

Today, I want to share with you a quick guide for preregistering your research and reporting its results using the relevant reporting guideline

Prereg = Preregistrations -- records made a priori about study designs and analysis plans and placed in (open) repositories -- should be used when designing a study Rep Guid =minimal information that has to be specified for a study to be useful, should be used when writing up a manuscript

Journal badge -- journal psychological science --



The structure of my talk will be as follows: I will briefly sketch the relevance of preregistration and will do the same for reporting guidelines later, I will distinguish a few broad types of preregistration, review their associated registries; the places where you make and upload your preregistration, and will then delve into selecting the right reporting guidelines



How come people are enthusiastic about prereg?

Here you see the standard empirical cycle, many of us are familiar with, but the cycle is, as some have argued, not fool-proof -- and here you see just some of the problems that might creep in at various steps that may lead to less reproducible science;

Ref: https://www.nature.com/articles/s41562-016-0021%C2%A0

RELEVANCE

- Reduce degrees of freedom
- Mitigate *publication bias*
- Strengthen the credibility and transparency
- Importance recognised by various stakeholders

In sum, preregistration is thought to narrow down the choices a researcher needs to make that may influence the study's results

It is also thought to help in combatting publication bias, as it means there is a record of the study conducted and its hypothesis or research question, independently of whether that is also published

openness of this information about the study encourages the researcher to carefully reflect on different study aspects and to systematically report on their design and analysis choices, including those made as the study progresses

the records about the study design and analysis plan help the reviewer or user of the study in assessing the study's quality, because the preregistration provides a structured insight into how the study was thought out and set up

Different funders now require prereg (Arnold), it is encouraged by journals and disciplinary organisation (APA)

TYPES

- Trials
- Animal studies
- Quantitative (e.g., cross-sectional/observational)
- Qualitative

since 2005 members of the International Committee for Medical Journal Editors only allow trial publications of trials that have been registered (DeAngelis et al., 2004). In the United States, trials are mandated to be registered in ClinicalTrials.gov that is managed by the National Library of Medicine, but the registry also accepts trials from outside the US since 2005. In Europe, drug trials must be registered in EudraCT database. The World Health Organization maintains its own registry, called the International Clinical Trials Registry Platform.

A similar approach is being applied to animal research with Germany being the first to launch a tailored registry (animalstudyregistry.org). Although the registration of animal studies is not yet mandated, it is argued that by prompting researchers to think about and commit themselves to quality measures when designing their study, preregistration has the potential to improve the reproducibility of animal research (Bert et al., 2019).

Extending this practice to cross-sectional research also allows for distinguishing between exploratory and confirmatory research (Nosek et al., 2018)

https://www.pnas.org/content/115/11/2600

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6793840/pdf/pbio.3000463.pdf

https://www.nejm.org/doi/full/10.1056/NEJMe048225



https://aspredicted.org

https://osf.io



And another registry important to those of you conducting yet another type of research, namely systematic reviews, is PROSPERO https://www.crd.york.ac.uk/prospero/

PROSPERO

International prospective register of systematic reviews



There are two main types of fears that researchers face when thinking about whether to preregister their work. The first is the fear of being scooped, or ideas being stolen -- this is why you can embargo your work for up to 4 years, or up to whatever point before that that fits your purposes.

The second is the fear of doing something wrong and then needing to update your preregistration, in short this can be done by either making a new preregistration or adding a summary note where you explain the changes and justify the rationale for them

Bowman, <u>Creating a Preregistration</u>	OSF guides
EXAMPLE	
SF REGISTRIES -	Add New
STEP 1 Do you have content for registration in an existing OSF project? YES NO	
STEP 2	
Which type of registration would you like to create? * OSF Preregistration Create draft	

I will now go through one example and show you the different steps of a preregistration

https://help.osf.io/hc/en-us/articles/360019738834-Create-a-Preregistration

Add motod	Bowman, <u>Cre</u>	ating a Preregistration OSF guide
Add merudo		
SSF REGISTRIES Environmental Science > New regist	ration	Help Donate 🕂 🗸
 Metadata Study information Design Plan Sampling Plan Variables Analysis Plan Other Review 	Registration Metadata This metadata applies only to the registration you are creating, and will not be applied to your project. Title * Environmental Science Description *	Next Auto-saved: a few seconds ago
<	Category © Project v Affiliated institutions	

