Clinical Practice Guideline for Management of Pulmonary Hypertension Patients

Undergoing Non-Cardiac Surgery

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Abstract

Pulmonary hypertension (PH) is a rare yet complex medical condition that exist worldwide, affecting individuals of all ages, genders, and ethnicities and is defined clinically by an elevated mean pulmonary artery pressure (mPAP) > 25 mmHg (Galie et al., 2015). PH can develop from a number of etiologies, all of which trigger progressive alterations to the structure and function of the pulmonary vessels, creating a high-pressure environment within the heart that can eventually lead to heart failure and death (Strumpher & Jacobson, 2011). Due to the medical advancements made in the diagnosis and treatment of PH, not only has the incidence of PH been steadily increasing (1.1 - 2.4 new cases per million residents each year), the patient population is living longer despite the severity of their condition (Ling et al., 2012). As a result, older and sicker patients with PH have been presenting for surgery which is an area of concern for anesthesia providers. PH is a significant risk factor for perioperative adverse complications and poor outcomes with a mortality rate of 1-7% and a morbidity rate ranging from 6-42% (Kaw et al., 2010; Meyer et al., 2013; Price et al., 2010; Ramakrishna et al., 2005). Anesthesia providers have noticed an increase in patient with pulmonary hypertension requiring surgery at a mid-sized community hospital, where standardize practices are currently not in place to guide the care of this vulnerable patient population.

The purpose of this scholarly project is to develop and evaluate a clinical practice guideline (CPG) that anesthesia providers can use in the perioperative management of all adult PH patients undergoing surgery. Three separate phases were utilized in the developed of the CPG. During the initial phase, a clinical practice guideline team was established and guideline revisions were made based on the AGREE II Tool quality appraisal. In the second phase, the facility’s anesthesia staff provided feedback by completing the Practitioner Feedback
Questionnaire (PFQ) survey after the CPG was presented by DNP student leaders. The project’s third phase involved presenting the finalized CPG to the facility’s Chief Anesthesiologist to review and provide feedback on the site’s usability.

All data was collected blindly and tabulated in Excel, where the statistical analysis was performed. The AGREE tool informed guideline revisions by identifying domains with low quality ratings, thus enhancing the quality of the guideline. The PFQ offered insight to the sample’s demographics and facilitated the CPG’s 82% approval rating among anesthesia staff. These results indicate that the CPG’s intended users support its utilization in practice, as well as the clinical setting’s need for standardized care to assist with the perioperative management of this patient population. The DNP student leaders were able to effectively collaborate with clinical experts to translate applicable evidence into the practice setting and utilize valid instruments to develop a site-specific CPG that can help facilitate management strategies that can improve perioperative outcomes for patients with pulmonary hypertension.
Overview

Pulmonary hypertension (PH) is a complex medical condition that progressively alters the structure and function of the pulmonary vessels, creating a high-pressure environment within the heart that can eventually lead to heart failure and death (Strumpher & Jacobsohn, 2011). At rest, a normal mean pulmonary artery pressure (mPAP) ranges between 14 ±3 mmHg; however, a mPAP that is equivalent to or greater than 25 mmHg, when measured during a right heart catheterization, is recognized as the clinical definition of pulmonary hypertension (Galie et al., 2015; Strumpher & Jacobsohn, 2011). The World Health Organization (WHO) developed a classification system for PH which categorizes each PH diagnosis into one of the five main groups that share similar etiologies, clinical manifestations, underlying pathophysiology, management strategies and treatment modalities (Simonneau et al., 2013). Pulmonary hypertension is a rare condition that exist worldwide, impacting individuals of all ages, genders, and ethnicities (Galie et al., 2015; George, Schieb, Ayala, Talwalkar, & Levant, 2014).

According to national studies published out of France, Ireland, and United Kingdom, the prevalence of PH continues to grow, ranging between 15 - 20 cases for every one million residents, as well as a steadily increasing incidence of 1.1 - 2.4 new PH cases per million each year (Humbert et al., 2006; Ling et al., 2012). The rise in PH cases has also been recognized within the United States, based on a recent report analyzing PH related deaths. The surveillance report found that mortality rates of individuals with PH had significantly increased from 5.5 to 6.6 per 100,000 over the 2001 to 2010 timeframe (George et al., 2014). Furthermore, the report concluded that Americans with PH were visiting the hospital more, due to a 44% increase in hospitalizations (George et al., 2014). The report also established that PH patients were living
longer since individuals aged 85 years and older were found to have the highest death rate within the PH patient population (George et al., 2014).

A movement of older and sicker patients with PH are presenting for surgery at an increasing rate, which is an area of serious concern for anesthesia providers, who are responsible for their care. The effects of PH impair normal hemodynamic and compensatory functioning, which surgery inhibits further, making the anesthetic management of these patients difficult and extremely risky (Strumpher & Jacobsohn, 2011). Additionally, pulmonary hypertension has been identified as a significant determinant of adverse complications and poor outcomes (Kaw et al., 2010; Minai et al., 2013; Price et al., 2010). Pulmonary hypertension is associated with a mortality rate of 1-7% and a 6-42% complication rate (Kaw et al., 2011; Meyer et al., 2013; Ramakrishna et al., 2005). An intervention that has been utilized in the clinical setting to assist anesthesia providers with the critical management of these tenuous patients is the development and implementation of a clinical practice guideline (Minai et al., 2013; Pilkington et al., 2015).

Similar to the increasing trends at the national level, a growing number of individuals with PH are presenting for surgery in the preoperative area at a mid-sized teaching hospital in the mid-Atlantic region. Despite the increasing number of patients with PH presenting for surgery at this organization, a uniformed method of care delivery and management does not exist for this vulnerable community of individuals. Due to this patient population’s prevalence, management challenges, and high risk of unfavorable outcomes, a need for more standardized care was identified through the development of a clinical practice guideline.

The purpose of this DNP scholarly project is to develop a clinical practice guideline on best practice measures that anesthesia providers can use in the perioperative management of all adult patients with pulmonary hypertension undergoing non-cardiac surgery. The 2015
pulmonary hypertension guidelines provided by the European Society of Cardiology (ESC) and European Respiratory Society (ERS) (Galie, et al., 2014) as well as the anesthetic management techniques outlined by Pilkington (2015) and Minai (2013), will be utilized in the development of the clinical practice guideline. These resources will provide members of the anesthesia care team the opportunity to acquire a greater knowledge base and a better understanding of how to effectively manage and optimize the care of patients with pulmonary hypertension. It is anticipated, that implementation of a clinical practice guideline to manage the perioperative care of patients with pulmonary hypertension, will reduce the incidence of adverse outcomes experienced by this patient population within the organization.

**Theoretical Framework**

The theoretical framework that will be utilized in this DNP scholarly project is the Knowledge-to-Action (KTA) framework. In an attempt to clarify the process of incorporating knowledge into action, Graham et al. (2006), conducted a thorough review of relevant planned-action theories, which informed and prompted the development of The Knowledge-to-Action framework. This dynamic conceptual framework is based on two interrelated concepts: knowledge creation and knowledge application, also known as the action cycle (See Figure 1) (Straus, Tetroe & Graham, 2013). According to Graham et al. (2006), the three components of knowledge creation: knowledge inquiry, knowledge synthesis, and the development of knowledge tools, are illustrated within a funnel-like format to represent the course of refining and tailoring knowledge to meet the needs that are specific to that clinical environment. The other key concept of the KTA framework, knowledge application, outlines several essential activities to facilitate the implementation of knowledge within the practice setting (Straus et al., 2013).
The KTA framework can be operationalized in the development of this clinical practice guideline by providing an organized implementation process that will expedite the integration of knowledge into practice. The knowledge creation concept will assist with gathering and synthesizing quality evidence to generate recommendations that can be complied into a clinical practice guideline on the preoperative management of PH patients. The actions outlined in the knowledge implementation portion of the KTA framework assist with designing a guideline that suits the needs of the practice setting by identifying supporters, creating user buy-in, addressing potential barriers, and developing measures to monitor and sustain its utilization. The KTA framework can facilitate the development of a clinical practice guideline that anesthesia providers can utilize to make the best-informed care decisions when managing PH patients in the perioperative period.

**Literature Review**

A literature review was conducted to locate evidence that pertained to the preoperative care management of adult patients with PH presenting for non-cardiac surgery (NCS). The literature was critically analyzed and assessed for well-supported management strategies that can be developed into recommendations in which a clinical practice guideline can be generated for anesthesia providers to initiate effective and safe care to an already vulnerable population. The literature presented in this review will emphasize the importance of preoperative medical optimization in PH patients by addressing two essential topics: preoperative evaluation and risk stratification.

