

Preregistration of studies with existing data

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Abstract

Preregistration of research plans is becoming an increasingly popular and common tool to enhance the transparency of a study's methodology. In a preregistration, researchers document their research plans and register them to a public repository prior to conducting their research. In this chapter, we provide arguments for why preregistration can protect scientific findings against Questionable Research Practices (QRPs), such as outcome swapping, selective reporting of conditions, unwarranted data exclusions, and post-hoc changing of hypotheses. Furthermore, we place particular emphasis on preregistering research plans when using existing data and we give an overview of preregistration templates and public repositories for different types of research designs. We conclude this chapter with highlighting some of the common criticisms of preregistration and our counter-arguments, and provide future reflections.

Keywords: Replicability; Transparency; Questionable Research Practices; Open Science; Existing Data

List of abbreviations:

- HARKing: Hypothesizing After the Results are Known
- NHST: Null Hypothesis Significance Testing
- QRPs: Questionable Research Practices

Introduction

Science relies for a large part on the collection and analysis of empirical data. Within the dominant hypothetico-deductive model of science, empirical data may be used to generate novel theories or test existing theories (De Groot 2014). The underlying idea is that less accurate theories to predict and explain empirical data are gradually replaced with new theories that are more accurate or simpler than the old theories.

Until recently, researchers nearly always had to collect new empirical data to test their theories. However, due to rapid advances in the capacity to easily store and share data on online servers, datasets are now easily available to researchers across the world. While this facilitates the work of scientists, it also brings about new challenges to ensure accurate inferences based on data. To illustrate, can hypotheses still be validly tested on a data set that has been collected for different purposes? And how can it be ensured that the hypothesis was really specified independently of the data?

Alternatively, are existing data merely useful for exploratory research (i.e., finding patterns in the data by the reanalysis of data)? In this chapter, we aim to answer these questions regarding the re-use of existing data to test hypotheses. First, however, we outline how the validity of hypothesis testing can be threatened through the use of Questionable Research Practices.

Threats to the validity of scientific inferences: Questionable Research Practices (QRPs)

Typically, when scientists want to test a theory, they will propose a falsifiable hypothesis and test this with empirical data (Popper 1959). Because empirical data are nearly always influenced by random noise, statistical models are applied to the data to quantify

the reliability of the observations. In addition, statistical inference frameworks are used to deduce the population distributions from the collected sample data. Such deductions, as well as the correction for random noise, is typically expressed within the Null Hypothesis Significance Testing (NHST) framework using “ p -values”. This refers to the probability of obtaining test results at least as extreme as the results observed, under the assumption that the null hypothesis is correct. This approach is widespread across the empirical sciences and many philosophers of science have defended this practice (e.g., Lakens, 2019; Mogie, 2004).

However, p -values and the NHST framework has also received much criticism by other scientists and philosophers (e.g., Carver, 1978; McShane et al. 2019). This has become apparent in the study by Bem (2011), where empirical data published in an influential psychology journal suggested the presence of pre-cognition (i.e., the ability to predict random future events). This has alarmed psychologists (e.g., Wagenmakers et al. 2011) regarding the limitations of the NHST framework. Specifically, it has become apparent that scientists can use *Questionable Research Practices* (QRPs) to influence the observed results and p -values, and thereby compromising the validity of scientific findings. Please note that we do not want to suggest that only the NHST framework is sensitive to QRPs (for arguments that it is not when applied properly see Lakens, 2021). Indeed, also alternative inferential approaches (e.g., Bayesian hypothesis testing) also suffer from limitations due to their sensitivity to misuse and QRPs (for a review see Tendeiro and Kiers, 2019).

Here we provide a short overview of such QRPs and how they can influence the reliability of hypothesis testing and scientific findings. However, note that we do not aim

to provide a complete list of such QRPs here. We merely intend to illustrate how different QRPs can result in unreliable findings and incorrect hypothesis test. For a more exhaustive list of QRPs see John et al. (2012).

