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I, Cynthia S. Pettit, hereby submit this DNP Project scholarly document in partial fulfillment of the requirements for the degree Doctor of Nursing Practice in Population Health Leadership.

Evaluation of Use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients

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Evaluation of Use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients

A scholarly project submitted to the Xavier University College of Professional Sciences School of Nursing in partial fulfilment of the requirements for the degree of Doctor of Nursing Practice

by

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Abstract

Psychosocial risks factors have been identified as having an impact on pediatric surgical health outcomes. Risk stratification is one methodology used in medical care to identify those patients requiring intensive interventions. Stratifying patients with psychosocial risk factors and applying appropriate interventions may be a modality to improve health outcomes. There are few tools in the literature to assess for psychosocial risk in for pediatric patients but the Psychosocial Assessment Tool (PAT) appears to be a promising tool. The PAT evaluates and stratifies psychosocial risk of the child from the perspective of a family dynamic. This DNP project is a feasibility pilot project using a convenience sample of potential pediatric tonsillectomy patients. The purpose of this project was to assess the feasibility of the use of the PAT in this population. The PAT was tested against the current practice of assessment for psychosocial risk to determine if there was an improvement in identification of psychosocial risk in potential and to determine if its use was feasible in an outpatient surgical clinic setting. Feasibility was determined by time to complete and impact to flow. The completion time for this population took longer than other reported studies, which was cited with completions between five to ten minutes. In this DNP project, only 60% of the participants completed the PAT in under ten minutes. Negative impact to flow occurred 51.4% of the time. The PAT was more effective than the current assessment in identifying psychosocial risk. The differences in proportions of the paired samples were determined to be statistically significant utilizing the McNemar’s nonparametric test for differences in proportions at al level of significance p<0.05, with p=.022. In light of the impact of psychosocial risks and their relationship to poor health outcomes and the information gained by the PAT, future projects or studies are needed to address the issue of impact to flow, such as adapting the tool to reduce the length of completion.

Keywords: psychosocial risk, Psychosocial Assessment tool, pediatric surgical patients
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Health equity is defined as the highest level of health for all people, with health equity being achieved by eliminating disparities and improving the health of all groups (US Department of Health and Human Services, 2010). The health of a population is determined by many factors but it is known that poor health outcomes, disease risk factors, and limited access to care have been identified among those groups with a social, economic and environmental disadvantage. Patients living in poverty have worse health outcomes and lower life expectancy than the general population, with no significant improvement over time in a reduction in these disparities measures (Agency for Healthcare Research and Quality [AHRQ], 2012). Minorities are disproportionately represented in the lower socioeconomic tiers, and therefore, at increased risk for poor health outcomes. Disparities in healthcare have important implications in that health has been tied to social justice, opportunity, and quality of life (The Henry J Kaiser Foundation, 2012). Health equity is important not only from a social justice perspective, but also an economic perspective. Economic losses due to health related disparities have been estimated to account for $309 billion per year in direct and indirect costs (The Henry J Kaiser Foundation, 2012). Improvement of the nation’s health and reduction in health care costs will not occur if health care disparities are not addressed (Smedley, Stith, & Nelson, 2003).

Background and Significance

Research on pediatric surgical patients from low socioeconomic and minority populations exhibit disparities in terms of access and outcomes (Stone et al., 2012). United States National KID Inpatient Database has shown more complications, longer length of stay, and higher costs
among pediatric surgical patients in lower socioeconomic quartiles in comparison to higher socioeconomic tiered patients (Stone et al., 2012). As stated previously, minority populations have greater prevalence of being in lower socioeconomic tiers. For example, in the City of Cincinnati, it is estimated 39% of children live in families below 100% of the federal poverty level (The Child Poverty Collaborative, n.d.). Minorities are represented at higher percentages among the children living in poverty in Cincinnati, with 75% being African-American and 5% Hispanic (The Child Poverty Collaborative, n.d.). Studies utilizing the United States National KID Database have shown that African American pediatric surgical patients are at a disproportionate risk for postoperative mortality, while African American and Hispanic pediatric surgical patients have increased morbidity and hospital resource utilization (Stone et al., 2013).

Access to surgical care providers requires a process of care phases. The surgical referral process occurs across a continuum. In a flawless system, the referral process begins with the primary care provider recognizing a potential surgical problem exists that is outside the primary care domain of practice, and a referral is made to an appropriate specialist. The referral, surgery and follow-up visits occur in a timely manner, and there is relevant information exchange between the primary care provider and specialty provider to prevent duplication and support care integration (Mehrotra, Forrest, & Lin, 2011). A lapse in one or multiple phases of care can impact the health outcome of the individual.

Studies on pediatric surgical patients have demonstrated the impact of the failure of a successful referral process with respect to low-income and minority high-risk patients. In a population-based longitudinal study of pediatric anterior cruciate ligament reconstruction, patients with private insurance were six times more likely to undergo repair in comparison to children with Medicaid (Dodwell et al., 2014). Minority and low-income children have had
lower odds of imaging for their organic abdominal pain, but higher odds of perforated appendicitis, risk for ICU and longer duration of hospitalization, and less likely odds of getting surgery even with a diagnosis of appendicitis (Wang, Haberland, Thurm, Bhattacharya, & Park, 2015; Putnam et al., 2016). Low-income children have been more likely to present to emergency rooms with the most serious of complications of bacterial sinusitis (Sedaghet, Wilke, Cunningham, & Ishman, 2014) while predominantly Caucasian and higher income children were seen in specialty clinics for the treatment of rhinosinusitis (Smith, Ishman, Tunkel, & Boss, 2013). Children in lower socioeconomic quartiles have been more likely to miss or cancel appointments (Hoffman, Matlow, Shroff, & Cohen, 2015; Miller, Chae, Peterson, & Ko, 2015), miss key pre-surgical testing resulting in delays (Boss et al., 2015) and miss follow-up appointments (Smilie, Yong, Harris, Wynne, & Russell, 2015; Mackie, Rempel, Rankin, Nicholas, & Magill-Evans, 2012) than pediatric patients from higher socioeconomic quartiles.

Disparities exist when there are gaps between health outcomes and social determinants in populations (Centers for Disease Control and Prevention [CDC], 2013). Social determinants of health are the social factors and physical conditions of the environment in which one lives, works and plays, and includes socioeconomic conditions such as poverty. Healthy People 2020 (CDC, 2015) has identified five broad categories of social determinants: policy making, social, health services, individual behavior and biology and genetics. Social determinants include factors such as lack of insurance, language barriers, and lack of availability of resources, but also include unmet health needs, delays in receiving appropriate care, inability to get preventive services, and hospitalizations that could have been prevented. Strategizing multiple interventions aimed at health determinants has shown to be the most effective in eliminating disparities (CDC, 2015). The American Academy of Pediatrics has stressed the importance of partnerships with public
health entities to address issues of social determinants (Council on Community Pediatrics, 2013). The question then arises as to not only what interventions are the most effective, but also to whom and at what intensity level.

An Association of American Medical Colleges (AAMC, 2016) report on high-risk patient identification found most organizations have access to commercially available population health management IT programs, but unfortunately these platforms are in an infancy stage. Case management and patient coordination are key mechanisms for addressing issues with identified high-risk patients. Social determinants of health have been identified as factors for requiring patient coordination but has not been available in IT diagnosis-based risk models. The AAMC (2016) report recommended a hybrid automatic and manual methodology for identifying patients at risk, in which the patient-provider relationship becomes one source of high-risk identification.

Identification of high-risk pediatric patients due to psychosocial risk becomes even more problematic for surgical clinics. For perioperative patients, the care model commonly exhibited is one of the physicians practicing individually with inconsistent preoperative evaluations and individuals working in silos (Cannesson, 2015). Successful referral processes require adequate communication between the medical home and the specialist, but a Robert Wood Johnson-funded study concluded this communication process was inadequate (O’Malley & Reschovsky, 2011).

The vision for a transformed health care system includes one in which there is quality care accessible to all diverse populations. No one professional group can reduce health disparities alone in low-income populations. Interprofessional collaborations are needed, and have been identified as a foundation for improving health care. Nursing leadership is crucial in addressing health care disparities. The nursing profession is well-positioned to implement wide-
reaching actions to close gaps in health care by scaling up nursing initiatives and programs. Research has suggested that quality care is dependent on nurses, access to care is improved with the use of registered nurses and advanced practice nurses, and increased gains are achieved in health care value due to nursing interventions (Institute of Medicine [IOM], 2010).

**Purpose and Aims of the DNP Project**

Unpublished data from Cincinnati Children’s Hospital Medical Center (CCHMC) looking at characteristics of patients who “no show” on the day of surgery has revealed associations with low socioeconomic communities. Improving surgical outcomes for low socioeconomic pediatric patients involves more than just improving the quality of the surgical procedure, but requires multifactorial interventions aimed at reducing risks from social determinants. Before proceeding with interventions, providers must be able to identify which patients need interventions, and some determination of what level of intensity of the interventions are needed. The purpose of this project was to assess the feasibility of use of a reliable and valid tool for psychosocial risk assessment, the Psychosocial Assessment Tool (PAT, 2015) in a pediatric surgical outpatient clinic setting of potential pediatric tonsillectomy patients. The tool was tested against the current practice of assessment for psychosocial risk to determine if there is an improvement in identification of potential risk factors in potential pediatric tonsillectomy patients.

The aims of the project were the following:

1. To determine if the PAT is a feasible tool to use in a pediatric surgical outpatient clinic setting of potential tonsillectomy patients.
2. To determine if there is an increase in the number of patients identified with psychosocial needs with the use of the PAT in comparison with current practice of psychosocial assessment for this pediatric surgical clinic population, potential tonsillectomy patients.

In this project of the evaluation of the PAT, a number of questions were explored. Since feasibility of the tool in this setting was a prime consideration, an important question to answer was to what extent the use of PAT impacted clinic flow and clinic resources. Secondly, since the goal was for improvement in identification of psychosocial risk, the second question was to determine whether the PAT is more effective over the current practice of risk identification. Finally, it was important to determine that the patients identified and stratified are actually at risk. The final question therefore, was what the reliability and validity of the PAT in a pediatric surgical population in which the pediatric patients are screened for a potential tonsillectomy procedure.

**Project Relevance to Key Stakeholders and Population Health**

**Relevance to CCHMC Strategic Plan**

The Cincinnati Children’s Hospital Medical Center (CCHMC) SP2020 strategic plan focuses on six domains: care; community; discovery; people; impact; and the data; infrastructure; and finance enablers (CCHMC, 1999-2017). The objectives of the community domain are to improve the health of local children, the children of Hamilton County, Ohio and reduce health disparities. Hamilton County rates of children living in poverty are 23%, which is 10% higher than the national average (Census Reporter, 2015). The City of Cincinnati resides within Hamilton County and has been identified as being among large cities in the United States that have the highest rates of child poverty, with Cincinnati being listed as fifth highest city with child poverty (National Center for Children in Poverty [NCCP], 2016). The goal of this project
is to determine if the use of the PAT will identify families at psychosocial risk who are
scheduled for surgical procedures. As noted previously in this chapter, children in lower
socioeconomic groups may be a higher risk for poorer health outcomes. Improvements in
identification of risks should lead to interventions to assist in ameliorating the risks experienced,
thus supporting the CCHMC strategic goal to improve the health of local children, the children
of Hamilton County and reduce health disparities.

A second strategic domain supported by this DNP project is care. A component of the
care domain is to work as a team with families and children to individualize care (CCHMC,
1999-2017). The tool not only identifies patients at psychosocial risk but has a scoring system
that stratifies risk. Risk stratification would, therefore, lead to an intensity of services based on
patient needs identified by the tool, supporting the concept of care.

Relevance to Concepts of Population Health

The definition of population health encompasses the “aggregate, community,
environmental/occupational and cultural/socioeconomic dimensions of health” (Zaccagnini &
White, 2014, p. 259). The population health management program model identified by the
Population Health Alliance (n.d.) includes components of assessment, stratification, person-
centered interventions and impact evaluation. Basic attributes of a population health paradigm
include risk stratification by identifying those patients at greatest risk for poor health outcomes,
personalized patient-centered care, and recognition of determinants of health (Nash, Fabius,
Skoufalos, Clarke, & Horowitz, 2016). Life expectancy and health outcomes are adversely
impacted by race, sex, socioeconomic status and geographic location (CDC, 2013). The Institute
of Healthcare Improvement (IHI) Model, the Triple Aim (2017), includes the components of
patient experience, population health and cost reduction. The IHI defines inequities as the
“worse type of variation in a system” (IHI, 2017) and has identified a need for health care organizations to develop structure and processes that support health equity work (Wyatt, Lauderman, Botwinick, Mate, & Whittington, 2016). A tool for identification of patients with psychosocial risk, and stratification of that risk, is therefore supportive of the tenets of population health.

**Relevance to Jesuit Philosophy**

Lack of equity in health impinges on social justice and human rights, in that all individuals should be able to obtain optimal health regardless of socioeconomic status or ethnic or racial background (Braverman et al., 2010). Jesuit principles include *cura personalis* which translated from Latin means “care to the entire person”. It implies that care is unique to the individual, and respectful of that person’s unique circumstances (Traub, n.d.). The Jesuit philosophy of “being men and women for others” and “promotion of justice” speaks to social justice and a commitment to transformation to rectify injustices. These principles are foundational in this project since its focus is in support of alleviating health disparities and inequality.

Social determinants of health and psychosocial risk factors are frequently cited as strong influences impacting health and health care costs. Leveraging interventions that are focused on those individuals and families most in need of services is challenging in terms of identifying who needs services, and what services are needed. Expanding the use of tools and methodologies for risk stratification of psychosocial risks are crucial components for making needed improvements. The purpose of this project is to increase the identification of patients and families who are at high risk due to psychosocial risks factors. The long term goal is that though identification and
risk stratification, appropriate interventions can be instituted, and evaluated regarding their effectiveness in improving outcomes and the patient experience.
Chapter 2

Literature Review

Disparities in health due to psychosocial risk issues are frequently identified within the literature as strong contributors to poor outcomes. To address these factors, multifocal interventions are required to improve care. Through a population based lens, features such as socioeconomic status, ethnicity, and type of insurance are commonly cited as factors leading to gaps in health care. These factors alone are not predictive of individual patient outcomes, nor give insight into interventions required to alleviate disparities. There is utilization of a hierarchy or risk stratification for treatment in medical care, and this is also needed from a psychosocial perspective. In order to do this successfully, tools and methodologies are required that lead to some form of accurate detection and prediction of needs. This review of literature provides information and evidence on what is available, research on the PAT, and what is known about factors impacting pediatric surgical outcomes.

Risk Stratification/Prediction

Leaders in population health have identified social determinants as accounting for a large percentage of health care risk (CDC, 2013). Unfortunately, there are few available tools to support prediction of risks in this area. Most models used for risk stratification are diagnosis based models that do not account for the impact of social determinants (Kivalahan et al., 2016). In a systematic review for risk prediction for adult hospital readmission, the investigators found that most models for risk predictions performed poorly (Kansagara et al., 2011). Medicaid as a source of insurance was the only psychosocial factor universally included, but varied in degree for risk. Therefore, public insurance by itself, was not predictive of risk. The review did find one model in which sociodemographic factors such as drug use and housing were included in the
model, and this was found be more predictive of risk than comorbidity based models (Kansagara et al., 2011).

In a systematic review looking at income only and health, the authors concluded that income was predictive of health when it served as a definer of social stratification (Wilkerson & Pickett, 2006). In areas in which income diversity did not have an impact on social stratification, there was less of an impact on health. The authors gave the example of black men in Costa Rica, despite having incomes four times lower than black men in America had longer life expectancy than black men in America by nine years (Wilkerson & Pickett, 2006).

Inequities are often limited to a single social factor to identify risk in current models of risk stratification, while in reality, they are multifactorial. Social economic status by itself has not been found to identify or improve health inequities. Frameworks such as the PROGRESS Framework include factors such as place of residence, ethnicity/race/culture and language, occupation, gender, sex, religion, education, and socioeconomic status (O’Neill et al., 2014). The context of these factors for the individual is more important in terms of impact than purely the factor by itself. In a qualitative study evaluating parental personas associated with pediatric surgery cancellations, five different personas were identified (Vaughn, DeJonckheere, & Pratap, 2017). Personas are defined as visual and narrative descriptions including context, motivation and perspectives that decribe an archetype of actual system users. The researchers included race, age, and income for the initial analysis but felt these alone were not salient in the patterns. Themes identified within the clusters included family support systems, access to transportation, flexibility in scheduling, previous hospital experience and trust in the medical systems (Vaughn et al, 2017). In addition, parental anxiety was identified as a common response in regards to the hospital experience, and was a factor in cancellation. Noncompliance with pre-surgical fasting
requirements has also been found to be associated with maternal anxiety, threat perception and lower threat conscientiousness (Kushnir, Djerassi, Sofer, & Kushnir, 2015). Because risk stratification based purely on social economic status or insurance type are the sole mechanisms for psychosocial risk identification in most stratification models, there is limited value provided in using this method of stratification to understand the scope of factors impacting health outcomes.

**Psychosocial Risk Assessment**

The definition of what is “psychosocial” in relation to health varies within the literature, and is used in connection with causes and risk factors, mediating factors and context and outcomes. This paradigm also exists within research, resulting in a diversity of theoretical frameworks, and little commonality in research questions, leading to psychosocial being referred to as an “umbrella term” (Markikainen, Bartley, & Lahelma, 2002). Despite the impact of psychosocial risks on health outcomes, there are limited resource tools within the literature, especially for the pediatric population. Research on assessment tools of family functioning to identify psychosocial risk that have a bearing on child health outcomes concluded that further research was needed in this domain (Barakat & Alderfer, 2011). Areas in particular need for further study were in underserved populations, with increased attention to screening to identify at-risk families for health, adherence and adaptation outcomes (Barakat & Alderfer, 2011).

Most available tools assess for youth behavioral risk or the psychosocial impact of a chronic disease, and not the impact of psychosocial factors on health outcomes. The available tools in these domains have limitations. Price and Masho (2014) evaluated commonly used tools to identify prenatal patients at risk for depression and concluded tools available were inconsistent in identifying women “at risk” for depression. The authors found in utilizing
available tools assessing for depression in a low income predominantly African American population, that the percentage of the population identified as having depression varied from 22% to 75% depending on the tool used. In a single blinded systematic review of 31 different instruments used for psychosocial assessments for young people identifying psychosocial risk, the investigators found only six instruments had evidence of construct, content and criterion validity (Bradford & Rickwood, 2012). Average time for completion of the instruments was 27.53 minutes which contributed to frequent incompletions. Due to the lack of longitudinal studies, there were also gaps in research regarding the long-term predictive ability of the tools. Lack of documentation regarding interventions to address psychosocial risks was also identified as a frequent finding in the systematic review (Bradford & Rickwood, 2012).

In this same review, Bradford & Rickwood (2012) identified that the HEEADSS tool was the most frequently studied tool interviewing adolescents for psychosocial risk. The components of the interview include information on Home, Education and Employment, Eating, Peer-related Activities, Drugs, Sexuality, Suicide and Depression, and Safety. The assessment is completed via a 20-30 minute interview that contains structured questions in each of the identified domains (Rosen & Goldenring, 2004). Only one study was found in the literature utilizing the HEEADSS as a tool for improving health outcomes (Jones, Mertyn, Alhucema, Monagle, & Newall, 2012). The authors conducted a database search of studies to determine the feasibility of using the HEEADSSS to develop structured education for adolescent patients requiring anticoagulation therapy. In this data base search, the authors were unable to locate articles that showed the impact of utilizing the HEEADSSS on structured education (Jones et al, 2012).

