IRB #	STU 2022-0306

COVER LETTER

Official Title: Exploration of Central Venous Catheter Protective Devices in the Pediatric Population: A Mixed Methods Study
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PROTOCOL FORM / RESEARCH DESCRIPTION

If an item does not apply to your research project, indicate that the question is "**not applicable**" – do not leave sections blank

Click once on the highlighted entry in each box to provide your response. Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

1. Purpose and objectives. *List the purpose and objectives:*

Title: Exploration of Central Venous Catheter Protective Devices in the Pediatric Population: A Mixed Methods Study

CVCs have multiple uses, including medication delivery (Government of Alberta., 2020) and provision of Total Parental Nutrition (TPN). While the CVC is necessary for the patient's treatment, it is not without risk. Patients with CVCs may experience catheter breaks, dislodgement, or central-line associated bloodstream infections (CLABSI). As a result, patients experience increased health care utilization, possible restriction of movement, and delayed development. The CDC established guidelines to prevent CLABSIs in hospitalized pediatric patients that include keeping the catheter clean, dry, and intact (CDC, 2015). A paucity of literature supports nursing practice for preventing contamination, catheter dislodgement, and catheter breaks (Chamblee et al., 2020; Langford et al., 2021). One promising intervention is a wearable device (Gus Gear Vest) that can keep the catheter secure while protecting it from contamination and other risks.

Gap: There is a lack of research that focuses on wearable devices in pediatric patients.

The primary purpose of this study is to explore caregiver and nurse satisfaction of pediatric patients with CVCs that utilize a wearable protective device.

The specific aims of this study are to:

1) to determine the feasibility of utilizing a wearable device
2) to prospectively measure and evaluate parent and nurse satisfaction with the protective wearable device.

2. Background.

- Describe past experimental and/or clinical findings leading to the formulation of your study.
- For research involving investigational drugs, describe the previously conducted animal and human studies.
- For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.
- Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference.

You may reference sponsor's full protocol or grant application (section number and/or title) or if none, ensure background includes references.

Please respond to all components of this item, or clearly indicate which components are not applicable.

a. Background

Previous studies have found that CVC complications and failure are recognized problems experienced by patients (Ullman et al., 2015b). One in four CVCs fail before completing intended therapy in the pediatric population (Ullman et al, 2015a). Mechanical complications may include catheter breaks and catheter dislodgement which may delay recovery or interrupt treatment (Cesaro et al., 2004). Mechanical complications are a common cause for repair, especially in the pediatric population, due to the child's lack of safety awareness, nearly constant movement, and poor impulse control (Cesaro et al., 2004). In 2020, 21,399 CLABSIs were reported by CDC (n.d.b). CVC complications lead to a significant burden on the patient and the healthcare system including additional time in the hospital, lost time receiving treatment, loss of access sites, and the potential for further complications including death (Peng et al., 2011; Ullman et al., 2015a). Additionally, there is a 3-fold increase in sepsis in the 30 days following line repair (Lungdren et al., 2012). There is a lack of research that focuses on preventing contamination of CVCs by bodily fluids, food/ liquids, and other contaminants outside of the traditional securement devices. CVC usage may impact the patient's quality of life (Tremolada et al., 2005). Parents of leukemia patients reported a higher quality of life when retaining prior activities or routines (Tremolada et al., 2005). However, there is a lack of research studies that focus on devices that promote normal levels of activities and routines in pediatric patients with CVCs while still maintaining the safety of the CVC.

Preventing CVC trauma impacts long-term outcomes by preserving central access. This is an essential task of registered nurses. Traditional securement devices are occlusive, adhesive, and transparent dressings covering the CVC entry point (Barnes et al., 2015; Bogart, 2015; Ista et al., 2016). In the United States, the CDC (n.d.a) and CDC (2015) provide guidelines and recommendations for managing and caring for pediatric patients with CVCs while in the hospital. Registered nurses are the primary role responsible for managing and accessing CVCs in hospitals and outpatient settings. There are many methodologies for mitigating CLABSIs, such as keeping an occlusive, transparent dressing clean, dry, and intact, as well as specific times to change the dressing, tubing, and other mechanisms needed to provide treatment and manage the CVC

(Barnes et al., 2015; CDC, 2015).

