

**Parafilm Application to Prevent Central Line Associated Bloodstream Infections
in Pediatric Patients Undergoing Hematopoietic Cell Transplantation**

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**Parafilm Application to Prevent Central Line Associated Bloodstream Infections in
Pediatric Patients Undergoing Hematopoietic Cell Transplantation**

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ABSTRACT

Central line associated bloodstream infections (CLABSI) result in significant morbidity and mortality, particularly in patients undergoing hematopoietic cell transplantation (HCT). HCT patients are at high risk for CLABSI due to multiple factors, including prolonged immune suppression and the need for long-term central venous access. Data in pediatric HCT patients is sparse and previous and current investigations have utilized interventions that may have downstream effects on bacterial flora and antibiotic resistance patterns. Parafilm is a plastic film made of paraffin that is primarily utilized to seal and/or protect containers in laboratories. Based upon its unique properties, parafilm was studied in a small series of TPN-dependent pediatric patients with short-gut syndrome. When applied as a protective barrier at the end of central lines, parafilm significantly reduced the incidence of CLABSI in this patient population. This non-randomized pilot quality improvement initiative will extend the use of a parafilm central line barrier as standard of care to pediatric HCT patients. The primary aims of this study are to determine the feasibility of this intervention and to reduce the incidence of CLABSI in pediatric HCT patients. The secondary aims of this study are to further characterize factors that impact the CLABSI rate and to evaluate patient, caregiver, and healthcare provider perception of this intervention.

1. GOALS AND OBJECTIVES (SCIENTIFIC AIMS)

1.1. Primary

1.1.1. To determine the feasibility of applying and maintaining parafilm as a protective barrier to the central lines of pediatric hematopoietic stem cell transplant (HCT) inpatients and outpatients in order to prevent central line associated bloodstream infections (CLABSI).

1.1.2. To determine if parafilm application reduces the rate of CLABSI in pediatric patients undergoing HCT.

1.2. Secondary

1.2.1. To characterize the pre- and post-HCT characteristics which impact the rate of CLABSI in pediatric patients undergoing HCT.

1.2.2. To evaluate patient and caregiver (family and healthcare provider) perception of the effectiveness of parafilm, including ease of use, ease of maintenance, and ability to prevent infection.

2. BACKGROUND

CLABSI are an important subset of hospital-acquired infections (HAI) that lead to significant morbidity and mortality. The Centers for Disease Control and Prevention (CDC) estimates that 31,000 CLABSI occurred in U.S. hospitals in 2009, and that each episode carries mortality of 15-25% and excess costs of \$16,550.¹ Due to this significant burden, the Centers for Medicare and Medicaid Services (CMS) decreased reimbursement for CLABSI in October 2008 and mandated that all acute care hospitals begin reporting CLABSI data to the CDC's National Healthcare Safety Network (NHSN) in January 2011.

Patients undergoing HCT are at particularly high risk for CLABSI due to need for longer term central venous access, prolonged period of neutropenia, breakdown of mucosal barriers (e.g. mucositis), and, in allogeneic HCT, the need for post-transplant immune suppression. Previous studies of pediatric and adult HCT patients report a 21-49% incidence for bacteremia and 17-36% for CLABSI.²⁻⁶ A recent report in pediatric HCT patients was strengthened by the number of patients (n=319), the prospective study design, the inclusion of both ambulatory and inpatient data, and the use of current CLABSI nomenclature, although this study combined pediatric HCT and oncology patients.⁷ They report 0.65 ambulatory CLABSI and 2.2 inpatient CLABSI, both per 1000 central line days, which is comparable to the 2011 NHSN report of 2.2 inpatient CLABSI per 1000 central line days in pediatric HCT (mean; 13 centers).^{7,8}

