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Using the TDF for Process Evaluation

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Implementation Research

- the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice...it includes the study of influences on healthcare professional and organisational behaviour *(Eccles et al. An Implementation Research Agenda, Imp Sci 2009)*
- Essential outcomes of implementation are:
 - Changes in professional behaviour
 - Changes in organizational structures
 - Changes in relationships to consumers, stakeholders and system partners *(Frixen,D et al Implementation Research: A Synthesis of the Literature. University of South Florida, 2005)*

Importance of Process Evaluation

- Targets implementation: how successfully the intervention is taking place
 - How the program's intentions are being interpreted
 - Experience of conducting the activity
 - Changing perceptions of different stakeholders
- Qualitative and quantitative data
- Can provide insight into the causal mechanisms and effect modifiers  better interventions

Importance of process evaluation

- Theory based process evaluations collect data on theoretical constructs to explore potential causal mechanism
- Ideally run alongside a trial but can be retrospective
- Proof of concept study to operationalize the Theoretical Domains Framework to conduct a theory based retrospective process evaluation

A tale of two rules.....

ABSTRACT

Background: The Canadian CT Head Rule was developed to allow physicians to be more selective in ordering computed tomography (CT) imaging for patients with suspected head injury. We sought to evaluate the effectiveness of implementing this validated decision rule in emergency departments.

Methods: We conducted a matched-pair cluster-randomized trial that compared the outcomes of 453 patients with minor head injury during two 12-month periods (before and after) at hospital emergency departments in which were randomly allocated as intervention or control sites. At the intervention sites, including education, reminders on radiologic referral for CT scan of the head, and implementation of the Canadian CT Head Rule, we sought to implement the Canadian CT Head Rule.

Results: Baseline characteristics were similar when comparing control to intervention sites. The proportion of patients who were referred for CT scan increased from the "before" period (76.2%) (difference between the control sites, the proportion increased, from 67.5% to 76.2% (2.6%–10.8%). The change in the "before" period to the "after" period in control hospitals was not statistically significant for missed brain injuries or deaths.

Interpretation: Our knowledge of the Canadian CT Head Rule in Canadian emergency departments is limited. We identify strategies to develop and evaluate this decision rule and evaluate knowledge translation. (NCT00993252)

CMAJ

RESEARCH

A prospective cluster-randomized trial to implement the Canadian CT Head Rule in emergency departments

BMJ

RESEARCH

Implementation of the Canadian C-Spine Rule: prospective 12 centre cluster randomised trial

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Canadian CT Head Rule

CT head is only required for minor head injury patients with any one of these findings:

High Risk (for Neurological Intervention)

1. GCS score < 15 at 2 hrs after injury
2. Suspected open or depressed skull fracture
3. Any sign of basal skull fracture*
4. Vomiting ≥ 2 episodes
5. Age ≥ 65 years

Medium Risk (for Brain Injury on CT)

6. Amnesia before impact ≥ 30 min
7. Dangerous mechanism ** (pedestrian, occupant ejected, fall from elevation)

*Signs of Basal Skull Fracture

- hemotympanum, 'racoon' eyes, CSF otorrhea/rhinorrhea, Battle's sign

** Dangerous Mechanism

- pedestrian struck by vehicle
- occupant ejected from motor vehicle
- fall from elevation ≥ 3 feet or 5 stairs

Rule Not Applicable If:

- Non-trauma cases
- GCS < 13
- Age < 16 years
- Coumadin or bleeding disorder
- Obvious open skull fracture

Stiell IG et al. The Canadian CT Head Rule for Patients with Minor Head Injury. Lancet 2001;357:1391-96.

Canadian C-Spine Rule

For all alert (GCS =15) and stable trauma patients where cervical spine injury is a concern

1. Any High-Risk Factor Which Mandates Radiography?

- Age ≥ 65 years
or
- Dangerous mechanism*
or
- Paresthesias in extremities

No

Yes

2. Any Low-Risk Factor Which Allows Safe Assessment of Range of Motion?

- Simple rearend MVC**
or
- Sitting position in ED
or
- Ambulatory at any time
or
- Delayed onset of neck pain***
or
- Absence of midline c-spine tenderness

No

Radiography

Yes

Unable

3. Able to Actively Rotate Neck?

- 45° left and right

Able

No Radiography

*Dangerous Mechanism

- fall from elevation ≥ 3 feet/5 stairs
- axial load to head, i.e. diving
- MVC high speed (> 100 km/hr), rollover, ejection
- motorized recreational vehicles
- bicycle struck or collision

