

Surgical Audit and Research

Objectives

- Describe the principle of process and outcome audit.
- Use audit to the benefit of your patients.
- Develop soundly based audit projects.
- Introduction to the basics of surgical research.

Introduction

- We are continuously being scrutinized.
- Living in the era of evidence based medicine and accountability.
- Must show that our standard of practice is satisfactory.
- Research and audit are processes by which evidence is developed.
- Audit generates information related to performance- both individual and collective.

Case 1

- You have discovered that over the last year there has been a 2 fold increase in the mortality of patients operated in your unit.
- **Key issues**
 - Patient scoring systems.
 - Case mix alterations process and outcome audit
 - Structure.

Audit has been divided:

❖ **Medical audit :**

An audit undertaken by doctors and consists of a review of clinical events.

❖ **Clinical audit :**

A review of all potential medical events surrounding the treatment of a patient. This will include nursing, physiotherapy, social aspects, etc.

Surgical Audit – What is it and why do it?

- The purpose of audit is to examine whether what you think is happening really , and whether current performance meets existing standards
- Critical study of all aspects of patient care.
- May address economy, efficiency and effectiveness.
- Covers structure, process and outcomes.
- Ultimate goal is improving the quality of care for patients.
- Stimulus and source of material for learning and quality improvement.

The aims of audit are:

- To identify ways of improving and maintaining the quality of care for patients;
- To assist in the continuing education of surgeons;
- To help make the most of resources available for the provision of surgical services.

Forms of Audit

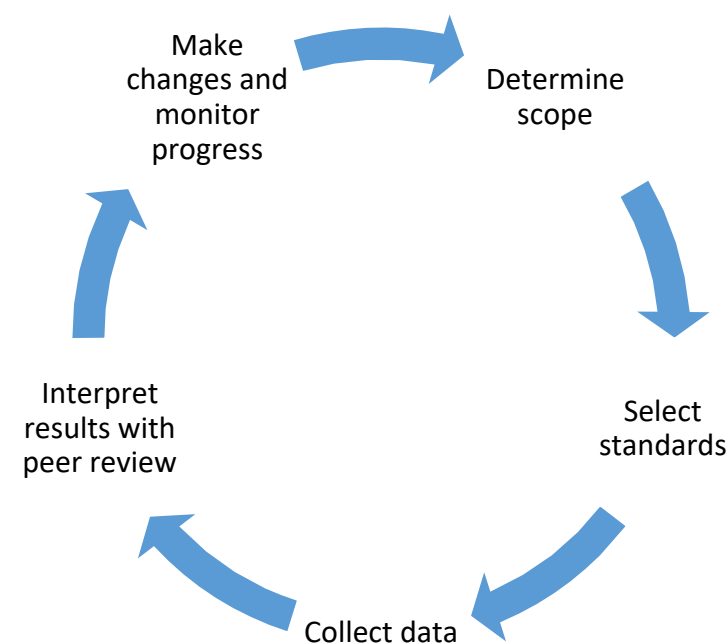
- **Total Practice or Workload Audit:** covers all the surgical operations performed.
- **Selected Audit from Surgical Practice:** covers all patients who undergo a selected procedure.
- **A Clinical Unit Audit:** conducted by a clinical unit in which individual surgeons may participate.
- **Group or Specialty Audit:** an audit conducted by or under the auspices of a group or Specialty Society.
- **A Focused Audit:** : e.g. what is the wound infection rate after large bowel surgery.

Surgical Audit and Continuing Professional Development

- Regarded as a cornerstone of professional development.
- Only by looking objectively at our own practice of surgery will we be able to compare our current proficiency and discover how to improve on this for the sake of our patients.
- Audit can help identify the difference between what surgeons think they are doing and what they actually do.