Lukenbill et al⁹ recently differentiated between standard definition CLABSI and "modified CLABSI," which excluded pathogens associated with mucosal breakdown, although this report was only in young adult and adult patients undergoing HCT for myelodysplastic syndrome and acute myeloid leukemia.⁹ This distinction is important as the 2014 CDC guidelines subdifferentiate mucosal barrier injury laboratory-confirmed bloodstream infections (MBI-LCBI) from CLABSI. MBI-LCBI include bloodstream infections with intestinal organisms or viridans group streptococci in patients who are neutropenic or who have undergone HCT within the prior year and currently complicated by grade III-IV graft-versus-host disease (GVHD). While this subgroup of CLABSI is currently only being utilized for reporting purposes,

it is possible that certain subgroups of CLABSI (such as MBI-LCBI) may be viewed differently in the future with differential CMS reimbursement (as opposed to current non-reimbursement for all CLABSI).

The collection and reporting of CLABSI data has allowed quantification of the burden, but most importantly, it allows for implementation of interventions to decrease CLABSI. Simple interventions, such as the use of central line maintenance bundles to improve compliance with evidence-based practices, have decreased CLABSI in pediatric ICU patients and shown promise in pediatric oncology.^{10,11} The electronic medical record can also be used to improve bundle compliance.¹⁰ In pediatric HCT patients, training of medical staff and patient caregivers in best practice central line care has been shown to decrease CLABSI.¹²

Therapies to prevent CLABSI are also being investigated. The use of quinolone antibiotics has been shown to decrease the incidence of CLABSI in pediatric HCT patients,³ and the use of levofloxacin is currently being investigated in a randomized fashion in pediatric patients with acute leukemia or undergoing HCT by the Children's Oncology Group (COG) (NCT 01371656). In another ongoing trial, the COG is comparing the use of standard central line cleansing to cleansing with chlorhexidine gluconate (CHG; NCT01817075). While these interventions hold promise in decreasing the incidence of CLABSI, both levofloxacin and CHG may alter bacterial flora and/or bacterial drug resistance; as such, both COG studies will be investigating these as secondary outcomes.

Parafilm is a plastic film made of paraffin (Sigma-Aldrich; St Louis, MO) that is used ubiquitously by laboratories to seal or protect containers based upon its unique properties of being waterproof, self-sealing, and moldable.¹³ Because of its physical properties and its ease of use, parafilm lends itself to use as an additional barrier to prevent exposure of CVL connections and caps to sources of infection. In infants and young children such a barrier could prevent exposure of CVL caps to environmental sources of infection such as the contents of the diaper. In six pediatric patients with total parenteral nutrition (TPN) dependent intestinal failure, the use of parafilm around central line hubs decreased the mean rate of CLABSI by about 76% ($p=0.01$).¹³ Parafilm has also been used as a standard of care CVC barrier in pediatric HCT patients at the Children's Hospital of Pittsburgh since 2013, although its use has not been studied. This intervention is simple and inexpensive, and as compared to antibiotic prophylaxis or CHG, it will not impact on bacterial flora or antibiotics sensitivity. The nonrandomized study we propose will extend the use of parafilm as standard of care to prevent CLABSI to pediatric patients undergoing HCT and will allow us to evaluate the intervention in a scientific manner.

3. SUMMARY OF TRIAL TO DATE AND OVERVIEW OF MODIFICATIONS TO PROTOCOL

This trial opened in May 2015 and met the initial accrual goal (of 6-8 months) in January 2015, when the last of 27 patients was enrolled on study. There are currently 8 patients who remain on study, and this cohort of patients will remain on study until their CVLs are removed. Importantly, there have been no unexpected serious adverse events (SAEs) or SAEs related to research in these 27 patients to date. The statistical plan will be modified to plan for interim data analysis on all 27 patients before CVL removal; this will include analysis of day +30 CLABSI as well as CLABSI during initial admission period for HCT. Data will still be analyzed at the completion of the study for this cohort, e.g. following CVL removal.

As this is a single arm pilot study, for the primary efficacy endpoint (section 1.1.2) and the secondary endpoint evaluating characteristics that impact the rate of CLABSI in pediatric HCT patients (section 1.2.2), a comparison group not receiving the parafilm intervention is needed.

