Neonatal Adhesive: Case Study in Needs-driven Innovation

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Institute for Pediatric Innovation

- 501(c)3 nonprofit corporation founded 2006
- National consortium of pediatric centers that provide funding and clinical expertise
- Focus on near-term product opportunities, not breakthrough technology
  - Re-engineered medical devices
  - Reformulated drugs
- Novel funding and collaborations to develop products
- Two devices and one reformulated drug licensed; clinical availability anticipated 2014

Context

- Special challenges facing ***pediatric*** medical devices
  - Investor's nightmare - Small market, high risk
  - Corporate partnering more likely than start-up
- IPI strategy
  - Survey clinical practitioners
    - 500 NICU clinicians interviewed
  - First vet product concept feasibility – then finance, develop, license.
  - Seek complementary support from non-dilutive sources
  - Follow through to evaluate clinical impact

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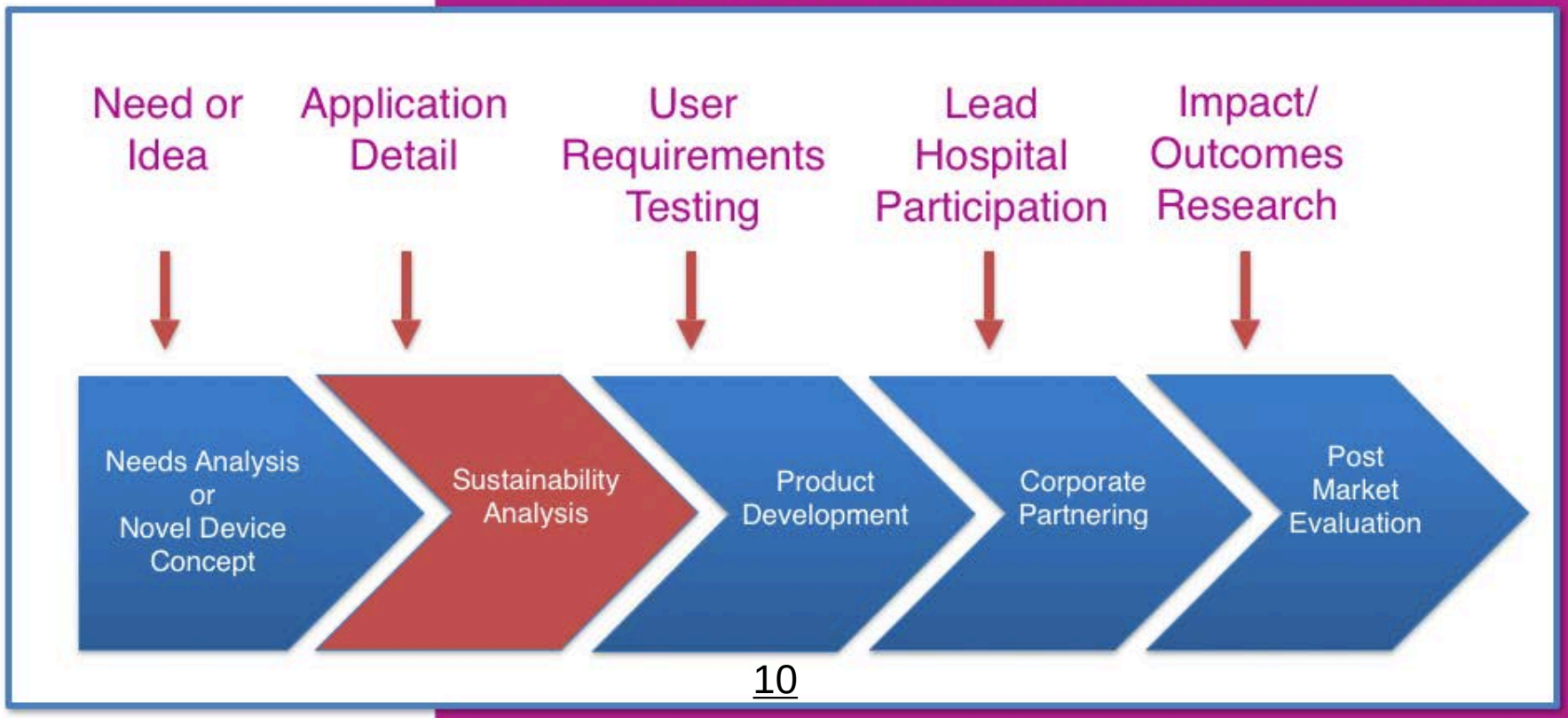
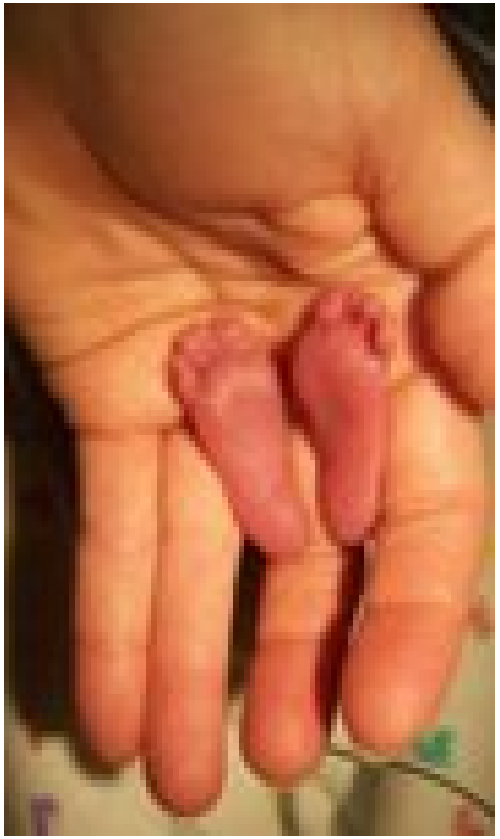
Clinician-Driven, Evidence-Based Medical Device Innovation



