Assessment of transparent and reproducible research practices in the psychiatry literature

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Objective: Reproducibility is a cornerstone of scientific advancement; however, many published works may lack the core components needed for study reproducibility. In this study, we evaluate the state of transparency and reproducibility in the field of Psychiatry.

Methods: An observational, cross-sectional study design was used. From a random sample of 300 publications in PubMed-indexed psychiatry journals, two researchers extracted data in a duplicate and blinded fashion using a piloted Google Form. For this study, we included publications from January 1, 2014 to December 31, 2018. The publications were evaluated for indicators of reproducibility and transparency, which included the availability of materials, data, protocol, analysis script, preregistration, open access, financial conflicts of interest, funding sources, and pre-registration in an online repository.

Results: Our study identified 158 journals meeting the inclusion criteria and 90,281 publications from within the timeframe. Of the 300 randomly sampled, 4 were inaccessible, resulting in a final sample of 296 publications. Of the 296, only 107 (36%) were publically available online. Regarding reproducibility, 17 publications gave access to necessary materials, 4 provided an in-depth protocol, and 1 contained the raw data required to reproduce the outcomes.

Conclusions: Currently, researchers in the field of Psychiatry do not adhere to practices that promote reproducibility and transparency. Change is therefore needed. This study presents a reference point for the state of reproducibility and transparency in psychiatry literature, and future assessments are recommended to evaluate progress.

Introduction

Reproducibility is a cornerstone of scientific advancement (1); however, many published works lack the core components needed for reproducibility and transparency. These barriers to reproducibility present serious immediate and long-term consequences for psychiatry, including poor credibility, reliability, and accessibility (2). Fortunately, methods to improve reproducibility are practical and applicable to many research designs. For example, preregistration of studies provides public access to the protocol and analysis plan. Reproducibility promotes independent verification of results (2) and successful replication (2, 3), and it hedges against outcome switching (4). Supporting this need in the field of psychology, the Open Science Collaboration's reproducibility project was an attempt to replicate the findings of 100 experimental and correlational studies published in three leading psychology journals. Researchers found that 97% of the original reports had statistically significant results ($P < 0.05$), whereas only 37% of the replicated studies had significant results (5). With regard to outcome switching, a recent survey of 154 researchers investigating electrical brain stimulation found that less than half were able to replicate previous study findings. These researchers also admitted to selective reporting of study outcomes (41%), adjusting statistical analysis to alter results (43%), and adjusting their own statistical measurements to support certain outcomes (6). Leveraging good statistical practices and using methods that promote reproducibility, such as preregistration, are necessary to protect against similar incidents of selective reporting (7).

Considerable advancements have been noted to promote and endorse reproducible and transparent research practices in the field of psychology. For example, the Center for Open Science, the Berkeley Institute for Transparency in the Social Sciences, and the Society for the Improvement of Psychological Science have all worked vigorously to establish a culture of transparency and a system of reproducible research practices. However, mental health researchers, including psychiatry researchers, have not kept pace with their psychology counterparts (8). A few editorials have circulated to promote awareness of reproducibility and transparency within psychiatric literature (7–9). For example, *The Lancet Psychiatry*

published an editorial addressing various topics of reproducibility, such as increasing the availability of materials, protocols, analysis scripts, and raw data within online repositories. The editorial author argued that few limitations exist within psychiatry that would impede depositing study materials in a public repository. The author additionally countered a commonly held position that raw patient data should not be made available, noting that the use of appropriate de-identification can make the information anonymous (8). A second editorial published in *JAMA Psychiatry* (7) argued for more robust statistical analysis and decision making to improve the reproducibility of psychiatry studies. The author of this editorial discussed several statistical considerations, including the effects of statistical assumption violations on validity and study power, the likelihood of spurious findings based on small sample sizes, *a priori* covariate selection, effect size reporting, and cross-validation. These efforts are good first steps to create awareness of the problem, which was deemed a “reproducibility crisis” by over 1,000 scientists in a recent *Nature* survey (10); however, further measures are needed. A top-down approach to evaluating transparency and reproducibility would provide valuable information about the current state of the psychiatry literature. In our study, we examined a random sample of publications from psychiatric literature for evaluating specific indicators of reproducibility and transparency within the field. Our results may be used both to evaluate for current strengths and limitations and to serve as baseline data for subsequent investigations.