The pre-procedure optimization of individuals with this complex condition will be addressed through the careful evaluation of two literature reviews (Minai et al., 2013; Pilkington et al., 2015), a practice guideline (Galie et al., 2015) and three cohort studies (Kaw et al., 2011;
Meyer et al., 2013; Ramakrishna et al., 2005). The content within each selected source was investigated and reviewed utilizing Melnyk & Fineout-Overholt’s Hierarchy of Evidence Rating System (Newhouse, 2006). Additionally, a quality rating was established for each piece through the application of Newhouse’s Quality Rating Scheme (Newhouse, 2006). The evidence level and quality ratings for the literature is located in the Evidence Rating Table displayed in Appendix A.

Throughout the literature the importance of a detailed preoperative evaluation was a focal point identified in most preoperative management considerations for PH patients presenting for NCS. A recent integrated literature review on the anesthetic management of PH patients undergoing NCS emphasized that the success of this patient population was related to implementing a comprehensive preoperative evaluation which consists of a focused history and physical, assessment of diagnostic tests and medication regiment, functional status identification, the proposed surgical procedure, and most importantly, a stratified risk assessment (Pilkington et al., 2015). The patient’s history and physical should address other underlying comorbidities, symptoms, functional status based on the New York Heart Association (NYHA) functional class and a 6-minute walking distance (6MWD) test. A NYHA functional class of 1 or 2 is associated with better outcomes and a poor exercise capacity demonstrated by a short 6MWD is linked to an increased mortality.

The 2015 ESC/ERS guidelines for PH diagnosis and treatment provided a series of recommendations to aid in the preoperative identification and evaluation of this disease process. The guidelines displayed a diagnostic algorithm as well as the varying intervals that diagnostic tests and labs should be completed. The echocardiogram is a diagnostic tool utilized to establish a PH probability. Once PH is diagnosed via right heart catheterization (RHC), an
echocardiogram can then be implemented as a monitoring tool to track the function of the right ventricle and the progression of the disorder. Additionally, Pilkington et al. (2015) and Minai et al. (2013) both agreed, in their reviews of the literature, on the use of RHC to definitively confirm PH and gain additional information related to the severity of the disease state. The 2015 ESC/ERS guidelines recommend conducting a comprehensive exam on this patient population since the severity of their condition is multifactorial (Galie et al., 2015).

In a review of the literature, Minai et al. (2013) provided perioperative management recommendations for PH patients undergoing NCS. The reviewers stated that a positive outcome for PH patients after NCS is contingent on the proper optimization and evaluation by providers in the preoperative period. This narrative review provided less written detail related to the management methods, the major weakness of this study; however, the reviewers offered a methodical outline of the recommended preoperative evaluation and management components. Furthermore, both reviews clearly illustrated perioperative risk factors as well as their origin (Minai et al., 2013; Pilkington et al., 2015)

The risk factors responsible for perioperative morbidity and mortality were identified through cohort studies conducted by Kaw et al. (2010), Meyer et al. (2013), and Ramakrishna et al., (2005). Additionally, the morbidity and mortality data presented in the retrospective studies conducted by Kaw et al. (2010) and Ramakrishna et al., (2005) were addressed in each review to demonstrate the significant risk for poor outcomes in this population, as well as to validate the need for perioperative management practices that anesthesia providers can implement to provide safe and effective care.

Kaw et al. (2011) conducted a retrospective controlled cohort study that evaluated perioperative risk factors as well as its associated outcomes in adult patients with (n = 96) or
without (n = 77) PH undergoing NCS at a leading tertiary medical facility in the United States. From 2002 to 2006, data on the subjects were collected and analyzed. As hypothesized, patients with PH were found to have an increased risk of developing perioperative complications (22%) and dying (1%) compared to individuals without PH undergoing the same surgeries. The researchers concluded that an elevated mPAP, an American Society of Anesthesiologists (ASA) physical classification status > 2, the presence of chronic renal insufficiency, as well as the underlying condition of PH were independent determinants for postoperative complications (Kaw et al., 2011). Limitations to this study consist of a sample that, for the most part, developed PH as a result of left sided heart failure and neglecting to report the NYHA functional class of each participant; however, the controlled cohort design was a strength.

In another retrospective non-controlled cohort study, Ramakrishna et al. (2005) examined the incidence of morbidity and mortality in adult PH patients (n = 145) undergoing NCS between 1991 and 2003. The researchers extracted data from the electronic health records located in their medical facility’s pulmonary hypertension database. The analysis of this data revealed that PH patients have an elevated perioperative morbidity (42%) and mortality (7%) rate. Furthermore, Ramakrishna et al. (2005) identified the following predictors associated with postoperative complications in this patient population: a NYHA functional class of 3 or 4, surgeries classified as an intermediate risk, a medical history of a pulmonary embolism, and procedures that last longer than 3 hours. Notable weaknesses of this study were related to the use of an echocardiogram to diagnosis PH, but more notably the early date of publication, which was prior to the introduction of PH-specific medication therapies. However, this classic and consistently referenced study provided results that are still applicable and support the topic of interest.
From 2007 to 2010, Meyer et al. (2013) collected outcomes of PH patients (n=114) who underwent NCS in 11 different international centers. This prospective study identified emergency surgery, an elevated right atrial pressure, preoperative vasopressor use, and a 6MWD > 399 meters prior to surgery, as major determinants responsible for postoperative complications. The researchers reported a noticeably lower morbidity (6.1%) and mortality (3.5%) rate, which might be related to the characteristics of the study’s sample. The PH population enrolled in this study is thought to be healthier due to over half of the sample exhibiting a NYHA functional class of 1 or 2 and a 6MWD of 399 meters or more. Thus, the underlying implication is that PH patients who are optimized prior to surgery have a reduced perioperative morbidity and mortality risk.

Despite the lower level of evidence associated with these observational studies, the identification of these risk factors is significant based on the awareness it can create among anesthesia providers. This knowledge can then enhance patient optimization through greater risk stratification in the preoperative period, ultimately leading to improved outcomes for this patient population.

Management of this patient population is challenging; therefore, prevention, preparation, and optimization are key. Currently, there is limited literature on the perioperative management of PH patients. However, the evidence provided in this literature review, has demonstrated that there is adequate evidence to create a clinical practice guideline that standardizes the perioperative management of this patient population. During the preoperative period, providers must demonstrate vigilance to ensure these patients are undergoing the stresses of surgery in their best possible state of health.

**Methods**
Design, Setting, & Sample

The design of this scholarly project involved the development of a clinical practice guideline (CPG), based on best practice measures to aid anesthesia providers in the perioperative management of adult patients with pulmonary hypertension undergoing non-cardiac surgery. The project was conducted in the perioperative setting at a mid-sized community teaching hospital in the mid-Atlantic area.

This CPG project called for the utilization of three different samples, with each sample representing and catering to specific stages of the project. An assortment of both certified registered nurse anesthetists (CRNA), student registered nurse anesthetists (SRNA), and anesthesiologists (MDA) were involved, to some degree, with each sample. This group of practitioners serve as key stakeholders and the intended users of the practice guideline, due to their role, which is responsible for managing the perioperative care of, the project’s target population, patients with PH presenting for non-cardiac surgery at this facility.

Procedures

Before a proposed CPG can be implemented into a practice setting, there are a series of steps and processes that need to be completed during its development to gain the support and authorization of its intended users. During the project’s first week, the initial step was fulfilled by recruiting an anesthesia provider from the facility to form a CPG team. The CPG team represents the first sample (n=4) of this project and consist of one anesthesiologist and three DNP student leaders. The MDA fulfilled the team member inclusion criteria, previous established by the DNP student leaders: have an active role in the perioperative care of patients, demonstrate expertise in the management of PH, and had expressed an interest in volunteering to
assist with the development of a CPG that focused on standardizing the management of this patient population.

The project’s first month consisted of collaborating with team members to establish three separate meetings during the course of the month, all of which provide the opportunity to obtain meaningful feedback that will further the development of the clinical practice guideline’s recommendations. The time and dates of the succeeding meetings were selected and planned out accordingly during the CPG team’s first meeting, which took place at the facility. Due to conflicting schedules, the subsequent weekly meetings were conducted over the phone as a telephone conference, for approximately one hour. Before each team meeting, the three DNP student leaders would create an agenda, which was disseminated to members via email and assign roles (leader, scribe, and facilitator), which alternated each meeting. The leader was responsible for guiding the meeting’s discussion. The scribe kept track of the time and took notes during the meeting. The following day, the scribe would electronically share the meeting’s notes with group members via email and apply the agreed upon modifications to the guideline. The facilitator was the other position rotated between the DNP student leaders, and it provided the necessary resources or supplies for the meeting, such as hard copies of documents. After each meeting, the DNP student leaders would briefly meet to discuss CPG feedback, review new revisions, and set objectives for the upcoming week.

