Implementation Science 1001

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Implementation research

The scientific study of methods to promote the systematic uptake of research findings into routine practice to improve the quality and effectiveness of health services and patient care

Evidence implementation

The dynamic and iterative process that includes the synthesis, dissemination, exchange and application of knowledge to improve health and health services
Implementation Science

• A different type of research

• More relevant to stakeholders

• Emergent field
  – Approaches still being developed, tested

• Interface between research and application

• Contextual

• Complex

• Multi-component programs / policies

• Non-linear

• Transdisciplinary

• Multi-level and multi-method
Evidence practice gap

• 30 - 40% of patients don't get treatments of proven effectiveness

• 20 - 25% of patients get care that is not needed or potentially harmful

• 57% of Australians are not receiving evidence-based care
## Ultimate Impact of a Magic Diet Pill

<table>
<thead>
<tr>
<th>Dissemination Step</th>
<th>Concept</th>
<th>% Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of Clinics Use</td>
<td>Adoption</td>
<td>50%</td>
</tr>
<tr>
<td>50% of Clinicians Prescribe</td>
<td>Adoption</td>
<td>25%</td>
</tr>
<tr>
<td>50% of Patients Accept Medication</td>
<td>Reach</td>
<td>12.5%</td>
</tr>
<tr>
<td>50% Follow Regimen Correctly</td>
<td>Implementation</td>
<td>6.2%</td>
</tr>
<tr>
<td>50% of Those Taking Correctly Benefit</td>
<td>Effectiveness</td>
<td>3.2%</td>
</tr>
<tr>
<td>50% Continue Taking After 6 Months</td>
<td>Maintenance</td>
<td>1.6%</td>
</tr>
<tr>
<td>Component</td>
<td>Evidence implementation</td>
<td>vs</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------</td>
<td>----</td>
</tr>
<tr>
<td>Aim</td>
<td>Brings about improvement</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>Applies interventions</td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>Iterative pragmatic design</td>
<td>(more) Classical design</td>
</tr>
<tr>
<td>Protocol</td>
<td>Flexible adaptive protocol</td>
<td>(more) Rigid protocol</td>
</tr>
<tr>
<td>Results</td>
<td>Context specific</td>
<td></td>
</tr>
</tbody>
</table>
Key Components of Implementation

Product

Process

Context

Evaluation

Outcome
Key Components of Implementation

- Research
- Guidelines
- Evidence
- Knowledge
- Knowledge tools
- EB Products
- EB Strategies
Key Components of Implementation

- Implementation interventions
- Change strategy
- Facilitation
- Theories
- Models
- Frameworks

Diagram:
- Product
- Process
- Context
- Evaluation
- Outcome
Key Components of Implementation

- Inner and outer setting
- Culture
- Resources
- Leadership
- Regulation
- Accreditation
Key Components of Implementation

- Theories
- Models
- Frameworks
- Methods
- Designs
Key Components of Implementation

- Product
- Process
- Context
- Evaluation
- Outcome

- System, process, outcome
- Individual, organisational, community
Key Components of Implementation

Product

Process

Context

Evaluation

Outcome

Theory, model, framework
IMPLEMENTATION RESEARCH
Broad Categories of Questions

- **Process of delivery** (*How do we make it work?*)

- **Salience** (*Does it matter?*)

- **Safety** (*Will it do more harm than good?*)

- **Acceptability** (*Will people be willing to use it?*)

- **Cost-effectiveness** (*Is it worth buying?*)

- **Appropriateness** (*Is this the right intervention?*)

- **Reach** (*How many people exposed?*)

- **Intensity/dose** (*What is the expected/needed strength of the intervention?*)

- **Satisfaction** (*Are stakeholders satisfied? To what degree?*)

- **Sustainability** (*Can it be continued over time?*)
NSW Health Translational Framework

Idea generation
- What form of innovation could solve the problem?

Feasibility
- Is this innovation practical to implement and acceptable?

Efficacy
- Can the innovation deliver expected outcomes under best possible circumstances?

Replicability and adaptability
- Can the innovation reproduce the same outcomes under different conditions?

Effectiveness
- Does the innovation deliver expected outcomes under normal operational conditions in the health system?

