Cost Savings When Nuclear Medicine Pulmonary Flow Scan Eliminated from Surveillance in Pediatric Pulmonary Vein Stenosis Management

Sara K LaBarge, RN, BSN

Oregon Health & Science University School of Nursing

NURS 703B: DNP Project

Spring Term, 2023

Submitted to: Sandra Banta-Wright – Chair

This paper is submitted in partial fulfillment of the requirements for

the Doctor of Nursing Practice degree.

Abstract

Pulmonary vein stenosis (PVS) in children is challenging to treat and requires close surveillance to determine disease progression and need for intervention. Despite advances in care for patients with PVS in recent years, evidence-based practices for surveillance have not yet been established. Thus, a lack of consensus in surveillance and variation in surveillance screening practices persists. The standard surveillance at one PVS center is echocardiogram (ECHO) and nuclear medicine pulmonary flow scan (NMPFS). To decrease cost and risk associated with NMPFS, the expert opinion at this PVS center at an academic center explored novel ECHO reading in comparison with NMPFS of 12 pediatric patients retrospectively. This project determined the annual cost savings per year when routine NMPFS was eliminated for pediatric patients (n = 12) with PVS was $51,502.00. There was a significant savings between pediatric patients and their families who traveled more frequently to the PVS center at the academic center (n = 7) to those pediatric patients and their families who traveled only one time per year to the PVS center (n = 5); t (5) = 2.02, p = 0.0002. To decrease healthcare costs and eliminate unnecessary procedures for children with PVS, this quality improvement project provided a cost-savings analysis when NMPFS is eliminated from standard surveillance.

Keywords: pulmonary vein stenosis, PVS, cost savings analysis, decrease healthcare costs, eliminate unnecessary procedures

Disclosures

This author is a full time Doctor of Nursing Practice student paying tuition to the institution where pediatric patients with PVS are managed by the pediatric cardiologist and previously worked in the department of pediatric cardiology. Otherwise, this author has no conflicts of interest or financial relationships to disclose.

Table of Contents

Problem Description

Pulmonary vein stenosis (PVS) in children is a condition that has been difficult for experts in the field of congenital cardiology and continues to be a daunting challenge to treat successfully. It is caused by neointimal lesions in one or more pulmonary veins that is progressive in nature. The silent clinical progression of PVS requires close surveillance to determine disease progression. Treatment for this condition has developed in recent years that can include surgical repair, catheter intervention and medical therapy. Despite treatment with catheter-based interventions including balloon angioplasty and endovascular stenting or suture-less surgical repair, prognosis remains poor for patients 1) diagnosed at an earlier age, 2) those with bilateral pulmonary vein involvement, and 3) stenosis in 3 or more pulmonary veins (Vanderlaan, et al., 2021). This is due in part to the progressive nature of the disease, and the high incidence of restenosis of the pulmonary veins following surgical or catheter intervention in these higher risk patients. The progression of PVS can lead to pulmonary hypertension, right sided heart failure, and death (Cory, et al., 2017). PVS requires careful surveillance, intervention and often re-intervention with catheter-based procedures to prevent disease progression.

Pulmonary vein stenosis is estimated to have an incidence ranging from 0.0017% to 0.03% (Nasr et al., 2019). It is associated with conditions such as prematurity, bronchopulmonary dysplasia, necrotizing enterocolitis, Smith-Lemli-Opitz syndrome, and Down syndrome. Historically, pediatric patients with PVS carried a grim prognosis with reported pediatric mortality rates approximately 60% at two years after diagnosis (Amin et al., 2009; Lo Ritto et al., 2016). Due to the rarity of this heterogeneous disease, it has been recognized that institutional PVS teams are important to optimize care, timely surveillance, and intervention for this small

population of patients (Vanderlaan & Honjo, 2019). The experts at one academic medical center in the Pacific Northwest established a team that continuously strives to improve outcomes for these patients.

Monitoring pediatric patients with PVS can be challenging. Echocardiogram (ECHO) can reveal stenosis in the form of increased flow velocity. However, it is technically difficult to visualize the pulmonary veins and especially if the pediatric patient has significant lung disease, such as bronchopulmonary dysplasia, a comorbidity (Pazos-Lopex et al., 2016). As lung perfusion redistributes away from the PVS obstruction, the effected segments of lung receive decreased blood flow, which ironically decreases the measured flow velocity as pressure gradients are proportional to blood flow. Consequently, ECHO is supplemented with other imaging to allow for improved quantification of blood flow to each lung segment.

Available Knowledge

Two themes were identified in the literature as challenges in the management of PVS surveillance: 1) lack of consensus in PVS surveillance, and 2) variation in PVS surveillance screening practices.