In a 2014 Robert Wood Johnson report on improving the health of our children and the communities in which they live, it was recommended that health professionals
include “nonmedical vital signs of health” when conducting health assessments (Robert Wood Johnson Foundation [RWJF], 2014). These “nonmedical vital signs” included factors such as employment, education, safe housing, financial resources, family structure, access to social supports, access to healthy foods, zip codes, and transportation. By assessing these factors, clinical decision making could be enhanced due to a better understanding of the patient and family. With this understanding, health care providers could provide supportive linkages between the community and health care organizations (RWJF, 2014). The American Academy of Pediatrics (2015) has also emphasized the need to screen for social, economic, educational, environment, and personal capital needs. More research is needed on effective screening tools and interventions that include community partnerships (Cheng, Emmanuel, Levy, & Jenkins, 2015).

There are few studies within the literature demonstrating the impact of screening on health care outcomes. A randomized control study using a subset of questions from the Children’s HealthWatch Survey evaluated if a clinic-based screening and referral system could improve outcomes through enrollment in new community-based resources (Garg, Toy, Tripodis, Silverstein, & Freeman, 2015). The questionnaire included six domains: child care, food security, household heat, housing, parent education level, and employment. Study participants were mothers with infants less than or equal to six months of age. Exclusion criteria were: primary caregiver who was not the mother; mothers less than 18; non-English speaking mothers; if there was anticipation of a change in the site of care; and infants less than 32 weeks gestation or who had chronic health problems or previous hospitalizations. Patients enrolled in the intervention group were given information and applications to community resources based on results of the questionnaire. Staff members also contacted mothers at one month after the
referral. The control group received standard care, which was defined as information about access to basic social work services and standard social history questions. Despite no significant difference of the needs and demographics between the control and intervention group, the researchers found that more intervention group mothers received referrals and had contacted a community resource than the controls. At their 12 month checkup, the researchers also found that mothers in the intervention group had greater odds of being employed, in child care, receiving fuel assistance and having lower odds of being in a homeless shelter, but the authors noted additional research is needed in this domain (Garg, Toy, Tripodis, Silverstein, & Freeman, 2015).

Another randomized control study evaluated the best format for use of a social needs screening tool; face to face contact versus electronic (Gottlieb, Hessler, Long, Amaya, & Adler, 2014). Although the study reported a high prevalence of social needs in both groups, there was a statistically significant higher disclosure rate in the computer generated tool on items related to household violence and substance use (Gottlieb et al., 2014). This issue of face to face versus self-completed tools may also be of significance in populations with English as a second language. In a cross-sectional, mixed method, explanatory design study evaluating behavioral health disparities in a pediatric population, the researchers found disparities existed in provider referrals for child behavioral issues in limited English proficient families (Herbst, Margolis, Millar, Muther, & Talmi, 2015). The study found that topics such as patient/family problem solving, strengths, behavioral health and development, educational issues, and psychosocial issues were all discussed less frequently with limited English proficient families (Herbst et al., 2015).
Psychosocial Assessment Tool (PAT)

One tool frequently referenced in the literature to assess for psychosocial risk in children with chronic illness was the Psychosocial Assessment Tool (PAT, n.d). The tool is based on the Pediatric Psychosocial Preventative Health Model (PPPHM) (Kazak, Schneider, Didonato, & Pai, 2015). The PPPHM (Appendix A) is a model based on Bronfenbrenner’s social ecological model (1979) of child development, applying the impact of childhood illness. The PPPHM provides an appreciation of the impact the functioning of the family has on the distress or adaptation of the child to a chronic illness. The PPPHM further investigates external systems impacting the family that have an indirect effect on the child functioning. The PPPHM provides a triangulated method of stratification, and thus a form of capacity management for care delivery. The bottom tier of the model is the Universal Risk level where the majority of families fall. Families at this level are normally functioning, moderately resilient and possess adequate to strong coping skills. These families may have other external stressors in addition to a child’s health issues, but these do not appear so demanding to impact overall adaptation. The second level of the three tiers is the Targeted level. Families at this level have stressors that may predispose them for risks in functioning, such as poverty, financial stressors or family conflict. Although these families have coping mechanisms, they may be challenged if there are significant changes in the health of the child impinging on available resources, both internal and external. The final tier is Clinical/Treatment. Families in this tier tend to account for the greatest number of resource usage and they include families with high anxiety, depression, legal issues, substance abuse and mental health issues. Scores from the PAT correspond with PPPHM levels (Kazak, 2006).
The original PAT was revised to the current version the PAT 2.0 (Kazak et al., 2015). The PAT 2.0 is a parental report screening tool for psychosocial risk that takes five to ten minutes to complete. Items on the tool assess potential stressors of the child, family and broader systems. The tool is available as web-based or REDCap, and can be used with broad range of ages of children; infant to adolescent. It has been used both in the US and internationally. The tool is written at the fourth-grade level reading level (Kazak et al., 2015).

The PAT 2.0 assesses 18 domains of psychosocial risk for families with a child diagnosed with cancer. These include: “family conflict, family resources, family structure, social support, stress reactions, family substance use, family psychological problems, child internalizing problems, child externalizing problems, child cognitive problems, child social problems, child school enrollment, child educational placement, patient’s medical status, child knowledge of cancer, family beliefs, family medical problems and sibling problems” (Pai et al., 2008, p. 53). The PAT 2.0 provides a total score, as well as seven subscale scores: Family and Structure and Resources, Family Social Supports, Family Problems, Parent Stress Reactions, Family Beliefs, Child Problems, and Sibling Problems (Pai et al., 2008, p. 53).

The PAT 2.0 has been evaluated for internal consistency, test-retest reliability, differences in reportings between fathers and mothers, and content validity (Pai et al., 2008). The PAT was also evaluated for criterion- related validity in relation to the PPPHM categories. Internal consistency was calculated using the Kuder-Richardson 20 coefficients. The Kuder-Richardson 20 coefficients measure overall tests reliability. Scores range from 0.0- 1.0, with the desired scores closer to 1.0. In evaluating internal consistency of the PAT overall and individual subscales, adequate internal consistency was considered to exist for overall PAT scores or subset scale scores $\geq 60$. For the overall total score, the PAT 2. had strong internal consistency (.81),
and six of the seven subscales had an alpha coefficient of .60 or above. The Family Beliefs subscale had an alpha coefficient of .59, but only four items were analyzed. The authors decided to keep the content due to it containing information about cancer-related beliefs. Pearson Product Moment correlations indicated very good test-retest reliability with both mothers (r=.78, p <.001 ) and fathers (r =.87, p<.001 ). In a comparison of mothers versus father’s tests results, only one difference existed. Mothers reported fewer sibling problems than fathers (Pai et al., 2008).

Content validity was evaluated by correlating PAT 2.0 subscale scores with other validated tools, the Behavioral Assessment Scare for Children (BASC-2), the Acute Stress Disorder Scale (ASDS), the Family Environment Scale (FES) and the State-Trait Anxiety Inventory (STAI-Y) (Pai et al., 2008). Mothers and fathers were evaluated independently, and in both groups statistically significant correlations between the PAT 2.0 subscales and tools existed. PAT 2.0 total scores and distributions between the three categories of risk, Universal, Targeted and Clinical were similar between the fathers and mothers. The scores were also consistent with risk factors on the ASDS, BASC-2, FES-Conflict scale and STAI-Y state scales. The ability of the tool to determine the impact of how these levels correlate with costs has not yet been established and has been identified by an area needing further study (Pai et al., 2008).

The PAT 2.0 was initially utilized for families caring for a child with cancer. Subsequent studies evaluating the tools ability to stratify for risk have been consistent throughout the studies for this population (Kazak et al, 2015). The PAT scores also remained consistent throughout the course of cancer treatment (Gilleland et al., 2013, McCarthy et al., 2009). The feasibility and usability in this population has been researched and had positive results (Schepers et al., 2017). Information derived from the tool was consistent with social workers’ assessments.
However, team members in the study felt that the PAT did not provide any additional information of risk factors that was not already known from current their practice (Schepers et al., 2017). The authors noted there were multiple limitations in this study. First, the population studied was predominantly highly educated and married or partnered. In addition, the assessment was completed at one-month post diagnosis, so contact and involvement with psychosocial staff members had already been established. Despite these limitations in 25% of the participants, information was gleaned that impacted resources or decision-making for the families (Schepers et al., 2017).

The PAT has also been used in other pediatric chronic illness populations including kidney transplant patients (Pai, Tackett, Ittenback, & Goeble, 2012), children with inflammatory bowel disease (Pai et al., 2014) and children with sickle cell disease (Crosby et al., 2016, Karlson et al., 2012). Conclusions from all studies on chronic illness populations were that the PAT was promising for evaluating for psychosocial risk factors. The tool has also been studied in chronic headache pediatric patients (Woods & Ostrowski-Delahanty, 2017) and with families of children with acute life-threatening illnesses (McCarthy et al., 2016). Both studies also established potential value for the tool in identifying psychosocial risk. A single study was found involving the use of the PAT in surgical patients, a population of children with serious congenital heart disease, who are more reflective of a chronic illness population versus an acute surgical population. The results of this study were consistent with other studies of pediatric patients with chronic illness in the distribution of the PAT scores (Hearps et al., 2014).

Only one pilot study was identified that researched the use of the PAT on patient and family outcomes (Barrera et al., 2014). In this study, the family completed the PAT early after diagnosis and at six months following diagnosis. The results of the inital PAT assessment were
shared with the family’s health care team in the intervention group but not in the control group. Initial stratification of risk was similar to previous studies in the same population. The researchers found that in comparison to the control group, the intervention group had a significant reduction in psychosocial difficulties, received more services for assistance, showed higher reductions in parental anxiety, and had improvement in the quality of life-related pain management in patients (Barrera et al., 2014). Although this was pilot data, it provided a provocative look into the possibilities of the usefulness of the PAT in improving outcomes.

**PAT Subscales and Relation to Outcomes**

The PAT provides a total score, but also provides scores in seven subscales. The subscales serve as the domains, or operational definition of psychosocial risk factors, as defined by the tool. These include: family problems including substance abuse and family medical issues; family structure and resources; family social support; parental stress reactions; family beliefs; child problems such as internalizing, externalizing and cognitive; and social issues and sibling problems (Kazak et al, 2015). The tool provides a fairly extensive assessment of risk factors, in addition to socioeconomic and ethnic factors, that could have a bearing on patient outcomes.

There is limited literature regarding the relationship between identification of nonmedical presurgical risk factors and poor surgical outcomes in children. In a systematic review of studies on adult patients evaluating psychosocial factors and surgical outcomes, only sixteen eligible studies were found. (Mavros et al., 2011). However, most of these studies found a statistically significant effect with at least one variable but were heterogeneous; variables that were found significant in one study, were not in other studies. Factors in adults that were
commonly identified as significant were state and trait anxiety, state anger, poor coping mechanisms, subclinical depression, and intramarital hostility (Mavros et al., 2011).

**Psychosocial Factors and Surgery**

In children, studies on psychosocial risk factors on surgical outcomes, in addition to socioeconomic status and ethnicity, have focused on the outcome of pain. Research in this domain is an emerging field at best, and only a few studies have been reported. A longitudinal study evaluated the impact of presurgical and behavioral factors including child trait or state anxiety, child pain catastrophizing, parent pain catastrophizing and sleep duration on postoperative pain and health-related quality of life (Rabbitts, Groenewald, Tai, & Palermo, 2015). Pain catastrophizing is a tendency in the individual to describe pain with more exaggeration than the normal population would. The researchers obtained baseline information and at two weeks post surgery. Children included were those having either a spinal fusion or pectus surgery. The study did not examine socioeconomic factors or racial differences. The study found that parental pain catastrophizing and poor sleep patterns were significantly associated with greater child pain intensity. The investigators also found child state anxiety was associated with lower health-related quality of life (Rabbitts, Groenewald, Tai, & Palermo, 2015). Another systematic review also found child anxiety was a contributing factor to poor surgical pain control (Sherman Chiang, Chan, Klainin-Yobas, & He, 2013).

There are studies on children with chronic illness and their psychosocial factors and outcomes, but again the literature is limited. Most studies of chronic illness have evaluated the long-term effects of the chronic illness on the child and family. Studies identified in the literature that evaluated predictive factors and poor health outcomes; had ethnic and socio-economic themes. For example, in a study evaluating psychosocial screening for predictive
outcomes in type 1 diabetes, children from single parent homes with a history of behavioral problems were most likely to be seen in the emergency room, whereas, African American children were most likely to miss appointments (Schwartz, Cline, Axelrad, & Anderson, 2011).

In pediatric inflammatory bowel disease, children living in lower income households with Crohn’s disease were found to have a higher likelihood of hospitalization and surgery (Benchimol, To, Griffiths, Rabenck, & Guttman, 2011).

**Data on Tonsillectomy Patients**

Tonsillectomies are one of the most common surgical procedures in children. Among children having tonsillectomies, obstructive sleep apnea and recurrent tonsillitis are the most common reasons for surgery. In a retrospective chart review of over 2000 cases, obstructive sleep apnea accounted for 67% of the patients (Patel, Straight, Lehman, Tanner, & Carr, 2014). Males accounted for 52% of the cases of the obstructive sleep apnea while more females had recurrent tonsillitis as the indication for surgery. Children having a tonsillectomy in the five-year old and younger age group predominantly had obstructive sleep apnea as the indication for surgery. A sleep study to verify obstructive sleep apnea was completed on 42% of all patients (Patel, Straight, Lehman, Tanner, & Carr, 2014).

In a qualitative systematic review of racial and ethnic disparities and sleep disordered breathing, researchers found children with socioeconomic deprivation may have higher prevalence and risk of sleep disordered breathing (Boss, Smith, & Ishman, 2011). Caucasian children and those with private insurance, were more likely to have an adenotonsillectomy. A study utilizing the National Health Interview Survey found that many otolaryngologic conditions were under-diagnosed in ethnic groups (Shay, Shapiro, & Bhattacharyya, 2017). The
identification of conditions leading up to tonsillectomy, such as recurrent streptococcal pharyngitis, was less likely diagnosed in black and Hispanic children.

There are very limited studies evaluating psychosocial factors and tonsillectomy outcomes and complications. The studies found were predominantly focused on socioeconomic or racial factors. For example, African American children were reported to have a greater risk of respiratory complications following tonsillectomies (Horwood, Nguyen, & Brown, 2013). In a multivariate study evaluating tonsillectomy complications in children, increasing household incomes were associated with a decrease in all complications (Bhattacharyya & Shapiro, 2014). Black and Hispanic children had higher risks for revisits in comparison to Caucasian children. No other studies evaluating psychosocial factors in relation to pediatric tonsillectomies were found.

**Concepts and Definitions**

As discussed previously, psychosocial risk can be viewed from many different aspects and contexts. Therefore, a delineation of the concepts and definitions of psychosocial risk is important to provide clarity. The PPPHM model and the PAT serve as the basis for the definition for psychosocial risk. Factors associated with risk are identified by the subscales of the tool.

The Pediatric Psychosocial Preventative Health Model (PPPHM) is “a conceptual model to guide screening and services for families of children entering the pediatric health care system” (Kazak, 2006, p. 384). The theoretical base for the model is Bronfenbrenner’s Ecological Model of Human Development (Bronfenbrenner, 1979). The foundational premise of the model is that all families, with or without children with handicaps or chronic illness, are similar with regard to parent and family adjustment, but there is a subset of families who experience more difficulties and disruptions in adjustment that can adversely impact their child’s health (Kazak,
Interventions that are supportive to family, in turn, ultimately support the health of the child.

The PPPHM stratifies psychosocial risk to three categories forming a pyramid. The “Universal” level is the base and largest group representing families with moderate resiliency and coping abilities. Even with other life stressors, the family is able to function adequately. The next level is the “Targeted” level and included families that present with social factors, such as poverty or family conflict, that put them at risk for ongoing difficulties. They are able to function adequately, but unlike the Universal level, additional stressors can adversely impact coping mechanisms. The final and smallest level is the “Clinical/Treatment” level in which families have multiple factors of high risk and exhibit behaviors of poor coping and functioning (Kazak, 2006).

The Psychosocial Assessment Tool (PAT) is a parent report screening tool of psychosocial risk based on the PPPHM, as has been discussed previously. The tool identifies family risk and resiliency across multiple domains represented by subscales within the tool. The PAT results not only provided an overall score and associated level of risk, but also subscale scores of the tool (Pediatric Assessment Tool, n.d.).

The components of the subscales are the factors associated with psychosocial risk as deemed by the PAT, and provide a conceptualization of the tool’s definition of psychosocial risk. An exploration of these terms and the items included in the scales are important in defining psychosocial risk for this DNP project.

There are seven subscales described in the PAT: Family Structure and Resources; Family Social Support; Family Problems; Parent Stress Reactions; Family Beliefs; Child Problems; and Sibling Problems. Items in each subscale include the following:
Family Structure and Resources: Family structure is the composition, membership and patterns of relationships between family members. Family resources include: financial resources, access to health care, adequate health insurance, access to transportation, and parental education.

Family Social Support: Family Social Support are those family members, friends, and others the family can count on to provide supports. Supports include child care help, emotional support, financial support, information, and help with everyday tasks.

Family Problems: Family Problems include family members experiencing substance abuse, mental illness including depression, marital discord, conflict, separation or divorce, child custody conflicts, incarceration, medical illness or death of a family member.

Parental Stress Reactions: Parental Stress Reactions include the presence of parental anxiety or parental catastrophizing.

Family Beliefs: Family beliefs include factors such as trust in the health care providers, parental views of the degree health stress will have on the family, and the level of hope in overcoming the health stress.

Child Problems and Sibling Problems: Both the Child Problems and Sibling Problems include the same factors. These are: chronic health concerns, psychological concerns, learning difficulties, depression, developmental delays, anxiety or excessive worry, lack of social support and substance abuse issues.

**Theoretical Framework**

The PAT and the PPPHM are based on Bronfenbrenner’s Ecological Model of Human Development (Bronfenbrenner, 1979). The model is depicted in a series of layers that represent the context in which the child is developing. The model delineates the relationships and other
influences that have direct and indirect impact on the child’s development (Appendix B).

Bronfenbrenner’s model is aligned with a population health perspective in addressing health outcomes. In fact, Bronfenbrenner (1979) stated, “basic science needs public policy even more than public policy needs basic science”. (Bronfenbrenner, 1979, p. 8).

Bronfenbrenner’s ecological model starts at the level of the child’s microsystem. The microsystem is where the child lives and grows, and includes the people and institutions with whom the child interacts. Components within the microsystem are the interpersonal structures occurring within the setting, in which there are defined roles and molar activities. Molar activities are forms of behavior that have momentum and meaning or intent by the participant (Bronfenbrenner, 1979). The parent/child relationship exists within the microsystem. Other influences such as parental stress and behaviors directed toward the child as a result of that stress, are included in this microsystem.

