York Foundation Trust R&D Unit
Guidance Document
R&D/G08

Audit, Service Improvement and Research: Guidance on data analysis and drawing conclusions

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	1st June 2015	
2.0	18th September 2017	Change of Author, change of title, review and re format
3.0	15th July 2019	Change of link to R&D website. Minor formatting changes

1 Introduction

Clinical audit, service improvement/ evaluation and research projects are sometimes confused because they have many things in common. For example;

- They all involve asking a question about clinical practice
- They can focus on the structure, process or outcome of that clinical practice
- All require careful identification of the sample
- Both use similar methods for collecting information.

Audit / service evaluation and research are also linked and help to inform each other: without research we don't know what constitutes best practice and without audit / service evaluation we don't know whether we are offering best practice to patients. However audit / service evaluation and research projects are distinct from each other in many ways. For example;

- The extent and type of formal approvals required
- Their purpose
- The rigour with which they are carried out
- How the data is analysed
- The claims that can be made from the data that is gathered.

When writing up audits and service evaluation projects, especially for external publication including conference presentations, great care has to be taken especially with the way the data are analysed and the conclusions that are reached. An audit or service evaluation cannot really tell us, for example, that a treatment is effective; only a research project in the shape of a randomised controlled trial can answer that question.

The following table provides guidance on data analysis and drawing conclusions for the different types of projects mentioned above.

<table>
<tr><th></th><th>Audit and Service Improvement / Evaluation</th><th>Research</th></tr>
<tr><td>Data Analysis</td><td></td><td></td></tr>
<tr><td><u>Descriptive Statistics</u></td><td> 
Frequencies (number counts)
Percentages
Mean (average)
Median (middle value)
Mode (most frequently occurring value)
Standard deviation or range (the extent to which the data varies)</td><td> 
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Percentages
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Standard deviation or range (the extent to which the data varies)</td></tr>
<tr><td>Examples</td><td>Audit of management of fractured neck of femur (# NoF)

College of Emergency Medicine Standard:
75% of patients with # NoF should have an X ray within 60 minutes of arriving at the ED
Result found in audit: 45% of patients with # NoF had an X ray within 60 minutes of arrival at the ED

Service review of patients having a paramedial forehead flap procedure
Of the 25 nasal paramedial forehead flaps undertaken, 23 were for skin cancer (age range 46-88 years) and 2 for traumatic nasal avulsion (ages 33 and 35 years). The average pedicle division time was 36 days (range 14 to 65 days). Five patients required a more complicated 3 stage procedure. All patients surveyed were satisfied with the cosmetic result (average score = 9.3 /10) and the service provided (average score = 9.5 /10).</td><td>Participants were randomised to be nursed on an alternating pressure mattress (n = 982) or an alternating pressure overlay (n = 990). Overall 207 (10.5%) people developed a total of 305 new pressure ulcers, most of which (n = 207) were grade 2 ulcers (97.4%). Eight people developed grade 3 pressure ulcers, three in the overlay group and five in the mattress group.

<table>
<tr><td></td><td>Overlay group</td><td>Mattress group</td></tr>
<tr><td>Men</td><td>365 (36.9%)</td><td>346 (35.2%)</td></tr>
<tr><td>Women</td><td>624 (63.1%)</td><td>636 (64.8%)</td></tr>
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<table>
<tr><td>Age</td><td></td><td></td></tr>
<tr><td>Mean</td><td>75.4 years</td><td>75.0 years</td></tr>
<tr><td>Std Dev</td><td>9.7 years</td><td>9.2 years</td></tr>
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</td></tr>
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Inferential Statistics and Confidence Intervals	 Not appropriate for this type of project. We use Inferential statistics when we want to 'infer' something about the data we have collected in terms of a wider population. In other words we are trying to 'generalise' the findings from our project to a wider population of patients or to other hospitals or settings. This is a feature of research.	 e.g. *t* tests, ANOVA, Mann Whitney U test, Wilcoxon test, Chi square test, Pearson correlation coefficient The results of the above tests are used to assess the probability that your study findings may just be due to 'chance'. You quote the probability or 'p' value in your results. Any p value less than 0.05 (5%) is regarded as 'statistically significant'. In other words there is only a small probability your findings are due to chance. 95% Confidence intervals are also frequently quoted in the results of research studies. Confidence intervals are used to estimate what the result might be for the whole population of relevant patients (rather than just the patients in your study). It is quoted as a range with a lower limit and an upper limit.
Examples	 Not relevant	The primary outcome was the number of participants who developed a new grade 2 pressure ulcer (nursed on an alternating mattress compared to an overlay). The data were analysed using a Chi square test. There was no difference in the proportion of participants who developed a new pressure ulcer of grade 2 or worse. The difference in proportion of patients developing an ulcer was 0.4% (10.7% of overlay patients; 10.3% of mattress patients); p = 0.75, 95% confidence interval = -2.3% to 3.1%)

Writing Conclusions	Audit and Service Improvement / Evaluation	Research
Guidance	In drawing conclusions from a local project, you must take care that you do not generalise the findings to a wider population as this is a feature of research. Your project has probably not been designed in a way that would allow you to draw generalised conclusions. If conclusions from a local project are generalised they may carry much more weight with readers than they deserve and have more influence on clinical practice than they should. A good way of avoiding this is to make it clear that the audit / service evaluation was only carried out in your institution / or locally e.g. 'The aim of this project was to look at outcomes following xxxx procedure carried out in our institution'.	If your research project has been designed properly, and has the appropriate approvals, you should be able to make 'generalisable' claims as this is the purpose of doing a research project. In other words the results from your study are being used to make claims that could be applied more widely. For example you are making a claim that an intervention is effective / not effective which is going much further than saying the outcomes for that intervention have been good within your institution.
Examples	❌ Not relevant	No difference was found between alternating mattresses and alternating pressure overlays in the proportion of people who develop a pressure ulcer.'
	When we offered additional physiotherapy to patients in our local intensive care unit, this appeared to improve the level of mobility they achieved on discharge from ICU.	If this service evaluation on physiotherapy in ICU had been designed and carried out as a proper research study, you would be able to make a wider (generalised) claim about its impact e.g. 'Increased physiotherapy staffing in the form of specialist critical care rehabilitation teams is effective in improving the level of mobility within critical care. This increased function was also associated with a reduced length of stay and shorter weaning times'.
	xxxx procedure was well tolerated by patients in our institution and they experienced very little short term morbidity. However these results would need to confirmed in a prospective randomised controlled trial.	If this service evaluation on xxx procedure had been designed and carried out as a proper research study, you would be able to make a wider (generalised) claim about its effectiveness etc e.g. 'xxxx procedure is well tolerated, safe, and only results in short term morbidity'.