The Surgical Audit Cycle

- Surgical audit activities are based on a five-step cycle:



- **Step 1 Determine scope:**
 - A thoughtful decision about which area(s) of surgical practice to review.
- **Step 2 Select standards:**
 - A clear description of what is good practice in this area against which the results of the audit will be compared.
- **Step 3 Collect data:**
 - The collection of relevant data.
- **Step 4 Present and interpret results with peer review:**
 - Comparison of results to standards , discussion with peers, decision about what changes may lead to improvement e.g. learning new skills, changes in practice, systems etc.
- **Step 5 Make changes and monitor progress:**
 - Alteration of practice in accord with the results and then checking that improvement has occurred.

Common topics for audit:

- 30 day mortality and significant morbidity;
- length of hospital stay;
- unplanned readmission or re-operation rates;
- positive and negative outcomes;
- operation-specific complications;
- process of care, such as pre-operative care;
- time on waiting list;
- numbers waiting for outpatient appointment;
- use of investigations;
- justification of management; and
- patient satisfaction.

How to select standards?

- use evidence-based research and guidelines;
- adapt existing local guidelines for local relevance;
- use an accessible library for evidence about effective practice and develop new guidelines; and/or
- look to your specialty group to define standards.

Collect Data

- what data you will collect, and how you will collect it.
- The most important principle here is to ensure that you collect quality data.
- Consider the following questions to help decide on the best quality assessment method:
- What information is necessary to answer the audit question(s)?
- From whom will it be collected?
- Should it be collected prospectively or retrospectively?
- How will it be collected?
- During or after the operation, on a PDA, on a computer, on a form, or by questionnaire, and by whom?
- How will follow up data be collected?
- By record review, by patient follow-up questionnaire, through the GP, by phone call, or by review of routine data, and by whom?

- How will the cases for review in a prospective project be identified or selected?
- All patients, random selection, consecutive operations, all patients on the same day each week, or checklist to determine eligibility?
- How will the cases in a retrospective review be identified or selected?
- From a register, medical records data, review of referrals, or from previous
- appointment schedules?

Present and Interpret Results with Peer Review

- The results of your audit should be presented at a clinical meeting.
- Peer review is a learning exercise. It is not an opportunity to blame or brag.
- Involves an evaluation of one's work by one's peers.
- Peers are other surgeons with comparable training and experience.

Make Changes and Monitor Progress

- The next step is to implement any changes that are recommended.
- Implementation involves not just making changes but ensuring that everyone involved is educated/ informed as to what changes are being made and why.
- The impact/ effects of the changes made then needs follow up action.

What Makes for Effective Audit?

- **Promotion of a culture of audit**
- **Allocate time and resources**
- **Oversee and verify data collection**
- **Productive peer review**

What Opportunities Arise from Surgical Audit?

- Educational opportunities
- Systemic improvement opportunities

What Resources are Required for Surgical Audit?

- Manual systems
- Computer systems
- Logbooks

Surgical research

What is Research ?

- Branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use.

- used for prevention, relieving symptoms of a disease.



Quantitative vs. Qualitative research

Quantitative:	Qualitative:
Designed to test a hypothesis.	Identifies themes following established methodology.
May involve evaluating or comparing interventions, particularly new ones.	Usually involves studying how interventions and relationships are experienced.
Study design may involve allocating patients to intervention groups.	Uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.

Research vs. Clinical Audit

Research:	Clinical audit:
<ul style="list-style-type: none">May involve experiments on human subjects, whether patients, patients as volunteers, or healthy volunteers.	Never involves experiments, whether on healthy volunteers, or patients as volunteers
<ul style="list-style-type: none">Is a systematic investigation which aims to increase the sum of knowledge	<ul style="list-style-type: none">Is a systematic approach to the peer review of medical care in order to identify opportunities for improvement.
<ul style="list-style-type: none">May involve allocating patients randomly to different treatment groups.	<ul style="list-style-type: none">Never involves allocating patients randomly to different treatment groups

Research:	Clinical audit:
<ul style="list-style-type: none">• May involve a completely new treatment.	<ul style="list-style-type: none">• Never involves a completely new treatment
<ul style="list-style-type: none">• May involve extra disturbance or work beyond that required for normal clinical management.	<ul style="list-style-type: none">• Never involves disturbance to the patients beyond that required for normal clinical management
<ul style="list-style-type: none">• Usually involves an attempt to test a hypothesis.	<ul style="list-style-type: none">• May involve patients with the same problem being given different treatments, but only after full discussion of the known advantages and disadvantages of each treatment.
<ul style="list-style-type: none">• May involve the application of strict selection criteria to patients with the same problem before they are entered into the research study.	<ul style="list-style-type: none">• The patients are allowed to choose freely which treatment they get.

