Slide 1

Writing clinical research papers

A brief guide

Prof Justine Davies

@drjackoids

Professor of Global Health University of Birmingham

Previously Editor in Chief, The Lancet Diabetes & Endocrinology

Slide 2

This is a high-level talk about manuscript writing

• Useful to people who are have written fewer than 8-10 papers previously

• I don’t go into specific types of studies, as different studies need to be written up in different ways

• However, there are general principles that apply across lots of study types; I will discuss those

Slide 3

Basic manuscript structure

Title

Authors and affiliations

Abstract

Methods

Results

Discussion

Limitations

Conclusion

Reference

Slide 4

Guidelines/resources

• <http://www.equator-network.org/>

• Look at the equator network before you start your study!

• Journal information for authors

Slide 5

The equator network

Picture of the landing page of the Network

**Your one-stop-shop for writing and publishing high-impact health research**

find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines

Slide 6

What is the process – how to do it?!

Where to start?

• The journal?

- Should you frame your research around the journal’s desires?

• The abstract?

- Should you start condensing your thoughts into a clear abstract?

• The title?

- Should you develop a snappy title first?

• The results?

- Should you start with the results?

- How about the minimum publishable unit?

• The discussion?

- Should you decide the spin you want to give the manuscript and then start writing from there

Slide 7

Start with the study proposal and protocol

Non biased, research that has been planned to address a specific question

will have come from

- a literature review to identify the gaps in knowledge

- posing a question to fill that gap

- developing a study protocol to answer the question

• “Cut and paste” the background and methods (you will already have them

developed)

• Follow the equator guidelines

• Make sure that the results follow on from the methods

• Write the discussion by putting the results into context

Slide 8

Example article

Developing and implementing an interventional bundle to reduce mortality from gastroschisis in low-resource settings

Version 1. Wellcome Open Res. 2019; 4: 46.

Published online 2019 Mar 8. doi: 10.12688/wellcomeopenres.15113.1

Slide 9

But the correct way is not always so easy, especially for general exploratory epidemiology studies

• I recommend that you always develop a protocol to address specific questions

• But for those more exploratory studies, you may want to start from the results and ask yourself what the message of the paper is

• I.e: What is the key one (or two) points that you want the reader of your paper to take away from reading it: The Elevator Pitch

Slide 10

The nitty-gritty

Slide 11

What do I want?

• Your paper published in the best journal for it so that your paper is be widely read

• Journal editors receive thousands of papers each year, but only publish a few.

• Journal editors start from the question – how can I reject this paper?

• They often only read the title and the abstract before making that decision

• So don’t neglect these!

Slide 12

The elevator

• 20 words

Picture: “Yes, that will work as an elevator speech if your client works in a skyscraper”

Slide 13

The Title

• Declamatory:

• “x causes y in z people”…

• Descriptive

• “A longitudinal cohort study looking at the effects of x on y outcomes

in z people”

• I prefer descriptive, but see what the journal publishe

Slide 14

The Authors

• Choose your authors wisely!

• In general in medicine:

• The first author has done most of the work

• The second author has done quite a lot of the work

• The last author has done an awful lot of work in supporting the second and first author

• The corresponding author has also done a lot of work and is knowledgeable enough to answer questions form the research community after publication.

Slide 15

ICMJE criteria for authorship

1. substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data;

2. drafting the article or revising it critically for important intellectual content;

3. final approval of the version to be published;

4. agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All of these criteria must be met

• In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

Slide 16

Inappropriate authorship or non-authorship

The three G’s

• Guests (invites him/herself)

• Gifts (authorship as a present – ie, department head, provider of a valuable reagent, etc)

• Ghosts (the disappearing author.....

Slide 17

The Abstract

Abstract must be clear and succinct (look at the journal for the word limit)

• What is the background? – convince us that this study is needed

• 2 sentences maximum!

