Technology to Improve Patient Care

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AGENDA

1. Discuss the critical role nurses play in technology development
2. Case Study in Developing Technology:
The Unmet Need for a Device to Track and Monitor Fluid Intake
3. Case Study in Testing Technology:
Theragnostic Wound Healing Technology: Moving from Bench-to-Bedside

Nurses are Innovators, Inventors and End-Users.

Nurses use technology and medical devices to aid in the assessment, monitoring, diagnosis, and treatment of health conditions.
Nurses and Technology Development
Identifying Unmet Need

1. Successful products are often designed around an unmet need
2. Need can lead to a new product or revision to an existing product
   • Easier to use
   • Used in different environment
   • New features for expanded use


Nurses and Technology Development
Getting Started

3. Getting started
   • Conduct a thorough search for products designed to meet the need
   • Identify products from other domains that could be adapted
   • Identify the essential functions you want the product to perform
     • Who will use the product, when and where it will be used, and what it should do
   • Consult with experts, engineers, computer specialists


Nurses and Technology Development
Pathway

4. Determine path to bring new product to market
   • Individual inventor can be risky (less than 1% of independent inventions become commercial products)
   • Capital and expert resources are needed
   • Failure is to be expected
   • Identify the issues to intellectual property
   • Large companies have internal product development teams vs start ups
   • Publishing ideas with trepidation

Nurses and Technology Development
Research and Development

5. New product development
   - Build a team
   - Find a funding source

6. Prototype Development and testing
   - Feasibility prototype
   - Early testing prototype
   - Late testing prototype
   - Commercial product development


Local Funding Mechanisms
Sciencecenter.org/discover/qed

OVERVIEW

CESQG stands for grant and demonstration or “grant or demonstration”.

Sometimes an idea alone isn’t enough. That’s where CESQG comes to the rescue.

The CESQG program provides grants to academic researchers, businesses, and non-profits to develop, test, and evaluate new technologies and ideas.

The program is open to proposals in multiple areas.

• Support for academic researchers
• Support for businesses
• Support for non-profit organizations

For information on how to apply for a grant, visit Sciencecenter.org/discover/qed.

CESQG is funded by the National Science Foundation and managed by the Pennsylvania Science Center.

The program provides grants to support the development of new technologies and ideas in areas such as healthcare, education, and transportation.
NIH Phases of Innovation Funding

Phase I: Proof-of-Principle. The objective of Phase I is to establish the technical merit, feasibility, and commercial potential of the proposed technology and to determine the quality of performance of the small business-awardee organization prior to proposing further research and development in Phase II. Phase I awards may not exceed $150,000 total costs for 6 months (or 1 year if 17T).

Phase II: Research and Development. The objective of Phase II is to continue the K.R43/R44 effort initiated in Phase I. Funding is based on the predicted potential of the project proposed in Phase I. Only Phase II awards are eligible for Phase II awardee. Phase II/R43/R44 Phase II awards normally do not exceed $2,000,000 total costs for 2 years.

Phase III: Commercialization. The objective of Phase III, where appropriate, is the licensing of the technology to a commercial organization for the purpose of bringing the technology to market. Phase III activities. The term 2018/2019 programs do not fund Phase III, and III does not generally proceed any Phase II funding to small businesses.

Source: NIH.gov

What is SBIR and STTR?
The Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs provide small businesses with funding and assistance for research and development activities. The SBIR program encourages small businesses to demonstrate the feasibility and potential commercial impact of advancing a technological innovation or to improve an innovation's likelihood of success in the marketplace through pilot project funding. The STTR program encourages small businesses to partner with academic institutions to enhance the commercial potential of innovative results derived from federally funded research.

Source: NIH.gov
Innovators Need to Learn How to Swim with the Sharks

- Bootcamps, Pitch events
  - Steve Blank and the Lean Start-up (Harvard Business Review)
- NSF I-Corp and NIH I-Corp

Self-Assessment
What are the proper sequence of events for technology development?

Case Studies

1. Case Study in Developing Technology:
   *The Unmet Need for a Device to Track and Monitor Fluid Intake*

2. Case Study in Testing Technology:
   *Theragnostic Wound Healing Technology: Moving from Bench-to-Bedside*
Wireless Device to Track/ Monitor Fluid Intake
Inventors: R. DiMaria-Ghalili, K. Pourrezezi, A. Pourshoghi

MEASUREMENT CHALLENGES

Need for digital health technology that records and monitors liquid intake.

