theta

Toronto Health Economics and
Technology Assessment Collaborative

Pragmatic Randomized Trials combined with Qualitative Methods in Evaluations of Complex Systems

May 31st, 2012

www.theta.utoronto.ca

Acknowledgements

Merrick Zwarenstein, MD, PhD – Sunnybrook Research Institute, Toronto

PUMTT research team (http://theta.utoronto.ca/projects/?23

Outline

- Pragmatic Trials
- Qualitative Methods
- Example: Pressure Ulcer Multi-disciplinary Teams via Telemedicine

What kind of RCT's do we need?

"*It is the thesis of this paper that most therapeutic trials are inadequately formulated (in that) trials may be aimed at the solution of one or other radically different …problem.*

Explanatory and pragmatic attitudes in therapeutical trials Schwartz D and Lellouch J. J Chron Dis 1967, 20:637

PRAGMATIC RANDOMIZED TRIALS

Relevant to real world decision making

- Evaluation of realistic intervention (often complex)
- Typical setting
- Typical patients
- Typical practitioners or practices
- Patient relevant outcomes

Explanatory

- **Intervention:** Optimised
- **Inclusion:** Narrow
- **Setting:** Ideal
- **Adherence:** Enforced
- **Outcomes:** Narrow, physiological or process measures

Pragmatic

- **Intervention:** Flexibly applied
- **Inclusion:** Broad
- **Setting:** “usual care”
- **Adherence:**
  Not monitored or corrected
- **Outcome measures:** Broad, Important.

Explanatory vs. Pragmatic attitudes

Sackett 2005

Explanatory:

Aimed at confirming causal hypothesis: Does this intervention change that outcome?

Pragmatic:

Aimed at a decision: Which intervention should we prefer?

Physiology-will tell us whether drugs, when prescribed by experts, taken faithfully by specific patients, exhibiting their full pharmacodynamic effects…. do more good than harm.

Population- will tell us whether drugs, when offered by a wide range of clinicians, to patients who might or might not take them, and causing an acceptably low risk of adverse effects, reduce the risk of an important event.

A spectrum of RCT's:
At each end an attitude, a purpose

"Pragmatic" – aimed at decision making

"Explanatory" -elucidation of causality

Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutical trials. J Chronic Dis. 1967 August;20(8):637-48.

Why use qualitative methods in RCTs?

- RCTs often cannot answer:
  - how the intervention was received
  - why the measured effects occurred
- ‘Unpack’ the change process - open the ‘black box’
- Explain variations in effectiveness within the sample
- Generate further questions / hypotheses

⇨Adds value to the RCT while providing useful information in its own right

Features of qualitative and quantitative methods

Quantitative

- Positivist
- Hypothesis testing / deductive
- How much ? Why?
- Sample representative of target population
- Quantified descriptions of factors e.g. prevalence
- Bottom-up, micro approach to explanation

Qualitative

- Interpretivist
- hypothesis generating / inductive
- Why? How?
- Sample 'representative' of relevant information in target population
- Narrative descriptions of how factors are constructed
- Holistic approach to explanation

(adapted from Reeves 2001)

- Qualitative and quantitative data provide different, but complementary, views
- Using qualitative methods in RCTs may ‘add value’ and create synergies
- Rigorous methods important for all methods
- Need to be reflective about the benefits and problems which result from mixing methods

How should the qualitative data be interpreted in relation to the quantitative data?

Effects: how much? Explanation: how? why?

- Research teams need to work closely together
- Develop an overarching conceptual framework for the project
- Design complementary questions
- Feedback qualitative findings as data is collected
- Interpret qualitative and quantitative data in relation to the overarching conceptual framework

Pressure Ulcer Multi-disciplinary Teams via Telemedicine (PUMTT)

PUMTT research team

Funded by CPSI, MOHLTC, Central CCAC

Primary Research Question

- Do Enhanced Multi-disciplinary Teams (EMDT's) increase the rate of pressure ulcer healing relative to Usual Care Teams (UCTs) in Long Term Care (LTC)?