Scalability
- How can the innovation be integrated into the wider health system?

Monitoring
- Does the innovation achieve sustained outcomes once integrated into the health system?
Implementation Research Framework (USA)

Implementation Research

- Pre-intervention
- Efficacy Studies
- Effectiveness Studies
- Replication
- Adaptation
- Implementation
- Sustainment / Scaling Up

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## Implementation Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Potential measure</th>
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<tbody>
<tr>
<td>Impact</td>
<td>Audit, administrative data</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Interview/ focus group, survey, take-up/ refusal</td>
</tr>
<tr>
<td>Adoption</td>
<td>Administrative data, interview/ focus group, observation, self-report, survey</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Interview/ focus group, survey</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Administrative data, survey, interview</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Self-report, checklists, observation</td>
</tr>
<tr>
<td>Implementation cost</td>
<td>Administrative data</td>
</tr>
<tr>
<td>Reach</td>
<td>Administrative data, audit</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Audit, interviews, survey, checklists.</td>
</tr>
</tbody>
</table>
## Clinical effectiveness vs. Implementation trial

<table>
<thead>
<tr>
<th>Study Feature</th>
<th>Clinical Research</th>
<th>Implementation Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study focus</td>
<td>Clinical intervention</td>
<td>Implementation intervention/ strategy</td>
</tr>
<tr>
<td>Primary outcome</td>
<td>Health outcomes</td>
<td>Processes of care, fidelity, adoption, reach…</td>
</tr>
<tr>
<td>Unit of randomization</td>
<td>Patient</td>
<td>Site, ward, clinician</td>
</tr>
<tr>
<td>Process evaluation</td>
<td>Sometimes</td>
<td>Always</td>
</tr>
<tr>
<td>Mixed method</td>
<td>Sometimes</td>
<td>Often</td>
</tr>
</tbody>
</table>
Implementation Trials

(a) Parallel cluster study

(b) Parallel cluster study with a baseline period

(c) Stepped wedge study

(d) Stepped wedge study including transition period
Hybrid Clinical Effectiveness/Implementation Designs (USA)

Hybrid Type 1: test clinical intervention, observe/gather information on implementation

Hybrid Type 2: test clinical intervention, test implementation strategy

Hybrid Type 3: test implementation strategy, observe/gather information on clinical intervention outcomes
Example: Hybrid Type III

Phase I
6 months
September 2012

- Enhanced REP (N=39)
- Standard REP (N=49)
- Low Response (N=35)
- Response (N=14)

Phase 2
6 months
February 2013

- Standard REP (N=53)
- Enhanced REP 35 Sites

Follow-up
12 months
September 2013

- Standard REP All Sites

National Implementation
March 2012
August 2012

- Standard REP 158 Sites
- Non-response (N=88)
Qualitative Methods in Implementation Research

- **Pre-Implementation**
  - Formative Evaluation
  - Tailor Intervention to each site

- **During Implementation**
  - Formative Evaluation
  - Improve & Adjust Implementation

- **Post Implementation**
  - Interpretive Evaluation
  - Explain summative evaluation results
  - Evaluate Sustainability & Dissemination prospects
Qualitative and Mixed Methods

- Ethnography
- Realist Evaluation
- Case Study
- Qualitative Comparative Analysis
- Network Analysis
Theories, Models and Frameworks

Theoretical approaches used in implementation science

- Describing and/or guiding the process of translating research into practice
  - Process models
- Understanding and/or explaining what influences implementation outcomes
  - Determinant frameworks
  - Classic theories
  - Implementation theories
- Evaluating implementation
  - Evaluation frameworks
Process Theory: Knowledge to Action
Determinant Framework: Consolidated Framework for Implementation Research

- Characteristics of the intervention:
  - Intervention source
  - Evidence strength and quality
  - Relative advantage
  - Adaptability
  - Trialability
  - Complexity
  - Design quality
  - Cost

- Inner Setting:
  - Structural characteristics
  - Networks and communications
  - Culture
  - Implementation climate

- Outer Setting:
  - Patient needs and resources
  - Cosmopolitanism
  - Peer pressure
  - External policies and incentives

- Individuals involved:
  - Knowledge and beliefs about the intervention
  - Self-efficacy
  - Individual stage of change
  - Individual identification with organisation
  - Other personal attributes