Methods

We conducted an observational study using a cross-sectional design based upon methodology by Hardwicke et al. (2). Our study is reported in accordance with guidelines for meta-epidemiological methodology research (11). We have made available protocols, materials, and other pertinent information on Open Science Framework (<https://osf.io/n4yh5/>). This study was not subject to institutional review board oversight because it did not include human participants.

Journal and Study Selection

We used the National Library of Medicine (NLM) catalog to search for all journals, using the subject terms tag Psychiatry[ST]. This search was performed on May 29, 2019 by DT. The inclusion criteria required that journals were in English and also MEDLINE indexed. The list of journals in the NLM catalog was then extracted along with their electronic ISSN (or linking ISSN if electronic is unavailable). The final ISSN search string was used to search PubMed to identify all publications between January 1, 2014, and December 31, 2018. DT then compiled a random sample of 300 publications from selected journals.

Extraction Training

Prior to data extraction, two investigators (CS and JP) underwent a full day of training to ensure inter-rater reliability. The training included a review of the study design, protocol, extraction form, and the identification of information from two publications selected by DT. The two investigators were given three articles from which to extract data as examples. Following extraction, the pair reconciled all differences. The training session was recorded and listed online for reference (<https://osf.io/tf7nw/>). Prior to extracting data from all studies, these two investigators extracted data from the first 10 publications from their specialty list. Discrepancies were resolved by discussion between the investigators.

Data Extraction

Two investigators (CS, JP) extracted data from the 300 publications in a duplicate and blinded fashion. Following extraction, a final consensus meeting was held by the pair to resolve disagreements. A third investigator (DT) was available for adjudication, but this process was not necessary. A pilot-tested Google form was created based on a study by Hardwicke et al. (2), with additions. This form included the indicators of reproducibility and transparency (<https://osf.io/3nfa5/>) and items related to study characteristics. The extracted data varied according to the study design, with studies that had no empirical data being excluded (e.g., editorials, commentaries [without reanalysis], simulations, news, reviews, and poems). We also expanded the study design options to include cohort, case series, secondary analysis, chart reviews, and cross-sectional studies. Finally, we used the following funding categories: university, hospital, public, private/industry, or nonprofit.

Open Access Availability

We searched Open Access Button (<https://openaccessbutton.org>) to assess whether studies were available by open access. If Open Access Button was unable to access the article, then two investigators (CS, JP) used the publication title and DOI to search Google or PubMed to find whether the full text version was publicly available.

Replication and Evidence Synthesis

We used the Web of Science (<https://www.webofknowledge.com/>) to determine whether the studies composing our sample were replication studies or included in systematic reviews. To do so, we reviewed each publication that had cited the studies included in our sample using Web of Science's citation listing feature. We performed this process in the same manner as data extraction, described previously.

Statistical Analysis

We report descriptive statistics for each category along with 95% confidence intervals (95% CIs) of proportions, calculated using Microsoft Excel.

Results

Sample Characteristics

Our search of the NLM catalog identified 346 journals, with only 158 meeting the inclusion criteria (Figure 1). The median 5-year impact factor for these journals was 3.20 (interquartile range: 2.2-4.2). Our PubMed search returned 407,656 studies initially, and this number was reduced to 90,281 after we applied the date limiter. From these search returns, 300 psychiatry research publications were randomly selected. Four were inaccessible, yielding a final sample size of 296 publications. The majority of the 296 publications had a primary author from the United States (155, 52%), United Kingdom (86, 29%), and the Netherlands (32, 11%). The top three publications types were cohort studies (46, 16%), surveys (45, 15%), and clinical trials (36, 12%). With regard to accessibility, 107 (36%) of the 296 publications were publicly available, whereas the additional 189 publications (64%) were only available behind a paywall. Remaining sample characteristics are displayed in Table 1.

