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**The Multidisciplinary Approach to the Development of Quality Clinical Practice
Guidelines: Piloting Management of the Patient Requiring Inhaled Nitric Oxide for Acute
Pulmonary Hypertension in the Neonatal Intensive Care Unit**

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Abstract

BACKGROUND: Clinical practice guidelines communicate recommendations to health care professionals. Poor quality guidelines decrease compliance, foster differences in practice, discordance with resources, and compound inequity in healthcare. The goal of this project was to develop a clinical practice guideline and chronicle the process. The intervention implemented was the creation of a clinical practice guideline with a family integrated and equity endorsing approach.

METHODS: A multidisciplinary team was formed and worked collaboratively to write a clinical practice guideline for inhaled nitric oxide for the management of acute pulmonary hypertension in neonates. The guideline was evaluated using the AGREE II instrument and GRADE adapted questionnaire. Parent education imbedded in the guideline was presented to the Parent and Family Advisory Council for review. During this project, the process of guideline development was systematized and templated with each step broken down as a reference for future guideline development projects. I termed the process the ELEVATE method.

RESULTS: The AGREE II score to rate the overall quality of this guideline was 92%. In response to the question, I would recommend this guideline for use, 100% of evaluators answered yes. After meeting each quality measure, the final guideline was proposed and adopted.

CONCLUSIONS: A process for writing clinical practice guidelines inclusive of family integration and a quality evaluation process supports quality improvement and family centered care. Future work will include team education for the implementation of the clinical guideline, ongoing evaluation to meet current practice standards, and validating the ELEVATE method.

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Introduction

The development of clinical practice guidelines in the Neonatal Intensive Care Unit (NICU) will enhance the quality of care we provide. According to De Leo, et al., (2023) clinical practice guidelines concisely communicate recommendations supported by evidence for clinicians to make informed decisions and reduce complications. Team and family communication can be improved by incorporating models of family centered care in the development process of clinical practice guidelines (Labrie, et al., 2021). Family communication empowers the family as an equal part of the health care team and allows the team to better meet their individual needs and preferences (Labrie, et al., 2021). By establishing an evidence supported, standardized method to clinical practices, safety and efficiency are optimized and outcomes better evaluated for quality improvement.

Problem Description

The specialty of neonatology has demonstrated significant changes with new evidence and technology resulting in variations in many aspects of practice. For example, the age of fetal viability has shifted from approximately 28 weeks gestation in 1971 to international reports of neonatal survival at 22 weeks gestation (Rysavy, et al., 2021). The Vermont Oxford Network (VON) is a collaboration of over 1,400 centers internationally striving for quality and equity in neonatal care (Vermont Oxford Network, nd.). VON data reflects the incidence of resuscitation at 22 weeks has increased by over 50% since 2014 with survival rates reported as high as 50% (Rysavy, et al., 2021).

Caring for neonates on the edge of viability requires new approaches to care delivery and family communication, but methods are not standardized. According to Rysavy (2021), care models for neonates at 22-23 weeks gestation are different across regions in the United States.

The American Academy of Pediatrics (AAP) recommends an individualized approach regarding resuscitation for neonates born at 22-24 weeks gestation based on known complications and parental values leading to differences in family and team styles (Rysavy, et al., 2021).

Ramaswamy, et al., (2022) demonstrated the clinical progress in neonatology leading to differences in practice with regard to management of the neonate with respiratory distress syndrome (RDS). RDS manifests from premature lungs and insufficient endogenous surfactant causing hypoxic respiratory failure despite respiratory support (van Kaam, et al., 2023). To decrease the risk of long-term lung complications, there has been a shift in practice to minimize invasive mechanical ventilation in preterm neonates opting for continuous positive airway pressure (CPAP). Neonatal providers are seeking less invasive methods to deliver exogenous surfactant intratracheally to neonates while maintaining CPAP support (van Kaam, et al., 2023). Surfactant is commonly used to treat RDS, but it remains unclear at what point in treatment and by what method surfactant should be administered (Ramaswamy, et al., 2022).

Reynolds et al., (2021) reviewed best practices for Less Invasive Surfactant Administration, known as LISA, noting successful process implementation but differences in premedication comfort strategies. Reynolds et al., (2021) also identified the need for parental education and partnering in care. Connecting families to clinical practice guidelines by identifying opportunities for education and communication during the treatment process enhances the family integrated care model in neonatology.

Poor quality clinical practice guidelines can negatively impact compliance. McDonald (2023) evaluated clinical practice guidelines related to delayed cord clamping. While developed guidelines encouraged the practice, they did not provide supportive evidence or details to promote best practice. McDonald (2023) attributes decreased rates of delayed cord

clamping with poor quality, inconsistent guidelines. The issues were discordance with guideline recommendations and cited references, lack of cited references, or references being other guidelines as opposed to primary sources or systematic reviews (McDonald, 2023).

