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

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STTI Research Congress

July, 2015

Puerto Rico

Background

- Clinical Practice Guidelines for PUP (AWMA 2012, EPUAP/NPUAP 2009, EPUAP/NPUAP 2014)
- 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

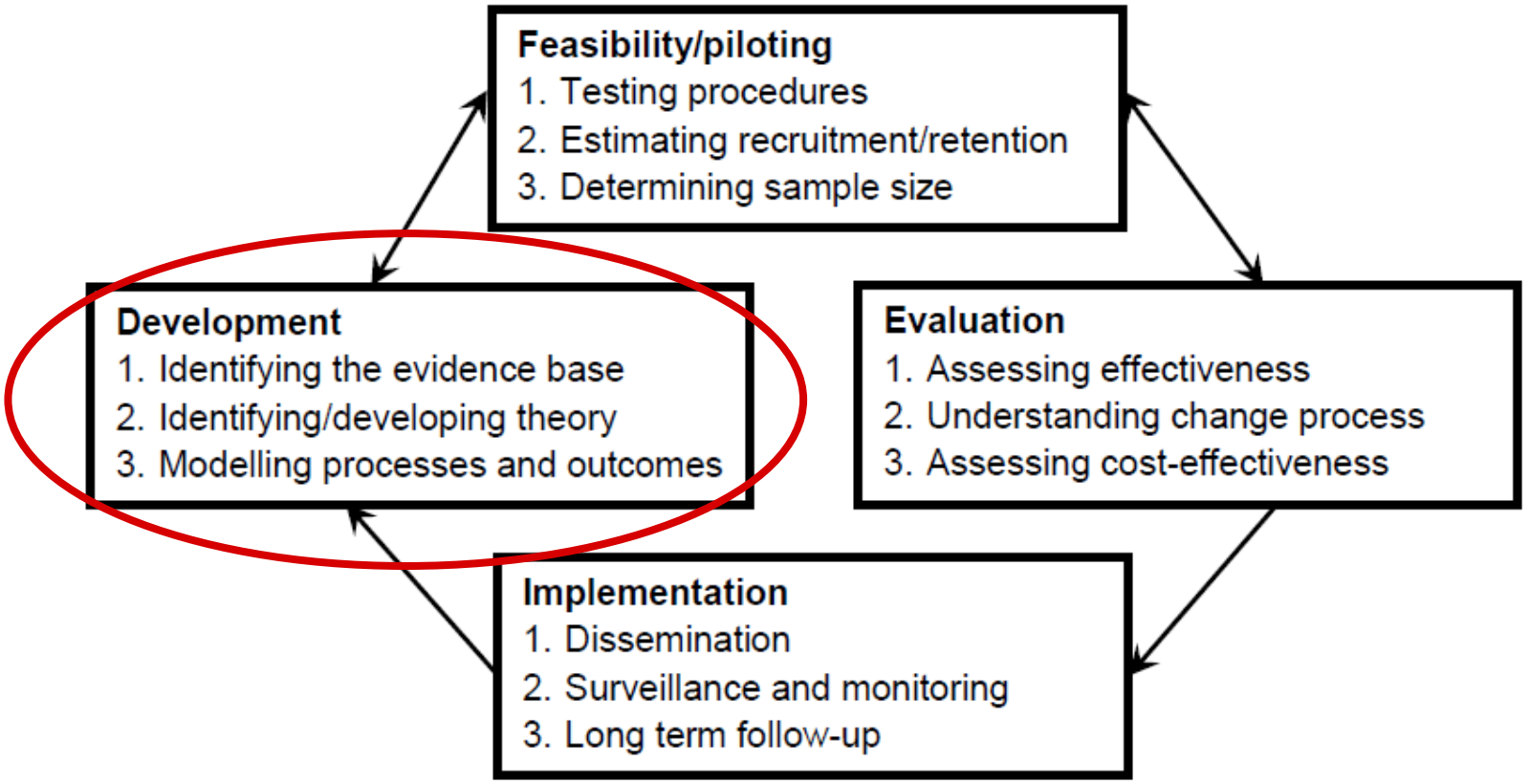
Complex Interventions

(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)



PUPCB Development

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)