Reproducibility Factors

Factors for reproducibility include the availability of materials, data, protocol, analysis script, and preregistration. Of the 296 publications, 185 were analyzed for a materials availability statement, and 211 were analyzed for a data availability, protocol availability, analysis script availability statement, and preregistration statement (Figure 1). These differences were the result of excluding particular study designs from certain analyses, such as excluding case studies from preregistration. Of the 185 publications analyzed for a materials availability statement, 22 (12% [95% CI, 8.2%-16%]) had a materials availability statement, yet only 17 provided an accessible materials document (Table 2). Only 14 (6.6% [95% CI, 3.8%-6.6%]) of the 211 publications provided a data availability statement, with one study including all the raw data necessary to reproduce its findings. Only 4 of the 211 publications (1.9% [95% CI, 0.4%-3.4%]) provided a protocol availability statement, and a single publication (0.47% [95% CI, 0%-1.3%]) contained an analysis script statement that was available upon request (Table 2). Of the

211 publications for which preregistration was analyzed, only 13 (6.2% [95% CI, 3.4%-8.9%]) included a statement that the study was registered in publicly accessible repositories (Table 2). All 13 publications were accessible; four (31% [95% CI, 26%-36%]) included their hypothesis, 10 (77% [95% CI, 72%-82%]) included their methods, and eight (62% [95% CI, 56%-67%]) included their analysis plan.

Conflict of Interest and Funding

All 296 publications were included in the conflict of interest and funding source analysis (Figure 1). Of these studies, 177 (60% [95% CI, 41%-69%]) included a conflict of interest statement, with 10% reporting a conflict of interest. With regard to funding, 185 (63% [95% CI, 43%-82%]) of the 296 articles had a funding statement. Of the 296 publications, 153 (52% [95% CI, 36%-68%]) were funded and 32 (11% [95% CI, 7.3%-14%]) did not receive funding. The majority (72, 24%) of funding came from public sources. Additional results are presented in Table 2.

Replication and Evidence Synthesis

Of the 296 publications, 211 were analyzed for being a replication study, and 201 were analyzed to determine how many had been cited in a meta-analysis or systematic review (Figure 1). Four (1.9% [95% CI, 0.4%-3.4%]) were identified as a replication study, and 82 (41% [95% CI, 30%-51%]) were cited in at least one systematic review or meta-analysis (Table 2).

Discussion

Our results demonstrate that the majority of publications within psychiatry literature lack the necessary materials, raw data, and detailed protocols to be easily reproducible. These findings are concerning, given the critical need for reproducible and transparent scientific research. In this section, we outline a few of the issues causing concern and offer suggestions to improve the current situation.

To begin, we found that only 13 publications had a statement about preregistration. Preregistration allows for independent evaluation of the consistency between the registered plan and what was actually performed in the study. Selective reporting bias—upgrading, downgrading, removing, or adding study outcomes based on statistically significant findings—is particularly problematic. Comparisons between preregistration documents and published reports enable independent researchers to determine whether this form of bias has likely occurred. Multiple studies indicate that selective reporting bias is a pervasive problem in the medical literature (12-16) including psychotherapy trials (17). Scott et al. evaluated selective outcome reporting of clinical trials published in *The American Journal of Psychiatry*, *Archives of General Psychiatry/JAMA Psychiatry*, *Biological Psychiatry*, *Journal of the American Academy of Child and Adolescent Psychiatry*, and *The Journal of Clinical Psychiatry* (18). They found that 28% of trials in their sample showed evidence of selective outcome reporting. As another example, the COMPare project was designed to evaluate all trials published in prestigious general medical journals. After completing evaluations for selective outcome reporting, members of the project drafted letters to the editor requesting clarification for discrepant endpoints. To date, they have identified 354 outcomes that were not reported and 357 outcomes that were silently added across 67 trials (19). To address this type of problem, stricter adherence to preregistration is needed. For example, although the Food and Drug Administration Amendments Act codified into law that all applicable clinical trials should be prospectively registered before trial commencement, penalties for non-compliant investigators have never been enacted (20). Given that this safeguard is already in place, greater enforcement is likely a viable first step toward improvement. The ICMJE mandates that ICMJE-endorsing journals require prospective trial registration as a precondition for publication for all clinical trials (21). However, studies have found that journals do not always enforce registration policies (22). Given that journals are gatekeepers of scientific knowledge and advancement, we advocate for journals adopting mechanisms to enforce their policies. Additional training is also warranted for junior researchers and students who may not be aware of the inherent issues involved in the failure to preregister studies. Responsible conduct of research courses are required for trainees participating in fellowships and training programs funded by the National Institutes

