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PROFESSIONAL DEVELOPMENT

HOW TO SELECT AN AUDIT SAMPLE

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Depending on your audit topic you might be auditing an aspect of care which applies to all patients. However, it is more likely that you will be interested in a defined group of people who share certain characteristics: most typically the fact that they have the same medical condition, or have received the same form of treatment. For example, patients over 50 years of age admitted to the hospital for a suspected MI - this forms your audit population.

In an ideal world you would audit the care received by all your audit population, i.e. every patient seen for a given condition over an extended period of time, every treatment received, every outcome achieved, to see whether this care met the agreed standards of best practice. However, if numbers of patients in this target population are large, this becomes impractical, and you will probably want to look at a sample of these cases instead. In most audits a small 'snapshot' sample will be sufficient to indicate where standards are not being met. This is the approach initially described and advocated here, however the more rigorous process of deriving a sample that is statistically representative of all patients (the audit population) is also explained, for when a more precise answer is required.

EVERY PATIENT OR A SAMPLE?

In deciding whether you are going to look at every patient in your population, or just a sample of them, there are two major considerations:

- How critical is the aspect of care that you are investigating? (so critical that you need to look at every single patient?).
- How much time do you have available to conduct the study? (if your population consists of 1000 patients and the data you require is only contained in their case notes, you will almost certainly want to audit a sample of the population).

If the subject of your audit is particularly critical, it may even be appropriate to monitor practice continuously (e.g. for outcomes of cardiac surgery).

Being pragmatic

For research it is very important to select a scientifically valid sample. This is because research is at its most powerful when its results are generalisable to a larger population, nationally or even internationally. Nobody would adopt a previously unproven surgical method, for example, without convincing evidence that it worked – otherwise the implications of a change in practice could be catastrophic. Clinical Audit, however, simply asks, "what is happening here?", so the answer does not have to be as definitive as it would need to be in research.

The pragmatic guideline for selecting an audit sample size is that **you need enough patients so that senior clinicians/managers will be willing to implement changes based on your findings**. For most simple audits, measuring whether processes are being followed as per the standards, a rough guide is that a sample size of between 20 and 50 should be sufficient to tell you whether these processes are being followed correctly or not. Choosing a larger sample size than is necessary takes up extra time and resources without adding value, and can mean that there is no time and energy left within your project team to address any issues of poor practice and bring about improvement.

A pragmatic sample size should be your default option however if you need greater assurance in your results (without looking at every patient in your population) you may need to calculate a sample size that is representative of the whole population. This is likely to be the case if you are auditing outcomes, to be assured that the results you get are within the expected range.

Choosing sample sizes - the scientific approach

Sample size calculations depend on four variables:

- Size of population
- Degree of accuracy required
- Degree of confidence required
- How often you expect your audit criteria to be met

The following example shows how this works in practice:

"A primary care team is planning an audit of the care of patients with hypertension. They have **300 patients** [size of population] being treated for the disorder, but do not have time to review the records of them all. They select one criteria as key - that patients on treatment should have had their blood pressure checked and the result below 150-90 on three occasions in the past 12 months - and hope to achieve a standard of 70% [how often audit criteria expected to be met]. However, they are willing to accept 5% inaccuracy [degree of accuracy] due to sampling - in other words, if their findings give a level of 70%, on 95% of occasions [degree of confidence] the true value would lie between 65% and 75%.

They use the public domain software programme Epi Info (www.cdc.gov/epiinfo) to calculate the sample size using these parameters, and the **sample required is found to be 155**"

Strictly speaking, a sample size calculation should be carried out for each criteria that you're going to measure in your audit. The sample size chosen for your project would be the largest that those calculations produce. In the example above, however, it sounds like a pragmatic decision has been taken to go with the sample size that's required for the most important criteria in the audit. The table below appears in a number of guides to choosing audit sample sizes and assumes an expected incidence of 50% (i.e. that standards will be met 50% of the time). It gives the sample size you will need in order to be 95% sure (degree of confidence) that the results you obtain from the sample will be within 5% (degree of accuracy) of the results you would have obtained for your whole population if you had collected data on them all. Put another way, there is a 1 in 20 chance that your results won't be representative.

Population size	Sample size (95% CI)
50	44
100	79
150	108
200	132
500	217
1000	278
2000	322
5000	357

Using this table, if your audit showed that criteria X was met in 56% of cases, you could be 95% sure that criteria X would have been met in somewhere between 51-61% of cases had we looked at the whole population. Note that sample sizes need to be proportionately smaller as the population size increases; looking at 357 out of 5000 patients giving you results with the same

degree of certainty as looking at 44 out of a population of 50 patients. This is because the chance of the results being unrepresentative is dramatically reduced as the population size increases. Imagine you tossed a coin five times and got four heads and one tail - that sounds quite reasonable (there could be a pattern emerging, but it's almost certainly just chance that you got four heads). If on the other hand, you tossed a coin 500 times, and got 400 heads to 100 tails, we could be pretty certain that there was something rather dubious about the coin!

Remember, sample sizes can vary according to any one of the following:

1. The expected incidence of the thing you are auditing.
2. The confidence level you want (it doesn't have to be 95% - could be 90%, 99% etc).
3. The level of accuracy you are prepared to accept (could be 5%, 10%, 1% etc).