Not reporting all collected variables

Often, different measurements can be used to test a certain hypothesis. For example, psychologists could test whether social pressure elicits arousal in anxious individuals by measuring skin conductance or heart rate, or perhaps both. Indeed, collecting multiple outcome measures is typically seen as good practice to check the generalizability of findings to different measures, as well as help in addressing different research questions within a single study (e.g., LoBue et al. 2020). However, it may be tempting for researchers to selectively report those dependent variables that showed a significant result only and disregard the rest of them. This is especially important since the more tests someone's performs within NHST, the higher the chances of a false positive (i.e., that is the result of random measurement error).

Only presenting the outcome variables that confirm the hypothesis is misleading, as the result can be due to random noise and the fact that the result was not obtained for the other outcome variables remains obscured. It is therefore commonly recommended by established reporting guidelines to always transparently report on all the collected outcome variables (e.g., Schulz et al. 2010).

Failing to report all conditions

Much like including different measures in their studies, researchers often also include different conditions in their studies to control for different factors (e.g., including both a placebo condition and a wait-list control condition next to the main experimental

intervention). When including multiple conditions, results can vary across conditions due to systematic or error variance. For instance, a certain intervention may work well when compared to the wait-list group, but not show a significant effect compared to the placebo group. A researcher can therefore be tempted to only report the comparison between two conditions in which the hypothesis was confirmed, and not report the other conditions. Once again, this compromises the validity of the findings. For instance, it is already well-known that interventions tend to have artificially inflated effect sizes when compared to a wait-list control group instead of placebo-control group (Cuijpers and Cristea 2016).

Interim analyses and selectively stopping data collection

A third way to influence the results of a study is to collect data and run statistical analyses until a significant result is detected. Due to a fundamental property of the p -values, namely that they tend to decrease with an increasing sample size, additional data-collection and uncorrected interim analyses can inflate the chance of a false-positive result. Particularly, p -values will always turn out to be significant given a large enough sample of observations (Wagenmakers 2007). Furthermore, p -values tend to fluctuate substantially (Cumming 2014) and it has been argued that the common evidence threshold of $\alpha = .05$ is too liberal and easily results in spurious findings (Benjamin et al. 2018). Given these properties of the p -value, *uncorrected* interim analyses and collecting data until the alpha level is crossed will guarantee that a researcher can find a false-positive statistical significant result, thereby greatly increasing the number of spurious results in the literature. Thankfully, there are

principled ways to perform interim analyses (e.g., Lakens, 2014; Schönbrodt et al. 2017).

Selectively excluding data

A fourth way in which results of scientific studies can be compromised is by selectively removing data from the dataset (e.g., Lonsdorf et al. 2019; Morís Fernández and Vadillo, 2020). Due to random noise, there is typically variability in the data of most scientific fields. Without clear pre-specified rules, it is often up to the researchers themselves to decide if certain outliers in the data are due to random error or because of a systematic error that may distort the results. This once again provides an opportunity to capitalize on chance and select those data points that selective support the hypothesis of the researcher, again increasing the chances of finding spurious results.

Changing the hypothesis after observing the results

Another potential way in which the results of a scientific study can be influenced is by adjusting the hypothesis to the observed results. This practice is sometimes referred as “Hypothesizing After the Results are Known” (HARKing) (Kerr 1998). For instance, a treatment may work in one condition (e.g., low dosage) and not in another (e.g., high dosage). Even though the researchers had initially predicted the opposite pattern, it may be tempting, or it may even happen unintentionally when the hypothesis was not articulated clearly enough beforehand, for the researchers to change their hypothesis. This, however, does not constitute a valid test of a theory because the hypothesis is based on the observed results, rather than specified a priori. Once again, due to random noise in much of the scientific data, this can result in spurious results that are presented as a priori predicted by a flawed theory.

Falsifying and fabricating data

Finally, arguably one of the most unethical ways to influence the results of a study is by outright fabrication or falsification of the data to obtain statistically significant “findings” (Neuroskeptic 2012). Though this practice is most likely rare, between 0.3% and 4.9% of researchers self-admit having fabricated or falsified data and between 5.2% and 33.3% reported personally knowing a colleague who had fabricated or falsified data (Fanelli 2009).

