

November 2019

Dear Editor(s)/ Editorial staff,

Re Manuscript submission:

OUTCOMES OF A NATIONWIDE DRUG SHORTAGE OF BALSALAZIDE REQUIRING SWITCHING TO OTHER AMINOSALICYLATES IN PATIENTS WITH ULCERATIVE COLITIS

This study was approved as a low-risk, quality assurance project by the Eastern Health Human Research ethics committee (see attached approval in manuscript submission). As per the accompanying guidelines published by NHMRC who oversee research and ethics in Australia, no consent is required for research conducted of a quality assurance, low risk nature. This project falls well within those guidelines and thus no consent was obtained from individual participants.

Yours Sincerely,



A/Prof Daniel van Langenberg
Corresponding Author



Australian Government
National Health and Medical Research Council

Ethical Considerations in Quality Assurance and Evaluation Activities

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1. Introduction

The National Health and Medical Research Council (NHMRC) recognises the important contributions that quality assurance (QA) and evaluation activities make to better outcomes, and more efficient and effective work processes. However, there can be uncertainty about what level of oversight QA and evaluation activities require and there can be confusion about whether an activity is research or evaluation or QA. This can be because QA and evaluation activities may include the use of methods or approaches also used in research such as surveys and observation.

Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably.¹ In this document the term 'quality assurance' is used to include all of these terms.

Evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives.²

In some circumstances, attempts to clearly separate QA from research are unhelpful. Moreover, QA, evaluation and research exist on a continuum of activity, and work that begins as one form of activity can evolve into another over time. Importantly, QA and evaluation commonly involve minimal risk, burden or inconvenience to participants, and, while some level of oversight is necessary, Human Research Ethics Committee (HREC) review processes are often not the optimal pathway for review of these activities. What really matters is that:

- participants in QA/evaluation are afforded appropriate protections and respect
- QA and/or evaluation is undertaken to generate outcomes that are used to assess and/or improve service provision
- those who undertake QA and/or evaluation adhere to relevant ethical principles and state, territory and Commonwealth legislation
- organisations provide guidance and oversight to ensure activities are conducted ethically including a pathway to address concerns.

This advice is designed to assist organisations in deciding the appropriate level of oversight for QA and evaluation. Organisations should consider this guidance when developing policies/advice on QA activities, particularly as related to the triggers for ethical review listed below.

2. Appropriate Oversight of Quality Assurance and Evaluation

Irrespective of whether an activity is QA, evaluation or research, the activity must be conducted in a way that is ethical. This should include consideration of whether the people involved will be exposed to any harm as a result of the activity. Those conducting the activity need to consider a range of issues including consent, privacy, relevant legislation, national/professional standards and whether ethical review is required.

In many situations, oversight of the activity is required, but ethical review is not necessary. These include situations where:

- The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols;

1 *When does quality assurance in health care require independent ethical review?* NHMRC 2003, http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e46.pdf

2 Australasian Evaluation Society Incorporated *Guidelines for the Ethical Conduct of Evaluations*, August 2010, <http://www.aes.asn.au/images/stories/files/About/Documents%20-%20ongoing/AES%20Guidelines10.pdf>

- The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;
- The data being collected and analysed is not linked to individuals; and
- None of the triggers for consideration of ethical review (listed below at point (e)) are present.

Organisations should develop policies on QA/evaluation which provide guidance for oversight of QA or evaluation activities. It is recommended that such policies address the following issues:

a) Collection and use of data for QA/evaluation including:

- Guidance on the identification of risks and burdens to participants:
 - Risks include not only physical risks, but also psychological, spiritual and social harm or distress (e.g. stigmatisation or discrimination) and may involve people associated with participants. Consideration should be given as to whether the proposed QA/evaluation activity poses any risks for participants beyond those routinely experienced in the environment where QA/evaluation is being conducted. Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, e.g. persistent phone calls, additional hospital visits or lengthy questionnaires.
- Guidance to assist in ensuring that consent from participants, where required, is adequate.
- Guidance on the provision of information to participants including related to the use of an opt-out approach. The opt-out approach is a method used in the recruitment of participants into an activity where information is provided to the potential participant regarding the activity and their involvement and where their participation is presumed unless they take action to decline to participate.