At the first meeting, a preliminary draft of the CPG and The Appraisal of Guidelines for Research and Evaluation (AGREE) II Tool were presented and thoroughly explained (See Appendix D). Additionally, an evidence review table along with all of the key articles utilized in the development of the CPG draft, were available to review. The CPG team had a one week timeframe to independently appraised the quality of the CPG draft using an electronic version of
AGREE II Tool before the second meeting, which was scheduled for the following week. Each team member had access to both electronic and paper copies of the CPG draft and AGREE II Tool. After the instrument was completed the CPG team, each item’s quantitative results and qualitative comments could be reviewed but were blinded to each appraiser’s evaluation. The second meeting focused on the AGREE II Tool’s scoring, evaluator’s comments, guideline strengths, and areas of weaknesses requiring modifications. At the third meeting, group members reviewed changes made to the CPG and discussed phase two of the project; presenting the CPG draft to the site’s anesthesia providers and collecting their feedback.

In the second stage of the project, the three DNP students presented the preliminary CPG draft to the facility’s staff of anesthesia providers and issued surveys to collect feedback on the CPG. The CRNAs, SRNAs and MDAs who attended the presentation and completed the survey represented the project’s second sample (n=19) of interest. The CPG presentation was scheduled during the anesthesia department’s weekly one hour staff meeting. The presentation was announced to staff two weeks ahead of time via e-mail and flyers posted around the anesthesia break room. During the last 15 minutes of the presentation’s allotted timeframe, staff were asked to submit feedback on the CPG by completing the Practitioner Feedback Questionnaire (PFQ) (See Appendix C) (Brouwers, Graham, Hanna, Cameron, & Browman, 2004). A paper copy of the PFQ survey along with a pencil were provided to each anesthesia provider who attended the presentation. Providers were instructed to place their completed PFQ survey face down in an open lockbox, that was positioned next to the exit, prior to leaving the meeting. Prior to starting the next stage of the project, revisions were made to the CPG based on the feedback collected from staff.

During the third stage of the project, the three DNP students met with the Department’s
Chief Anesthesiologist to present CPG, share staff’s feedback, and establish approval for implementation. The final phase of the project, occupied the end of the second month and proceeded into the third month. The Chief Anesthesiologist (n=1) characterizes the project’s final sample. During the hour-long meeting, the Chief Anesthesiologist was presented with copies of the CPG, appraisal tools, and literature review. The DNP student leaders and Chief Anesthesiologist discussed results of the appraisals tools, offered suggestions, addressed concerns, and determine whether the guideline was suitable to manage the PH patient population requiring services from this facility’s perioperative area.

To guide the CPG development, advancement, modification, and submission process, a scholarly project timeline (See Appendix F) was created by the DNP student leaders. All phases of the project were clearly outlined to ensure all necessary components are completed within its anticipated timetable.

**Data Collection**

Quantitative data was captured and extracted from the AGREE II Tool and the PFQ survey to assist with the development of a CPG that is applicable and comprehensive. The AGREE II Tool was originally published in 2003 by international guideline developers and researchers, to serve as a reliable instrument that would holistically and meticulously evaluate guidelines for quality, thus informing the decisions made by healthcare providers in the clinical setting. Revised in 2013, the AGREE II Tool continues to be recognized worldwide as the premier instrument to direct guideline development (Brouwers et al., 2013).

The AGREE II Tool consist of 23 main topics that are further grouped into 6 domains each catering to a specific aspect of the guideline’s quality. The tool concludes with 2 items which directly ask the appraiser to assess the guidelines overall quality and recommendation for
use in the practice setting. Each item is rated using a 7-point Likert scale, where 1 represents strongly disagree and 7 indicates strongly agree. Based on the comprehensiveness of the content and the methodology of the guideline, a score should be assigned by each reviewer using the designated 7-point rating scale (Brouwers et al., 2013).

The tool’s international use, utilization in various publications, generic applicability across the healthcare field, and the instrument’s recent update contributes to its overall validity and reliability (Brouwers et al., 2013). Brouwer et al., (2010b) demonstrated the AGREE II Tool’s construct validity by examining each item’s ability to correctly differentiate between guideline content that demonstrates high and low quality. Additionally, the AGREE II Tool’s user manual was recognized for providing instructions that were easy to apply and supported the successful discrimination between strong and poor guideline reporting, all of which contributes to the tool’s validity (Brouwer et al., 2010b). The internal consistency measurement of the 6 unique domains demonstrated the reliability of the AGREE II tool with a Chronbach alpha score, ranging from 0.64 to 0.89 (Brouwer et al., 2010a). Furthermore, the tool’s inter-rater reliability was also considered adequate (Brouwer et al., 2010a). The AGREE II Tool will be utilized in the project’s first stage to assess the quality of the CPG and guide its future development.

Developed in 2004, The Practitioner Feedback Questionnaire (PFQ) is a tool used to assess the likelihood of clinicians adopting a proposed CPG and will serve as the other instrument used in this scholarly project. The survey’s 23 items address four major factors that have been shown to be statistically significant (p < .0001) in persuading a provider’s intention to use and endorse a CPG: quality, applicability, acceptability, and comparative value (Brouwers et al., 2004). Each item within the tool is scored using a 5-point Likert scale, where 1 represents strongly agree and 5 indicates strongly disagree. Four of the survey’s questions (#10,13,14,15)
are phrased negatively or in opposition of the CPG, thus requiring reverse scoring of the items. This instrument aims to identify an assortment of beliefs and attitudes; therefore, a variance component analysis was utilized to establish the tool’s reliability (Brouwers et al., 2004). The reliability of the PFQ can be verified by the internal consistencies of the four main components, represented by a Chronbach alpha that ranges from 0.75 to 0.85 (Brouwers et al., 2004). Furthermore, these four factors were found to be directly related to whether a provider will ultimately adopt the CPG into their practice. The tool’s construct validity was demonstrated by using a multilevel modeling technique to identify the four main factors responsible for approximately 60% of the variance found in the scores associated with the two outcome measures: guideline endorsement and intentions to use (Brouwers et al., 2004). To meet the needs of this project, the PFQ was modified to incorporate an area to collect demographic data, including gender, age, ethnicity, years practicing anesthesia overall and at the facility, and whether the individual is a SRNA, CRNA or MDA. This source of data will serve to describe the sample of anesthetist providing feedback and also to ensure that the sample is representative of the population of anesthesia providers at this practice setting.

Data Analysis

The raw data generated by the AGREE II Tool and PFQ survey were manually entered and tabulated into separate Excel spreadsheets, where the statistical analysis of data from each dataset was performed using descriptive statistical testing. Excel’s format also fostered the evaluation of data for potential themes and the synthesis of data into tables and graphs. All values were closely examined to negate any manual inaccuracies.

The AGREE II Tool was utilized by each member of the CPG team (n=4) to evaluated the CPG based on its quality and comprehensiveness. Each item was rated using the provided 7-
point Likert scale and a quality score was calculated for each domain, as instructed by the instrument’s user manual (Brouwers et al., 2013). A quality domain score was generated for each domain by summing together all item scores, located under that domain, for each appraiser. That score was then scaled as a percentage of the maximum possible score for that domain. A minimum domain score to distinguish between strong and weak quality guidelines has not been defined by the AGREE II Tool developers; therefore, it is up to the guideline’s users to use their judgment to determine which domain scores represent adequate quality from poor quality (Brouwers et al., 2013).

The domain scores were examined by the CPG team and the areas generating lower domain score were evaluated for deficits to inform the proceeding revisions. Additionally, the domains that earned higher scores were also reviewed to gain insight as to what elicited those results and to see if it can be replicated to strengthen other sections of the guideline. The AGREE II Tool’s domain quality scores and resulting descriptive statistics for each domain are displayed in Table 1.

The modified PFQ survey anonymously collected data to determine the usability and intent to adopt the guideline by key stakeholders, the anesthesia providers at this designated facility. Additionally, the PFQ was modified to incorporate an additional 6 questions that aimed to collect baseline demographic data of the sample of anesthesia providers that participated in the CPG presentation and PFQ survey. The demographic data reported by the PFQ was synthesized and analyzed using descriptive statistics (n, %) (See Table 2). The sample’s demographic variables were assessed to ensure that it adequately reflected the characteristics of facility’s population of anesthesia providers.
Following the CPG presentation, anesthesia providers (n=18) voluntarily completed the Modified PFQ survey to provide guideline feedback. The survey’s data was synthesized and analyzed using descriptive statistical testing. The aggregated mean score for each item as well as the percent of participants that indicated agreement with item’s statement are displayed in Table 3.