Lack of consensus in PVS surveillance

Despite the advances in recent years of the cardiac management of children who have PVS, standardized surveillance has not been established in the treatment of this disease. Timely intervention in the care of patients with PVS is of utmost importance due to the frequent rapid progression of stenosis (Jadcherla, et al., 2021; Vanderlaan, et al., 2021). Adequate surveillance is necessary in order to appropriately assess need for further intervention or confirm freedom

from progressive stenosis; however, best practices have not yet been established for these patients.

Variation in PVS surveillance screening practices

The PVS teams at different institutions utilize different screening modalities in the care of patients with PVS including computerized tomography (CT), magnetic resonance imaging (MRI), ECHO, cardiac catheterization, and NMPFS (Vanderlaan, et al., 2021). Imaging options such as MRI and NMPFS along with CT and cardiac catheterization carry significant disadvantages in comparison to ECHO. MRI is significantly more expensive, less available when compared to ECHO, and difficult to schedule on a routine basis. In addition, in order to obtain a good MRI scan, infants and young children require sedation or anesthesia, which necessitates intravenous access. This is not without concern due to the immediate complications and the neurodevelopmental risks associated with this population. While NMPFS is more available and does not require sedation, it does require intravenous access to allow infusion of ionizing radiation. This exposes these infants and young children to increasing amounts of ionizing radiation over time, which can lead to cancer and need for chemotherapy (Callahan et al., 2018). Issues with cardiac catheterization in children include risks of radiation, general anesthesia for infants and young children, hypothermia, hypoxia, and arrhythmias. Computerized tomography scans use radiation, which increases the risk of cancer. Children and especially infants and young children have a greater risk as their brains are still developing.

A lack of evidence-based consensus due to variations in PVS surveillance screening for families with a child, who has PVS, results in multiple procedures and costs incurred traveling to

the regional academic medical center. This lack of consensus is recognized by an international group of experts from different institutions within the United States and Canada, who realize the importance of sharing data among institutions to establish best practices in surveillance for these patients. This collaboration formed the PVS Network in efforts to determine best practices in all areas of care for pediatric patients with PVS (PVS Network, n.d).

Rationale

While the research study will compare the accuracy of ECHO measurement to determine the degree of PVS compared to NMPFS, the quality improvement (QI) project estimated the calculated cost savings for families if the NMPFS was eliminated. This QI project utilized The Institute for Healthcare Improvement model for improvement (IHI MIF), an evidence-based improvement framework capitalizing on clinical inquiry and utilizing an iterative process to test theories and accelerate change (Institute for Healthcare Improvement [IHI], 2022; Langley et al., 2009). This allowed the ability to track effort to improve the system in the measurement of eliminating unnecessary procedures and decrease in healthcare costs and associated travel cost to families of affected pediatric patients with PVS.

Specific Aims

The specific aim of the retrospective chart review research study was to determine the accuracy of measuring the degree of PVS using doppler flow and cross-sectional measurement of the pulmonary arteries on the ECHO when compared with the NMPFS results by the PVS team. The QI project specific aim was the determination of an estimated calculation of the cost-savings associated with elimination of the NMPFS surveillance procedure for these pediatric patients with PVS for their families.

Methods

Context

The pediatric PVS team is a team of experts in cardiology at an academic medical center in a metropolitan area in the Pacific Northwest. While the PVS team recognizes providing adequate and effective surveillance is imperative in the care of these patients, the expert opinion at this institution predicts that adequate information is available by the sole evaluation of doppler flows of the pulmonary arteries during routine ECHO alone. This would eliminate the need for the NMPFS, which would decrease exposure to radiation, and subsequent cancer risk, as well as cost to society.

The current surveillance at this institution includes frequent ECHO and NMPFS. The echocardiogram is non-invasive, while NMPFS exposes the patient to radiation, requires IV access, and involves additional cost and burden to families. The NMPFS requires patients to spend an additional day at this institution. This includes an extra day of travel for pediatric patients and at least one caregiver, for those who live outside the metropolitan area. This extra day adds a multitude of additional costs for these families. Additional travel costs often include overnight hotel expenses and meals as well as childcare for siblings who stay at home with family or friends. There is also the cost on the family vehicle with increased maintenance needs as there is limited bus and train service outside the Portland metropolitan area to rural areas within the state where many of these families live. The additional day at the institution also requires parents of these patients to miss work resulting in a loss of income for the missed workdays or having to use vacation time or paid time off to cover their absence. By decreasing

this additional surveillance screening procedure, the burden on the families and the healthcare system will be decreased.

