Ethics – QI vs Research

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What are the features of research

Research: activities which attempt to create new **generalisable** knowledge in response to an acknowledged information gap.

Generalisable = designed and described to allow the results to be applied to a wider population (quantitative) or other settings (qualitative). NEAC standards 2019

Quantitative

- acceptance or rejection of a hypothesis in relation to treatment, cause, risk or diagnosis of a health problem.

Qualitative

- description and interpretation of something in its natural setting. May address how treatments and relationships are experienced.

Interventional

- allocate treatment, care or service provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s).

Observational

- no influence on the assignment of any variable. Observation and analysis of natural relationships between variables and outcomes.

Is it research?

Research: activities which attempt to create new **generalisable** knowledge in response to an acknowledged information gap.

Is it research?

Most commonly asked in relation to "Audit"

Table 1.2 – Differentiating research from quality improvement. NEAC guidelines.

Clinical Audit = Not research

- Are we doing what we should be doing?
- Compares to service or standard.
- E.g. measuring adherence to clinical practice guideline.

Research audit = Observational study = Research

- What should we be doing?
- No known standard.
- E.g. nutrition support in paediatric ICU and analysis of outcomes

Approval process research

- Ethics approval: HDEC or AHREC
- Locality approval
- Māori review
- Key documents: Protocol, Data management plan
- *May be needed: Participant Information Sheet & Consent, contract/data sharing agreement, budget*
- *Medsafe SCOTT when using unapproved medicines*

Types of research ethics review - HDEC

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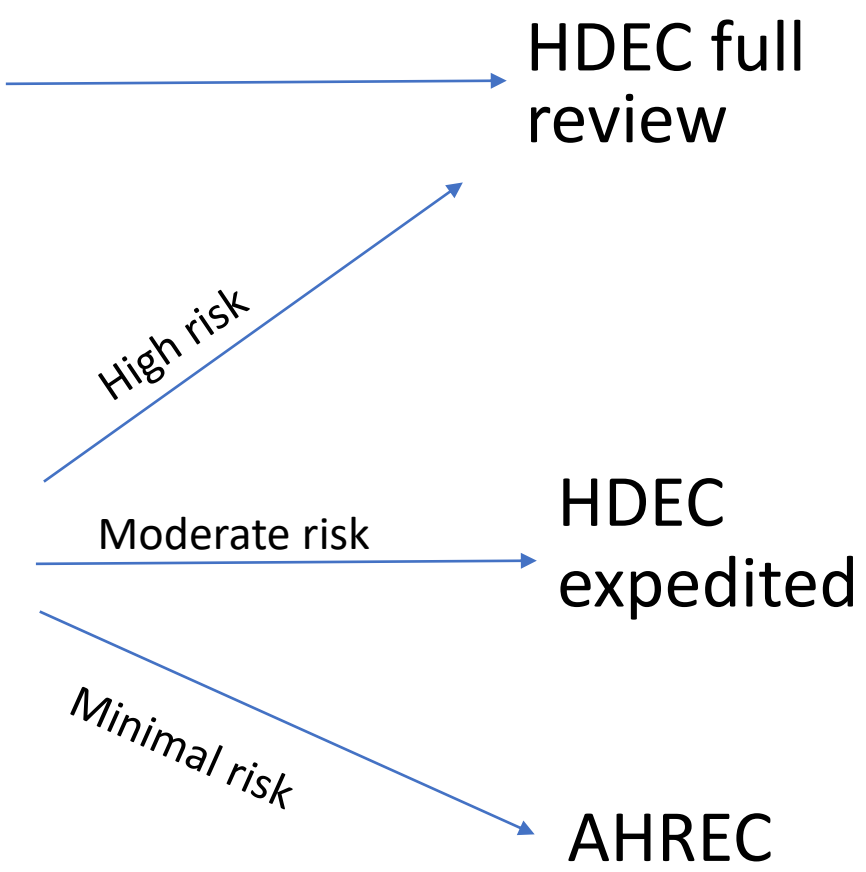

Types of research ethics review - HDEC

HDEC Ethics RM https://nz.forms.ethicalreviewmanager.com/

The first page is a screening form & confirms review type needed.