b) Privacy and data security including:

- Advice on the management of data (i.e. how it is collected, stored, used and destroyed).
- Advice on who is able to access data.
- Advice on confidentiality.

c) Relevant legislative requirements including:

- *Privacy Act 1988*.
- State and territory privacy acts.
- Any other relevant Commonwealth, state, or territory legislation or guidance.

d) Relevant national/professional standards:

- Organisations should provide a listing of relevant documents.

e) Triggers for consideration of ethical review including:

- Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- Secondary use of data - using data or analysis from QA or evaluation activities for another purpose.
- Gathering information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations.
- Testing of non-standard (innovative) protocols or equipment.
- Comparison of cohorts.

- Randomisation or the use of control groups or placebos.
- Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity.

Where one or more of the triggers above apply, the guidance provided in the *National Statement on Ethical Conduct in Human Research, 2007* (National Statement) should be followed.

Where ethical review by an HREC is not required, organisations should consider providing a statement which affirms that an alternative approach to ethical review was considered to be appropriate for the specific QA/evaluation activity if this is required for publication purposes.

f) The level of ethical review (if required):

Where ethical review is required, organisational guidance should assist in the identification of situations where HREC review should be sought and situations when other forms of ethical review are appropriate. The National Statement provides guidance in paragraphs 5.1.18-5.1.23.³ There are a number of different methods that organisations could adopt. They include delegating responsibility to:

- A QA/low-risk committee
- A sub-committee of the HREC
- The HREC Chair or appropriate HREC member(s)
- Another appropriate committee or individual involved in / responsible for clinical governance

Any proposal causing unresolved concern may be referred to an HREC constituted and operating in accordance with the National Statement. Organisations with no regular access to an HREC should build a relationship with a properly constituted HREC.

3. Clinical Quality Registries

Clinical quality registries systematically collect health-related information on the quality, safety and outcome of care provided to individuals who are:

- treated with a particular surgical procedure, device or drug, e.g. joint replacement;
- diagnosed with a particular illness, e.g. stroke; or
- managed via a specific health care resource, e.g. treated in an intensive care unit.

The purpose of clinical quality registries is to inform improvements in the quality of health care by routinely collecting, analysing and reporting on information about the care provided to patients, how well that care is being provided, and the outcomes. In particular, clinical quality registries provide specific information about:

- the appropriateness of health care (whether the care delivered to patients is based on the best available evidence)
- the effectiveness of health care (measured by the degree to which the care benefits the patient).

This information is used to inform improvements in the healthcare system.⁴

³ *National Statement on Ethical Conduct in Human Research, 2007* <http://www.nhmrc.gov.au/guidelines/publications/e72>

⁴ <http://www.safetyandquality.gov.au/our-work/information-strategy/clinical-quality-registries/what-are-clinical-quality-registries/>

The Australian Commission for Safety and Quality in Health Care (ACSQHC) Strategic Principles for a National Approach to Australian Clinical Quality Registries provides guidance for the operation of clinical quality registries.⁵ Those establishing a clinical quality registry may consider employing an opt-out approach for **quality assurance activities** without the need for ethical approval where none of the triggers for consideration of ethical review listed in Section 2 (e) above are relevant. Otherwise, ethical review for the use of the opt-out approach should be sought.

In accordance with the guidance provided in the National Statement, clinical registries which are established for the purposes of research are databanks. Those establishing a databank should be familiar with the requirements of the National Statement, particularly *Chapter 3.2: Databanks*.

⁵ *Strategic Principles for a National Approach to Australian Clinical Quality Registries*: <http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Strategic-and-Operating-Principles-for-Australian-Clinical-Quality-Registries-AHMC-endorsed-Nov-2010.pdf>