Guideline: Ethical Guideline for Quality Improvement

Background/ Overview
Quality improvement (QI) initiatives have become a major feature of healthcare services in recent years, reflecting an increasing focus on the quality and safety of healthcare. QI is viewed generally as desirable and even mandatory: it is actively promoted internationally by agencies, such as the Institute for Healthcare Improvement, and supported both locally and nationally by Ko Awatea and the Health Quality and Safety Commission. There are accepted methodologies and statistical approaches to data analysis and activities often result in publication.

QI projects and research projects in healthcare are on a continuum of activities concerned with making changes and measuring their impacts with the aim of improving processes or outcomes. However, QI generally involves implementation of what is already known or reasonably assumed to be beneficial and thus is perceived to be lacking the elements of risk and uncertainty about impact which mandate ethical appraisal for research. Nonetheless, QI may still have unexpected adverse consequences, may involve activities requiring patient consent and may contribute to knowledge which influences the ongoing provision of healthcare. It would therefore appear reasonable that healthcare QI projects should receive at least some consideration of ethical implications, undergo an approval process when indicated, and be underpinned by the same ethical principles as those which apply to research in healthcare.

Frameworks and processes for ethical appraisal and approval of healthcare research, such as those overseen by the National Ethics Advisory Committee in New Zealand, are well-established. However, there is a lack of similar frameworks and processes for healthcare QI activities, which are commonly undertaken without any ethical appraisal or approval. Therefore, these guidelines have been developed as a process to enable the ethical implications of quality improvement activities to be considered.

When consideration of ethical implications is not well addressed, this can impact both patients and the reputation of our health professionals and our organisation. Being transparent, correctly managing patient information, minimising risk to patients and keeping them an informed (and therefore engaged) participant in their healthcare journey are integral aspects of ethical conduct, and effective health care delivery.

Purpose
These guidelines and practical tools have been developed as a resource to support staff of Counties Manukau Health to consider ethical implications of quality improvement. The tools (checklist and decision tree) are intended to:

- Build knowledge and awareness of potential ethical issues encountered in Quality Improvement.
- Build knowledge to respond to ethical issues arising in Quality Improvement work.
- Provide further resources to support ethical conduct of QI.
Maintain an ongoing conversation and relationship between health professionals, quality improvement and research and evaluation staff to ensure use of respective skills and expertise of others.

These guidelines have been developed with the underpinning belief that considering the ethical implication of our work in healthcare settings is not restricted only to those fields with existing bodies or governance structures. We would encourage all staff to consider the ethical implications of their work.

**Note:** This guideline is based on, and should be considered in conjunction with:

- Privacy Act New Zealand (1993)

**Scope of Use**

These guidelines are aimed at supporting all staff at Counties Manukau Health who undertake improvement work beyond the guidance of recognised ethics bodies. The guidelines also aim to direct staff to various other available resources to assist them in making decisions about their project and potential ethical implications.

**Guideline**

This guideline provides two tools for application by staff: a checklist and a decision tree. The tools can be used in any order, and both serve the purpose of identifying ethical ‘risks’ in QI activity, directing staff to available support resources, and clarifying when a more formal ethical approval process may need to be undertaken. Many QI activities will not have any ethical risks identified, and can therefore proceed without ethical review.

Staff are encouraged to draw on these tools and the broader guidelines in the project planning phase of their work, to assist them in identifying and responding to any potential ethical concerns in a timely manner. However, they are also encouraged to reflect on them throughout the project phases and in day-to-day clinical practice. Quality improvement is a cyclical process in which directions, processes and interventions are adapted as we learn. This infers that we need to maintain vigilance to ethical issues as QI activities evolve.
Step | Action
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1 | Utilise checklist and decision tree to assist in identifying ethical risks.
2 | Where necessary, seek further advice from an ethical body or the Research and Evaluation Office (CMH).
3 | Where indicated, lodge ethics approval with an Ethics Committee.
4 | As QI activities evolve, identify and respond to emerging ethical issues

When a preliminary ethical review or advice is sought, the CMH Clinical Ethics Advisory Committee may be approached. If formal ethical review is required then this will need to be sought from a regional Health and Disability Ethics Committee (HDEC - the Research and Evaluation Office can assist with this). Where projects are out of scope for the Health and Disability Ethics Committee, The New Zealand Ethics Committee can offer advice and ethical appraisal.

Below is a brief description of some issues to consider when using the tools provided.

