Several shades of grey – When is audit research?

AAGBI Core Topics Meeting

Aberdeen 2020

AUDIT

RESEARCH

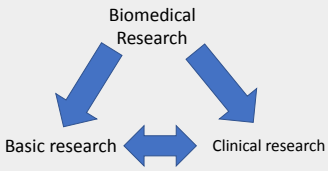
QUALITY IMROVEMENT

SERVICE EVALUATION

Principles

- Research what *should be done* to help patients
- Audit whether this is *being done*, and if not, why not
- Service evaluation examines the effect of care on *patient experiences and outcomes*.
- QI is a methodology that aids change

Research Definition



Research Definition

The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them".

Review by an NHS REC is required for research within the scope of the UK Health Departments' Governance Arrangements for Research Ethics Committees
http://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements

Health Research Authority

Research Ethics

- Field of ethics that examine and analyse the legal and ethical aspect of research involving human subjects
- Main focus is to ensure that study participants are protected

AND

- That research is conducted in away that serves the need of the participants and society as a whole

The wellbeing of the individual should take precedence over that of science or Society

Audit

Calman training 1997

Anaesthesia, in its notice to contributors
"Prospective ethics approval should be acquired for papers based on clinical audit data." **1997**

1989

"Working for Patients, 1989" – This White Paper defined medical audit, (as it was then known), as "the systematic critical analysis of the quality of medical care including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient."

1993

"clinical audit is the systematic analysis of the quality of healthcare, including the procedures for diagnosis, treatment and care, the use of resources and resulting outcome and quality of life for the patient." (NHS Executive 1993)

1998

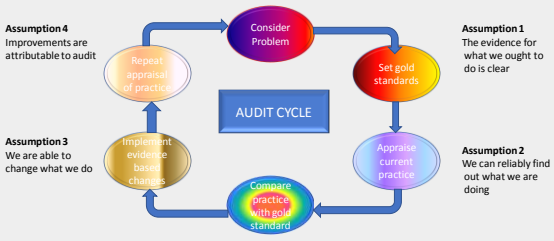
"Clinical Audit forms an integral part of the Clinical Governance of a healthcare system and Clinical Governance is the framework through which NHS organisations are accountable for continually improving the quality of services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." (BMJ), (4 July 1998)

2003

"a quality improvement process that seeks to improve patient care and outcomes through a systematic review against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement to healthcare delivery." (NICE 2003)

Standards

- Clinical Audit is the process whereby actual practice is compared against explicit standards
- Valid standards which are measureable are chosen
- Published, expert opinion, evidence based
- If no evidence exists then local consensus **of expected** practice is acceptable



Clinical Audit

Studies show ineffective in improving systems

Only 5% of audits led to any change in the practice or process studied.

22% completed, 25% repeated

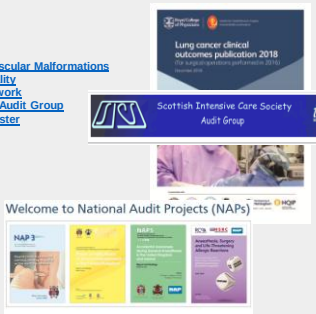
RCS 2009

No increase in compliance with recommendations of NAP 5

Myles et al BJA 2018

Scottish Healthcare Audits

Home
JAG/GRS
Scottish Arthroplasty Project
Scottish Audit of Intracranial Vascular Malformations
Scottish Audit of Surgical Mortality
Scottish ECT Accreditation Network
Scottish Intensive Care Society Audit Group
Scottish Multiple Sclerosis Register
Scottish Renal Registry
Scottish Stroke Care Audit
Scottish Trauma Audit Group
The Musculoskeletal Audit



SICSAG 2017 Report Summary

1. 19% of patients admitted to Intensive Care Units died before they were discharged from hospital.
2. No unit was found to have a significantly higher mortality rate compared to the rest of Scotland.
3. Shortage of beds was a theme impacting on critical care in 2017. Units were not always able to discharge their patients at an appropriate time with 22% and 25% of discharges from High Dependency Units and Intensive Care Units delayed more than four hours respectively. This is also reflected in figures for night time discharges and early discharges.
4. Overall there has been improvement in units attaining the minimum standards and quality indicators from 2016, however some remain challenging for units.

NAP 2 evaluation or Audit?

- … To explore the role that anaesthetists play in M&M meetings and the value they obtain from them
- To ascertain the beliefs, (professed) practice and possible scope for improvement, from two viewpoints:
- A) The official department position (from clinical director or deputy)
- B) The perspective of consultants.