Ms Sharon Latimer

Dr Shelley Roberts

Observational Research

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

Dr Kim-Huong Nguyen A/Prof Jenny Whitty

Cost-of-Illness Data

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

Activity Monitoring Study

(Chaboyer, Mills et al. 2013)

Dr Peter Mills

- **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

International Journal of Nursing Practice 2013; ••: ••–••

RESEARCH PAPER

Physical activity levels and torso orientations of hospitalized patients at risk of developing a pressure injury: An observational study

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Accepted for publication April 2013

Scandinavian Journal of Caring Sciences

EMPIRICAL STUDIES

doi: 10.1111/scs.12088

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

Sharon Latimer RN, BN, MN, MAP Grad Dip Learn&Teach (PhD Candidate, Lecturer)[1], **Wendy Chaboyer** RN, BSc(Nu)Hon, MN, PhD (Professor, Director)[2] and **Brigid Gillespie** RN, B Hlth Sc (Hons), PhD (Senior Research Fellow)[2]

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J Wound Ostomy Continence Nurs. 2014;41(6):528-534.
Published by Lippincott Williams & Wilkins

WOUND CARE

CE 2.5 ANCC Contact Hours

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

An Interpretive Study

Shelley Roberts ■ Ben Desbrow ■ Wendy Chaboyer

Griffith UNIVERSITY

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

Nutrition 30 (2014) 841–846

Contents lists available at ScienceDirect

Nutrition

journal homepage: www.nutritionjrnl.com

Applied nutritional investigation

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

Shelley Roberts MNutr.Diet.[a,*], Wendy Chaboyer Ph.D.[b,c,d], Michael Leveritt Ph.D.[e], Merrilyn Banks Ph.D.[f], Ben Desbrow Ph.D.[a,c,d]

THE OFFICIAL JOURNAL OF THE BRITISH DIETETIC ASSOCIATION

Journal of Human Nutrition and Dietetics

Journal of Human Nutrition and Dietetics

RESEARCH PAPER

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

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Cochrane Reviews

Repositioning for pressure ulcer prevention in adults (review)

Gillespie BM, Chaboyer WP, McInnes E, Kent B, Whitty JA, Thalib L

Published in *The Cochrane Library* 2014, Issue 4

Support surfaces for pressure ulcer prevention (review)

McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, Cullum N

Published in *The Cochrane Library* 2011, Issue 4

PUPCB Development

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

PUPCB

Care bundle to prevent PU, incorporating:

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

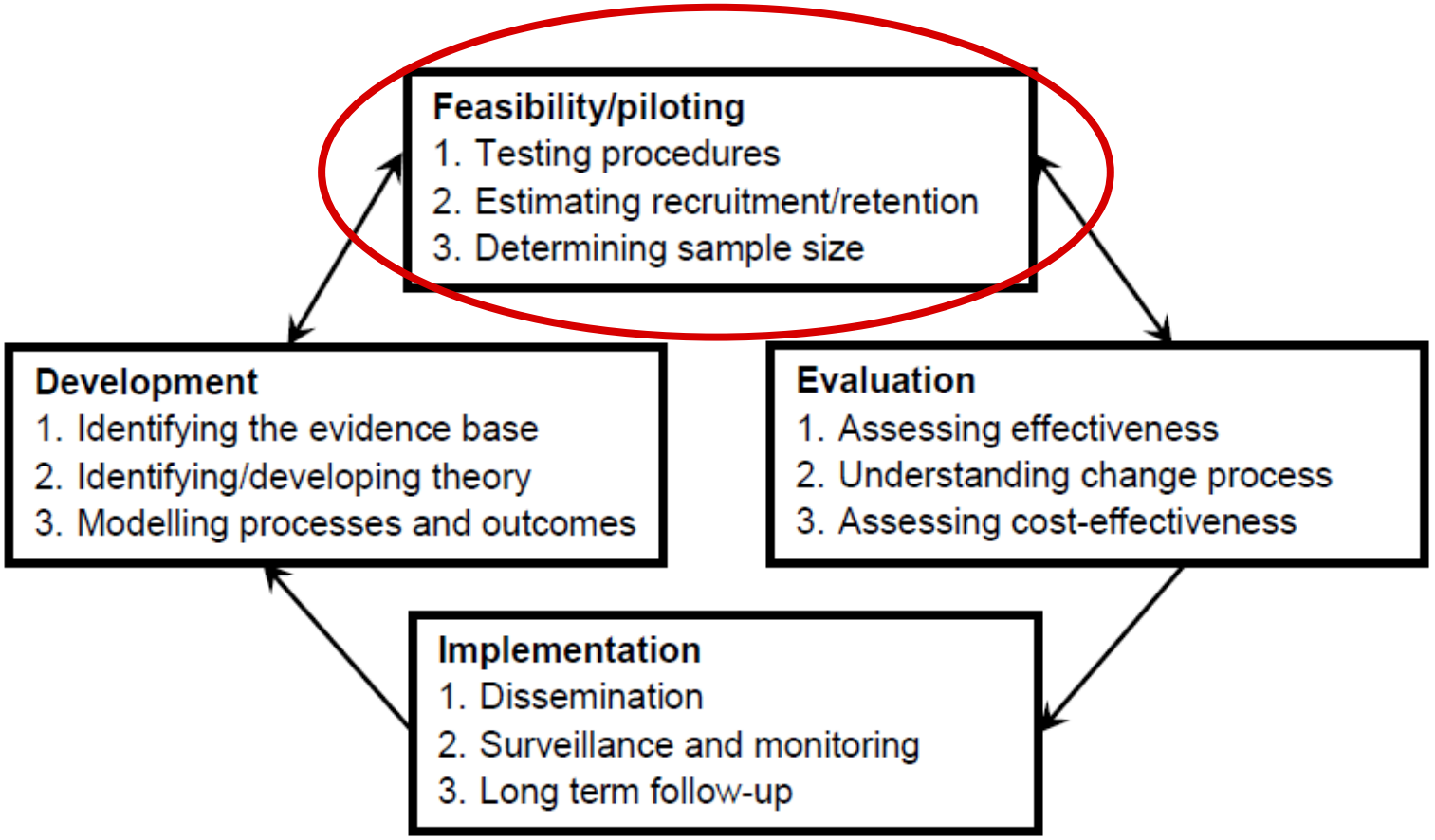
Three main messages:

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 Testing

1. Testing procedures

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

A/Prof Brigid Gillespie

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

J Nurs Care Qual
Vol. 29, No. 1, pp. 74–82

Development and Pilot Testing of a Patient-Participatory Pressure Ulcer Prevention Care Bundle

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Mark Sykes, MBus, BPsych (Hons);
Jennifer O'Brien, BN, RN;
Susan Brandis, B Bus (Health Admin), B Occ Thy