1. Are EMDT's cost effective?

2. Are EMDTs more effective in healing a greater proportion of pressure ulcers than UCTs?

3. Are EMDTs more effective in reducing incidence rates of pressure ulcers than UCTs?

4. Are EMDTs more effective in reducing wound related pain than UCTs?

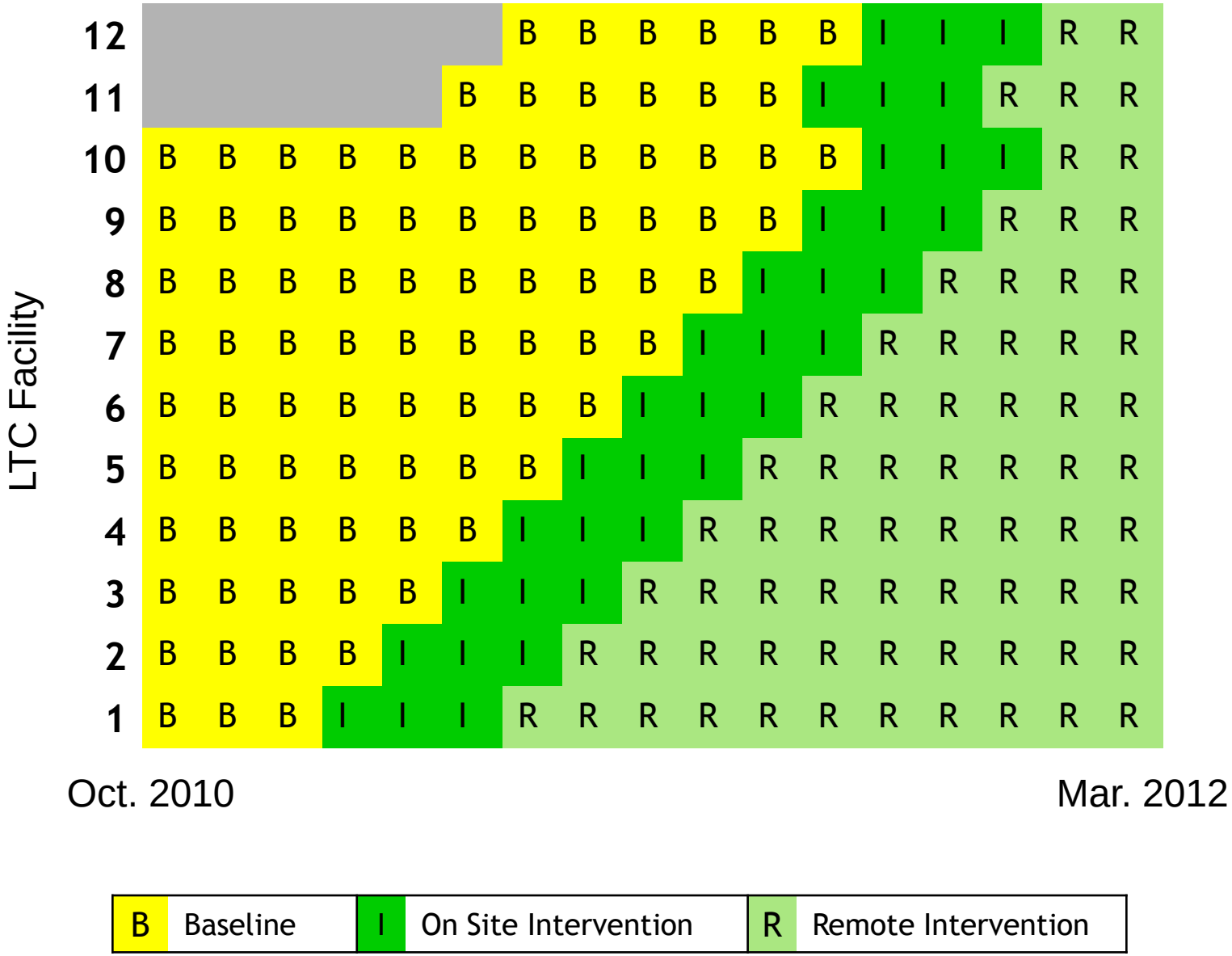
5. What are LTC facility staff perceptions and experiences associated with pressure ulcer management?

6. If the intervention worked, why did it work? If not, why not?

Mixed Methods

Quantitative: Stepped wedge pragmatic randomized controlled trial

Qualitative: Ethnography, in-depth interviews


LTC Facility
12 B B B B B B I I I R R
11 B B B B B B I I I R R R
10 B B B B B B B B B B B B I I I R R
9 B B B B B B B B B B B I I I R R R
8 B B B B B B B B B B I I I R R R R
7 B B B B B B B B B I I I R R R R R
6 B B B B B B B B I I I R R R R R R
5 B B B B B B B I I I R R R R R R R
4 B B B B B B I I I R R R R R R R R
3 B B B B B I I I R R R R R R R R R
2 B B B B I I I R R R R R R R R R R
1 B B B I I I R R R R R R R R R R R
Oct. 2010
Mar. 2012
B Baseline
I On Site Intervention
R Remote Intervention

Intervention

•Advanced practice nurses (APNs) visited facilities once weekly for 12 wks. Followed remotely for varying lengths of time.