**Protection of Human Rights and Plans for Submission to IRB Committee**

The CPG query was submitted for Institutional Review Board (IRB) for Non-Human Subjects Research (NHSR) determination. IRB approval was granted from the University of Maryland Baltimore (See Appendix B), as well as the local institution hosting the CPG project. The following tasks were applied to protect the privacy of all participants involved in this project, no identifying data or data points were collected, all project related documents were filed into a locked filing cabinet and electronic data was stored on password protected computers. The findings generated by the scholarly project were only shared with stakeholders at the facility for quality improvement purposes. With the permission of the facility, the project may be presented at professional meetings, conferences or published in peer-reviewed journals. The project has been presented with the intent to suggest strategies and tools that were found effective in this unique practice setting.

**Results**

Two valid and reliable instruments provided the quantitative data needed to evaluate the quality and usability of the proposed CPG, which aims to assist anesthesia providers, at a designated facility, with the perioperative management of pulmonary hypertension patients. All members of the CPG team (n=4) independently appraised the CPG draft using an electronic format of the 23-item AGREE II Tool. A quality domain score was calculated for each of the
tool’s 6 domains: scope and purpose (86%), stake holder involvement, (92%) rigour of development (80%), clarity of presentation (85%), applicability (60%) and editorial independence (100%). Of these 6 domains, higher quality scores were earned by the following 4 domains: editorial independence (100%), stake holder involvement (92%), scope and purpose (86%) and clarity and presentation (85%). Lower quality scores were obtained by the other 2 domains: rigour of development (80%) and applicability (60%). In the final section of the AGREE II instrument, appraisers rate the overall assessment of the guideline and indicate whether the use of the guideline is recommended by selecting one of the three provided responses (Yes, Yes with modifications, or No). The guideline’s overall assessment received a quality rating of 71% from the CPG team. Additionally, all of the appraisers recommended the guideline’s use (Yes 25%; Yes, with modifications 75%; No 0%). A visual depiction of the quality domain scores are presented in Figure 2.

A total of 18 anesthesia providers attended the CPG presentation and completed the modified PFQ. The demographic variables were collected from subjects: age, gender, current role of clinician, ethnicity, total number of years practicing anesthesia and the number of years practicing at the facility (See Table 2). The sample included MDAs (26%), SRNAs (26%), and CRNAs (47%), who demonstrated a greater presence. A majority of practitioners were aged 30-40 years (42%). The sample’s ratio of males (47%) and females (53%) was almost equally distributed. The ethnicity representing more than half of the sample were Caucasians (67%). Most practitioners in attendance had been practicing in their current role (39%) for then less 5 years, which was also the highest-ranking timeframe (less than 5 years) practitioners had been practicing at the facility (50%). Of note, 21% of the total participants (n=19) that completed the modified PFQ survey were also members of the CPG team (n=4). Also, it was noted upon the
CPG’s team’s initial review of the reported data that 1 participant completed the demographic section of the survey but failed to complete the attached PFQ survey. Thus, n=19 was used in the demographic data calculations and n=18 was used to calculations involving the PFQ survey items.

The modified PFQ survey aimed to evaluate the guideline’s applicability, acceptability, and whether provider’s intent to integrate the recommendations into practice. For each item, participants (n=18) were directed to rate each item using the 5-point Likert scale (1=Strongly Disagree and 5=Strongly Agree) to best represents their opinion in terms of agreement. The guideline’s rational for development, need in current practice, ability to produce benefits and utilize resources efficiently, each represent content areas from the survey where providers (88%) indicated the most agreement or strong agreement. Thus, 88% of participants selected 4 for “Agree” or 5 for “Strongly Agree” on those items within the PFQ survey. Furthermore, 88% of participants indicated that if the guideline was approved, they would use it in their practice and apply its recommendations to their patients. Interestingly, an item stating that the guideline should be approved as a practice guideline, only received 77% of provider agreement. The following two items: clarity of the recommendations and guideline’s use will noticeably produce the expected patient outcomes, received the lowest amount of agreement among practitioners at 72%. Overall, the CPG received a mean approval rating of 82% from participants. Written feedback from providers were identified in 27% (n=5) of the survey’s designated comment section. See Table 4 for additional survey results and a list of the items (n=18) used in the instrument’s statistical analysis. Of note, one participant completed the survey, marking “1” indicating “strongly disagree” for each item and proceeded to include the written statement “Good job” in the survey’s comment section at the bottom of the page. This may indicate that the
participant may have misunderstood the directions and score the items in appropriately, which could have slightly altered the results of the PFQ survey.

**Discussion**

Anesthesia providers at a mid-size community hospital, started recognizing a higher volume of patients with PH presenting for surgery, which led to providers verbalizing a need for practice guidelines to inform their care decisions and assist with the management of this vulnerable patient population. Pulmonary hypertension has been identified as a significant risk factor for perioperative adverse outcomes with a morbidly rate ranging as high as 42% and a mortality rate that can reach up to 7%. Currently the facility does not have a uniformed method in place to manage the complex needs of the diverse PH patient population. The current practices at this facility demonstrated practices that are inconsistent and divergent, resulting in case cancellations, the mismanagement of patients, and unfavorable outcomes.

Three DNP student leaders, collaborated with a MDA at the designated site, to address this practice deficit through the development and evaluation of a CPG that offers anesthesia providers a compilation of best management strategies that are based in evidence. It is anticipated that the utilization of practices based in evidence to guide patient care will reduce perioperative complications and adverse outcomes experienced by this diverse patient population. A comprehensive literature review was conducted and recommendations were generated best on evidence, expert opinion, and stakeholder feedback. A major factor, affecting the recommendations included in the guideline, was the clinical setting; however, this also served as an indication of needing a CPG to inform the care practices of this care environment. The perioperative setting lacks the equipment and drug therapies to manage patient that are suffering from PH that is unstable or not controlled. The CPG was able to serve as a platform to
start addressing resources that are need by staff to deliver quality care and the ineffective system processes of the anesthesia department. Recommendations from stake holder lead to the development of condensed CPG to foster usability and adoptability. Additionally, providers indicated the need for an algorithm to guide the care pathway of PH in the preoperative setting (See Figure 4).

The AGREE II Tool overall appraisal the PH CPG draft was favorable with all the CPG team appraisals recommending the guideline for use and the overall guideline assessment obtaining a quality score of 71% and a mean score of 5.3 (1.5). The highest possible score was obtained by Domain 6, with a quality score of 100% with a mean score of 7 (0). The CPG obtain this rating by demonstrating transparency by including statements which addressed financial disclosure and conflicts of interested. Stakeholder Involvement (Domain 2) received the second highest rating with a quality score of 92% and mean score of 6.5(1.2). This domain ensures that the appropriate target users were involved and their views were considered. Additional identification information was added to recognize the members of the CPG team; thus, a high scoring domain still requires a rating assessment because modifications or updates can still be made. Scope and purpose (Domain 1) contains 3 item that examine the following guideline component: objectives, expected benefits, and target populations. The domain’s quality score was 86% with a mean score of 6.1 (1.5), indicating the guideline’s need for additional clarification. The CPG objectives and anticipated outcomes lacked specifics, thus clarity was facilitated by rewording the objectives and offering further explanations regarding the CPG’s potential benefits.

Applicability (Domain 5) received the lowest domain quality score of 60% and a mean score of 4.6 (2.2). Additionally, the descriptive statistics indicate variation among ratings
selecting for the 4 items within the domain. The inconsistent scoring is reflected in item 19 and 20, where appraiser’s scores ranged from 1 to 7 (the highest to lowest possible score). The CPG team addressed elements contributing to the domain’s low ratings by incorporating adjunct tools and resources to support the guidelines uptake, such as diagrams and algorithms. Rigour of development (Domain 3) also obtained a lower quality score at 80% and a mean score of 5.8 (1.5). The 8 item in this domain focus on the guideline’s evidence and subsequent recommendations to guide care. The contents of this domain were addressed by including: inclusion and exclusion criteria and the link between recommendations and evidence.