Given this as a retrospective chart review study, a request for a waiver of consent was obtained. Consents were not obtained due to the following reasons:

i) All information was retrieved from existing medical records. There was no direct patient contact.

ii) The retrospective chart review involved no procedures. There is a plan to protect PHI was protected from improper use and disclosure and identifiers contained in the PHI were destroyed at the earliest opportunity.

iii) No data beyond that collected during routine care was collected for this project.

iv) It was logistically infeasible to obtain consent from historical patients given contact information may be out of date given this is retrospective research. Given the common lethality of PVS, some of these children may have died by the time of this retrospective chart review. Contacting the family may potentially introduce undue emotional trauma by obtaining consent from the surviving caregiver.

Interventions

During Fall 2022, a retrospective chart study of pediatric patients with PVS was identified through an internal pediatric cardiology database. Data was recorded from multiple encounters for each child, consisting of a transthoracic ECHO and NMPFS between December of 2019 and September of 2022. The procedures, a NMPFS and ECHO, must have been completed within one week of each other without any pulmonary vein intervention between the surveillance

screening procedures. Based upon the research findings and the cost-saving analysis, a recommendation to eliminate or continue with NMPFS will be determined.

In the retrospective chart review, data collection from 12 pediatric patients with PVS who had a transthoracic ECHO and NMPFS surveillance screening procedures between December of 2019 and September of 2022 were collected. Pediatric patients with PVS who have any structural heart disease of the right ventricle, right ventricular outflow tract, pulmonary valve or pulmonary arteries were excluded from the analysis. The calculation of the number of NMPFS procedures for the 12 pediatric patients with PVS during this time period and the cost savings associated with the elimination of this procedure occurred. In addition, data was extracted from the electronic medical record through manual review by a team member. This data was stored on two excel spreadsheets. One "Study Key" contains all patient identifying information (PII) associated with randomly assigned anonymous identification assigned to each patient. The second file contains all patient health information (PHI) include demographic characteristics of the children and their families, clinical and imaging study data associated with each anonymous identification. Both files were stored on the secure password protected and VPN protected computers within the academic medical center. Only required team members had access to each file. No one besides those listed on eIRB as team members had access to these files.

Study of Intervention

The primary outcome of the retrospective chart review was to determine the accuracy of measuring the degree of PVS using doppler flow and cross-sectional measurement of the pulmonary arteries on the ECHO when compared with the NMPFS results by the PVS team. The QI project outcome was the determination of an estimated calculation of the cost-savings

associated with elimination of the NMPFS surveillance procedure for these pediatric patients with PVS for their families. While there was no ability to quantitatively determine the cost of travel for each family, this could be estimated to be a significant savings to the family with the elimination of extra hotel stays, meals, loss of income due to absence from work, vehicle maintenance and arrangement for other children in the household who stay within the community while at least one caregiver accompanies the child with PVS to the regional academic medical center for cardiac evaluation.

Measures

The process measures for the QI project included the number of pediatric patients who had both an ECHO and NMPFS within one week of each other without any intervention during the data collection timeline. In addition, the number of NMPFS was identified to aid in the calculation savings. The outcome measure assessed the cost savings to families should NMPFS be eliminated from the institution's surveillance screening for pediatric PVS.

Data Analysis

Pediatric patients with PVS demographics were summarized using means and standard deviations for continuous variables and frequency counts and percentages for nominal variables. In the research study, comparative analyses were performed using Wilcoxon Mann-Whitney U test and Chi squared testing as appropriate. The PVS team utilized Spearman correlation coefficients to assess relationships between echocardiographic right/left perfusion ratio (ECHO-PR) to nuclear medicine derived perfusion ratio (NM-PR). All analyses were performed by SPSS software. In the QI project, the calculation of the cost determination included the NMPFS only without sedation or radiologic interpretation plus lodging and food expenses for one night stay

within the metropolitan area. The number of surveillance screening procedures eliminated on average per patient by using ECHO imaging instead of NMPFS was calculated. An ad hoc analysis using one-way t-tests was performed to compare if there was a difference in saving for those families who had to travel to the academic medical center more than one time a year to those families who only traveled once a year to the academic medical center for PVS screenings. The results from the PVS experts and the cost saving with the elimination of the NMPFS surveillance screening procedures will determine if elimination of NMPFS procedures for pediatric patients with PVS can be instituted without sacrifice to patient care.

Ethical Considerations

This project was a retrospective analysis of patient data, therefore, patient autonomy was protected. This author was added to the retrospective chart review protocol with IRB approval and the QI project was deemed not research involving human subjects (Appendix A). Deidentified data sheets were used for data analysis to protect patient identity.

Results

Pediatric Patients with PVS

Twelve pediatric patients with PVS were identified in a retrospective chart review between December 2019 and September 2022 who qualified for ECHO and NMPFS comparison. The average age of patients with PVS was 2.3 years. Six of the 12 patients were assigned female at birth. Four patients identified as Hispanic, 5 as non-Hispanic, and 3 declined ethnic identification. The third of the patients with PVS (n = 4) were from a city with a population between 100,001 to 500,000 individuals. All patients had medical insurance. The demographics of the pediatric patients with PVS are summarized in Table 1.

