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*Osservatorio Regionale per l'Innovazione*

# **Integrating new health technologies: Use of the Normalization Process Model**

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# Summary

- **HTA and Organisational issues**
- **The role of theories – Normalization Process Theory**
- **NPT applied in HTA of robotic-assisted surgery:**
  - adoption
  - evaluation (multicentre RCT)
- **Conclusions**



# HTA domains and Methods

**Technical Performance**

**Feasibility \ Safety**

**Clinical Effectiveness**

**Systematic Review of Literature**

**Tables of Evidence**

**Grading of Evidence ....**

**Economic issues**

**Cost-benefit / Cost-opportunity**

**Cost- effectiveness**

**Value of Perfect Information ...**

**Organisational ethical  
social issues**



# The analytical tool: Normalization Process Theory

<http://normalizationprocess.co.uk>

**BMC Health Services Research**



Research article

**A rational model for assessing and evaluating complex interventions in health care**

Carl May\*

**Implementation Science**

Research article

**Development of a theory of implementation and integration: Normalization Process Theory**

Carl R May\*<sup>1</sup>, Frances Mair<sup>2</sup>, Tracy Finch<sup>1</sup>, Anne MacFarlane<sup>3</sup>, Christopher Dowrick<sup>4</sup>, Shaun Treweek<sup>5</sup>, Tim Rapley<sup>1</sup>, Luciana Ballini<sup>6</sup>, Bie Nio Ong<sup>7</sup>, Anne Rogers<sup>8</sup>, Elizabeth Murray<sup>9</sup>, Glyn Elwyn<sup>10</sup>, France Légaré<sup>11</sup>, Jane Gunn<sup>12</sup> and Victor M Montori<sup>13</sup>

Open Access

**BMC Health Services Research**



Research article

Open Access

**Understanding the implementation of complex interventions in health care: the normalization process model**

Carl May\*<sup>1</sup>, Tracy Finch<sup>1</sup>, Frances Mair<sup>2</sup>, Luciana Ballini<sup>3</sup>, Christopher Dowrick<sup>4</sup>, Martin Eccles<sup>1</sup>, Linda Gask<sup>5</sup>, Anne MacFarlane<sup>6</sup>, Elizabeth Murray<sup>7</sup>, Tim Rapley<sup>1</sup>, Anne Rogers<sup>5</sup>, Shaun Treweek<sup>8,9</sup>, Paul Wallace<sup>10</sup>, George Anderson<sup>2</sup>, Jo Burns<sup>7</sup> and Ben Heaven<sup>1</sup>



# NPT model: is “it” going to integrate?

## 4 main constructs

1. **INTERACTIONAL WORKABILITY:** How is the technology going to impact on doctor/patient – system/patient interaction?
2. **RELATIONAL INTEGRATION:** How is the technology going to impact on relations b/w professionals in terms of agreement on knowledge and expertise necessary to use the technology
3. **SKILL-SET WORKABILITY:** How is the technology going to impact on current division of labour?
4. **CONTEXTUAL INTEGRATION:** How is the technology going to impact on current assignment and use of resources?



# Adoption of the technology

## Plan for adoption

**Adoption intended as:**

**investment in research and development for the whole regional system, targeted at specific clinical conditions, accessible to all eligible patients and to a wide number of surgeons.**

## Focus group



**1. Interactional workability**

Will robotic surgery affect users and impact on consultation ?

Encounter generally episodic, but great emphasis on trust

Demonstrable expected benefits

Low

**2. Relational integration**

Will staff require extensive training before they can use it ?

New practice – knowledge and expertise yet to be developed and gained (how many ?)

Training and criteria to assess trainers/trainees to be defined

Moderate

**FAILED ?**

**3. Skill-set workability**

How will robotic surgery impact on the allocation of tasks, resources and responsibilities?

As new skills will be developed, shifts in tasks assignment, responsibilities and rewards need to be defined (Who?)

Low

**4. Contextual integration**

Will org have the capacity to fit robotic surgery within its goals and activity ?

Structural changes - risk management

Fitting w/in hub + spoke system

Moderate

# Adoption and Integration of the technology

## Plan for adoption

**Adoption intended as:**

**investment in research and development for the whole regional system, targeted at specific clinical conditions, accessible to all eligible patients and to a wide number of surgeons.**

## Strategy for integration

**hub + spoke system, inter- departmental location, centralized staged training, communication plan, protocols to ensure equity of access for all target patients economic and structural interventions**





# Evaluation of a technology

## Aim of evaluation

comparative effectiveness trial capable of producing robust/conclusive results on clinical effectiveness, on appropriate target patients with no inclusion bias, relevant clinical outcomes and appropriate comparator.

Thematic workshop on clinical trials in surgery



**1. Interactional workability**

Will trial procedures impact on doctor-patient relation?

Deeply affected by enrolment procedure  
Sharing uncertainty

Very low

**2. Relational integration**

Will trial procedures fit with existing skills and training ?

Specific criteria of inclusion / exclusion of surgeons based on skills

Differential distribution of funds and prestige

Low

**KILLED ?**

**3. Skill-set workability**

Will trial procedures require staff to take on new responsibilities or additional works ?

Novelty of prospective multicentre trial vs retrospective case series  
New skills required by trial (randomization, data management ecc)

Low

**4. Contextual integration**

How will the trial impact on the work of the organisation ?

Substantial commitment needed (ethical approval, risk management, protected time ...)

Moderate

# Evaluation and Feasibility of trial

## Aim of evaluation

comparative effectiveness trial capable of producing robust/conclusive results on clinical effectiveness, on appropriate target patients with no inclusion bias, relevant clinical outcomes and appropriate comparator.

## Strategy for integration

2 Non-randomized controlled prospective trials, 1 RCT with “accompanying” surgeon, stringent criteria of eligibility for surgeons, programme of risk management, protection for excluded patients, protected time and resources



# Application of the NPT model

## ADOPTION

**Effective plan of implementation of the technology to ensure its integration in the health system**

## EVALUATION

**Effective plan of implementation of a clinical trial to ensure filling of research gaps**



# Conclusions

**DISRUPTION**



**NORMALIZATION**

**A theory allows :**

- Accurate description (components)
- Systematic explanation (mechanisms)
- Testable hypothesis (implementation)

**THANK-YOU**