of Health. For more established faculty, universities offer modules related to research ethics, human participant protections, data management, informed consent, and anonymity. Such courses could likely incorporate training into issues involving preregistration, transparency, and reproducibility. Academic conferences offer a potential avenue for training of all parties regarding open research practices.

Transparency of the methodological process, data collection, and data analyses increases the credibility of study findings (8). Thus, access to the complete protocols and materials used to perform a study is imperative for replication attempts. This need is illustrated by the Reproducibility Project in Cancer Biology, which attempted to reproduce 50 landmark studies after concerns were raised by two drug companies regarding replication of cancer study findings (23). Replication of 32 of the 50 studies was abandoned, in large part because methodological details were not available from the original researchers in these published papers (5). In addition, a review of 441 biomedical publications from 2000 to 2014 found that only one study provided a full protocol, and none made all of their raw data available (24). Given the significant deficiency of materials availability in psychiatry, looking to other fields to garner ideas would be wise. For example, the *American Journal of Political Science* requires authors of manuscripts accepted for publication to provide sufficient materials to enable other researchers to verify all analytic results reported in the narrative and supporting documents (25). Furthermore, this journal requires the materials of the final draft manuscript to be verified to confirm that the analytic results are reproducible for each study. In this process, both the quantitative and qualitative analyses have verification processes conducted at universities. Following verification, the university staff release the final data for public access, and then final publication can occur.

Our study has both strengths and limitations. With regard to strengths, this study included a random sample of the psychiatry literature from a large selection of journals. We used extensive training to ensure interrater reliability between investigators. Data were extracted in duplicate and blinded fashion with joint reconciliation to minimize human error. This double data extraction methodology is the gold standard in

systematic reviews and is recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* (26). Furthermore, all relevant study materials have been made available to ensure transparency and reproducibility. Regarding limitations, we acknowledge that although our sample size was 50% greater than that of Hardwicke et al. (2), it still only represents a small fraction of the published literature. In addition, the current indicators of reproducibility and transparency have not been completely established. We used factors previously identified in social sciences and applied them to psychiatry. Our study findings should also be interpreted in light of our sample, which included only MEDLINE-indexed journals and studies published during a set time period. Differences in indicators might exist in other journals or outside this timeframe.

In conclusion, we stress the importance of adopting transparent and reproducible practices in research. Certainly, if the public lacks trust in science, it could evolve into a lack of trust in clinical practices (27). Lack of transparency is not an unknown issue (1), but when faced with change, we must reform our current practices. This study presents a reference point for the state of reproducibility and transparency in psychiatry literature and future assessments are recommended to evaluate progress.

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Figure 1. Prisma Diagram of Article Selection:

Table 1. Publication Characteristics

Characteristic		Variables	
		N (%)	95% CI
Test Subjects (N=296)	Animals	5 (1.69)	—
	Humans	189 (63.85)	—
	Both	0 (0)	—
	Neither	102 (34.46)	—
Country of journal publication (N=296)	United States	130 (43.92)	—
	UK	19 (6.42)	—
	Australia	16 (5.41)	—
	Netherlands	15 (5.07)	—
	Germany	15 (5.07)	—
	Canada	12 (4.05)	—
	China	11 (3.72)	—
	Italy	8 (2.7)	—
	France	6 (2.03)	—
	Spain	5 (1.69)	—
	Portugal	5 (1.69)	—
	Israel	5 (1.69)	—
	Brazil	5 (1.69)	—
	Unclear	3 (1.01)	—
	Other	41 (13.85)	—
Country of corresponding author (N=296)	United States	155 (52.36)	—
	UK	86 (29.05)	—
	Netherlands	32 (10.81)	—
	Ireland	8 (2.7)	—
	Germany	5 (1.69)	—
	Switzerland	3 (1.01)	—
	France	3 (1.01)	—
	Canada	1 (0.34)	—
	Brazil	1 (0.34)	—
	Australia	1 (0.34)	—
	Unclear	1 (0.34)	—
Open Access (N=296)	Yes found via Open Access Button	95 (32.1)	26.8-37.4
	Yes found article via other means	12 (4.1)	1.8-6.3

