Developing and Testing a Patient Centred Pressure Ulcer Prevention Care Bundle; Findings from a c-RT

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Puerto Rico
Background


- Adherence to PUP strategies is sub-optimal (Vanderwee 2011, Gunningberg 2005, Centre for Healthcare Improvement 2012)

- Australian National Safety and Quality Health Service Standards (ACSQHC 2011)
  - Consumer Participation
  - Preventing Pressure Injuries (PU)

- Care bundles are groups of interventions, that together improve patient care and outcomes (IHI 2013)
Complex Interventions

- **Intervention with several interacting components** (Craig 2008; Campbell 2000)

- **Used when:**
  - Complex problems are being addressed
  - Multidimensional influencing factors
  - Single interventions have been ineffective

- **Common terms:**
  - Multifaceted intervention
  - Multicomponent intervention
  - Care bundle or bundled intervention
Complex Interventions
(Craig, 2008)

- Complexity may arise from:
  - Number of and interactions between components
  - Number and difficulty of behaviours by those delivering/receiving intervention
  - Number of groups or organisational levels targeted by intervention
  - Number and variability of outcomes
  - Degree of intervention flexibility or tailoring permitted

- This complexity can make intervention development and evaluation difficult → framework recommended
Process for developing and evaluating complex interventions (Medical Research Council; Craig 2008)

**Development**
1. Identifying the evidence base
2. Identifying/developing theory
3. Modelling processes and outcomes

**Feasibility/piloting**
1. Testing procedures
2. Estimating recruitment/retention
3. Determining sample size

**Evaluation**
1. Assessing effectiveness
2. Understanding change process
3. Assessing cost-effectiveness

**Implementation**
1. Dissemination
2. Surveillance and monitoring
3. Long term follow-up
1. **Evidence base**

- PU prevalence: 10 – 30% in hospitals
- Hospital acquired PU (prevalence): 7 – 17% in Australian hospitals
- PU impacts: significant patient burden and health care costs
- PU risk factors: ↓mobility, poor nutrition, compromised skin integrity, etc

**Observational research (local practices)**

- PhD students Dr Shelley Roberts, Ms Sharon Latimer
- Activity monitoring study (24 hours)
- Cost-of-illness study
Observational Research

- **Aims:**
  - Describe current PUP practices (PUP guidelines)
  - Patients’ perceived role in PUP

- **Setting:** 4 wards in 2 hospitals

- **Sample:** patients deemed at risk of PU (i.e. reduced mobility)

- **Data Collection:**
  - 24 hour patient observation including nutritional intake \(n = 241\)
  - In-depth interviews \(n = 20\)
Results Summary: (Roberts 2014a, Roberts 2014b, Latimer in press, Latimer 2014)

- About 50% of patients consumed <75% of required energy and protein
- PUP strategies were not consistently implemented
- 27 (11%) of patients received PUP education
- Patients were willing to actively participate in PUP including strategies to improve nutrition
Cost-of-illness study
(Nguyen, Chaboyer & Whitty, 2015)

- **Aims:** Understand the costs of PUs in Australia by state and by severity of PI
- **Methods:** Cost-of-illness study
- **Data:** Prevalence approach; 1-year time horizon; simulation methods
- **Results:**
  - Tx costs across all states and PU stages in 2012/3 estimated to be A$983 million per annum (US $766 million)
  - 1.9% of all public hospital expenses
  - 0.6% of recurrent health expenditure
  - Estimates associated with 121,645 cases of PI and 524,661 bed days lost
## Cost-of-Illness Data

<table>
<thead>
<tr>
<th>State</th>
<th># Cases/Annum Mean (sd)</th>
<th>Total Cost/Annum Mean (sd)</th>
<th>Extra Bed Days Mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSW</td>
<td>42,062 (3669)</td>
<td>$339 (30)</td>
<td>181,416 (27,987)</td>
</tr>
<tr>
<td>Victoria</td>
<td>28,300 (2469)</td>
<td>$229 (20)</td>
<td>122,060 (18,825)</td>
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<tr>
<td>Qld</td>
<td>22,901 (1,998)</td>
<td>$185 (16)</td>
<td>98,775 (15,233)</td>
</tr>
<tr>
<td>WA</td>
<td>12,376 (1,080)</td>
<td>$100 (9)</td>
<td>53,380 (8,232)</td>
</tr>
<tr>
<td>SA</td>
<td>10,035 (875)</td>
<td>$81 (7)</td>
<td>43,282 (6,675)</td>
</tr>
<tr>
<td>Tas</td>
<td>2,254 (197)</td>
<td>$18 (2)</td>
<td>9,772 (1,499)</td>
</tr>
<tr>
<td>ACT</td>
<td>1,912 (168)</td>
<td>$16 (1)</td>
<td>8,313 (1,282)</td>
</tr>
<tr>
<td>NT</td>
<td>1,778 (156)</td>
<td>$15 (1)</td>
<td>7,713 (1,189)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>121,645 (10,612)</strong></td>
<td><strong>$983 (86)</strong></td>
<td><strong>524,661 (80,915)</strong></td>
</tr>
</tbody>
</table>
Activity Monitoring Study
(Chaboyer, Mills et al. 2013)