Variations in practice in the neonatal population emphasize the need for increased research and dissemination of best practices in neonatology. One strategy is the development of clinical practice guidelines. Quality clinical practice guidelines will support clinicians in delivering care backed by scientific evidence; a standard of practice that can be evaluated, and improved on to meet the needs of this growing area of medicine.

Available Knowledge

In order to establish attributes of quality in clinical guidelines, guidelines must be evaluated in a standardized, validated manner. The AGREE collaboration was comprised of an international team of researchers and guideline developers that created the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument in 2003 (Brouwers et al., 2010). The original tool was evaluated and opportunities for improvement were identified with regard to methodology, utility, and ease of use. This reassessment led to the development of the AGREE Next Steps Consortium. Following two subsequent studies and user feedback, the tool was refined for efficiency, accuracy, and validity and the AGREE II was developed (Brouwers, et al., 2010). The AGREE II instrument was validated in identifying high quality and low-quality information within a guideline (Brouwers, et al., 2010).

Wang et al, (2019) used the AGREE II instrument to evaluate clinical practice guidelines for post stroke aphasia noting inconsistency in treatment recommendations among the eight guidelines assessed. Three guidelines recommended intensive therapy, four cited group treatment as supportive therapy, three referenced computerized language therapy

considerations to support other therapies, two referenced training a communication partner to improve compliance (Wang, et al., 2019). Additionally, two guidelines recommended the same therapy, but graded the evidence differently (Wang, et al., 2019). This evaluation highlighted the need to focus on rigor of development and applicability when creating clinical practice guidelines (Wang, et al., 2019).

Almazrou et al. (2021) performed a regional review of clinical practice guidelines using the AGREE II instrument from countries in the Middle East and North Africa, known as the MENA region. This research differed from other studies as it assesses regionally developed as opposed to disease specific guidelines. The MENA region represents low, middle, and high-income countries with varying health care systems. MEDLINE and EMBASE databases were searched using keywords for clinical practice guidelines and MENA countries, but limited to English language. The resulting 346 papers plus 19 from gray literature were further screened and ultimately 61 clinical practice guidelines were reviewed. According to Almazrou et al., (2021), two authors reviewed the guidelines for quality. The results were noted as a percentage of the maximum total score in each domain of the AGREE II (Almazrou, et al., 2021), consistent with the user's guide instructions (AGREE Next Steps Consortium , 2017). The lowest mean scores were in the areas of rigor of development (28%), applicability (29%), and stakeholder involvement (53%). Almazrou et al., (2021) noted the healthcare administration and economic variations around the MENA region potentially impacting the AGREE II results. The areas represented included rural regions, areas that lack of physician availability and training, health care costs beyond what can be afforded, and communicable and non-communicable diseases impacting population health. These findings emphasized areas to improve the quality of the clinical practice guidelines. Partnering with stakeholders and local

agencies were identified opportunities to enhance guidelines from the MENA region. This strategy can minimize bias and improve care to populations served by removing assumptions for access to care and resources available. These opportunities were reflected in the scores in the domains of applicability and rigor of development further supporting the findings of the AGREE II. Almazrou et al., (2021) recommended using a multidisciplinary team in the development of clinical practice guidelines and training to incorporate the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool to assess the guidelines.

Rationale

A literature review was performed to apprise the use of clinical practice guidelines in neonatology. The keywords “clinical practice guidelines” and “neonatal” were entered in the PubMed database culminating in a search incorporating MeSH, terms to develop the search ("Practice Guidelines as Topic"[Mesh]) AND "Infant, Newborn"[Mesh]. Inclusion criteria was all published research within the last five years, studies available in the English language, and access to full text articles. Exclusion criteria were when English language translation was not available and full text articles were not accessible. The search resulted in 24 articles. Nine were excluded because they were based on pregnancy or pediatric models resulting in 15 articles. The 15 articles were reviewed for the use of the AGREE II instrument. One out of the 15 articles referenced the AGREE II instrument. Acknowledging limitations of this search, there is an identified opportunity to assess clinical practice guidelines in neonatology with AGREE II.

In 2023, the NICU Quality Improvement Team (QIT) at Albany Medical Center was reestablished as a multidisciplinary group of colleagues to review current practices, create

practice guidelines, and provide a forum for quality improvement in the NICU (M. Fay, personal communication, May 10, 2023). The initiative to evaluate current practices and develop referenceable guidelines inspired me to concurrently develop a guideline for a clinical area I am passionate about and follow the development process. At the beginning of this project, the NICU did not have a guideline for inhaled nitric oxide leading to variations in practice. Therefore, I opted to work on a clinical practice guideline for nitric oxide for the management of acute pulmonary hypertension for patients with hypoxic respiratory failure cared for in the NICU at Albany Medical Center.

