

Management of Opioid and Sedative Weaning in Pediatric Congenital Heart Disease Patients

Assessing the State of Practice

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Background: Opioid and sedative medications are commonly used to treat pediatric patients with congenital heart disease; however, their use is not without adverse effects. Symptoms of withdrawal can occur if the medications are discontinued abruptly or weaned too quickly.

Objective: The aim of this study was to understand and describe the current management of opioid and sedative weaning in pediatric congenital heart disease patients in freestanding children's hospitals across the United States.

Methods: A Web-based survey of pediatric congenital heart centers was conducted. Survey participants were recruited from the Consortium of Congenital Cardiac Care–Measurement of Nursing Practice. Quantitative data were summarized using frequency and proportions. Qualitative data were summarized using content analysis.

Results: Twelve sites participated in the survey (44% response rate).

Methadone was used as a weaning medication at 100% of participating sites, lorazepam at 83% of sites, and clonidine at 75% of sites.

Seventy-five percent of sites reported using a clinical assessment tool to monitor withdrawal symptoms. Twenty-five percent of sites used a standardized clinical pathway when weaning opioid and sedative medications. Eighty-three percent of sites will consider discharging a patient to complete the medication wean at home.

Discussion: Weaning practices varied across sites. While some similarities were observed among sites, substantial practice variation exists. The majority of sites used a clinical assessment tool to assess for withdrawal

symptoms. Few sites reported using a standardized approach to weaning patients. Discharging patients to complete an opioid or sedative wean at home was common practice. Opportunities exist for the development of weaning practice guidelines.

Keywords: Heart defects, congenital; Weaning; Withdrawal symptoms

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The population of pediatric patients with congenital heart disease being cared for in a hospital setting has become increasingly medically complex over the years.¹ As a result of the continued advancement of science and technology, children with even the most severe types of congenital heart disease are offered treatment in the form of advanced cardiac medical and cardiothoracic surgical techniques.² The recovery period for these patients can be lengthy, and they often experience extended stays in the intensive care unit where they receive prolonged courses of opioid analgesics and sedatives to alleviate pain, reduce anxiety, and diminish physiologic stress responses.³ Although it is certain that the delivery of life-sustaining therapies would not be possible without the administration of opioid and sedative medications, use of these medications can negatively impact patients and, in certain cases, contribute to longer hospital lengths of stay.⁴⁻⁶ In addition, when used for a prolonged period, patients can develop tolerance to these medications, necessitating larger doses in order to achieve the desired level of analgesia and sedation.^{4,5} When the patient's disease trajectory changes and large doses of opioids and sedatives are no longer necessary, symptoms of iatrogenic withdrawal such as tachypnea, tachycardia, hypertension, hyperirritability, jitteriness, anxiety, sleep disturbances, diaphoresis, poor feeding, vomiting, diarrhea, seizures, increased muscle tone, and abnormal muscle movements can occur if the medications are discontinued abruptly or weaned too quickly.^{4,9} It is therefore imperative that these medications are weaned as expediently as possible while taking care to avoid symptoms of iatrogenic withdrawal.

Iatrogenic withdrawal in pediatric patients is a significant problem. For the purposes of this article, the term *pediatric* is meant to include patients from newborns through 21 years of age. It has been estimated that as many as 50% of children exposed to a continuous fentanyl infusion for 5 days, or with a cumulative dose exposure of 1.5 mg/kg, will develop withdrawal symptoms when the infusion is discontinued. This percentage is estimated to increase to 100% when the children are exposed to 9 days of continuous fentanyl infusion or a cumulative dose of 2.5 mg/kg.⁹ Similar findings have been identified with use of benzodiazepines.⁷ Iatrogenic with-

drawal can be prevented or mitigated by gradually tapering opioid and sedative medications.¹⁰ The optimal length of time for weaning medications is specific to each individual patient with the goal of maintaining patient comfort without significant withdrawal symptoms while minimizing intensive care unit and overall hospital length of stay.⁵

With an incidence of 8 in every 1000 live births, congenital heart disease is the most common form of birth defect affecting newborn babies in the United States.¹¹ Because this population will continue to grow in the future, it is essential that providers optimize the care that is delivered to this medically complex population. Currently, there is little evidence available to guide health care providers with regard to the safest and most effective way to wean children with congenital heart disease from opioid and sedative medications. The majority of the relevant literature focused on the overall population of pediatric patients in intensive care unit settings and neonates who have been exposed to opioids while in utero. Children and neonates with congenital heart disease are a unique population and may present special considerations or challenges with respect to weaning opioid and sedative medications. To the authors' knowledge, the present project is one of just a few to look at weaning practices and iatrogenic withdrawal specifically in the pediatric congenital heart disease population.⁶ Therefore, it was decided that a national survey would be the best initial approach to better understand and define this topic.