JCN *Journal of* Clinical Nursing

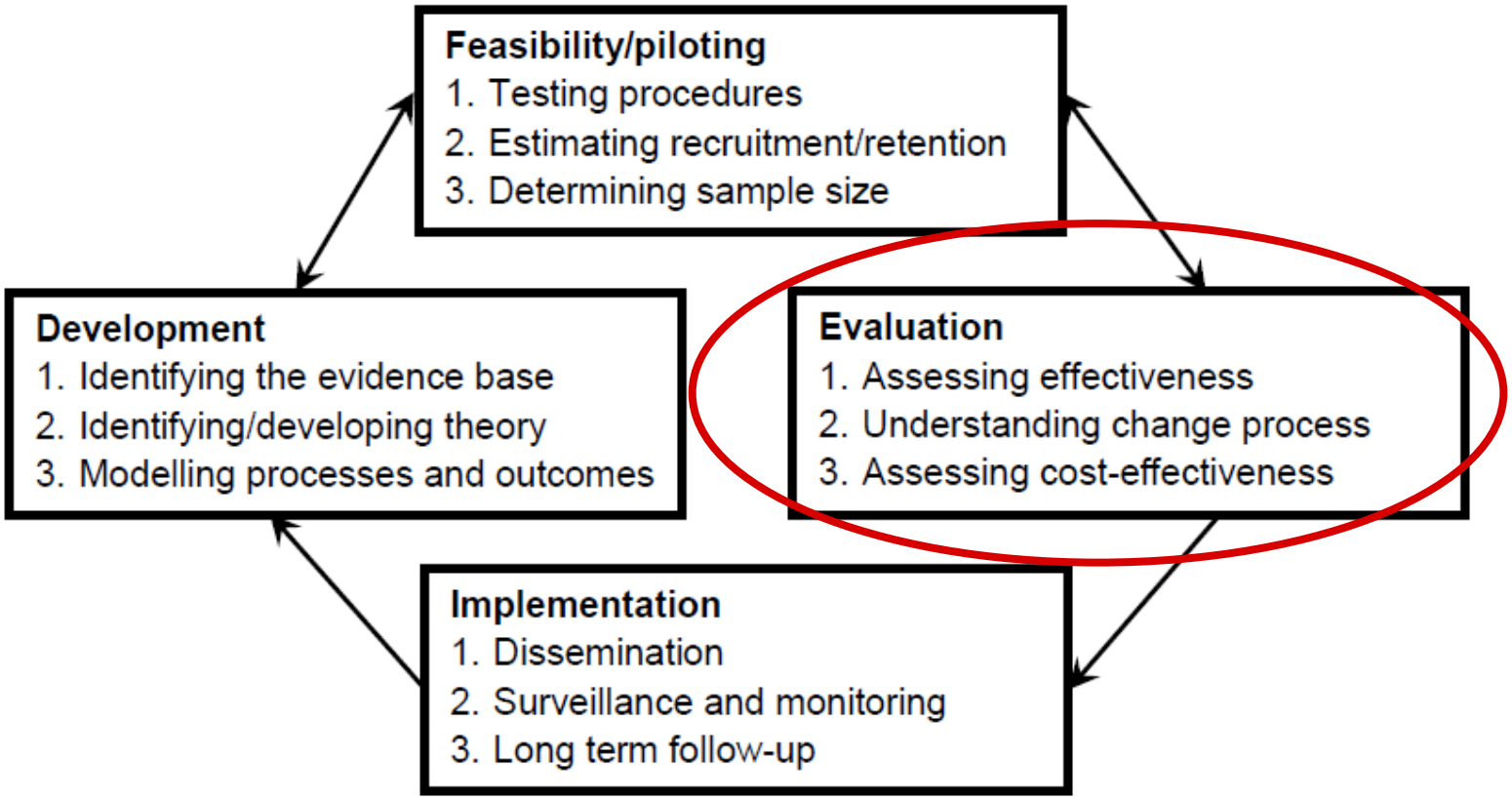
Journal of
Clinical Nursing

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)