Inhaled nitric oxide is a selective pulmonary vasodilator used to treat neonates with progressive hypoxic respiratory failure secondary to pulmonary hypertension (Tzanetos, et al., 2015). There is a significant cost associated with this level of intensive care and treatment. According to Tzanetos (2015), inhaled nitric oxide costs \$100 per hour independent of the dose with an annual cost of \$1.8 million. Vermont Oxford Network (2018) reports \$100,000 in cost per inhaled nitric oxide session per infant.

According to Lakshminrusimha and Keszler (2015), the management of pulmonary hypertension in the neonatal population has significantly progressed due to improved ventilation and hemodynamic management strategies. However, complications of inhaled nitric oxide therapy can include an increased risk of methemoglobinemia, prolonged mechanical ventilation, bleeding, adverse neurodevelopmental outcomes, and if the patient is not responding to inhaled nitric oxide therapy, possible escalation to Extracorporeal Membrane Oxygenation (ECMO) (Tzanetos, et al., 2015). Currently, the ECMO program at Albany Medical Center is in development (Bakar et al, 2023), therefore, ECMO candidates would require transfer to an ECMO Center.

Specific Aims

Quality clinical practice guidelines are important in complex, intensive care, therefore the development process is crucial. The aim of this project was to use an evidence based, scientific process to develop and evaluate a clinical practice guideline for the NICU patient requiring inhaled nitric oxide for the management of acute pulmonary hypertension. An additional aim was to outline the steps necessary to create and implement evidence-based guidelines in the NICU.

Methods

Context

The NICU at the Bernard and Millie Duker Children's Hospital at Albany Medical Center (AMC) is a Level IV Regional Perinatal Center with over 30,000 births within the region and 300 neonatal air and ground transports annually (Albany Medical College, 2024). The neonatology team cares for approximately 800 patients per year (Albany Medical College, 2024). Identified stakeholders representing Neonatology, Pediatric Cardiology, and Pediatric Respiratory Therapy were invited to participate in a multidisciplinary NICU pulmonary hypertension team. The purpose of the NICU pulmonary hypertension team was to identify current practices and policies related to inhaled nitric oxide therapy including documentation standards, communication practices, approval for therapy, and escalation of treatment. For this project, the team did not access or collect protected health information. The Albany Medical Center Institutional Review Board (IRB) uses an online rapid determination tool to obtain documentation of exemption for a quality improvement project and this process was followed.

Interventions

As a first step in reaching project aims, the NICU pulmonary hypertension team reviewed evidence supported practices, clinical practice guidelines from clinical leaders including Brigham and Women's Hospital and Children's Hospital of Philadelphia, and began to develop a clinical practice guideline with a health equity and family integrated approach. The team held bimonthly meetings in person with an online option to identify goals, share updates, review drafts, and provide feedback. Representatives of the NICU pulmonary hypertension team actively participate in the NICU QIT monthly meeting to discuss relevant quality initiatives in the NICU.

As the project lead, I compiled evidence for the development of the clinical practice guidelines, educated team members regarding the required quality elements, created family education for the practice guideline, held team meetings, and oversaw the clinical guideline development process. Throughout the project, I compiled practices and resources and organized them in logical steps of the guideline development. I broke down each step to smaller, achievable portions, so teams can work collaboratively to identify objectives through each stage of the clinical practice guideline development process. Each phase builds upon previous work. The process was packaged into a template for creating a clinical practice guideline.

This template is referred to as the ELEVATE method. ELEVATE is an acronym for Examine, Listen, Evidence, Validate, Analyze, Teach, and Evaluate. The ELEVATE method resulted from this project where each step was assembled into a comprehensive timeline. The Examine phase is for the developer(s) to identify clinical passions and use that inspiration to create clinical questions for exploration. A guideline developer could be any member of the multidisciplinary care team. Current practices and workflows are reviewed to identify areas of

opportunity and goals are defined. Institutions should use a clinical practice guideline or pathway development worksheet (Barry, n.d.) to support this process and organize ideas.

The Listen, Evidence and Validate phases are when a multidisciplinary team of stakeholders is organized and meets to discuss goals, determine team meeting frequency and strategy, identify concurrent, interrelated projects, and perform a literature search and/or systematic review. The team should follow Institutional Review Board policies and obtain appropriate documentation for the project. It is recommended to identify and connect with institutional resources that may already be established. During this time, the team may perform data collection and begin a rough draft of the clinical practice guideline with ongoing revisions as needed.

During the Analyze phase, the team should look for bias, assess quality, family integration opportunities, readability, and applicability. The GRADE and AGREE tools are recommended to guide the assessment. Other validated tools may be employed. If the institution has a family council, it is a valuable resource to improve team and family communication. At this stage, the final draft should be shared with independent reviewers, stakeholders and areas of impact. If applicable, the team may begin building the guideline associated provider order panel(s).

