

Clinical Audit: How can I be sure?

**GPDR & CLINICAL AUDIT**

## Clinical Audit

### 4.3.1 What is clinical audit?



**“Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.”**

DOHC (2008, p. 152)

*“Clinically-led” includes all health and social care professionals.*

## Clinical Audit

- ❑ Clinical audit is a key element of clinical governance.
  
- ❑ Aims of clinical audit:
  - Improved patient care
  - Increased professionalism
  - Better use of resources
  - Support continuing education
  - Increased transparency & accountability

## Clinical Audit



We know the right  
thing to do.

Are we doing the  
right thing?

## Choice of Topic

- Strong impact on health
- Convincing evidence available about appropriate care
- Good reasons of believing that current performance can be improved
- Readily accessible data which can be collected within a reasonable length of time
- Consensus on the audit topic among the practice members

## Audit Criteria

- ❑ Audit criteria are **systematically** developed statements that can be used to assess the appropriateness of health care decisions, services and outcomes (Institute of Medicine, 1992).
- ❑ These criteria must be based on evidence, prioritized, measurable and appropriate to the setting (Evidence-based audit in general practice, 1998).

## Audit Standard

The standard is defined as the percentage of events that should comply with the criterion (Baker and Fraser, 1995).

- Reflect the clinical importance of the criterion
- Be realistic & attainable
- Example
  - 100% for the “Must Do” process criteria
  - 95% for the “Should Do” process criteria
  - 80% for the outcome criteria

## The Right Things

- ❑ STRUCTURE – staffing, bed occupancy,
- ❑ PROCESS – eg time to surgery, CT scan, medication, tests, follow ups, patient education
- ❑ CLINICAL OUTCOME– survival, pressure ulcer, infection rates, revision rates, CD management eg Diabetes - HbA1c levels, blood pressure,



# Ethics & Audit

## **GDPR Q&A**

## Planning Ethics Checklist

- NO legal requirement REC approval
  
- Suitable local oversight to identify and address any ethical issues
  - Included in planning of audit
  
  - Implementation of changes

## Planning Ethics Checklist

- 1. Is the audit GDPR compliant ? **Y/N**
- 2. Infringe on any patient's rights? **Y/N**
- 3. Risk breaching any patient's confidentiality or privacy? **Y/N**
- 4. Place a burden on a patient beyond those of their routine care? **Y/N**
- 5. Involve any clinically significant departure from usual routine care? **Y/N**
- 6. Involve a potential conflict of obligation? **Y/N**
- 7. Involve the use of any untested clinical or systems intervention? **Y/N**
- 8. Allocate interventions differently among groups of patients or staff? **Y/N**

# Publication of Audit Findings

**GDPR EVENT**

## Publishing Clinical Audit Findings

- Publishing Audit Findings – improvement publishing/ not research
- Ensure followed ethical consideration checklists at planning and findings stage.
- Journal editors may refuse to publish articles if there are ethical concerns / REC approval

# Patient Safety Incident

**GDPR EVENT**

## Potential Patient Safety?

- May arise
  - Audit data collection
  - Analysis of findings
  
- Information that indicates an incident has/**may** have occurred
  
- Responsibility to bring this information to the attention of the responsible senior person/clinician in the organisation eg nominated clinical lead or clinical director

## Potential Patient Safety Incident

- Managed via internal processes as per the HSE Incident Management Framework and HSE Open Disclosure Policy (HSE, 2018; HSE, 2019a; HSE,2019b)].
- Not** through processes of clinical audit.



# Registers, Service Evaluation & Research

**GDPR &A**

## Service Evaluation

### 4.3.2 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.”**

Twycross and Shorten (2014, p. 65)

*Unlike clinical audit, it does not compare the service to a predefined standard.*

## Service Evaluation



What do our service users think?

## Registry

### 4.3.3 What is a registry?

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**“A clinical registry is described as a system which collects a defined minimum data set from patients undergoing a particular procedure or therapy, diagnosed with a disease or using a healthcare resource.”**

Hoque et al. (2019)

## Research

### 4.3.4 What is research?



**“Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses.”**

Health Research Board (2018)

## Audit V Research

“Research is concerned with discovering the right thing to do; audit with ensuring that it is done right”.

Smith R. Audit & Research. BMJ 1992; 305: 905-6.

## Summary

- Part of routine care to audit care
- Improvement aim
- Data collection – retrospective, concurrent or prospective
- Existing criteria for best practice care – doing right think
- Ethical consideration/ does not require REC approval
- Short and simple – Did we meet this criteria/ standard
- 2<sup>nd</sup> audit cycle to evaluate changes
- Can be published – as audit findings