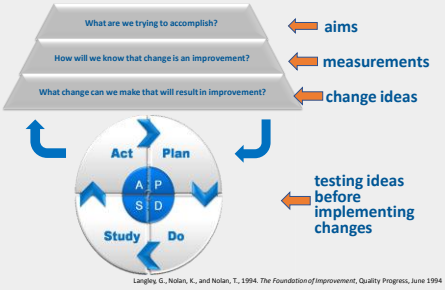
What is service evaluation?

- Service evaluation seeks to assess how well a service is achieving its intended aims.
- It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the **sole** purpose of defining or judging the current service.
- The results of service evaluations are mostly used to generate information that can be used to inform local decision-making

National Research Ethics Service (NRES). Defining research. 2013

Quality Improvement

- A systematic approach that uses specific techniques to improve quality. Change is implemented in a systematic and consistent approach
- Ideas are tested and feedback is crucial to success



Clinical Audit	Research	Service Evaluation
Based on facts, (standards)	Aims to establish what expected practice is	Designed and conducted solely to define or judge current care
Aims to evaluate how close practice is to expected practice	Is often a one off study	Identifies the standards that the service achieves
Is specific & local to one particular patient group, (results are not transferable to others)	Is designed so it can be replicated and results generalised to other similar groups	Measures current service without reference to a standard
Aims to improve services	Aims to generate new knowledge or increase the sum of knowledge	Usually involves analysis of existing data,
Is practice based	Is usually initiated by researchers	-
Never involves a new treatment	Is theory driven	-
-	Is usually testing a hypothesis and follows a protocol	-
May require Ethical review	Requires Ethical review	

Service Evaluation and Audit

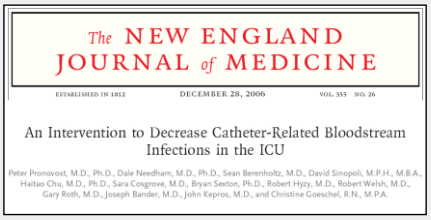
Service Evaluation	Audit
To define or judge current care	To produce information to inform delivery of best care
What standard does this service achieve?	Does this service reach a predetermined standard?
Measures current service without a standard	Measures against a standard
Involves an intervention in use only Care given is normal everyday practice	Involves an intervention in use only Care given is normal everyday practice
Analysis of existing data (may include interview or questionnaire)	Analysis of existing data (may include interview or questionnaire)
No allocation or intervention	No allocation or intervention
No randomisation	No randomisation
Does not require REC review	Does not require REC review

Health research Authority 2017

Research Ethics

The moral principles that govern how **researchers** should carry out their work.
These principles are used to shape **research** regulations agreed by groups such as university governing bodies communities or governments

- Clinical audit by definition does not involve anything **being done** to patients other than their normal clinical management.
- This does however mean that it is essential that projects undertaken in the name of clinical audit are not in fact research.
- All clinical audits must be conducted within an ethical framework. In practice this means that consideration should be given to such issues as confidentiality and disclosure of audit results.



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 28, 2006 VOL. 355 NO. 26

An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

Project Title: Statewide Efforts to Improve Care in Intensive Care Unit

Specific aims are to implement and evaluate:

- impact of the Comprehensive Unit-based Safety Program that includes the ICU Safety Reporting System;
- effect of an intervention to improve communication and staffing in ICUs;
- effect of an intervention to reduce/eliminate catheter related blood stream infections;
- effect of an intervention to improve the care of ventilated patients; and
- effect of an intervention to reduce mortality.

Results Good

CONCLUSIONS

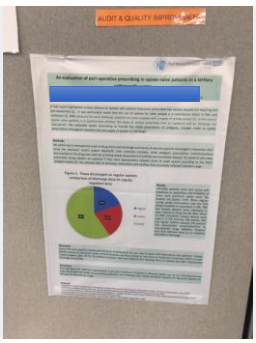
An evidence-based intervention resulted in a large and sustained reduction (up to 66%) in rates of catheter-related bloodstream infection that was maintained throughout the 18-month study period.