The mesosystem is the next layer surrounding the microsystem in Bronfenbrenner’s Ecological Model. Within the mesosystem there is interrelating between two or more settings in which the person is an active participant. These interrelationships between settings can occur in many ways. For example, a multi-setting interrelationship could be participation the child being part of a home setting and a school setting. There can also be indirect linkages in which the individual of interest does not actively participate in both settings, but there is a connector, an intermediary link, between the two settings. For example, the parent could be the connector, and the two settings are home and the parent’s work, with both having a potential impact on the child. Transmission of messages can occur between one setting to another to provide specific information but also, intersecting knowledge can occur where one setting has knowledge of the other setting, of which the other setting is not aware (Bronfenbrenner, 1979). This type of
EVALUATION OF THE USE OF THE PAT

message transmission is representative of health care and patient relationships. It is at the mesosystem layer that health care provider interactions occur with patients and their families. It is also at this level that interactions occur between primary care providers and specialty care providers. The most critical link identified by Bronfenbrenner in the setting is transition, which occurs when the person enters a new environment, and relies on a supportive link. This supportive link is created when there is mutual trust, positive orientation and goal consensus.

The third layer of the model is the exosystem, which is defined as settings in which the individual is not an active participant, but events occurring within those settings can impact the individual. Examples include the community in which an individual lives, and the decision-making and allocation of community resources that have an impact on the individual. Social determinants of health and the impact of local policy are examples, as are health organizations’ policies and practices (Bronfenbrenner, 1979). Finally, there are the macrosystems within the overarching layer that includes the cultural and subcultural perspectives, values, ideology and belief systems. History, world events, and social and industrial change are found within the macrosystem. For example, the expansion in electronic technology which is currently occurring impacts the way individuals communicate with one another. There are many positives in this technology, but also risks. An example of technology risk is electronic bullying, which can adversely impact the mental health of the child.

Bronfenbrenner’s theory aligns well with Leininger’s Cultural Care Diversity and Universality Theory. Leininger’s theory is illustrated in her Sunrise Enabler model (Appendix C. Sunrise Enabler), which was initially described by Leininger in 1965, fully developed as a conceptual model in 1991, and was most recently revised in 2004 (Leininger & McFarland, 2006). One of the assumptive premises of the theory is that nursing decisions and actions should
be guided by knowledge of meanings and practices derived from world views, social structure factors, cultural values, language and environmental context (Leininger, 1988). Many of the terms used by Leininger fit well within Bronfenbrenner’s ecological model. The multiple layers of systems that interact and impact in the ecological model, align with terminology of Leininger’s theory. These terms speak to the social interactions, emotional interactions, interrelated structures and organizations, meanings and values that impact an individual and their health. Much like Bronfenbrenner, Leininger recognizes that impact of nursing is more than just care delivery, and includes an understanding that nursing decisions must be “culturally congruent” (Leininger, 1988, p. 155).

To truly care for patients and families goes well beyond the treatment of their illness or health issue, and encompasses an understanding of those interacting systems that have an impact. This requires assessment of the multiple factors. In fact, Leininger speaks to obtaining first-hand emic data versus etic viewpoints to understand meanings and interpretations of a culture (Leininger, 1988). The emic view is from the perspective of the individual within the culture including the meaning of that perspective, in contrast to the etic, in which the view is the perspective of an individual outside of the culture. The etic observer sees the culture through their own cultural lens and what is observed to be of importance is through that lens. There are risks in solely relying on the etic view, especially in terms of poverty. There is a risk of dehumanizing those experiencing health disparities, and in a sense, pathologizing a group or population of people if defining them as a group only. Understanding the intrinsic and extrinsic factors, including the impact of social determinants in the context of their homes, their lives, and their culture broadens this perspective. Utilizing Leininger’s (1988) transcultural view of nursing and understanding the individual at the center, and in relation to many interacting
systems (Bronfenbrenner, 1979) reduces the risk of losing sight of the individual and promotes true discovery (Clark, 2014).

As mentioned, health care providers risk pathologizing certain groups. Factors such as race and socio-economic factors are often the only considerations cited in the literature and research studies, implying that these elements alone account for health disparities. The breadth of understanding that is needed, therefore, can be lost without the conscious recognition of the multiplicity of factors contributing to the individual's health. This may result in ineffective care interventions, and wasted opportunities to improve health. The PAT, utilizing a stratification approach in defining risk and looking at multiple influences associated with risk, can improve discovery of other contributors to psychosocial risk and poor health outcomes. Clearly, an awareness of the extensiveness of factors impacting an individual’s development and health is essential in a DNP nursing leader’s advanced practice.
Chapter 3

Methodology

The purpose of this project was to evaluate the feasibility of utilizing the Psychosocial Assessment Tool (PAT) with a pediatric surgical population of potential tonsillectomy patients. The aims of the study are to evaluate the impact of the use of the PAT on surgical clinic flow and resources, and to determine if the PAT improves identification of psychosocial risks factors over the current practice. The methodology of this DNP student project was focused on addressing the purpose and the aims of the project.

Project Design

The study design of this DNP project to determine if the PAT is a useful tool for improving the assessment of psychosocial risk among pediatric surgical patients, was that of a feasibility pilot project utilizing a convenience sample of potential pediatric tonsillectomy patients. Feasibility studies can serve many purposes, one of which is the appropriateness and quality of the use of an instrument (Polit & Beck, 2011). The PAT has been identified to be a promising tool for use in the chronic illness population, but there is no knowledge of its utility in pediatric surgical patients, except in congenital cardiac disease (Hearps et al., 2014). Data from feasibility pilot studies can also provide information on the acceptability of the use of the tool by patients and staff members as is planned in this DNP student project. If positive pilot study results are realized, this could impact the continued use of the PAT, and its possible spread. A feasibility study may also provide insight into any unforeseen side effects of the tool (Polit & Beck, 2011). The identification of psychosocial risk factors will require referrals for interventions, and the availability of the required resources within the institution was an
important factor to assess. The impact on clinic flow and productivity was also an important consideration.

**Organizational/Environmental Assessment**

The intended population for the testing of the PAT was a subset of pediatric surgical patients seen in the Otolaryngology Clinic. The population of this DNP project were pediatric patients with complaints that might warrant a tonsillectomy and/or tonsillectomy and adenoidectomy. According to the American Academy of Otolaryngology (2017), 20% of all tonsillectomies are done for repeated infection, 80% for sleep disordered breathing and tonsillectomies account for 16% of all ambulatory surgeries. Delayed discharge occurs in 1.3% of cases of pediatric tonsillectomies cases, and up to 3.9% have readmissions due to complications; the more common reasons for readmissions are pain, vomiting, fever, and tonsillar hemorrhage (Baugh et al., 2011).

The Division of Otolaryngology (ENT) at Cincinnati Children’s Hospital Medical Center (CCHMC) is known as a center of excellence in disorders of the ears, nose and throat. The ENT division is also recognized for treatment of severe upper airway problems and airway reconstruction. ENT is the busiest of the surgical subspecialties at CCHMC with more than 36,000 visits and 15,000 surgeries performed each year. The most common ENT procedures are the placement of ear tubes, adenoidectomies and tonsillectomies (CCHMC, 1999-2017). Based on unpublished, internal data, the ENT Division at CCHMC performed over 2000 tonsillectomies in the last year.

The most common entry for a patient to an otolaryngologist is via a referral from the primary care provider. The patient’s family is required to contact the CCHMC scheduling department by telephone to set up this appointment. As is illustrated in a flow diagram
developed by the ENT division (Appendix D), the initial stop on the day of an appointment is with registration. From there, vital signs are taken by a patient care assistant, followed by electronic health record (EHR) intake by a registered nurse or medical assistant. Included in this intake is a psychosocial assessment, which records who the patient is accompanied by, the demeanor of the child, and whether interpreter services are needed. The assessment also asks two screening questions for abuse; the first is about the child’s exposure to abuse, and the second is about safety and the parent’s currently relationship. In addition to these questions there are two questions focused on pain; pain that day, and if there has this been a history of chronic pain (Appendix E). In addition to this information, located in various sections of the electronic health record, is current information on insurance source and guardianship. Historically, there is information on past contacts with social workers within the institution, and the percentage of CCHMC missed appointments. There are no data available on the mining and use of this additional information in the EHR by the care providers in the Division of Otolaryngology. The only required elements of the process are the intake information.

The perioperative division was a late adopter of electronic health records (EHR), and the Division of Otolaryngology was one of the last adopters. It is only within the last five years that all departments have transitioned fully to documentation in the EHR. Communication between providers utilizing the EHR, and supporting its meaningful use through pertinent exchange has been a challenge for care providers. Meaningful use is defined as utilizing electronic health record technology to: “improve quality, safety, efficiency and reduce health disparities, engage patients and families, improve care coordination and population and public health, and maintain privacy and security of private health information” (Health IT, 2015). The extent to which the Division of Otolaryngology has used this information is lacking; this lack of use may contribute
to failures to identify important patient information. The current CCHMC electronic health system provides different views of information by provider preference. Finding information within the record is not always intuitive and takes some experience with the process.

After completion of the initial intake, the patient has an average wait time of 14.32 minutes, prior to seeing the otolaryngologist. After the visit, unless additional tests are required, the last two steps in the process are a teaching session by the nurse, and a checkout process in which follow-up appointments and surgeries are scheduled and payment is obtained. Total time for this entire clinic process ranges between 1 hour and 1.5 hours. Therefore, a significant concern is the impact the completion of an additional tool may have on the process in terms of time and flow, and how best to prevent delays in flow and increased wait time for the patient and family.

**Evidence-Based Project Intervention Plan**

1. The DNP student attended a minimum of eight clinic sessions of one otolaryngologist. To facilitate completion of data collection, clinic sessions of a second otolaryngologist were added. A session is defined as a four-hour increment of time. Prior to each clinic setting, the DNP student obtained a list of all patients being seen with tonsil related complaints and the times of their appointments. Tonsil related complaints include recurrent infections, and hypertrophic tonsils with or without sleep disorder breathing.

2. Parents/guardians of children attending both provider’s otolaryngologic clinic with tonsil related complaints that may require a tonsillectomy received the normal intake process for psychosocial assessment.

3. After completion of the intake process, parents/guardians were asked to complete the PAT via a web-based format by the DNP student. Prior to completion of the PAT, parents/guardians were
given a written information sheet (Appendix F) on the DNP project purpose, what they were expected to do if they agreed to participate, risks and benefits, protection of PHI and ability to refuse participation without impact to care. Parent/Guardians were told that the PAT results would be shared with their CCHMC ENT provider, but it would not be part of the medical records. Parents/Guardians were also told that if the tool identified factors for which supportive resources could be provided, CCHMC social workers will be notified of this need. Although the PAT is written on a 4th grade level, if participants had difficulty in reading of the tool or information sheets, the researcher read the questions and information on the research to the family member.

4. The time required to complete the tool was documented, as well as notations recorded on any delays in the care flow.

5. Scores for the overall PAT, and any identified high scores in any subscales, were communicated to the provider. The web-administration of the tool automatically provided the overall PAT score, the level of risk and subscale scoring (Pediatric Assessment Tool, n.d.). Communication occurred with the provider about any additional identified concerns that were not reflected in the PAT scores. This information was provided in a paper format (Appendix G) and was not be a component of the patient’s medical record.

6. Any patients having scores that place them in the upper tier of psychosocial risk, “Clinical” range, representing severe, escalating or persistent distress (Pediatric Assessment Tool, n.d.), were referred to the social work department. This referral occurred via an email correspondence to the designated ENT social workers, unless deemed as an urgent need. If deemed urgent after discussion with the ENT health care provider, an ENT social worker was contacted via phone on the day of the visit. A meeting was held with the ENT social workers about the project, so they
would be aware of the potential increase of referrals due to the DNP project. Since previous studies have shown that only 15% of studied populations stratified in the “Clinical” range and the sample size was small, it was felt that the number of referrals would be doable.

7. Data was collected on patient PAT scores, whether these necessitated a referral, and if similar findings were identified by the current process of intake psychosocial assessment (Appendix H).

8. Feedback was obtained from the health care provider and social worker on the usefulness of the tool, and appropriateness of referrals based on the tool’s scoring after each clinic session.

9. Potential DNP project participants were identified by the DNP student for no less than eight clinic sessions in a patient population of a defined otolaryngologic provider.

Inclusions: English-speaking parents/guardians, patients age two years or older to less than 18, patients referred for a tonsillar/throat complaint of hypertrophic tonsils, sleep disordered breathing, or recurrent infections. Based on the American Society of Anesthesia Physical Status Classification ([ASA], 1995-2017), patients who are included will be rated as an ASA 1 or ASA 2 which would represents an otherwise healthy child or a child with mild systemic disease.

Exclusions: Non-English-speaking parents/guardians, patients in foster care, children less than two or aged 18 years or older, and any patients with an ASA status of ASA 3 or greater.

Market Analysis/Financial Analysis/Strategic Analysis

From a financial perspective, there are many long-term potential savings of this project. For example, non-use of operating time due to cancellations related to preventable causes, are an economic burden to an institution. The top three reasons for day of surgery cancellation identified at CCHMC are patient illness (33.0%), ‘no show’ (21.8%), and failure to comply with
eating/drinking instructions (‘nothing by mouth (NPO) violation); (13.6%). This equates to lost operating room time averaging 4.7 hours each day (4.5% of total), which is equivalent to almost $100,000 per week in potential lost revenue (Pratap et al., 2015). Although, child illness may be unavoidable, the other preventable causes, no show and NPO violation, account for greater than one-third of all causes of cancellation. The use of the PAT has the potential to identify at-risk families during their initial surgical clinic visit, which may reduce cancellations and lead to a reduction of lost revenue.

The family also incurs loss due to cancellations. Although no recent studies could be found on this topic, one older study looked at the burden on families due to “day of surgery cancellations in a pediatric outpatient population (Tait, Voepel-Lewis, Munro, Gutstein, & Reynolds, 1997). The investigators found that 38.5% of mothers and 50% of fathers had missed work, of which 53.3% of the mothers and 42.1% of the fathers experienced unpaid leave for the missed day. In addition to lost wages, there were transportation costs, babysitter costs and costs of lodging. There were also families who were held responsible by their insurance company for the rescheduling of surgery (Tait et al, 1997).

Complications and readmissions add to the societal health care economic burden. A study evaluating the cost and risks for an unplanned return to the hospital after adenotonsillectomy in children, found that children with Medicaid and Hispanic children were two groups with increased risks (Duval, Wilkes, Korgenski, Srivastava, & Meier, 2015). The investigators found the median cost associated with an unplanned return visit was $425 with a range of $95-$18,820. When a readmission occurred, the median cost increased to $1820 (Duval et al, 2015). Delays in surgery due to cancellations and rescheduling can result in a need for more expensive procedures and add to the health care economic burden. For example, if a parent
misses the opportunity for endoscopic repair with helmet treatment of their child’s craniosynostosis due to the age of their child, it would lead to the more expensive and riskier open approach for neurosurgical repair (Voegel et al., 2014). The age of the child in which endoscopic repair is applicable varies by institution, with a range of an infant being between two to four months. The endoscopic repair requires less inpatient days, less risk for blood transfusion, and less operating room time resulting in a cost savings close to $20,000. It is known that cancellations of endoscopic repair with helmet treatment of their child’s craniosynostosis due to psychosocial risk factors, have contributed to delays in surgery resulting in the need for an open approach at CCHMC. This is also the case in other surgical procedures. Interventions aimed at identifying psychosocial risk factors have the potential of prevention of delays, complications, and reduced costs.

In addition to complications, readmissions and delays in surgeries, there are also long-term health risks associated with a lack of or delayed surgery. One study identified children from lower socioeconomic quartiles had lower odds of having needed anterior cruciate ligament (ACL) surgeries for repairs (Dodwell et al., 2014). Lack of repair of an ACL tear often leads to osteoarthritis, with a risk for knee replacement surgery. In a study looking at the long-term societal costs of ACL repair in an adolescent verses knee rehabilitation, the mean lifetime cost to society for a typical patient undergoing ACL reconstruction was less than half of that for rehabilitation ($38,121 versus $88,538) considering lost wages, productivity and disability (Ramski, Kanj, Franklin, Baldwin, & Ganley, 2014).

**Personnel, Technology and Budget Resources**

There are costs associated with the use of the PAT. There is a $350 user fee yearly for the use of the tool. There were negotiations between Nemours, the PAT’s author, and CCHMC
to have this as an overall institutional fee versus each individual department. Therefore, for this project there was no cost for the use of the tool. Permission was obtained from Nemours and the PAT’s authors for use of the PAT through the User application and agreement process (Appendix I). As per stipulations of the agreement process, quarterly aggregate non-identifying reports were provided (Appendix J).

For this DNP project, there was an opportunity to apply for internal research grant monies to off-set the costs if needed. There are costs associated with the use of technology and the IT associated support to maintain the tool. An internal research grant was awarded for the cost of this technology. In addition, staff resources will be needed to help families with the completion of the tool and interpretation of the results. For this project, the DNP student fulfilled this role. As risks are identified, there will be the need for referrals to internal and external resources, resulting in additional staff time for case management. The percentage of patients needing interventions based on PAT scoring and institutional costs are unknown for this population. This DNP project will provide information that will assist with the forecasting of this potential long-term cost. However, potential savings from reduced cancellations could be significant, which may offset any associated costs. For example, if only half of cancelled cases due to NPO violations or “no show” for surgery were prevented by use of the PAT and interventions, the institutional savings could equate to savings of over $900,000/year. Appendix K presents an overall SWOT analysis of the strengths, weakness, opportunities and threats associated with this DNP project.

Timeline of Major Tasks Required for Project Completion

The following table (Table 3.1) illustrates the timeline for the DNP student project:
Table 3.1

*Student project Timeline*

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<tr>
<th>DNP Project Timeline</th>
<th>Jul-17</th>
<th>Aug-17</th>
<th>Sep-17</th>
<th>Oct-17</th>
<th>Nov-17</th>
<th>Dec-17</th>
<th>Jan-18</th>
<th>Feb-18</th>
<th>Mar-18</th>
<th>Apr-18</th>
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<td>Submit Project for CCHMC and XU IRB approval</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Complete application for use of PAT</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Make Revision as needed for IRB</td>
<td>X</td>
<td>X</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Obtain web-based PAT from Nemours</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Evaluate Clinic flow via site-based observation</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Work with internal IT resources to upload and understand technological issues for PAT</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<td>X</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Identify, recruit and invite participants</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td>X</td>
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<td></td>
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</tr>
<tr>
<td>Feedback from Clinic Participants</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Complete study write up</td>
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<td>Write article for potential publication</td>
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</tbody>
</table>
Resources and Barriers

Resources identified included the following:

1. Contact was made with authors and researchers of the PAT, Dr., Kazak and Dr. Pai. Dr. Pai is on staff at CCHMC and was available for further consultation, if needed. Both felt the PAT was appropriate for use in the study population and were interested in the findings of the DNP project.

2. The primary otolaryngologist involved in the study was supportive and engaged in the project. For example, in a recent discussion about this DNP project, she related a story regarding a teenaged patient that was re-admitted due to complications post tonsillectomy. It was discovered on the readmission that the patient was homeless. The otolaryngologist stated, “Had I known that information on her pre-surgical visit, the patient would have avoided an unplanned admission post tonsillectomy due to the psychosocial risk”. The physician’s understanding of the potential benefit and need, was a major resource. The second otolaryngologist added, also was supportive and engaged.