Objective and Aims

The purpose of this project was to understand and describe the management of opioid and sedative weaning in pediatric congenital heart disease patients in freestanding children's hospitals across the United States. The aims of the project were (1) to describe current practice of weaning opioids and sedatives in the pediatric congenital heart disease population, (2) to describe the use of a standardized approach to weaning opioids and sedatives in pediatric congenital heart disease patients, and (3) to describe the pre-discharge education and post-discharge follow-up that occurs when a patient with congenital heart disease is discharged from the hospital to complete their medication wean in the home setting.

METHODS

A Web-based national survey of pediatric congenital heart centers was conducted to investigate this area of practice. The electronic survey was composed of 21 questions with a combination of fixed-choice and open-ended responses in order to maximize participants' description of their practice. The survey underwent testing prior to distribution to ensure both content validity and reliability. This was accomplished by sharing the survey with several advanced practice colleagues and subsequently interviewing these colleagues to learn their cognitive responses to the questions and thought processes when answering them. In addition, the survey was reviewed by a member of the student investigator's affiliated institution's pain team, considered a subject expert in current weaning methods. Once available in electronic form, the survey underwent a second round of pilot testing by the same group of advanced practice colleagues to ensure that the electronic format was easy to use and inclusive of all aspects of the paper survey. This was done to ensure completeness of the data obtained from the survey participants. Based on feedback provided during the cognitive interviews, it is estimated that the survey took approximately 15 to 20 minutes to complete. The survey was developed as the student investigator's doctor of nursing practice scholarly project. Both institutional review boards within the student investigator's affiliated hospital and academic institution determined that this project met the criteria for quality improvement and expedited review.

A purposive sampling approach was used; survey participants were recruited from the Consortium of Congenital Cardiac Care–Measurement of Nursing Practice (heretofore referred to as the Consortium), a nationwide collaborative of 28 cardiovascular programs across the United States whose overall aim is to identify nursing care actions/behaviors for measurement in the highly complex pediatric cardiovascular patient environment. Consortium members include advanced practice nurses, nurse administrators, clinical nurse specialists, researchers, and bedside clinicians. A list of the 28 participating programs is provided in Table 1; together they have a median volume of 279 congenital heart defect repairs per year (range, 107-806 congenital heart defect repairs per year).

The project's purpose and aims were described briefly by the student investigator during a regularly scheduled monthly conference call several months prior to the distribution of the survey. An informational e-mail was then sent to the key contact at each Consortium site. The e-mail explained the project in detail and invited the key contact to complete the electronic survey or designate another provider to complete the survey on behalf of their program. According to inclusion criteria, the survey participant had to be a health care provider (nurse practitioner