	Could not access through paywall	189 (63.9)	58.4-69.3
5 Year Impact Factor (N=296)	Median	3.2	—
	1st quartile	2.2	—
	3rd quartile	4.2	—
	Interquartile range	2.2-4.2	—
Most Recent Impact Factor Year (N=296)	2014	0	—
	2015	0	—
	2016	0	—
	2017	270	—
	2018	0	—
	Other	30	—
Most Recent Impact Factor (N=296)	Median	3	—
	1st quartile	1.9	—
	3rd quartile	4	—
	Interquartile range	1.9-4.0	—
Abbreviations: CI, Confidence Interval.			

Table 2. Characteristics of Reproducibility in Psychiatry Studies

Characteristics		Variables	
		N (%)	95% CI
Funding† (N=296)	University	14 (4.73)	—
	Hospital	2 (0.68)	—
	Public	72 (24.3)	—
	Private/Industry	16 (5.41)	—
	Non-profit	3 (1.01)	—
	Mixed	46 (15.54)	—
	No statement listed	111 (37.5)	—
	No funding received	32 (10.81)	—
Conflict of Interest statement (N=296)	Statement, one or more conflicts of interest	31 (10.47)	7-13.9
	Statement, no conflict of interest	146 (49.32)	43.7-55
	No conflict of interest statement	119 (40.2)	34.7-45.8
Data Availability (N=211)	Statement, some data are available	14 (6.64)	3.8-6.6
	Statement, data are not available	0 (0)	0-0
	No data availability statement	197 (93.36)	90.5-93.4
Material Availability (N=185)	Statement, some materials are available	22 (11.89)	8.2-15.6
	Statement, materials are not available	0 (0)	0-0
	No materials availability statement	163 (88.11)	84.4-91.8
Protocol Available (N=211)	Full Protocol	4 (1.90)	0.4-3.4
	No Protocol	207 (98.10)	96.6-99.6
Analysis Scripts (N=211)	Statement, some analysis scripts area available	1 (0.47)	0-1.3
	Statement, analysis scripts are not available	0 (0)	0-0
	No analysis script availability statement	210 (99.53)	98.7-100
Replication Studies (N=211)	Reports a replication or novel study	4 (1.90)	0.4-3.4
	Does not report replication or novel study	207 (98.10)	96.6-99.6

Cited by Meta-Analysis or Systematic Review§ (N=185)	No Citations	119 (59.20)	53.6-64.8
	A Single Citation	39 (19.40)	14.9-23.9
	One to Five Citations	39 (19.40)	14.9-23.9
	Greater than Five Citations	4 (2.00)	0.4-3.6
Pre-registration (N=211)	Statement, says was pre-registration	13 (6.16)	3.4-8.9
	Statement, was not pre-registration	0 (0)	0-0
	No, there is no pre-registration statement	198 (93.84)	91.1-96.6
Abbreviations: CI, Confidence Interval. † - Some studies included multiple funding sources. § - No studies were explicitly excluded from the systematic reviews that cited the original article.			