3. Within the Anesthesia Department, Division of Research, research on pain and pain control has been an area of study that has obtained grant funding. In addition, there has been research and interventions on factors contributing to surgery cancellations. There is interest within the department regarding potential research utilizing the PAT and subscale scores. Resources such as application for internal grant monies, use of I-Pads and statistician were offered to complete the DNP project. A future potential co-investigator has also been identified from the Department of Anesthesia.

4. Leadership with the Departments of Anesthesia and Surgery were supportive of the DNP project.
5. A DNP cohort peer holds a leadership position within the Division of Otolaryngology and provided access to key individuals within the division, information on current practice and clinic flow information.

Barriers identified include the following:

1. A potential barrier was a historical lack of acceptance of the PAT by the social workers at CCHMC. The PAT was presented as a resource for use by the social workers, but the decision was made to utilize a more intensive process that exists across the institution. This intensive process is used predominantly with long term care patients by providers in a variety of settings at CCHMC. The length of the tool used in other areas would not be conducive to the surgical clinic setting. In a meeting with CCHMC Otolaryngology Clinic social workers, there was no resistance to the use of the PAT for this project.

2. There is an identified risk of non-adherence or change in the intake process system-wide, or individually by nurses in the otolaryngology clinic that could impact the outcome of this DNP project. However, during this DNP project this was not an issue.

**Evaluation Plan and Data Analysis**

Aim 1. To determine if the PAT is a feasible tool to use in a pediatric outpatient surgical clinic with potential tonsillectomy patients.

The maximum time identified to complete the PAT by the authors is ten minutes. Based on clinic flow data, the average wait time for patients is 14.32 minutes, therefore the timeliness for completion becomes a key factor in feasibility. Data was collected on the project’s tool created for this purpose (Appendix L and M) to address this aim and included time required to complete the tool, and whether or not flow was impacted.
Operational definitions for this aim include the following:

*Time for completion of tool:* Time to complete tool from parental/guardian start time to parental completion of the tool measured in minutes and seconds. Comments on issues contributing to prolonged completion times, greater than 10 minutes, will be recorded if known.

*Impact to flow:* Delays in the next step in patient processes, interaction with otolaryngologist, delays due to completion of the tool, or the tool not being completed in time to continue with patient flow process. A code of yes will designate that a delay occurred. Comments on issues contributing to delays in flow will be recorded if known.

Baseline data for the completion of the tool are only known for other populations and been defined as a maximum of 10 minutes. Data obtained for time of completion is reported as a continuous variable with equal intervals (Sylvia & Terhaar, 2014) and therefore represents a ratio-level variable. Descriptive statistics were utilized in the analysis of this data and included measures of mean, median, range and frequency distribution of time. In addition to these measures, comments on issues contributing to prolonged completions, defined as greater than 10 minutes, were assessed and a content analysis completed for themes and patterns.

Data obtained on impact to flow is considered a nominal categorical variable (Sylvia & Terhaar, 2014) and the data was descriptive utilizing a percentage. The denominator for the percentage was all parents/guardians initiating the PAT, and numerator was the number of patients in which there was an impact to flow. Baseline data is zero, since an additional step is being added in the flow process. In addition to this measure, comments on issues contributing to delays in flow will be evaluated and a content analysis completed for themes and patterns.
Aim 2. To determine if there was an increase of patients identified with psychosocial needs with the use of the PAT in comparison to current practice of psychosocial assessment for potential pediatric tonsillectomy patients seen in a surgical outpatient clinic.

Operational definitions for this term include the following:

*Identification of psychosocial risk by current practice:* Patient was referred or identified as requiring additional psychosocial resources utilizing the current method of psychosocial risk assessment based on EHR documentation by the nurse of medical assistance. These data will be coded as either yes, and a referral was made, or no, a referral was not made.

*Identification of psychosocial risk by the PAT:* An overall score resulting in a stratification to the Targeted or Clinical/Treatment category was considered an identification of psychosocial risk. A PAT score falling in the Clinical/Treatment category represented a need for further resources, and will necessitate a social work referral.

The data was from paired samples, with the independent variable being the type of psychosocial assessment completed, either standard practice versus PAT. The dependent variable was the percentage of patients identified as needing resources due to identification of psychosocial risk. A McNemar’s test to test the difference in the proportions between the two paired samples (Sylvia & Terhaar, 2014) was utilized for data analysis. The McNemar’s test utilizes a two by two contingency table to assess the differences between two correlated proportions, and is applicable to paired samples (Lowrey, 2001-2017). The accepted level of significance for this analysis of data was .05 and a minimum $n$ of 35 was required. This was based on baseline identification of psychosocial risk of 5% of the population, and lowest documented psychosocial risk by PAT score of 37% of the population. Data will be collected on the presence of subscale elevations but will not be used in the evaluation for this aim. A
Cronbach Alpha was planned to be used to analyzed internal consistency of the subscales and compared to the Cronbach Alpha scores of the subscales reported by the PAT’s authors (Kazak et. al, 2015). The sample size was not of an adequate size to complete this.

In summary, psychosocial risk factors have been identified as being associated with disparities in health outcomes for pediatric surgical patients. Risk stratification has been identified as a mechanism to determine needs for interventions or resources. Unfortunately, there are few models or tools to assess and stratify for psychosocial risk factors existing in the literature. The Psychosocial Assessment Tool (PAT) has been identified as a promising tool for psychosocial risk assessment and stratification in pediatric chronic disease populations, but has not been studied in pediatric surgical populations. The purpose of this DNP project was to evaluate the use of the PAT in a pediatric surgical population, potential pediatric tonsillectomy patients. The aims of the study were to determine if the tool is feasible for use in the surgical clinic population and to determine if there is improvement in psychosocial risk identification through the use of tool in comparison to the current practice. The feasibility of the tool was evaluated by assessing the impact the addition of the tool has on patient flow. A comparison of current practice and PAT identification of psychosocial risk was utilized to evaluate improvement. The time line for data collection was Fall 2017 with completion of this project by April 2018.
EVALUATION OF THE USE OF THE PAT

Logic Model

Strategies and Activities

1. Test out the feasibility of using the PAT with potential tonsillectomy patients.

2. Assess the ability of the PAT to identify psychosocial risk factors in comparison to the current practice

Short-Term Outcomes

1. Improvement in identifying families with psychosocial risk factors that is amendable to the surgical population.

2. Initiate awareness and problem solving regarding factors impacting family within the surgical and anesthesia departments.

Mid-Term Outcomes

1. Improved case managements with care coordination that is community based, therefore creating a bridge between the specialist, PCP and the community

2. Provides an opportunity for further research in what factors need amelioration and how best to intervene.

Long-Term Outcomes

1. Improved outcomes reducing the disparity gap in pediatric surgical patients.

2. Decrease in overall in the economic burden associated with disparities.
Chapter 4

Results

The results of the DNP project will be presented in this chapter. The process of data collection, and modifications from original plan will be discussed. The demographics of the sample population and a comparison to similar populations will be examined. Finally, the results of the aims of the project; that of evaluating feasibility of the use of PAT for pediatric potential tonsillectomy patients and improvement in identification of psychosocial risk factors, will be presented.

Data Collection

Data were collected over a three-month period, from mid-October 2017 to mid-January 2018. A total of 11 four-hour clinic sessions, plus two additional partial sessions were required to obtain a convenience sample of 35 participants. The sessions were both at hospital-based campuses; CCHMC Base and CCHMC Liberty, and at community-based campuses; Mason and Anderson. Both morning and afternoon sessions were included, as well as weekday and Saturday sessions. Patients of two CCHMC ENT physicians were included within the project. The initial plan was to include the patients of only one ENT physician, but it become clear early in the project that the numbers required would not be obtained in a reasonable time frame with only one ENT physician. In early November, after receiving permission from a second CCHMC ENT physician, patients of this physician were also included in the DNP project. This not only increased the availability of potential sessions and patients, but also allowed for the availability of Saturday sessions for data collection.

The initial time line for this project had planned for data collection through the months of September through December 2017. The length of IRB approval process delayed the data
collection process to mid-October 2017. The anticipated plan speculated that only eight, four-hour sessions would be required to obtain the intended sample size. Three additional full sessions and two partial sessions were needed to obtain the study population. Thus, the addition of another ENT physician’s patient population became a key adjustment for the timely completion of this project.

**Demographics of Participants**

A convenience sample size of 35 was obtained for this DNP project and included children between the ages of two to seventeen years of age (Table 4.1). The age demographics of this sample was similar to a sample from a large data review of 305,860 tonsillectomy patients evaluated for post tonsillectomy complications (Harounian, Schaefer, Schubart, & Carr, 2016). Children between the ages of three years and six years of age accounted for 45.1% of all cases in the large data review; this age group accounted for 42.8% of all participants in this DNP sample size. In addition, the average age of participants was also similar, 6.4 years for this DNP project sample, and 7 years in the large data review (Table 4.2). The sex percentages in the DNP project population, 51.4% female and 48.6% male, (Table 4.3) were the same as those of the large data review.
Table 4.1

*Age of Participants*

<table>
<thead>
<tr>
<th>Age</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid</td>
<td>2</td>
<td>6</td>
<td>17.1</td>
<td>17.1</td>
</tr>
<tr>
<td></td>
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<td>8.6</td>
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<td>6</td>
<td>17.1</td>
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</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100.0</td>
<td>100.0</td>
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</tr>
</tbody>
</table>

Table 4.2

*Histogram of Age Distribution of Sample Population*

![Histogram](image)
Table 4.3

**Distribution of Sample by Sex**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid</td>
<td>Female</td>
<td>18</td>
<td>51.4</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>17</td>
<td>48.6</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>35</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Similar to a study by Boss, Smith, & Ishman (2011), Caucasian children were the most frequent racial group represented in the project population (Table 4.4). United States Census Data for Hamilton County, Ohio reports the county’s racial mix as 68.3% Caucasian, 26.4% African American/Black and 2.4% Biracial (United States Census Bureau, 2012-16). Caucasian children with private insurance were the largest group represented for race and insurance, which was also similar to the sample in the Boss, Smith and Ishman study (Table 4.5). Overall, the largest source of insurance for the project population was Medicaid, with over half (54.3%) stating this was the source of their child’s insurance (Table 4.6). No families identified had no source of insurance for the child being seen, although one family was lacking insurance for a non-study child cared for by a guardian. Data on children and sources of insurance from the Kaiser Foundation from a 2016 report (The Henry J. Kaiser Family Foundation [KFF], 2016) show that in the State of Ohio 41% of children are on Medicaid and 49% are insured by employer sponsored insurance programs. Although the data for employer sponsored insurance for the sample of this project (42.9%) was similar to the Kaiser report, the Medicaid population was higher (54.3%). Discussions with leadership at CCHMC, confirmed that the percentage of 54.3% Medicaid population in the project population is comparable to the overall population seen at CCHMC outpatient clinics.
Table 4.4

**Distribution of Sample by Race**

<table>
<thead>
<tr>
<th>Race</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
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<td>White</td>
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<td>54.3</td>
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<td>AA</td>
<td>10</td>
<td>28.6</td>
<td>28.6</td>
<td>82.9</td>
</tr>
<tr>
<td>Biracial</td>
<td>5</td>
<td>14.3</td>
<td>14.3</td>
<td>97.1</td>
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<tr>
<td>Arabic</td>
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<td>2.9</td>
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</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100.0</td>
<td>100.0</td>
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</tr>
</tbody>
</table>

Table 4.5

**Distribution of Sample by Race and Insurance**

Table 4.6

**Type of Insurance**

<table>
<thead>
<tr>
<th>Insurance</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
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<tbody>
<tr>
<td>Valid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>19</td>
<td>54.3</td>
<td>54.3</td>
<td>54.3</td>
</tr>
<tr>
<td>private through work</td>
<td>15</td>
<td>42.9</td>
<td>42.9</td>
<td>97.1</td>
</tr>
<tr>
<td>self-purchased</td>
<td>1</td>
<td>2.9</td>
<td>2.9</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
In studies reported in literature on the use of the PAT, mothers were the predominant completer of the tool (Barrera et al., 2014, Melissa et al., 2009, Hearps et al., 2014). This was also the case in the sample of this project, with 31 of the 35 of the PAT completed by mothers, two by fathers and two by legal guardians. Overall, 65.7% of those completing the tool had not completed a college or trade school education (Table 4.7). This percentage is similar to that reported by the US Census Bureau on Hamilton County data, in which 35.6% of the population indicated having a college degree or greater (United States Census Bureau, 2012-16). Having some college or trade school education was the predominant level of education in this project population (28.6%). The predominant marital status of the families utilizing the PAT was married, with slightly over half indicating they were married (Table 4.8). This again is similar to census data for Hamilton County in which 52% of the population report being a married couple.

Table 4.7

*Education of PAT Completer*

<table>
<thead>
<tr>
<th>Education</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
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<td>17.1</td>
<td>17.1</td>
<td>17.1</td>
</tr>
<tr>
<td>Completed HS/GED</td>
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<td>20.0</td>
<td>20.0</td>
<td>37.1</td>
</tr>
<tr>
<td>Some College/trade</td>
<td>10</td>
<td>28.6</td>
<td>28.6</td>
<td>65.7</td>
</tr>
<tr>
<td>Completed college/trade</td>
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<td>20.0</td>
<td>85.7</td>
</tr>
<tr>
<td>Masters or greater</td>
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<td>14.3</td>
<td>14.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
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</table>
### Table 4.8

**Marital Status of PAT Completer**

<table>
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<th>Marital Status</th>
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<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
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<td>Married</td>
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<td>51.4</td>
<td>51.4</td>
</tr>
<tr>
<td>Single</td>
<td>10</td>
<td>28.6</td>
<td>28.6</td>
<td>80.0</td>
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<tr>
<td>Div/Sep</td>
<td>5</td>
<td>14.3</td>
<td>14.3</td>
<td>94.3</td>
</tr>
<tr>
<td>Widowed</td>
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<td>5.7</td>
<td>5.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

**Aim 1: Feasibility of the Use of the PAT**

The CCHMC otolaryngology clinic schedule typically schedules patients in 15-minute increment and one to three patients can be scheduled in each 15-minute slot. In the encounter process of potential tonsillectomy patient, the patient is encouraged to arrive 15 minutes prior to their scheduled appointment. The patient begins in registration, which is followed by an intake history by a RN or medical assistant. The patient is then seen by the ENT provider. If it is deemed that surgery is indicated, the family and patient are educated on the procedure and postsurgical care by an RN. The patient and family complete their visit with a check-out in which co-pays are obtained, and the family schedules follow-up appointments and surgical dates. An analysis of this process was completed by the Otolaryngologic department and is illustrated in the Otolaryngology Flow Model (Appendix D). A lag time of 14:32 minutes was determined to exist between the time in which the medical assistant (MA) or registered nurse (RN) completed the intake assessment and the patient was seen by the ENT provider. Feasibility for this DNP project was determined by two factors: if the PAT could be completed by the parents in 14 minutes, or less and if by observation, whether flow in real time was impacted or would be impacted when PAT was completed during this lag time.
Since there was a limited time frame to complete the tool for it to be feasible in the visit process, the length of time for PAT completion was an important factor. Therefore, the time required for the parent/legal guardian to complete the tool was measured and documented based on time of start to time of completion of the PAT, using a stopwatch to measure time. Thirty-two of the parents/legal guardians completed the tool utilizing the web-based version without assistance. Three of the participants required assistance with the tool due to their concerns of the ability to use technology or limited reading skills.

Kazak, Schneider, Didonato and Pai (2015) reported a range of five to ten minutes to complete the PAT. The PAT completion range for this project was five minutes and 17 seconds to over 15 minutes. The mean and median amount of time needed to complete the tool was between nine and ten minutes. Feasibility determination for this project was participants’ completion of the PAT within a ten-minute time frame which Kazak, et.al (2105) identified as the time needed for completion. Only 60% of the DNP project participants completed the PAT in under ten minutes. Three of the five participants who required more than 15 minutes completing the tool, were those needing to complete the tool on paper or by having the DNP read the questions to them. Other impacts on time of completion were interruptions by the patient or patient’s sibling, and the participants asking for clarification on questions or commenting about questions on the tool. Other than the three participants requesting assistance and identifying need, it is difficult to determine the impact that literacy had on the time needed to complete the tool.
Table 4.10

*Time to complete PAT*

<table>
<thead>
<tr>
<th>Time in minutes</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>2.9</td>
<td>2.9</td>
</tr>
<tr>
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<td>2.9</td>
<td>2.9</td>
<td>5.7</td>
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<td>7-7:59</td>
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<td>20.0</td>
<td>25.7</td>
</tr>
<tr>
<td>8-8:59</td>
<td>4</td>
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<td>11.4</td>
<td>37.1</td>
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<tr>
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<td>14.3</td>
<td>14.3</td>
<td>74.3</td>
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<td>5.7</td>
<td>5.7</td>
<td>80.0</td>
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<td>2.9</td>
<td>82.9</td>
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<td>2.9</td>
<td>2.9</td>
<td>85.7</td>
</tr>
<tr>
<td>15 or &gt;</td>
<td>5</td>
<td>14.3</td>
<td>14.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

During this project attempts were made to not adversely clinic impact flow. If it was determined that completion of the tool would impact clinic flow, the completion of the tool was delayed. Typically, this delay occurred prior to check-out. Situations that were deemed as impacting flow were if the ENT physician was delayed in seeing the patient due to completion of the tool, or when the tool was not completed during the designated time frame allotted in the process. Based on the data, 51.4% of the time, flow would have been or was negatively impacted by completing the tool during the defined project time frame.

Many factors contributed to this impact on flow and it became apparent that within the process the “lag time” between intake completion to the start of the ENT provider visit had a wide range. The time of appointment was one factor impacting the “lag time”. The ENT provider’s early appointments in a clinic session had very little lag time, with providers often being ready to see patients as soon as intake was completed. Although, families were encouraged to arrive 15 minutes early, there was much variance in arrival times, with some
arriving early and others arriving late. This resulted in a difference between times of appointments and patient availability, which led to inconsistency in number of patients available. The number of rooms available for use during a clinic session also impacted flow, as well as number of RNs or medical assistants available to see patients. Finally, the types of patients scheduled also had a bearing on flow. Patients needing additional testing or procedures in addition to the history and exam by the ENT provider, could adversely impact flow. Overall, the availability of having 14.32 minutes of lag time to complete the PAT with families was not consistent. There was much variance in this time because of many impacting factors, including those that were unpredictable.

