6. Audit and Research

This chapter provides information about the key components required for clinical audit and conducting robust research. Clinical audit is now mandatory in many contexts and research, although optional, can contribute to the existing evidence base and advance clinical practice.

6.1. Audit

Clinical audit is an essential aspect of good clinical governance with regards to improving and maintaining high clinical standards and patient safety. Clinical audit should form an intrinsic part of clinical activity and should be conducted at regular intervals to monitor clinical practice and performance. In recent times, good practice in clinical audit has shifted from a purely profession-centred perspective towards a patient-centred approach. As such, clinical audits aim to improve the quality of patient care and outcomes by systematically reviewing the standard of care against agreed criteria and consequently implementing changes to clinical practice.[107]

Clinical audits should follow a systematic process,[108] but may vary depending on the location, terminology and steps. The five key stages are outlined below.

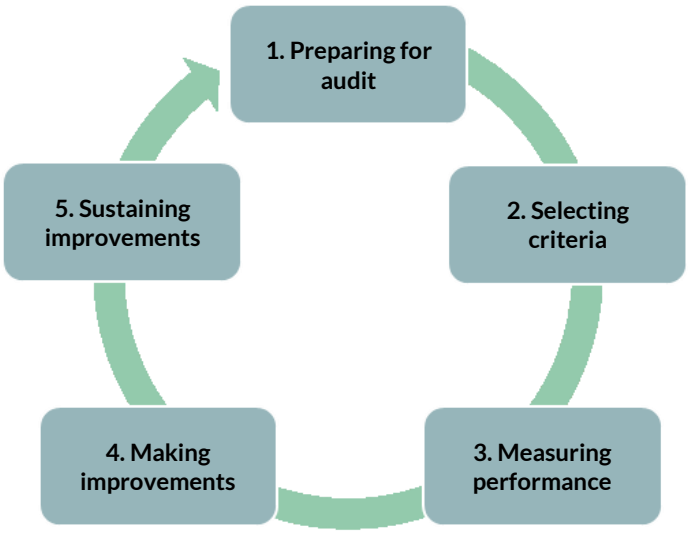

Figure 77. Chronological steps involved in a systematic clinical audit.

1. Preparing for audit: The first step is to identify an issue that requires improvement. Complaints or critical incidents can be useful to help identify problems. Thorough and honest clinical record keeping will aid this process.

2. Selecting criteria: Audit criteria establish measurable outcomes and standards prescribe the level of care for each of the audit criteria to meet. Both audit criteria and standards should always be

[107] National Institute for Clinical Excellence. *Principles for Best Practice in Clinical Audit*. Abingdon: Radcliffe Medical Press (2002).
[108] National Institute for Clinical Excellence. *Principles for Best Practice in Clinical Audit*. Abingdon: Radcliffe Medical Press (2002).

objective, set in advance, based on the best available evidence and feasible in relation to the local context.[109]

3. Measuring performance: It is essential to clearly identify the information sources, data collection techniques and participants (e.g. patients and healthcare professionals) required to accurately establish current standards. Information gathered should cover a sufficient period of time, so that patterns can be identified and monitored. Ethics and patient confidentiality must be respected throughout the data collection process. Analyse the collected data and compare performance with the preidentified criteria and standards. The comparison will identify areas for improvement in clinical care and outcomes and should guide the implementation of changes.

4. Making improvements: An action plan to implement the necessary changes will need to be developed and should be outcome oriented, time bound, realistic and objective. It is good practice for the action plan to be agreed at all levels before sign-off and implementation.

5. Sustaining improvements: Ensuring any improvements are sustained is essential and, therefore, every clinical audit should include plans to monitor and to maintain changes, e.g. through re-audits.

6.2. Research

As with any medical subspecialty, robust and up-to-date research is needed to develop knowledge, new surgical techniques and improve practices and patient outcomes. In the field of obstetric fistula, the pool of new research remains limited and it is therefore recommended that surgeons carry out their own studies and try to publish in order to increase the evidence base.[110] Even if research projects are not published, the process can help improve surgeons' own practices and results. Prior to initiating a research project, a systematic review of the literature related to the topic is necessary to understand the existing evidence and to identify gaps.

Research participants are of vital importance and the researchers have a duty of care to protect participants and their rights. To protect patient participants and to preserve the integrity of the research, it is vitally important to adhere to generally accepted research ethics as well as the institutional ethical guidelines.

There are a few key principles to help conduct ethical research:[111]

Socioclinical value: The aim of the research should be directed towards improving ways of managing or caring for patients to justify exposing participants to the risk and burden of research.

Risk–benefit ratio: The risks and discomfort associated with the research should be mitigated as far as possible and, overall, the benefits should outweigh the risks.