•Built internal team capacity in wound care-staff education

•Connected with MDT at St. Mike's Hospital via e-mail, phone, or video link following referral rubric

Outcome Measures

- Rate of change in surface area (primary outcome)
- Quality of Life (EQ5D)
- Pain (VAS)

- Bi-weekly

Inclusion Criteria

- Located in Toronto Central or Central LHIN.
- within 100Km from EMDT.
- -administrator consents.
- -PU prevalence rate >5.5% as reported in 2009 MDS.
- -Individual with PU (or legally responsible representative) must provide informed consent

Facility Selection

Total Potential LTC facilities
n =63

<100 km St. Mikes, >100 beds
n=63

Administrator consented
n=21

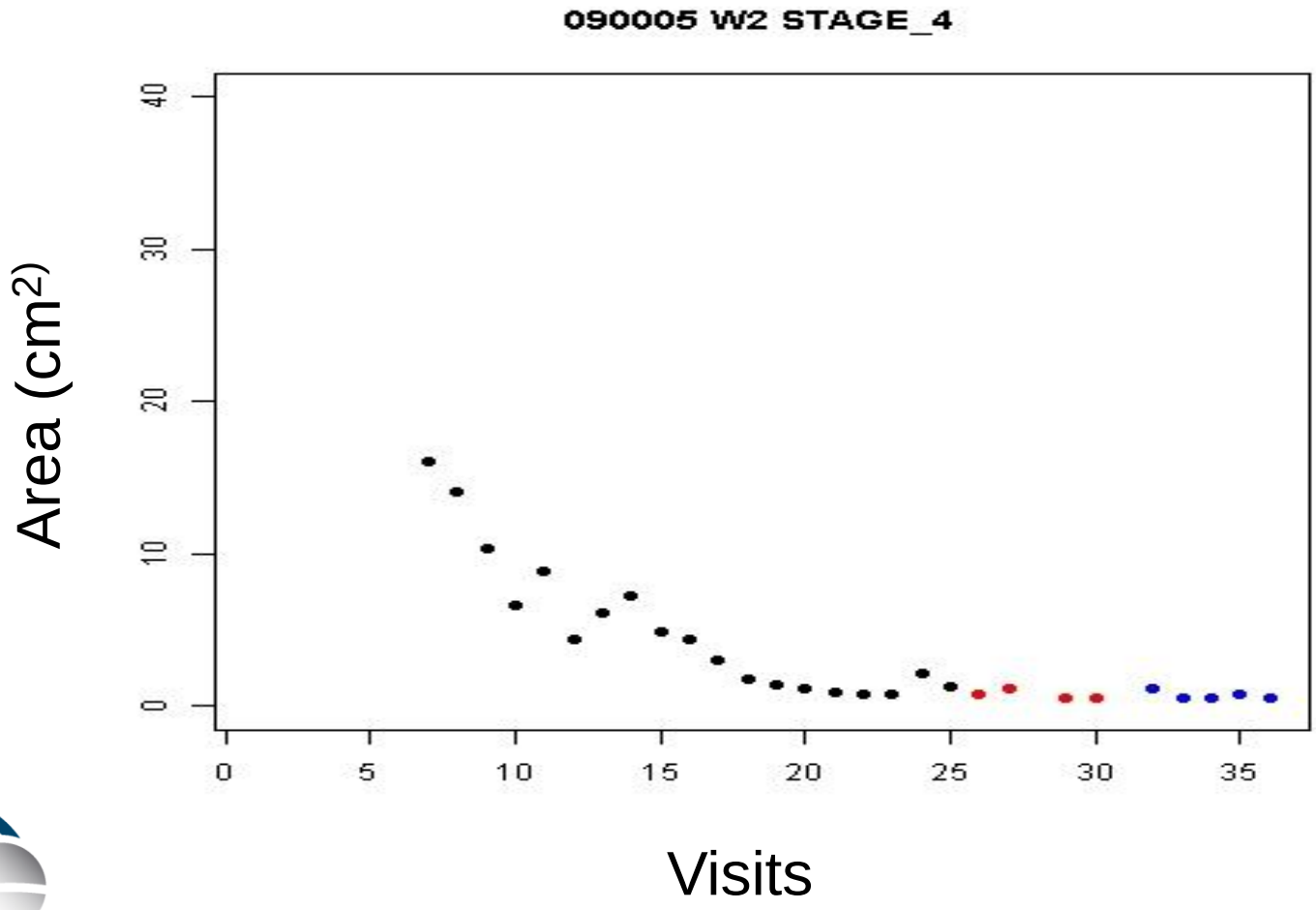
PU Prevalence rate >5.5%
n=15

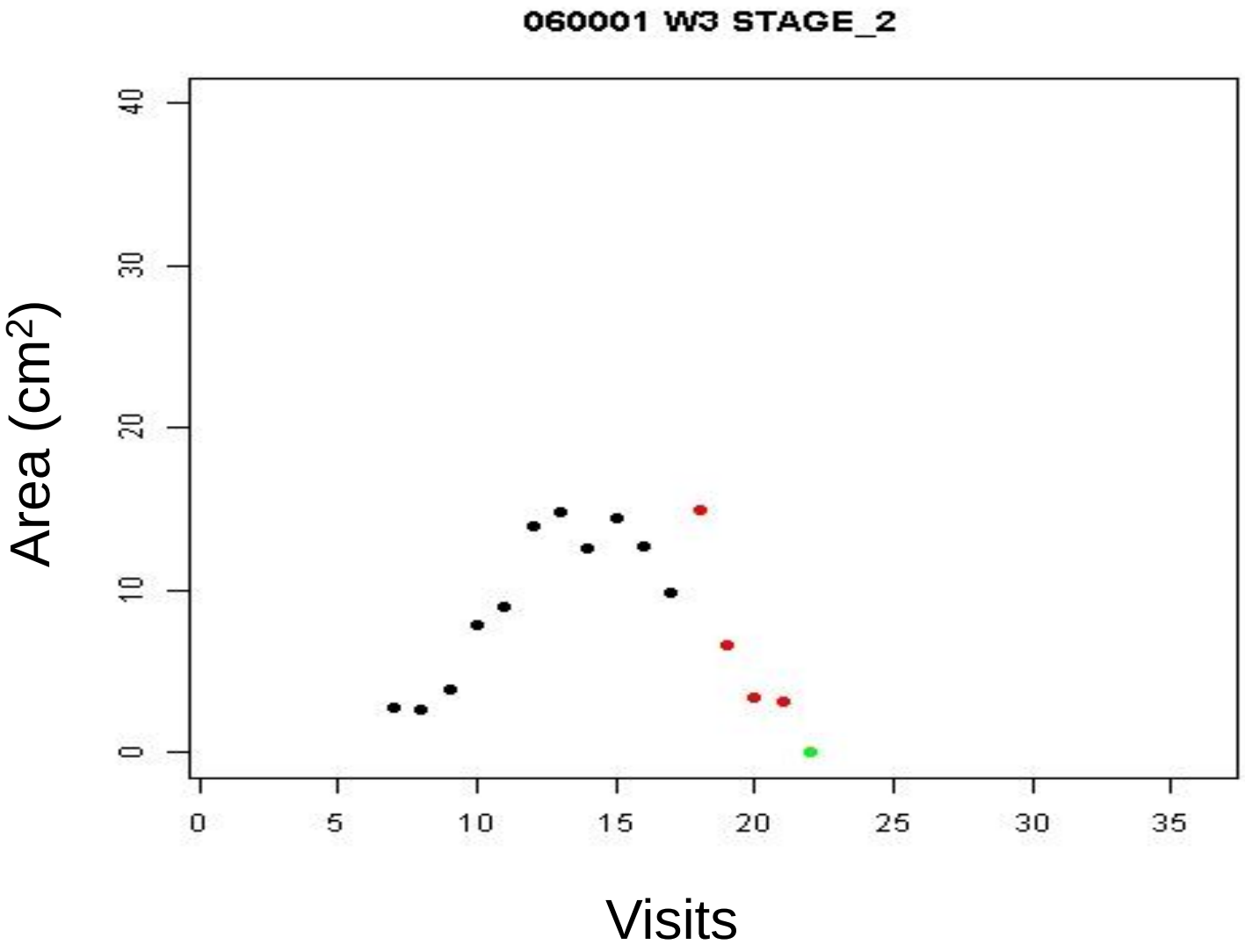
Randomly selected
n=12

LTC	LTC Size (#beds)	PUs REPORTED	DIED	NOT PU	HEALED	POA REFUSED	AMPUTATION	LEFT FACILITY	ELIGIBLE	POA REFUSED	RESIDENT REFUSED	NO CONTACT	PARTICIPANTS	SIGNED CONSENT
1	160	**24**	1	1	2	0	0	0	**20**	1	0	0	**19**	**16**
2	202	**44**	0	7	8	0	0	0	**29**	1	0	0	**28**	**26**
3	120	**22**	1	3	2	0	1	0	**15**	1	0	0	**14**	**12**
4	203	**17**	1	2	0	0	0	0	**14**	1	0	0	**13**	**12**
5	160	**18**	1	3	3	0	0	1	**10**	1	0	0	**9**	**9**
6	238	**19**	1	0	5	0	0	0	**13**	0	1	0	**12**	**12**
7	126	**14**	2	0	1	0	0	0	**11**	0	0	0	**11**	**10**
8	158	**20**	4	1	1	2	0	0	**12**	0	1	1	**10**	**10**
9	160	**10**	0	0	0	0	0	0	**10**	0	0	0	**10**	**10**
10	160	**15**	1	0	1	1	0	0	**12**	3	0	0	**9**	**8**
11	160	**8**	0	0	0	0	0	0	**8**	1	0	0	**7**	**7**
12	192	**11**	1	1	2	0	0	0	**7**	0	1	0	**6**	**6**