You start with adding meta data about your study, this allows OSF to make your study findable;;



You then specify the relevant details about your design/sampling/variables, etc. For various parts, you can either write a description or upload the relevant files



Close with a quick review your prereg, assuring everything is as you wanted it to be, you might also want to ask others of your team to do the same, as once uploaded, the prereg is a frozen-non editable and timestamped version of your research plan



And then it is time to actually register!





Finally, choose how you want your preregistration to appear -- linking back to the challenges

Need	support?				
OSF REGISTRIES -			Add New	Help Do	nate
OSF				Submit a request	Sign in
OSF Guides > Registrations			Q Search		
	Registrations				
	Learn More About Registrations	Create Regist	rations		
	Select a Registration Template	Create a Preregi	istration		

Don't be shy to ask for help;

Pre-registration will improve discoverability of research, but discoverability does not guarantee usability. Poor usability reflects difficulty in evaluating what was done, in reusing the methodology to assess reproducibility, and in incorporating the evidence into systematic reviews and meta-analyses. Improving the quality and transparency in the reporting of research is necessary to address this.

REPORTING

- Relevance guidelines
- Endorsed by various stakeholders
- **Types** guidelines (some examples)
 - PRISMA
 - STROBE
 - CONSORT
 - o Stard
 - COREQ
 - SPIRIT

Thus far we talked about preregistration, but just preregistrering your work does not mean it is automatically useful to others -- To ensure that others can use or build on your work, there are certain aspects that must be reported so that readers can critically appraise the study (Moher, 1998; Altman et al., 2001; Kilkenny et al., 2010; Percie du Sert et al. 2020). It has become apparent that biomedical research reports across different subfields are frequently incomplete (Kjaergard, Nikolova & Gluud, 1999; Adetugbo & Williams, 2000; Kilkenny et al., 2009; Macleod et al., 2015). Reporting guidelines were designed to bridge this gap and include a list of items that authors must report to allow others to reproduce, critically appraise and build on the work.

Prisma = Sys reviews Strobe = Observational studies Consort = RCTs Stard = Diagnostic/prognostic studies Spirit = Study protocols

// relationship PREREG/REP GUIDELINES; similar things are considered / too late to come in?



There exists a broad array of reporting guidelines, and I flashed out just a few before. great resource is the equator network that has classified reporting guidelines that allows you to select the one most relevant for your work -- <u>https://www.equator-network.org</u>

When I completed my focus groups as part of PhD, I was advised to use COREQ -- but some of you may not know immediately which reporting guideline to use

Selecting the r	ight checklist
Reporting checklists for medic	cal researchers
For most study types there are specific checklists that medical journals will expect you to upload alongside your manuscript. Using a checklist can help you get published faster and	Need some help choosing?
maximise the impact of your work. This tool was made by the <u>EQUATOR Network</u> in collaboration with <u>Penelope ai</u> .	

See: <u>https://www.goodreports.org</u>

You either start with specifying what you are writing, using their dropdown menu

OR -- you use their 'help'



See: https://www.goodreports.org

This is the dropdown menu option, it shows and array of examples

Find the right reporting checklist to help you plan, write or review medical research.			
14 What type of article is it?		start press Enter ↔	
Key A Original research	Protocol or methods article		
C Systematic review	Clinical case report		
E Another type of article			
a. Where is the data from?	b	Did you exclusively use qualitative research methods, such as interviews or focus groups, in your study?	
Key A People	✓		
Laboratory animals		Key X Voc	
C Farm, domestic or wild animals		Tes 165	
P Human tissue		No	
C Other			
ОК 🗸			

This is the menu that goodreports walks you through when you ask for help, it then ends with a recommendation