The team should return to the beginning of the process to reflect on meeting objectives and integrating them in the implementation and distribution plan in the Teach and Evaluate phases. Team education is essential prior to implementation. Following the launch of the guideline, it is necessary to evaluate benchmarks and have ongoing evaluation of metrics, compliance, and efficacy. Guidelines should be updated minimally every three years for current

literature and practices. To maintain quality, this is an ongoing process. The ELEVATE method will be shared with the neonatology team as a resource for future projects.

Study of the Interventions

The guideline drafts were evaluated for readability and ease with which the process can be followed by other team members. An additional aspect introduced to this process is the integration of family education. Family education in this guideline serves to standardize communication and improve consistency. The Patient and Family Advisory Council (PFAC) at Albany Medical Center is comprised of current and former patients and families to improve team communication. On March 28, 2024, I attended the PFAC meeting to share the drafted family education element and the guideline for context. Based on feedback from the council, modifications were made to the family education. Changes included simplifying language, defining complex terms, clarifying roles, and including interventions to empower the parent recognizing them as a member of the treatment team.

Measures

The AGREE II instrument provides a system to evaluate the methodology and transparency in guidelines to decrease variability and uphold standards (AGREE Next Steps Consortium, 2017). The tool can be used in the guideline development process or as an evaluation tool. It is accessible for free online complete with a user manual (<https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf>). It has 23 items within six domains including scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence (Brouwers et al., 2010). In the review process, each item is graded with a 7- point scale See Appendices B and C for tool items and scoring

methods) . It is recommended that two to four individuals review the guideline for validity (Brouwers et al., 2010). Currently, quality scores are not correlated with outcomes (AGREE Next Steps Consortium, 2017).

Clinical guidelines can promote health equity on a population and individual level (Welch, et al., 2017). The goal of the development of a clinical practice guideline is to decrease bias with a standardized approach based on evidence improving access to care (Shaver, et al., 2023). However, guidelines can also negatively impact equity with recommendations that may not be accessible to all patients (Shaver, et al., 2023).

Grading of Recommendations Assessment, Development and Evaluation (GRADE) implements a scientific method to evaluate clinical guidelines and outcomes to support decision making (Schunemann, et al., 2023). To assess equity and minimize the risk of bias within the guideline, the GRADE Guidelines and Health Equity assessment prompts (Welch, et al., 2017) (see Appendix A) were used. These questions were selected by Welch et al. (2017) in collaboration with the GRADE working group. The team applied this questionnaire in the development process. Responses to the questionnaire were collected using Microsoft forms.

The outcome is the final draft of a clinical practice guideline for the NICU patient requiring inhaled nitric oxide for the management of acute pulmonary hypertension. The guideline should meet each quality benchmark including the GRADE questionnaire, PFAC parent education review, scoring using the AGREE II tool, and presentation to the QIT. The experience culminates in a chronicled process and framework for replication to promote the development of future practice guidelines held to the same rigor and standard to optimize patient safety and cost efficiency.

Analysis

The GRADE adapted questionnaire (see Appendix A) was used to assess for equity and bias within the guideline. The NICU pulmonary hypertension team reviewed the GRADE adapted questionnaire during a team meeting. The draft of the guideline was sent via email to the team as well as the link to the questionnaire. Responses were collected anonymously. Any answer of “yes” or “maybe” provided an opportunity for the respondent elaborate on their response.

The AGREE II tool and supplemental score sheet (see Appendix B) was used to evaluate the quality of the guideline. Volunteers from the Neonatal Advanced Practice Provider team, comprised of nurse practitioners and physician assistants, were asked to complete a review. The tool assesses the quality of the clinical practice guideline and identifies areas of opportunity within the defined domains to further strengthen this and future guidelines created by the NICU multidisciplinary team.

The AGREE II tool and supplemental score sheet were used to evaluate the clinical practice guideline in six separate domains. Domain scores were completed and calculated following the process outlined in the AGREE II User Manual according to the AGREE Next Steps Consortium (2017):

Domain scores are calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain. The scaled domain score is calculated as:

$$\frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}}$$

$$\text{Maximum possible score} - \text{Minimum possible score}$$

The score is be reflected as a percentage of the maximum possible score. Domain scores can be evaluated independently, together, or with changes in score following guideline modifications.

Ethical Considerations

The team implemented considerations for health equity throughout the guideline development process (Shaver, et al., 2023). The clinical recommendations were reviewed for accessibility acknowledging the systemic and social inequities in the health care system of the United States (Shaver, et al., 2023).

There were no conflicts of interest identified. Participation in the NICU pulmonary hypertension team, NICU QIT, and PFAC is voluntary. There was no funding or financial incentive for this project.