Cost Savings

The number of NMPFS screenings each patient had during the review period ranged from 1 to 11 (Figure 1). An estimated cost of $1,500.00 was used for the cost of the NMPFS screen as estimated by the PVS institution. Distance from the PVS center from each patient home community was calculated. Two patients lived more than 100 miles in distance from the PVS center, and 10 lived between 5 and 94 miles from the PVS center (Figure 2). The federal per diem meal rate for Multnomah County in the state of Oregon of $74.00 per day was used to calculate meal cost. One full day meal cost was used for those who lived more than 100 miles from the PVS center. Twenty-five dollars per day was used for those who lived less than 100 miles from the PVS center. Meal expense was calculated for one parent. The overnight motel cost of $84.00 which included a patient discount at a local hotel was used for those who lived greater than a 100-mile distance from the PVS center. The total cost per year for NMPFS, motel and meals for the 12 patients was $51,502.00 (Figure 3).

Ad hoc analysis was performed after the identification of a difference between the number of PVS a child received within a year, which ranged from 1 to 13. The results revealed a significant difference in savings between pediatric patients and their families, who traveled more frequently (> 1) to the PVS center at the academic center (n = 7) to those pediatric patients and their families who traveled only one time per year to the PVS center (n = 5) using unmatched 1-tail t-test: t (5) = 2.02, p = 0.0002 (Figure 4). This is not a surprising finding as more NMPFS in addition to hotel and food expenses within a 12-month period would increase a family's expense significantly.

Discussion

Summary

Pulmonary venous stenosis in the pediatric population is a rare condition that is challenging to treat. This is due to the complex characteristics of the disease that include silent clinical progression, progressive nature, and high incidence of re-stenosis following intervention on the pulmonary veins (Jadcherla, et al., 2021; Vanderlaan, et al., 2021). Therefore, PVS requires close surveillance screening throughout treatment. There is a lack of consensus in PVS surveillance screening, and variation in PVS screening practices among centers who treat these children. The lack of evidence-based consensus has resulted in multiple procedures and costs incurred for families with a child who has PVS.

This QI project was completed in conjunction with a research study conducted at one academic medical center. While the research study is pursuing the accuracy of novel ECHO measurements in PVS compared to NMPFS, the QI project calculated cost savings for families if NMPFS was eliminated from routine surveillance of children with PVS. This included a retrospective chart review which identified children with PVS who had transthoracic ECHO and NMPFS within one week of each other without any pulmonary vein intervention between surveillance screening procedures. A significant cost savings was calculated for patients in this QI study when the NMPFS was eliminated from surveillance screening for pediatric patients with PVS and especially if more than one visit to the academic health university occurred in a year.

Interpretation

This project identified the annual cost savings per year when routine NMPFS was eliminated for pediatric patients (n = 12) with PVS was $51,502.00. This number reflects the cost of the NMPFS, meals, and motel expenses. Additional unmeasured costs include the healthcare costs of sedation and radiology interpretation associated with NMPFS, and cost to families including loss of income due to absence from work, vehicle maintenance, and childcare for other children in the household.

This cost savings was measured using pediatric patients at one academic institution who met strict criteria for transthoracic echocardiogram and NMPFS comparison. Twelve (12) pediatric patients were included in this QI project. The cost savings, if applied to a larger sample size of patients with PVS would likely increase the dollar amount of healthcare cost savings by a significant amount.

Limitations

This DNP project had multiple limitations. The data was collected at one academic university in the Pacific Northwestern United States, which limits the generalizability of the findings. Further, the retrospective cost analysis evaluated only pediatric patients who met strict criteria for NMPFS and ECHO comparison, resulting is a small sample size (n=12). Future cost savings analysis should include patients who underwent NMPFS without the strict timing rule for comparable ECHO imaging. Healthcare costs associated with NMPFS were calculated using only the estimated cost of the screen itself without pediatric sedation and nuclear medicine physician expenses. Future analysis of cost savings should include additional costs as identified by families that they incur with PVS screening which includes ECHO and/or NMPFS.

Conclusion

This DNP project documented the cost savings to families when NMPFS is eliminated from routine surveillance of children with PVS. Preliminary findings in the ongoing research study by the PVS experts at this institution comparing transthoracic ECHO and NMPFS are promising. In effort to decrease healthcare costs and eliminate unnecessary procedures, this QI project provided a cost-savings analysis that along with the study findings, can be used to determine if the elimination of NMPFS procedures in the routine surveillance for pediatric patients with PVS can be instituted without sacrifice to patient care.