TOTAL	2,039	**222**	13	18	25	3	1	1	**161**	9	3	1	**148**	**138**
%									**72.5%**					**85.7%**

#PUs/Resident

LTC Facilities	1	2	3	4	5	6	7	8	9	10	11	12	TOTAL
# Residents	16	26	12	12	9	12	10	10	10	8	7	6	138
# PUs	31	47	25	18	28	30	22	16	15	16	13	9	270
#PUs/Resident	1.9	1.8	2.1	1.5	3.1	2.5	2.2	1.6	1.5	2.0	1.9	1.5	2.0


090005 W2 STAGE_4
Area (cm2)
0
10
20
30
40
0
5
10
15
20
25
30
35
Visits


060001 W3 STAGE_2
Area (cm2)
0
10
20
30
40
0
5
10
15
20
25
30
35
Visits

Methods: Ethnographic Approach

- Ethnographers commonly **triangulate** (*compare and contrast*) interview and observation methods.
  - *"what people say about their behavior can contrast with actual actions."*

Reeves S, Kuper A and Hodges. BMJ Aug 30 2008, vol 337

Research Questions

- 1. Describe LTC staff perceptions of, and experiences with PUMTT team.
- 2. Describe organizational culture.
  - How does organizational culture influence PU process?
  - How does organizational culture interact with PUMTT intervention?
- 3. Describe broader context (ministry policies &regulations).
  - How does it influence PU care in LTC? Interact with intervention?

All three components were important

PUMTT ⟷ Organizational ⟷ Provincial

Intervention Culture Context

|

PU processes

|

PU outcomes

Limitations

- Intervention did not work when recommendations were not followed:
  - resources were not available.
  - no dedicated WC nurse; or staffing turn-over.
  - No management follow up; need consistency across floors and shifts.
  - Poor safety culture.

