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Medical Devices: from Innovative Idea to Clinical Impact

Nigel Lovell
Graduate School of Biomedical Engineering
University of New South Wales, Sydney

Translational Research in Biomonitoring and Bionics

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- Wearable sensors for falls detection and prevention

- Telehealth systems for management of chronic disease
  (regulatory approved CE mark/FDA)

- Implantable bionics

Falls Management: Laboratory to Real World

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- Wearable technologies for falls detection and prevention
  - Fall detection
    - Combining accelerometry with barometric pressure and gyroscopy
  - Falls risk estimation
    - Using triaxial accelerometry and a directed routine

Fall Detection

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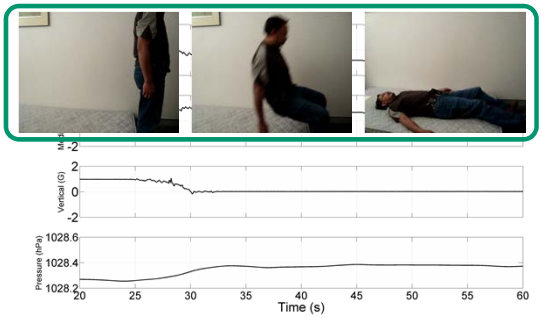
- Fall backwards with attempt to break fall



Fall Detection

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- Indoor
- Outdoor

	Algorithm 1	Algorithm 2	Algorithm 3
Accuracy (%)	70	85.3	**96.9**
Sensitivity (%)	75	75	**97.5**
Specificity (%)	67	91.5	**96.5**

Algorithm 1: triax alone (Karantonis *et al.*)
Algorithm 2: triax & tilt angle
Algorithm 3: triax & tilt & pressure

	Algorithm 1		Algorithm 2		Algorithm 3	
Subject No.	Fall Alarms	Events generating a Fall Alarm	Fall Alarms	Events generating a Fall Alarm	Fall Alarms	Events generating a Fall Alarm
1	2	• Wearing the device after dropping it on the floor • Wearing the device after going to the toilet	0	N/A	0	N/A
2	2	• Dropping the device on the floor • Running	1	• Running	0	N/A
3	1	• Walking down four big steps	0	N/A	0	N/A
4	2	• Getting into the car • Dropping the device on the car's seat	1	• Getting into the car	0	N/A
5	4	• Dropping the device on the floor • Wearing the device after going to the toilet • Getting into the car • Dropping the device on the car's seat	1	• Getting into the car	0	N/A

Bianchi *et al. 2011* (IEEE Trans Neural Systems and Rehab Eng)

Fall Risk Estimation: Directed Routine

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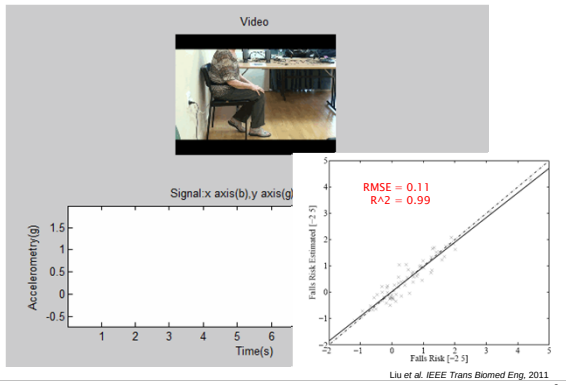

Liu *et al. IEEE Trans Biomed Eng*, 2011

Falls Management: Unsupervised Setting

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- Compliance
- Device positioning
- Losing device
- Night time falls
- Lack of real falls data
- Key challenge remains in turning laboratory-based studies into systems that can be used in free-living environments with demonstrated clinical efficacy

Evidence for Telehealth Cost Benefit

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	Visits to GP	GP visits to home	Phoned surgery	Seen nurse at home	Admissions to hospital	Bed days
Pre Telehealth	90	24	51	8	10	40
Post Telehealth	45	20	42	1	3	12*
Change	-50%	-16.7%	-17.6%	-87.5%	-70%	-70%

N=13, 9 months before and after telehealth. * 11 of the 12 bed days were within the first 3 weeks of installation.

- Cost of Care Coordination/Home Telehealth was $1,600 per patient per annum – cf home-based primary care services of $13,121 pa and market nursing home care rates of $77,745 pa
- 25% reduction in numbers of bed days of care, 19% reduction in numbers of hospital admissions, and mean satisfaction score rating of 86% (N=17,025)

Darkins et al. "Care Coordination/Home Telehealth (CCHT): The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions", TeleMedicine and eHealth, 2008.

