(Study authors, year)

Outline of a QA/QI Project Design

(Note. Questions are included to guide you in what goes where, not to be repeated in the actual protocol!)

Title

Project Champion(s) and Residency Program/Department

Please use Times New Roman 12 pt. as the font and set the spacing at 1.5. Remember that in scientific writing, the first sentence of a paragraph is not indented, but you do leave an extra line between paragraphs.

Summary

Write this section last—after the protocol is complete but before IRB submission. Provide a brief summary of the project, including rationale, project objectives, study group of interest, project design, proposed sample size and data analysis.

Introduction

Based on the relevant scientific literature, write the background for your project. What do we know about your question? What do we not know? This sets the stage for your project. Make sure to cite the relevant literature from your literature search.

Include citations as appropriate (North, West, and South 2002) and add to Reference list

Project objective:

What quality gap with this project address? The objective(s) should be specific, not vague.

Say this: Will the use of a new order set in eCare improve compliance with asthma medication guidelines for children seen in the ED?

***Not** this:* What is our experience with asthma guidelines?

Methods & Materials

Project Design (How will the objectives be approached?)

Who are the patients who will participate (inclusion and exclusion criteria)

What is the time frame?

What information are you collecting? How you will get it? (interview, records review, etc)

Any other pertinent info you are collecting (Patient #, date of surgery)

How will you insure patient anonymity and confidentiality of records?

Draft of data collection form is included

Data Quality and Validity:

How will you assure the quality of the data? Data abstraction and entry errors are common.

If there is one person collecting data, then a random sample of about 10% of the cases should be re-abstracted. The re-abstracted data should be compared to the original data to determine the number of errors, type of errors and to create a plan for error reduction. A data dictionary should be created.

If there are multiple people collecting data, you could:

1. Clearly define what each data element means (create a data dictionary);
2. Define where the data should be collected from (for example, collect blood pressure data from the "flowsheet" tab in eCare);
3. Conduct a training session with the other investigators or individuals collecting data;
4. Prior to the start of the study, have all individuals who are collecting data abstract several of the same charts and compare results. Determine where the mistakes are occurring and how to avoid them;
5. Develop an audit plan, for example, where 10% of the data are re-abstracted by the principal investigator to look for routine errors.

Talk with your medical researcher to help design the data quality process that is suitable for your project.

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2. Develop an audit plan, for example, where 10% of the data are re-abstracted by the principal investigator to look for routine errors.

Number of subjects

How many patients will be included in the project? How many practitioners?

Statistical Analysis—The medical researcher will help you to write this section.

Describe how you will analyze the data to answer your research objectives. Explain what descriptive statistics you will use and what inferential analyses you will do.

HIPAA/Patient Confidentiality

Describe what measures you will take to protect patient data and confidentiality.

Next Steps: (If your project succeeded in closing the gap, how will you sustain the improvement? If it failed, what would you propose as a next step to try?)

References

In the text, references should be cited as they are mentioned, usually at the end of the sentence. The first authors' last names should be followed by the year, as follows:

single author - (Franklin, 1776)
dual authors - (Franklin and Washington, 1776)
three authors - (Jefferson, Franklin and Washington, 1776)
four or more authors - (Hamilton et al., 1777)

Mentioning the first author by name to attribute an aspect directly should be handled as:

Franklin (1776) was the first to report the electrifying properties of lightening.

At the end of the article, a list of references should be included that is alphabetized by the first author's last name. Complete guidelines for reference types are available from the National Library of Medicine NLM via the library's Web site (http://www.nlm.nih.gov/). Below is the citation format that the Research Director recommends for protocols.

Standard journal article:

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996;124:980-3.

For more than six authors, list the first 6 followed by et al.:

Parkin DM, Clayton D, Black RJ, Masuyer E, Friedl HP, Ivanov E, et al. Childhood--leukaemia in Europe after Chernobyl: 5-year follow-up. Br J Cancer 1996;73:1006-12.

(From Uniform Requirements for Manuscripts Submitted to Biomedical Journals. International Committee of Medical Journal Editors, March 19, 1997.)