Smart Cup

intake ➔ Record ➔ Monitor ➔ Outcome

Malnutrition ➔ Alerts

Student Success Magazine
Clinical Applications

- Self-care management
  - Under and over nutrition
  - Heart Failure
  - Renal Failure
  - Dehydration
  - Athletes, health and wellness
- Clinical Decision Support

Technical Background

1. Prototype
   - Hardware: Two-piece system (disposable cup and cup holder with sensors)
   - Volume measuring sensory system (VMSS): time, volume, spillage

2. Software
   - Apps for clinical decision support

Milestones

- The early-testing Smart Cup prototype met the proof-of-feasibility for measuring time and volume of each drinking event.
- Refined the VMSS to account for spillage events
- Enhanced human factor design and usability
- Tested in hospital patients (proof-of-concept): malnourished, heart failure
- Surveys of nursing practices and readiness of mHealth adoption of CNos
- Total fluid intake for heart failure patients (food + fluid)
- Queried heart failure patients for potential interface
- Interface for real-time monitoring
Next Steps

- Develop the alerts and enhance clinical interface
- Enhance human-factor design and usability evaluation
- Further testing in targeted populations

Team

- Co-inventors: Kambiz Pourrezaei, PhD, Ahmad Pourshoghi, PhD, Biomedical Engineering
- Collaborators: Ellen Bass, PhD, CNHP, College of Computing and Informatics, Arun Ramakrishnan, PhD, CNHP, Zachary Hathaway, BS
- Students: Keyanna Bynum, Swathi Veeravalli, Hoang Nam Le

Funding

- Drexel CNHP Dean’s Seed Fund
- IPART
- Drexel-Coulter Translational Research Seed Grant from the Wallace A. Coulter Foundation
- NIH-NINR STTR (1 R41 NR15191-01 PI: DiMaria-Ghalili)

Case Study:
Theragnostic Wound Healing Technology: Moving from BENCH to BEDSIDE
Enhanced Ultrasound Treatment of Chronic Leg Wounds, Wound Healing, QOL

**Background**
- Up to 2,000,000 Americans have venous ulcers (VU).
- 15-25% of diabetics have a diabetic foot ulcer (DFU).
- New treatment modalities are needed to lessen the burden of chronic wounds and improve health-related quality of life (HRQOL).
- We developed a lightweight, battery-operated low-frequency (20 kHz) low-intensity (<100 mW/cm² spatial peak-temporal peak intensity) ultrasound (LFLI US) device to treat chronic wounds (Figure 1).
- LFLI US treatment improved healing by 15% per week compared to sham treatment in pilot studies.

**Aims**
- Evaluate the effect of LFLI US on VUs and DFUs by measuring wound closure as primary endpoint and generic and disease-specific HRQOL as secondary endpoints.
- Monitor the effects of LFLI US on wound perfusion and oxygenation using non-invasive optical methods.
- Determine the impact of nutritional status and inflammation on closure of DFUs and VUs.

This project is funded by NIH 1R01NR015995 (PI: Lewin). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Early Detection of Deep Tissue Injury

- Diffuse optical spectroscopy can non-invasively measure blood flow and tissue oxygenation in subcutaneous tissue.
- How does it work?
  - Near infrared light (safe, non-ionizing) enters tissue through an optical fiber.
  - Light that scatters back to the surface is detected by a second optical fiber.
  - Detected light carries information about blood flow and oxygenation within the probed volume of tissue.

Light In

<table>
<thead>
<tr>
<th>skin</th>
<th>subcutaneous muscle</th>
<th>bone</th>
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~ 3 to 5mm

Light Out

Optical Probe

Optical Probe with Wavelengths
Recently Completed Study

- **Patient Population**
  - Rehabilitation patients (Magee Rehab)
  - Diagnosed with sacral Stage 1 PI or Suspected Deep Tissue Injury (i.e. intact skin)
  - No pre-existing open pressure injuries or diabetes
  - 18+ years of age
- **Protocol**
  - Measured blood flow beneath red skin using diffuse optical device
  - Up to 4 optical measurement sessions over 2 week period
  - Identified patients who developed open PI within 2 weeks after last optical measurement

Study Results

- 4 subjects developed advanced PIs (stage 2-4 or unstageable)
- 12 subjects Injury Reversed / Resolved

**Measured Blood Flow Index (BFI)**

<table>
<thead>
<tr>
<th>Measurement Number</th>
<th>BFI – All Patients by Measurement</th>
</tr>
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<tbody>
<tr>
<td>Healthy (~8 * 10^-9 cm^2/sec)</td>
<td>~8 * 10^-9 cm^2/sec</td>
</tr>
<tr>
<td>Moderate (~8 * 10^-9 cm^2/sec)</td>
<td>~8 * 10^-9 cm^2/sec</td>
</tr>
<tr>
<td>Developed (&gt;12 * 10^-9 cm^2/sec)</td>
<td>&gt;12 * 10^-9 cm^2/sec</td>
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**Optical Device used in study**

Team

- Research Team: Peter A. Lewin, PhD (PI), R. DiMaria-Ghalili, PhD, RN, M. Weingarten, MD, MBA, M. Neidrauer, PhD, L. Zubkov, PhD, D. Margolis, MD, PhD
- Ultrasound and optic technology is patented

**Funding**

- Ultrasound Wound Healing: NIH: NINR, Alzheimer’s supplement from NIA
- Deep Tissue Injury: Department of Defense, Drexel Coulter Foundation, Drexel College of Medicine Clinical Translational Research Institute
Thank-You!