The PFQ survey indicated the anesthesia staff’s positive view of the guideline with a mean approval rating of 82%. The participants (n=18) demonstrated a strong agreement (88%) with CPG draft’s recommendations. Additionally, participants responded favorably (with 88% agreement) to the use of the guideline in their own practice and applying the recommendations to their patients if indicated. In Figure 3, select items from the PFQ survey are illustrate. The CPG’s mean approval rating is noted in the farthest column on the right and at 82% it sits in-between items that generated agreement score on both side of the spectrum. With an 88% agreement, practitioners clearly expressed a need for a guideline on PH and found the rational for developing a guideline clear. The items regarding the completeness of the literature search and summary of evidence received a lower agreement (77%) rating among the survey’s practitioners. A reason as to why these two items, addressing evidence, demonstrated lower agreement scores is due to the limited research on PH due to conflicts with ethical considerations and the weaker levels of evidence that is available is what clinicians have to use to inform care decision of PH’s complex conditions.

Conclusion
This DNP Scholarly project focuses on the development and evaluation of a CPG that can be used in the perioperative area of a mid-sized community hospital to offer anesthesia providers access to current best practices from the literature to manage PH patients undergoing surgery. It is anticipated that a CPG can reduce perioperative complications and adverse outcomes experiences by this patient population at this institution. The purpose of this scholarly project was to develop and evaluate a clinical practice guideline (CPG) that anesthesia providers can use in the perioperative management of all adult PH patients undergoing surgery. The CPG recommendations were shaped by integrating current evidence identified in the literature, expert recommendations, and feedback from key stakeholders. It is anticipated that application of this CPG can aid in reducing perioperative complications and adverse outcomes experienced by this patient population at this institution. PH is serious health deterrent but patients are living longer despite the status of their condition and are presenting for surgery at an increasing rate. PH can easily go mismanaged and even undetected, subjecting these patients to significant hemodynamic instability and devastating consequences when exposed to anesthesia and the stresses of surgery, without the proper preparation, therapies, or equipment. The development of a CPG for the management of PH has the ability to enhance the care provided through each perioperative phase, especially the preoperative phase. This CPG is a resource that staff is able to access and by utilizing these recommendations, they will create a better care experience by increasing the quality of care delivered and supporting better patient outcomes through the standardization of care for this patient population.
References


Kingdom and Ireland. *American Journal of Respiratory and Critical Care Medicine, 186* (8), 779-796. doi: 10.1164/rccm.201203-0383oc


10.1097/ASA.0b013e3182287f2f


Studer, S; et al. (2013). Preoperative consideration in patients with Pulmonary Hypertension. *Advances in Pulmonary Hypertension, 12*(1), 13-17. Received from: 

http://www.phaonlineuniv.org/Journal/IssueList.cfm

Table 1

<table>
<thead>
<tr>
<th>Domains</th>
<th>Items</th>
<th>Mean (SD)</th>
<th>Domain Score %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Scope and Purpose</td>
<td>3</td>
<td>6.2 (1.5)</td>
<td>86</td>
</tr>
<tr>
<td>2. Stakeholder Involvement</td>
<td>3</td>
<td>6.5 (1.2)</td>
<td>92</td>
</tr>
<tr>
<td>3. Rigour of Development</td>
<td>8</td>
<td>5.8 (1.5)</td>
<td>80</td>
</tr>
<tr>
<td>4. Clarity and Presentation</td>
<td>3</td>
<td>6.1 (1.6)</td>
<td>85</td>
</tr>
<tr>
<td>5. Applicability</td>
<td>4</td>
<td>4.6 (2.2)</td>
<td>60</td>
</tr>
<tr>
<td>6. Editorial Independence</td>
<td>2</td>
<td>7.0 (0)</td>
<td>100</td>
</tr>
<tr>
<td>Overall Guideline Assessment</td>
<td>1</td>
<td>5.3 (1.5)</td>
<td>71</td>
</tr>
</tbody>
</table>

*Note.* N=4. SD=standard deviation; CPG=clinical practice guideline. Table illustrates the CPG team’s AGREE II Tool appraisal results.
<table>
<thead>
<tr>
<th>Variables</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
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<tr>
<td><strong>Age</strong></td>
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<td>30-40</td>
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<td>40-50</td>
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<td>16</td>
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<td>50-60</td>
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<td>16</td>
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<tr>
<td>60-70</td>
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<td>5</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
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<td>Male</td>
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<tr>
<td>Female</td>
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<td><strong>Participant’s Role</strong></td>
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<td>MDA</td>
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<td>26</td>
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<td>Caucasian</td>
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<td>Other</td>
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<td>17</td>
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<td>Missing</td>
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<td>6</td>
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<tr>
<td><strong>Years Practicing in Role</strong></td>
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<tr>
<td>&lt;5</td>
<td>7</td>
<td>39</td>
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<tr>
<td>5-10</td>
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<td>28</td>
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<td>10-15</td>
<td>2</td>
<td>11</td>
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<tr>
<td>15-20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>20-25</td>
<td>2</td>
<td>11</td>
</tr>
</tbody>
</table>

*Practitioner Feedback Survey Demographics*
Table 3

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Percentage of Agreement (%)</th>
<th>Mean +/- SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The rationale for developing a guideline is clear.</td>
<td>88</td>
<td>4.5 +/- 1.06</td>
</tr>
<tr>
<td>3. There is a need for a guideline on this topic.</td>
<td>88</td>
<td>4.6 +/- 1.04</td>
</tr>
<tr>
<td>4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.</td>
<td>77</td>
<td>4.1 +/- 1.09</td>
</tr>
<tr>
<td>5. I agree with the methodology used to summarize the evidence included in this draft guideline.</td>
<td>77</td>
<td>4.4 +/- 1.15</td>
</tr>
<tr>
<td>6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.</td>
<td>77</td>
<td>4.3 +/- 1.13</td>
</tr>
<tr>
<td>7. The draft recommendations in this report are clear.</td>
<td>72</td>
<td>3.9 +/- 1.09</td>
</tr>
<tr>
<td>8. I agree with the draft recommendations as stated.</td>
<td>88</td>
<td>4.3 +/- 1.05</td>
</tr>
<tr>
<td>9. The draft recommendations are suitable for the patients for whom they are intended.</td>
<td>83</td>
<td>4.3 +/- 1.07</td>
</tr>
<tr>
<td>11. When applied, the draft recommendations will produce more benefits for patients than harms.</td>
<td>88</td>
<td>4.3 +/- 1.05</td>
</tr>
<tr>
<td>12. The draft guideline presents options that will be acceptable to patients.</td>
<td>77</td>
<td>3.8 +/- 0.99</td>
</tr>
<tr>
<td>16. The draft guideline recommendations are likely to be supported by a majority of my colleagues.</td>
<td>83</td>
<td>4.1 +/- 1.06</td>
</tr>
<tr>
<td>17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.</td>
<td>72</td>
<td>3.9 +/- 1.10</td>
</tr>
<tr>
<td>18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is</td>
<td>83</td>
<td>4.3 +/- 1.11</td>
</tr>
</tbody>
</table>
current usual practice.

19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice.

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</table>

20. I would feel comfortable if my patients received the care recommended in the draft guideline.

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</table>

21. This draft guideline should be approved as a practice guideline.

<p>| | | |</p>
<table>
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<tr>
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</table>

22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.

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<thead>
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23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients.

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Mean Approval rating/score

<p>| | | |</p>
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</tbody>
</table>

Note. Total of 6 questions were omitted from dataset due to need for reverse scoring (Questions # 1, 10, 13, 14 &15) and use of nominal level of measurement (Question #1).

Figure 1

Figure 2
Note. n=4. Visual representation of the AGREE II Tool’s domain quality score.

Figure 3
Practitioner Feedback Survey Questionnaire Respondent Agreement
Note. n=18. Four select items from PFQ. The scores represent the overall Agreement percentage. Results generated from a sample of anesthesia providers (n=18). DNP student leaders selected four items from the PFQ survey, two of the highest-ranking items and two of the lower scoring items. The mean approval rating of PFQ items is represented in the far-right column at 82%.