Results

The NICU pulmonary hypertension team of faculty from the Bernard and Millie Duker Children's Hospital at Albany Medical Center in Albany, NY was formed in September 2023. The goal was to develop a clinical practice guideline for the neonatal patient with acute pulmonary hypertension requiring inhaled nitric oxide with a health equity and family integrated approach. From September 2023 to April 2024, four drafts were created and revised in collaboration with Dr. Suzanne Barry, Director, Clinical Pathways Program at Albany Medical Center.

The pulmonary hypertension team applied the GRADE adapted questionnaire to the third draft. A Microsoft Form was shared with the members of the team via email and two out of ten team members responded were. There were four questions with possible replies of yes, no, or maybe. Results were compiled and presented in Table 1.

Table 1

GRADE Adapted Questionnaire Results (N=2)

| Question | Yes | No | Maybe |
|--|-----|----|-------|
| Are there groups or settings that might be disadvantaged in relation to the problem or intervention of interest? | 0 | 1 | 1 |
| Are there plausible reasons for anticipating differences in the relative effectiveness of the intervention for disadvantaged groups or settings? | 0 | 0 | 2 |
| Are there different baseline conditions across groups or settings that affect the absolute impact of the intervention or the importance of the problem for disadvantaged groups or settings? | 0 | 1 | 1 |
| Are there important considerations that people implementing the intervention should consider to ensure that inequities are reduced, if possible, and that they are not increased? | 1 | 0 | 1 |

The questionnaire yielded one “yes”, two “no”, and five “maybe” replies. Each question had at least one response of maybe. The written responses to the questionnaire brought forward consideration for out born patients requiring transport to Albany Medical Center for assessment and management, off label use of inhaled nitric oxide in very low birth weight patients, and the use for patients with pulmonary hypertension secondary to bronchopulmonary dysplasia or other complication. To address concerns raised, the pulmonary hypertension team proposed regional

education and modifications to the guideline. The current guideline will include a process implementation for the very low birth weight population. The management of the patient with pulmonary hypertension secondary to bronchopulmonary dysplasia will be brought to the QIT. There is a current quality initiative to provide education throughout the region through the perinatal outreach program.

The family education component of the guideline was presented to the Parent and Family Advisory Council on March 28, 2024. The council provided valuable feedback with regard to clarity, comprehension, and an opportunity for family empowerment. Specifically, a parent recommended adding an intervention the parent could do to support their baby and actively help them to feel included within the treatment section of the education. This feedback was incorporated in the family education.

According to the AGREE Next Steps Consortium (2017), a minimum of two evaluators is recommended, four is preferred. Four members of the Neonatal Advanced Practice Provider team at Albany Medical Center completed the appraisal. The respondents were either nurse practitioners or physician assistants. These team members would be responsible for applying the guideline in clinical practice. The reviewers were not members of the NICU pulmonary hypertension team. This was their first review of the guideline. Selection was based on the team members staffed for the shift and represented different team member roles, eg an MD, NNP, ... The results were tabulated and presented in Table 2. See Appendix C for scoring calculations. The score sheet does not provide an option for not applicable, the AGREE Next Steps Consortium (2017) offers two methods to address. The options are to either have the appraisers omit the item or rate the item as a score of 1 with an explanation (AGREE Next Steps Consortium, 2017). For this project, the appraisers were instructed to omit an item they deemed

not applicable. Domain and overall quality score categories from the score sheet were calculated by summing all scores of the individual items in the domain which is the obtained score. The obtained score minus the minimum possible score was divided by the maximum possible score minus the minimum possible score. The score of each domain and for the category of overall quality is displayed as a percentage.

The goals set were a minimum score of 70% in two or more domains and positive response indicated as either yes or yes with modifications on the overall guideline assessment question was achieved. The lowest score was in Domain 3 rigor of development which received a score of 80%. The overall quality of the guideline was 92%. One hundred percent of appraisers replied yes to the question “I would recommend this guideline for use” (AGREE Next Steps Consortium 2017, p.41) indicating a positive response.

Table 2

AGREE II Scoring (N=4)

| | | |
|----------|-------------------------|------|
| Domain 1 | Scope and purpose | 97% |
| Domain 2 | Stakeholder involvement | 99% |
| Domain 3 | Rigor of development | 80% |
| Domain 4 | Clarity of presentation | 93% |
| Domain 5 | Applicability | 98% |
| Domain 6 | Editorial independence | 100% |

Overall guideline assessment:

| | |
|--|------|
| Rate the overall quality of this guideline | 92% |
| I would recommend this guideline for use (yes) | 100% |

The final quality measure was the proposal of the final draft to the NICU QIT. At the April 11, 2024 QIT meeting, the final draft was presented to the NICU QIT. After final review, the clinical practice guideline will be implemented into practice. The NICU pulmonary hypertension team will continue to meet to develop team education, evaluate benchmarks and metrics. The guideline and its components will continue to be evaluated a minimum of every three years to ensure it meets current standards of practice reflected in the literature and ongoing quality review.