TABLE 1 List of Participating Consortium Sites

Site Name	Location
Advocate Children's Hospital	Chicago, Illinois
All Children's Hospital	St Petersburg, Florida
Ann & Robert H Lurie Children's Hospital of Chicago	Chicago, Illinois
Arkansas Children's Hospital	Little Rock, Arkansas
Boston Children's Hospital	Boston, Massachusetts
Brenner Children's Hospital	Winston-Salem, North Carolina
Children's Hospital Colorado	Aurora, Colorado
Children's Hospital Los Angeles	Los Angeles, California
Children's Hospital of Philadelphia	Philadelphia, Pennsylvania
Children's Healthcare of Atlanta at Egleston	Atlanta, Georgia
Children's Hospital of Pittsburgh	Pittsburgh, Pennsylvania
Children's Hospitals and Clinics at Minneapolis	Minneapolis, Minnesota
Children's Medical Center of Dallas	Dallas, Texas
Children's National Medical Center	Washington, District of Columbia
Cincinnati Children's Hospital Medical Center	Cincinnati, Ohio
Doernbecher Children's Hospital, Oregon Health and Science University	Portland, Oregon
Johns Hopkins Children's Center	Baltimore, Maryland
Lucile Packard Children's Hospital at Stanford	Palo Alto, California
Miami Children's Hospital	Miami, Florida
Nationwide Children's Hospital	Columbus, Ohio
Nemours/Alfred I. duPont Hospital for Children	Wilmington, Delaware
Phoenix Children's Hospital	Phoenix, Arizona
Primary Children's Medical Center	Salt Lake City, Utah
Rady Children's Hospital San Diego	San Diego, California
Golisano Children's Hospital, University of Rochester Medical Center	Rochester, New York
Riley Hospital for Children	Indianapolis, Indiana
Texas Children's Hospital	Houston, Texas
University of Michigan C. S. Mott Children's Hospital	Ann Arbor, Michigan

[NP]/advanced practice registered nurse [APRN], physician, or physician assistant), older than 18 years, and working in a step-down unit, ward, or other intermediate care environment. The survey participant had to speak and read English and be directly involved in weaning patients with congenital heart disease from opioid and sedative medications. The student investigator's affiliated

hospital organization was not invited to participate in the survey, leaving a total of 27 potential participants.

To ensure confidentiality, all survey participants received a site number that was assigned by a member of the project team. Survey responses were directly entered into REDCap (Research Electronic Data Capture) electronic data capture tools.¹² REDCap is a secure, Web-based application designed to manage and support data capture for research and quality improvement. Data were exported deidentified for analysis. All data were summarized using descriptive statistics. Quantitative data were summarized using frequency and proportions. Qualitative data were reviewed and summarized by the project team using content analysis to assess for similarities across programs. Results were then examined by the student investigator and synthesized to describe the current state of practice. Survey results were shared with members of the Consortium during a monthly conference call. Although survey participants were not compensated for their participation, each site had the potential to benefit from the knowledge generated by the project.

RESULTS

Twenty-seven sites were invited to participate in the electronic survey. A total of 12 sites responded, yielding a response rate of 44%. The majority of the respondents were advanced practice nurses (NP/APRNs and clinical nurse specialist/nurse educators) working in cardiology or cardiac surgery. Table 2 describes the demographics of the survey respondents in detail.

Current Weaning Practices

With respect to opioids, all 12 sites (100%) reported using methadone to treat or prevent iatrogenic withdrawal, whereas only 4 of 12 sites (33%) used morphine. With respect to sedatives, 10 of 12 sites (83%) reported using lorazepam, 2 of 12 sites (17%) used midazolam, and 2 of 12 sites (17%) used diazepam. In addition, 9 of 12 sites (75%) reported using clonidine as an adjunctive agent. Figure 1 displays the most common opioids and sedatives used by respondent sites.

Nine of 12 participant sites (75%) used a clinical assessment tool to evaluate for withdrawal symptoms in their patient population. Of the 9 sites that used an assessment tool, 8 sites (89%) reported using the WAT-1 (Withdrawal Assessment Tool Version 1),¹³ 2 sites (22%) used the NAS (Finnegan Neonatal Abstinence Score),¹⁴ and 1 site (11%) used the SOS (Sophia Observation Withdrawal Symptoms Scale).¹⁵ One participant site reported that a clinical assessment tool was used occasionally, but not consistently. At this site, the tool was most often used when trying to differentiate between withdrawal symptoms and another process such as pain or feeding intolerance.

TABLE 2 Survey Respondent and Site Demographics (n = 12)

Current job title
Nurse practitioner/advanced practice registered nurse: 5 (42%)
Clinical nurse specialist/nurse educator: 4 (33%)
Attending physician: 1 (8%)
Quality improvement registered nurse: 1 (8%)
Staff nurse III/rounding nurse: 1 (8%)
Respondents work in the following departments
Cardiology: 3 (25%)
Cardiac surgery: 3 (25%)
Pain team: 1 (8%)
Cardiac intensive care unit: 5 (42%)
Congenital heart disease patients no longer requiring critical care are transferred to
N/A (patients stay in the intensive care unit from admission to discharge): 3 (25%)
Cardiac-specific step-down or intermediate care unit: 7 (58%)
General ward: 2 (17%)

Survey participants identified symptoms, conditions, and factors that contribute to their decision whether to wean a patient on a given day. As displayed in Figure 2, tachycardia, hypertension, vomiting, diarrhea, irritability, jitteriness, diaphoresis, sleep disturbances, and concerns raised by either the parent(s) or bedside nurse were the most common factors that influenced the decision to wean. Tachypnea, desaturation, elevated temperature, abnormal muscle movements, increased muscle tone, and seizures were reported less frequently.