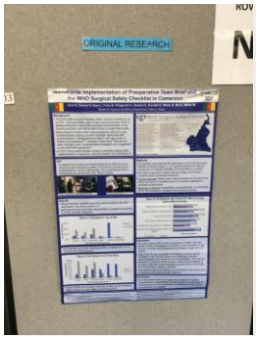
Office for Human Research Protection

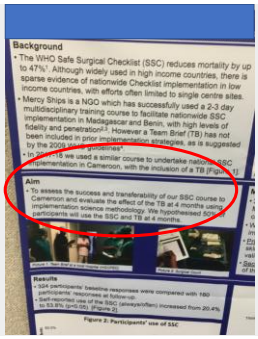
OHRP found that the implementation of the Comprehensive Unit-based Safety Program that included the ICU Safety Reporting System at Michigan and Rhode Island hospitals, the subsequent collection and analysis of data from ICU patients exposed to those interventions, and the surveys of hospital personnel, represented non-exempt human subjects research that was conducted without appropriate IRB review and approval, in contravention of HHS regulations at 45 CFR 46.103(b) and 109(a). In addition, OHRP found that JHU failed to ensure that all collaborating institutions engaged in the research operated under an appropriate OHRP-approved assurance of compliance as required by terms of the JHU institutions' FWAs.

OHRP found that, given that the project involved non-exempt human subjects research, JHU failed to ensure that the requirements for obtaining and documenting the legally effective informed consent of the subjects or the subjects' legally authorized representative under HHS regulations at 45 CFR 46.116 and 46.117 were satisfied. OHRP notes that the subjects of the research were both the healthcare providers at the participating ICUs and their patients.

First, we believe that the actual implementation of the five part catheter-related bloodstream infection reduction program in the participating hospitals is a quality improvement activity that does not meet the regulatory definition of *research*. This is because none of the parties involved are implementing the program as a research intervention in order to evaluate its effectiveness. Here, the program is being implemented solely for the purpose of improving the quality of care.







1. It is illogical to attempt to define the indefinable
2. Criteria for classifying projects into research/not-research are neither reliable nor consistent
3. From an ethical point of view (it) is what's being done, not what a project is called.

''..absurd situation in this country whereby projects deemed to be 'research' require independent review by a research ethics committee (REC), whilst those deemed to be 'non-research' (audits, surveys and 'service evaluations') are not...''

Alternative Classification

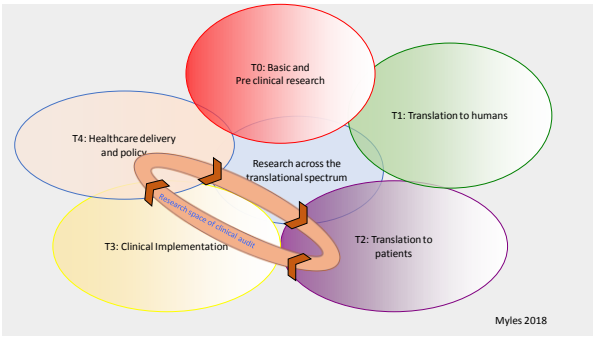
- The motivations and the objectives of a project could help to distinguish audit from research.
- 'Audit has the objective of directly improving services against a standard.
- Research may include the objective of defining best practice.'

Sears 2017

Spectrum

Research	**Audit**
• Not all about randomised controlled trials • also about *how* a treatment works, how a disease process develops, etc.	• Not all are classic audit cycle • Collection of data when no standard ...

'From an ethical point of view, the focus should be on 'what is being done, not what it is called'

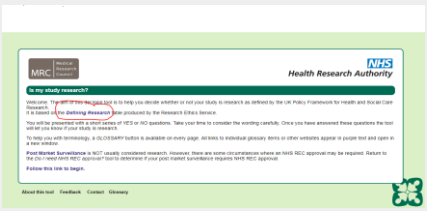


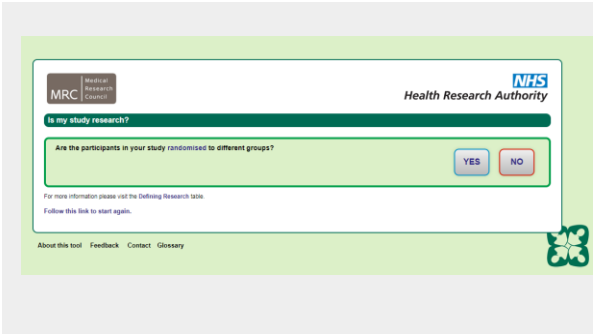
Association of Anaesthetists

We suggest you should always get advice from your hospital R&D department
before
starting a study and follow their advice, and err on
the side of contacting a REC for further advice.
You will never be rejected for having approval from too many bodies
but only for not having approval (or consent)!