Clinical Measurements

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Telehealth Management System

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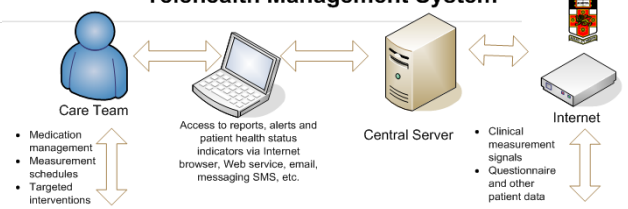
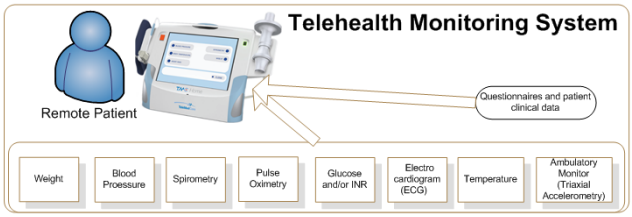


Telehealth Monitoring System



Early Clinical Telehealth Trials

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Signal Quality During Unsupervised Recordings

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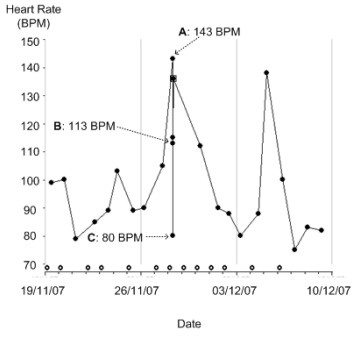
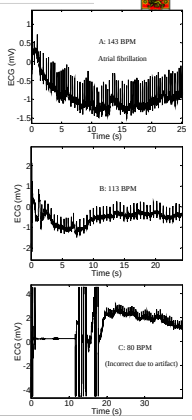
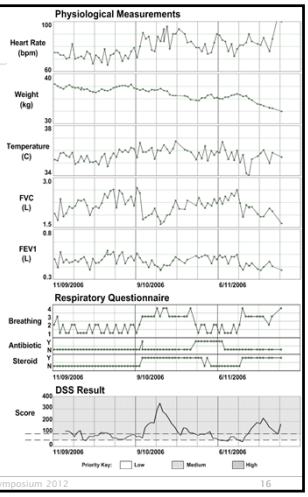




Data Complexity

- Chronic disease has complex co-morbidities
- Not all factors are necessarily captured nor codified (e.g. medications changes)
- Trends in certain parameters can be good for some people and bad for others (weight loss in COPD vs weight gain in CHF)
- Hugely complex pattern recognition task
- Data overload!



Telehealth: Device to Commercial Product

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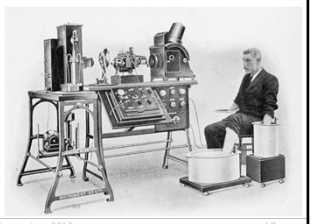
- How far have we really come?
- Laboratory to real world issues still exist
  - Alerts/decision support systems for data overload
  - Biosignal processing for improving quality of unsupervised measurements
- BUT they are not the primary barrier
- Finding how the technology either fits best into an existing health service delivery model … or creating a new model



Bionic Eye – Implantable System

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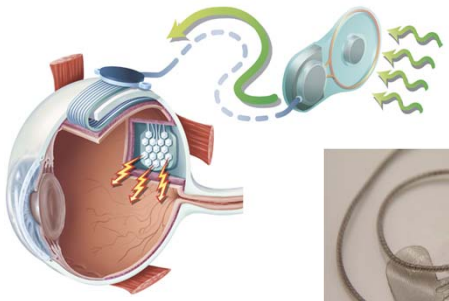

Translating Technologies to Future Bio-Businesses

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- Hugely topical and media attractive
- Understandable technology to investors
- Capacity building for Australian neuroprosthesis industry
- Some freedom to operate in IP space

- Demonstrated improvements in QALY
- Chronic disease management is the largest emerging health care problem
- Diffuse, integrative technology
- Hard to protect IP
- Often not technological barriers but political and economic
- Not a single, nor simple business model (public funded, private health insurance, community/nursing home, occupational health, individuals)

To Win in Translational Research and Development

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- Innovation essential in driving change in health
  - Can be in design, delivery, practice or integration …
- Recognise that in many cases technology is not weakest link
  - Interoperability, data access, cultural, legal, political, market-related, user acceptance, organisational changes, legal framework (liability, data security and privacy), reimbursement
- Two current key challenges
  - Turning clinic/lab-based devices into systems that can be used in free-living (unsupervised) environments
  - Pathways to regulatory approval – addressing safety and efficacy in risk averse environments
- Multi-disciplinary collaborations and partnering