The consequences of QRPs for scientific findings

QRPs can drastically inflate false positives and thus produce unreliable research findings. This has alarmed more and more researcher in recent years. Particularly, several survey studies have shown that scientist self-admit engaging in QRPs (Fanelli 2009; John et al. 2012) and some researchers have raised concerns that as much as 50% or more of the findings in scientific journals are actually false positive results, in part due to the common (intentional and unintentional) use of QRPs (Ioannidis 2005; Simmons et al. 2011). For example, within the field of psychology, a large-scale replication project of research was only able to replicate 39% of published research findings (Open Science Collaboration 2015). Furthermore, a recent study showed that the results of register reports (a type of journal submission where an article gets accepted before data are collected merely on the hypotheses and methods to be followed; see below) reported significantly lower percentages of positive results, compared to traditional submissions, casting doubts on how reliable the reported results in the literature are (Scheel et al. 2021). Results such as these have led several researcher to conclude that psychology and related disciplines are currently suffering

from a “replicability crisis” (e.g., Pashler and Wagenmakers, 2012; Tackett et al. 2017). Nonetheless, similar concerns about the replicability of findings have been raised in other scientific fields, such as cancer research (Wen et al. 2018), nutrition research (Sorkin et al. 2016), and neuroscience (Button et al. 2013; Botvinik-Nezer et al. 2020), indicating that QRPs likely undermine the reliability of scientific findings in many different research areas. This state of (some parts of) the scientific literature is problematic as it has the potential to undermine public trust in scientific research (Wingen et al. 2020) and does not provide stable foundation for further research to be built on.

Unique challenges when using existing data

The availability of existing datasets to test hypotheses on can add to the above-mentioned problems. Particularly, given that the datasets are already available and that researchers may have pre-existing knowledge of their properties, they can use this knowledge to increase their chances to observe statistically significant results, although it is more likely that these results will be spurious or biased. Furthermore, available datasets can often be very large (e.g., more than millions of observations) and include many different variables, thereby further increasing the opportunities for using QRPs and finding false positive results (Mertens and Kryptos 2019; Weston et al. 2019).

Additionally, it is more difficult to show with an existing database that a hypothesis was posited prior to looking at the data. When collecting new data, a hypothesis can be publicly announced (for instance, through a preregistration, see the next section) prior to collecting the data. However, when the data are already available, the independence of the hypothesis from the data is more difficult to prove. One exception is when a dataset

can only be accessed after approval. In this case, the date of obtaining access to the data can be used to show that a hypothesis was developed independently of the data.

Finally, the widespread availability of datasets to (re-)analyze is relatively new and there are few guidelines on how to do this correctly. Therefore, it can be argued that establishing guidelines for how to do reliable research and preventing QRPs is particularly important for studies making use of existing data (van den Akker et al. 2019; Weston et al. 2019).

Preregistration as a tool to protect the reliability of scientific findings

In order to combat these problems with QRPs and unreliable scientific findings, study *preregistration* has been proposed as a possible solution (e.g., Munafò et al. 2017; Nosek et al. 2015). In a preregistration document, scientists specify the details regarding their hypotheses, the design of their study, the way in which data are collected, the statistical analysis plan, and the evaluation of the results prior to the execution of the study. This preregistration is typically archived in a (publicly accessible) registration repository prior to conducting the research. By timestamping this document (i.e., archiving when the preregistration was uploaded to the registry), it can be checked whether the preregistration was available prior to the execution of the study. The preregistration is typically publicly shared prior to the study execution or once the study is accepted, but it could also remain private and only accessible to a selected audience (e.g., co-authors, reviewer, etc.). The idea is that by preregistering important choices in the execution of a study (e.g., sample size, outcome measures, etc.), the flexibility of researchers to (intentionally or unintentionally) influence the results through QRPs is reduced (Nosek et al. 2019) because researchers now specified a plan to follow. If

deviations of this plan occur (which can of course happen in a research project), this should then be transparently reported and not presented as an a priori choice.