**Simple Rearend MVC Excludes

- pushed into oncoming traffic
- hit by bus/large truck
- rollover
- hit by high speed vehicle

***Delayed

- i.e. not immediate onset of neck pain

Stiell IG, Clement CM, McKnight RD, Brison R, Schull MJ, Rowe BH, Worthington JR, Eisenhauer MA, Cass, D, Greenberg G, MacPhail I, Dreyer J, Lee JS, Bandiera G, Reardon M, Holroyd B, Lesiuk H, Wells GA. The Canadian C-Spine Rule Versus the NEXUS Low-Risk Criteria in Patients with Trauma. New Engl J Med 2003;349:2510-2518.

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Intervention

- Consensus process agreement to adopt rule
- Distribution of educational materials (pocket cards, manuscripts, poster)
- 1-hour educational session
- Mandatory real-time reminder at point of care

Results from intervention trial

- CT imaging rates from before to after period
 - Control: 67.5% to 74.1%, (AD = +6.7%)
 - Intervention: 62.8% to 76.2%, (AD = +13.3%)
- Physicians misinterpreted rule in 17.5% cases
- Order CT imaging in 141 of 909 cases where not indicated
- C-Spine rule: RR 12.8% (61.7% vs 53.3%)

Proof of Concept Study Design

- Purposive sampling: Physicians from 6 intervention sites in the trial (3 Academic/ 3 Community EDs)
- Telephone interviews, audio recorded
- Interview guide based on 12 domains in TDF
- 2 independent coders, Nvivo 9
- Relevant domains were determined using 3 criteria:
 - Frequency of specific beliefs across interviews
 - Presence of conflicting beliefs
 - Perceived strength of the belief impacting the behaviour

Theoretical Domains Interview Framework

(Michie S, Qual Saf Health Care. 2005;14:26-33)

Theoretical Domain	Interview Questions
(1) Knowledge	Do you use the Canadian CT Head rule in your practice? What do you think of the evidence that supports the rule?
(2) Skills	How do you use the rule? What steps do you normally follow when using the rule? What skills are needed to use the rule?
(3) Social/professional role and identity (Self-Standards)	Is there anything about your professional role as an ED physician that influences your use of the rule? Do your colleagues generally agree with you regarding your use of the rule?
(4) Beliefs about capabilities (Self-efficacy)	How confident do you feel in your ability to apply the rule? What problems have you encountered when using the rule?
(5) Beliefs about consequences (Anticipated outcomes/attitude)	What do you think are the consequences of using the rule? What are the specific patient, financial or provider benefits or harms that occur as a result of using the rule?
(6) Motivation and goals (Intention)	How important is the Canadian CT Head rule for managing patients with minor head injury? Are there incentives for using the rule?
(7) Memory, attention and decision processes	How easy or difficult is it to remember the rule? Do you sometimes forget? When? What triggers your use of the rule?
(8) Environmental context and resources (Environmental constraints)	What factors in your clinical environment influence your use of the rule? Are there competing tasks or time constraints that influence your use of the rule?
(9) Social influences (Norms)	Do other physicians in the ED influence your use of the rule? If so, how? Do physicians outside your ED influence your use of the rule?
(10) Emotion (Emotion)	Does using the rule ever evoke an emotional response in you? Do your patients emotions ever affect your decision to use the rule?
(11) Behavioural regulation	What do you think is needed to ensure you consistently use the Canadian CT Head rule?
(12) Nature of the behaviour	How often do you see patients with minor head injury? Do you usually use the rule when managing these patients?

Results

- 8 ED Physician participants (3 were site champions) from 4 sites (2 academic/ 2 community)
- 7 to 30 years of experience
- 6 with specialty or subspecialty training
- Interviews lasted 20-40 minutes
- Mandatory reminders identified as the most useful strategy to encourage use

Domains likely to explain response

Domain	Intervention	Effect
Beliefs about consequences	Persuasive communication	Improved/hindered
Beliefs about capabilities	Techniques for self-monitoring	Difficult to interpret Department is busy
Memory, attention and decision processes	Reminders that target complex situations	Rule make it
Environmental context and resources	of the rule	es/discourages use
Social influences	Social processes of encouragement	s discourages use can influence my use
Behavioural regulation	Education about how to use clinical decision rules	ignment to guide uncertain

Conclusion

- TDF provided us with useful information which might help with post-hoc interpretation of the results of the trial
- Encourage further development for using the TDF to guide theory based process evaluations running alongside trials

Contact details

Thank you

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