[109] W. Graham, P. Wagaarachchi, G. Penney, A. McCaw-Binns, K.Y. Antwi, M.H. Hall. Criteria for Clinical Audit of the Quality of Hospital-Based Obstetric Care in Developing Countries. *Bull World Health Organ* (2000).
[110] R. Pope and M. Beddow. A Review of Surgical Procedures to Repair Obstetric Fistula. *Int J Gynecol Obstet* (2020).
[111] E.J. Emanuel. What Makes Clinical Research Ethical? *JAMA* (2000).

Ethics approval: All research involving people requires ethical approval by a relevant and qualified ethics committee. This process protects both researchers and participants. If not ethically approved, then modifications will need to be made to the study design.

Validity: The research should be based on reasonable and realistic goals and the methods should be valid, clear and feasible. The research should always be conducted within the ethical limits. Thorough and robust data analysis is key to any research validity. If the researcher does not possess this skill set then it is advisable to collaborate with skilled data analysts. It is of vital importance to make data available, as well as to adequately store, share and reuse it to avail the true potential of the research.

Participant selection and respect: Participant selection should be relevant and unbiased, and participants should have enough details to make informed autonomous decisions. The participants' privacy and confidentiality need to be respected at all times and they should be allowed to withdraw from the study at any time. They should also be provided with appropriate support in case they experience adverse reactions or unexpected effects. Participants should also be informed of the research results.

6.3. Research Methods

A variety of research methods can be used for auditing and research purposes and should be selected based on their suitability to meet the research objectives.

Quantitative Methods

Quantitative methods focus on collecting numerical data through, for example, polls, questionnaires and surveys, which may be carried out in person, via phone or email, on paper or using freely available software, e.g. SurveyMonkey, Google Forms and SurveyPlanet. [112] The data are usually analysed using Excel (Microsoft) or more sophisticated statistical software, e.g. SPSS, R, STATA. [113] Quantitative research often uses larger sample sizes to generalise the results across a population and/or to test a hypothesis or particular intervention, i.e. that a particular treatment is effective or not. The latter is especially relevant when conducting randomised controlled trials.

Quantitative research has the advantage that it follows established standards and can be replicated and compared with other studies. It is generally seen as more objective as it reduces the risk of researcher bias and breaches of participant confidentiality. However, quantitative methods are limited in their capacity for more in-depth investigation and explanation of the reasons behind unexpected results.

Qualitative Methods

Qualitative research investigates the nature of reality, with a focus on processes and meanings and recognition of the relationship between the researcher and participants. Qualitative data can be collected using a variety of creative methods, most commonly in-depth, semistructured or

[112] SurveyMonkey. www.surveymonkey.co.uk. Accessed November 5, 2020; Google Forms. www.google.co.uk/forms/about. Accessed November 5, 2020; surveyplanet. www.surveyplanet.com. Accessed November 5, 2002.
[113] IBM SPSS software. www.ibm.com/analytics/spss-statistics-software. Accessed November 5, 2020; The R Project for Statistical Computing. www.r-project.org. Accessed November 5, 2020; STATA software. www.stata.com. Accessed November 5, 2020.

unstructured interviews and focus groups, either face to face, via email or telephone. During analysis, the researcher seeks to identify emergent themes to inform findings, which can be done by hand or using software, e.g. ATLAS.ti, NVivo.[114] Due to the relatively small sample sizes often used in qualitative research, in most cases the research should be treated as a case study and findings cannot be generalised to a wider population.

Qualitative methods have the advantage of collecting in-depth data, enabling more detailed responses to research topics, and allowing for unexpected results. However, they tend to be time-consuming and resource heavy.

Mixed Methods Research

This approach combines both quantitative and qualitative methods within a single piece of research to capitalise on strengths and minimise weaknesses of each approach, thereby enhancing the validity and reliability of the research.

Publication of Research

For clinicians interested in conducting research who have developed a good understanding of research methodologies and analysis, publishing research might be a possibility. The existing body of literature in the field of obstetric fistula is extremely limited, therefore well-conducted new research is needed to improve clinical practice and fistula patient care.

When seeking to publish a journal article, it is important to find a scientific journal that is suitable for the research topic, peer reviewed, well-regarded and has a relatively wide reach. Each journal will have author guidelines that must be carefully followed. It is generally prohibited to submit an article to more than one journal at a given time.

The journal might request that the author revises the article after peer review before the article is accepted and then published. If the article is rejected in the first instance, it might be possible to rectify the issues and resubmit depending on individual journal policy. In both scenarios, it is vital for authors to be responsive, to maintain good relations with the editors and it is good practice to accept invitations to participate in peer review of others' research.

Alternatively, there are often opportunities to present research at appropriate conferences and meetings. Authors are usually asked to submit an abstract for either an oral or poster presentation, which will be reviewed and accepted or rejected by an organising committee.

[114] ATLAS.ti. www.atlasti.com. Accessed November 11, 2020; NVivo. www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home. Accessed November 5, 2020.