One of the first areas where the use of preregistrations became widespread is in clinical trials. Many scientific journals within the medical sciences now require clinical trials to be registered in a public repository (e.g., <https://www.clinicaltrials.gov/>) in order to be considered for publication. More recently, preregistration templates and repositories have also been developed for meta-analyses and systematic reviews (e.g., <https://www.crd.york.ac.uk/prospero/>), and within the behavioral sciences (e.g., Kryptos et al. 2019; van 't Veer and Giner-Sorolla, 2016). For behavioral sciences, the two most common websites for preregistration of a study are www.osf.io and www.aspredicted.org, both of which allow researchers to upload their preregistrations for free. An important difference between the two repositories is that although preregistrations in www.osf.io can stay private for up to 4 years (after which preregistrations become available publicly), in www.aspredicted.org preregistrations can stay private forever.

Is preregistration necessary for analyses on existing data? Exploratory and confirmatory studies

As mentioned above, the typical preregistration document includes primary a study's hypotheses, methods, planned sample, outcome measures, data transformations, and statistical analyses (van 't Veer and Giner-Sorolla 2016; Nosek et al. 2018). In case of the analyses of preexisting data, though, such a complete preregistration is not possible because the study has already been done and the data have already been collected. As such, preregistration of the analyses of preexisting data requires using a different

format. However, a first question that needs to be answered is whether the study requires preregistration? Indeed, whether a study really requires preregistration depends on the goal(s) of that study.

First, it may be that a researcher would want to use preexisting data for purely exploratory purposes. In this case, no preregistration is required, given that the researcher has no concrete hypotheses but just performs various tests, attempting to find any interesting data pattern in the data. Although such type of analyses could seem spurious, they are not if they are introduced as such because the reader can evaluate the provided evidence as stemming from pure exploration. Indeed, exploration is an integral part of the empirical cycle and of scientific discovery (De Groot 2014). Still, when observing a novel phenomenon in exploratory research, often a follow up confirmation study is appropriate (i.e., using novel data collection) in order to confirm the novel findings.

For such a “confirmatory study”, a researcher could test a clearly specified hypotheses on a dataset that already exists (e.g., the European Social Survey database, the UK Biobank data, etc.). In this case, the hypothesis is specified beforehand and it is “confirmed” (or disconfirmed) by analyzing independent data (i.e., data that was not used to initially come up with the hypothesis, such as in a prior exploratory study). In a confirmatory study, a preregistration is appropriate and helps ensure that the test of the hypothesis is not tainted by QRPs (Lakens 2019b).

We have previously introduced such a template for the preregistration of confirmatory studies on preexisting data (see Mertens and Kryptos, 2019). This template consists of 10 simple questions, ranging from stating the hypotheses and

planned statistical analyses, to the provision of clear statements regarding what is already known about the data. This last statement is particularly important because prior knowledge about the data (e.g., when dealing with a dataset that has been used before by the same researcher) could limit a study being truly confirmatory (i.e., perhaps the researcher already knows that the hypothesized pattern is present in the data). Apart from our own template, also other templates for analyzing secondary data have been recently introduced (e.g., van den Akker et al. 2019).

What and how to preregister: Preregistration templates and repositories

Currently, preregistration is variably common the different scientific disciplines. Whereas a preregistration is mandatory in many medical journals to publish the results of clinical trials, other fields are only taking their first steps in applying preregistration for their studies (e.g., experimental philosophy; see Polonioli et al. 2018). Therefore, the elements that should be included in the preregistration still differ widely across scientific fields and, for some types of research designs and in certain scientific fields, no generally accepted standards or templates for preregistration are available as of now (e.g., Haven et al. 2020). In Table 1, we provide a non-exhaustive overview of currently available templates and repositories for some of the most common types of research designs and studies to help guide researchers in choosing an appropriate preregistration format, including preregistration templates for studies using existing data (van den Akker et al. 2019; Mertens and Krypotos 2019; Weston et al. 2019).

