Project Planning Tips

Thinking of a question

Is there anything that we do that turns out to not be based on evidence? If you read around, you may be shocked at how much of what we consider standard practice is not grounded in evidence.

Within guidelines, there's usually a 'recommendations for research' section highlighting unmet needs – literally lists of project ideas.

If clinical practice varies between hospitals or individuals due to personal preference, a collaboration between such sites could evaluate these differences in practice and outcomes.

PICOT is a good way to structure a question in a focused way.

- Population – which patients will you be able to identify?
- Intervention – aspect of care in question
- Comparator – is there a control group? They do not have to be randomised (unless you are able to set up an RCT!) but should be comparable/matched to the intervention group.
- Outcome – what can be measured that will give us a useful answer?
- Timeframe – during which time period will outcomes be assessed?

Planning a project

Write down your thoughts in a structured way – the act of writing a protocol for a project is great for this. Search pubmed to see what's already out there. Also, this will be the basis of the intro & methods section of the eventual write-up, so it's worth doing. Think of ways to avoid bias where possible.

Prospective data collection is much preferred to retrospective, especially if publication is the goal. Multi-centre is better than single centre – hence collaboration!

The NW-CORR committee is happy to chat through ideas early on to help get you on the right track, and will look through your protocol if it's a project for NW-CORR.

Who to involve

It's important to assemble a core group of authors who will write the eventual poster/paper. Too many people risks complicating and slowing down the writing process (too many cooks!) but you need suitable skills and time between you to get it done. For example:

- 2-3 SpRs, ideally including people from both deaneries, to lead the project
- 1 consultant with expertise relevant to the project
    - They are valuable in finalising the question and protocol, as well as for reviewing the paper before submission.
- Statistician
    - Consider enlisting one if the project will require more than very basic description of data.
    - Even for more basic analysis, Excel is very limited and it's useful to have someone able to use statistical software such as R, Stata, SPSS etc
    - It is worth discussing this with your consultant/senior author early to clarify whether a statistician is needed and involve them as early as possible.

Again, the NW-CORR committee is happy to help if you're not sure who to involve. There's a lot of talent around the region that may not be immediately obvious.

Approval

Depending on the type of project, different approval processes are involved.

Get it early, get a code from whomever you registered with, and keep documentation of the approvals from each site. Journals require an ethics statement, and you don't want to get to the stage of submission and not have approvals in place.

The Health Research Authority (HRA) has useful tools:

> Definitions of research – differences between audit, service evaluation & research
>
> Is my study research? – short questionnaire to establish the status of a project. Boils down to randomisation, whether it's standard treatment or not, and generalisability.

Research: research & ethics committee (REC) approval is often needed, requiring a more detailed application (IRAS).

Service evaluation: can be used to compare different practices if there's no established standard of care. Depending on Trust, may be registered through Audit or R&D.

Audit: a standard of care exists. Register with Audit Dept.

Once a project is approved at a Trust, it should be easier to get approval for the same protocol at other sites. Each site must approve data collection performed there.

Tips

- Contact your local R&D early if you want to clarify whether a proposed project counts as research. You may need to ask around to find the right person to advise.
- *Stats* – plan your analysis early, ideally at protocol-writing stage, so that you know how much data you need to collect and what you can do with it.
- If a condition is super rare, it's less likely to arise much during your data collection window (especially if examined prospectively), and all the cases may be restricted to tertiary centres.
- *Seasonality* – some conditions have changing prevalence through the year e.g. infection in winter, so bear this in mind when choosing timeframes.
- *Limitations* – even brilliant research has limitations. This doesn't mean it shouldn't be done; it just needs to be acknowledged honestly. Otherwise reviewers will point them out and you'll end up describing them anyway, but with added delay.