Appendix 2.5.1
Sample Need Specification

Need Statement

A way to prevent bacteria from entering the blood stream in neonates with umbilical cord catheters in order to reduce the rate of BSI infections

The Problem – Disease State

- 80% of low birth weight babies admitted to the neonatal intensive care unit (NICU) receive umbilical catheters (UCs)
- Average catheterization = 6 days
- UCs are the preferred route of catheterization because they offer reliable access to the venous system with the necessary flow required to deliver medication, fluids, and parenteral nutrition
- Infants in the NICU are vulnerable to blood stream infections (BSIs) due to multiple factors
  - Rate of catheter-related BSIs in adults = 1%
  - Rate of catheter-related BSIs in neonates with UCs = 5-15%
- Infants with catheter-related BSIs face severe morbidities and a 7-11% mortality rate

The Problem – Disease State (cont.)

- There are several potential sources of infectious agents that lead to catheter-related BSIs
  - Infectious agents can pass along the external surface of the UC from the insertion site to the tip, where colonization most often occurs
  - Organisms may colonize in the catheter hub, stopcock, or other entry ports when the closed UC system is opened for the administration of fluids, medications, or nutrition
  - Infectious agents may enter through administered parenteral fluid
- Between 20-50% of catheter-related BSIs are associated with stopcock contamination

The Problem – Existing Treatments

- Central venous and arterial catheterizations are relatively common in adults
- An expansive industry surrounds technologies used to perform these procedures
- However, the unique needs of neonates and technologies optimized for safe, effective umbilical catheterizations have been largely neglected
- Vygon, EPSA, Covidien, NeoMed, and Utah Medical offer Ucs and associated products

The Problem – Existing Treatments (cont.)

Common Problems

Umbilical Venous Catheters

- Malposition
- Portal vein thrombosis
- Hepatic necrosis
- Arrhythmia
- Perforation/tamponade
- Sepsis
- Thrombotic endocarditis
- Hemorrhagic infarction in lungs

Umbilical Arterial Catheters

- Vasospasm/thrombosis/emboli
- Trauma
- Perforation
- Catheterization of the urachus
- Hypoglycemia/hyperglycemia
- IVH
- NEC
- Sepsis
- Hypertension
- Hematuria
- Aneurysm/pseudoaneurysm
- Hemolysis

The Problem – Existing Treatments (cont.)

Current Strategies for Reducing the Risk of UC-Related BSI Infection

- Hand hygiene
- Maximal barrier precautions for insertion of central catheters – sterile cap, mask, gown, gloves, and drape
- Skin antisepsis at the catheter entry site – use CHG solution
- Select the appropriate site
- Minimize access ports
- Change line setups and access ports in a timely manner
- Sterilize access ports before entry
- Implement a real-time positive blood culture review process
- Monitor emerging practices - intravenous immunoglobulin, vancomycin prophylaxis, reduced intravenous lipid duration

The Problem – Existing Treatments (cont.)

Gap Analysis

- Sterile dressing, surgical equipment, and techniques work well to reduce infection stemming from the patient's or physician's skin at the time of UC placement
- However, these solutions are inadequate for preventing infections after UC insertion
- Existing technologies that have shown promising evidence in the adult market have not been used in neonates (e.g., antimicrobial catheters and adult catheter covers)

The Market

The Estimated U.S. Market for UCs is Relatively Small at $12.5 million

Driver	Value
US births	4.13 M
NICU admit rate	6%
UC use	15.5%
UCs per year	38,415
Average cost per unit	$320
UC market size	$12.5 M

Neotec NeoBridge Umbilical Cath Holder $145-$153

Kendall Argyle Umbilical Catheter $250-375

Average daily fee in NICU $3k

Catheterization (0$ with **DRG** or $400) + xray (~$250)

The Market (cont.)

However, Medical Expenses Associated with UC BSIs are $76.8M

Driver	Value
US births	4.13 M
NICU admit rate	6%
UC use	15.5%
UC per year	38,415
Days with UC	5
UC Infection Rate (per 1k cath days)	10/1000
Cost per BSI	$40,000
Total medical cost	$76.8 M

Opportunity to reduce days in NICU and fees
NICU daily cost ~$3,000

Healthy baby ~$2.8k versus preterm $41.6k versus <26 weeks $250k+

Very low birth weight infants are $79,000, compared with $1,000 for a normal newborn

The Market (cont.)