-  **Scientific Research asks**
Are we doing the right operation ?
-  **Audit Research asks**
Are we doing the operation right ?

Types of study:

- 1) Observational
- 2) Case-control
- 3) Cross-sectional
- 4) Longitudinal
- 5) Experimental
- 6) Randomized
- 7) Randomized controlled

1) **Observational study:**

- Evaluating **results of condition or treatment** in a defined population.
- ✓ **Retrospective:** analyzing past events
- ✓ **Prospective:** collecting data contemporaneously.

2) Case-control study:

- Series of patients with a particular disease or condition contrasted with matched control patients.

3) Cross-sectional study:

- Measurements made on a single occasion, not looking at whole population but selecting small similar group & expanding results.

4) longitudinal study:

- Measurements are taken over a period of time, not looking at whole population but selecting small similar group & expanding results.

5) Experimental study:

- Two or more treatments are compared. Allocation to treatment groups is under the control of the researcher.

6) Randomised study:

- Two randomly allocated treatments.

7) Randomised controlled study:

- control group with No treatment.
- GOLD STANDARD.

Types of study

Type of study	Definition
Observational	Evaluation of condition or treatment in a defined population
Case - control	Series of patients with a particular disease or condition compared with matched control patients .
Cross – sectional	Measurements made on a single occasion , not looking at the whole population but selecting a small similar group and expanding results
Longitudinal	Measurements are taken over a period of time , not looking at the whole population but selecting a small similar group and expanding results
Experimental	2 or more treatment are compared
Randomised	2 randomly allocated treatment
Randomised controlled	Include a control group with standard treatment

Sample size

- Calculating the number of patient required to perform a satisfactory investigation is a very important prerequisite to the study.
- An incorrect sample size is probably the most frequent reason for research to be invalid.
- Never forget that more patients will need to be randomized than the final sample size to take into account patients who die, drop out or are lost to follow up.

Types of error:

❖ Type I:

Benefit is perceived when really there is none (false positive).

❖ Type II:

Benefit is missed because the study has small numbers (false negative).

❖ The Eliminating bias:

➤ Blinded observer:

- The observers or recorders who do not know which treatment has been used.

➤ Single blind:

- The patient is unaware of the treatment allocation.

➤ Double blind:

- Neither patient nor researcher is aware of which therapy has been used until after study has finished, & these are the best

Confidence Interval “CI”

- Confidence intervals are used to indicate the reliability of an estimate.
- Depends on p value.

P value:

- The probability that results (difference between groups) of this magnitude would be observed if the null hypothesis is true .
- The lower the p-value the more strongly you can reject the hypothesis .

- If **p value** is **small** (<5%) probability of obtaining observed difference by chance alone is low – H_0 **rejected**.
- If **p value** is **large** it is conceivable that data are consistent with H_0 ,which **cannot be rejected**.

Evidence based surgery:

- Surgical practice has been considered an art, ask 50 surgeon how to manage a patient and one will get 50 different answers .
- is a move to find the best ways of managing patients using clinical evidence from collected studies.

❖ **Levels of evidence:**

➤ **Evidence grade I:**

- (High)The described effect is plausible, precisely quantified and not vulnerable to bias.

➤ **Evidence grade II:**

- (Intermediate) the described effect is plausible but is not quantified precisely or may be vulnerable to bias.

➤ Evidence grade III:

- (Low): concerns about plausibility or vulnerability to bias severely limit the value of the effect being described and quantified.

The Cochrane Collaboration:

- ❖ An international not-for-profit and independent organization, of over 27,000 contributors from more than 100 countries .
- ❖ It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions.
- ❖ The Cochrane Collaboration was founded in 1993 and named after the British epidemiologist, Archie Cochrane.