[Insert Table 1 here]

When researchers want to preregister their study, they should complete an appropriate preregistration template for their study and submit this to a relevant repository before conducting their study (or, in the case of analyses on existing data, before inspecting the data and performing the statistical analyses). Furthermore, researchers should refer to this preregistration in the scientific paper resulting from the study. In some journals, preregistration is already required (e.g., DeAngelis et al. 2005) and in other journals, papers with preregistration are designated with open science badges (Kidwell et al. 2016).

Finally, a special and powerful version of preregistration are *Registered Reports* (Chambers 2013). In this format, researcher specify the background of a study, the hypothesis, the design, the sample, the procedure, and the statistical analysis plan, and this is reviewed by a journal *prior* to conducting the study. Once the reviewers and the editor accept this study plan, the authors receive an “in principle acceptance” by the journal and they can start collecting the data and thereafter submit their final paper. The final paper will again undergo peer review to check whether the study plan was followed. Crucially, the journal will publish the final version of the manuscript, regardless of the obtained results. With this format, QRPs are maximally controlled and publication of the findings is not based on the direction of the results but merely on the idea and methodology of the study. An updated list of journals offering this publishing format can be found on the Open Science Framework (<https://osf.io/rr/>).

Limitations and critiques of preregistration

Despite our enthusiasm about preregistration, there are often criticisms voiced against it. The most common criticism against preregistration is that it does not fit all types of

studies (e.g., Pham and Oh, 2021). For example, in longitudinal studies, where the final data set is available only years after the beginning of a study. Given that nowadays statistical methodologies develop rapidly, it is probable that by the end of a study, a better method for addressing the research question will be available. However, since this analysis was not preregistered, researchers may worry that it is not allowed to perform it anymore.

This idea stems from the common misconception that after the submission of a study's preregistration, researchers' hands are tied and any deviation from the plan should be interpreted as engaging in QRPs. In our view, however, this is an unfortunate misrepresentation and misinterpretation of the goals and implementation of preregistrations. The preregistration, is a plan, and a plan can be changed or updated (DeHaven 2017). As long this is done in a transparent manner (e.g., by updating the preregistration template before the data are inspected with the authors describing the changes in their preregistration or by listing the deviations from the preregistration in the final paper), there is no reason to hang on to the choices made in the preregistration and for the authors to be accused of QRPs.

Another common argument is that preregistration cannot really protect from QRPs, simply because someone could preregister a study after the data have been inspected, or preregister multiple studies, keep the preregistrations private, and then only releases the preregistration that better fits the direction of the results. Alternatively, and less dramatically, preregistrations could simply not be clearly specified enough and/or not followed by researchers and thereby not really protect against QRPs (Claesen et al. 2019; Bakker et al. 2020). We agree that indeed a study's preregistration

is not a tool that can guarantee a 100% safeguard against QRPs and a preregistered study is not necessarily a good study. Still, we caution against throwing the baby out with the bathwater. Given that QRPs are fairly common and often happen unintentionally (Fanelli 2009; Grant et al. 2018), preregistration is a valuable tool to encourage researchers to be transparent in their choices. Furthermore, even if an intervention is not 100% effective, it can nonetheless be a useful tool to reduce, though perhaps not eliminate, (unintentional) QRPs.

Closing remarks and future perspectives

In this chapter, we considered the threat that QRPs pose for the reliability of scientific findings and the use of preregistration to prevent QRPs. In particular, we placed emphasis on the use of preregistration to improve the reliability of research using existing data. It should be noted that we focused mostly on preregistration as a tool to reduce (unintended) QRPs and increase transparency, and did not evaluate preregistration in its ability to test the severeness of a test, a topic that is most relevant for the field of philosophy of science (see Lakens, 2019b).