This protocol will be modified to allow for retrospective data collection in a historical cohort of pediatric HCT patients.

Further, this study will be modified to extend the accrual goal for an additional 6-8 months. This modification will enable us to increase the power of this study to detect a difference in CLABSI between patients receiving parafilm (on current study) and receiving standard CVL care (historical cohort), particularly in higher risk subsets of patients (such as our youngest patients in diapers).

4. RESEARCH DESIGN AND METHODS

4.1. Study Design

This will be a non-randomized pilot quality improvement initiative designed to evaluate the feasibility and efficacy of using parafilm as a protective central line barrier to prevent CLABSI in pediatric HCT patients.

4.2. Study Enrollment

Patients will be recruited through the Aflac Blood and Cancer Center's Pediatric Blood and Marrow Transplant Division and will be enrolled by the research nurse who will confirm eligibility and assign a subject number.

4.3. Eligibility Criteria

4.3.1. Inclusion Criteria

- 4.3.1.1. Must be between the age of 0 and 21 years at the time enrollment
- 4.3.1.2. Must be undergoing allogeneic or autologous HCT for a malignant or non-malignant disorder
- 4.3.1.3. Must have or be scheduled to have a tunneled CVC

4.3.2. Exclusion Criteria

- 4.3.2.1. Patients undergoing other interventions to prevent CLABSI (e.g. COG ACCL1034 with CHG, antimicrobial lock therapy, etc.) are ineligible.
- 4.3.2.2. Patients who only have a port are ineligible.

4.4. Comparison Group

Data will be collected in a retrospective fashion from a historical cohort of pediatric HCT patients receiving standard of care CVL care. This will include patients undergoing HCT during the same period of time that the study is open, but that do not either consent or assent to participate on study. Additionally, this will include patients undergoing HCT during the same calendar months 1 year prior and for the initial months preceding the study period. For example, for the initial cohort of 27 patients enrolled over the 8 month period of May 2015 to January 2016, we will compare to historical cohorts both from May

2014 to January 2015 and from the immediately preceding 8 months (October 2014 to May 2015).

5. TREATMENT PLAN

5.1. Overview

This is a non-randomized, open-label pilot quality improvement initiative to evaluate the feasibility and efficacy of using parafilm as a protective barrier to prevent CLABSI in pediatric HCT patients with CVCs. All Aflac HCT patients with central lines who do not meet exclusion criteria will have parafilm applied to their CVC at the time of admission for HCT. Parafilm will be maintained on the CVC and routine CVC care will be continued, per institutional standard of practice, until the CVC is removed. Prior to discharge from the inpatient HCT unit, at home caregivers will be taught how to apply and maintain parafilm on the line so the barrier is maintained as an outpatient.

To track inpatient compliance, a nurse and physician will document the application of parafilm to the CVC on a weekly basis during interdisciplinary inpatient line rounds on a spreadsheet. To facilitate adherence to the intervention and to quickly identify any practical concerns, nursing will confirm that parafilm is being used on a patient's line during daily rounds when lines and drains are discussed and will document appropriate application to each lumen on a daily basis in the EMR. Any non-compliance discussed during daily rounds will be documented. To track outpatient compliance, the clinic nurse or physician/advanced practice practitioner will document correct application of parafilm during all outpatient clinic visits. Parent/guardian will maintain a log documenting application of parafilm at home which will be reviewed at the subsequent outpatient clinic visit.

5.2. Concomitant Treatment Restrictions

Standard CVC care should be per institutional guidelines (see Appendices I-IV for CHOA Standard Operating Procedures for CVC care). Patients may receive systemic anti-fungal therapy (for prophylaxis or treatment) and systemic antibiotics (for treatment) without any restrictions.

5.3. Schedule for Parafilm

Nursing (or parent/guardian during outpatient period) will apply pre-cut, single use sections of parafilm over the CVC hub (if not connected) or around the CVC hub connection (if connected). A new section of parafilm should be reapplied approximately once per day as well as following any break into the CVC or CVC disconnection. A new section of parafilm may be reapplied at the discretion of the caregiver or medical provider (e.g. if concern that it may not be applied properly or that it is coming off).