Seven of 12 sites (58%) reported that the attending physician managing the patient was the health care provider responsible for deciding whether to wean or modify the wean on a daily basis. Four of 12 sites (33%) reported that NP/APRNs made this decision, and 1 site (8%) stated that the pain team made the decision. Two sites suggested that the decision to wean a patient was made using a team approach, and 2 sites reported the involvement of a clinical pharmacist in making this decision.

Three of 12 sites (25%) reported use of a standardized process such as a clinical pathway, guideline, or policy when weaning opioid and sedative medications. One site reported that a clinical pharmacist proposes a plan for weaning that is then executed by the health care team. Another site reported that medications are weaned “10% to 20% every 24 to 48 hours.” Two sites reported that weans are held if the WAT-1 score is 3 to 4 or greater, and then weaning is reassessed the following day.

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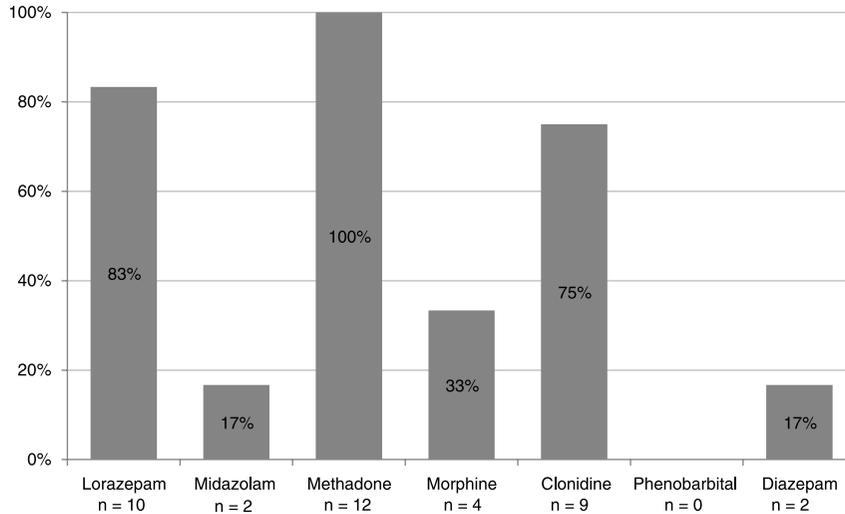


Figure 1. Opioid and sedative medications used to treat or prevent iatrogenic withdrawal (n = 12).

With regard to specific weaning practices, 8 of 12 sites (67%) reported that weans were attempted daily. One site attempted weans every other day. Another site attempted them daily in the intensive care unit but only every 3 days in the step-down unit. Seven of 12 sites (58%) gave consideration to patient factors such as age, seizure disorder or other neurologic condition, history of premature birth, and/or the severity of the patient's underlying heart defect when deciding which medication to wean first.

Preparing for Discharge: Weaning Education for Families and Caregivers

Ten of 12 sites (83%) reported that they will consider discharging a patient who is receiving opioid and/or sedative medications to complete the weaning process at home. The decision was made on a case-by-case basis for 90% of

these sites. Standard practice accounted for only 10%. As displayed in Figure 3, the most important factors that affect the decision whether a patient can be discharged on a wean included the number of opioids/sedatives the patient was receiving and the severity of the underlying heart defect. Less important considerations included the distance from the hospital that the patient and family lived and the primary language of the family. Sites also stated that the family's ability to follow the weaning instructions/schedule and the patient's tolerance of the current weaning plan were additional factors considered when deciding whether a patient could be discharged on an opioid and/or sedative wean. One site related that their patients are no longer discharged on opioid or sedative weans because of past "poor experiences." When patients live a far distance from the hospital and experience withdrawal symptoms,