Although the idea of preregistering studies has been around since the 1960's, researchers have only relatively recently started using preregistration for research in different areas (e.g., psychology, philosophy, social sciences). As such, for these fields, preregistration is a relatively new tool and it is still being further developed and evaluated (e.g., Haven et al. 2020; Polonioli et al. 2018). Given the relatively quick developments in the field of open science in psychology and beyond, we anticipate that a study's preregistration will become more common for different types of research designs and scientific disciplines. This will be a good step towards promoting more

transparency in our research. Such transparency is important for science consumers in evaluating scientific research and for having trust in scientific research findings (Wingen et al. 2020). As such, we believe it is important for researchers from different fields to become familiar with preregistration and the relevant templates and repositories, and adopt them in their research practices.

It should be noted though that, as we showed above, preregistrations are in no way a foolproof solution for all possible kinds of QRPs and intransparency. If scientists want to commit fraud and manipulate their results, preregistration is unlikely to prevent this, though it does arguably makes it more difficult. Furthermore, preregistration is not a catchall solution for other problems that may exist in different scientific fields, such as vague theories or poor external validity (see Szollosi et al. 2020). Finally, it is important that preregistration are sufficiently specific and actually followed. Indeed, a number of recent studies found that preregistrations are not always followed carefully and this is often not reported transparently (Claesen et al. 2019; Bakker et al. 2020). In these cases, the usefulness of preregistration to protect against QRPs is obviously diminished and papers may undeservedly receive credit for good practices that were not actually adhered to. That said, a preregistration does not and should not prevent researchers from choosing the optimal statistical models and data points for their research aims, and researchers should always be allowed to explore their data to discover new patterns and findings (provided that this is reported as such). Instead, preregistration is intended to help making a distinction between what was predicted beforehand, and what is an unexpected discovery. As such, we believe that preregistration is a promising tool to improve our scientific practices and to foster more robust scientific discoveries.

The wider acceptability of preregistration in the community is likely going to take more effort as it calls for a wider change in the scientific culture and the current way of doing science. Particularly, typically most of the important decisions (e.g., the exact hypothesis, the statistical model, data exclusions, etc.) are now commonly taken during or at the end of the study, while this should preferably be done beforehand.

Furthermore, most researchers are under significant pressure to publish articles and journals often prefer publishing positive results. Flexibility in the specification of the details of a study can help researchers find such positive results and thus publish more easily (Fanelli 2010; Grant et al. 2018). As such, many researchers are still disincentivized from adopting the practice of preregistering their study. Nonetheless, given that preregistration provides important advantages to the transparency and reliability of scientific research, we expect that more funders, universities and journals will require researchers to preregister their studies in the future. As such, we anticipate that the widespread requirement of preregistration by major journals and funding bodies, and/or the need to provide of concrete arguments for why it was not possible to preregister a study, will likely be a matter of time. Therefore, we think it is good for all researcher to familiarize themselves with preregistration.

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Tables

Table 1. Non-exhaustive overview of different possible preregistration templates and repositories for different types of studies

Type of study	Preregistration templates	Possible public repositories
Qualitative studies	Qualitative Preregistration template (Haven et al. 2020)	https://osf.io/
Quantitative behavioral research	AsPredicted template (https://osf.io/fnsb6/) Pre-Registration in Social Psychology (van 't Veer and Giner-Sorolla, 2016; https://osf.io/ce3hr/)	https://osf.io/ https://aspredicted.org/
Analyses on existing data	Mertens and Kryptos (2019) template (https://osf.io/3tbwc/) Weston et al. (2019) template (https://osf.io/x4gzt/)	https://osf.io/
Randomized controlled trials	Use the Protocol Registration and Results System (see www.clinicaltrials.gov)	https://www.clinicaltrials.gov/ https://www.clinicaltrialsregister.eu/
Systematic reviews/meta-analysis	Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P)	https://www.crd.york.ac.uk/prospero/ https://srdhr.ahrq.gov/

Note: A more exhaustive list of preregistration templates can be found on the Open Science Framework: <https://osf.io/zab38/wiki/home/>.