http://www.hra-decisiontools.org.uk

http://www.hra-decisiontools.org.uk/research




MRC Medical Research Council
NHS
Health Research Authority
Is my study research?
Are the participants in your study randomised to different groups?
YES
NO
For more information please visit the Defining Research table.
Follow this link to start again.
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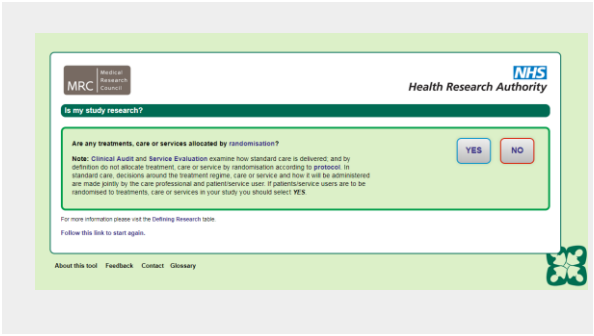
MRC Medical Research Council
NHS
Health Research Authority
Is my study research?
Are any treatments, care or services allocated by randomisation?
Note: Clinical Audit and Service Evaluation examine how standard care is delivered; and by definition do not allocate treatment, care or service by randomisation according to protocol. In standard care, decisions around the treatment regime, care or service and how it will be administered are made jointly by the care professional and patient/service user. If patients/service users are to be randomised to treatments, care or services in your study you should select YES.
YES
NO
For more information please visit the Defining Research table.
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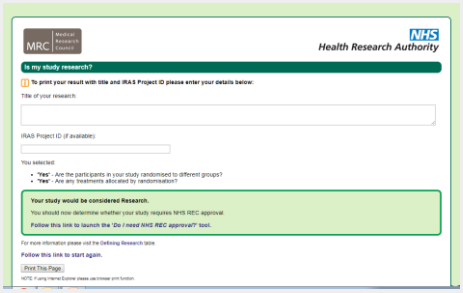
MRC Medical Research Council
NHS
Health Research Authority
Is my study research?
To print your result with title and IRAS Project ID please enter your details below:
Title of your research:
IRAS Project ID (if available):
You selected:
"Yes" - Are the participants in your study randomised to different groups?
"Yes" - Are any treatments allocated by randomisation?
Your study would be considered Research.
You should now determine whether your study requires NHS REC approval.
Follow this link to launch the 'Do I need NHS REC approval?' tool.
For more information please visit the Defining Research table.
Follow this link to start again.
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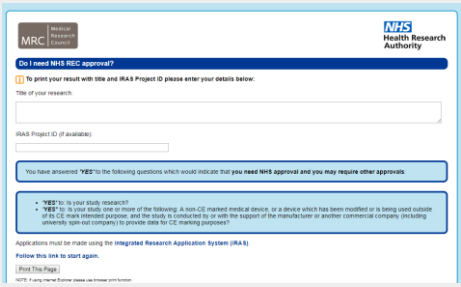
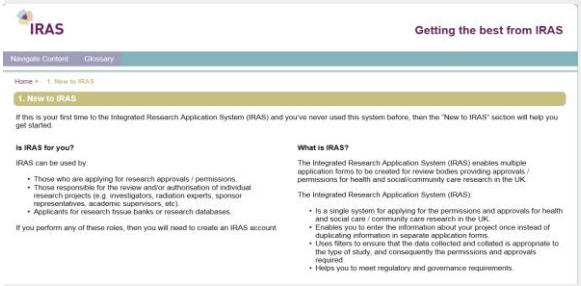
Do I need NHS REC approval?
Do any of the following apply to your study?
Is your study a clinical trial of an investigational medicinal product (CTIMP)?
A study investigating how safe, and/or how effective, a drug or potential drug might be when used to treat, prevent or diagnose human illness. This can include studies involving drugs with Marketing Authorisations, healthy volunteers and some pharmacodynamic studies, where the study outcomes relate to safety and/or efficacy of the investigational medicinal product.
For more information please visit the MHRA website
YES
Is your study one or more of the following:
A non-CE marked medical device; or
A device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
YES
Does your study involve exposure to any ionising radiation?
Include here studies that involve ionising radiation, even when these exposures are not additional to normal clinical care.
YES
Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority (HFEA) by researchers, without consent?
Disclosable protected information means identifying information held by the HFEA, on a database register, about patients who have undergone assisted reproduction treatments and services and any resulting children. Answer YES to this question if it is not practicable to obtain consent for the disclosure of this information.
YES





Principles

- Research what *should be done* to help patients
- Audit whether this is *being done*, and if not, why not
- Service evaluation examines the effect of care on *patient experiences and outcomes*.
- QI is a methodology that aids change

Summary

Do you want to measure current practice against evidence based clinical standards? If the answer is yes – It is probably Clinical Audit

Do you want to investigate the effect of a **new or existing treatment or technique on patients/carers? If** the answer is yes – It is probably Research

Do you want to evaluate the effectiveness and/or efficiency of current practice or service? If the answer is yes – It is probably Service Evaluation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What you need to know!