References

Amin, R., Kwon, S., Moayedi, Y., & Sweezey, N. (2009). Pulmonary vein stenosis: Case report and literature review. *Canadian Respiratory Journal, 6*(6), e77-80. https://doi.org/10.1155/2009/791653

Callahan, R., Kieran, M. W., Baird, C. W., Colan, S. D., Gauvreau, K., Ireland, C. M., Marshall, A. C., Sena, L. M., Vargas, S. O., & Jenkins, K. J. (2018). Adjunct Targeted Biologic Inhibition Agents to Treat Aggressive Multivessel Intraluminal Pediatric Pulmonary Vein Stenosis. *Journal of Pediatrics, 198*, 29-35.e.5. https://doi.org/10.1016/j.jpeds.2018.01.029

Cory, M. J., Ooi, Y. K., Kelleman, M. S., Vincent, R. N., Kim, D. W., & Petit, C. J. (2017). Reintervention is associated with improved survival in pediatric patients with pulmonary vein stenosis. *JACC: Cardiovascular Interventions, 10*(17), 1788-1798.

Drubach, L. A., Jenkins, K. J., Stamoulis, C., Palmer III, E. L., & Lee, E. Y. (2015). Evaluation of primary pulmonary vein stenosis in children: Comparison of radionuclide perfusion lung scan and angiography. *American Journal of Roentgenology, 205*(4), 873-877.

Institute for Healthcare Improvement [IHI]. (2022). *Science of improvement: Setting aims*. http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementSettingAims.aspx

Jadcherla, A. V., Backes, C. H., Cua, C. L., Smith, C. V., Levy, P. T., & Ball, M.K. (2021). Primary pulmonary vein stenosis: A new look at a rare but challenging disease. *NeoReviews, 22*(5), e296–e308. https://doi.org/10.1542/neo.22-5-e296

Jones, J., Lee, D., & Bayhi, L. (2018). The data-driven policy analysis framework as a template for healthcare policy analysis. *Annals of Nursing Research & Practice, (1)*, 1005.

Langley, G. J., Moen, R. D., Nolan, K. M., Nolan, T. W., Norman, C. L., & Provost, L. P. (2009). *The improvement guide: A practical approach to enhancing organizational performance* (2nd ed. Ed.). Jossey-Bass.

Lo Rito, M., Gazzaz, T., Wilder, T.J., Vanderlaan, R.D., Van Arsdell, G.S., Honjo, O., Yoo, S. J., Caldarone, C. A. (2016). Pulmonary vein stenosis: Severity and location predict survival after surgical repair. *Journal of Thoracic and Cardiovascular Surgery, 151*(3), 657-666.e2. https://doi.org/10.1016/j.jtcvs.2015.08.121

Nasr, V.G., Callahan, R., Wichner, Z., Odegard, K.C., & DiNardo, J.A. (2019). Intraluminal pulmonary vein stenosis in children: A "new" lesion. *Anesthesia and analgesia, 129(1),* 27-40.

Pazos-López, P., García-Rodríguez, C., Guitián-González, A., Paredes-Galán, E., Álvarez-Moure, M. Á., Rodríguez-Álvarez, M., Baz-Alonso, J. A., Teijeira-Fernández, E., Calvo-Iglesias, F. E., & Íñiguez-Romo, A. (2016). Pulmonary vein stenosis: Etiology, diagnosis and management. *World Journal of Cardiology, 8*(1), 81-8

PVS Network. (n.d.). *Participating institutions*. http://www.pvsnetwork.org/surveillance-imaging.html

Vanderlaan, R. D., Rome, J., Hirsch, R., Ivy, D., & Caldarone, C. A. (2021). Pulmonary vein stenosis: Treatment and challenges. *Journal of Thoracic and Cardiovascular Surgery*, 161(6),2169-2176.

Vanderlaan, R. D., & Honjo, O. (2020). Commentary: It takes a village: Changing the trajectory

of pulmonary vein stenosis outcomes. *Journal of Thoracic and Cardiovascular Surgery*, *159*(3), 1037-1038.

Yuan, M. K., Chang, S. C., Yuan, M. C., Foo, N. P., Chan, S. H., Wang, S. Y., Lin, C. L., Hsu, C. Y., & Kao, C. H. (2021). Pediatric nuclear medicine examinations and subsequent risk of neoplasm: A nationwide population-based cohort study. *Frontiers in Medicine, 8,* 764849. https://doi.org/10.3389/fmed.2021.764849

Tables and Figures

Table 1

Demographic characteristics of the Pediatric Patients with PVS who met Criteria

Demographics (*n* = 12)	Mean ± SD (range)
Age (years)	2.3 ± 4.6 (2-13)
	n (%)
Sex (males)	6 (50)
Ethnicity	
Hispanic	4 (33)
Non-Hispanic	5 (42)
Declined	3 (25)
Residence	
< 10,000	3 (25)
10,000 – 50,000	3 (25)
50,001 – 100,000	1 (8)
100,001 – 500,000	4 (33)
500,001 – 1,000,000	1 (8)
Insurance	
Private	5 (42)
State Health Care	7 (58)