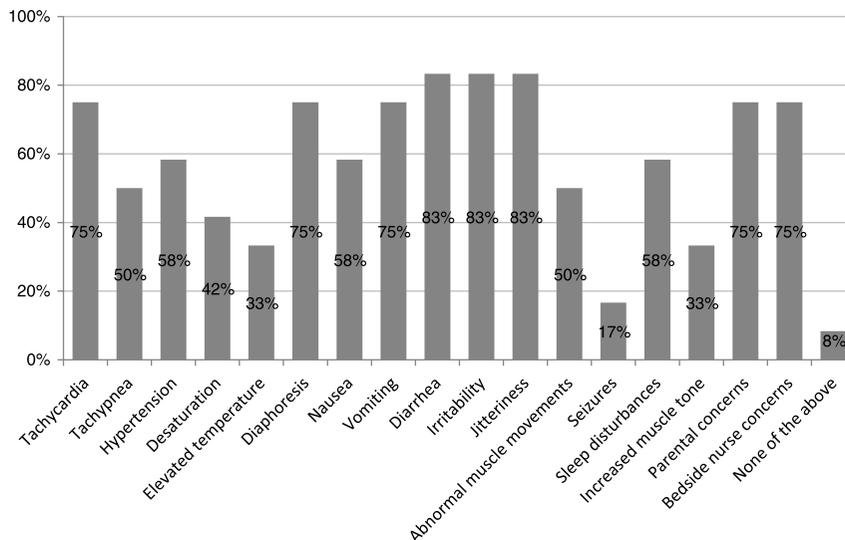


Figure 2. Symptoms or factors impacting the decision to wean a patient (n = 12).

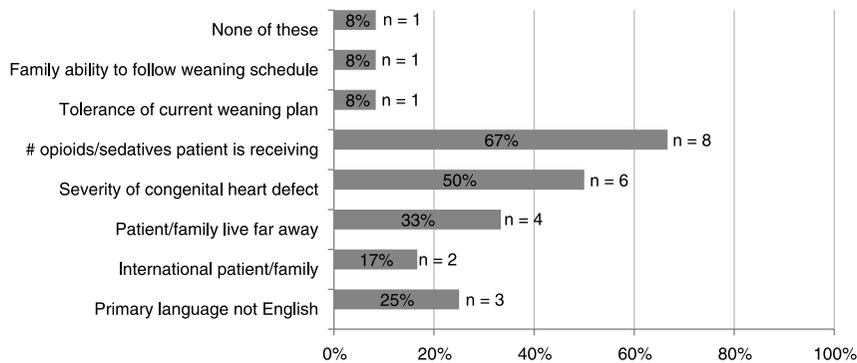


Figure 3. Factors considered when deciding whether a patient can be discharged to complete wean at home (n = 12).

they rely on a provider that is unfamiliar with their diagnosis and recovery trajectory, and the risk for error in dosing and/or conversion of medication potentially increases.

Of the 10 sites that discharge patients to complete their wean at home, 8 (80%) provided specialized education or training to prepare families and caregivers for the transition home. Most frequently, the patient's bedside nurse (75%) or pharmacist (63%), and less frequently the NP/APRN (25%) or the discharge planner (13%), provided the education content. Of the 8 sites that offered specialized education, 6 (75%) sites provided written materials to families and caregivers. Medication information sheets were the most common type of written material provided (100%), followed by medication administration schedules and/or medication administration calendars (67%). While 3 of 6 sites (50%) provided families with information about iatrogenic withdrawal, no sites provided them with a withdrawal clinical assessment tool to use in the home setting.

All 10 sites (100%) that consider discharging a patient on an opioids and/or sedative wean provided families and caregivers with contact information for a health care provider if they had specific questions or concerns regarding the administration of these medications at home. Seven of 10 sites (70%) provided the contact information for the patient's primary cardiologist. Three of 10 sites (30%) provided contact information for the pain team and/or the NP/APRN who primarily managed the patient in the hospital. Less frequently, contact information for the pediatrician (20%), discharging unit (20%), on-call physician or surgical physician assistant/NP/APRN (10%), pharmacist (10%), primary surgeon (10%), or attending physician who primarily managed the patient in the hospital (10%) was provided.