Figure 4
Preoperative Algorithm

*Note.* Site-specific Algorithm developed by DNP student leaders to guide the care decisions of anesthesia providers in the preoperative setting. Algorithm was presented to anesthesia providers as an adjunct tool to the Pulmonary Hypertension Clinical Practice Guideline.
## Appendix A

### Table 1 Evidence Rating Table

<table>
<thead>
<tr>
<th>Authors, year</th>
<th>Study objective/intervention or exposures compared</th>
<th>Design</th>
<th>Sample (n)</th>
<th>Outcomes studied</th>
<th>Results</th>
<th>Level of Evidence and Quality Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galie et al., 2015</td>
<td>Collection of recommendations based on current evidence and expert knowledge focusing on the diagnosis and management of the 5 different classes of PH</td>
<td>Practice Guideline Recommendations</td>
<td>A total of 456 articles were utilized in the development of the taskforce’s recommendations within this guideline</td>
<td>Recommendations for treatment, management, and diagnosis were graded based the quality of evidence</td>
<td>Guidelines for diagnoses, prevention, and treatment of the various pathogenesis of PH were provided. The level of evidence as well as the recommendation’s strength were provided</td>
<td>I A</td>
</tr>
<tr>
<td>Kaw et al., 2011</td>
<td>Evaluate postoperative outcomes of patients with or without PH who underwent NCS. Aim to establish associated perioperative risks factors of adverse outcomes of PH patient population</td>
<td>Retrospective controlled cohort study</td>
<td>Adult patients undergoing NCS who had a recent RHC that demonstrated PH (n=98) or without PH (n=77; control group)</td>
<td>NCS within two years of RHC with mPAP &gt;25 mmHg indicating PH-collected preoperative morbidity data from patient’s EHR and IMPACT record - postoperative outcome data collected from EHR notes and records -statistical analysis was performed on complete sample to identify adverse outcomes. Then outcomes of patients with or without PH were compared</td>
<td>PH patients had a greater risk of morbidity (28%) and mortality (1%) -PH has a significantly poor influence on postoperative outcomes - independent risk factors for postoperative morbidity included: mPAP, ASA class, chronic renal insufficiency - concluded that PH has a significantly poor/negative impact on outcomes postoperatively - CHF the single most frequent contributor to postop morbidity and</td>
<td>IV B</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Title</td>
<td>Methodology</td>
<td>Results</td>
<td>Section</td>
<td></td>
<td></td>
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<tr>
<td>------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Meyer et al., 2013</td>
<td>Evaluation of perioperative outcomes in PH patients undergoing NCS</td>
<td>Prospective international multicenter, observational study using a 3-year questionnaire based survey</td>
<td>114 patients enrolled from 11 PH centers undergoing NCS or non-obstetric surgery between 2007 and 2010. A structured questionnaire with various data sets were completed by the investigators for each PH patient undergoing NCS. Statistical analysis was initiated to determine the risk factors of perioperative adverse outcomes. PH patients had a mortality rate of 3.5% and a morbidity rate of 6.1%. Identified major risk factors for postoperative complications to be: elevated right atrial pressure, a 6-minute walk distance less than 399m prior to surgery, preoperative vasopressor use, and emergency surgery with an associated mortality risk of 15%</td>
<td>IV B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minai et al., 2013</td>
<td>Provide anesthetic management recommendations of PH patients undergoing surgery based on a review of literature and expert advice</td>
<td>A narrative review of PH related cohort studies and expert recommendations</td>
<td>Presented morbidity and mortality data and summaries of 5 studies evaluating NCS outcomes of PH patients. Compared and contrasted sample size and demographics, Perioperative morbidity and mortality rates. Perioperative anesthetic management techniques for PH patients -provided a compilation of perioperative complication risk factors</td>
<td>VII B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilkington et al., 2015</td>
<td>Evidence based review of current PH studies with a focus on perioperative anesthetic management and preoperative identification</td>
<td>Review of PH related cohort studies and expert recommendations</td>
<td>Presented morbidity and mortality data and summaries of 6 studies evaluating outcomes of PH patients undergoing NCS. Compared and contrasted sample size and demographics, Perioperative morbidity and mortality rates. Perioperative anesthetic management techniques for PH patients</td>
<td>VII A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author(s)</td>
<td>Description</td>
<td>Methods</td>
<td>Findings</td>
<td>Level of Evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
<td>---------</td>
<td>----------</td>
<td>------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramakrishna et al., 2005</td>
<td>To evaluate the morbidity and mortality incidence of patients with PH who underwent NCS in last 30 days.</td>
<td>Retrospective non-controlled cohort study 145 subjects with PH who underwent general anesthesia for NCS between 1991 and 2003</td>
<td>EHR of patients were reviewed to extract preoperative data, Intraoperative information was collected from the patient’s operative record, and perioperative outcomes were identified by reviewing patient’s records and notes. Statistical analysis was utilized to assess for morbidity and mortality incidence</td>
<td>Surgical procedures &gt;3 hours elevated the mortality risk by 2.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Studer et al., 2013</td>
<td>Review current preoperative management practices of Pulmonary arterial hypertension (PAH) patients</td>
<td>Review of expert recommendations and PH related studies on the optimal preoperative evaluation</td>
<td>Focused on Pulmonary arterial hypertension (PAH) patients Addressed preoperative surgical risk of PH patients undergoing elective, noncardiac surgery</td>
<td>Utilized a total of 25 article to outline important assessment steps to complete when evaluating PH patient facing surgery</td>
<td>Preoperative considerations of PH patients, indicates need for further evidence Outline key preoperative management approaches: WHO classification, RV function, optimizing treatment therapy, communicating a clear plan for each perioperative phase - discuss health care proxy and overall care goals if complications occur</td>
<td></td>
</tr>
</tbody>
</table>


PAC = pulmonary artery catheterization; NCS = non-cardiac surgery; EHR = electronic health record; IMPACT = Internal medicine preoperative assessment consultation and treatment; NYHA = New York Heart Association; PE = pulmonary embolism;
Appendix B

University of Maryland Baltimore Institutional Review Board Approval

NOT HUMAN RESEARCH DETERMINATION

Date: May 6, 2016

To: Joseph Pellegrini
RE: HP-00069525

Name: Clinical practice guideline for the anesthetic management of patients with pulmonary hypertension

This letter is to acknowledge that the UMB IRB reviewed the information provided and has determined that the submission does not require IRB review. This determination has been made with the understanding that the proposed project does not involve a systematic investigation designed to develop or contribute to generalizable knowledge OR a human participant (see definitions below).

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are human subject research as which the organization is engaged, please submit a new request to the IRB for a determination.

Definitions —

Human Research: Any activity that either:
  • Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
  • Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research as Defined by FDA: Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:
  • Must meet the requirements for prior submission to the Food and Drug Administration under section 505(g) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
  • Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
  • Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:
  • Intervention means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
  • Interaction means communication or interpersonal contact between investigator and subject.
  • Private Information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
  • Identifiable Information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Please keep a copy of this letter for future reference. If you have any questions, please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-3037 or HRPO@umaryland.edu.
Appendix C

Modified Practitioner Feedback Questionnaire

For each item, please check off the box that most adequately reflects your opinion.

<table>
<thead>
<tr>
<th>Please complete demographic data:</th>
<th>Ethnicity: AA CAUC OTHER</th>
<th>Years practiced in current role:</th>
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</thead>
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<tr>
<td>Age: 20-30 30-40 40-50 50-60 60-70</td>
<td>□ □ □ □ □ □</td>
<td>□ □ □ □ □</td>
</tr>
<tr>
<td>CRNA MDA SRNA</td>
<td>□ □ □ □</td>
<td>□ □ □ □ □ □ □</td>
</tr>
<tr>
<td>Gender: Male Female</td>
<td>□ □</td>
<td>□ □</td>
</tr>
<tr>
<td>Years at current hospital:</td>
<td>□ □ □ □ □ □ □</td>
<td></td>
</tr>
</tbody>
</table>

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.  
1 (Strongly Disagree - 5 = Strongly Agree) □ □ □ □ □

If you answered “No” or “Unsure”, there is no need to answer or return this questionnaire. If you answered “Yes”, please answer the questions below and return to [enter expected destination of surveys].

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The rationale for developing a guideline is clear.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3. There is a need for a guideline on this topic.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>5. I agree with the methodology used to summarize the evidence included in this draft guideline.</td>
<td>□</td>
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<td>6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.</td>
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<td>7. The draft recommendations in this report are clear.</td>
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<td>8. I agree with the draft recommendations as stated.</td>
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<td>9. The draft recommendations are suitable for the patients for whom they are intended.</td>
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<td>10. The draft recommendations are too rigid to apply to individual patients.</td>
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<td>11. When applied, the draft recommendations will produce more benefits for patients than harms.</td>
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<td>12. The draft guideline presents options that will be acceptable to patients.</td>
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<td>13. To apply the draft recommendations will require reorganization of services/care in my practice setting.</td>
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<td>14. To apply the draft guideline recommendations will be technically challenging.</td>
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<td>15. The draft guideline recommendations are too expensive to apply.</td>
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<td>16. The draft guideline recommendations are likely to be supported by a majority</td>
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of my colleagues.

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<td>17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.</td>
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<td>18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (If they are the same as current practice, please tick NA). NA</td>
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<td>19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick NA). NA</td>
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<td>20. I would feel comfortable if my patients received the care recommended in the draft guideline.</td>
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<td>22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.</td>
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Appendix D

Appraisal of Guidelines for Research & Evaluation (AGREE) II Tool

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

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Comments

2. The health question(s) covered by the guideline is (are) specifically described

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Comments

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

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DOMAIN 2. STAKEHOLDER INVOLVEMENT
4. The guideline development group includes individuals from all relevant professional groups

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5. The views and preferences of the target population (patient, public, etc.) have been sought.