• What is the hypothesis? – in the background convince us that you have a sound hypothesis

• 1 sentence maximum!

• How did you do the study? – convince us that the methods are sound

• More space here

• Present the methods used to address your main research question (the primary outcome) – the one that will

answer your hypothesis

• Present methods to address any important other (secondary) outcomes, including side effects for trials

• What are the results (simply, please. No abbreviations if possible)

• More space here too

• Only present results that pertain to the methods that you have presented in the methods section

• Don’t introduce results that you haven’t presented methods for

• Don’t omit results that you have presented methods for

• What are your conclusions – have you shown something new?

• don’t oversell results and don’t spin.

• Put the conclusions simply and state what this adds to clinical practice/research/guidelines

• 2 lines maximum

Slide 18

The Background

• Short and snappy

• Aim for around three to four paragraphs (less than 1 side of A 4)

• Set the scene

- what is the problem/the current state of play?

- where are important gaps in knowledge that would allow that

problem to be addressed?

- how this study contributes knowledge to fills those gaps

• rationale for any broad methodological reasoning (e.g: geographical region, broad methodological

approaches)

- hypothesis

(our hypothesis is that blah…)

- aims

(we aimed to prove or refute our hypothesis by doing…)

Slide 19

The Methods

• Different journals may have sections in different orders to those presented on the next slide

• Different study types (trials, qualitative, epidemiology, testing a diagnostic method) have different structures for methods

• I will present a general structure that can be adjusted

Slide 20

The Methods

• Study location

• Study population

- inclusion and exclusion criteria

• Ethical considerations

• Outcomes

- primary, secondary, exploratory

• Outcomes assessments (how the outcomes were measured)

• Statistical considerations

- power calculation (prospective, preferably)

- statistical analysis methods (preplanned)

• Funding

• Registration

Slide 21

A special plea for epidemiology studies

• Need a data collection section which describes which variables were

collected

• E.g: marital status was asked as: married, single, widowed, cohabiting,

divorced

• E.g: education was asked as: none, primary, secondary, tertiary

• Need an outcomes or variables section which describes how those

variables were handled to create those used in the study

• E.g.: marital status was categorised as married or cohabiting, or single,

widowed, or divorced

• E.g.: education was cateogrised as none or primary education and above

Slide 22

The Results - Simply

The Rules

• Don’t report what isn’t in the methods

• Don’t miss out something that is in the methods

• Start with numbers of people in the study

• Next add baseline characteristics

• Then report outcomes in order

• Primary

• Secondary

• Exploratory

• Report differences, spread, and p value

Slide 23

The Tables

• Aim for three maximum

• First – background characteristics (no p values)

• Second – main results (primary and secondary outcomes)

• Third – exploratory outcomes/multivariate assessments

Slide 24

The Figures

• Aim for 2-3

• Figure 1: study profile

• Figure 2: main comparisons

• Figure 3: extra analyses

Slide 25

The Discussion

• Don’t restate the results - no numbers allowed!

• Don’t restate the background

• The first paragraph describes the findings in words

• The second to fourth paragraphs discuss the findings in more detail and compares them to other studies to address the question – what does it all mean when considered together

Slide 26

The Limitations

• Where you air your dirty laundry!

• State plainly and simply what the limitations were ….

• ….whilst thinking of a positive spin

• “a main limitation of this study is that we only did it in three countries in sub-Saharan Africa, which limits generalizability. However, that the countries were diverse in culture, geography, and economics and the findings were highly similar across all settings suggests that the findings may be transferable to other countries.”

Slide 27

The references

• Look at the journal guidelines re numbers and style

• In general too many references is a bad thing…

Slide 28

Issues of language?

• PLEASE DO NOT USE ABBREVIATIONS (unless they are well recognized in that particular context – e.g.: HIV)

• Reading by a native speaker?

• A well written manuscript make it easier for reviewers and editors to read – makes them happy and more likely to accept!

Slide 29

The End ☺