

Writing clinical research papers

A brief guide

Prof Justine Davies

@drjackoids

Professor of Global Health University of Birmingham

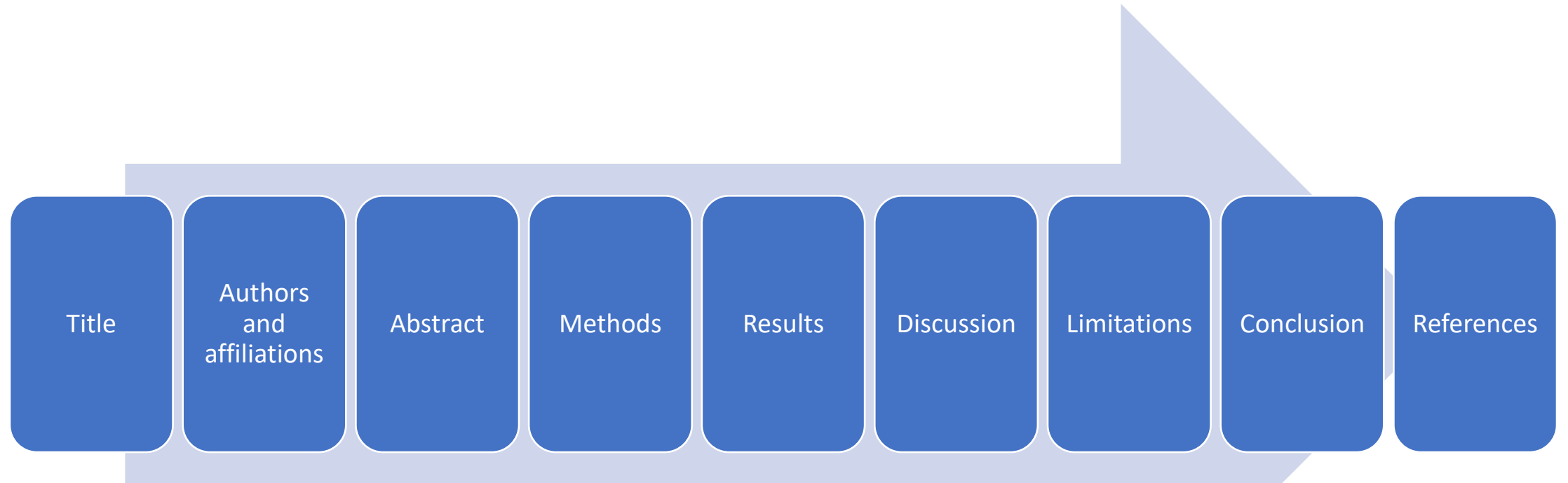
Previously Editor in Chief, The Lancet Diabetes & Endocrinology



- This is a high-level talk about manuscript writing
- Useful to people who 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



Basic manuscript structure



Guidelines/resources

- <http://www.equator-network.org/>
- **Look at the equator network before you start your study!**
- **Journal information for authors**



The equator network



Enhancing the **QUALITY** and
Transparency Of health Research



EQUATOR resources in
Portuguese | Spanish

Home

Library

Toolkits

Courses & events

News

Blog

About us

Contact

Essential resources for writing and publishing health research



Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



Search for reporting guidelines



Not sure which reporting guideline to use?



Reporting guidelines under development



Visit the library for more resources



Reporting guidelines for main study types

[Randomised trials](#)

[Observational studies](#)

[Systematic reviews](#)

[Case reports](#)

[Qualitative research](#)

[Diagnostic / prognostic studies](#)

[Quality improvement studies](#)

[Economic evaluations](#)

[Animal pre-clinical studies](#)

[Study protocols](#)

[CONSORT](#)

[STROBE](#)

[PRISMA](#)

[CARE](#)

[SRQR](#)

[STARD](#)

[SQUIRE](#)

[CHEERS](#)

[ARRIVE](#)

[SPIRIT](#)

[Extensions](#)

[Extensions](#)

[Extensions](#)

[Other](#)

[Other](#)

[Other](#)

[Other](#)

[Other](#)

[Other](#)

[Other](#)

[See all 328 reporting guidelines](#)

Possible strategies

Open data

Openly sharing results and the underlying data with other scientists.



Pre-registration

Publicly registering the protocol before a study is conducted.



Collaboration

Working with other research groups, both formally and informally.



Automation

Finding technological ways of standardising practices, thereby reducing the opportunity for human error.



Open methods

Publicly publishing the detail of a study protocol.



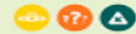
Post-publication review

Continuing discussion of a study in a public forum after it has been published (and are reviewed before publication).



Reporting guidelines

Guidelines and checklists that help researchers meet certain criteria when publishing studies.



[Research funders identify reporting guidelines as key for reproducibility and reliability of biomedical research](#)



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?



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





STUDY PROTOCOL

Developing and implementing an interventional bundle to reduce mortality from gastroschisis in low-resource settings [version 1; referees: awaiting peer review]

Naomi Wright ¹, Francis Abantanga², Michael Amoah³, William Appeadu-Mensah⁴, Zaitun Bokhary⁵, Bruce Bvulani⁶, Justine Davies ⁷, Sam Miti⁸, Bip Nandi ⁹, Boateng Nimako ³, Dan Poenaru ¹⁰, Stephen Tabiri², Abiboye Yifieyeh³, Niyi Ade-Ajayi¹¹, Nick Sevdalis¹², Andy Leather¹

¹King's Centre for Global Health and Health Partnerships, School of Population Health and Environmental Sciences, King's College London, London, SE5 9RJ, UK

²Department of Surgery, Tamale Teaching Hospital, Tamale, P.O. Box TL 16, Ghana

³Department of Surgery, Komfo Anokye Teaching Hospital, Kumasi, P.O.Box 1934, Ghana

⁴Department of Paediatric Surgery, Korle-Bu Teaching Hospital, Accra, P.O. Box 77, Ghana

⁵Department of Paediatric Surgery, Muhimbili National Hospital, Dar es Salaam, P.O Box 65000, Tanzania

⁶Department of Paediatric Surgery, University Teaching Hospital of Lusaka, Lusaka, 10101, Zambia

⁷Global Health and Education Department, University of Birmingham, Birmingham, B15 2TT, UK

⁸Department of Paediatrics, Arthur Davison Children's Hospital, Ndola, Zambia

⁹Department of Paediatric Surgery, Kamuzu Central Hospital, Lilongwe, P.O. Box 149, Malawi

¹⁰McGill University, Montreal, Quebec, H3A 0G4, Canada

¹¹Department of Paediatric Surgery, King's College Hospital, Denmark Hill, London, SE5 9RS, UK

¹²Centre for Implementation Science, King's College London, London, SE5 8AF, UK



- But the correct way is not always so easy, especially for general exploratory epidemiology studies
- I recommend that the 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**



The nitty-gritty



What do 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!



The Title

- The elevator
- 20 words



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 publishes



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 from the research community after publication.



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.



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.....)**



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



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...)



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



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



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



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



The Tables

- Aim for three maximum
- First – background characteristics (no p values)
- Second – main results (primary and secondary outcomes)
- Third – exploratory outcomes/multivariate assessments



The Figures

- Aim for 2-3
- Figure 1: study profile
- Figure 2: main comparisons
- Figure 3: extra analyses



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



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.”



The references

- Look at the journal guidelines re numbers and style
- In general too many references is a bad thing....



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!



The End 😊

