DISCUSSIONS

- ***Domains*** - The expert consensus group was assembled to establish the important domain information that pediatric wound experts found crucial to extract from the literature search.
- After review of the systematic reviews, we determined that very few articles discussed the desired domains either in the description of their objectives ,nor within the written content of the review
- Some reasons for this lack of information may include varying levels of research priorities amongst the scientific community, the lack of priority for a cost savings approach to wound care, etc.

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PAPER 2 - DISCUSSIONS

- ***Limitations*** - Despite my best efforts, there were several limitations that were noted.
- Our search strategy, as discussed in Methods section, while not all inclusive, was validated and deemed appropriate by the clinical consensus group.
- Eligibility criteria used discrete terms, therefore, I may have missed other reviews that had varying phrases or terminology.
- I excluded all non-English publications.
- Our search only included pediatric systematic review of systematic reviews, which limited the search total to eight studies.
- In reviewing the studies, it was difficult to discern exact or mean age of the pediatric population in the various studies.
- A lack of "gold standard" quality assessment tool prevented linear comparison.
- I feel that the heterogeneity of the selected studies limited the breadth of the study results

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PAPER 2 - CONCLUSIONS

- This is the first article to summarize the systematic review literature on pediatric wound care intended to shed light on the extent of quality and content of the work used to make critical decisions and guidelines.
- The breadth of work done has been widely influential in the decision-making process of wound care.
- Even though there is not necessarily a lack of expressing the need for more literature and research, there seems to be a lack in direction, uniformity and methodology in carrying out high quality research and publications.
- With patience and tenacity, rigorous efforts must be undertaken in order to achieve publications worthy of influencing critical decision-making processes in pediatric wound care.

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PAPER 3 - PROVIDE ANALYTICAL OUTLINE FOR THE CREATION OF GUIDELINES FOR EVIDENCE BASED CLINICAL PRACTICE

- ***Evidence Based Guidelines for Policy*** - Evidence-based guidelines, also called clinical practice guidelines, "are systematically developed statements to assist clinicians and patient decisions about appropriate health care for specific clinical circumstances".
- These guidelines are widely developed tools, that improve the quality of care.
- The topic for guideline development will usually need to be refined before the evidence can be assessed in order to answer exact questions. ***
- The usual way of refining the topic is by a dialogue among clinicians, patients, and the potential users or evaluators of the guideline. Discussions about the scope of the guideline will also take place within the guideline development panel. Therefore a group needs to be clear which areas are and are not within the scope of their activities.

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PAPER 3 – PROVIDE ANALYTICAL OUTLINE FOR THE CREATION OF GUIDELINES FOR EVIDENCE BASED CLINICAL PRACTICE

- The IOM (2011) defined clinical practice guidelines as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options
- Trustworthy guidelines should be based on a systematic evidence review, developed by panel of multidisciplinary experts, provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations.
- The goal of this paper will be to define the steps required to take the evidence from our systematic review and consensus group and apply it in practice through the development of a clinical decision tree.

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PAPER 3 - UTILIZATION OF AN EXPERT CONSENSUS GROUP

- A variety of methods on using a consensus group have been outlined in the literature.
- Several studies had clinical consensus group members meet face to face during a 2-day period.
- ***Achieving Consensus*** - A key issue during guideline development, during formulation of recommendations, is acquiring consensus among a diverse group of individuals, often with competing interests and values. One such way is using the Delphi method

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PAPER 3 – DEVELOPING PRACTICE GUIDELINES

The Five Steps to Practice Guideline Development Include:

(1) Identifying and refining the subject area is the first step in developing a guideline
(2) Convening and running guideline development groups is the next step
(3) On the basis of systematic reviews, the group assesses the evidence about the clinical question or condition
(4) This evidence is then translated into a recommendation within a clinical practice guideline
(5) The last step in guideline development is external review of the guideline.