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Comments

6. The target users of the guideline are clearly identified.

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Comments

**DOMAIN 3. RIGOUR OF DEVELOPMENT**

7. Systematic methods were used to search for evidence.

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Comments

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 risk have been considered in formulating the recommendations.

12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.

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Comments

14. A procedure for updating the guideline is provided.

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Comments

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

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Comments

16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

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Comments

**DOMAIN 5. APPLICABILITY**

18. The guideline describes facilitators and barriers to application.

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Comments

19. The guideline provides advice and/or tools on how the recommendation can be put into practice.

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<th>7 Strongly Agree</th>
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Comments

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

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.

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Comments

2. I would recommend this guideline for use. (Yes/ Yes, with recommendations/ No)
Appendix E

Guideline Title: Clinical Practice Guideline for the Anesthetic Management of Patients with Pulmonary Hypertension

Guideline Status: Guideline developed in 2016

Scope
Disease/Condition(s)

Confirmed Pulmonary Hypertension

Guideline Category
Preoperative evaluation and risk assessment
Intraoperative Management
Postoperative care

Clinical Specialty
Anesthesiology

Intended Users
Nurse anesthetists
Anesthesiologists
St Agnes Hospital

Guideline Objective
To reduce the risk of adverse outcomes in pulmonary hypertension patients by improving the perioperative management of adult patients with pulmonary hypertension who receive general, regional, neuraxial, or MAC anesthesia care from anesthesia providers at St Agnes Hospital

Target Population
Patients with confirmed Pulmonary Hypertension (PH) (as diagnosed by right heart catheterization) who are at increased risk of perioperative morbidity and mortality due to the physiologic alterations of the disease.
This population includes patients who have Idiopathic Pulmonary Hypertension, Pulmonary Arterial Hypertension (WHO classification Group 1), Pulmonary veno-occlusive disease (PVOD) and/or pulmonary capillary haemangiomatosis (PCH) (WHO classification group 1), Pulmonary Hypertension due to left heart diseases (WHO classification group 2), Pulmonary Hypertension due to lung diseases and/or hypoxemia (WHO classification Group 3), Chronic thromboembolic Pulmonary Hypertension (WHO classification group 4), or PH of unclear mechanisms (WHO classification group 5).

**Note:** These guidelines do not focus on patients with the following conditions:

- Eisenmenger syndrome
- Obstetrics
- Cardiac Surgery
- Pediatric population

**Interventions and Practices Considered**

**Preoperative Evaluation**

1. Development of a perioperative, anesthetic management plan
2. Medical records review, surgical clearance by primary care provider
3. Review (dates and) results of Right heart catheterization, pulmonary artery pressures, echocardiogram results, electrocardiogram, laboratory values
4. Thorough patient/family interview for patient’s medical history and physical examination
5. Risk evaluation (consideration of severity of PH, active signs or symptoms, associated comorbidities, functional capacity, invasiveness of the surgery, risk level of surgery, requirement for postoperative analgesics)
   - Identify duration of surgery and whether is high, intermittent, or low risk
   - Assess for CAD, CKD, and history of PE due to their associated elevated risk
6. Consideration of inpatient vs. outpatient surgery
7. Provide a detailed informed consent

**Preoperative Preparation and optimization strategies**

1. NYHA functional class
2. 6 minute walk test
3. Continue patient’s PH-specific medications
4. Assess for anticoagulant therapy
   - Warfarin should be held 5-7 days before the procedure with bridging heparin
5. Provide supplemental oxygen and treat pain if applicable

**Intraoperative Management**

1. Consideration for best type of anesthetic for patient
2. Prevent increase in PVR
3. Maintain adequate SVR
4. Prompt treatment of hypoxia, hypercarbia, acidosis
5. Consideration of the potential for postoperative respiratory distress (Judicious use of narcotics and benzodiazepines)
6. Consideration for intraoperative adverse events (inhaled agents, IABP, LVAD)
7. Acute decompensation strategies (Support Right Ventricle)
8. MAC considerations
9. Regional anesthesia/peripheral anesthesia
10. General anesthesia with a secure airway
11. Neuraxial anesthesia (spinal/epidural) (prevent swings in hemodynamics)
12. Protective ventilation (low tidal volumes and PEEP sparing strategies)
13. Extubation: Verify the patient meets full extubation criteria and are fully awake. Avoid hypoxemia, hypercarbia

Postoperative Management

1. Continuation of vigilantly executed preoperative and intraoperative safety measures into the postoperative phase
   - Avoidance of hypoxia, hypothermia, hypercarbia, and hyper/hypervolemia
   - Inotropic support of the right ventricle when indicated
2. ICU monitoring during immediate post operative time.
3. Prolonged PACU stay if an ICU care is not readily available
4. Adequate postoperative pain management. Continuation or establishment of pain management modalities such as regional/neuraxial analgesia
5. Supplemental oxygen
6. Continuous pulse oximetry monitoring

Major Outcomes Considered

Risk of adverse outcomes in patients with Pulmonary Hypertension (PH) such as:

- Right sided heart failure
- Respiratory arrest
- Hypoxemic events
- Sepsis
- Unexpected intensive care unit admission
- Acute congestive heart failure
- Intraoperative hemodynamic instability/ abortion of surgical procedure,
- Renal failure
- Myocardial infarction
- Hemodynamic collapse

Methodology

Methods Used to Collect/Select the Evidence
• Search of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

• Evidence used in the development of these guidelines is based on an extensive literature review. Literature citations are obtained from PubMed, One Search, CINHAL, EBSCO, and MedLine

State of the Literature

The focus of the articles examined related to the perioperative management of patients with pulmonary hypertension in the following areas:

• Preoperative Evaluation
• Intraoperative Management
• Postoperative Management

Initially, the literature review was conducted via electronic searches of databases. The electronic search covered a 10 year period from 2005 to 2015. After review of the articles, studies that did not provide directly pertain to the CPG topic, and overlapping articles were eliminated. A total of 13 articles contained direct linkage-related evidence were used in this review.

Limitations: The evidence lacked literature with well-defined experimental designs or randomized controlled trials.

Number of Source Documents
Methods Used to Assess the Quality and Strength of the Evidence

Melnyk & Fineout-Overholt’s Rating Scheme for the Strength of the Evidence (Newhouse, 2006).

Quality Rating Scheme (Newhouse et al., 2007)

Methods Used to Analyze the Evidence
Literature Review

Methods Used to Formulate the Recommendations
Task force Consensus, AGREE II tool, Practitioner feedback Survey

Description of Methods Used to Formulate the Recommendations

The guidelines were developed by a Task Force of 5 members, consisting of anesthesiologists, Certified Registered Nurse Anesthetists, and Registered Nurses
The Task Force developed the guidelines by means of a staged model. In the first stage sources of evidence were acquired via literature review, and the evidence was graded using Melnyk & Fineout-Overholt. A literature review table is included (See Appendix A). A multidisciplinary team of stakeholders then drafted guidelines based on the available evidence. At this organization the multidisciplinary team included anesthesiologists, nurse anesthetists, and registered nurses. After drafting guidelines, the task force used the AGREE II tool to evaluate the CPG. The second stage consisted of feedback from practitioners, who were asked to review and comment on a draft of the guidelines developed by the Task Force via a modified practitioner feedback survey (See Appendix C). The multidisciplinary team then revised guidelines, determined barriers to implementation and submitted the guideline to administration for review. After administrators gave feedback, the guideline was once again revised, and submitted for final approval.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The updated guideline will seek IRB approval. The validity of the AGREE II tool and Brower’s 2004, Clinicians’ assessments of practice guidelines in oncology is well established.

Major Recommendations

I. Preoperative Evaluation

- The anesthesia provider should work with surgeons to develop a protocol whereby patients who are clinically suspected to have Pulmonary Hypertension, are evaluated before the day of surgery to allow preparation of a perioperative management plan.
  - This evaluation may be initiated in a pre-anesthesia clinic (if available) or by direct consultation from the operating surgeon to the anesthesiologist.
  - A preoperative evaluation should include a comprehensive review of previous medical records (if available), an interview with the patient and/or family, and conducting a physical examination.
    - Medical records review should include (but not be limited to) checking for a history of dyspnea, cardiovascular problems especially CAD and PE, CKD, and other congenital or acquired medical conditions.
The patient and family interview should include focused questions related to symptoms, METS, exercise tolerance, how previous surgeries were tolerated.