- Implementation Process:
  - Planning
  - Engaging
  - Executing
  - Reflecting and evaluating
Classic Theories: Theory of Diffusion
Implementation Theories: Behaviour Change Wheel
## Evaluation Frameworks: RE-AIM

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>How many and what proportion of the target population is participating in the intervention?</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>What are the effects of the intervention in eligible patients?</td>
</tr>
<tr>
<td>Adoption</td>
<td>What is the percentage of providers participating in the program?</td>
</tr>
<tr>
<td>Implementation</td>
<td>Was the intervention implemented as intended?</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Is the intervention maintained after the study period?</td>
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</tbody>
</table>
## Change Strategies

<table>
<thead>
<tr>
<th>Category</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>• Audit &amp; feedback; educational meetings and materials; opinion leaders; reminders</td>
</tr>
<tr>
<td>Organisational</td>
<td>• Systems reengineering; redefining professional roles</td>
</tr>
<tr>
<td>Regulatory</td>
<td>• Policy directives; outcomes based funding</td>
</tr>
<tr>
<td>Patient directed</td>
<td>• Decision aids; patient held guidelines</td>
</tr>
<tr>
<td>Mass media</td>
<td>• Disease prevention media campaigns</td>
</tr>
</tbody>
</table>
## Align Strategies to Barriers

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety about new task</td>
<td>Simulation</td>
</tr>
<tr>
<td>Perception/ reality mismatch</td>
<td>Audit and feedback</td>
</tr>
<tr>
<td>Relevance</td>
<td>Flexible standardisation</td>
</tr>
<tr>
<td>Beliefs and attitudes</td>
<td>Local consensus meetings</td>
</tr>
<tr>
<td>Logistics and timing</td>
<td>Process redesign</td>
</tr>
</tbody>
</table>
Align Strategies to Stage of Change

- **Awareness**
  - Group presentation

- **Agreement**
  - Consensus meeting

- **Adoption**
  - Audit & feedback

- **Adherence**
  - Reminders
Building a Change Strategy

- Address identified barrier
- Evidence strength and quality
- Relative advantage
- Adaptability
- Trialability and measurability
- Complexity
- Design quality
- Cost
EVIDENCE IMPLEMENTATION
Knowledge-to-Action

- Assess barriers to knowledge use
- Select implementation interventions
- Knowledge generation
- Synthesis
- Adapt knowledge to local context
- Tools
- Monitor knowledge use
- Sustain knowledge use
- Identify knowledge needed
Knowledge Creation

- Knowledge generation
- Knowledge synthesis
- Knowledge tools
Knowledge Application

- Identify need
- Adapt to context
- Assess barriers
- Select interventions
- Monitor use
- Sustain use
Identify Knowledge Practice Gaps

- Clinical databases
- Chart audits
- Direct observations
- Questionnaires
- Incidents
- Feedback
Adapt Knowledge to Local Context

- Workforce
- Skill mix
- Resources
- Models of care
Assess Barriers to Knowledge Use

- Observation
- Discussion
- Surveys
- Literature
Common Barriers

Opportunity
- Time
- Resources

Capability
- Skills
- Knowledge

Motivation
- Internal
- External

Behaviour
Selecting Interventions

- Theoretically informed
- Mapped to barriers
- Aligned to stage of change
- Feasible, acceptable, measurable
Implementing Interventions

- **ACT**: Implement the changes that have been proven to be effective
- **PLAN**: Plan the change that is to be trialled
- **STUDY**: Evaluate the impact of the trial
- **DO**: Conduct a trial of the proposed change

**PDSA Cycles - single test**
- Hunches, theories and ideas
- Changes that result in improvement
Pilot then Spread Change

Population defined by project aim

Test population

Test population

Test population

Spread

All Patients

Spread

Spread
Monitor Knowledge Use

- Systems
- Processes
- Outcomes
Sustaining Knowledge Use

- Standardisation
- Documentation
- Measurement and review
- Training and education
Resources
Resources

- Consolidated Framework for Implementation Research (http://www.cfirguide.org/)


- A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems (https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0605-9)

- Knowledge Translation (https://ktcanada.org)
DISCUSSION

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