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Collaborative Research in Medical Sensing: Wearable Wireless Sensor for Pressure Ulcer Prevention

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Collaborative Research in Medical Sensing: Wearable Wireless Sensor for Pressure Ulcer Prevention

John McNeill, Ph.D.
WPI ECE Department

May 16, 2017
Disclosures

• Grant/Research Support:
  – In-kind support, Boston Scientific

• Graphic content warning: Images of
  – Pressure ulcer wound
  – Porcine model animal experiment
### Development of Biomedical Collaboration

#### Greatest Engineering Achievements of the 20th Century

1. Electrification
2. Automobile
3. Airplane
4. Water supply & distribution
5. Electronics
6. Radio & television
7. Agricultural mechanization
8. Computers
9. Telephone
10. Air-conditioning & refrigeration
11. Highways
12. Spacecraft
13. Internet

#### Engineering's Grand Challenges

- Make solar energy economical
- Provide energy from fusion
- Develop carbon sequestration methods
- Manage the nitrogen cycle
- Provide access to clean water
- Restore & improve urban infrastructure
- Advance health informatics
- Engineer better medicines
- Reverse engineer the brain
- Prevent nuclear terror
- Secure cyberspace
- Enhance virtual reality

- **General direction: NAE Grand Challenges**
  - Health; Sustainability; Security

Collaboration History

2011-12
• MQPs: Wired / Wireless pressure ulcer prevention device
  Morianos, Jones, Gutierrez; Williams, Truhanovitch, Hause
  Advisors: Mendelson (BME), Bitar (WPI ECE), Dunn (UMMS)

2015
• McNeill, Dunn meet at UMMS/WPI Research Collaboration event
• $20K + $5K WPI/UMMS Seed Grant funding
  Partial support for MS student Matthew Crivello

2016-17
• McNeill ½ sabbatical at UMMS
• TA support for PhD student Devdip Sen
• 2 MQPs (ECE, BME)
  Agdeppa, Hussain, Kim, Loehle; Ooyama-Searls, Pachucki, Parent
  Advisors: McNeill, Mazumder, Mendelson

2017-18
• $25K UMass Technology Commercialization (OTCV) funding
• $10K Massachusetts Technology Transfer Center (MTTC)
Motivation: Pressure Ulcer Prevention

- Painful
- Increases risk for secondary infection
- Wound healing takes up to several months
  - May not heal at all in compromised patients
- Adds $11B annually to US health care costs
- Demographics: Increasing cost, incidence, prevalence
  ➔ Need compact, low-cost prevention for patients:
    - In hospital setting
    - Confined to bed at home
    - With limited mobility in wheelchairs

Healing of pressure ulcer over several months

Cause: Localized Pressure

- External pressure over ~30mmHg restricts blood flow
- Ischemia; tissue deprived of oxygen
- Can lead to tissue necrosis
Opportunity for Prevention

- Well-known locations on body at risk for pressure ulcer formation
- Location depends on patient environment:
  - Hospital setting
  - Confined to bed at home
  - With limited mobility in wheelchair

• Device: Low-cost, disposable, wearable sensor patch
• System: Wireless data collection from multiple at-risk sites
• Algorithm: Assess risk from pressure vs. time profile
• Low-cost, disposable, wearable sensor patch
• Measure local pressure, temperature
• Small size, comfortable to wear for long duration
Benefits of Our Approach

• Low cost: $10 / sensor
• 7-day wearable; disposable
• Meet needs for multiple populations:
  – Caregiver: Reduces workload
  – Doctor: Detailed pressure-time information
  – Patient: Improved independence

Drawbacks of Existing Techniques:

• 2-hour turn protocol
  – Workload, injury risk for caregivers
  – Not supported by controlled trials
• Offloading beds
  – Expensive (> $10K), fixed location
• Pressure mapping pad
  – Expensive (> $1K), caregiver interpretation
$11B annual cost in US for pressure ulcer treatment

- Potential annual market population:
  - Hospitals: 35.1 million (2014: No Medicare reimbursement)
  - Nursing homes: 1.4
  - Long term / residential care: 1.0
  - In-home care: 5.3

Potential Population (5% at risk): 2.1 million
Estimated Gross Annual Market: > $120 million