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

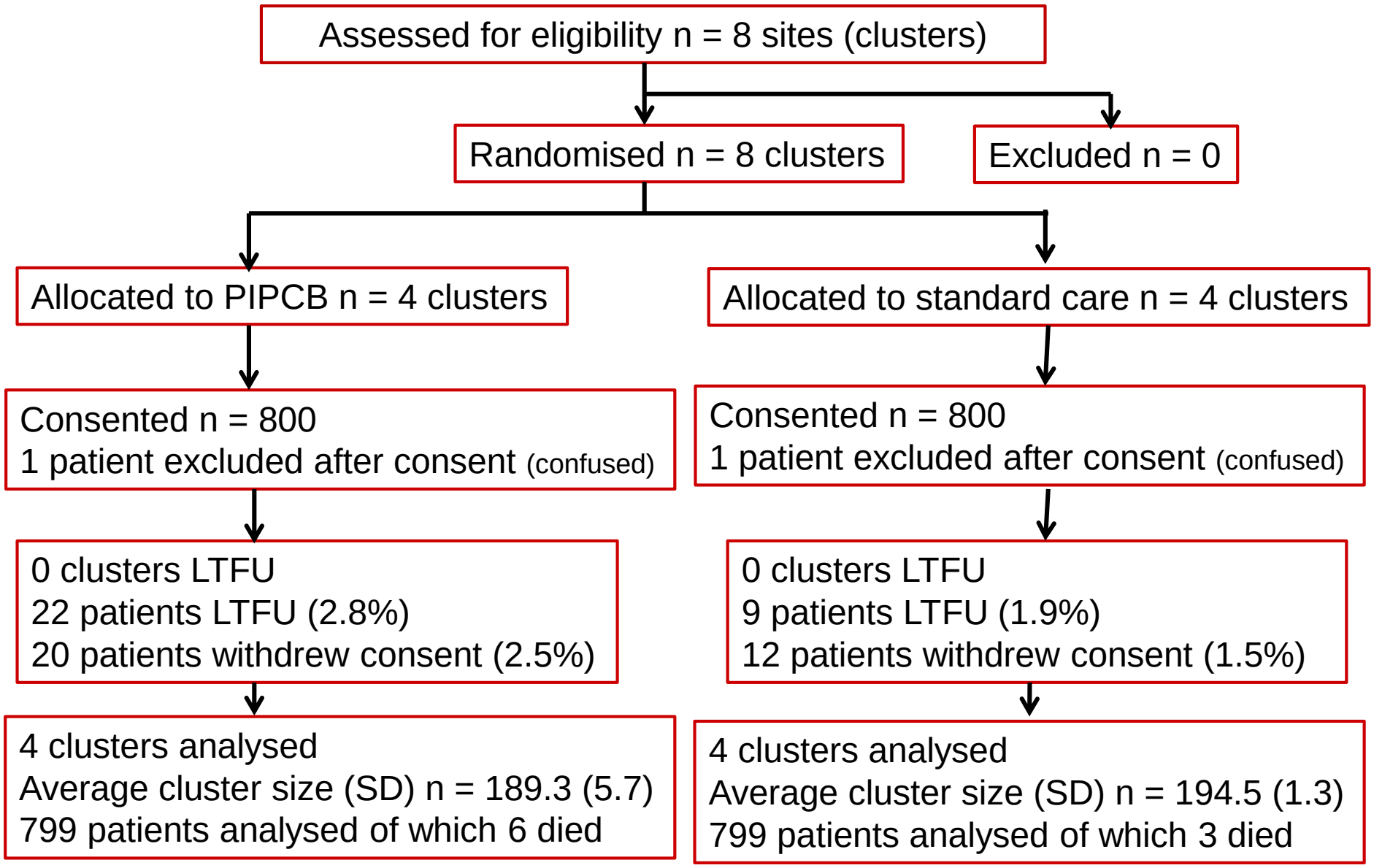
  - Patients: only aware they are in a study of PUP strategies, not that there are other sites or the exact intervention

  - 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

Patient Flow Diagram



Sample

Characteristic (no group differences)	PUPCB n = 799	Control n = 799
Female	393 (49.2%)	434 (54.3%)
Medical	558 (69.8%)	463 (57.9%)
Surgical	232 (29.0%)	316 (39.5%)
Cancer	9 (1.1%)	20 (2.5%)
Number of co-morbidities		
N % of patients with 1	207 (25.9%)	232 (29.0%)
N % of patients with 2	197 (24.7%)	193 (24.2%)
N % of patients 3 or more	207 (25.9%)	181 (22.6%)
Current Smoker	50 (6.3%)	49 (6.1%)
Number of PU present on baseline	60 (7.7%)	95 (12.0%)
Age (years)	70.0 (20.0)	74.0 (22.0)
Median (IQR) range	18.0-100.0	19.0-104.0
BMI	27.4 (7.4)	27.0 (7.6)
Median (IQR) range	13.1-65.7	14.5-69.4
Hospital length of stay (days)	6.0 (5.0)	5.0 (5.0)
Median (IQR) range	1-77	1-97