Four of 10 sites (40%) scheduled follow-up visits specific to the opioid and/or sedative wean following discharge. Of the 4 sites that arranged this follow-up, 3 sites (75%) reported the follow-up was provided by the patient's primary cardiologist. Less frequently, the postdischarge follow-up was provided by the pediatrician,

pain team, or NP/APRN who primarily managed the patient in the hospital (25%). One site reported that the pain team provided outpatient follow-up only to those patients with a history of difficulty with weaning, those with prolonged weans, or those who were discharged on more than 1 medication. All 4 sites scheduling routine follow-up for patients did so in the form of a clinic visit; however, communication by phone, e-mail, and other electronic devices occurred as well.

DISCUSSION

Recommendations for weaning opioids and sedatives in pediatric patients have not been well defined to date. Review of the literature revealed that weaning strategies were varied, and the approach chosen was often determined by many factors including type of opioid, total length of drug exposure, and practitioner preference.³ Three types of weaning strategies have been described: (1) gradual reduction of continuous opioid and sedative infusions, (2) transition of medications administered intravenously to subcutaneous administration, or (3) substitution of the intravenous medication for an enteral medication of the same potency.¹⁰ Generally, recommendations included reducing total doses by 10% to 20% per day every 24 to 48 hours and consideration of adding adjunctive agents or longer-acting medications, such as clonidine and/or methadone, respectively.^{8,16} Because the focus of this project was to evaluate the weaning strategies used for patients no longer receiving care in a critical care environment, the survey questions did not inquire about the use of continuous infusions administered by the intravenous or subcutaneous route.

Information generated from this assessment provided a current statement of the practice and management of opioid and sedative weaning in pediatric patients with congenital heart disease. Survey responses showed some similarities among participant sites; however, substantial practice variation was revealed as well. Numerous medications used to prevent or treat iatrogenic withdrawal have been described in the literature including methadone,

morphine, lorazepam, midazolam, dexmedetomidine, chloral hydrate, and clonidine.^{3,7,10,16-22} Among the sites surveyed for this project, methadone, lorazepam, and clonidine were the most commonly used. Methadone was generally looked upon favorably in the literature secondary to its good oral bioavailability and long half-life, which permits extended dosing intervals.¹⁰

The literature supported use of an assessment tool when evaluating patients for symptoms of iatrogenic withdrawal.^{3,6,10,17-20,23} Results from this project were similar, as 75% of sites confirmed their use of an assessment tool. Many tools are available to assess for withdrawal symptoms; some were originally developed for use in neonates, making them less ideal for use in the pediatric population. The WAT-1 assessment tool was the most frequently used tool at participant sites (89%). In general, it is preferred because of its strong psychometric properties and ease of use at the patient's bedside.⁴ The NAS, although cited frequently in the literature,^{3,10,17,18,20} was used by only 2 participant sites (17%).

Many authors have described the day-to-day decision of managing a patient's wean from opioids and sedatives as the responsibility of the attending physician.^{10,24} The current project replicated this pattern as attending physicians were identified as the health care provider responsible for making the decision to wean at 58% of participant sites. Nurse practitioners were the second most common health care provider responsible for weaning decisions at participant sites (33%). This fact has not been reported previously in the literature. In addition, while many authors describe programs where weaning decisions were led by a clinical pharmacist,^{17,20} none of the sites surveyed reported this to be the case at their institution.

There was no consensus in the literature regarding the practice of weaning 1 medication at a time^{10,16,24} versus concurrent weaning of opioids and sedatives.^{3,6,18,21,25} Responses from the participant sites were divided as well. Six of 12 sites (50%) reported that they weaned one medication at a time, whereas the remaining 6 sites reported that their approach was dependent on the specific clinical situation. Of the 6 sites that weaned 1 medication at a time, 2 sites (33%) weaned benzodiazepine medications first, and 1 site (17%) weaned opioid medications first. The remaining 3 sites (50%) reported that it depended on the specific clinical situation.