**Aim 2: Psychosocial Risk Identification with the PAT**

Levels of risk based on PAT completion on various studies have shown a range in each level. In a study evaluating the results of various studies utilizing the PAT (Kazak, Schneider, Didonato, & Pai, 2015), percentages of ranges were reported from 14 population groups. Ranges in the Universal Category were from a low of 40% in an organ transplant population to a high or 76% in a population of inflammatory bowel disease. Among all users reporting, the average was 55%. The range for the Targeted Category of risk was 19-49%, with an average of 34% and for the Clinical Category of risk ranged from 3-18%, with an average of 11%. All populations included children with chronic disease, and with cancer in ten out of the fourteen groupings. For this DNP study population, 68.6% of the study participants fell in the Universal Category, 28.6% in the Targeted Category and 2.9% in the Clinical Category (Table 4.9 and 4.10). Although the Universal and Targeted Category ranges were similar to ranges reported in previous study, the Clinical range was lower in comparison to previous studies.
Table 4.9 and 4.10

*Percentages and Frequencies of Stratification*

<table>
<thead>
<tr>
<th>Stratification</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal</td>
<td>24</td>
<td>68.6</td>
<td>68.6</td>
<td>68.6</td>
</tr>
<tr>
<td>Targeted</td>
<td>10</td>
<td>28.6</td>
<td>28.6</td>
<td>97.1</td>
</tr>
<tr>
<td>Clinical</td>
<td>1</td>
<td>2.9</td>
<td>2.9</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Prior to the initiation of this DNP project, psychosocial risk was determined to exist if the information was included in the patient’s referral or if the patient was identified as requiring additional psychosocial resources utilizing the current psychosocial risk assessment questionnaire (Appendix E) based on EHR documentation by the nurse or medical assistants. With the use of the PAT, identification of risk was determined to exist if an overall score resulted in a stratification to the Targeted or Clinical Category. For the study population, only two of the 35 participants were identified as having risk by the current practice, and 11 participants of the 35 were identified at risk by the PAT. Surprisingly, no cases were identified by both the PAT and
psychosocial risk assessment questionnaire, though 22 cases were identified as having no risk by both the PAT and the current practice (Table 4.11).

Table 11

_Crosstabulation of Risk by Current Practice versus PAT_

<table>
<thead>
<tr>
<th>Risk ID by current practice</th>
<th>PAT risk</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>yes</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>no</td>
<td>11</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>24</td>
</tr>
</tbody>
</table>

Since these data were from a paired sample of nominal data with an _n_ of 35, nonparametric statistics that test the difference in proportions for paired samples are applicable for this study. A McNemar’s test was determined to be appropriate for use in this data sample. The accepted level of significance for the data analysis is .05. A power analysis was done, and its was determined, prior to initiation of the study that a minimum _n_ of 35 was required. This was the number of participants in the study. Data were analysed utilizing IBM SPSS (2012). The differences in proportions of the paired samples were determined to be statistically significant utilizing the McNemar’s nonparametric test for difference in proportions at a level of significance of _p_ < 0.05, with _p_ = 0.022 (Table 4.12).

Table 4.12

_McNemar Results for Differences in Proportion between Current Practice and PAT_

<table>
<thead>
<tr>
<th>Value</th>
<th>Exact Sig. (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>McNemar Test</td>
<td>.022^a</td>
</tr>
<tr>
<td>N of Valid Cases</td>
<td>35</td>
</tr>
</tbody>
</table>

^a. Binomial distribution used.
There were plans for this project to evaluate the internal consistency of the PAT score with this population, but based on the time limitations of this study, acquiring the number of needed participants to evaluate this measure was unobtainable. Evaluation of this measure by the PAT’s authors on the total score, showed internal consistency was strong with alpha = 0.81. Six of the seven categories have an alpha coefficient of .60 or above, with the only subscale below .60, being the caregiver belief subscales. The authors opted to retain the four questions regarding the caregiver beliefs because of the need to assess cancer related caregiver beliefs, the original population for the tool (Pai et al., 2008).

A recent study by Woods & Ostrowski-Delahanty (2017), evaluating the use of the PAT with families of children with headaches, also found an overall alpha coefficient of .80 and six of the seven subscales in the moderate to high internal consistency. Again, the exception was the caregiver belief subscale. This population is more comparable to this DNP project population than studies evaluating use of the PAT in families with children with significant chronic illnesses. Since the PAT measures the psychosocial risks that families bring with them, and the study evaluating its use with children with headaches had comparable internal consistency to childhood cancer populations, there is reasonable probability that if internal consistency was measured in this DNP project’s population, it would be similar to other populations.
Chapter 5

Discussion and Conclusions

The focus of this chapter will be an interpretation of the results of the PAT in relation to the aims of the project, the feasibility of the use of the PAT during a clinic visit and improvement in identification of risk. These sections will provide insight into the project and provide suggestions for continuation or adaptations to the PAT’s use with the project population. This chapter will also discuss any limitations. In addition, applications to future settings and future studies and projects will be discussed. Alignment with organization and considerations to public policy issues will be presented in this section.

Feasibility of Use of the PAT

Feasibility of using the PAT was based on whether the tool could easily be completed by parents via a web-based platform without adversely impacting the flow of the ENT outpatient clinic. ENT leadership had identified a time break identified of 14 minutes and 32 seconds between the time of intake and provider exam by process mapping. This was a period in which the PAT could be administered so flow would not be impacted. The PAT’s authors had identified that the tool could be completed in five to ten minutes (Kazak et al., 2015). Feasibility, therefore included two factors; the PAT completion in five to ten minutes and no impact to flow when administered during the time selected.

Unfortunately, the lag between intake and physician exam was highly variable due to a number factors. Research assessing factors impacting flow has identified many variables associated with flow and productivity of outpatient clinics (Chand, Moskowitz, Morris, & Willis, 2009). These include variability in arrival time, such as late or early arrivals resulting in clustering of patients. Variability in registration times were especially true for patients who were
non-English speaking, new patients and patients with incorrect or missing information.

Variability of time spent with the patient by providers either due to missing information such as test results, language barriers, or complexity or needs of the patient also impacted flow (Chand, Moskowitz, Morris, & Willis, 2009).

Patient no shows were also a factor impacting outpatient clinic flow. One academic pediatric otolaryngologic practice reported rates of no shows between 15-19%. Factors increasing the odds of no shows include lower median income, morning appointments and public insurance (Zhen, Miriam, Heather, & Pamela, 2017). For this project, charts of potential patients were assessed within a few days prior to sessions, with a total of 66 patients identified as potential participants. Of these potential participants, 13 of the 66 (19.7%) were either no shows or late cancellations. Schedules often account for the probability of no shows, but there are no predictive measures to determine when or the extent of patients not showing daily.

Finally, earlier appointments in a clinic session had very little wait time available between the nurse intake and the physician visit, and often the physician was waiting on the nurse. All these factors impacted the availability of the time for tool completion, and as a result over half (51.4%) of the time, completion of the PAT during this time would have resulted in delays in the physician seeing the patient.

The participant’s time for completion for of the PAT was also a factor in consideration for feasibility with a goal of completion between 5-10 minutes. Only 60% of the participants were able to complete the PAT within this time frame, and 14.3 % took greater than 15 minutes to complete the tool. Three of the five participants who took over 15 minutes to complete the PAT required assistance in reading or in utilizing the technology involved.
Literacy can be an issue with any parent or guardian completing tools. Although the PAT was written at a fourth grade and was available in both English and Spanish versions (Kazak et al., 2015), according to data from the National Center of Education Statistics, 9% of Ohioans and 12% of Kentuckians lack basic prose literacy skills (National Center of Education Statistics, 2003). Basic prose literacy skills are considered the lowest level of literacy and are defined as being “unable to read and understand written text to being able to only locate easily identified information in short prose commonplace text in English” (National Center of Education Statistics, 2003). Of these data only 2% were due to language barrier cases. Factors impacting literacy include educational attainment, being foreign born or for migrants, continuing to speak their native language, and parental education level (Organization for Economic Cooperation and Development [OECD], 2016).

In addition to literacy, basic computer literacy is required to complete web-based tools, such as the PAT. In a study completed by the Organization for Economic Cooperation and Development (OECD) on computer literacy across predominantly affluent countries, one in seven adults (14.2%) lacked basic computer literacy. Those lacking skills had lower levels of education, had semi-skilled blue-collar or elementary occupations, and never to almost never used computer skills in everyday life (OECD, 2016). The Pew Research Center has been evaluating internet access in America over the last 15 years and have found that older adults lag behind younger adults, those with lower incomes and less than a high school education has lower rates of usage, is slightly lower in Hispanics and African Americans but increasing and lower among those living in rural areas. Overall, 84% of Americans reported utilizing the internet in 2015 data (Pew Research Center, 2015). Of those with less than a high school education, 66% reported utilizing the internet. Only 74% of people with annual incomes less than $30K reported
utilizing the internet. Asian and English-speaking participants had the highest rate of internet use (97%) while African Americans had the lowest at 78%.

In discussion with the otolaryngology providers, the time commitment to complete the tool was significant in terms to impacting flow. One solution proposed by the otolaryngology providers to address the time barriers of using the tool during the clinic visit, was the use of a web-based link through the patient portal via the internet prior to the visit. The DNP student’s concern of utilizing this as the only methodology for completion of the PAT were poor literacy and lack of internet skills associated with those of ethnic backgrounds, lower education and lower incomes, which also are all factors associated with increased risk for poorer surgical outcomes. Patient health portals are a technology that is used to improve health outcomes, but there is mixed data on its usage among low income and minority patients. A research study has shown that patients from minority populations have a greater risk of never using the internet, with a concern that increasing its usage may increase disparities further (Sarkar et al., 2011). Although studies have acknowledged lower rates of usage among disadvantaged populations, other researchers have felt these issues were less important than the overall advantages of the patient portal and outweighed the variance in lack of adoption (Anker et al., 2011).

One solution to this issue was to have a two-fold strategy in which links were sent to complete the PAT through the patient portal, and those patients with non-completions would be asked to complete the PAT prior to clinic visit’s end. In discussion with the one of the authors of the tool, who is employed by CCHMC, there are currently plans to develop this process for patient populations. In this process, a link will be sent for PAT completion through a patient portal, and when completed will upload to the current EHR. Patients who do not have a completed PAT in their chart would be flagged in the EHR, so providers could obtain this
information at the next visit. This may be one method of increasing feasibility of use but would still require a provider to review and act on the information garnered.

**Improvement in Risk Identification with PAT Usage**

The PAT shows promise in improving information regarding psychosocial risk factors in families. The population studied in this project had similar stratifications as other populations, except this population was slightly below the ranges reported for the highest level of risk, the Clinical Category. Samples included in previous study ranges were predominantly oncology patients or populations with long term chronic illness, such as congenital heart disease, diabetes, organ transplant and sickle cell disease (Kazak et al., 2015). Patient/provider relationships were longer term, and the patient population had more ongoing contact with their providers. This resulted in more opportunities to administer the PAT to patients with previously cancelled visits. For this DNP project, there was a one-time opportunity to administer the PAT; therefore, there may be limitations that this project is missing a segment of potential tonsillectomy population, those who never made it to the clinic. For this project, 66 potential participants were identified as potential participants but 13 (19.7%) of those potential participants either had late cancellations or did not show for appointments.

In a study evaluating factors affecting patient cancellations and no shows in outpatient clinics, researchers found that only 7% of patients represent 43% of cancellations and no-shows (John et al., 2014). The concern is, therefore, that this population may have greater psychosocial risk accounting for their chronic missed appointments. Inclusion of families who cancelled or did not show for appointments in the population for this DNP project, may have impacted the rates of stratification such that the Clinical Category was more aligned with the results of other
studies. One area of study that would be beneficial to explore is the administration of the PAT in the population of families with chronic cancellations.

Despite this limitation in this project, there was much information garnered from the use of the PAT regarding this tonsillectomy population and risk. For example, having public insurance is noted to be more representative of families in the Targeted or Clinical Level. Although more families with private or self-purchased insurance were in the Universal range, close to half of the families reporting public insurance were also stratified in this range (Table 5.1). Public insurance is considered a factor associated with risk but may not be the sole factor of predicting psychosocial risk.

Table 5.1

Stratification and Source of Insurance
Other factors such as marital status, education and race were also evaluated for their impact regarding stratification. Those married, which were 51.4% of the population, were less represented in the targeted or clinical range (Table 5.2). Level of education, frequently identified as a factor for psychosocial risk, was not as clear in this population. Families with college or trade school educations were found in the targeted range, and families with lack of a high school education in the universal range (Table 5.3). Only families identifying as biracial represented more in the targeted or clinical range; however, there was no obvious trends noted (Table 5.4), again supporting that no sole factor showed a trend for risk.

Table 5.2

<table>
<thead>
<tr>
<th>Stratification by marital status</th>
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</thead>
</table>

Table 5.2

<table>
<thead>
<tr>
<th>Marital status</th>
<th>Universal</th>
<th>Targeted</th>
<th>Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>married</td>
<td>25</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>single</td>
<td>10</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Sep/Div</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Widowed</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Table 5.3

*Stratification by Level of Education*

![Stratification by Level of Education](chart1.png)

Table 5.4

*Stratification by Race*

![Stratification by Race](chart2.png)
For this DNP project, overall scores that stratified in the Targeted or Clinical range were considered to define risk. The PAT also has seven sub-scale score categories. They included: Family structure/resources, Social/family support, Child (patient) problems, Sibling problems, Caregiver problems, Caregiver stress reactions, and Caregiver beliefs. Each sub-scale score can also be evaluated for risk; a score of 0.50 or higher in any of the sub-scale scores may suggest the family is at elevated risk despite their overall scores being low.

**Limitations of the Project**

The results on the PAT are reliant on parental truthfulness regarding risk. Although surveys and questionnaires are a common methodology for obtaining information, there are limitations regarding the reliability of the information. In a review of studies of surveys with sensitive information, Tourangeau & Yan (2007) found that misrepresenting is very common in surveys with information of this type. This is believed to be either to avoid embarrassment or repercussions from third parties. The PAT contains many questions of the sensitive nature and therefore, the risk of misrepresenting is a limitation of this project.

Although the demographics of the population were similar to larger studies involving pediatric tonsillectomy patients, the population of no-shows and late cancellation families was missing from the data sample. Most studies evaluating risks for cancellation are based on factors in retrospective data sets, so little is known regarding individual factors that may impact missed appointment, and are not predictive (Hoffman, Matlow, Shroff, & Cohen, 2015; Miller, Chae, Peterson, & Ko, 2015). For example, public insurance is frequently cited as a factor associated with missed appointments, but over 50% of the DNP project population was Medicaid. Using Medicaid alone as a factor for the risk of late cancellations or no-shows would not be cost effective when planning intervention strategies. Other limitations in this DNP project are that it...
included only English-speaking participants, and there may also have been potential participants decline involvement if illiterate.

**PAT Results and Implications to Public Policies**

The most frequent sub-scale range with risk was in child problems, with 25.7% of the participants identifying issues in this category. Child problems included identified medical or mental health diagnosis, symptoms or characteristics suggestive of behavioural health problems or mental health disorders such as ADHD, depression or anxiety, exposure to violence or crime, or at-risk behaviour. According to the Child Mind Institute, 20% of children in the United States meet criteria for a mental health disorder (Child Mind Institute, 2016). Despite these high rates of mental health issues in children, not a single state has adequate supply of child psychiatrists and forty-three states have severe shortages (Tyler, Hulkower, & Kaminski, 2017).

From a population health perspective, addressing the lack of services is crucial in supporting the health of families and children. According to the National Alliance on Mental Illness (National Alliance on Mental Illness [NAMI], 2018) the average delay between onset of mental health symptoms to intervention is eight to ten years. The consequences of this delay are significant in that 37% of students with a mental health condition who are 14 years and older, drop out of school, and 70% of youth in state and local juvenile justice facilities have a mental illness (NAMI, 2018).

It is estimated that 31% of American women and 17% of men have a mental health condition that has a 12-month prevalence (Costea, 2011). Of those percentages, 65% are mothers and 52% are fathers. Rates of mental health conditions in children who have a parent with mental illness range between 30-50%. This trend was apparent in this DNP project. In children reported to have symptoms of potential anxiety, 60% of the time, a caregiver also
reported symptoms of potential anxiety. The participants also reported that 11% of families had a family member in jail, 5.7% had someone suicidal, and 8.6% of the caregivers experienced violence or witnessed a crime.

Globally, mental health conditions have the highest percentage for life long disability in comparison with other causes (Insel, 2011). It is estimated that 50% of the global economic burden for non-communicable disease, will be due to mental illness by 2030. Insel (2011) also noted this may be an under estimation in terms of cost, since individuals with mental health disorders also have higher rates of other diseases such as cardiovascular, diabetes and respiratory conditions (Insel, 2011) Clearly, addressing this issue is not only a socio-ethical one, but economic one as well.

One other area of concern that has policy implications is with the number of families living on the financial edge. In this DNP project, 34.3% of families completing the PAT indicated that they were experiencing financial difficulties. They were unable to pay for basic expenses such as phone/utility bills, rent/mortgage, food, car payments, insurance or upkeep or medical expenses. Nationally, in families with children under 18 years of age, 17.4% live below the poverty level, 70% of which are children of color (United States Census Bureau, 2016). In households, with female heads of household, 39.7% live in poverty (United States Census Bureau, 2016). The Children’s Defense fund reports that about three million children live on less than two dollars/day. In addition, in families in which a person was working full time at minimum wage, none would be able to afford a two-bedroom rental unit in any state or the District of Columbia and also have money for food, utilities and other necessities (Children’s Defense Fund [CDF], 2017).
According the Bureau of Labor Statistics, access to paid vacation and sick leave in civilian and private industry for all employees working full time was 87-91% for vacation time and between 81-84% for paid sick time. For those working part-time or in the lowest 25% of average wage categories, this percentage decreased significantly. Only 35-36% of part-time employees received paid vacation and sick time. Those in the lowest 25% of average wage, regardless of employment status, received paid vacation 50-52% of the time and paid sick time only 43-46% of the time (Bureau of Labor Statistics, 2017). Under the Family Medical Leave Act (FMLA), employees have the right to up to 12 weeks unpaid job-protected leave per year to deal with personal or family medical issues. FMLA only exists though, if your employer has 50 or more employees in 75-mile radius, an employment of at least one year and have worked 1250 hours in that year (Ohio State Bar Association, 2016). For those not covered or who must take the leave as unpaid, a medical need within the family requiring time from work would lead to greater financial pressures.

The United States is the only developed country that does not guarantee paid leave for some portion of parental leave (Povich, Roberts, & Mather, 2014). Lack of income in an already financial stressed family, may lead to poor health outcomes. The Human Rights Watch (2011) looked at short or unpaid leave after childbirth and reported lower rates of immunizations and health care visits, higher infant mortality, lower rates of breastfeeding, and higher rates of maternal depression among those with short or unpaid leave. Legislation to support improvements include not only expanded access to insurance, such as the Child’s Health Insurance Program, but also minimum wage and paid leave policies.
Alignment with Organization Strategic Plan

This DNP project is in alignment with the CCHMC 2020 strategic plan (Cincinnati Children’s Hospital Medical Center [CCHMC], 1999-2017) in at least two strategic priorities, care and community. The care priority included the components of working with families and providing individualized care. By understanding the struggles that families are facing in their lives, providers can help with resources that have the potential to improve outcomes. The use of the PAT increased the amount of information regarding psychosocial risk over the current assessment practice. Although, there is limited research of its use regarding outcomes, there is promising research that showed with its use, families obtained more resources leading to better outcomes in parent anxiety and child pain (Barrera et al., 2014).

The strategic plan also prioritizes the facet of community. Within this priority is the goal to address social determinants of health. Information from this project regarding families and the stressors they are facing, adds knowledge to discussions on interventions. Clearly, public policy issues that impact children’s health from the social domain, such as minimum wage and unpaid leave and lack of mental health resources, are advocacy issues the institution can address.