5.4. Training and Education on Parafilm Use

Inpatient and outpatient HCT nurses will receive formal education on the proper use and application of parafilm and documentation of its use, prior to the opening of this study. Upon admission for HCT, patients and their caregivers will also receive training on the

use/application and documentation and such training will be repeated prior to discharge. Ongoing education will be provided during visits to the outpatient clinic.

5.5. Positive Blood Culture

If treatment for a positive blood culture requires line removal and the line is replaced (or if the CVC is removed for any reason and not replaced), the patient will not be followed for CLABSI beyond two days from CVC removal. These patients will continue to be followed through day 100 for clinical outcomes/endpoints.

6. AGENT INFORMATION

Parafilm

6.1. Source

Parafilm is a plastic film with paper backing that is made from paraffin and has unique properties including being waterproof, self-sealing, moldable and translucent. It is able to be stretched to 3-4 times its original size without breaking. It is primarily used in laboratories to seal containers from outside contamination, but it has been shown to decrease the incidence of CLABSI in parenteral nutrition dependent pediatric patients with intestinal failure when used as a protective barrier at the CVC hub.¹³

6.2. Toxicity

No known toxicity when used as a CVC protective barrier, although the experience is small. However, toxicity is not expected given that the parafilm will be used only as a protective barrier on the outside of the CVC.

6.3. Formulation and Stability

Parafilm is 0.005 inches thick and is supplied in 4 inch wide, 250 foot long rolls. Recommended storage parameters include 50% relative humidity and temperature ranging from 7-32 degrees Celsius, where it can be stored for up to 3 years.

6.4. Supplier

Parafilm is supplied by Sigma-Aldrich (St Louis, MO) and is commercially available.

7. EVALUATIONS

7.1. History and Demographic Information

Baseline demographic data will be collected including age, race, gender, performance status, height and weight, diagnosis, presence of severe malabsorption (e.g. short gut syndrome), presence of stoma (e.g. colostomy or ileostomy), and previous BSI (particularly within 30 days prior to enrollment). HCT related variables will also be collected, including donor type, stem cell source, HLA match, conditioning regimen, and indication for HCT. The identical data will be collected from the historical cohort in a retrospective manner.

7.2. Clinical Information

Clinical data will be collected including positive blood cultures (number; see section 7.3 below), dates of administration of TPN, date of first ANC <500, date of neutrophil engraftment (first of three consecutive days when ANC >500), date of platelet engraftment (first day with platelet >20,000 without transfusion in the preceding 7 days), hospitalizations (reasons for hospitalization and dates of admission and discharge), ICU admissions (reasons for admission and dates of admission and discharge), use of systemic antibiotics or antifungals (with dates and types), GVHD prophylaxis, and development of GVHD (with date of diagnosis) and treatment, if applicable. CVC specific data will be collected including date of placement, type of line, number of lumens, date of removal, reason for removal, and date of repair, if applicable. The identical data will be collected from the historical cohort in a retrospective manner.

7.3. CLABSI

Patients will be followed for BSI throughout the study period (from enrollment through CVC removal). Data on all BSI will be collected including date of culture, CVC status (present or absent), inpatient or outpatient status, concurrent infections at other sites of the body, and concurrent positive cultures at other sites of the body. Data will be reviewed to determine if the BSI meets criteria for CLABSI, including MBI-LCBI, according to CDC definitions (see section 13). The identical data will be collected from the historical cohort in a retrospective manner.

7.4. Compliance Data

Data will be collected on a periodic basis on both inpatient and outpatient compliance. Inpatient compliance will be documented by a nurse and physician on a weekly basis during interdisciplinary inpatient line rounds and will be documented by the patient's nurse on a daily basis in the EMR. Outpatient compliance will be documented during all outpatient clinic visits by the clinic nurse or physician/advanced practice practitioner. Compliance will be documented as "yes" (parafilm in place), "no" (parafilm not in place), or "yes-inc" (parafilm applied but is applied incorrectly, not fully intact, or visibly contaminated). Caregivers will document use of the parafilm barrier by making a tally mark on a provided log. Every attempt will be made to collect the log at the end of treatment, but in the event that the log is unable to be collected, this will not be considered a study deviation.

