



**Australian
Clinical
Trials
Alliance**

ACTA Reference Group D

Embedding Clinical Trials in Healthcare

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Overview



- Describe objectives of working group
- Describe our definition of embedding and rationale
- Present *some* recent activities of the working group
 - International scan
 - Survey of research directors
- Present what next for the working group agenda

Objectives of working group

- Promote the concept and definition of embedding within **‘routine health care’**
- Identify the barriers and enablers to successful embedding; develop **‘model of embedding’** to effectively achieve it
- Highlight exemplars of successfully embedded clinical trials in routine care, creating a **‘community of practice’**
- Develop **‘guidance’** for networks and health-service providers to optimise embedding of clinical trials

Definition of Embedding

Embedding is the process of integrating research activities into routine patient care, to facilitate the appropriate, timely and efficient generation and implementation of the best available evidence

Rationale for Embedding

‘The clinical research enterprise is not producing the evidence decision makers arguably need in a timely and cost effective manner, research currently involves the use of labor-intensive parallel systems that are separate from clinical care’

Weinfurt et al: BMC Medical Research
Methodology

The consequence

Inadequate evidence to guide care

A Learning Healthcare System (LHS) is defined as a system in which...

“science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”

Institute of Medicine (US)

International Best Practice Towards a Learning Healthcare System

International Scan

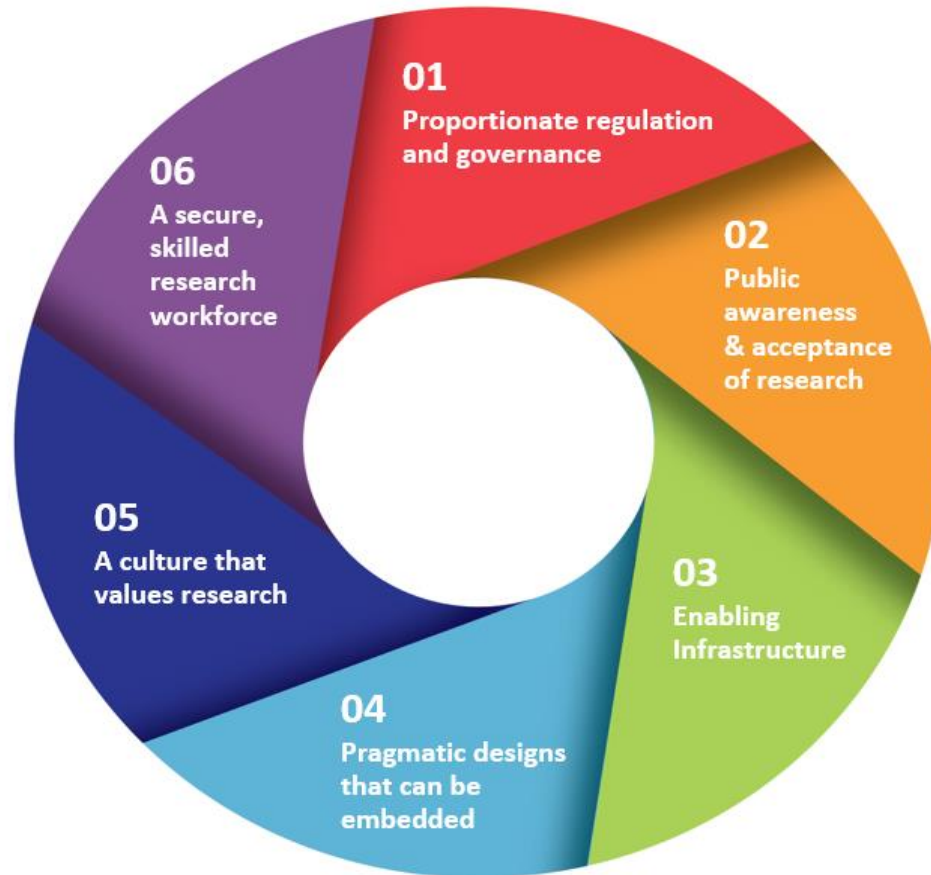


- A Learning Healthcare System (LHS) is gaining traction as a way to achieve the best possible patient outcomes at reasonable cost.
- Health systems need better, meaningful and more timely evidence.
- Embedded trials are core of LHS
 - continuously and reliably produce (high quality) evidence to guide and improve clinical decision making and care (safety and quality)

International Scan – challenges

- Changing the culture of the health service is seen as one of the biggest challenges.
- Traditional ethics and governance frameworks apply poorly to pragmatic trials.
 - The lack of clarity around privacy and the use of health data.
- Access to research design and trial coordination services
 - necessary to avoid the potential for missed opportunities or wasteful research practice.
- The lack of interoperable digital infrastructure makes it difficult to conduct rapid-pace trials of sufficient size to support decisions in an LHS.

ELEMENTS TO SUPPORT THE EMBEDDING OF CLINICAL TRIALS



Survey of Research Directors



- **41% (15/37)** completed consultation;
 - Public & Private Health Service Directors / Executives
 - NSW, VIC, QLD, WA
- Number of dedicated research units within organisation;
 - **54%** 4-10 research units
 - **31%** 10+ research units
- **93%** of organisations have dedicated research strategy
 - **54%** report their organisation fulfils strategic intent
 - Seems to included current and future plans

Survey of Research Directors

Strategic Plans for Research

- Most have them and believe there is a general commitment to deliver
- Common barriers and enablers of embedding often experienced at an institution or service level
 - Funding
 - Competing (clinical) priorities
 - Adequate communication about the strategy
 - Inadequate mechanisms to quantify activity



Objectives of working group - what next?

- Promote the concept and definition of embedding within **'routine health care'**
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Identification of Australia exemplars of embedded trials

- Identify groups that have successfully embedded trials within the health system
 - to help others interested in designing trials that can be embedded into the health system

Metrics of embedding

- Measuring activity, success/effectiveness, accountability...
- Significant challenge > likely be an evolution than set and go
- Traditional KPIs (e.g. papers/grants) may not be appropriate
- New KPIs
 - Number of engaged clinicians
 - Increased participation in CETs (number of pts/trials)
 - Enhanced pathways to implement research findings
 - Improved patient outcomes/experience

Results of embedding...

ECONOMIC EVALUATION OF INVESTIGATOR-INITIATED CLINICAL TRIALS CONDUCTED BY NETWORKS

If the results of 25 high-impact clinical trials were implemented in 65% of the eligible Australian patient populations for one year:

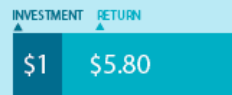
\$1.4 billion in better health
outcomes for patients

\$580 million in reduced
health service costs



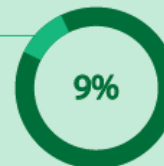
**GROSS BENEFIT TO
THE AUSTRALIAN
ECONOMY**

**A RETURN OF
\$5.80 FOR EVERY
\$1 INVESTED IN
NETWORK TRIAL
RESEARCH**



Trial results only needed
to be implemented in 11%
of the eligible patient
populations for benefits to
exceed costs

JUST 9% of the \$2 billion
gross benefit from the trials in
this study was equivalent to all
NHMRC funding received by all
Australian networks between
2004 and 2014



**A RETURN OF
\$51.10 FOR EVERY
\$1 AWARDED
BY THE NHMRC**

**TRIALS CONDUCTED
BY NETWORKS:**

- ✓ Identify opportunities for better use of resources
- ✓ Improve safety and quality
- ✓ Influence clinical guidelines

QUESTIONS