- **Aims:** Describe mobility patterns of at risk patients
- **Setting:** 2 acute medical wards in 1 hospital
- **Sample:** 84 patients who had been in hospital for at least three days and were deemed at risk of pressure injury because of limited mobility
- **Data Collection:** 24 hours of data collection using a physical activity monitor (Actigraph GT3X+)
- **Results:**
  - 94% ± 3% participants’ time was spent in the sedentary activity range
  - Patients changed posture (greater than 10º for ≥ 5 min) a median of 94 (IQR 48) time in the 24 hour period (range 11-154); the equivalent of almost 4x/hr
  - We don’t know if these were independent/assisted movements
Physical activity levels and torso orientations of hospitalized patients at risk of developing a pressure injury: An observational study

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PhD Student and Director, Research Centre for Health Practice Innovation, Griffith Health Institute & School of Public Health, Griffith University, Gold Coast, Australia

*Sharon Latimer RN PhD Candidate*
Lecturer and PhD Student, Research Centre for Health Practice Innovation, Griffith Health Institute & School of Nursing and Midwifery, Griffith University, Gold Coast, Australia

Accepted for publication April 2012

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Patient participation in pressure injury prevention: giving patient’s a voice

*Sharon Latimer RN, BN, MN, MAP Grad Dip Learn&Teach (PhD Candidate, Lecturer)*, *Wendy Chaboyer RN, BSc(Nut) Hon, MN, PhD (Professor, Director)* and *Brigid Gillespie RN, B-Hlth Sc (Hons), PhD (Senior Research Fellow)*

School of Nursing and Midwifery, Griffith University, Logan Campus, Meadowbrook, Qld, Australia and Griffith University, Gold Coast Campus, NHMRC Research Centre for Excellence in Nursing Interventions (NCREIN), Southport, Qld, Australia

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Patient Perceptions of the Role of Nutrition for Pressure Ulcer Prevention in Hospital

An Interpretive Study

*Shelley Roberts* ■ *Ben Desbrow* ■ *Wendy Chaboyer*

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Acute care patient mobility patterns and documented pressure injury prevention — an observational study and survey

*McInnes E, Chaboyer W, Allen T, Murray E & Webber L*

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Nutritional intakes of patients at risk of pressure ulcers in the clinical setting


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Nutrition care-related practices and factors affecting nutritional intakes in hospital patients at risk of pressure ulcers

*S. Roberts*, *W. Cheboyer*, *B. Desbrow*

1School of Allied Health Sciences, Griffith University, Gold Coast, QLD, Australia
2Centre for Health Practice Innovation, Griffith University, Gold Coast, QLD, Australia
3Griffith Health Institute, Griffith University, Gold Coast, QLD, Australia
4NHMRC Centre of Research Excellence in Nursing, Griffith University, Gold Coast, QLD, Australia
Cochrane Reviews

Repositioning for pressure ulcer prevention in adults (review)
Gillespie BM, Chaboyer WP, McInnes E, Kent B, Whitty JA, Thalib L

Support surfaces for pressure ulcer prevention (review)
McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, Cullum N

Published in *The Cochrane Library* 2014, Issue 4
Published in *The Cochrane Library* 2011, Issue 4
2. Identifying/developing theory

- Patient centred care: ↓adverse events, ↑patient safety, ↑health outcomes
- Care bundles: ↑care processes, ↑patient outcomes, ↑patient safety

3. Modelling processes and outcomes

- Patient education for PUP
- Patient participation in care
Care bundle to prevent PU, incorporating:

- Patient participation in care
- Patient education on PUP
- Engagement of nursing staff in patient participation

Three main messages:

1. Keep moving
2. Look after your skin
3. Eat a healthy diet

Resources:

1. 5-minute DVD
2. Poster
3. Brochure
Process for developing and evaluating complex interventions (Medical Research Council; Craig 2008)

**Feasibility/piloting**
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Feasibility Testing

1. Testing procedures
   - Intervention delivery
   - Acceptability (patient / staff interviews)
   - Methods (i.e study protocol)

2. Recruitment
   - Recruitment rate 52% (58/112) patients willing to participate and use the care bundle
   - Patients willing to participate in a study where their skin is inspected daily and they were required to watch a DVD and review a brochure and poster

3. Acceptability
   - Interviews with 11 patients and 20 nurses found the bundle user friendly
Development and Pilot Testing of a Patient-Participatory Pressure Ulcer Prevention Care Bundle

Brigid M. Gillespie, PhD, RN; Wendy Chaboyer, PhD, RN; Mark Sykes, MBus, BPsych (Hons); Jennifer O’Brien, BN, RN; Susan Brandis, B Bus (Health Admin), B Occ Thy

JCN  Journal of Clinical Nursing

ORIGINAL ARTICLE

Understanding nurses’ views on a pressure ulcer prevention care bundle: a first step towards successful implementation

Wendy Chaboyer and Brigid M. Gillespie
Process for developing and evaluating complex interventions (Medical Research Council; Craig 2008)

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Evaluation: Assessing Effectiveness (Main Trial)

Prof Tracey Bucknall

Prof Joan Webster

A/Prof Liz McInnes

Dr Merrilyn Banks

Prof Mariane Wallis

A/Prof Brigid Gillespie

A/Prof Jenny Whitty

A/Prof Lukman Thalib

Prof Nicky Cullum
Evaluation: Assessing Effectiveness (Main Trial)

- **Design**: Cluster Randomised Trial (c-RT)
- **Clusters**: 8 hospitals (public/private, 200+ beds), stratified by most recent PI rates and randomised 1:1 block allocation
- **Recruitment**: 1,600 patients (200/site)
- **Sample**: Patients at risk of PU as demonstrated by limited mobility (in hospital < 36 hours prior to recruitment)
- **Primary outcome**: incidence of hospital acquired PU
- **Secondary outcomes**: PU stage, patient participation in care, health care costs
- Australian New Zealand Clinical Trials Registry (registration number ACTRN12613001343796)
Main Trial

- **Data collection**: 4 types of Research Assistants (all different people and site specific) 1) Recruitment ; 2) Intervention (intervention sites only); 3) Outcome assessor (daily skin inspection and other data); 4) Health economic data for substudy of 320 patients

- **Data analysis**: led by a biostatistician, individual pt analysis adjusted for the clustering effect

- **Blinding**:
  - Recruiters: only award they are recruiting for a a study of PUP strategies, not that there are other sites or the exact intervention
  - Outcome assessors: Only aware they are assessing the use of PUP strategies and the skin
  - Patients: only aware they are in a study of PUP strategies, not that there are other sites or the exact intervention
  - Data analysts: Blinded analysis by Group A/B
Implementation
Processes

- Project manager: Experienced clinical trial coordinator
- RA training: on site; good clinical practice, role, e-CRF
- Start up site visit
- Telephone contact available daily
- Weekly recruitment graphs
- Monthly newsletters
- Chief Investigator team teleconferences monthly
- Monitoring site visits
- Chief Investigator team 2- day face-to-face meeting at the end of study
Assessed for eligibility n = 8 sites (clusters)

Randomised n = 8 clusters
Excluded n = 0

Allocated to PIPCB n = 4 clusters
Consented n = 800
1 patient excluded after consent (confused)

0 clusters LTFU
22 patients LTFU (2.8%)
20 patients withdrew consent (2.5%)
4 clusters analysed
Average cluster size (SD) n = 189.3 (5.7)
799 patients analysed of which 6 died

Allocated to standard care n = 4 clusters
Consented n = 800
1 patient excluded after consent (confused)