8. CRITERIA FOR REMOVAL FROM PROTOCOL THERAPY AND OFF STUDY CRITERIA

8.1. Criteria for Removal from Protocol Therapy

- 8.1.1.1. Physician concludes removal from protocol therapy is in the patient's best interest
- 8.1.1.2. Patient or patient's guardian refuses to use parafilm. In this case, the parent (or patient, if over 18 years old) must sign a form acknowledging that they acknowledge that the use of parafilm is our departmental standard of practice and that not using it may increase their risk for CLABSI.

8.2. Off Study Criteria

- 8.2.1.1. Completion of intended data collection and assessments
- 8.2.1.2. Patient is lost to follow up
- 8.2.1.3. Death

Patients who require admission to the intensive care unit (e.g. PICU) will not be removed from study. It is acceptable to not apply parafilm while in the PICU.

9. STATISTICAL CONSIDERATIONS

9.1. Statistical Design

This is a non-randomized pilot quality improvement initiative to assess the feasibility and efficacy of using parafilm to prevent CLABSI in pediatric HCT patients. Every patient admitted to the Aflac HCT inpatient unit on the HCT service will have parafilm applied to and maintained on their CVC from the time of admission to the time of line removal.

9.2. Patient Accrual and Expected Duration of Trial

The initial accrual period for this study was 8 months, and the study will be reopened for an additional up to 8 months. Follow up will occur until the last patient enrolled has their CVC removed, is taken off study, or is discharged from the BMT service, whichever occurs first. Total study duration is expected to be an additional 9-12 months, based on the typical length of time BMT patients retain their CVC (3 months).

9.3. Statistical Analysis Methods

9.3.1. Study Endpoints

The primary outcome measure is compliance with the intervention, which is defined as the percentage of catheter days that patients had parafilm correctly applied and intact during the study period. Inpatient and outpatient compliance will be measured separately. For both inpatient and outpatient compliance, there will be two measures: reported and observed. In the inpatient setting, reported compliance will be measured during daily discussions of parafilm at patient care rounds and by daily recording of the nurse in the EMR (by lumen). Nurses will report whether or not parafilm is in use for a given patient or if parafilm was not intact or incorrectly applied during the preceding day. For each patient, parafilm status will be recorded as “yes,” “no,” or “yes-inc,” (if parafilm was incorrectly applied or applied but not intact). The percentage of catheter-days with intact, correctly applied parafilm, as reported by nursing staff, will be calculated. Observed compliance will occur during weekly line rounds. Again, rounding providers will indicate whether a patient’s parafilm is intact and correctly applied, not applied, or incorrectly applied or not intact. The percentage of “observed catheter-days” where patients had correct use of intact parafilm will be calculated. For outpatient reported compliance, parents will provide their logs to outpatient staff who will document a summary measure of the number of days parafilm was correctly in use/intact vs not in use or incorrectly in use/not intact. For example, if

Patient A was last seen in clinic 4 days ago on day -4 (today is day 0), and Patient A's mom recorded that parafilm was intact on days -3 and -2 but yesterday she found the parafilm off, nursing would record "yes" for 2 days and "no" for 1 day. The percentage of catheter-days where parafilm was intact will again be calculated. For observed compliance, the outpatient nurse will record whether the patient's parafilm was correctly applied/intact (yes), not applied (no), or incorrectly applied/not intact (yes-inc) at the beginning of the visit. The percentage of outpatient "observed catheter-days" where parafilm was correctly in use/intact will be calculated.