Sustainability Analysis

- Product Concept
- Clinical applications
- Opportunity
- Market Technical plan
- Research Plan and IP Strategy
- Regulatory Plan
- Clinical Testing Plan
- Risk analysis



Product Concept

- New adhesive for neonatal use that can be removed without damaging fragile neonate skin

Lily

Alyssa

Clinical Applications

Use	Current method	Problems/Challenges
Secure temperature probes	• Hydrogel tabs on bare skin	Adhesiveness fails in high humidity – need to interrupt infant to change ~ 3 hours
Secure ECG sensors	• Hydrogel electrodes on bare skin (chest; extremities)	Adhesiveness fails in high humidity – need to interrupt infant to change ~ 3 hours
Secure Oxygen sensors	• Adhesive tapes on bare skin (foot) Compression/velcro tapes	Skin tearing with removal or adjustment
Friction site protection	• Protective films (e.g., Tegaderm; Opsite; Bioclusive) placed on elbows, knees, heels, behind ears. Left on until falls off.	OK at present
Secure IV and A-Lines – arm, scalp, umbilicus	• Protective film to secure IV – often need adhesive "paint" (e.g., Mastisol) underneath film • Adhesive tape adhering to film and to skin to secure tubing and accessories	• Quick access to IV site without damaging skin • Reliably adhering to avoid accidental pull-out while minimizing damage to skin • Duoderm opaque (can't see products underneath) and almost impossible to remove without damaging skin
Stoma/Ostomy/Urine management	• Pectin-based stomahesive wafer used to adhere appliance to skin • Additional adhesive tapes used to secure ostomy/urine pouch or feeding tubes, often without underlying film adhesive to protect skin	• Frequent changes of pouches and wafers (1+/24 hours) damage fragile skin • Opaque wafers do not enable visualizing underneath
Endotracheal tube management	• Tegaderm used to provide protective skin barrier for stronger adhesives needed to secure ET tube • Adhesive tapes used to secure ET tube and associated accessories (Alternate – Neobar with adhesive strips)	• Accidental extubation due to adhesive failure • Adhesive failure due to high humidity (especially Neobar) • Emergency access to infant leads to skin tearing • Duoderm bonds too well to tiniest patients – skin damaged when removing

Opportunity

- Tape or adhesive that adheres well in a high humidity/moist environment for securing temperature probes and ECG electrodes or ET tube holders, yet can be repositioned or removed without damaging the skin. A secondary step to properly and delicately remove the adhesive is acceptable.

- This product can potentially find uses with the fragile skin of burn patients as well as the elderly patient whose skin is thinning and becoming fragile.

Market Assessment - Total

	Millions per year		
	tape attachment	Electrodes	Patches
IV Line attachment	16.4		
ET tube attachments	0.7		
Friction site protection			0.2
Stoma/Ostomy/Urine	0.2		
Oxygen sensor	1.6		
ECG sensor		4.9	
Temperature probe	27.9		
TOTALS	46.8	4.9	0.2

Assuming a single use patch or tape like attachment with unit selling price of $0.25, this equates to a 46.8 X $0.25 = $11.7 million opportunity or $21.39 per average neonate

Market Assessment - Example

Temperature Probe Adhesive Utilization (single Hospital data)

- A temperature probe is taped on the baby's skin on admission.
- 2-3 probes are attached to each baby at a time.
- The temperature probes adhesive is changed once per shift.
- 50% of babies get these probes for one week; 4% get them for 10 to 12 weeks
- Mean stay time per patient is 20 days.

Calculation (population)

Assume 50% of 546,047 new born admits get temperature probes for one week and 25% get temperature probes for 20 days

273,023 babies/yr X 7 days X 2 probes/baby X 3 changes/day = 11.5 million
+ 136,511 babies/yr X 20 days X 2 probes/baby X 3 changes/day = 16.4 million

Total: 27.9 million adhesive applications annually for attachment of temperature probes in NICUs

Basis: Detailed data from 1000 admissions to *** Hospital's 84 bed NICU in 2006-7
Scaled to 525,571 premature births in US in 2005 (AHA data)