Discussion

The results of this project show that a process for writing clinical practice guidelines inclusive of family integration and a quality evaluation processes supports development of a high quality clinical practice guideline. The GRADE questionnaire was effective in identifying an opportunity to review education regarding risk factors for acute pulmonary hypertension and initial management for hospitals within the region prior to transport. By asking relevant questions, the team was able to consider populations effected and how to optimize care prior to transfer.

The ELEVATE method and preparation for the AGREE II appraisal demonstrated effectiveness in the development of clinical practice guidelines. ELEVATE applies a team

model with attention to equity and family integrated care. The approach to the development of clinical practice guidelines supports excellence in health care initiatives and allows multidisciplinary team members to serve in a leadership role in a supported manner. My intention is that other members of the multidisciplinary team can use this template to guide them in developing future guidelines. With the reinstatement of the NICU QIT, there is a forum to review best practices and quality initiatives inclusive of future guidelines. The approach can be further studied and validated. The AGREE II scores were all greater than 70% indicative of quality. The lowest score was in rigor of development with a score of 80%. This score may be improved upon in the evaluate phase by incorporating institutional data and outcomes following the guideline implementation. Clarity of presentation received a score 93%.

The guideline follows a comprehensive flow chart. Consideration could be made for reorganization of processes or streamlining information within the guideline. The guideline incorporates hyperlinks to the family education component and guidance for cardiovascular support. It would be interesting to rescore the guideline following team education to see if clarity is improved. The score of 100% for recommendation for use reflects acceptance of the guideline by representatives of the Neonatal Advanced Practice Provider team. It is humbling to have achieved this score and feel supported by my team. The feedback from participation in the PFAC was well received. Future clinical practice guidelines and other quality improvement initiatives would benefit from using this forum to have open discussion and feedback to enhance a family centered approach, especially in neonatology and pediatrics.

The importance of a team approach to critical care is imperative for sustainability and resilience of health care professionals. Working collaboratively on quality initiatives could

increase clinical judgement and opportunities for future projects. Future research in this area would be of benefit to multidisciplinary teams.

Limitations

The NICU pulmonary hypertension team was limited by the timeline of the project with the goal to bring the guideline to the point of proposal and adoption. Another limitation was the low response rate for the GRADE questionnaire. While responses emphasized areas of opportunity for equity promoting practices, there may be other areas that were not mentioned.

Conclusion

Decreasing variations in practice with a standardized model that can be evaluated and revised as new evidence and clinical advancements are disseminated will support quality, safety, and efficiency. Clinical practice guidelines can enhance care delivery especially in complex and intensive care. Readability and applicability are necessary in creating a sustainable, quality guideline. The AGREE II and GRADE questionnaire are validated assessment tools available to support quality and evaluate for bias. The ELEVATE method employs an evidence supported, standardized approach to create quality clinical practice guidelines including the assessment tools and a family integrated approach. Reviewing this process may benefit future projects.

Future Considerations

Patient outcomes were not evaluated in this project. With clinical practice guidelines providing standardization of care, there is an opportunity for future quality improvement analysis. Following implementation of the developed guideline, the team can assess quality

measures associated with the care of neonates requiring inhaled nitric oxide for acute pulmonary hypertension. Potential future analysis will include duration of inhaled nitric oxide therapy and associated costs, protocol compliance and understanding, standardization of echocardiogram diagnostic criteria language, improved parental education and support, decreased incidence of escalation to ECMO, and improved long term developmental outcomes.

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Appendix A

GRADE Methodology Adapted Questionnaire

According to Welch et al., (2017), this questionnaire uses the GRADE methodology to assess for and promote health equity within clinical practice guidelines. The pulmonary hypertension team used this questionnaire in the development process of the clinical practice guideline. The questionnaire was reviewed during a team meeting and shared via Outlook Forms. Results were compiled and documented. Information gained was used to minimize bias within the guideline development. The reply options for each question were yes, no, or maybe.

Are there groups or settings that might be disadvantaged in relation to the problem or intervention of interest?

Are there plausible reasons for anticipating differences in the relative effectiveness of the intervention for disadvantaged groups or settings?

Are there different baseline conditions across groups or settings that affect the absolute impact of the intervention or the importance of the problem for disadvantaged groups or settings?

Are there important considerations that people implementing the intervention should consider to ensure that inequities are reduced, if possible, and that they are not increased?

Appendix B

AGREE II Score Sheet

According to the AGREE Next Steps Consortium (2017), the AGREE II score sheet used to summarize evaluation of the clinical practice guidelines with 23 items in 6 domains. Following the user guide posted on <https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf>, the evaluator will use the AGREE II score sheet to document the evaluation of the clinical practice guidelines. The evaluator will enter a rating in each of the 23 items in the six domains of the AGREE II instrument.

