PROFESSIONAL DEVELOPMENT

Audit Design

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When designing a clinical audit project you will need to address the following questions:

- Who will be involved?
- How will the project be carried out?

1. Data collection: What information?
   What type to data?
   How should the data be collected?
   How can reliability and validity be ensured?
   How can the collection method be piloted?
2. Sample: What size?
   How should the sample be selected?
3. Data analysis: Who will analyze the data?
   How will the data be analyzed?
4. Feedback of findings to whom and how?

- When will the project begin and end?

WHO WILL BE INVOLVED?

As many of the key stakeholders as possible should be involved in designing the audit:

- Clinical staff
- Non-clinical staff
- Service users (patients)
- Managers
- Referrers
- Authorities

HOW WILL THE PROJECT BE CARRIED OUT?

1. Data collection

By conducting the first three stages of an audit cycle (topic selection, literature review, setting standards), the type of information you will require for the project will become increasingly evident. Most data collected for clinical audit are quantitative. It can also be useful to collect some qualitative data to increase understanding of complex areas (e.g. patient satisfaction). More time tends to be required for the analysis of qualitative
data than quantitative data.

When undertaking a clinical audit project, people often decide to collect a range of data
which they feel could be of clinical importance, although not strictly relevant to the objectives of the audit (e.g. demographic data). This may prove useful, but will clearly increase the time and costs required to complete the project.

Clinical audit data can be collected retrospectively or prospectively. The following table outlines the differences between these two methods and some of the advantages and disadvantages of each.

Differences between retrospective and prospective data collection.

	Retrospective	Prospective
Definition	Data collected by looking back over your practice	Data collected from this point onwards, or starting at a future date
When to use	When looking at what has been happening in a chosen topic	When data are currently unavailable (i.e. has not been recorded as part of daily practice When data are of a very poor quality / incomplete and it is therefore not possible to audit
Advantages	Can be faster Provides a baseline	Avoids using poor-quality, incomplete data Allows design of a clear and concise data collection sheet
Disadvantages	Past service users do not benefit Data may be difficult to collect (e.g. poor-quality, information missing)	Provides no baseline for the audit Can be time-consuming since a number of individuals must be relied upon to collect the data

Data may be collected using a number of research methods. The most appropriate method for your project will depend on number of factors such as the available time, budget and data source. Examples of different data collection strategies are shown in the following table.

Examples of data collection methods.

Area for audit	Examples of sources of data	Examples of methods
Structure Patient satisfaction with consultation room	Patient	Questionnaires or interviews
Process Therapeutic intervention	Observation of intervention	Check-list to record information about intervention
Outcome Impact of surgery on quality of life	Patient and family	Questionnaire or interviews

There is no one 'correct way' of collecting data for a clinical audit project. As with research, clinical audit information needs to be collected in a way that it is both valid and reliable.
Validity = the degree to which you are measuring what you are supposed to be measuring.

Reliability = the degree to which you are consistently measuring what you want to measure (e.g. the same data would be collected by a different person, or by the same person at a different point in time).

One way of improving the reliability and validity of your clinical audit project findings is to ensure that your standards are rigorously developed (i.e. they are clearly defined and measurable). For example, if one of your standards is that 100% of surgeons should explain clearly during the preoperative consultation the details of the surgery to the patient, then it will be necessary to decide the components of a clear explanation in order to design a valid and reliable check-list to be used by the data collector.

With all clinical audit projects, especially those for which you have designed your own data collection tool (e.g. an interview schedule), it is advisable to pilot your method prior to beginning the main data collection. This will help to identify any problem areas at an early stage. It should also ensure that you will be able to meet the original objectives of the clinical audit project from the data collected, and will reveal whether the tool is both appropriate and usable.

The reliability of data can also be improved by providing appropriate training in data collection for the person undertaking this task. For qualitative information where subjective assessments may sometimes be required (for example, rating whether a surgeon makes sufficient eye contact with the patient during consultation), having one person to collect the data helps maintain consistency. Most of the time, however, this is unnecessary and/or the time and resources make it an impractical option.

Where several people are involved in collecting information, liaison and communication are important. You may even decide you want to include an additional 'safety measure' by testing for inter-rater reliability, for example by having two individuals separately rating the same surgeon for eye contact, and then comparing their ratings.

2. The sample

For some audits it may be possible to examine all of the relevant cases, where the total number in the population being studied is small. In most circumstances, however, it will be necessary to select a sample from the population. A sample should be selected which reflects the characteristics of the population from which it has been drawn

If you select your sample from those cases most easily at hand (e.g. case notes currently in the office), then your sample is likely to differ systematically from the total population and will therefore contain bias. To avoid bias, established methods of sampling should be pursued such as random, systematic, stratified, cluster sampling. For more details about sampling methods and sample size calculation please read article on audit sample published in the previous edition of the Egyptian Journal of Surgery. (EJS.2006;25:127-30).