Maintaining a clean and dry transparent dressing is challenging for active, mobile pediatric patients. Nurses are aware of the many risks associated with CVC care and need to invest in new options to keep their patients safe. Nursing practices surrounding CVC care continue to change as new evidence regarding management evolves (Jarding & Makic, 2021). Patients and families have designed wearable devices to mitigate CVC risk factors and promote normal growth and development (Gus Gear, n.d.). The CVC protective wearable device assists in protecting the CVC without interfering with the child's mobility (Gus Gear, n.d.). Therefore, nurses are interested in evaluating parents' and nurses' satisfaction of pediatric patients with CVCs that utilize a wearable protective device.

References

Barnes, S., Olmsted, R., & Monsees, E. (2015). Guide to preventing central line-associated bloodstream infections. *Association for Professionals in Infection Control and Epidemiology*.

Bogart L. (2015). Preventing central line associated blood stream infections by use of bundle care in the oncology patient population. Grand Canyon University

Centers for Disease Control and Prevention. (2015). *Summary of Recommendations.* https://www.cdc.gov/infectioncontrol/guidelines/bsi/recommendations.html#rec8

Centers for Disease Control and Prevention. (n.d.a). *Checklist for prevention of central line associated blood stream infections.* https://www.cdc.gov/hai/pdfs/bsi/checklist-for-clabsi.pdf

Centers for Disease Control and Prevention. (n.d.b). Central line-associated bloodstream infections. https://arpsp.cdc.gov/profile/infections/clabsi?redirect=true

Cesaro S., Corrò R., Pelosin A., Gamba, P., Zadra, N., Fusaro, F., & Zanesco, L. (2004). A prospective survey on incidence and outcome of Broviac/Hickman catheter-related complications in pediatric patients affected by hematological and oncological diseases. *Annals of Hematology,* 83(3), 183-188. https://doi.org/10.1007/s00277-003-0796-9

Chamblee, T. B., Patton, L. J., Young, V. B., Marusich, J., Bowens, C. D., & Miles, D. K. (2021). Reducing central line-associated bloodstream infection in contaminated central venous catheters: case studies of a pediatric contamination guideline. *British Journal of Nursing*, *30*(19), S24-S29. https://doi.org/10.2309/JAVA-D-20-00038

Creswell JW, Miller DL. Determining validity in qualitative inquiry. *Theory into practic*e. 2000;39(3):124-130.

Government of Alberta. (2020). *Learning about a central venous catheter for children.* https://myhealth.alberta.ca/Health/aftercareinformation/pages/conditions.aspx?hwid=abq5687

Gus Gear. (n.d.). Gus gear central line vest. https://gusgear.net/product/central-line-vest/

Hsieh H, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Re*s. 2005;15(9):1277-1288.

Ista, E., Hoven, B. V., Kornelisse, R. F., Starre, C. V., Vos, M. C., Boersma, E., & Helder, O. K. (2016). Effectiveness of insertion and maintenance bundles to prevent central-line-associated bloodstream infections in critically ill patients of all ages: A systematic review and meta-analysis. *The Lancet Infectious Diseases, 16*(6),724-734.

Jarding, E. K., & Flynn Makic, M. B. (2021). Central line care and management: Adopting evidence-based nursing interventions. *Journal of PeriAnesthesia Nursing*, 36(4), 328-333.

https://doi.org/https://doi.org/10.1016/j.jopan.2020.10.010

Langford, M., Leal, M., & Patton, L. (2021). Managing central venous catheter dressings: a short gut syndrome case study. *Journal of the Association for Vascular Access*, 26(4), 28-31. https://doi.org/10.2309/JAVA-D-21-00009

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. sage.

Lundgren, I. S., Zhou, C., Malone, F. R., McAfee, N. G., Gantt, S., & Zerr, D. M. (2012). Central venous catheter repair is associated with an increased risk of bacteremia and central line-associated bloodstream infection in pediatric patients. *The Pediatric infectious disease journal, 31*(4), 337-340. Https://doi.org/10.1097/INF.0b013e31823eeec5

Namey, E., Guest, G., McKenna, K., & Chen, M. (2016). Evaluating bang for the buck: A cost-effectiveness comparison between individual interviews and focus groups based on thematic saturation levels. *American Journal of Evaluatio*n, 37(3), 425-440. https://doi.org/10.1177/1098214016630406

Peng, C., Monagle, P., & Newall, F. (2011). Clinical outcomes of management of CVAD occlusions. *Archives of disease in childhood, 96*(9), 885–887. https://doi.org/10.1136/adc.2010.194969