Supplemental Table A: Additional Reproducibility Characteristics

Characteristics		Variables
		No. (%)
Type of Study	No empirical	69 (23.3)
	Meta-analysis	26 (8.8)
	Commentary	0 (0)
	Cost effectiveness	0 (0)
	Clinical Trial	36 (12.2)
	Case Study	7 (2.4)
	Case Series	9 (3.0)
	Cohort	46 (15.5)
	Retrospective	0 (0)
	Case Control	32 (10.8)
	Survey	45 (15.2)
	Laboratory	8 (2.7)
	Multiple	2 (0.7)
	Other	16 (5.4)
Material availability	Personal or institutional	4
	Supplementary information hosted by the journal	3
	Online third party	12
	Upon request	3
	Yes, material was accessible	17
	No, material was not accessible	5
Data availability	A personal or institutional webpage	1
	Supplementary information hosted by the journal	2
	An online third party repository (e.g., OSF, Figshare, etc.)	0
	Upon request	6
	Other	5
	Yes, data could be accessed and downloaded	2
	No, data could not be accessed and downloaded	12
	Yes, data files were clearly documented	2
	No, data files were not clearly documented	0
	Yes, data files contain all raw data	1
	No, data files do not contain all raw data	1
	Unclear if all raw data was available	0
Pre-registration	Pre-registered on <i>ClinicalTrials.gov</i>	7

	Pre-registered on Open Science Framework	1
	Other	5
	Yes, pre-registration was accessible	13
	No, pre-registration was not accessible	0
	Hypothesis was pre-registered	4
	Methods were pre-registered	10
	Analysis plan was pre-registered	8
Protocol	Hypothesis was included in the protocol	2
	Methods were included in the protocol	4
	Analysis plan was included in the protocol	4

Supplemental Table B: Factors Analyzed. The factors examined in each article were based upon study type. Further details about extraction and coding is available at: <https://osf.io/x24n3/>

Reproducibility Factors		Impact on research transparency and reproducibility.
Articles		
Is the publication accessible publicly or only through a paywall?	All studies (n=300)	Open access to publications can improve reproducibility by increasing the occurrence of replication studies, collaboration, and universal access to current findings.
Funding		
Does the publication indicate a funding source or lack of one?	All included studies (n=296)	Funding sources have an influence on the roles and practices of the investigators.
Conflict of Interest		
Does the publication indicate a conflict of interest or lack of one?	All included studies (n=296)	Statements disclosing conflict of interest or funding allow the investigators to disclose or deny potential bias. Transparency of all possible conflicts of interest or funding sources promotes the validity and reliability of findings. .
Evidence synthesis		
Has the article been cited by a systematic review or meta-analysis?	Empirical studies † (n=201)	Citing of published studies in systematic reviews and meta-analyses is used to incorporate multiple publications and produce new assessments.
Protocols		
Does the publication state whether it includes an availability statement or not?	Empirical studies § (n=211)	Access to a comprehensive, detailed protocol is essential for accurate replication of a study.
Which components does the protocol contain?		
Materials		
Does the publication state whether it includes a materials statement or not?	Empirical studies ¶ (n=185)	Lack of access to materials inhibits the quality and accuracy of a replication study.
Does the publication state how to retrieve an available materials statement?		
Can these materials actually be accessed?		
Raw data		
Does the publication include a data availability statement?	Empirical studies § (n=211)	The sharing of raw data allows for more accountability and increases the quality and efficiency of the replication.
How can the data be retrieved (e.g., upon request or via online repository)?		

Can the data be accessed?		
Does the data include all the raw data necessary?		
Is the data file clearly documented?		
Analysis scripts		
Are the analysis scripts availability stated?	Empirical studies§ (n=211)	Analysis scripts contains a step-by-step of instructions needed to perform precise analyses, particularly via computer code such as Python or R, allowing a more accurate replication of the data analysis.
How can the analysis script be retrieved (e.g., upon request or via online repository)?		
Are the scripts accessible?		
Pre-registration		
Does the publication include a pre-registration statement?	Empirical studies§ (n=211)	Pre-registration limits reporting bias, including outcome switching and P-hacking.
Which registry did the publication use?		
Is it possible to access the pre-registration?		
What content was available in the pre-registration?		
†: ‘Empirical studies’ encompass the following study designs: cohort, case series, case reports, case-control, secondary analysis, chart review, commentaries [with data analysis], laboratory, and cross-sectional study designs, clinical trial.		
§: Includes empirical studies without case reports and case series		
¶: Includes empirical studies with case reports, case series, meta-analysis or systematic review, and commentaries with analysis		