### 1.1 Informed consent
Informed consent originates from the ethical and legal premise that people have the right to direct what happens to their body, and that healthcare professionals have an ethical obligation to involve consumers\(^1\) in their healthcare (De Bord, 2014). “When risks, suffering or inconvenience resulting from a QI activity may be present, patients need to be provided with sufficient information in an environment free of undue pressure to enable them to decide whether they wish to be involved, just as occurs in clinical care or research” (NSW guideline, p.1).

The decision tree can be used to identify areas where informed consent may be required. Informed consent, when required, should be obtained prior to commencing QI or evaluation activities, preferably in writing. Verbal consent and discussions related to written consent should also be documented. Information provided about QI activities needs to be clear and understandable to enable consumers to make informed decisions. Consumers should also have an opportunity to ask questions, and think and reflect on their involvement and what it means for them. Features of informed consent and examples of consent forms are available from the Health and Disability Ethics Committee (see resources below).

Resources for direction around informed consent include:

- NEAC Guidelines
- HDEC Informed Consent Checklist available from HDEC website.
- The Counties Manukau DHB Guideline: Informed consent

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\(^1\) Consumers means health care consumers, patients or users of health care services.
Further, the Health and Disability Ethics Committee (HDEC) also provide participant information sheet and consent form templates. These are publically accessible for downloading on HDECs website: http://ethics.health.govt.nz/

1.2 Privacy and confidentiality

During the delivery of QI activities, there are many instances when we need to consider the privacy and confidentiality of personal and health information. Practices to ensure privacy and confidentiality apply throughout the collection, storage and ongoing management of data, and the distribution, sharing or publishing of QI activity findings/learnings/outcomes. Privacy and confidentiality need to be protected except in circumstances of overriding concern where release of information is required for the safety of the individual.

Many QI activities may only draw on summary or de-identified\textsuperscript{2} data collected as part of routine clinical care. However, other QI activities involve direct contact with patients/consumers, with or without their explicit informed consent for the QI activity (as something distinct from usual clinical care), which may warrant ethical review by HDEC or other ethical body. Ethical appraisal legitimises the presence of QI or other staff and their access to information and events that are typically only accessible to consumers’ clinical care team.

Generally, data generated from QI activities should be de-identified when stored and prior to sharing with any party who would not normally have access to this information. Data should only be stored in password protected folders with restricted access to only the QI or research and evaluation team. The NEAC guidelines draws particular attention to activities involving rare, unique or small communities or individuals- for example, people with a rare health condition- who may be easily identified by others. Privacy is well articulated in New Zealand’s Privacy Act (1993) and the NEAC guidelines. ‘Confidentiality’ refers to the respectful handling of information that is shared within relationships of trust (Lowrance 2002).

For further information about ensuring privacy and confidentiality in QI activities, please utilise the below resources:

- CMH’s Privacy Committee, contact John Hansen (Chief Legal Advisor).
- The Counties Manukau DHB Policy: Safe Management and Privacy of Personal Health Information

\textsuperscript{2} De-identified information is anonymised or anonymous and not able to be re-identifiable. This means there is no identifiable information such as names, addresses or NHI’s, but also further information that may allow people to be identified through cross referencing with other databases. Types of data from identified to anonymous data are explained in the National National Ethics Advisory Committee (2012). Ethical Guidelines for Intervention Studies: Revised edition. Wellington: Ministry of Health.
1.3 Change in standard of care

It is critical to consider if a QI project is going to involve a significant change in the standard or nature of clinical care and, if so, how firm the grounds are for expecting that this will be an improvement, or at least not detrimental, from the consumer's perspective. Ethical review may be required where there is a change in the standard of care for the purposes of piloting a new approach that does not have clear evidence of benefit in a similar population, or if the change is being made solely to improve efficiency or otherwise benefit the healthcare provider, with potential adverse effects for consumers.

Where proposed changes or other QI activities are based on national and internationally recognised best practice standards, ethical considerations still apply but it is likely that implementation would not require ethical review. However, innovation and improvement inevitably involves piloting and implementing novel approaches, or known approaches but in different contexts or situations. In such instances, patients/consumers may need to be informed, and ethical approval obtained, for the protection of consumers and QI staff alik
Does your QI involve **ONLY** recording, classifying, counting and/or analysing of data already collected as part of patient care? For example, Concerto/analyst team data.

- **Yes**
- **No**

Will this involve collecting or receiving identifiable or private information about individuals? For example, names, NHI’s, addresses, unique characteristics that would enable a person to be identified?