Health and Disability Ethics Committees

	HDEC Levels of Review- Risk Features				
	Observation Study Specific	Observational and Intervention		Intervention study specific	
		Involves use or disclosure of health information	Involves use/ storage/ preservation of human tissue		
Out of Scope	Research wholly for attainment of a qualification- Masters or below	Using/accessing identifiable data without consent for audit or related activities Health information is disclosed to researchers in a de-identified form (NHI numbers are identifiers) Consent for secondary use of health information (i.e. using it for research) has already been obtained	Tissue is disclosed in a non-identifiable form **AND** has existing informed consent for use (i.e. anonymous tissue from a biobank that has samples that are stored with consent for future research is given to a researcher)	Intervention studies always require review *Most* require full review	Except low-risk device- Class I
Expedited Review		Using/accessing identifiable information without consent for research Using/accessing identifiable health information to screen for potential participants for health research	Consent for future **unspecified** research (FUR)	Using a medical device that is class IIa Any Intervention that does not contain any features in the full review section below	
Full Review	Establishing a tissue bank	Use of large datasets, linking sensitive information or small potentially identifiable dataset	Use/storage/preservation without consent	New Medicine*	Vulnerable human participants
	Vulnerable human participants			Use of a medical device that is Class IIb or III or an active implantable device or new surgical intervention	Approved medicine used for a different treatment or delivered in a new way*
	If any participants are not consenting	Use of AI	Use of Guthrie cards	Withholding standard of care	If any participants are not consenting (or not able to)

**These studies will also require submission to SCOTT and/or GTAC in addition to HDEC. Please check and confirm with these committees.*

Types of research ethics review - AHREC

Auckland Health Research Ethics Committee (AHREC)

- Human health research out of scope for HDEC conducted by staff at Te Toka Tumai Auckland, Counties Manukau, Waitematā; staff & students of University of Auckland.
- E.g.
  - Observational study/research audit – data without identifiers
  - Research involving healthcare professionals in their capacity as providers
  - Quality/service improvement with high risk features

Requires a UoA log in, request this before first use.
https://www.auckland.ac.nz/en/research/about-our-research/human-ethics.html

Locality approval

Submission to central research office

- Standard pathway: HDEC full applications
- Expedited pathway: HDEC expedited or AHREC projects
- Forms available here: https://www.adhb.health.nz/health-professionals/research/approval-process/

Starship research office

- HDEC expedited or AHREC projects, conducted only in child health

Māori research review

Provided by He Kamaka Waiora Māori Health Research Services (Auckland and Waitemata).
Organised by the central review office.
Forms available here: https://www.adhb.health.nz/health-professionals/research/approval-process/

Training & Support

Resources and training

- HDEC SOPs, NEAC Guidelines
- Privacy Act & Privacy training on KoAwatea
- Māori data sovereignty & Te Ara Tika Guidelines
- GCP: investigators conducting intervention studies

Support - Starship Research team

Our team can assist with research ethics, locality approvals, protocol development, database builds, finance, contracting, and resources to conduct research.

- Research Operations Manager
- Clinical Research Practitioner
- Biostatistician
- Database manager (REDCap)
- Clinical research coordinators
- Research nurse

Contact Us

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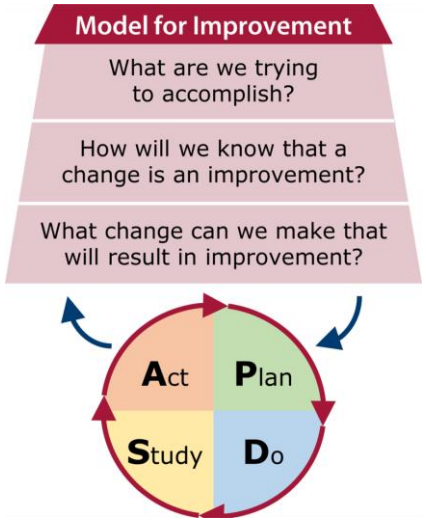
What are the features of quality improvement

Quality Improvement:

Involves cycles of change that are linked to measurable assessment, with the goal of improving the experience, process, safety and efficiency of health care.



What are the features of quality improvement

Quality Improvement:

Must not be conducted to generate evidence to support an intervention's efficacy, but it can involve evaluating and changing practice (Provost and Murray 2011).

What does that mean?!