A new technology that reduces UC BSIs would capture value by eliminating the costly treatment for neonates who contract BSIs and could decrease associated morality

- Catheter-related BSIs are classified as a "never event" by Medicare, which means hospitals are responsible for their treatment costs
- An example at an individual facility level can help forecast willingness to pay:
  - Each year, at Lucile Packard Children's Hospital (LPCH), approximately 247neonates receive a UC, with 6.5 contracting a BSI
  - At $40,000 per BSI, the annual treatment cost for UC-related BSIs at LPCH is $260,000
  - Spread across 247 NICU patients, LPCH would pay a maximum of $1,053 per patient to prevent UC-related BSIs
  - However, since the current price for equipment per umbilical catheterization averages $320 per neonate, it may be difficult to command an additional $1,053 per neonate to prevent a possible BSI

Need Criteria

A way to prevent bacteria from entering the blood stream in neonates with umbilical cord catheters in order to reduce the rate of BSI infections

Must Haves

- BSI rate <7.1/1k patient days
- Can be used immediately after birth
- Can be used in babies with APGAR score <7
- Integrates into existing procedure
- Does not increase net healthcare expenses to system

Nice to Haves

- Safely and effectively utilized for >14 days
- Can be used in very low birth weight infants (<1000g)
- Does not increase antibiotic resistance
- Can be inserted without x-ray confirmation
- Simple training to facilitate rapid adoption

References

- Simanovsky N, Ofek-Shlomai N, Rozovsky K, Ergaz-Shaltiel Z, Hiller N, Bar-Oz B, Umbilical venous catheter position: evaluation by ultrasound. *Eur Radiol.* Sep 2011; 21(9):1882-1886.
- Tiffany KF, Burke BL, Collins-Odoms C, Oelberg DG. Current practice regarding the enteral feeding of high-risk newborns with umbilical catheters in situ. *Pediatrics*. Jul 2003; 112(1 Pt 1):20-23.
- Edwards JR, Peterson KD, Mu Y, Banerjee S, Allen-Bridson K, Morrell G, Dudeck MA, Pollock DA, Horan TC. National Healthcare Safety Network (NHSN) report: data summary for 2006 through 2008, issued December 2009. *Am J Infect Control*. Dec 2009; 37(10):783-805.
- Kabra NS, Kumar M, Shah SS. Multiple versus single lumen umbilical venous catheters for newborn infants. *Cochrane Database SystRev*. 2005 (3):CD004498.
- Ramasethu J. Complications of vascular catheters in the neonatal intensive care unit. *Clin Perinatol*. Mar 2008; 35(10):199-222,x.
- Tebbs SE, Trend V, Elliott TS. The potential reduction of microbial contamination of central venous catheters. *J Infect*.Mar 1995; 30(2):107-113.
- K M Brosnan, A M Parham, B Rutledge, D J Baker, J S Redding. Stopcock contamination. *Am J Nurs.* Mar 1988; 88(3):320-324.
- Mueller-Premru M, Gubina M, Kaufmann ME, Primozic J, Cookson BD. Use of semi-quantitative and quantitative culture methods and typing for studying the epidemiology of central venous catheter-related infections in neonates on parenteral nutrition. *J Med Microbiol*. May 1999; 48(5):451-460.
- Peter Chun, Seom Gim Kong, Shin Yun Byun, Su Eun Park, Hyung Du Lee. Analysis of neonatal sepsis in one neonatal intensive care unit for 6 years. *Korean J Pediatr*. 2010; 53(4):495-502.
- Grisaru-Soen G, Sweed Y, Lerner-Geva L, Hirsh-Yechezkel G, Boyko V, Vardi A, Keller N, Barzilay Z, Paret G. Nosocomial bloodstream infections in a pediatric intensive care unit: 3-year survey. *Med Sci Monit*. Jun 2007; 13(6):CR251-257.