- **Yes**
- **No**

**Action:** apply ethical checklist

Are any possible ethical risks identified?

- **Yes**
- **No**

- **Yes**
  - Is it possible the results will be published in a journal that requires ethical review for publication?
  - **Yes**
    - Ethical approval is likely to be required. Obtain advice from the Research Office or HDEC
  - **No**
    - No ethical review required
      - Proceed with QI process

- **No**

**Actions:**
1. Register as an ‘audit or related activity’ with the CMH research office
2. Review data storage practices (guideline 1.2)
3. Sign confidentiality agreement with CMH Research Office

Does your QI process comply with ethical guidelines for data storage, transport and sharing?

- **Yes**
- **No**

**Actions:**
1. Complete relevant ethical review process as advised
2. Register with the CMH Research Office

Do any outputs (for example reports, business cases) include identifiable or private information about patients or other study participants?

- **Yes**
- **No**

**Get support from the CMH Research Office**

This QI activity cannot be undertaken as it does not comply with the Privacy Act 1993

**Actions:**
- **Outside of HDEC scope:** use alternative ethics
- **Expedited review**
- **Full review**

**Proceed with QI process**

**Feedback results with the Research Office**
Checklist

The checklist is designed to assist in identifying when a proposed QI activity entails ethical 'risks'. It has been adapted from the NSW Health Quality Improvement and Ethics Review: A Practice Guide for NSW.

Please note that any QI processes involving the following would be classified as clinical intervention studies or research and therefore applicable to full ethical review through the Health and Disability Ethics Committee, or the Ethics Committee on Assisted Reproductive Technology:

- Use or creation of a human gamete, human embryo or hybrid embryo
- Establishment or maintenance of a tissue bank
- Use of Guthrie cards
- Use, collection or storage of human tissue/bio samples (for example blood, or urine)
- Allocation of patients to groups to enable comparisons

Section 1: Issues that may require informed consent

1. The QI activity involves contact (by QI staff or clinicians/medical staff) with patients/consumers, their family or whaanau or members of the public

2. The QI activity poses additional risks to or burdens on the patient and/or their family or whaanau beyond their routine care

3. Data will be collected beyond that which is normally collected in routine clinical care

4. The QI activity involves a change in standard of care for patients/consumers and/or their family/whaanau. See section 1.3 of Ethical Guidelines for Quality Improvement for further discussion about changes in standard of care.

5. The data to be collected is of a sensitive nature or application. For example, data which could be emotional for participants to share, or highly confidential.

6. Use of Health Information is not aligned with, or related to, its 'purpose for collection' (the patient’s clinical condition or anticipated treatment).

If the response to any of the above statements is ‘Yes’, you should review the ‘informed consent’ guidelines (see section 1.1 of Ethical Guidelines for Quality Improvement) and contact the CMH Research Office for further support.

Section 2: Privacy and confidentiality

7. The data will be used, stored, transported, or available (including in written outputs) in such a way that may identify individuals.
8. Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient’s record, or to other relevant data sets

9. The QI activity involves individuals, people or communities who are rare, small or unique and therefore could be easily identified (for example, QI involving people with a rare condition)

If the response to any of the above statements is ‘Yes’, you should review the Privacy and Confidentiality section 1.2 of the Ethical Guidelines for Quality Improvement and contact the CMH Research Office for further support.

Section 3: other considerations

10. The QI activity is likely to generate data that may lead to publication.

11. The activity may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions

12. Impact on cultural groups (such as Maaori, Pacific and Asian) or other relevant equity groups has not been considered in planning, research or evaluation of this QI activity

If the response to any of the above statements is “Yes”, it is highly likely you would be required to submit a full ethics application to the Health and Disability Ethics Committee. Contact the HDEC or the CMH Research Office for further support.

If you have not answered “Yes” to any of the above statements, it may still be useful for you to seek advice about ethical aspects of your QI. Possible sources for further advice and information include:

- The Research and Evaluation Office
- Clinical Ethical Advisory Committee (CMH)
- Senior colleagues
Health and Disability Ethics Committee resources


New South Wales Health (2007). Human research ethics committee- Quality improvement & ethical review: A practice guide for NSW. Ministry of Health: NSW, Australia

Associated Documents

Other documents relevant to this guideline are listed below:

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<th>CM Health Documents</th>
<th>Guideline: Informed Consent</th>
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| Other related documents | None |