0 clusters LTFU
9 patients LTFU (1.9%)
12 patients withdrew consent (1.5%)
4 clusters analysed
Average cluster size (SD) n = 194.5 (1.3)
799 patients analysed of which 3 died
<table>
<thead>
<tr>
<th>Characteristic (no group differences)</th>
<th>PUPCB n = 799</th>
<th>Control n = 799</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>393 (49.2%)</td>
<td>434 (54.3%)</td>
</tr>
<tr>
<td>Medical</td>
<td>558 (69.8%)</td>
<td>463 (57.9%)</td>
</tr>
<tr>
<td>Surgical</td>
<td>232 (29.0%)</td>
<td>316 (39.5%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>9 (1.1%)</td>
<td>20 (2.5%)</td>
</tr>
<tr>
<td>Number of co-morbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N % of patients with 1</td>
<td>207 (25.9%)</td>
<td>232 (29.0%)</td>
</tr>
<tr>
<td>N % of patients with 2</td>
<td>197 (24.7%)</td>
<td>193 (24.2%)</td>
</tr>
<tr>
<td>N % of patients 3 or more</td>
<td>207 (25.9%)</td>
<td>181 (22.6%)</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>50 (6.3%)</td>
<td>49 (6.1%)</td>
</tr>
<tr>
<td>Number of PU present on baseline</td>
<td>60 (7.7%)</td>
<td>95 (12.0%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>70.0 (20.0)</td>
<td>74.0 (22.0)</td>
</tr>
<tr>
<td>Median (IQR) range</td>
<td>18.0-100.0</td>
<td>19.0-104.0</td>
</tr>
<tr>
<td>BMI</td>
<td>27.4 (7.4)</td>
<td>27.0 (7.6)</td>
</tr>
<tr>
<td>Median (IQR) range</td>
<td>13.1-65.7</td>
<td>14.5-69.4</td>
</tr>
<tr>
<td>Hospital length of stay (days)</td>
<td>6.0 (5.0)</td>
<td>5.0 (5.0)</td>
</tr>
<tr>
<td>Median (IQR) range</td>
<td>1-77</td>
<td>1-97</td>
</tr>
</tbody>
</table>
Results

- After adjusting for the cluster effect, no differences between groups in the use of air mattresses, chair cushions, pillows for heel elevation, wedges or elbow/heel booties
- Mean time spent delivering the PUPCB $9.6 \pm 5.4$ minutes
- Taking into consideration the follow up days in the study, the incidence rate:
  - PIPCB group 11.1/1000 days
  - Control group 23.5/1000 days
- Incidence rate ratio of 2.1 (95% CI: 1.5 to 3.0; p value <0.001)
## Hazard Ratios

<table>
<thead>
<tr>
<th>Intervention effect (reference is control)</th>
<th>Hazard Ratio</th>
<th>Robust 95% CI (robust SE estimate to account for the correlation of outcomes within each cluster; Lin &amp; Wei 1989)</th>
<th>Cluster adjusted 95% CI (more conservative approach; Rogers, 1993)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crude</td>
<td>0.49</td>
<td>0.34 to 0.69</td>
<td>0.20 to 1.21</td>
</tr>
<tr>
<td>Age adjusted</td>
<td>0.53</td>
<td>0.38 to 0.76</td>
<td>0.22 to 1.32</td>
</tr>
<tr>
<td>Age, gender adjusted</td>
<td>0.53</td>
<td>0.38 to 0.75</td>
<td>0.22 to 1.30</td>
</tr>
<tr>
<td>Age, gender, baseline PI adjusted</td>
<td>0.57</td>
<td>0.40 to 0.81</td>
<td>0.25 to 1.29</td>
</tr>
<tr>
<td>Age, gender, baseline PI BMI, cause of admission, place of residence prior to admission, comorbidity at admission adjusted</td>
<td><strong>0.59</strong></td>
<td>0.41 to 0.85</td>
<td>0.26 to 1.35</td>
</tr>
</tbody>
</table>

inter-class correlation (ICC) of a new PI event to be 0.0364; 95% Asymptotic CI = 0.0000, 0.0781.
Kaplan Meier Survival Curves

Group A = PUPCB
Group B = Control
### Numbers Needed to Treat

<table>
<thead>
<tr>
<th>Time</th>
<th>Survival Probability in Control</th>
<th>Survival Probability in PUPCB</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 days</td>
<td>0.89</td>
<td>0.93</td>
<td>27</td>
</tr>
<tr>
<td>10 days</td>
<td>0.76</td>
<td>0.88</td>
<td>8</td>
</tr>
<tr>
<td>15 days</td>
<td>0.64</td>
<td>0.86</td>
<td>5</td>
</tr>
</tbody>
</table>
Process Evaluation (Grant, 2013)

Processes involving clusters

Recruitment of clusters: How are clusters sampled and recruited? Who agrees to participate?