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PAPER 3 – RESULTS FOR GUIDELINE DEVELOPMENT

Figure 4

Type of Communication	Number of Responses	Percentage Value
In-Person Meetings	5	83%
Conference Call Meetings	4	67%
Email Communication	5	83%
No Participation in Guideline Development	0	0%
Other	0	0%

Table 6

	# of Responses	%age
Longer meetings, less frequency	3	50%
Shorter meetings, more frequency	3	50%
Face to face meetings only	3	50%
Communication via email only	3	50%
Skype / telecommunication meetings only	3	50%
e not participated in guideline formation	0	0%
Other (please specify)	3	50%

Table 7

	Responses	%age
Multiple face to face meetings with all consensus group members to review data in a series	2	33%
Receive all information via email to individually review with one-2 hour Skype/face to face meeting to discuss guideline creation	3	50%
One hour face to face meeting to review data with a mock clinical guideline developed by the PI, then to follow up via email to discuss edits and recommendations on the proposed clinical guidelines	3	50%
Other (please specify)	1	17%

Table 8

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PROPOSED GUIDELINE DEVELOPMENT-NEXT STEPS

- The first step proposed is to present the survey results to the expert consensus group to discuss the agreed upon method of communication for the decision-making process.
- The next step would be to use this method of communication to establish a decision tree based upon the primary domains of clinical practice determined by the results of the consensus group and the systematic review.
- Upon establishing a evidence based clinical decision tree, the PI will distribute the mock guideline developed to the consensus group for discussion.
- The developed guideline/guidelines will be utilized to evaluate wound care products for usage in the clinical setting.

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DISSERTATION - LESSONS LEARNED

- ***Paper 1*** - Through the use of this Consensus group and conducted surveys, we were able to identify a more complete systematic review process, as well as identify additional domains that are important in clinical practice. These results revealed true clinical insight into databases, search terms, and domains that provide the most impact to pediatric wound care.
- ***Paper 2*** - This is the first article to summarize the systematic review literature on pediatric wound care intended to shed light on the extent of quality and content of the work used to make critical decisions and guidelines. Producing systematic reviews with recommendations from expert consensus panelists and disseminating survey results does not naturally bring more awareness and use of evidence in wound care practices. However, it is important the overall concept has been supported by a quantitative analysis to invoke necessary improvements in the field.
- ***Paper 3*** - This study was proposed to evaluate what shapes the complete clinical guideline decision-making process in variable wound care practices on a national and local scale. Identifying this process to be important to advancing wound care research and clinical practice, particular information and how it was acquired through the use of expert consensus panelists and systematic reviews, guided this study through the best course of action necessary to develop the conceptual framework of establishing clinical guidelines.

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REFERENCES

- Chhabra s, Chhabra N, Kaur A, Gupta N. (2017). Wound Healing Concepts in Clinical Practice of OMFS. Journal of maxillofacial oral surgery, 16(4): 405-423. DOI: 10.1007/s12663-016-0880-x
- King A, Stellar JJ, Blevins A, Shah KN. (2014). Dressings and Products in Pediatric Wound Care. Advances in Wound Care, 3(4): 324-334. DOI: 10.1089/wound.2013.0477
- Dabiri G, Damstetter e, Phillips t. (2016). Choosing a Wound Dressing Based on Common Wound Characteristics. Advances in Wound Care, 5(1): 32-41. DOI: 10.1089/wound.2014.0586
- Ennis, W.J. (2012). Wound Care Specialization: The Current Status and Future Plans to Move Wound Care into the Medical Community. Advances in Wound Care, 1(5). DOI: 10.1089/wound.2011.0346
- Bernabe, K.Q., Desmarais, T.J., Keller, M.S. (2014). Management of Traumatic Wounds and a Novel Approach to Delivering Wound Care in Children. Advances in Wound Care, 3(4). DOI: 10.1089/wound.2013.0465
- Bani, I.A. (2008). Health Needs Assessment. Journal of Family Community Medicine, 15(1), 13-20.
- Community Health Needs Assessment (2001). World Health Organization. ISBN: 92 890 1194 7
- Oliver S, Dickson K, Bangpan M (2015) Systematic Reviews: Making Them Policy Relevant. A Briefing for Policy Makers and Systematic Reviewers. London: EPPI-Centre, Social Science Research Unit, UCL Institute of Education, University College London. ISBN: 978-1-907345-83-8
- Kasvarni G, Sundeep (2015)Adv Wound Care (New Rochelle). Oct 1; 4(10): 583–586. doi: 10.1089/wound.2015.0675 PMCID: PMC4593974 PMID: 26487976 Second Annual Meeting of the International Society of Pediatric Wound Care
- Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. Wound Repair Regen 2009;17:763–771
- Baharestani, Mona Myriam ; An Overview of Neonatal and Pediatric Wound Care Knowledge and Considerations, wound management and prevention, Issue: Volume 53 - Issue 6 - June, 2007 Index: Ostomy Wound Manage. 2007;53(6):54-55.
- More references upon request

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DISSERTATION SUMMARY
Questions