When selecting your sample you should also consider:

- what would be an appropriate sample size
- whether there are any cases which should be excluded from the sample and why
- the time period from which cases will be drawn (e.g. cases seen over past six months = population being studied)
- how cases will be identified (e.g. a number).

The sample needs to be large enough to be representative of the population you are studying. Factors which may influence the sample size chosen are listed below.

Practical issues	For example, time, audit budget and availability of appropriate cases
Methodology	For example, postal surveys tend to have a low response rate so a reasonably large sample would be required
Population study size	For example, if you were auditing patient satisfaction with surgical treatment of breast cancer, and the total number treated in one year was 20, then it would not be appropriate to take a sample of 20% of this population (i.e. four patients); if 200 patients were treated in one year, however, then a sample size of 40 could be acceptable.

3. Data analysis

When designing a clinical audit project it is helpful to discuss and decide how the data you collect will be analyzed and by whom.

When analyzing your data you will generally want to try to reach conclusions about:

- The general pattern of actual practice
- The degree to which actual practice (results of audit) is meeting the standards set
- Those cases for which it is clinically acceptable for the standards not to be met.

Analyzing audit data does not usually require complex statistical tests, although these may be necessary in certain situations. Clearly the type of data you have collected will determine the type of analysis employed. The following approaches may be used in analyzing your data.

Descriptive statistics

This is where the data are described numerically. You may wish to calculate:

- The frequency of certain events/values occurring (i.e. rates and percentages).
- The mean, and/or the median – the most 'typical value' for the data.
- The range and/or standard deviation – to show the variability of the individual results.

It is often useful to present descriptive statistics graphically using, for example, bar or pie charts.

Statistical tests

These may be used:

- when conducting an outcome audit, for example comparing 'before' and 'after' results on questionnaires to find out whether there has been a statistically significant improvement in patient symptom scores.
- when wanting to show whether the results you have obtained can be attributed to chance variation.

Qualitative analysis

Where open-ended questions have been asked as part of the clinical audit project, qualitative data will be obtained. There are a number of ways of analyzing qualitative data. It may be possible, for example, to conduct a content analysis of the major recurring themes and a frequency count may then be performed.

Comparing with standards

Where standards have been set, the final part of your analysis will entail calculating the percentage of cases meeting and not meeting each standard. Discussions with colleagues about specific cases may highlight some situations in which it is considered clinically acceptable for standards not to be met. In these situations, your results may prove most meaningful if you calculate the following percentages:

- Percentage of cases meeting each standard (calculated from whole sample including no applicable cases).
- Percentage of cases not meeting each standard (again including non-applicable cases).
- Percentage of cases considered non-applicable (not meeting standards for clinically acceptable reasons).
- Percentage of applicable cases meeting each standard.
- Percentage of applicable cases not meeting each standard.

Where there is only a small difference between the target set and the percentage of cases
meeting the standards in the clinical audit, it may be difficult to know whether this is just due to chance. Confidence intervals can be calculated to obtain a more accurate idea of whether there is a statistically significant difference between your results and the set standards.

4. Feedback of findings

Ideally, a strategy for feeding findings back to the relevant stakeholders should be developed at the outset of the clinical audit project. Communicating your findings to the relevant stakeholders is an important part of the clinical audit process if it is to have any impact on the quality of the service you are providing.

It is important that all of the key stakeholders are made aware of the findings of the project and are provided with an opportunity to comment on them. This will include those individuals:

- whose practice was examined.
- who are on the clinical audit project team.
- who would be involved in making changes to improve the particular aspect of care in question.

Different people may have access to different levels of information. For example clinicians may know the 'scores' of all of the other clinicians if previously agreed, but it may not be appropriate for commissioners to have access to this level of detail.

A combination of passive feedback (written information) and active feedback (discussion of findings) is preferable when communicating the findings of your project.

Passive feedback (audit report)

It is important to produce a written record of your clinical audit project, which clearly outlines how you approached each stage in the clinical audit cycle and the results you obtained. This can then be disseminated to the relevant people as a way of feeding-back findings. This also ensures that a record of the study is kept for future external and internal use, for example by individuals wishing to conduct a similar clinical audit project, or by commissioners requiring evidence that the quality of service provision is addressed by the department.

Active feedback (discussion of results)

Discussing the results of the clinical audit project with key stakeholders is an essential exercise through which areas of practice which need to be changed can be identified and agreed.

WHEN WILL THE AUDIT BEGIN AND END?

The time period over which the data is collected will depend on your data sources, collection methods and the numbers required for a representative sample. For some projects you may be able to collect all of the data in one morning (e.g. retrospective study of attendance rates), whereas in others the data may need to be obtained over a one-year period. However, in designing the audit you must consider whether the results of an audit which would take two years to complete would still be beneficial in improving practice. Over long time periods many changes to service delivery may occur which could render the results of your project meaningless.