- Demographic demand accelerating
  - Aging, longer lived population

Flexible Wired Prototype

- Implement sensors, measurement circuitry on flexible substrate
**Animal Experiment Data Acquisition**

- **Surgical protocol:** Anesthetized pig immobile on back for ~ 7 hours
- **Identified at-risk sites for placement of wired sensors**
- **Acquire data from multiple sites**
Experimental Results

- Pressure, temperature vs. time over 7 hour duration
- Surgical protocol: Animal repositioned every 90 minutes
Experimental Results

• Pressure, temperature vs. time over 7 hour duration
• Verified ability to resolve threshold, pressure relief events
• Importance of multiple sensors for each at-risk point
Current Status

- Wireless prototype verified
  MS: Matt Crivello
  PhD student: Devdip Sen
  WPI Undergraduate project:
  ECE MQP: Amanda Agdeppa
  Ali Hussain
  David Kim
  Victoria Loehle
## Development Plan Status

<table>
<thead>
<tr>
<th>Activity / Milestone</th>
<th>Status</th>
<th>Funding Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure contact pressure, temperature, moisture</td>
<td>Verified</td>
<td></td>
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<tr>
<td>Wireless self-powered measurement</td>
<td></td>
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<tr>
<td>Human wearable, biocompatible sensor</td>
<td>IN PROGRESS (OTCV, MTTC, M2D2)</td>
<td></td>
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<tr>
<td>Animal model trials</td>
<td></td>
<td></td>
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<tr>
<td>Evidence based algorithm</td>
<td></td>
<td>FUTURE FUNDING (NIH, NSF, SBIR, STTR, PARTNERS)</td>
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<tr>
<td>Human trials (Class 2)</td>
<td></td>
<td></td>
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<tr>
<td>Clinical use</td>
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- Licensing most likely path to commercialization
- IP Status: Provisional patent application filed June 2016

Potential Partners
- Boston Scientific: Wearable sensors
- Johnson & Johnson: Managing diabetes, surgery recovery
- Convatec, Acelity, Smith & Nephew, Medtronic, GE, ...

➡️ M2D2 support: Preliminary results for future funding

**Technology: Disruptive shift in pressure ulcer prevention**
# Interdisciplinary Development Team

** UMMS Division of Plastic Surgery **

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Specialty</th>
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</thead>
<tbody>
<tr>
<td>Raymond Dunn, M.D.</td>
<td>Chief; P.I.</td>
<td>Head, Wound Care</td>
</tr>
<tr>
<td>Kelli Hickle, M.D.</td>
<td>Resident</td>
<td>Surgical resource</td>
</tr>
<tr>
<td>Heather Tessier</td>
<td>Lab Director</td>
<td>Animal model resource</td>
</tr>
</tbody>
</table>

** WPI Electrical & Computer Engineering **

<table>
<thead>
<tr>
<th>Name</th>
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<th>Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>John McNeill, Ph.D.</td>
<td>Professor</td>
<td>Sensor electronics</td>
</tr>
<tr>
<td>Xinming Huang, Ph.D.</td>
<td>Professor</td>
<td>Internet of Things</td>
</tr>
<tr>
<td>Devdip Sen</td>
<td>Student</td>
<td>Prototype fab / test</td>
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** WPI Biomedical Engineering **

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<tr>
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</thead>
<tbody>
<tr>
<td>Yitzhak Mendelson, Ph.D.</td>
<td>Professor</td>
<td>Skin-friendly materials</td>
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Acknowledgments

- Supported by a grant from the UMMS/WPI Collaborative Seed Funding Initiative.

- William Appleyard [WPI]
  - Assistance with sensor fabrication

- Heather Tessier [UMMS]
  - Access to experimental resources
  - Compliance with the IACUC-approved protocol
Summary: Lessons Learned

- Find an important problem: Listen to practitioners
  - Reduce cost, improve quality of care
  - Meets needs for majority of patient populations
  - Reduce workload on caregivers
- Clinical partner a must
- Engineers:
  - Interdisciplinary team
  - Different experimental constraints
  - Rapid prototyping
- Need credible plan for entire development cycle
  - Bring in partner resources (business, IP, …)
- Multiple funding sources
  - Get out of your comfort zone