A second area of debate is whether weaning protocols should be standardized^{3,10,16,17,20,21} or tailored to meet the needs of each individual patient.^{6,8,18,19,22,25} Only 25% of participant sites reported routinely using a standardized clinical pathway, guideline, or policy when weaning medications. This finding differed from the literature, where more than half of the sites favored standardization.^{3,10,16,17,20,21} Potential advantages of using a

standardized weaning protocol include consistency in calculating dosages, avoidance of errors when converting dosages (for those transitioned to an alternative agent such as methadone), increased awareness of withdrawal symptoms, fewer days of opiate exposure, and decreased intensive care unit and hospital length of stay. A potential disadvantage of standardization of medication weaning is increased frequency of withdrawal symptoms.²¹ The fact that so few of the participating sites followed standardized weaning protocols may suggest that the population of pediatric congenital heart disease patients responds differently to weaning than does the general population of pediatric patients. Certainly clinician judgment is essential when evaluating and treating a patient for iatrogenic withdrawal. Rather than a standardized algorithmic approach cited in the literature, development of generalized practice guidelines may prove more useful in helping support pediatric cardiovascular programs define or refine their approach to weaning.

The literature offered evidence that pediatric patients could be discharged home while being weaned from opioid and sedative medications and that this is both feasible and cost-effective.^{10,18,20,24} The majority of the participating sites (83%) will consider discharging a patient to complete the wean at home. This practice has been found to be safe and can result in substantial cost savings, estimated by one group of researchers to exceed \$150 000 per patient.²⁴ Many researchers have cited educating parents about the signs and symptoms of withdrawal so that patients can continue to be monitored appropriately after discharge.^{10,18,24} All 10 participant sites who discharged patients receiving an opioid or sedative wean reported the provision of specialized education or training to help families assume this responsibility. This included both written materials such as information about monitoring for withdrawal symptoms and medication information sheets. While no site reported providing families with a withdrawal assessment tool for use in the home setting, this has been suggested as a way to more accurately monitor and support patients undergoing weans at home.²⁴

Similar to what has been reported in the literature,^{7,10,18} participant sites routinely provided families and caregivers with a health care provider's contact information to answer questions or address concerns specific to the medication wean. Most often, it was the contact information for the primary cardiologist, pain team, or the NP/APRN who primarily managed the patient in the hospital. This practice was slightly different than some of the literature sources including 1 study that endorsed daily phone contact with the pain team until 72 hours after the last dose of medication¹⁰ and another study that reported weekly consultations by phone with a pediatric intensive care unit physician.²⁴

In evaluating the current project, there were several strengths and limitations that deserve mention. A strength of this study was that it was the first national survey to investigate opioid and sedative weaning practices specific to the pediatric congenital heart disease population. The survey response rate was 44%, which is considered satisfactory for survey participation. If this study were to be replicated in the future, it may be advisable to personalize the e-mail invitations in order to increase the response rate. With respect to limitations, the nature of this important topic is complex and multilayered, and in hindsight, survey format may have limited the student investigator's ability to completely capture such detailed information. It should be mentioned that at the conclusion of each section of the electronic survey additional space was provided for the survey respondents to input free text regarding their program's specific weaning practices. This was done by the student investigator in an attempt to collect detailed information about the weaning practices used by each program; however, few respondents provided additional information in this section. As such, future studies may want to use structured interviews or focus groups in order to gather the most complete information and better understand each program's specific weaning practices. In addition, because only 1 survey was completed for each site, there is a possibility that the responses submitted were biased by clinician practice variation and therefore are not entirely representative of that site's practice. While the sample size was small and could limit the external validity of the project, the survey response rate was relatively high, and therefore it is likely that the results can be considered representative of weaning practices used by large pediatric cardiovascular programs across the United States.

Conclusions

Pediatric patients with congenital heart disease are a particularly complex and vulnerable population. The current project revealed certain similarities that exist among sites with respect to weaning practices. However, substantial practice variation remains, including which health care provider is primarily responsible for weaning decisions, how medications are actually weaned (one at a time vs concurrently, which class of medication to wean first), what education materials are provided to families at time of discharge, and what type of follow-up occurred after discharge. Because of this variability in practice and the potential for improvement in patient safety and quality of care, opportunities exist for the development of generalized practice guidelines to support pediatric congenital heart centers nationwide in their practice of opioid and sedative weaning.

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