Evaluating Efficacy

- **Purpose:** Measures the effectiveness of an intervention under controlled, ideal conditions (e.g., clinical trials).
- **Goal:** Determine whether the intervention works as intended, isolating it from external factors.
- **Context:** Typically performed in research settings with rigorous controls to minimize variability.

Evaluating an Intervention

- **Purpose:** Assesses how well the intervention performs in real-world settings.
- **Goal:** Evaluate implementation, effectiveness, and practical outcomes in context.
- **Context:** Includes considerations like feasibility, stakeholder engagement, and adaptation to local conditions.

Suggested approval process QI

1. **If collecting patient data**

- **Project plan**
- **Clinical audit form**
- **Data plan**
- Sign off by SCD

2. If not collecting patient data (bigger project):

- Project plan
- Sign off by SCD

3. If not collecting patient data (small project):

- Just do it
- Let your SCD know

First do no harm

- collection and use of data in QI

- By doing the project
- By losing the data
- By inappropriately sharing the data

First do no harm

Principles for ethical data collection in quality improvement (QI) projects:

- **Informed Participation**: Ensure transparency and inform participants about how their data will be used.
- **Minimise Harm**: Prioritise participant safety, privacy, and wellbeing.
- **Purpose-Driven Use**: Collect only data necessary for the QI objectives.
- **Privacy and Confidentiality**: Apply strict measures to protect personal information.
- **Equity Considerations**: Address potential biases or inequities impacting vulnerable groups.

NEAC National Ethical Standards.

Data security

Collection storage, Data management, training needs when working with sensitive data

- The courses are available via LearnOnline
  - Working with Sensitive Health Data 1: Introduction
  - Working with Sensitive Health Data 2: Ciphered Identifiers
  - Working with Sensitive Health Data 3: Identifiers and Identifiable

Training and support available

Training:

- Te Whatu Ora Improving Together programmes
- Te Whatu Ora Improvement Fundamentals

Support:

- Project workshops – Drop ins
- Projects, Pathways and Outcomes team
  - We can support with all parts of an improvement project either leading the work alongside clinical champions or supporting you to lead the work
  - Data requests – we can support you to access the right data and to make a data plan
- In team champions

How to decide whether your project is research or audit

Human Participant Research:	Quality Improvement Activities:
Activities which attempt to create new generalisable knowledge in response to an acknowledged information gap.	• Activities which aim to improve healt by assessing current situation and systematically implementing/testing evidence -based knowledge within a l organisation.
Goal: **Quantitative research** Acceptance or rejection of a hypothesis in relation to treatment, cause, risk or diagnosis of a health problem. Small differences may represent a significant finding. **Qualitative research** Description and interpretation of something in its natural setting. May address how treatments and relationships are experienced.	• Ensure healthcare delivered by organisations are effective, safe, and equitable through the applications of improvement science methodology.
Setting: May be conducted within a healthcare setting or primary research setting. Methods: **Quantitative research** Emphasis on prespecified aims, clearly protocolised methods, high precision measures, careful bias control, sample size calculations and statistical analysis. May involve random allocation and blinding to intervention. Attempts to remove/minimise contextual influences. **Qualitative research** Obtains information from interviews, focus groups, observations, or documents or other materials	• May be conducted within a health and or community setting • Uses established, structured quality improvement methodologies to evalu baseline performance, implement cha and retest for sustained improvement • Approaches include diagnosing and understanding the issue, followed by testing an intervention (usually a kno intervention) to ascertain if it results improvement in the local context prio full implementation. Small samples a often adequate. • Tools to understand the issue may be similar to those used for research suc auditing against a standard and quali experience capture through interview /focus groups/observations. Tests of change are undertaken through PDSA cycles. Methods such as Lean Thinkin Six Sigma are used to identify and re waste and unjustified variation. • Group randomisation may occur in cl or step-wedge designs.
Data collection: Usually collects data additional to that collected for routine healthcare, sometimes by invasive diagnostic techniques. May also repurpose healthcare data for research.	• Uses existing healthcare data but ma require additional data gathering.
Outcomes from Activity: Results published /presented beyond the immediate environment in which they were collected. May be applicable elsewhere. Dissemination may be slow. No presumption that local practice will alter quickly.	• Primary audience is the organisation which the activity was conducted.

Contacting us Projects, Pathways and Outcomes

Please get in touch to discuss your improvement ideas – whether you would like support to do the project on your own or hands on help from our team.

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