		No Item	Guide guestions/description
Search for reporting g	guidelines		
Use your browser's Back button	to return to your search results	Domain 1: Research team and re Personal Characteristics	eflexivity
Consolidated 32-item chec	d criteria for reporting qualitative resea klist for interviews and focus groups	 Interviewer/facilitator Credentials Occupation Gender Experience and training 	Which author/s conducted the interview or focus group? What were the researcher's credentials? E.g. PMD, MD What was their occupation at the time of the study? Was the researcher male or female? What experience or maining did the researcher have?
Reporting guideline provided for? (i.e. exactly what the authors state in the paper)	Qualitative research interviews and focus groups	Relationship with participants 6. Relationship established 7. Participant knowledge of the interviewer 8. Interviewer characteristics	Was a relationship established prior to study commencement? What did the participants know about the researcher? e.g. personal goals, reasons for doing the research What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic
Full bibliographic reference	Tong A, Sainsbury P, Craig J. Consolidated criteria for reportir (COREQ): a 32-item checklist for interviews and focus groups 2007;19(6):349-357.	Domain 2: study design Theoretical framework 9. Methodological orientation and <u>Theory</u> Participant selection	d What methodological orientation was stated to underpin the study? e.g. grounded theory, disourse analysis, ethnography, phermuralogy, content analysis
Language	English	10. Sampling 11. Method of approach	How were participants selected? e.g. purposive, convenience, consecutive, snowball How were participants approached? e.g. face-to-face, telephone, mail, email
PubMed ID	17872937	 Sample size Non-participation 	How many participants were in the study? How many people refused to participate or dropped out? Reasons?
Relevant URLs (full-text if available)	Full-text available from: <u>http://intqhc.oxfordjournals.org/conte</u>	Setting 14. Setting of data collection 15. Presence of non-participants 16. Description of sample	Where was the data collected? e.g. <i>home, dinic, workplace</i> Was anyone else present besides the participants and researchers? What are the important characteristics of the sample? <i>e.g. demographic data, date</i>
Reporting guideline acronym	COREQ	Data collection 17. Interview guide 18. Repeat interviews	Were questions, prompts, guides provided by the authors? Was it pilot tested? Were repeat interviews carried out? If yes, how many?
Study design	Qualitative research	 Audio/visual recording Field notes 	Did the research use audio or visual recording to collect the data? Were field notes made during and/or after the interview or focus group?
Applies to the whole report or to individual sections of the report?	Whole report	 21. Datation 22. Data saturation 23. Transcripts returned 	winat was use outsuon of the interviews or focus group? Was data starturation discussed? Were transcripts returned to participants for comment and/or correction?
Record last updated on	March 12, 2015		

Again, for me, that was COREQ, now what really is that -- you are linked to the paper and in the paper is the checklist that you can use -- some journals will ask this, such as NATURE series, to submit also on the side of your ms., but many journals will endorse a reporting guideline, meaning that they would encourage you to use this checklist when writing up your results to ensure others can critically appraise them