Figure 1

Geographic Location of Pediatric Patients' Homes and Mileage to PVS Center

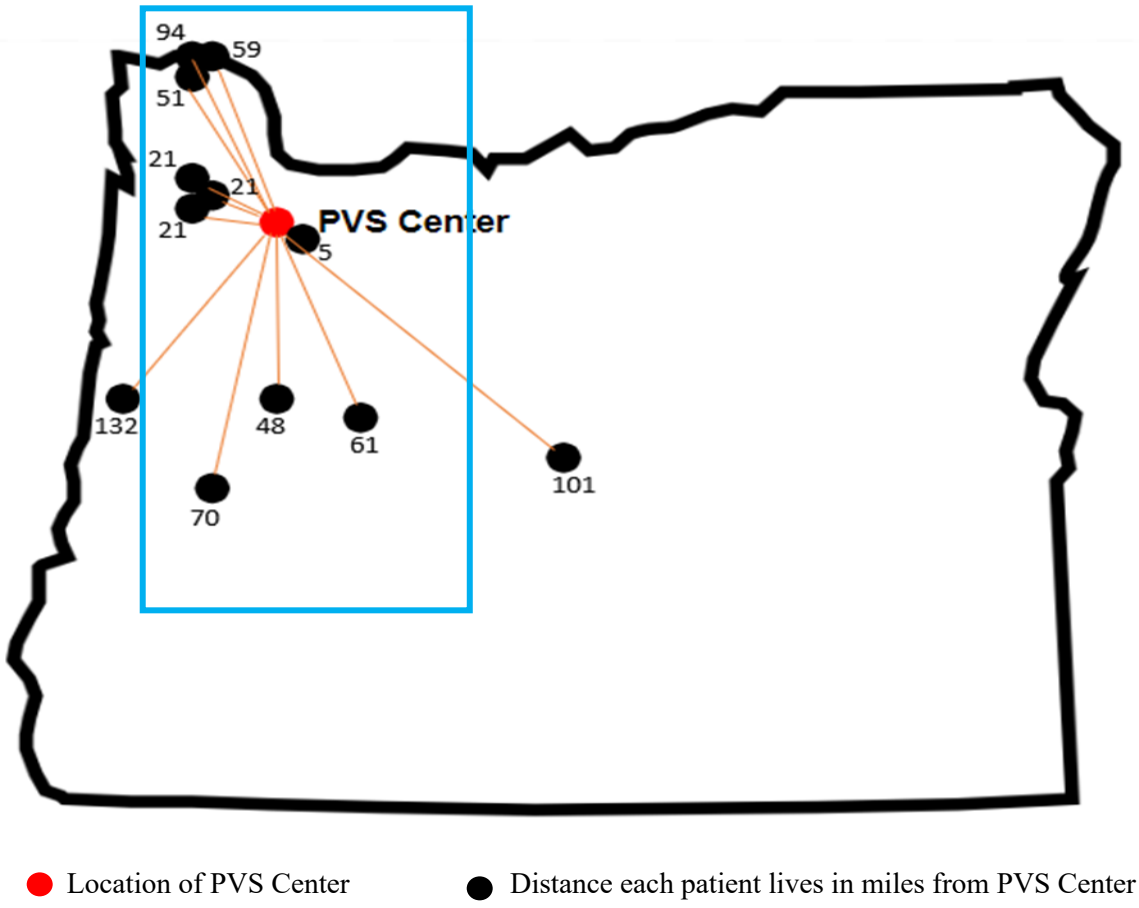
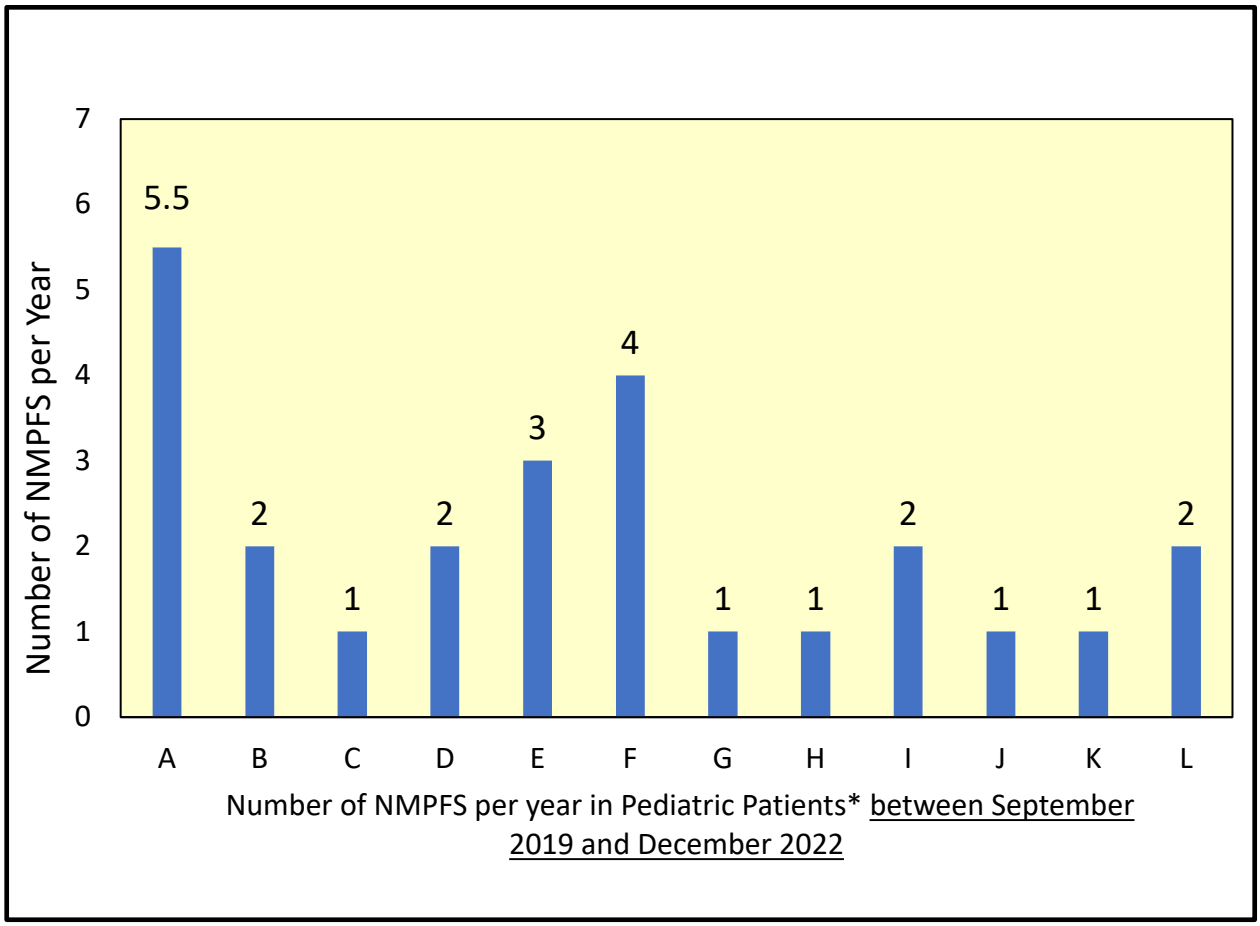


