Is my project Quality Improvement or Research?

This document is a guideline for staff to assist them to determine if their project is classified as Quality Improvement (QI) or Research in the organisation.

Quality Improvement definitions

- **Clinical audit:** "A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria. Where indicated, changes are implemented and further monitoring is used to confirm improvement in healthcare delivery".[1]
- **Continuous improvement:** "A systematic, ongoing effort to raise an organisation's performance as measured against a set of standards or indicators".[1]
- **Quality improvement activities:** "Activities conducted by a Health Service Provider in order to improve the quality and/or safety of the care they provide to patients. Quality improvement activities should use the Health Service Providers own data in combination with current best-evidence".[1]

Research definitions

- "The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions".[2]
- The Australian Code for the Responsible Conduct of Research (2007): "The meaning of 'research', as used in this Code, is original investigation undertaken to gain knowledge, understanding and insight. It is a broad concept and there is no simple, single way to define research for all disciplines".[3]

"Without research we cannot know the most effective practice. Without audit we cannot know it if is being practised".[4]

1 http://www.health.wa.gov.au/circularsnew/frameworks/Clinical_Governance,_Safety_and_Quality.pdf
2 https://en.oxforddictionaries.com/definition/research
3 https://www.nhmrc.gov.au/guidelines-publications/r39
4 http://hospital.blood.co.uk/media/26838/difference-between-clinical-audit-research.pdf

Guidance notes

Criterion	Quality Improvement (QI)	Research
Aim of project	• Measurement of performance to assess or improve a process, program or system and evaluate against current evidence based practice / standards	• To test a hypothesis • To establish new practice standards • To establish best practice by the creation of new knowledge
Questions	• Are we doing the right thing? • Are we doing what we think we are?	• What is the right thing to do? • Why does this happen?
Participant cohort	• Patients • Consumers • Staff	• Patients • Consumers • Staff
Direct effect on participants	• Participant is unaware of the retrospective audit and consent is not required – no contact with participant **OR:** • Participant is aware of an audit and verbal, implied or written consent is required • No additional risk or burden to routine care[5] • Participant is not or minimally inconvenienced and privacy will not be breached[5]	• Consent (verbal, implied, written or waiver) is required as per research protocol • Participant has the right to be informed, to refuse consent and to leave the study at any time • May have some degree of risk or burden beyond that associated with routine care; may also reflect no additional risk projects comparing standards of care
Treatment type	• Standard routine care	• Experimental or comparing common care when there is variability in care
Length of study	• Short term – usually less than 1 year	• Long term – can be 1-20 years or more
Breadth of study	• Service being audited or improved – ward or department	• Broader healthcare implications : state, national, international
Data type	• Randomisation for treatment, control group or placebo **excluded** • Retrospective or prospective data with varying sampling techniques i.e. random sample • Comparative analysis – internally within WA Health sites or against set criteria / standards • Generally descriptive • Usually within one hospital site, ward or department; however a clinician may work across multiple WA Health sites conducting the same audit at each site • Usually de-identified data • Patient records • Usually basic statistical analysis	• Randomisation for treatment, control group or placebo **included** • Retrospective or prospective data with varying sampling techniques dependant on the research protocol • Comparative analysis • Can be one hospital site, multiple sites, national or international sites • As per research protocol : usually de-identified data • Patient records • Usually extensive statistical analysis
Methodology / tools	• Improvement methodology: Plan Do Study Act (PDSA); Six Sigma; LEAN etc. • Surveys/ questionnaires • Observational audits • Clinical audit using an audit tool	• Research methodology such as Quantitative, Qualitative, Mixed Methods, Delphi study etc. • Surveys / questionnaires • Interviews • Focus groups • Clinical Trials • Observational studies • Laboratory work
Ethical implications	• Minimal risk: *"risk that is no more likely and not greater than that attached to routine medical or psychological examination."* • Risks – clinical, social, psychological (e.g. staff stressed if practice audited) , economical • Baseline data for QI might be innocuous but consideration should be given to the rest of the PDSA cycle when changes are implemented that can have unintended patient safety consequences.[6]	• Level of risk is assessed as per the National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)[7]

5 Ethical Considerations in Quality Assurance and Evaluation Activities, 2014 : https://www.nhmrc.gov.au/guidelines-publications/e111
6 http://www.who.int/patientsafety/research/ethical_issues/en/
7 https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf

Criterion	Quality Improvement	Research
SMHS Ethics approval	• Not required	• Approval is required via the SMHS HREC process using the Research Governance Service (RGS) online system https://rgs.health.wa.gov.au/Pages/Home.aspx
SMHS Governance approval : site authorisation	• Approval is required via the WA Health Governance, Evidence, Knowledge, Outcomes (GEKO) approvals process : https://geko.hdwa.health.wa.gov.au/Login	• Approval is required via the SMHS Research Governance process in RGS https://rgs.health.wa.gov.au/Pages/Home.aspx
GEKO	• Registration required – *external staff (such as university students) need to have a site based Clinical Supervisor who is employed in SMHS and has a He number to access GEKO. The GEKO proposal should detail what is happening with the data and if this is being shared offsite and for what purpose i.e. a Masters project.*	• Registration not required
Funding	• Uncommon to have external sponsors , funding or grants	• Common to have external sponsors, funding or grants
Publication	• Publication and presentation of findings permitted: o *Indicate the intent to publish on the GEKO application; approval needs to be obtained from the respective Service Safety, Quality and Risk Committee with a letter that is signed off by the Committee Chair or Service Co-director. Approval for hospital wide activities is to be obtained from the Clinical Governance Committee with a letter that is signed off by the Chair of the committee*[8]*.*	• Publication and presentation of findings permitted: o *Researchers need to check organisational policies and procedures; Sponsor or funding body protocols or refer to a contract or agreement such as a Clinical Trial Research Agreement.*
Legal liability	• Usual duty of care	• May require a Contract, Confidentiality Agreement and / or a legal opinion, Therapeutic Goods Administration (TGA) approval etc.

Further information

- SMHS Research Ethics and Governance intranet page:https://smhshealthpoint.hdwa.health.wa.gov.au/directory/REG/Pages/default.aspx
- FSFHG Performance Review and Audit intranet page:https://fshhealthpoint.hdwa.health.wa.gov.au/directory/clinicalsupport/sqr/pra/pages/default.aspx
- RkPG intranet page: https://rkpghealthpoint.hdwa.health.wa.gov.au/directory/SafetyQualityRisk/Pages/QualityImprovementandInnovation.aspx
- WA Health Research Policy Framework 2016: http://www.health.wa.gov.au/circularsnew/frameworks/Research.pdf

8 https://fsh-healthpoint.hdwa.health.wa.gov.au/directory/clinicalsupport/sqr/pra/Documents/Clinical%20Audit%20and%20Quality%20Improvement.pdf