➔***PUMTT nurse provided expertise; but had no power to implement changes.***

High-Performance Organizational Culture

Leadership Values

- Setting high goals & expectations
- Systems thinking
- Empowering culture (responsibility & expertise)

Management Processes

- Highly Responsive
- Consultative Decision-making
- Regular follow-up
- Respectful

Communication

Outcomes

- Team-work is encouraged
- Staff are accountable
- Resources are available
- Workload is reasonable
- Good staff retention

Provincial Context

- LTC facilities deal with hospital-acquired Pressure Ulcers.
- High Intensity Needs is Reactive; not Preventative.
- ET services are infrequent and often tied to vendor contracts.
- Restorative is positive when implemented properly.
- Staffing levels requirements: only 1 RN in the facility – not sufficient.

Model: promoting prevention and on-going bed-side teaching

- Emphasis on prevention

(adopted by the MOHLTC and by LTC facilities).

- Weekly visits by an ET specialist (not tied to a product vendor).
- On-site wound care coordinator (liaises with nurse, OT, PT, diet??)
- Resources are available to support preventative practices.
- Front-line staff are accountable for PU prevention and treatment.
- Staffing levels/workload are reasonable

Study timeline

Final report to be submitted in Sept. 2012.

Results will be shared with facilities and family councils in the fall.

Additional examples of pragmatic trials mixed with qualitative methods

- Wound Interdisciplinary Teams study
- Integrated Client Care Program_Wound

Thank you!

www.theta.utoronto.ca