Results

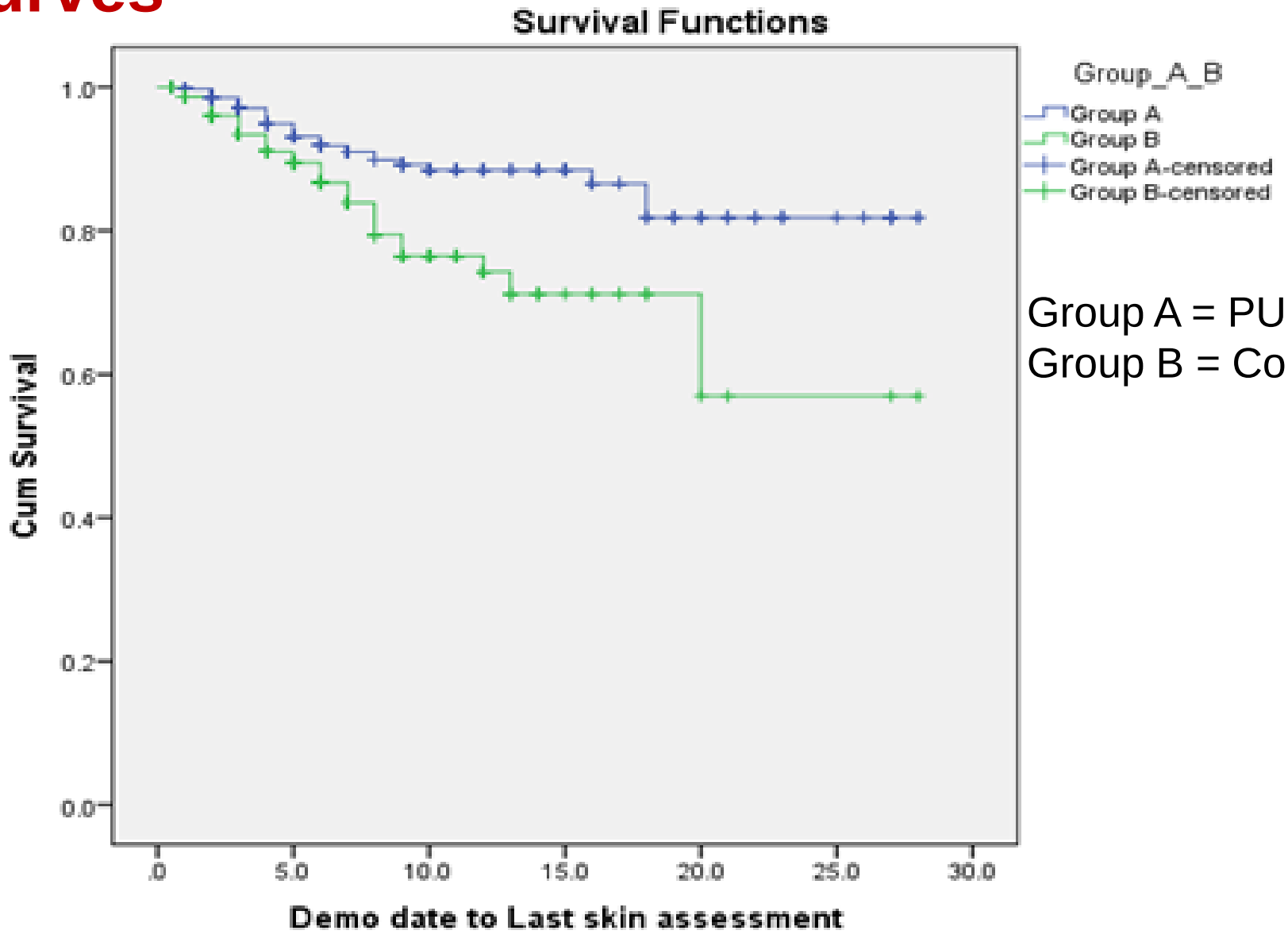
- After adjusting for the cluster effect, no differences between groups in the use of air mattresses, chair cushions, pillows for heel elevation, wedges or elbow/heel booties
- Mean time spent delivering the PUPCB **9.6±5.4 minutes**
- Taking into consideration the follow up days in the study, the incidence 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

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

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

Time	Survival Probability in Control	Survival Probability in PUPCB	NNT
5 days	0.89	0.93	27
10 days	0.76	0.88	8
15 days	0.64	0.86	5

Process Evaluation

(Grant, 2013)