A physical examination should include an evaluation of lungs, heart, kidneys, and vascular system functionality.

I. Assess for episodes of chest pain, arrhythmia, syncope, shortness of breath, haemoptysis, enlarged jugular veins, edema and their medication compliance.

If any characteristics noted during the preoperative evaluation suggest that the patient has PH, the anesthesia provider and surgeon should jointly decide whether to (1) manage the patient perioperatively based on clinical criteria alone or (2) obtain further studies, conduct a more extensive examination, and initiate the indicated PH treatment in advance of surgery.

If the preoperative evaluation does not occur until the day of surgery, the surgeon and the anesthesia care team together may elect for presumptive management based on clinical criteria or a last-minute delay of surgery.

The severity of the patient's PH, the invasiveness of the diagnostic or therapeutic procedure, and the requirement for postoperative analgesics should be taken into account in determining whether a patient is at an increased perioperative risk from their underlying PH.

The patient and his or her family as well as the surgeon should be informed of the potential implications of PH on the patient's perioperative course.

III. Preoperative Preparation and optimization

- Multidisciplinary team approach
- Evaluate the patients need for surgery, assess risks and benefits
- Detailed history and physical
- Preoperative testing should include:
  - Laboratory blood tests: complete blood count, comprehensive metabolic panel, coagulation studies, B-type natriuretic peptide (if available)
  - Electrocardiogram
  - Echocardiogram: there is no strong evidence to support when this needs to be done before surgery, however the practitioner should obtain the most recent report on the patient’s ejection fraction
  - RHC in patients with RVF signs and symptoms
- Risk assessment for 1-year mortality in PAH:
  - Low risk (<5%): NYHA functional class I or II, reports no syncope episodes, 6MWD >440m, RA area <18cm2, no pericardial effusions, RAP <8mmHg, CI >2.5 l/min/m2, SvO2>65%
  - Intermediate risk (5-10%): NYHA functional class III, reports occasional syncope, 6MWD 165-440m, RA area 18-26cm2, non to minimal pericardial effusion, RAP 8-14mmHg, CI 2.0-2.4 l/min/m2, SvO2 60-65%
  - High risk (>10%): NYHA functional class IV, reports repeated syncope episode, 6MWD <165 m, RA area >65cm2 and pericardial effusion, REP >14mmHg, CI <2.0 l/min/m2, SvO2 <60%
• Strong indicators of function and prognosis of RV are: RA pressure, cardiac index, and missed venous oxygen saturation
• Evaluation patient’s 6MWT, if available, to assess exercise capacity

IV. Intraoperative Management
• Due to the fragility of the PH population and the heightened surgical risk all anesthetic goals should focus on the maintenance of right ventricular function and avoidance of PH crises.
• Regardless of type of anesthetic used, the practitioner should uphold the following principles: Maintain SVR, Prevent an increase in PVR, Avoid hypoxemia, hypercapnia, acidosis, fluid overload and pain.
• Because of their propensity for hemodynamic collapse and right sided heart failure, patients at increased perioperative risk from PH are especially susceptible to the respiratory depressant and airway effects of sedatives, opioids, and inhaled anesthetics; therefore, the potential for postoperative respiratory compromise, and subsequent increased PVR, should be considered in selecting intraoperative medications. The anesthesia provider should maintain a judicious use of benzodiazepines and opioids during the procedure
• There is no strong evidence to support one type of anesthetic has an influence on morbidity and mortality, any approach may be used as long as hemodynamic instability is avoided and rapidly recognized
• For superficial procedures, consider the use of local anesthesia or peripheral nerve blocks, with or without MAC. If MAC is used, ventilation should be continuously monitored by Capnography, because hypercapnia must be avoided in these patients.
• General anesthesia with a secure airway is preferable to deep MAC sedation without a secure airway, particularly for procedures that may compromise the airway.
• For general anesthesia, the sympathetic response to direct laryngoscopy must be avoided and depth of anesthesia should be adequate before airway instrumentation is attempted.
• Consideration for an awake Fiberoptic intubation must be weighed against the possibility of avoiding a period of hypoxia or poor ventilation
• Etomidate and Ketamine are preferable to Propofol as induction agents in that they preserve SVR with little effect on PVR
• Of all the inhalation agents Nitrous Oxide causes the greatest increase in PVR this drug should be avoided in the PH population
• Neuraxial anesthesia (spinal/epidural) should be considered for peripheral procedures, but the sympathectomy associated with neuraxial anesthesia must be avoided.
• No recommendations consistently support the use of an arterial line, central line or a SWAN GANZ catheter; however, these may be beneficial in higher risk procedure. Specifically, invasive arterial monitoring allows the anesthesia provider to quickly recognize hemodynamic changes, and allows access to frequent arterial blood gas monitoring.
• Intraoperative trans-esophageal echocardiography should be considered for guiding fluid management in patients with severe PH. Fluid overload must be avoided in this population as it can propensities right sided heart failure.
• Sympathomimetic vasopressors may be necessary to maintain adequate SVR
• Epinephrine, dobutamine, norepinephrine, and levosimendan have been shown effective in the treatment of right sided heart failure.
• In the face of acute decompensation, measures should be taken to reduce PVR.
• The use of inhaled nitric oxide, prostacyclin, or parenteral sildenafil should be used to acutely reduce PVR.
• Inhaled agents combined with intravenous inotropes may be more beneficial than either class of medication used alone.
• If pharmacologic management is not adequate to maintain hemodynamics then a surgically implanted device, such as an intra-aortic balloon pump, or left ventricular assist device for hemodynamic support should be considered.
• Full reversal of neuromuscular block should be verified before extubation, to ensure the patient has full and adequate use of the diaphragm. Reduced muscular function may cause hypercapnia, hypoxia and acidosis and precipitate right sided heart failure

V. Postoperative Management
• Regional analgesic techniques or other pain management modalities such as a patient controlled analgesia (PCA) should be considered for post-operative pain control
• If patient-controlled systemic opioids are used, continuous background infusions should be avoided or used with extreme caution, avoid respiratory depression
• Supplemental oxygen should be administered continuously to all patients who are at increased perioperative risk from PH until they are able to maintain their baseline oxygen saturation while breathing room air.
• If possible, patients at increased perioperative risk from PH should be placed in the intensive care unit for close monitoring where early signs of hemodynamic instabilities will be recognized and acted up on.
• Hospitalized patients who are at increased risk of respiratory compromise from PH should have continuous pulse oximetry monitoring after discharge from the recovery room.
• If frequent or severe airway obstruction or hypoxemia occurs during postoperative monitoring, initiation of nasal CPAP or noninvasive positive pressure ventilation should be considered.
• Pharmacological treatments that pulmonary hypertension patients were on preoperatively should be continued during the postoperative phase
  • Prostacyclin analogues
  • Endothelin receptor antagonists
  • Phosphodiesterase-5 inhibitors (Sildenafil, Tadalafil)

Clinical Algorithm(s)

None provided
**Evidence Supporting the Recommendations**

Evidence was obtained: narrative reviews, retrospective cohort studies, and opinion-based evidence (see Appendix A)

**Benefits/Harms of Implementing the Guideline Recommendations**

Potential Benefits

Improved perioperative care and reduced risk of perioperative morbidity and mortality in patients with PH who receive general, regional, neuraxial, or MAC anesthesia care from an anesthesia provider

Potential Harms

None indicated

**Qualifying Statements**

Practice guidelines recommendations based off of evidence that the practitioner may use to guide decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints, and are not intended to replace local institutional policies.

Source(s) of Funding

None

**Identifying Information**

Guideline Committee: Task Force on Perioperative Anesthetic Management of Patients with Pulmonary Hypertension

*Task Force Members:* Amlakie Gebeyehu, Katy Woods, Jessica Naper

Financial Disclosures/Conflicts of Interest

The authors declare no competing interests.

References:


international prospective survey. *European Respiratory Journal, 41* (6) 1302-1307; DOI: 10.1183/09031936.00089212


Appendix F

Scholarly Project Timeline

- Scholarly Project Proposal to committee members - March 2016
- Present CPG to committee members for approval - April 2016
- Submit CPG Proposal to Institutional Review Boards
  - University of Maryland - May 2016
  - Facility of Project setting - June 2016
- Conduct Scholarly Project – May & August 2016
  - Develop CPG with team members - May & June 2016
  - Present CPG to Anesthesia providers (Phase 2) - August 2016
  - Submit CPG to Chief Anesthesiologist for review (Phase 3) - September 2016
- Analyze, synthesize and evaluate data - October 2016 - January 2017
- Submit final scholarly project manuscript to committee for review - February 2017
- Present final scholarly project to committee - February 2017