AGREE II Score Sheet

AGREE II Score Sheet

| Domain | Item | AGREE II Rating | | | | | | |
|-------------------------|---|-------------------------------|---|---|---|---|---|----------------------------|
| | | 1 <i>Strongly Disagree</i> | 2 | 3 | 4 | 5 | 6 | 7 <i>Strongly Agree</i> |
| Scope and purpose | 1. The overall objective(s) of the guideline is (are) specifically described. | | | | | | | |
| | 2. The health question(s) covered by the guideline is (are) specifically described. | | | | | | | |
| | 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described. | | | | | | | |
| Stakeholder involvement | 4. The guideline development group includes individuals from all the relevant professional groups. | | | | | | | |
| | 5. The views and preferences of the target population (patients, public, etc.) have been sought. | | | | | | | |
| | 6. The target users of the guideline are clearly defined. | | | | | | | |
| Rigor of development | 7. Systematic methods were used to search for evidence. | | | | | | | |
| | 8. The criteria for selecting the evidence are clearly described. | | | | | | | |
| | 9. The strengths and limitations of the body of evidence are clearly described. | | | | | | | |
| | 10. The methods for formulating the recommendations are clearly described. | | | | | | | |
| | 11. The health benefits, side effects and risks have been considered in formulating the recommendations. | | | | | | | |

| Domain | Item | AGREE II Rating | | | | | | |
|------------------------------|---|--|-------------------------|----------|----------|----------|----------|---|
| | | 1 <i>Strongly Disagree</i> | 2 | 3 | 4 | 5 | 6 | 7 <i>Strongly Agree</i> |
| | 12. There is an explicit link between the recommendations and the supporting evidence. | | | | | | | |
| | 13. The guideline has been externally reviewed by experts prior to its publication. | | | | | | | |
| | 14. A procedure for updating the guideline is provided. | | | | | | | |
| Clarity of presentation | 15. The recommendations are specific and unambiguous. | | | | | | | |
| | 16. The different options for management of the condition or health issue are clearly presented. | | | | | | | |
| | 17. Key recommendations are easily identifiable. | | | | | | | |
| Applicability | 18. The guideline describes facilitators and barriers to its application. | | | | | | | |
| | 19. The guideline provides advice and/or tools on how the recommendations can be put into practice. | | | | | | | |
| | 20. The potential resource implications of applying the recommendations have been considered. | | | | | | | |
| | 21. The guideline presents monitoring and/ or auditing criteria. | | | | | | | |
| Editorial independence | 22. The views of the funding body have not influenced the content of the guideline. | | | | | | | |
| | 23. Competing interests of guideline development group members have been recorded and addressed. | | | | | | | |
| Overall Guideline Assessment | 1. Rate the overall quality of this guideline. | 1 <i>Lowest possible quality</i> | 2 | 3 | 4 | 5 | 6 | 7 <i>Highest possible quality</i> |
| Overall Guideline Assessment | 2. I would recommend this guideline for use. | Yes | Yes, with modifications | | | | No | |
| | | | | | | | | |

Appendix C

Agree II Scoring Worksheet

This document was created to tabulate the scores of the AGREE II completed by 4 reviewers who are members of the Neonatology Advanced Practice Provider team at Albany Medical Center.