Tremolada, M., Axia, V., Pillon, M., Scrimin, S., Capello, F., & Zanesco, L. (2005). Parental narratives of quality of life in children with leukemia as associated with the placement of a central venous catheter. *Journal of Pain and Symptom Management, 30*(6), 544-552. https://doi.org/10.1016/j.jpainsymman

Ullman, A. J., Marsh, N., Mihala, G., Cooke, M., & Rickard, C. M. (2015a) Complications of central venous access devices: A systematic review. *Pediatrics (Evanston), 136*(5), E1331-E1344. https://doi.org/10.1542/peds.2015-1507

Ullman, A. J., Cooke, M., & Rickard, C. M. (2015b). Examining the role of securement and dressing products to prevent central venous access device failure: A narrative review. *Journal of the Association of Vascular Access, 20*(2), 99-110. https://doi.org/10.1016/j.java

b. Current practice
Once a patient receives a CVC they are dressed with an occlusive, adhesive, transparent dressing, and a chlorhexidine impregnated sponge unless chlorhexidine is contraindicated for the patient. Standard of care in the hospital setting is to change the dressing every 7 days or when soiled or no longer occlusive. The standard of care and implications for changing the dressing will not be altered with this study.

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3. Study Design.
Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design.

This is a sequential, convergent mixed methods study design in which qualitative interview data will be collected first followed by quantitative data.

Scheme and Outcomes: Identify eligible patients--Informed Consent--Provide education and two protective wearable device--Demographic data (electronic health record)--Interview parent on device--Every month complete 30-day satisfaction survey for a total of three data collection period-Discharge from study.

Nurse data collection scheme: Study participants hospitalized at time of enrollment in study or anytime during the study period. Nurse of patients using device will complete satisfaction survey.

1.Feasibility measurement from Parents of Children using the Gus gear vest device
Interview parents (of children using Gus gear vest) on device.
[Time Frame: Two weeks from recruitment, plus or minus seven days.]

2.Satisfaction survey from Parents of Children using the Gus gear vest device
Every month complete 30-day satisfaction survey for a total of three data collection period
[Time Frame: Every month for a total of three data collection periods up to 3 months. Team will have plus or minus seven-day timeframe around the 30-day window to collect the data.]

3.Satisfaction survey from nurses
Satisfaction survey from nurses of Children using the Gus gear vest device
[Time Frame: Anytime during the study period up to nine months.]

4. Research Plan / Description of the Research Methods:

4.a. Provide a **comprehensive narrative** describing the **research methods**.

1) Provide the **order in which tests/procedures will be performed**,
2) Provide the **setting** for these events and a description of the **methods used to protect privacy** during the study.
3) Provide the **plan for data analysis** (include as applicable the **sample size calculation)**

Please respond to all components of this item, or clearly indicate which components are not applicable.

The PI and Co-PIs will provide training to the research team to promote consistency in data collection. Study team personnel will approach eligible patients for consent. Once consented, patients/ parents will be provided two protective wearable devices. Education on how to wear the protective wearable device will be provided. Demographic data will be captured utilizing chart review.

An interview with the parent on the device will be obtained at enrollment to the study. Interviews will be audio-recorded and transcribed verbatim using the TranscribeMe Application. Qualitative analysis will require thematic saturation which typically requires at least 8 interviews (Namey et al., 2016). Parents will be interviewed using the feasibility interview guide. Interviews will be open-ended questions lasting 15 to 45 minutes long utilizing an interview guide for consistency of interviewing probes may be utilized such as, “Can you tell me more about that?”.

Parents will be requested to complete 30-day satisfaction survey every month for a total of three data collection period. Sampling will continue for up to 30 patients to meet minimum requirements for statistical analysis for feasibility and satisfaction data.

Nurse data collection scheme: If the patient is hospitalized, the nurse caring for the patient will be asked to complete the nurse satisfaction survey. Study participants hospitalized at time of enrollment in study or anytime during the study period.

Setting: The study will be conducted at a large, tertiary pediatric healthcare system on the primary Dallas campus. Primary targeted patients are within the inpatient and ambulatory settings for patient specialties: 1) gastroenterology, 2) transplant, and 3) pulmonary.