Dr Shelley Roberts

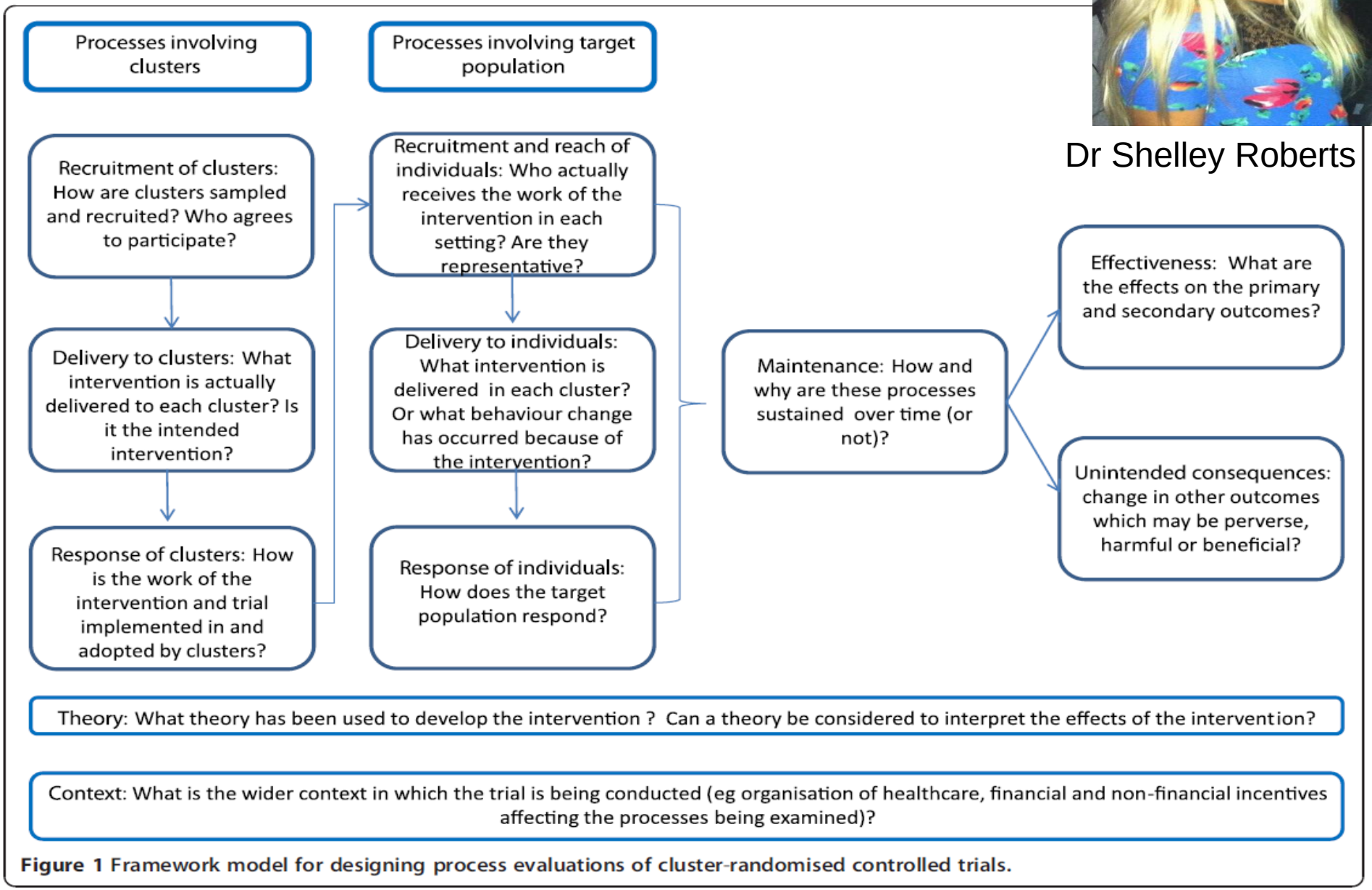


Figure 1 Framework model for designing process evaluations of cluster-randomised controlled trials.