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349-357

Article			
	Heading	Term	Elaboration
Preregistering Qualitative Research: A Delphi Study	Study information	Research aim(s)	Please specify the overall purpose(s), objective(s), or aim(s) of the research. If helpful, please select the type(s) of aim. Examples include, but are not limited to: * exploring, "describing," theory evaluating "comparing "understanding In addition, please reflect on whether your aim is different across different domains (e.g., knowledge generation, policy development, community resourcing). If so, specify your aim for each domain that is relevant for your study.
Tamarinde L. Haven ¹ , Timothy M. Errington ² , Kristian Skrede Gle Leonie van Grootel ⁵ , Alan M. Iacobs ⁶ , Florian G. Kern ³ , Rafael Piñeire		Research question(s)	Please specify your research question(s) as they are guiding your research now. If relevant, you may also specify here any hypotheses to be assessed. The research questions may break down your aim into smaller, distinct inquiries. I relevant, you may distinguish between primary and secondary research questions or hypotheses.
Fernando Rosenblatt ⁸ , and Lidwine B. Mokkink ⁹		Anticipated duration	Please indicate the estimated project start date (mm/yyyy) and estimated project end date (mm/yyyy).
	Design Plan	Study design	Please provide a brief, overarching characterization of the study design. Your response might consist of a succinct label (e.g., "case study" or "ethnography") and/or a brief elaboration of that label's meaning.
Abstract	,		A study may involve a combination of different designs, including a mix of quantitative and qualitative methods.
Preregistrations—records made a priori about study designs and analysis plans and placed in ope strengthen the credibility and transparency of research. Different authors have put forth argum practice in qualitative research and made suggestions for what to include in a qualitative prereg		Sampling & case selection strategy	Please describe your sampling or recruitment strategy (examples include, but are not limited to: purposive, snowball, theoretical, and maximum variation sampling) and/ or your case selection strategy (examples include, but are not limited to: typical case, most similar case, most different case, diverse case, and deviant case).
study was to gauge and understand what parts of preregistration templates qualitative reser- informative. We used an online Delphi study design consisting of two rounds with feedback r researchers participated (response rate: 16%). In round I, panelists considered 14 proposed i preregistration form, but two items had relevance scores just below our predefined criterion (users put feat panel Me combined items underso particle large to L particle items. In particle 15 parts and the part of the particle part of the particle large to the particle part of the part of the particle part of the particle large to the part of the particle particle part of the particle particle part of the particle particl	Data Collection	Data source(s) and data type(s)	Please provide a short rationate for why you selected this type of strategy. Please describe the source(s) and type(s) of data you will be using. In describing the data, distinguish between data that existed prior to your study (ag, archival documents, newspaper articles, [social] media, secondray literature, or data collected for a different purpose than the current study) and original data (i.e., data that will be collected/generated for the current study).
where put for traggaint, we contract them the possible are possible reading to the remser tents, in routed 2,1 two remaining items. Parellists also converged on suggested terminology and elaborations, excep provided clear arguments. The result is an agreement-based form for the preregistration of qu 13 items. The form will be made available as a registration option on Open Science Framework (o to argue to the personal of qualitative preserve).		Data collection method(s)	Please describe your method(s) of data collection or data generation. Examples of methods include, but are not restricted to: interviews, focus groups, enabling techniques, self-reports, field notes, diaries, (participative) observation, archival research, or mixed methods. Please provide o hiefr attoined for why you plan to use each particular data collection/
The preregistration should provide a systematic starting point.		Data collection tool(s), instrument(s), or plan(s)	generation method in your study. Please describe or upload the tool(s), instrument(s), or plan(s) you will use in collecting or generating your data. Examples could be, but are not limited to: topic guide, interview questionnaire, focus group guide, observation scheme, creative tools (e.g., photos, videos, musical pieces, paintings, etc.), or a description of your archival search balas.
		Stopping criteria	Pless describe the criteria or rationale behind when you will stop data generation or collection. Possible criteria include, but are not limited to: data saturation [*] , when inclusion criteria are satisfied, resource constraints (e.g., dimefunding), or when the analysis has produced an enriching anwere to the research question(s). * We follow Fusci & Nets (2015) and interpret saturation to be reached when there is enough information tepfacets be study, the oblity to obtain new information has been attained, and further coding is no longer feasible.

And here putting that the preregistration side by side, you see that similar items have been considered, both in the study design phase and in the phase of writing up the work, that is just one example about how preregistrations and reporting guidelines may mutually enforce one another to make research more transparent

https://journals.sagepub.com/doi/full/10.1177/1609406920976417



Reporting guidelines have been endorsed by many leading journals, professional societies and biomedical research funders (<u>http://www.consort-statement.org/about-consort/endorsers1</u>). However, surveys and reviews examining the adherence to reporting guidelines in journals that endorsed the guidelines found mixed results (Agha, Cooper & Muir, 2007; Baker et al., 2015). This shows that to endorse something is not the same as to enforce something (Baker et al., 2015), and that ultimately reviewers, editors and you as individual researchers are responsible for assuring manuscripts that they submit, review and approve comply with the relevant reporting guidelines.

QUESTIONS?

tamarinde.haven@charite.de