The gastroenterology floor has approximately 1124 admissions per year with about 40 TPN dependent patients that require external CVCs for treatment. Gastroenterology diagnosis that are seen include short gut syndrome, microcolon-intestinal hypoperistalsis syndrome. The gastroenterology population is also seen in the ambulatory setting with approximately 14,000 visits per year. Patients with central venous catheters admitted to inpatient oncology, transplant, pulmonary, general pediatrics, and rehabilitative floors will be considered as identified by the central line associated bloodstream infection committee or infectious disease to be approached by the study team.

Inclusion Criteria:

- Patients with CVCs ages 0 to 12 years of age
- May currently utilizing or historically utilized the interventional wearable protective device
- Caregiver or parent available
- English and Spanish speaking subjects

Exclusion Criteria:

- Females with Tanner 2 breast or greater breast development. Justification: the wearable device will not fit properly to secure the CVC and may increase the risk of complications. If the patient does develop breast during the time of the study, then the patient will no longer wear the wrap and will go back to securing their device in the traditional way. Tanner 2 breast development will be evaluated in the screening process of patients.
- Patients in critical care services such as neonates, trauma/ neurology intensive care unit, or cardiac intensive care unit. Justification: These patients are not mobile with their CVC and not the targeted population.

Screening for eligibility will take each morning through review of the inpatient and ambulatory patient census. Patients charts will be reviewed to determine if they meet inclusion criteria. Once an eligible patient is identified, an individual from the study team will approach the family and introduce the study. If the family is interested in the study, an individual from the research team will consent the family and measure the patient for the wearable device. The caregiver and nurse will have the opportunity to simulate placement of the wearable device on a manikin. Two wearable devices will be provided to the patient/ caregiver. Together the caretaker and study team personnel will fit the protective wearable device on the patient.

Study personnel will collect study participant demographic data from the electronic health record using the demographic form. Caregivers will be interviewed using the feasibility interview guide. Interviews will be audio-recorded and transcribed verbatim using the TranscribeMe Application. Qualitative analysis requires thematic saturation or no new themes emerging in the

interviews which typically requires at least 8 interviews (Namey et al., 2016). Interviews will be open-ended questions lasting 15 to 45 minutes long utilizing an interview guide for consistency of interviewing. Probes may be utilized such as, "Can you tell me more about that?". Following each interview, recordings will be transcribed verbatim.

Data Analysis:

Descriptive statistics will be used to summarize the demographic data. Transcriptions will be uploaded into DeDoose, a cloud based qualitative analysis app. The research team will analyze the data using a conventional, inductive content analysis to provide knowledge and understanding of risk points in the home and hospital setting for catheter breaks, dislodgement, infections, and contamination and feasibility of the wearable device in both settings (Hsieh & Shannon, 2005). Qualitative, conventional content analysis is defined as a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns (Hseih & Shannon, 2005). Preconceived categories will be avoided allowing for categories to arise from the data itself.

To analyze the data, the study team will:

1. Individually read each transcript word by word several times for data immersion and to obtain a sense of the whole;
2. Individually read transcripts to derive a priori codes by highlighting the exact words from the text that appear to capture key thoughts or concepts of minimal stimulation.
3. Individually, make notes of first impressions, thoughts, and initial analysis using the participants words.
4. Meet to discuss and define initial coding scheme through labels and codes that emerged.
5. Individually code each transcript using initial coding scheme and adding codes when data does not fit within designated code.
6. As a team, all data within each code will be examined to combine and create subcategories as necessary.
7. Codes will be sorted and organized into meaningful clusters ideally between 10 and 15 to keep broad enough to sort to a large number of codes.

Thematic saturation, prolonged engagement with the data, triangulation, and member checking, a process of returning to the participants for feedback on codes will ensure trustworthiness of the qualitative data and analysis (Lincoln & Guba, 1985; Hsieh & Shannon; 2005; Creswell & Miller, 2000). Acknowledgement of bias and assumptions of the researchers will occur throughout the research study. To control for bias, investigators will not deviate from the feasibility interview guide and an external research team member will serve for member checking.

If the patient is hospitalized, the nurse caring for the patient will be asked to complete quantitative surveys on the satisfaction of wearable protective device.

Every thirty days for 3 months parent satisfaction and feasibility of the protective wearable device will be collected using a quantitative survey. Patients may be approached within ambulatory clinic visits, inpatient visits, or by telephone. Study team will have a plus or minus seven-day timeframe around the 30-day window to collect the data. If the caregiver is present, then the caregiver will complete the survey on a Children's issued iPad via Microsoft Forms. If for some reason, the iPad is not working, which would be a rare occurrence, the caregiver will fill out a paper survey. Additionally, the electronic medical chart will be audited for any CVC complications such as line dislodgement, breaks, contamination, or CLABSIs. At the end of the study data will be analyzed and collated.