Market: Adoption Issues

Clinical Adoption Issues: 1) How well the adhesive adheres to the skin especially in difficult environments such as high temperature, high humidity and moist skin conditions 2) How well the adhesive is deactivated and removed without damaging the skin 3) How quickly and easily the adhesive is deactivated 4) How long the adhesive tape continues to work as an adhesive [working-life] 5) Deactivation method employed 6) Convenience in NICU environment [no special shielding required, etc.] 7) Tape flexibility
Operational Adoption Issues: 8) Deactivation method and difficulty 9) Special devices or processes for deactivation cycle 10) Time for deactivation 11) Available forms of the adhesive tape
Economic Adoption Issues: 12) Cost per unit 13) Cost for deactivating method [any special equipment, materials] 14) Savings for reduced skin burns and damage caused by traditional adhesive tapes

Market: Vendors and Products

Medical Tape Providers
▪ **3M Products** ▪ **Hollister Products** ▪ **Coloplast Products** ▪ **Convatec Products** ▪ **Johnson and Johnson Products** ▪ **Kendall Products** ▪ **Smith and Nephew Products**
Medical Adhesive Tape Products
1) Tegaderm Transparent Dressing ĞPolyurethane Thin Film, Acrylate adhesive, STERILE, 3M 2) Opsite ĞTransparent Film, Acrylic adhesive, Smith & Nephew 3) Bioclusive Transparent Dressing ĞPolyurethane Thin Film, STERILE, Johnson & Johnson 4) Versaderm Dressing ĞTransparent Polyurethane Film, Polyacrylate adhesive, STERILE, Centurion 5) Hypafix ĞNon-woven fabric, flexible, used for securing lines and wound dressings, Smith & Nephew, NS 6) Hytape ĞOpaque Pink Tape, Zinc-Oxide adhesive, HyTape International 7) Steristrips ĞReinforced non-woven backing with pressure sensitive adhesive, STERILE, 3M 8) Red Dot Neonatal ECG Electrodes ĞConductive adhesive, conformable, solid-gel, STERILE, 3M 9) Various bulk adhesive tape rolls Ğwoven cloth backing, paper backing [Transpore White], perforated plastic backing [Transpore] Ğ3M

Research Plan & IP Strategy

1. Proof-of-Principle
   - Two-year, $340,000 engineering research program

2. Engineering development to release-to-manufacture
   - (TBD)

Regulatory Plan

- US
  - Class 1. Product code XXX. Medical Adhesive
  - 510(k) pathway
- Europe
  - Class 1 (nonsterile) tape for intact skin, or Class 1S (sterile)
  - Technical File, Declaration of Conformity, Registration
- Time frame: Months

Clinical Testing Plan

Clinical Study Type	# of Patients	Study Objective / Endpoint	Follow-up period	Estimated Cost / Pt Enrolled	Region(s) Involved in Study
Efficacy	TBD Ğ depends on the statistical requirements for the test in question.	Test the efficacy of the adhesive tape and the method used for deactivation of the adhesive via a reduction in peel force to remove. These tests will be conducted against competitive medical adhesive tapes.	Acutely and 30 days to assess if adhesive tape and deactivation method induced any skin damage or reduced in effectiveness	TBD	Three IPI consortium hospitals

Risk Factors

Product / Process	Failure Mode Effect Root Cause	Risk Level	Plan to Address
Product fails to adhere as intended	Adhesive failure	High Ğloss of associated devices relying on adhesive tape	Focal point of development effort Will test in all likely environmental conditions
Product produces irritation of tissues underneath tape	Adhesive material composition	High Ğinfection	Full suite of Biocompatibility testing, irritation testing, allergen testing
Product fails to remove without damaging underlying tissues	Deactivation process failure	High Ğcauses skin irritation and discomfort when removing	Focal point of development effort Will test in all likely environmental conditions

11:44 AM, Wednesday, January 12, 2011

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Tuesday, January 11, 2011

IPI granted $340K for neonatal adhesives

By Lori Valigra, Mass High Tech correspondent

Ross Trimby, chief operating officer of the Institute for Pediatric Innovation Inc.

The nonprofit Institute for Pediatric Innovation Inc. (IPI) in Cambridge, working with Brigham and Women's Hospital and Children's Mercy Hospitals and Clinics, has received a $340,000 grant from Philips Healthcare to develop an adhesive medical device to be used in neonatal intensive care units (NICUs).

Some 250,000 to 350,000 premature babies each year need treatment in NICUs involving sensors and other devices attached to their still-underdeveloped skin, which can tear using today's adhesive tapes, said Ross Trimby, chief operating officer of IPI.

"Skin in premature infants can feel more like a gelatinous cover than the dried and formed skin of adults or babies," Trimby explained. "We are developing a mechanism with an adhesive containing various layers that can be released from an infant's skin without destroying it."

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Tech Pulse Poll

What should be Gov. Patrick's priority in supporting Massachusetts' tech sectors?

- ○ Expansion of STEM education initiatives
- ○ Increased financial support for technology clusters in local communities
- ○ Expanded grants and tax incentives for startups in statewide industry-specific clusters
- ○ Additional mid-career technology training programs
- ○ Across-the-board state spending cuts

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(Completed Q3 2012; patent application filed; MS in press)

Return on Investment

Lily and Alyssa