This project is also in alignment with the goals of the National Quality Forum, which impacts care priorities for Medicaid providers and hospitals. One component the National Quality Forum provides is quality measures to evaluate care across states for children enrolled in Medicaid and the CHIP programs (National Quality Forum, 2017). The National Quality Forum’s expert panel has recommended that data are collected about social needs that impact health, and the development of linkages between providers and community (National Quality Forum, 2018). The data provided by this project provide information regarding those needs, and adds to the literature that could influence interventions.
Future Projects/Research and Application to Other Settings

There are many potential improvement projects and research studies in which the PAT could be utilized. Although there are several studies evaluating the use of the PAT with different pediatric populations, mostly chronic care, there are very few studies evaluating the impact of utilizing that information to improve outcomes. There were also no studies found that correlated the results of the PAT stratifications or subscale categories with poor outcomes. When discussing the results of this DNP project with the team members for this project, a follow-up study was suggested to compare PAT results with patient cancellations and surgical outcomes, including pain.

The one subscale category of the PAT that had lower internal consistency was the caregiver belief subscale (Pai et al., 2008). In a study evaluating children with chronic headaches the researchers found this to be present and problematic for that subscale, but not the overall scoring of the tool (Woods & Ostrowski-Delahanty, 2017). The PAT was initially developed for screening in families with cancer, and therefore, caregiver belief subscales were more geared towards that population. Although internal consistency was not evaluated for this DNP project, the questions asked regarding caregiver beliefs did not seem to fit the project population. For example, one statement rated by the family in this subscale was the belief they “would beat” the medical situation. This would be applicable to a family experiencing a child with cancer, but less so with a child having a tonsillectomy. The PAT does allow for adaptations of the tool with permission from the authors. Adaptations of the PAT to address other populations is one area for improvement of its use but would require studies to evaluate the psychometrics of the adapted tool. There were also revisions that could be made to the technology supporting the web-based tool, and this was shared with the authors.
Although there are studies evaluating factors associated with patients who cancel or miss appointments, most of these data are from large categorical retrospective studies, and include factors such as lower income or public insurance (Hoffman, Matlow, Shroff, & Cohen, 2015; Miller, Chae, Peterson, & Ko, 2015; Smilie, Yong, Harris, Wynne, & Russell, 2015; Mackie, Rempel, Rankin, Nicholas, & Magill-Evans, 2012). These factors alone are not predictive of risk (Kansagara et al., 2011) and therefore, further research is needed in this area. For this project close to 20% of the potential participants were either no shows or late cancellations. Therefore, there is a degree of selection bias in this project, because the population that participated included only those who came for their clinic visit and agreed to participate. What is not known is whether the PAT results of patients who cancelled or were a no show would be different from the sample population and whether their information would provide input into additional factors of risk. A suggested future study is utilizing the PAT with families who cancel and are no shows.

The tool could be applicable in other settings. For example, one surgical peer recommended its use for patients emergently admitted on their service. In the past they had high no show follow-up appointment rates, and as a result their social worker had to follow-up with all of these patients. The PAT could be utilized to identify patients in need of potential follow-up interventions to improve resource utilization. The PAT could also be used pre- surgically or on admission for discharge planning needs. With adaptations to the tool, there may also be the potential for its use in education systems to identify children and families at risk, and provide additional interventions.

Projects improving health information exchange are needed to improve care with regards to high risk patients. The Center for Medicare and Medicaid Services (CMS) in 2011 developed
incentive programs to assist health care professionals and hospitals in the adoption, implementation and meaningful use of EHR (CMS, 2016). Stage 2 of the CMS incentive program is predominantly focused on health information exchange, in which a summary of care record is exchanged during transitions in care or referrals between health care providers. Health information exchange (HIE) has the potential to improve quality in care, make care more efficient and less costly, and lead to improving overall public health (Joshua, Thomas, & Rainu, 2013). Coordination and collaboration have significant relevance for at risk populations. A vision for the utilization of the electronic health information is one in which all collaborators work together to identify and use relevant information, contact and intervene, use and monitored care so patient issues are not missed or dropped. (Rudin & Bates, 2014).

The overarching issue that needs to be addressed in the use of the PAT is resource availability. The utilization of tools such as the PAT, and identification of needs in families, is like opening Pandora’s box. Gathering information about risk and its impact on outcomes, means there must be interventions and provision of resources for families. However, improvements will only occur if resources are available, social determinants altered and policies changed. These factors will not occur with a mere study or project but need interprofessional teams to bridge the gap between providers and community, including community leadership. Models of intervention, such as the Collective Impact Model (Kania & Kramer, 2011), may be helpful to impact change. Collective impact is a model of bringing organizations together in a structured way to achieve social change. Collective impact consists of five key elements: a common agenda, shared measurement, mutually reinforcing activities, continuous communication and backbone support organizations. Improvement strategies for psychosocial
risk factors are complex and require a team model and investment by leadership in such endeavors.

**Importance of DNP Leadership**

Nursing leadership is crucial in addressing health care disparities, and to be full partners in redesigning health care. Full partnership entails not only leadership and competency within the profession, but also in the collaboration with other professions (IOM, 2010). The DNP is well positioned to be a full partner as an upper level decision maker for healthcare policy development and strategic planning to address health disparities for families and children living in poverty. The DNP education encompasses a system-wide approach and macroscopic view of health care that prepares the DNP for leadership roles. Current policy makers rarely have clinical experience, and risk developing policies that do not target the needs of a population. The DNP can bridge this gap between the clinical world and policy development and identify and evaluate the implications in state and national policies (Lathrop & Hodniki, 2014).

Nursing has a rich history of being in the forefront of healthcare reform. Florence Nightingale published in the 1850’s *Notes on Matters Affecting the Health, Efficiency and Hospital Administration of the British Army*. This publication resulted in reconstruction of barracks and the establishment of a military medical college (Ellis, 2008). Lillian Wald is recognized as creating public health nursing in 1893. The charge of the public health nurse was to visit the homes of the poor who were sick since illness was part of one’s social and economic context (Buhler-Wilkerson, 1993). In addition to public health nursing, Wald also advocated for insurance coverage for home-based care, established a national public health nursing service and started a school of nursing in the US (Buhler-Wilkerson, 1993). Historically, nursing has repeatedly shown its ability to establish comprehensive interventions to address population-based
health issues. It is evident that nursing input is imperative in addressing current health care reform (IOM, 2010).

Despite a historical background of success and the recognized need for nurse leadership by the IOM, nurses are absent at the highest decision making and policy development levels of health care services (Khoury, Blizzard, Moore, & Hassmiller, 2011). When looking at nursing leadership, American opinion leaders have felt that nurses were not perceived to be important healthcare decision makers compared with physicians. Additionally, physicians, not nurses, have been seen as revenue generators, whereas nursing’s focus should be on acute care, and not on prevention and health maintenance. Many see the nurse’s role as delivering bedside care and have not wanted to divert attention from this. It was felt that nurses did not have the skill sets for leadership without more education (Khoury et al., 2011). The DNP prepared nurse is educationally prepared to shift this perspective and should be at the helm of upper level decision making and strategic planning in improving the health of populations (Barry & Winter, 2015).

The DNP is on an equal plane with other practice doctorates, such as the MD and PharmD. DNP education is geared towards producing “practice scholars in such areas as clinical practice, leadership, quality improvement, and health policy” (IOM, 2010, p. 194). Health care systems are complex in nature and therefore, need interprofessional collaboration and communication to construct effective teams that are capable of implementing improvements and change (IOM, 2001).

Florence Nightingale defined nursing as an art, and as leaders, DNPs can infuse the art of nursing in leadership. The profession of nursing’s caring and science is needed in macro – level decision making to ensure that decisions will be holistic, ethical and always focused on the health of populations. The art of nursing includes interactions in which one is truly listened to,
EVALUATION OF THE USE OF THE PAT

professional values that are based on love, respect and ethical considerations, and the creative and innovative ways in which nursing knowledge is transferred to the patient (Duran & Cetinkaya-Uslosoy, 2015). Successful leadership is dependent on one’s core qualities. Characteristics of successful leaders are those that tap into a higher purpose, forge a shared direction, foster productive relationships, unleash human potential, seize on new opportunities and drive high performance (Rosen & Ross, 2014). DNP\'s not only have the knowledge and art of the nursing profession as a base but advanced education that elevates them as leaders.

Florence Nightingale was depicted as “the lady with the lamp”. The lamp has symbolized many things such as divinity, wisdom, intellect, and good works but can also represent a gateway to another plane or illumination of the spirit. DNP\'s are well positioned to carry that lamp forward for a new generation. It is not appropriate that in large health care systems, nurses are represented in single digit percentages as voting board members. It is unacceptable that American opinion leaders feel that nurses are not sufficiently skilled to have representation in upper level decision making (Khoury et al., 2011). DNP\'s can shift those opinions in all levels of systems, whether micro, meso or macro. To meet these population health needs, DNP\'s must exhibit the leadership for which they have been educated. It is time for DNP\'s to be upper level decision makers as advocates, health policy generators and strategic planners to impact socioeconomic issues impacting health in families and children. It is time for DNP\'s to carry that lamp forward and to lead the charge in reducing health disparities in low income populations.

Research and quality improvement projects to improve knowledge regarding factors impacting health outcomes in at risk populations are a starting point, but clearly more interventions are needed. Bronfenbrenner’s (1979, p. 8) statement that “basic science needs
public policy even more than public policy needs basic science” rings true in regards to this project. Bronfenbrenner’s Ecological Model of Human Development speaks to how the various layers of a system and their relationship and influences can have direct impact on a family, and ultimately the child (Bronfenbrenner, 1979). This is poignantly seen in the lack of legislation guaranteeing paid sick and vacation time.

Leininger’s Cultural Care Diversity and Universality Theory with its viewpoint that nursing decisions and actions should be guided by knowledge of meanings and practices derived from world views, social structure factors, cultural values, language and environmental context (Leininger, 1988) also is supported by this DNP project. More knowledge is needed regarding psychosocial risk factors, beyond general categories of big data studies, in order to intervene.

Finally, it is clear that nursing’s involvement is needed in order to improve outcomes for patients at high psychosocial risk. Nurses represent the largest workforce in healthcare and are the professionals who spend the most time with health care consumers and therefore need to have leadership roles in healthcare transformation (Shalala & Vladeck, 2011). The nursing profession is well positioned to implement wide reaching nursing initiatives and programs to decrease gaps in health care. Research has suggested that the quality of care is dependent on nurses, access to care is improved with the use of RNs and APRNs. There is increasing evidence showing an increase in health care value through the presence and actions of nurses (Institute of Medicine [IOM], 2010).
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Appendices

Appendix A. Pediatric Psychosocial Preventive Health Model

![Pediatric Psychosocial Preventive Health Model](imageURL)
Appendix B. Bronfenbrenner’s Ecological Model of Human Development

(Bronfenbrenner, 1979)
Appendix C. Leininger’s Sunrise Enabler

(Leininger & McFarland, 2006, p. 25)
Appendix D Otolaryngology Flow Model
Appendix E. Current Psychosocial Assessment Questions for Otolaryngology Clinic

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**Psychosocial Assessment**

**Interpreter Services**

Language Services Documentation Tool (LSDT)

- English Used Effectively By Patient (as jointly determined by the provider and patient with no formal waiver of rights)
  - Face to Face Interpreter
  - Videoconference Interpreter
  - Bilingual Employee Interpreter (Tested and Trained)

- Provider/Staff Proficient in Patient’s Language (Not English)
  - Face to Face Interpreter
  - Videoconference Interpreter
  - Bilingual Employee Interpreter (Tested and Trained)

- Declined Interpreter Services (Rights Informed but Waived)
  - Friend or Family Preferred by Patient (Rights Informed but Waived)

- Other (Please Add Comments)

Interpreter ID if must be documented for each interpreter used with the following:

- Face to Face Interpreter
- Videoconference Interpreter
- Bilingual Employee Interpreter (Tested and Trained)
- Provider/Staff Proficient in Patient’s Language (Not English)
- Declined Interpreter Services (Rights Informed but Waived)
- Other (Please Add Comments)
Appendix E. Current Psychosocial Assessment Questions for Otolaryngology Clinic
Appendix F. Parental Information Sheet

CINCINNATI Children’s Hospital Medical Center

PARENTAL INFORMATION SHEET
FOR PARTICIPATION IN A RESEARCH STUDY

Study Title: Evaluation of the Use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients
Principal Investigator: Cynthia S. Pettit MSN, APRN, PNP

Introduction: We are asking you to participate in a study so that we can learn more information about a web-based tool. This web-based tool may help us identify if there is a need to refer patients having surgery with supportive services to help the family with needs they may have. We are evaluating this tool to see if it is something that could be used in the future for patients having surgery.

Why are we doing this study? The tool helps in having the family let us know stressors that a family or child may be experiencing that could have an impact on their health. Some examples of these stressors may be lack of health insurance, concerns about money, lack of transportation, not having someone to help them in the care of their child or having other family members with health issues. It can also include feelings of worry in the child or the parent. We know that all these factors can have an impact on health. Finding tools that would help us in identifying those family and children having these types of stressors, could help us in connecting families with resources at Cincinnati Children’s and the community to help families.

What will happen in this study? This study involves you completing a web-based tool during your visit today. The tool takes about 5-10 minutes to complete. The results of the tool will be shared with you ENT provider today but will not become a part of your permanent medical record.

What are the good or bad things that can happen? There is no compensation for participating in this study. The information gained from this study could help us to provide better care for patients in the future. It could also allow us to help any families identified as needing help prior to the day of surgery. In fact, today if the tool shows that you or your child needs any help, we will get you in touch with our social workers to assist you. The risks associated with this study are minimal and may include feelings of uncomfortableness in sharing information about one’s situation and child. Remember the purpose of this study is to help families with needs and not to judge them. We want to improve your experience at Cincinnati Children’s by helping when we can. Choosing to be in this study does not change your child’s medical care. Your child will receive the same standard care that is provided regardless of participation in this study.

How will information about your child be kept private? Making sure that information about your child remains private is important to us. The only information we will be collecting from this study is the child’s age, race, sex, who completed the tool such as father, mother, or guardian, the time it took to complete and the results of the tool in comparison to what we currently do. We will also be obtaining feedback on the appropriateness of any referrals made based on the tool. The data will still be stored in a secure database. Paper records will be stored in a secure locked area. To use the tool, there is information that must be shared with the tool’s developer. This information is group data and includes many patients screened by race, age and the overall distribution of scores. No individual data will be shared.
What other choices are there? Taking part in this study is your choice. If you choose not to be in the study there will be no change in your child's medical care. Please ask us any questions you have. You may also ask more questions after you decide to participate in the study. You can ask questions at any time.

Who do you call for questions or problems? If you have questions, comments or complaints about this research study, you can contact Cynthia Pettit at 513-636-7422. You may contact the CCHMC Institutional Review Board (513-636-8039) if you would like to talk with someone that is not a part of the research staff for this study.

Use/disclosure of health information for research: We will not be collecting individually identifiable health information in this study. All study participants will be assigned a study number which will link their age, race, sex, time to take the tool, the tool’s results compared to current practice and if referrals were made if they were needed. No other data will be collected.

Will your child’s other medical care be impacted?
If you do not participate, your child’s rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.
Appendix G. Provider Communication Tool

Psychosocial Assessment Tool Results

- **Low Risk/Universal**: The family reports many supportive resources and relatively low psychosocial risk (in number or severity). Any at-risk items are listed below. Recommendation: Universal interventions are recommended, including education about psychosocial impact of diagnosis / treatment, focusing on positive coping strategies and support-seeking among family members when needed.

- **Moderate Risk/Targeted**: The family reports some supportive resources but also some psychosocial risk factors, which may impact illness adjustment or treatment adherence. Specific at-risk items are listed below. Recommendation: Further evaluation or close monitoring may be necessary. Targeted interventions are recommended, focusing on specific family problems, parent / child stress reactions, or parent beliefs that can negatively impact adjustment or adherence.

- **High Risk/Clinical**: The family reports few supportive resources and multiple areas of difficulty that may impede illness adjustment or treatment adherence. Specific areas of difficulty are listed below. Recommendation: Clinical interventions, including mental health evaluation and more intensive family-based psychosocial services may be necessary. A team-based approach may be needed to ensure treatment adherence.

**Sub-Scale Scores**: Listed below are the 8 sub-scales that comprise the total PAT score. A score of 0.50 or higher in any of these areas may suggest the child or family is at elevated risk and warrant targeted intervention, even if the overall risk score is low

**Family Structure / Family Resources:**

**Social / Family Support:**

**Child (Patient) Problems:**

**Sibling Problems:**

**Caregiver Problems:**

**Caregiver Stress Reactions:**

**Caregiver Beliefs:**

**Additional Comments**
Appendix H. Data Collection Worksheet

Individual DATA Collection Worksheet

Date ___________________________________________ Study Number __________________________

MRN # ______________________________ Pt’s Initials ____________

Sex _______ AGE_____________ RACE _____________________

Completed by __________________________________________

Completion Time __________________ Impacted Flow__________

Risk ID by Current Practice________________________

Comments ________________________________________________________________________________

Psychosocial Assessment Tool Results

  o  Low Risk/Universal
  o  Moderate Risk/Targeted:
  o  High Risk/Clinical:

Sub-Scale Scores: Listed below are the 8 sub-scales that comprise the total PAT score. A score of 0.50 or higher in any of these areas may suggest the child or family is at elevated risk and warrant targeted intervention, even if the overall risk score is low

Family Structure / Family Resources:

Social / Family Support:

Child (Patient) Problems:

Sibling Problems:

Caregiver Problems:

Caregiver Stress Reactions:

Caregiver Beliefs:

Referral __________________________ Appropriate________________________

Comments
Appendix I. Application for Use of the PAT

PAT User Application and Agreement

Thank you for your interest in the Psychosocial Assessment Tool (PAT) ©. The PAT is a parent/caregiver report screener of family psychosocial risk. It was originally developed for use with families of children newly diagnosed with cancer. It has subsequently been adapted for use with other pediatric illness groups and is available in English and Spanish.

- **Copyright and Dissemination:** The PAT© is copyrighted by The Center for Pediatric Traumatic Stress (CPTS) and is distributed by the CPTS site at The Nemours Foundation, a Florida not-for-profit corporation (Nemours). It may not be used or modified in any form without prior written permission from CPTS.

- **User Fees:** The annual license fee for PAT use is $350.00. In January of each calendar year, users will be required to pay the license fee. Fees will be prorated for users who initiate PAT use prior to the start of the next calendar year. To begin the payment process, please email psychosocialassessmenttool@nemours.org for directions.

User Agreement:

Please read this agreement carefully. Your signature at the end of this document indicates that you have agreed to comply with the following:

- **Public Distribution of the PAT:** Do not distribute the PAT to anyone outside of your institutional group, division, or department, or place it on a public website without first obtaining CPTS’s written permission, which may be withheld at CPTS’ sole discretion. Please contact psychosocialassessmenttool@nemours.org to obtain permission.

- **Use of the PAT:** For clinical use, the PAT is available in pen/paper and web-based formats (see page 5 for more information on web-based format). You may not convert the PAT to any other paper/pencil, online or web-based administration without prior permission from CPTS. For those institutions wishing to conduct research using the PAT, you may transfer the PAT into REDCap, with prior written permission. Please see page 6 of this application for more information.