AGREE II scoring

| Domain 1: Scope and purpose 97% | | | | | | | | | |
|---------------------------------------|---------|---------|---------|---|---------|---------|---------|---------|---|
| | Item 1 | Item 2 | Item 3 | total | | | | | |
| Appraiser 1 | 7 | 7 | 7 | 21 | | | | | |
| Appraiser 2 | 7 | 7 | 7 | 21 | | | | | |
| Appraiser 3 | 7 | 7 | 5 | 19 | | | | | |
| Appraiser 4 | 7 | 7 | 7 | 21 | | | | | |
| | | | | 82 | | | | | |
| | | | | Max poss score 7x3x4=84 | | | | | |
| | | | | Min poss score 1x3x4= 12 | | | | | |
| | | | | Obtained score – Minimum possible score/ | | | | | |
| | | | | Maximum possible score – Minimum possible score | | | | | |
| | | | | 82-12=70 | | | | | |
| | | | | 84-12=72 | | | | | |
| | | | | 70/72x100=97% | | | | | |
| Domain 2: Stakeholder involvement 99% | | | | | | | | | |
| | Item 4 | Item 5 | Item 6 | | | | | | |
| Appraiser 1 | 7 | 7 | 6 | 20 | | | | | |
| Appraiser 2 | 7 | 7 | 7 | 21 | | | | | |
| Appraiser 3 | 7 | 7 | 7 | 21 | | | | | |
| Appraiser 4 | 7 | 7 | 7 | 21 | | | | | |
| | | | | 83 | | | | | |
| | | | | Max poss score 7x3x4=84 | | | | | |
| | | | | Min poss score 1x3x4= 12 | | | | | |
| | | | | Obtained score – Minimum possible score/ | | | | | |
| | | | | Maximum possible score – Minimum possible score | | | | | |
| | | | | 83-12=71 | | | | | |
| | | | | 84-12=72 | | | | | |
| | | | | 71/72x100=99% | | | | | |
| Domain 3: Rigor of development 80% | | | | | | | | | |
| | Item 7 | Item 8 | Item 9 | Item 10 | Item 11 | Item 12 | Item 13 | Item 14 | |
| Appraiser 1 | 7 | 7 | 4 | 6 | 4 | 7 | 3 | 5 | |
| Appraiser 2 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| Appraiser 3 | 7 | 5 | 4 | 4 | 7 | 4 | 7 | 7 | 45 |
| Appraiser 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 56 |
| | | | | | | | | | 185 |
| | | | | | | | | | Max poss score 7x32= 224 |
| | | | | | | | | | Min poss score 1x32= 32 |
| | | | | | | | | | Obtained score – Minimum possible score/ |
| | | | | | | | | | Maximum possible score – Minimum possible score |
| | | | | | | | | | 185-32=153 |
| | | | | | | | | | 224-32=192 |
| | | | | | | | | | 153/192x100=80% |
| Domain 4: Clarity of presentation 93% | | | | | | | | | |
| | Item 15 | Item 16 | Item 17 | | | | | | |
| Appraiser 1 | 7 | 2 | 7 | 16 | | | | | |
| Appraiser 2 | 7 | 7 | 7 | 21 | | | | | |
| Appraiser 3 | 7 | 7 | 7 | 21 | | | | | |
| Appraiser 4 | 7 | 7 | 7 | 21 | | | | | |
| | | | | 79 | | | | | |
| | | | | Max poss score 7x3x4=84 | | | | | |
| | | | | Min poss score 1x3x4= 12 | | | | | |
| | | | | Obtained score – Minimum possible score/ | | | | | |
| | | | | Maximum possible score – Minimum possible score | | | | | |
| | | | | 79-12=67 | | | | | |
| | | | | 84-12=72 | | | | | |
| | | | | 67/72x100=93% | | | | | |
| Domain 5: Applicability 98% | | | | | | | | | |
| | Item 18 | Item 19 | Item 20 | Item 21 | | | | | |
| Appraiser 1 | 7 | 7 | 7 | 7 | | | | | |
| Appraiser 2 | 7 | 7 | 7 | 7 | | | | | |
| | | | | 28 | | | | | |
| | | | | 28 | | | | | |

| | | | | | |
|-------------|---|---|---|---|-----|
| Appraiser 3 | 7 | 7 | 7 | 5 | 26 |
| Appraiser 4 | 7 | 7 | 7 | 7 | 28 |
| | | | | | 110 |

Max poss score 7x4x4=112 Obtained score – Minimum possible score/ 110-16=94
 Min poss score 1x4x4=16 Maximum possible score – Minimum possible score 112-16=96
 94/96x100=98%

Domain 6: Editorial independence 100%

| | | | | | |
|-------------|---------|---------|---|---|----|
| | Item 22 | Item 23 | | | |
| Appraiser | | 7 | 1 | 7 | 14 |
| Appraiser 2 | | 7 | | | |
| Appraiser 3 | | | | | |
| Appraiser 4 | 7 | 7 | | | 14 |
| | | | | | 35 |

Max poss score 7x5=35 Obtained score – Minimum possible score/ 35-5=30
 Min poss score 1x5=5 Maximum possible score – Minimum possible score 35-5=30
 35/35x100=100%

Overall guideline assessment rating 92%

| | |
|-------------|----|
| Appraiser 1 | 6 |
| Appraiser 2 | 7 |
| Appraiser 3 | 6 |
| Appraiser 4 | 7 |
| | 26 |

Max poss score 7x4= 28 Obtained score – Minimum possible score/ 26-4=22
 Min poss score 1x4=4 Maximum possible score – Minimum possible score 28-4=24
 22/24x100=92%

Overall guideline assessment recommendation for use 100%

| | | | |
|-------------|-----|------------------------|----|
| | Yes | Yes with modifications | No |
| Appraiser 1 | Yes | | |
| Appraiser 2 | Yes | | |
| Appraiser 3 | Yes | | |
| Appraiser 4 | Yes | | |

Yes 100%

Appendix D

The ELEVATE Method

The ELEVATE method is displayed as a multistep comprehensive timeline to support the development of quality clinical practice guidelines with a multidisciplinary team approach. Each phase has goals to achieve, although they may overlap.