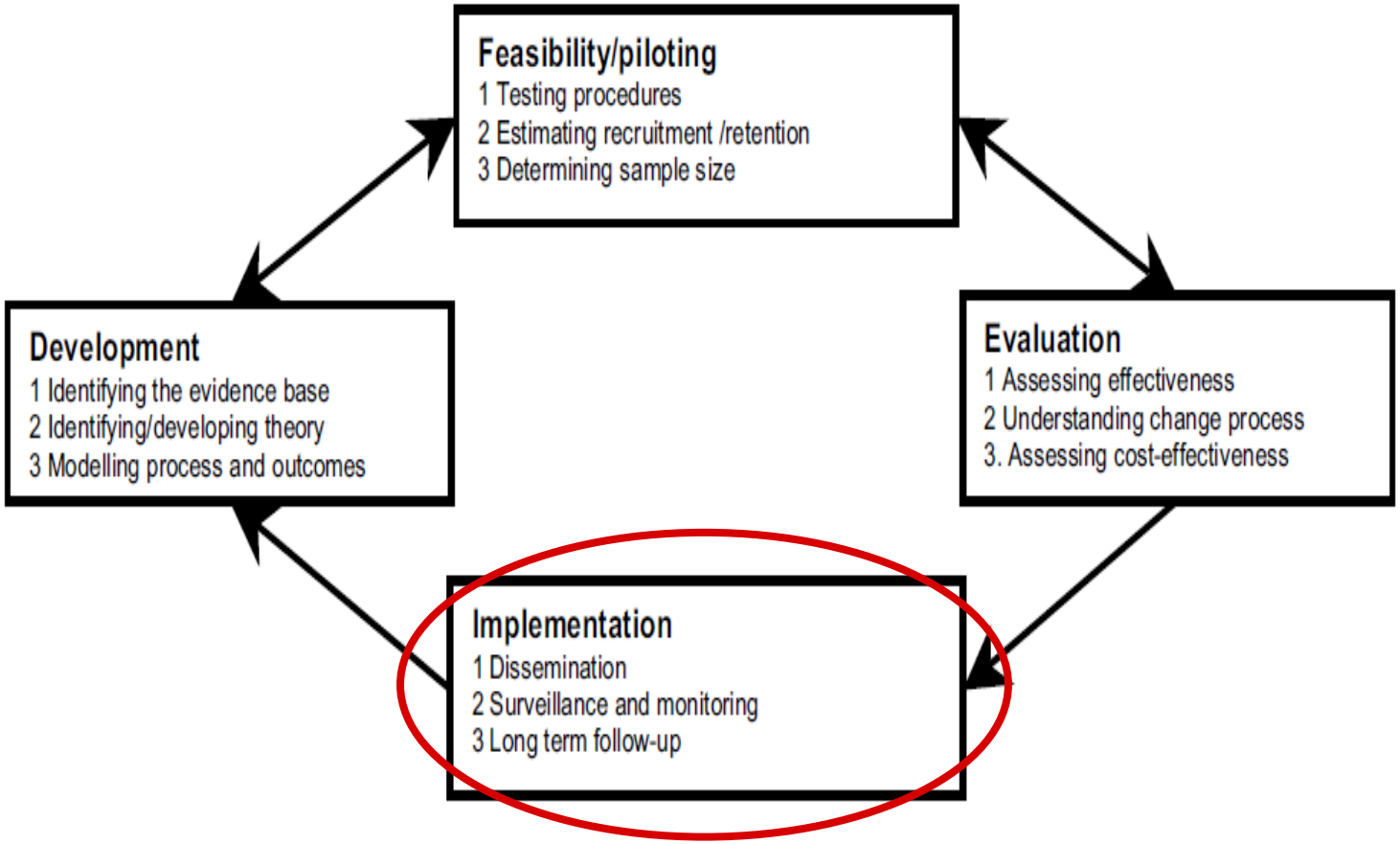
Assessing Cost-Effectiveness

(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

A/Prof Jenny Whitty

Implementation: Future Work



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

Professor Tracey Bucknall	Deakin University (Melbourne)
Professor Joan Webster	Royal Brisbane and Women's Hospital)
A/Professor Liz McInnes	Australian Catholic University (Sydney)
Dr Merrilyn Banks (Dietitian)	Royal Brisbane and Women's Hospital)
Professor Marianne Wallis	University of Sunshine Coast (Qld)
A/Professor Brigid Gillespie	Griffith University (Gold Coast
A/Professor Jenny Whitty (Health Economist)	University of Queensland (Brisbane)
A/Professor Lukman Thalib (Statistician)	Kuwait University
Professor Nicky Cullum	University of Manchester

- 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)

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