- **Contact Information:** Indicate the name and full contact information for the person responsible for overseeing / supervising the use of the PAT at your institution. Please provide updated contact information within thirty (30) days in the event of personnel changes.

- **Quarterly Reports:** Every quarter, you must provide CPTS with aggregate, non-identifying information on the number of families screened, the number of patients by race, gender and age group, and the distribution and range of PAT scores at your site (see pg. 6 for an example). The quarters are as follows: January – March; April – June; July – September; and October – December. We will send you a reminder each quarter.

- **Using the PAT with Non-oncology Pediatric Populations:** While the PAT was designed and validated for use in pediatric oncology, CPTS researchers are also interested in evaluating its applicability to other pediatric populations. Currently, the PAT has been adapted and validated for use with caregivers in the NICU, with caregivers of children with sickle cell disease, with caregivers of children in need of kidney transplant, and with caregivers of children with inflammatory bowel disorder. For clinical purposes, we have a generic version of the validated PAT that you can use with non-oncology populations. If you wish to adapt the PAT to conduct research with patient populations for whom the PAT has not been validated, you must contact CPTS in writing and in advance of such usage. CPTS’ established adaptation guidelines must be followed.
Other Languages / Translation: The PAT is available in English and Spanish. The PAT is being implemented in other languages clinically and CPTS is working with other institutions on additional translations and has established guidelines that must be followed for the process of translating PAT into other languages.
Research use of the PAT: If you plan to use the PAT for research, you must obtain any required institutional approvals prior to use. Please provide CPTS with a brief 1-2 page written summary of your current or proposed research, highlighting the study questions, design, sample, and outcome measures. In addition to the quarterly report, provide CPTS with a brief final report at the end of the study, summarizing your study outcomes and data, including any papers, posters or manuscripts that reported PAT data.

Clinical use of the PAT: If you plan to use the PAT clinically, please provide CPTS with a brief description of your setting and the patient population.

Scientific Publications / Presentations: Please provide an abstract of the article or presentation. We will send you specific language and references you must include when describing the PAT in your manuscript or presentation.

After receiving and reviewing your completed application form, CPTS will communicate with you about any questions and provide permission to use the PAT. CPTS will send you your official copy of the PAT to use, as well as the scoring materials.

Additional Information:

Customization of the PAT: To add your institutional logo to the PAT paper / pencil form, or if you would like to include customized instructions at the end (e.g. who to contact with questions, who to return the PAT form to) please send CPTS a copy of your institutional logo as a .jpg or .gif file and your customized wording. CPTS will supply you with an official copy for your use.

Implementation and Evaluation: We are available to consult with and assist you in conducting research using the PAT and on the process of adapting, translating or implementing the PAT in practice. There is no additional charge for this consultation.

Updates on the PAT: We will provide you updated information on the PAT as it becomes available.

Changes to the PAT: The PAT is a copyrighted measure. You may not modify or change the PAT in any way without prior written permission from CPTS. To obtain written permission, please email psychosocialassessmenttool@nemours.org

Please complete and sign the PAT user application on pages 3 and 4. Web-based PAT users must also complete and sign the agreement on page 5. REDCap PAT users must also complete and sign the agreement on page 6.
The Psychosocial Assessment Tool (PAT) ©

PAT User Application

1. Name and mailing address of hospital/agency where the PAT will be implemented (please include center/department/division):
   Cincinnati Children's Hospital Medical Center
   Department of Anesthesiology
   3333 Burnet Ave
   Cincinnati, OH 45229

2. Name, title and contact information for the person responsible for overseeing the use of the PAT and for providing quarterly reports (please include primary phone, backup phone, and email address)
   Amanda S. Pat Read, AGACNP
   Clinical Manager, Department of Anesthesiology
   Xavier University, 513-478-5788 ext. 128
   alyba@xavier.edu

3. How will you use the PAT?
   ☐ Research study
   ☐ Clinical application
   ☑ Both

4. Will you use the Spanish version of the PAT?
   ☑ Yes
   ☐ No

5. With what pediatric patient group will you use the PAT?
   ☑ Pediatric Oncology
   ☐ Other (please describe)
   Potential pediatric oncology patients

6. CLINICAL USE ONLY:
   Will you be administering the PAT in the Web-based format?
   ☑ Yes
   ☐ No

7. RESEARCH USE ONLY:
   Will you be administering the PAT in REDCap?
   ☐ Yes
   ☑ No

   (If yes, please review/sign REDCap agreement on p. 5, in addition to signing the other terms and agreements on p. 4)

8. Research Use: If the PAT will be implemented as part of a research study, please provide a brief summary of the proposed research, and attach a one to two page summary, including study questions, design, samples, and outcome measures. Please include information about how the research is funded. The description of the participants should include estimates for gender and ethnicity.
   See attached

9. Clinical Use: If the PAT will be implemented for clinical use, please provide a brief description of the setting in which it will be used in, the patient population provided to, and the implementation plan and timetable. The description of the patient population should include estimates of gender and ethnicity.

10. What is the proposed timeline to begin using the PAT? - Oct/Nov 2017 - Jan/Feb 2018
Other Terms and Conditions

1. **Warranty Disclaimer.** YOU WILL ACCEPT THE PAT “AS-IS.” CPTS MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PAT OR ANY ADAPTATIONS OR TRANSLATIONS DERIVED THEREFROM. BY WAY OF EXAMPLE BUT NOT LIMITATION, CPTS MAKES NO REPRESENTATIONS OF COMMERCIAL UTILITY, MERCHANTABILITY, OR FITNESS FOR ANY PARTICULAR PURPOSE, OR THAT THE USE OF THE PAT WILL NOT INFRINGE ANY RIGHTS OF ANY THIRD PARTY. CPTS SHALL NOT BE HELD TO ANY LIABILITY WITH RESPECT TO ANY CLAIM FROM A THIRD PARTY ON ACCOUNT OF, OR ARISING FROM, THE USE OF THE PAT.

2. **Indemnification.** To the extent permissible by law, Recipient Institution agrees to defend, indemnify, and hold harmless CPTS, and The Nemours Foundation for all claims, liabilities, and costs (including reasonable attorneys’ fees) arising from the use of the PAT. The terms of this Section 2 shall survive the termination of this Agreement.

3. **Term and Termination.** This agreement will remain in force for one year from the signing date below. The agreement will be renewed annually, along with the license fee. Either party may terminate this agreement for any reason upon thirty (30) days written notice to the other party. Upon termination, Recipient will cease use of the PAT and send to CPTS any outstanding reports.

4. **These terms and conditions shall survive termination of this Agreement.**

I agree to the terms of using the PAT specified on pages 1-2.

*Signature*  
Cathy Shaunt  

*Print Name*  
Cynthia S. Patrit  

*Date*  
8/8/17

*Title*  
Chief, Manager  

*Institution*  
Coombe Department of Development  

*Note: you may use a digital signature, or simply type your name in lieu of a digital signature.*

Please return the completed user agreement to: Psychosocialassessmenttool@nemours.org; one of our team members will follow up promptly after receipt.

*WEB-BASED USERS: Please review / sign Web-Based agreement on next page.  
*REDCAP USERS: Please review / sign REDCap agreement on page 6.
The Psychosocial Assessment Tool (PAT) ©

PAT Web-Based Agreement:

Institution Name: CCHMC

Center / Department Name: Department of Psychiatry

Name of primary individual responsible for PAT implementation (use, reporting, etc.):

Cynthia S. Reifert, M.D.

Name of second individual responsible for PAT implementation (if applicable):

The data from the PAT web-based will be stored on a secured Nemours server. There will be no identifying information used in the PAT web-based version; the child’s first name will be collected, but is not stored in the database. The name is only used for administration purposes ONLY.

In using the PAT web-based format, I agree to the following:

1. Not to release your username or password to other departments within your institution without prior written permission from CPTS.

2. Not to release your username or password to any outside institutions.

3. To provide quarterly usage statistics, through the web-based program.

We agree to allow CPTS to store item level data (unidentifiable) from PAT web-based administrations on the Nemours secured server and for statistical analysis of the PAT. As a PAT user, we will keep you informed of any changes to the PAT derived from the analysis. Your institution may be named as one of the contributing sites for PAT data in subsequent publication of these aggregate data.

Primary User’s Signature: [Signature]

Date: 8/19/17

*Note: you may use a digital signature, or simply type your name in lieu of a digital signature.

Please return the completed user agreement to: PsychosocialAssessmenttool@nemours.org; one of our team members will follow up promptly after receipt.
Study Title:  Evaluation of Use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients

Principal Investigator:
Cynthia Pettit CRNP, MSN
Xavier University Doctoral Candidate
Cincinnati Children’s Hospital Medical Center
Department of Anesthesia
513-478-5788
Cindy.perry@cchmc.org
pettitc@xavier.edu

Abstract

Psychosocial risks factors have been identified as having an impact on pediatric surgical health outcomes. Risk stratification is one methodology used in medical care to identify those patients requiring intensive interventions. Stratifying patients with psychosocial risk factors and applying appropriate interventions may be a modality to improve health outcomes. There are few tools in the literature to assess for psychosocial risk in for pediatric patients but the Psychosocial Assessment Tool (PAT) appears to be a promising tool. The PAT evaluates psychosocial risk of the child from the perspective of a family dynamic. The PAT will also stratify psychosocial risk based on scored results. This DNP project will be a feasibility pilot study using a convenience sample of potential pediatric tonsillectomy patients. The purpose of this study is to assess the feasibility of the use of the PAT in a pediatric surgical outpatient clinic population with potential tonsillectomy patients. The PAT will be tested against the current practice of assessment for psychosocial risk to determine if there is an improvement in identification of psychosocial risk in potential pediatric tonsillectomy patients, and to determine if its use is feasible in a outpatient surgical clinic setting with regards to flow and resources. Data obtained will be primarily be presented as descriptive but differences in psychosocial risk between the use of the PAT and the current assessment practice will be analyzed with a McNemar’s test.

Keywords:  psychosocial risk, Psychosocial Assessment tool, pediatric surgical patients

Purpose of the Study

The purpose of this project is to assess the feasibility of use of a reliable and valid tool for psychosocial risk assessment, the Psychosocial Assessment Tool (PAT) ([PAT], 2015) in a pediatric surgical outpatient clinic setting of potential pediatric tonsillectomy patients. The tool will be tested against the current practice of assessment for psychosocial risk to determine if there is an improvement in identification of potential risk factors in potential pediatric tonsillectomy patients.

The aims of the project are the following:
1. To determine if the PAT is a feasible tool to use in a pediatric surgical outpatient clinic setting of potential tonsillectomy patients.
2. To determine if there is an increase of patients identified with psychosocial needs with the use of the PAT in comparison with current practice of psychosocial assessment for this pediatric surgical clinic population, potential tonsillectomy patients.
Design of the Study

The study design of this DNP project to determine if the PAT is a useful tool for improving the assessment of psychosocial risk among pediatric surgical patients, is that of a feasibility pilot study utilizing a convenience sample of potential pediatric tonsillectomy patients.

Sample

Anticipated sample size of a minimum of 35 patients

*Inclusions:* English-speaking parents/guardians, patients age two years or older to less than 18, patients referred for a tonsillar/throat complaint of hypertrophic tonsils, sleep disordered breathing, or recurrent infections. Based on the American Society of Anesthesia Physical Status Classification ([ASA], 1995-2017), patients who are included will be rated as an ASA 1 or ASA 2 which would represents an otherwise healthy child or a child with mild systemic disease.

*Exclusions:* Non-English-speaking parents/guardians, patients in foster care, children less than two or 18 years or older, and any patients with an ASA status of ASA 3 or greater.

Outcome Measures

Aim 1. To determine if the PAT is a feasible tool to use in a pediatric outpatient surgical clinic with potential tonsillectomy patients.

The maximum time identified to complete the PAT by the authors is ten minutes. Based on clinic flow data, the average wait time for patients is 14.32 minutes, therefore the timeliness for completion becomes a key factor in feasibility. Data collected on the study data collection tool (Appendix G and H) to address this aim will include time required to complete the tool, and whether or not flow was impacted.

Descriptive statistics will be utilized in the analysis of this data and will include measures of mean, median, range and frequency distribution of time. In addition to these measures, comments on issues contributing to prolonged completions, greater than 10 minutes, will be assessed and a content analysis completed for themes and patterns.

Aim 2. To determine if there is an increase of patients identified with psychosocial needs with the use of the PAT in comparison to current practice of psychosocial assessment for potential pediatric tonsillectomy patients seen in a surgical outpatient clinic

The data will be from paired samples, with the independent variable being the type of psychosocial assessment completed, either standard practice versus PAT. A McNemar’s test to test the difference in the proportions between the two paired samples will be utilized for data analysis. The accepted level of significance for this analysis of data will be .05 and a minimum n of 35 would be required based on baseline identification of psychosocial risk of 5% of the population and lowest documented psychosocial risk by PAT score of 37% of the population. Data will be collected on the presence of subscale elevations but will not be used in the evaluation for this aim. A Cronbach Alpha will be used to analyzed internal consistency of the subscales and compared to the Cronbach Alpha scores of the subscales reported by the PAT’s authors (Kazak et. al, 2015).

Funding

Project costs are minimal but will be provided through internal department small grant monies.
## Evaluation of the Use of the PAT

### Appendix J. Psychosocial Assessment Tool Report

**Psychosocial Assessment Tool (PAT) Report**

- Your Name:
- Your Institution:

I am reporting on: **___ Clinical Use _____ Research Use** *(please complete separate reports for clinical vs. research use)*

Time frame for reports (i.e., beginning, end dates in which the PAT was administered): ____________________

- **Total overall # of families** screened with the PAT:
- **Of those, total # of families** screened with the Spanish language PAT:

### Diagnosis #1

<table>
<thead>
<tr>
<th>Dx #1: Race (total # patients who are...)</th>
<th>Dx #1: Age (total # patients who are...)</th>
<th>Dx #1: Gender (total # patients who are...)</th>
<th>Dx #1: Family Risk (total # families who...)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White: (# Hispanic):</td>
<td>3 and under:</td>
<td>Male:</td>
<td>Scored 0 - .99:</td>
</tr>
<tr>
<td>Black / African American: (# Hispanic):</td>
<td>4-5 yrs:</td>
<td>Female:</td>
<td>Scored 1.0 – 1.99:</td>
</tr>
<tr>
<td>Asian:</td>
<td>6-8 yrs:</td>
<td>Gender Unknown:</td>
<td>Scored 2.0 and over:</td>
</tr>
<tr>
<td>Multiracial: (# Hispanic):</td>
<td>9-12 yrs:</td>
<td># children / families receiving intervention due to PAT, regardless of score:</td>
<td></td>
</tr>
<tr>
<td>American Indian / Alaskan Native:</td>
<td>13-17 yrs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hawaiian / Pacific Islander:</td>
<td>18-21 yrs:</td>
<td>Age Unknown:</td>
<td></td>
</tr>
<tr>
<td>Race Unknown:</td>
<td>22-25 yrs:</td>
<td></td>
<td></td>
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</tbody>
</table>

### Diagnosis #2

**Please specify:**

Total # of families screened w/ this diagnosis:

<table>
<thead>
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<th>Dx #2: Race (total # patients who are...)</th>
<th>Dx #2: Age (total # patients who are...)</th>
<th>Dx #2: Gender (total # patients who are...)</th>
<th>Dx #2: Family Risk (total # families who...)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White: (# Hispanic):</td>
<td>3 and under:</td>
<td>Male:</td>
<td>Scored 0 - .99:</td>
</tr>
<tr>
<td>Black / African American: (# Hispanic):</td>
<td>4-5 yrs:</td>
<td>Female:</td>
<td>Scored 1.0 – 1.99:</td>
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<td>6-8 yrs:</td>
<td>Gender Unknown:</td>
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<tr>
<td>Multiracial: (# Hispanic):</td>
<td>9-12 yrs:</td>
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<td></td>
</tr>
<tr>
<td>American Indian / Alaskan Native:</td>
<td>13-17 yrs:</td>
<td># children / families receiving intervention due to PAT, regardless of score:</td>
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<tr>
<td>Hawaiian / Pacific Islander:</td>
<td>18-21 yrs:</td>
<td>Age Unknown:</td>
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</tr>
<tr>
<td>Race Unknown:</td>
<td>22-25 yrs:</td>
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</table>
### Appendix K. SWOT Analysis of PAT use for Pediatric Surgical Patients

<table>
<thead>
<tr>
<th><strong>Strengths</strong></th>
<th><strong>Weaknesses</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Supports the strategic goals of the organization.</td>
<td>1. PAT has only been tested on pediatric patients with chronic illnesses and not with a healthier population.</td>
</tr>
<tr>
<td>2. Supports identifying external factors (social determinants) that impact health outcomes and disparities.</td>
<td>2. No current knowledge of the overall indirect costs of use for the institution in terms of case management and referrals based on results of the tool.</td>
</tr>
<tr>
<td>3. The cost of use of the tool is minimal. The PAT fits the surgical clinic environment in terms of length of time needed to administer.</td>
<td>3. No information of parental/guardian receptiveness in completing the tool in this population.</td>
</tr>
<tr>
<td>4. The PAT has established reliability and validity with other populations.</td>
<td>4. No prior experience of the use of the tool by the DNP student.</td>
</tr>
<tr>
<td>5. Provides information on psychosocial risk within multiple domains (subscale scores).</td>
<td>5. Authors of tool state tool take 10 minutes to complete, no knowledge is available on the impact on surgical clinic flow.</td>
</tr>
<tr>
<td>6. In alignment with the Triple Aim’s Goals.</td>
<td></td>
</tr>
<tr>
<td>7. Internal resource of the co-author of the PAT is at CCHMC, and interest and support garnered.</td>
<td></td>
</tr>
<tr>
<td>8. Support for DNP project to evaluate for feasibility has been obtained by anesthesia and surgical upper management, key team members supportive and engaged in the DNP project.</td>
<td></td>
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</tbody>
</table>
### Opportunities

1. Has the potential for cost benefits for the institution and societal health care costs.
2. In alignment with the Triple Aim’s goal of patient experience.
3. Has the potential for further research on risk factors and specific outcomes. For example, factors associated with poor pain control, based on subscale scores. Potential may equate to large grant funding.
4. Initiates the discussion within the surgical/anesthesia domain at CCHMC of psychosocial risk factors and potential interventions.
5. Improve bridging and communication between the surgical specialists, the primary care provider and community resources.