Additionally, CLABSI rate (total number of CLABSI/1000 catheter-days) will be calculated and compared to pre-intervention CLABSI rate in Aflac HCT patients over a similar time period (historical cohort). A stratified analysis will be performed to assess the rate in allogeneic vs autologous HCT recipients. CLABSI is defined as the identification of a bacterial infection from a blood culture drawn from a CVC in the absence of a primary source of infection from another body site (e.g. pneumonia, wound, skin abscess), in accordance with the CDC definition. Time is measured in catheter-days, wherein only the line most at risk for infection is counted in patients who have multiple CVCs. Catheter-days start at the time of enrollment or line placement, whichever occurs later. Secondary endpoints include number of antibiotic treatment courses per patient, total duration of antibiotic treatment exposure (excluding prophylactic antibiotics), number of ICU admissions secondary to sepsis, death from infection, death from any cause, total amount of parafilm used and associated expense, and subjective measures of caregiver perception of parafilm (ease of use, effectiveness, etc).

9.3.2. **Sample Size and Power Consideration**

Because CLABSI is a rare event in a relatively small population, calculations of sample size based on a normal distribution are invalid. As a quality improvement initiative, this intervention will be applied to all pediatric HCT patients as the standard of practice. We will accrue patients to include in the dataset for analysis of feasibility and efficacy during the first 6-8 months.

9.3.3. **Analysis Plan**

Primary outcome (Parafilm Compliance): The percentage of catheter-days where parafilm was correctly used and intact (both reported and observed compliance) for inpatients and outpatients will be reported.

Secondary outcomes: For CLABSI rate, a univariate Poisson Regression Model or a Negative Binomial Model (depending on the results of goodness-of-fit tests) will be used to compare CLABSI rate before and after the use of parafilm and the χ^2 test of significance will be reported. A multivariate Poisson Regression Model (or Negative Binomial Model) will be used to explore the covariates that may influence CLABSI rate, such as type of HCT (allogeneic vs autologous), ANC, GVHD, compliance with parafilm, etc, and the Likelihood Ratio Test will be used to assess the relative contribution of individual covariates. Additionally, descriptive statistics reporting the total number of antibiotic courses, length of antibiotic exposure (days), total number of ICU admissions for sepsis, death from infection,

and death from any cause both pre- and post-intervention will be reported and between groups differences will be assessed using two-sample T-tests to compare the means of these outcomes. Finally, descriptive statistics of the subjective data collected from provider and caregiver surveys regarding parafilm ease of use, perceived benefit, and other parameters will be reported. The Kruskal-Wallis Test will be used to compare the responses from nursing surveys to those from parental surveys.

10. ADVERSE EVENT REPORTING

10.1. Common Toxicity Criteria for Adverse Events (CTCAE)

Adverse events will be described using event terms and severity grading from the National Cancer Institute (NCI) CTCAE version 4.0. Adverse events will be characterized by severity grading, attribution (relationship to study treatment), and expectedness (based upon prior experience).

10.2. Reporting Requirements

All unexpected serious adverse events (SAEs) or SAEs related to research that occur through completion of study should be reported within 5 business days. Fatal events must be reported within 24 hours of knowledge of the event. Unexpected problems that are not AE should be reported within 5 business days. Documentation of SAE should be submitted to aflacpi@choa.org. The IRB should be notified of reported SAEs and unexpected problems in accordance with IRB guidelines.

11. CLABSI

Patients will be followed for BSI throughout the study period, and each BSI will prompt additional data collection (see section 7.3). CHOA Infection Control (Lea Kendrick, epidemiologist) will determine whether the BSI meets criteria for CLABSI (or MBI-LCBI; according to CDC definitions).

11.1. CDC Criteria for CLABSI

The most recent CDC definitions will be used for determining CLABSI (http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf).

11.2. BSI Committee

Determination of CLABSI is an ongoing occurrence happening in parallel to this research study by the Aflac Cancer and Blood Disorders Center BSI Committee. The BSI Committee meets biweekly to discuss every BSI occurring in an Aflac patient to review clinical details and to determine if any events could have been prevented. The BSI Committee also meets monthly for a BSI Prevention Taskforce Meeting during which monthly CLABSI rates are tracked and discussed and quality initiatives are discussed, including this study.

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