Data Analysis:

Descriptive statistics will be used to describe the sample population, total satisfaction scores, and feasibility and fidelity of the protective device. Frequencies of nurse and caregiver reporting completion of the patient wearing the protective device will be calculated to evaluate feasibility and fidelity. Nurse satisfaction scores will be analyzed using a one sample t-test and descriptive statistics. Parent satisfaction scores will be analyzed using repeated measures ANOVA and descriptive statistics.

Protected Health Information (PHI):

- Patient names will be collected to assign a unique identifier code by the study team

- The PHI/Codes will be stored behind Children's firewall in a password protected, limited access file to only study team personnel for the entire project.
- Consent forms will be collected and locked in a file in a research cabinet in a locked office.
- Once the study is completed and data analyzed the PHI/codes will be destroyed upon study publication acceptance.
- Nursing data gathered will be on an anonymous basis and will not have any of the 18 HIPPA privacy rule identifiers cited by the U.S. Department of Health and Human Services. All survey records will be recorded anonymously in Microsoft excel used within the Children's firewall.

References

Creswell JW, Miller DL. Determining validity in qualitative inquiry. Theory into practice. 2000;39(3):124-130.

Hsieh H, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res. 2005;15(9):1277-1288.

Lincoln, Y. S., & Guba, E. G. (1985). Naturalistic inquiry. sage.

Namey, E., Guest, G., McKenna, K., & Chen, M. (2016). Evaluating bang for the buck: A cost-effectiveness comparison between individual interviews and focus groups based on thematic saturation levels. American Journal of Evaluation, 37(3), 425-440. https://doi.org/10.1177/1098214016630406

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4.b. List of the study intervention(s) being tested or evaluated under this protocol

☐ **N/A -** this study does not test or evaluate an intervention. Skip to item 4.d.

#	Study intervention(s) being tested or evaluated under the protocol *Add or delete rows as needed*	Affiliate Place a check next to institution(s) where the intervention will be performed	Local Standard Practice? Indicate whether the intervention is considered acceptable practice locally for applicable institutions
	N/A	☐ UTSW	☐ Yes
		☐ PHHS	☐ Yes
		CMC	Yes
		☐THR	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes

4.c. Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol

For each study intervention identified in section 6b above, complete a risk:benefit analysis table.

(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)

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4.c.
N/A

List each group exposed to this intervention on a separate line. (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects	For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none".

If you are requesting a Waiver of Informed Consent, complete the table below.

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

	Not serious	**Serious**
Likely These risks are expected to occur in more than **20** out of **100** subjects.	•	•
	Not serious	**Serious**
Less likely These risks are expected to occur in **5- 20** subjects or less out of **100** subjects.	•	•
		Serious
Rare These risks are expected to occur in less than **5** subjects out of **100**		•

	4.d. List ALL other research procedures or components not listed in table 4.b. ***The combination of Tables 4b and 4d should account for all of the research procedures that will take place during this study.*** Consider grouping similar procedures under a single component (e.g., blood work, CT = safety assessments)

#	Research component • **individual procedures** *example:* Eligibility Assessments • History and physical • Questionnaire • Laboratory tests	**Column A** **Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be performed if the participant were not participating in the**	**Column B** **Research Only** Indicate the number of times each procedure will be performed solely for research purposes *(meaning that the participant would not undergo the same number of procedures or would not undergo the procedure(s) at the same frequency if*	**Column D** **Risks** **If you are requesting a Waiver of Informed Consent, complete the table below.** List the reasonably expected risks for each procedure or group of procedures under the following categories as appropriate: • Serious and likely; • Serious and less likely; • Serious and rare; • Not serious and likely;

	Add or delete rows as needed	**study.**	*they were not participating in the study)*	• Not serious and less likely
1				
2				
3				
4				
5				
4				

5. Safety Precautions. *(Describe safeguards to address the serious risks listed above.)*

a. Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above.

The risks are not "More than minimal risk"

b. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects.

The risks are not "More than minimal risk"

c. Will the safeguards be different between/among groups?

☐ Yes ☐ No

The risks are not "More than minimal risk"