### Threats

1. The PAT is found to be not a useful tool in the surgical domain.
2. Current health care policy changes on insurance access and impact on insurance coverage of the population. Decrease in coverage could impact hospital revenues, thus decreasing supportive resource positions.
3. CCHMC is currently undergoing efforts to decrease patient related costs. This again could impact the availability of support services such as social work.
4. Key members and supports terminate employment prior to completion of the DNP project.
Appendix L. Data Collection Tool

<table>
<thead>
<tr>
<th>Date</th>
<th>MRN</th>
<th>Sex</th>
<th>Age</th>
<th>Completed by</th>
<th>Completion Time</th>
<th>Impacted flow</th>
<th>Risk IDed current practice</th>
<th>PAT Score</th>
<th>Stratification</th>
<th>Subscales</th>
<th>Referral</th>
<th>Appropriate</th>
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</thead>
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Appendix M. Date Coding

<table>
<thead>
<tr>
<th>Coding Definitions for Data Collection Tool</th>
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<tr>
<td><strong>Definition</strong></td>
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<tr>
<td>Date</td>
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<tr>
<td>Calendar date</td>
</tr>
<tr>
<td>MRN</td>
</tr>
<tr>
<td>CCHMC unique identifier</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>1 - Female</td>
</tr>
<tr>
<td>2 - Male</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Age in Years</td>
</tr>
<tr>
<td>Tool Completed By</td>
</tr>
<tr>
<td>1 - Mother</td>
</tr>
<tr>
<td>2 - Father</td>
</tr>
<tr>
<td>3 - Other legal guardian</td>
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<tr>
<td>Tool Completion Time</td>
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<td>Time in minutes and secs</td>
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<td>Impact to flow</td>
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<tr>
<td>1 Yes</td>
</tr>
<tr>
<td>2 No</td>
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<tr>
<td>Risk Identified by</td>
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<tr>
<td>1 - Yes</td>
</tr>
<tr>
<td>2 No</td>
</tr>
<tr>
<td>Current Practice</td>
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<tr>
<td>Stratification</td>
</tr>
<tr>
<td>1 Universal</td>
</tr>
<tr>
<td>2 Target</td>
</tr>
<tr>
<td>3 Clinical</td>
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<tr>
<td>Subscale Elevations</td>
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<tr>
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<tr>
<td>Comments</td>
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<td>referral Made</td>
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<tr>
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<tr>
<td>2 No</td>
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<td>Based on PAT</td>
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<tr>
<td>If referral Made</td>
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<tr>
<td>1 Yes</td>
</tr>
<tr>
<td>2 No</td>
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<tr>
<td>Appropriate</td>
</tr>
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Appendix N. Innovation and Research Student Review - CCHMC

Patient Services Innovation and Research Tenet Council Employee Student Project Review

Title: Evaluation of the use of Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients

PI: Pettit, C.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Met</th>
<th>Not Met</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project is aligned with CCHMC/PS strategic priorities.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Project is a unique contribution and does not duplicate effort from another site of care.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progress and deliverables are clearly articulated.</td>
<td></td>
<td>x</td>
<td>Dissemination efforts including planned publication(s) need articulation.</td>
</tr>
<tr>
<td>Academic program agrees to provide mentorship and required resources.</td>
<td></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

This project may proceed to Divisional Scientific Review/IRB Review.

☐ This project requires revision and resubmission to the I & R Council prior to submission for Divisional Scientific Review/IRB Review.

Signed,

Jessica Thielen, MSN, APRN, CNP 8/10/17
Co-Chair, Innovation & Research Tenet Council Date
Appendix O. CCHMC IRB Approval

Institutional Review Board - Federalwide Assurance

#00002988

Cincinnati Childrens Hospital Medical Center

Date: 10/4/2017
From: CCHMC IRB
To: Principal Investigator: Cindy Pettit
PACC

Study ID: 2017-4563
Re: Study Title: Evaluation of Use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients

The above referenced protocol and all applicable additional documentation provided to the IRB were reviewed and APPROVED using an EXPEDITED review procedure in accordance with 45 CFR 46.110(b)(1)(see below) on 10/4/2017.

This study will be due for continuing review at least 30 days before: 10/3/2018.

The following was reviewed:

Study Documents
Current Psychosocial Assessment - Appendix E
Data Coding Appendix H
Data Collection Tool - Appendix G
Evaluation of the Use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients
Participant Information Sheet
The IRB reviewer has determined that this research presents **no greater than minimal risk**.

**Please note the following requirements:**

**Consent Requirements**

*Per 45 CFR 46.117 (21 CFR 56.109)* the IRB has waived the requirement to obtain DOCUMENTATION of informed consent for all adult participants.

**HIPAA Requirements**

*Per 45 CFR 164.512* the IRB has granted a waiver from the requirement to obtain an authorization for the use and/or disclosure of protected health information (PHI).

**AMENDMENTS:** The principal investigator is responsible for notifying the IRB of any changes in the protocol, participating investigators, procedures, recruitment, consent forms, FDA status, or conflicts of interest. Approval is based on the information as submitted. New procedures cannot be initiated until IRB approval has been given. If you wish to change any aspect of this study, please submit an Amendment via ePAS to the IRB, providing a justification for each requested change.

**CONTINUING REVIEW:** The investigator is responsible for submitting a Continuing Review via ePAS to the IRB at least 30 days prior to the expiration date listed above. Please note that study procedures may only continue into the next cycle if the IRB has reviewed and granted re-approval prior to the expiration date.

**UNANTICIPATED PROBLEMS:** The investigator is responsible for reporting **unanticipated problems** promptly to the IRB via ePAS according to current reporting policies.

**STUDY COMPLETION:** The investigator is responsible for notifying the IRB by submitting a Request to Close via ePAS when the research, including data analysis, has completed.
Please note: This approval is through the IRB only. You may be responsible for reporting to other regulatory officials (e.g. VA Research and Development Office, UC Health – University Hospital). Please check with your institution and department to ensure you have met all reporting requirements.

Statement regarding The International Conference on Harmonization and Good clinical Practices: The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials: prepares written minutes of convened meetings and retains records pertaining to the review and approval process all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

Thank you for your cooperation during the review process.

Research Categories

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
Appendix P. IRB Reliance Agreement

IRB Reliance Agreement
CCHMC IRB of Record

Relying Site

This Agreement by and between Cincinnati Children's Hospital Medical Center (CCHMC) and allows the Relying Site Institutional Review Boards (IRB) to cede IRB review to The Cincinnati Children's Hospital Medical Center Institutional Review Board (CCHMC IRB) for human subject research (Research) that will be conducted collaboratively by investigators at CCHMC and the Relying Site (Reliance Agreement).

Name of Institution Providing IRB Review:

<table>
<thead>
<tr>
<th>Name of Institution</th>
<th>Cincinnati Children's Hospital Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>3333 Burnet Ave MLC 7040 Cincinnati, OH 45229</td>
</tr>
<tr>
<td>Institutional Official</td>
<td>Margaret Hostetter, MD</td>
</tr>
<tr>
<td>Designated Contact</td>
<td>Jeremy Corsino, <a href="mailto:jeremy.corsino@cchmc.org">jeremy.corsino@cchmc.org</a> 513-636-8039</td>
</tr>
<tr>
<td>Assurance (FWA)</td>
<td>FWA00002988</td>
</tr>
<tr>
<td>Registration (IRB)</td>
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Name of Institution Relying on CCHMC IRB:

<table>
<thead>
<tr>
<th>Name of Institution</th>
<th>Xavier University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>3800 Victory Parkway Cincinnati, OH 45207</td>
</tr>
<tr>
<td>Institutional Official</td>
<td>Steven Herbert, Ph.D.</td>
</tr>
<tr>
<td>Designated Contact</td>
<td>Morrie Mullins, Ph.D. <a href="mailto:mullinm@xavier.edu">mullinm@xavier.edu</a></td>
</tr>
<tr>
<td>Assurance (FWA)</td>
<td>00003152 (University of Cincinnati)</td>
</tr>
<tr>
<td>Registration (IRB)</td>
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</table>

This Agreement is limited to the following specific protocol(s) (Study):

<table>
<thead>
<tr>
<th>Title of Study</th>
<th>Evaluation of the use of the Psychosocial Assessment Tool (PAT) with Pediatric Surgical Patients</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>CCHMC Principal Investigator</td>
<td>Cindy Pettit</td>
</tr>
<tr>
<td>Relying Site Principal Investigator</td>
<td>Cindy Pettit</td>
</tr>
</tbody>
</table>
## Responsibilities

**Cincinnati Children's Hospital Medical Center IRB/Institutional Responsibilities** - The CCHMC IRB agrees that it will:

1. Maintain an FWA with OHRP and maintain registration with both OHRP and the FDA. (Please note that CCHMC only applies the Common Rule and its subparts to federally funded research. Equal protections are provided to all non-federally funded research).

2. Maintain IRB board membership that satisfies the requirements of 45 CFR 46, 21 CFR 56 and provide special expertise as needed from IRB members or consultants to adequately assess all aspects of the Study.

3. Make available to the Relying Site upon request, the CCHMC IRB Standard Operating Procedures.

4. Perform initial reviews, continuing reviews, reviews of unanticipated problems that involve risks to subjects or others, amendments, reviews of DSMB reports, and reviews of any other documents submitted by the Principal Investigator of the Study.

5. Maintain and make accessible to the Relying Site TRB the CCHMC IRB application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, approved consents, minutes of the CCHMC IRB meetings relevant to the Study and the Relying Site.

6. Provide an approved study-wide informed consent form. The form will indicate areas where the Relying Site may add language or otherwise customize the form for its own site (HIPAA, payment research related injury, local contacts). Any modifications will be subject to approval by the CCHMC IRB, which will then provide a final approved consent form to the Relying Site for use.

7. CCHMC IRB will perform those determinations required by the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, “HIPAA”) with respect to the mechanisms for permitting the use and disclosure of Protected Health Information (“PHI”) for the research protocol in this Agreement, including authorization and waivers of authorization for use and disclosure of PHI.

   Relying Sites will provide their own authorization but will ensure that its form of authorization explicitly permits PHI to be used and shared by and with CCHMC and all participating Study sites and their investigators as necessary for conducting, reviewing, and overseeing the Study as contemplated by the protocol and this Agreement.

8. Review Relying Site management plans related to conflicts of interest reported by Relying Site investigators and others involved in the Study, as required under Relying Site policies. Determine if the management plan(s) is acceptable to the CCHMC IRB under CCHMC policies and practices. If the CCHMC IRB determines the management plan is not acceptable, the CCHMC IRB will promptly inform the Designated Site Contact and the Study will not be eligible for review under this Agreement.

9. Notify the Designated Site Contact promptly if there is ever a suspension or restriction of the CCHMC IRB's authorization to review studies.

10. Notify the Designated Site Contact promptly of any CCHMC IRB policy decisions or regulatory matters that might affect the institution's reliance on CCHMC IRB reviews or performance of the Study at the Relying Site.

11. Notify the Designated Site Contact promptly in writing of injuries or unanticipated problems involving injury or risk to subjects or others in the Study discovered by the CCHMC IRB.

12. Notify the Designated Site Contact promptly if the CCHMC IRB determines that serious or continuing non-compliance has occurred in the Study at the Relying Site, and the steps the CCHMC IRB deems necessary for the remediation of the non-compliance, including but not limited to, any suspension, disapproval or termination of the Study, or any sanctions or limitations imposed on researchers at the Relying Site. CCHMC may request that the Relying Site conduct its own investigation and report back to CCHMC or CCHMC may work cooperatively to conduct its own investigation.
If the CCHMC IRB determines that it must report the findings of an investigation to OHRP, the FDA and/or other oversight entities, it will notify the Relying Site in advance. The CCHMC IRB will provide the involved Relying Site the opportunity to review and comment on the report before it is sent to OHRP, the FDA or others. Nothing in this Agreement shall prevent a Relying Site from making its own report to OHRP or from taking additional remediation steps at its own institution.

13) Notify the Relying Site promptly if it decides to suspend, disapprove or terminate the Study as a consequence of receiving allegations of serious or continuing non-compliance or unanticipated events that have the potential to cause harm to research subjects.

14) Notify the Relying Site about the need for a CCHMC Quality Review/Audit at the Relying Site. CCHMC may ask the Relying Site to conduct its own Quality Review/Audit and supply results to the CCHMC IRB or work cooperatively to conduct such a review.

**Relying Site - Institutional Responsibilities:** The Relying Site agrees that it will, at all times while this Agreement is in effect:

1) Maintain a Federal Wide Assurance (FWA).

2) Maintain a human subject’s protection program, as required by the DHHS OHRP.

3) Designate a Site Contact, who is responsible for, and has Relying Site authority for, all communication regarding the Study and provide to the CCHMC IRB the name and contact information for that individual.

4) Provide the Relying Site Principle Investigator and other research personnel involved in the Study a resource from the Relying Site IRB to address any questions or concerns they may have regarding the appropriate resource at the CCHMC IRB, as necessary.

5) Ensure that the investigators and other personnel at the Relying Site who are involved in the Study are appropriately qualified and meet the Relying Site’s standards for eligibility to conduct research. This includes, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the Study.

6) Educate and train its investigators to perform research in compliance with human research protection regulations.

7) Perform local analysis of any specific requirements of state or local laws, regulations, policies, standards (social or cultural) or other factors applicable to this Study, and include any relevant requirements or results of the analysis that would affect its conduct of the research as part of the information provided to CCHMC for consideration.

8) Perform local review by other local auxiliary committee reviews as applicable and required by its policies (such as nursing review, radiation safety, pharmacy and any others), and include any relevant requirements or results of the reviews that would affect its conduct of the research as part of the information provided CCHMC for consideration.

It is the sole responsibility of the Relying Site to identify and interpret the requirements of its applicable state or local laws, regulations, policies, and auxiliary review processes as are relevant to the Study and to communicate the requirements to the CCHMC IRB.

9) Provide to CCHMC IRB the Relying Site’s authorization language for HIPAA but ensure that it includes authorization that explicitly permits PHI to be used and shared by and with CCHMC and all participating Study sites and their investigators as necessary for conducting, reviewing, and overseeing the Study as contemplated by the protocol and this Agreement.

Remain independently responsible for your own HIPAA compliance and obligations (for example, minimum necessary requirements, or accounting of disclosures of PHI made pursuant to a waiver of authorization) in connection with the research protocol covered under this Agreement other than the initial determinations regarding mechanisms for use and disclosure of PHI.

10) For Studies funded in whole or in part by a non-federal entity (corporation, foundation, etc) ensure that the provisions of the grant or contract that funds the Study are consistent with the approved Study protocol and...
IRB Reliance Agreement
CCHMC IRB of Record

11) Notify the CCHMC IRB within twenty-four hours of becoming aware of a suspension or restriction of a Relaying Site investigator or other personnel involved in the Study, or the discovery of serious or continuing non-compliance, or an unanticipated problem that involves risks to subjects within the Study.

12) Cooperate promptly and upon request with any CCHMC investigation regarding serious or continuing non-compliance or an unanticipated problem related to the Study.

CCHMC may ask the Relaying Site to conduct a full investigation and report its findings to CCHMC, which the Relaying Site will do promptly and in compliance with all rules, regulations and requirements. The Relaying Site will provide to CCHMC updates, as reasonable and upon request and a copy of the report of its findings. If the investigative process, by CCHMC or the Relaying Site, results in the production of a report that will be made available externally, CCHMC will afford the Relaying Site an opportunity to comment on a draft of such report with appropriate consideration of any confidentiality issues. Nothing in this Agreement shall prevent the Relaying Site from conducting its own investigation. However any findings of fact made by a Relaying Site will be shared promptly with CCHMC to ensure the safe and appropriate performance of the Study at the Relaying Site.

13) Ensure an institutional mechanism exist by which complaints about the Study can be made by local Study participants or others. Promptly report such complaints to the CCHMC IRB if they meet the criteria of a potential unanticipated event that causes risk to subjects or others, as defined by the CCHMC policies.

14) Ensure that the Relaying Site maintains policies regarding the disclosure and management of conflicts of interest related to research and share those policies with the CCHMC IRB as requested.

Ensure that Relaying Site investigators and other personnel involved in the Study disclose financial interests as required under the Relaying Site policies. Ensure that conflicts of interest are reviewed and a management plan is implemented, if and as required under Relaying Site policies. Provide all management plans to the CCHMC IRB for its review. The CCHMC IRB will determine if the management plan(s) is acceptable to the CCHMC IRB under CCHMC policies and practices.

If the CCHMC IRB determines the management plan is not acceptable, the CCHMC IRB will promptly inform the Designated Site Contact and the Study will not be eligible for review under this Agreement. The Relaying Site will ensure the compliance of all management plans related to the Study.

15) The CCHMC IRB will apply its standard policies regarding confidentiality of review of information and disclosures submitted to it regarding potential investigator conflicts of interest.

16) Maintain policies and procedures for dealing with injuries to human research subjects and share those policies and procedures with the CCHMC IRB as requested.

To the extent of its own policies, the Relaying Site shall provide or arrange for treatment of injuries to human subjects, if any, that may result from Study-related procedures that occur at the Relaying Site. Nothing in this Agreement shall prevent institutions collaborating on a specific Study to make other arrangements between them at the outset of a specific Study to allocate differently the responsibility for costs associated with injuries to human subjects that might occur in the course of the Study.

17) Cooperate with and use all reasonable efforts to ensure Relaying Site investigators' cooperation with any inquiry by the CCHMC Quality Review/Audit team requests relating to a Study. Such cooperation will include, but is not limited to, providing research records and related information and meeting with institutional research representatives upon request. In addition, the CCHMC may ask the Relaying Site to conduct its own Quality Review/Audit which the Relaying Site shall promptly conduct and will supply the Relaying Site results to the CCHMC IRB.

18) Ensure compliance by its investigators and research staff (including, but not limited to, physicians, research nurses, coordinators, data managers, or other members of the research team) in the conduct of the Study.

19) Require Relaying Site investigators to maintain records of all Study and related activities conducted under this Agreement for at least seven years and longer if required by law, after completion of any Study.
IRB Reliance Agreement
CCHMC IRB of Record

Authority

Once IRB review for a Study has been ceded to the CCHMC IRB pursuant to this Agreement, the research protocol will remain under the CCHMC IRB review for the life of the research protocol unless this Agreement is terminated as set forth below.

This Agreement will become effective as of the date of the last signature below and will remain in effect until the conclusion of the Study, defined as the time when all human subject activities at the Relying Site conclude. The Agreement may be terminated by: (i) either party without cause; such termination will be effective upon the CCHMC IRB receiving notification from the Relying Site IRB that the Relying Site IRB has assumed responsibility for the Study; (ii) by either party upon breach of the other party which in the sole discretion of the non-breaching party is capable of cure, if the breach has not been cured to the satisfaction of the non-breaching party within 30 days of notification of breach; or (iii) by either party immediately upon written notice upon breach of this Agreement which in the sole discretion of the non-breaching party is not capable of cure, including but not limited to any activity or reason that may place human subjects at risk.

All notices under this Agreement shall be sent to the addresses set forth above addressed to the appropriate Designated Site Contact.

This Agreement is governed under the laws of the State of Ohio.

By signing this Agreement, both institutions agree that the CCHMC IRB will serve as the IRB of record and agree to uphold their individual responsibilities as set forth in this document and as required by law and regulation. This Agreement is not effective until all institutional official and PI signatures have all been obtained. This document must be kept on file by both CCHMC and the Relying Site and provided to OHRP upon request.

SIGNATURES

SIGNATURE OF CCHMC DESIGNATED OFFICIAL

Jeremy Cosimo, Sr. Director - ORCRA
Cincinnati Children's Hospital Medical Center

Signature: ____________________________

DATE: 10/7/2017

SIGNATURE OF DESIGNATED OFFICIAL RELYING INSTITUTION

Morrie Mullins, Ph.D., Chair, Xavier University IRB

Signature: ____________________________

DATE: 10/17/2017

PRINTED NAME AND TITLE

Cincinnati Children's Hospital Medical Center