This table gives an idea how sample size might vary for a population of 500:

Confidence level	Degree of accuracy	Expected incidence	Sample size
95%	+- 5%	50%	217
90%	+-105%	50%	176
95%	+- 5%	40%	213
95%	+- 5%	20%	165
95%	+- 5%	5%	64
95%	+- 2.5%	50%	378
95%	+-2. 5%	5%	185

EXACTLY WHICH CASES DO I SELECT?

Once you have decided to take a sample and have decided on the size of that sample (whether this has been calculated pragmatically, or to be representative of the whole population), the next question is which cases you are going to include in your audit.

There are four sampling methods that are commonly used in clinical audit, the first three of which are forms of probability sampling:

Simple Random Sampling

Simple random sampling means that each subject has an equal chance of being selected. An easy way of selecting your cases is to use a **random number table** (as per the few lines given below), e.g. by taking one number at a time from left to right (2 0 1 7 4 etc) or two at a time, reading down table (20 74 04 22 etc). These cases then form your sample, e.g. the 20th, 74th, 4th, 22nd cases from a list of all the patients in your population

2 0 1 7 4 2 2 8 2 3 1 7 5 9 6 6 3 8 6 1 0 2 1 0 9 6 1 0 5 1 5 5 9 2 5 2 4 4 2 5
7 4 4 9 0 4 4 9 0 3 0 4 1 0 3 3 5 3 7 0 2 1 5 4 4 7 8 6 9 4 6 0 9 4 4 9 5 7 3 8
0 4 7 0 4 9 3 1 3 8 6 7 2 3 4 2 2 9 6 5 4 0 8 8 7 8 7 1 3 7 1 8 4 7 8 4 0 5 4 7
2 2 4 4 8 9 6 5 6 8 9 5 3 2 5 2 3 8 3 7 1 5 1 2 5 4 0 2 0 1 3 7 5 6 8 7 6 5 8 9

Quasi Random Sampling

Quasi random sampling (Systematic Sampling) is a more convenient alternative to simple random sampling. Imagine that our population is 1500, our representative sample is 306. We therefore need to select every fifth patient from the total population (5 x 306 = 1500 approx). To ensure that every patient in your population stands a chance of being selected, your starting point needs to be picked randomly, e.g. by rolling a dice to choose a first number between 1 and 5 (in this case). This means the patients you end up with could be 1,6,11,16, etc, or 2,7,12,17, etc - if you always started with the first patient, the second would never have a chance of being selected – this is important from a statistical point of view.

Startified Sampling

Stratified Sampling ensures the proportion of different groupings present in the population is reflected in the sample. For example if our patient population is made up of 75% men and 25% women, taking a simple or quasi random sample runs the risk of selecting only men when it might be there are particular aspects of care being audited which relate specifically to

women. So, if our population is 500, split 3:1 in favour of men (375:125), our representative sample of 217 would need to be split 163:74. To do this, separate men and women into two groups and randomly select from both - 74 women from a population of 125, and 163 men from a population of 375.

Probability sampling methods should result in samples that are representative of the characteristics of the whole population, due to random selection reducing the possibility of any systematic bias that would make the selected group different in character from the population. Therefore, if you have statistically calculated a valid sample size you **must** use one of these sampling methods to select your sample group of patients.

Consecutive Sampling

Consecutive Sampling (Convenience Sampling) involves choosing the next (or last) however many cases. For instance, conducting an audit of local prescribing by going round the beds on each ward until you had collected data on an agreed number of patients, or collecting data on the next (or last) 50 diabetic patients admitted to the BRI.

Consecutive sampling is a form of non-probability sampling. This means that the sample produced may differ in character from the population and therefore the audit results may not be representative of the overall care that is given. However, it is often the most practical way of selecting cases for a snapshot sample of the population.

If you are using this methodology to look at a small number of cases, or a narrow time period, you should take particular care to consider and eliminate potential sources of bias in your sample – the sample of cases you audit needs to chosen in such a way that you can reasonably draw inferences about the care given to the whole population. Beware of daily, weekly or seasonal fluctuations which may skew your data, e.g. conducting an audit in the week of school holidays may not be representative of care given in the rest of the month or year, due to some staff being off work at these times. In general, the narrower your time frame, the greater the risk of introducing bias, i.e. that your results won't be representative of how well the standards are being met for the population as a whole. Taking a random sample across a longer time period/number of cases may be a better way to ensure your results are representative.

You should also make every effort to ensure every case in your sample is included in your audit, as missing cases may skew your results, e.g. if case notes cannot be located in file, they may be with complaints, legal services or held on to by the consultant, because of problems in care - not including that case in your audit would then indicate care was better than it actually is. So try more than once to find those missing notes! Cases can be missed from prospective audits too, skewing results if there is a non-random element to missing cases, e.g. one staff member who never completes forms.

ENSURE YOUR SAMPLE REPRESENTS CURRENT PRACTICE

If your audit is retrospective (going back in time), be aware that you should select your sample from recent patients, e.g. those treated in recent weeks/months or in the last year. This is because clinical audit is aiming to assess current practice in order to improve future practice, so finding out how good (or poor) practice was in the distant past is usually irrelevant.