Delivery to clusters: What intervention is actually delivered to each cluster? Is it the intended intervention?

Response of clusters: How is the work of the intervention and trial implemented in and adopted by clusters?

Processes involving target population

Recruitment and reach of individuals: Who actually receives the work of the intervention in each setting? Are they representative?

Delivery to individuals: What intervention is delivered in each cluster? Or what behaviour change has occurred because of the intervention?

Response of individuals: How does the target population respond?

Maintenance: How and why are these processes sustained over time (or not)?

Effectiveness: What are the effects on the primary and secondary outcomes?

Unintended consequences: change in other outcomes which may be perverse, harmful or beneficial?

Theory: What theory has been used to develop the intervention? Can a theory be considered to interpret the effects of the intervention?

Context: What is the wider context in which the trial is being conducted (e.g., organisation of healthcare, financial and non-financial incentives affecting the processes being examined)?

Figure 1 Framework model for designing process evaluations of cluster-randomised controlled trials.
Assessing Cost-Effectiveness

(A/Prof Jenny Whitty)

- Economic sub-study alongside main trial (20% of trial cohort)
- Data collected via direct observations and chart audits:
  - Costs of providing PUPCB (i.e. time educating patients/staff, costs of resource development)
  - Clinical staff time for patient repositioning and other PUP strategies
  - Costs of PUP equipment and products (i.e. mattresses, skin care products)
- Allows for calculation of direct costs to the hospital for PU-related assessment and prevention for each participant across all sites
- Overall cost-effectiveness of intervention
Implementation: Future Work

Feasibility/piloting
1. Testing procedures
2. Estimating recruitment/retention
3. Determining sample size

Development
1. Identifying the evidence base
2. Identifying/developing theory
3. Modelling process and outcomes

Evaluation
1. Assessing effectiveness
2. Understanding change process
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Implementation
1. Dissemination
2. Surveillance and monitoring
3. Long term follow-up
Discussion

- Despite CPG and many targeted interventions, PUs continue to occur in hospital; with penalties attached to new PUs.

- Guided by the MRC framework for the development of complex interventions, a simple patient-centred PUPCB was developed.

- Feasibility testing was positive.

- Main trial showed about half the incidence of PU in the PIPCB group compared to the control group (non-significant effect).

- Numbers needed to treat: 27, 8 and 5 as LOS increases from 5 to 10 to 15 days.

- The PUPCB is simple, quick and relatively easy to implement.

- Process evaluation and cost-benefit study underway.
Lessons Learned

Successful research programs rely on:

- Multidisciplinary, flexible research team(s)
- Study a problem/issue of importance:
  - Affects lots of people
  - Causes harm/serious consequences
  - Priority for policy or practice
- Supportive context such as:
  - Good hospital/organisational partners who prioritise the problem
  - Access to a variety of expertise (human resources)
  - Funding (cash and in-kind support)
- Series of studies:
  - Qualitative, descriptive, observational studies to understand the problem and contributing factors, systematic reviews
  - Methodological work to develop the intervention
  - Intervention research including pilot or preliminary studies
## Acknowledgements

### Research Team

<table>
<thead>
<tr>
<th>Team Member</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Professor Tracey Bucknall</td>
<td>Deakin University (Melbourne)</td>
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<tr>
<td>Professor Joan Webster</td>
<td>Royal Brisbane and Women’s Hospital)</td>
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<tr>
<td>A/Professor Liz McInnes</td>
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<tr>
<td>Dr Merrilyn Banks (Dietitian)</td>
<td>Royal Brisbane and Women’s Hospital)</td>
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<td>Professor Marianne Wallis</td>
<td>University of Sunshine Coast (Qld)</td>
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<td>Griffith University (Gold Coast)</td>
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<tr>
<td>A/Professor Lukman Thalib (Statistician)</td>
<td>Kuwait University</td>
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<tr>
<td>Professor Nicky Cullum</td>
<td>University of Manchester</td>
</tr>
</tbody>
</table>

- Preliminary research: Chronic Diseases Area of Strategic Investment (Griffith University) grant ($100,000 AUD; $79,000 US)

- NHMRC project grant ($1 million AUD; $790,000 US)
References