Figure 2

Number of NMPFS screenings done per year for each of the 12 patients



- The criteria for inclusion were a NMPFS and ECHO within one week of each other without any intervention.
- NMPFS = Nuclear Medicine Pulmonary Flow Scan

Figure 3

Cost per Year for 12 Pediatric Patients for NMPFS at Academic University = $51,502

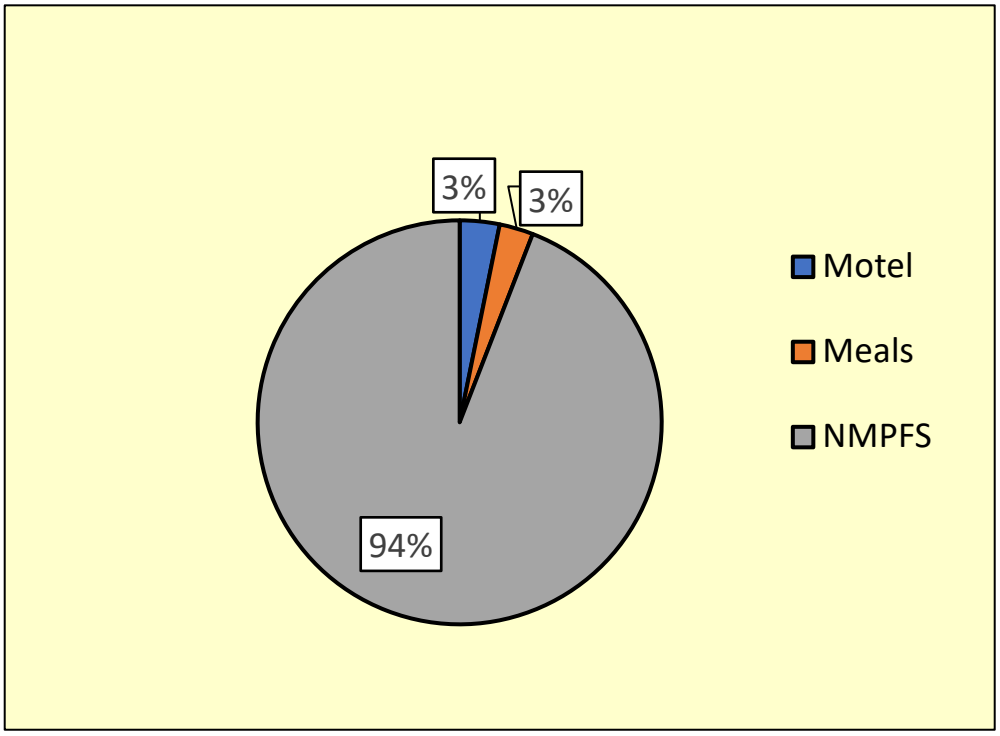
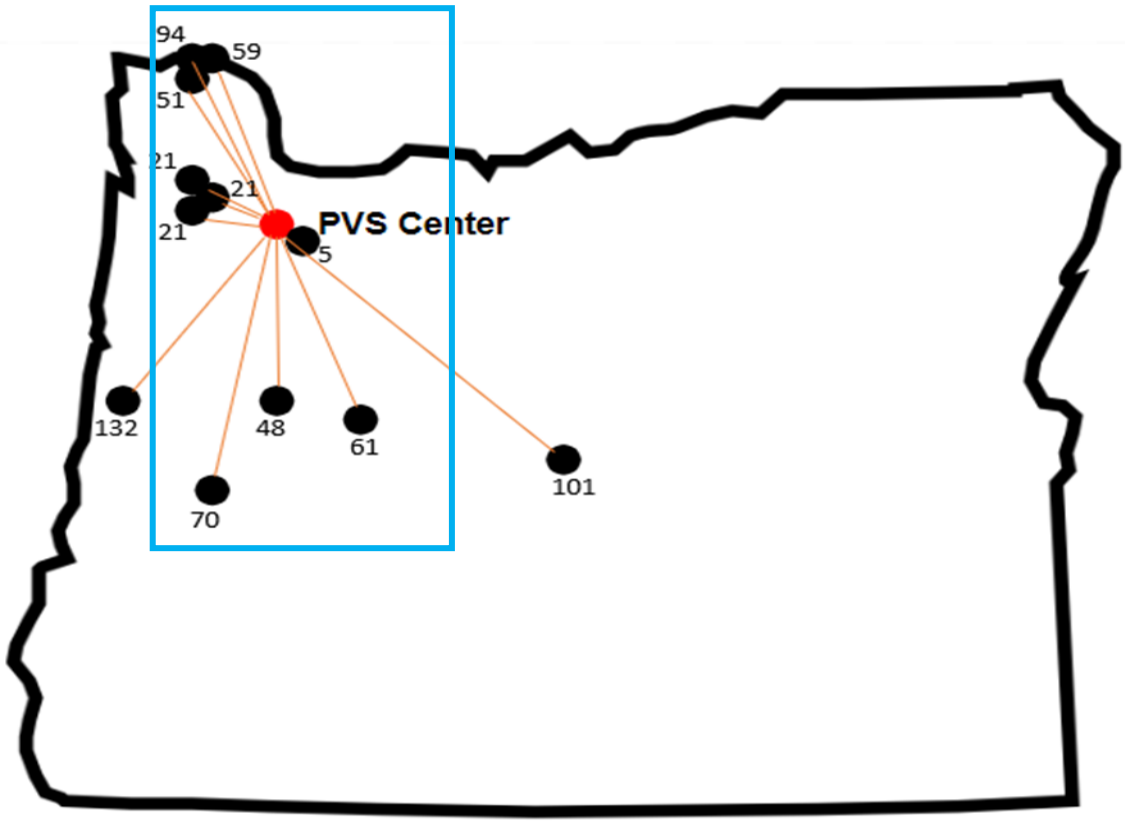


Figure 4

Cost Savings Based upon Number of Trips to the Academic Center for NMPFS a Year versus distance from the PVS Center at the Academic Medical Center



t (5) = 2.02, p = 0.0002

Location of PVS Center Distance in miles each patient lives from PVS center

Appendix A

Oregon Health & Science University IRB Determination

NOT HUMAN RESEARCH

May 2, 2023

Dear Investigator:

On 5/2/2023, the IRB reviewed the following submission:

Title of Study:	Cost Savings When Nuclear Medicine Pulmonary Flow Scan Eliminated from Surveillance in Pediatric Pulmonary Vein Stenosis Management
Investigator:	Sandra Banta-Wright
IRB ID:	STUDY00025786
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office