Adding Standards and Procedures to the Prevention Services Clearinghouse Handbook on the Transparency, Openness, and Reproducibility of Research on Programs and Services to Enhance Support for Children and Families and Prevent Foster Care Placements

Sean Grant,¹ Evan Mayo-Wilson,² Lauren Supplee³

¹ Indiana University Richard M. Fairbanks School of Public Health, Indianapolis, IN, USA.

² Indiana University School of Public Health-Bloomington, Bloomington, IN, USA.

³ William T. Grant Foundation, New York, NY, USA.

Corresponding Author: Sean Grant, Department of Social & Behavioral Sciences, Richard M. Fairbanks School of Public Health, Indiana University, 1050 Wishard Blvd, Indianapolis, IN 46202, USA. Phone: +1-317-274-3245. Email: spgrant@iu.edu.

Submitted in response to: Administration for Children and Families, U.S. Department of Health and Human Services. (2021). Title IV-E Prevention Services Clearinghouse Handbook of Standards and Procedures. *Federal Register*, 86(133), 37332- 37334.

Adding Standards and Procedures to the Prevention Services Clearinghouse Handbook on the Transparency, Openness, and Reproducibility of Research on Programs and Services to Enhance Support for Children and Families and Prevent Foster Care Placements

The credibility of Prevention Services Clearinghouse designations of programs and services as “promising,” “supported,” and “well supported” are threatened by the prevalence of questionable research practices (e.g., selective non-reporting of results) in the bodies of evidence that the Clearinghouse reviews. Internationally accepted standards for reporting and interpreting the results of systematic reviews of evidence—including the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Grading of Recommendations Assessment, Development and Evaluation (GRADE)—recommend that reviews take steps to mitigate bias associated with these questionable research practices. Moreover, Department of Health and Human Services (HHS) policies require that contractors and grantees engage in transparent, open, and reproducible research. We propose that the Clearinghouse adopt standards to mitigate the effects of these questionable research practices, which would be consistent with international guidelines and with complementary HHS policies and procedures.

Importance of Open Science to the Mission of the Prevention Services Clearinghouse

The Clearinghouse systematic review of evidence relies on published research literature and information obtained through contacting study authors. Unfortunately, published reports often do not provide all of the information needed by the Clearinghouse to assess the relevance and quality of an impact study, nor to provide Clearinghouse users with sufficient detail to select the best programs and services for state and/or local needs. Moreover, publication bias, selective outcome reporting, p-hacking, statistical errors, and other questionable research practices threaten the credibility of information on intervention effects reported in the research literature.

In response to these concerns, intervention researchers are increasingly expected to use open science practices such as: registering studies; sharing protocols and analysis plans; sharing data, analytic methods (statistical code), and other research materials; and reporting and disclosing all study methods and findings. These practices facilitate the detection and prevention of questionable research practices that threaten the credibility of the research literature. Such practices also benefit the Clearinghouse because they facilitate access to and synthesis of information on existing research without requiring the Clearinghouse to conduct extensive author contact. In other words, a prevention research literature that is transparent, open, and reproducible would enable better identification of studies eligible for the Clearinghouse, more detailed summaries of research on programs and services, and more reliable ratings for programs and services. Thus, we propose that considerations of open science practices should be integrated explicitly throughout the Title IV-E Prevention Services Clearinghouse Handbook of Standards and Procedures.

Open Science Practices within the Department of Health and Human Services

The federal Department of Health and Human Services has been a leader in codifying and requiring open science practices. The Food and Drug Administration Modernization Act of 1997 led the way for requirements on registering trials and the creation of [clinicaltrials.gov](https://www.fda.gov/clinicaltrials) (<https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-modernization-act-fdama-1997>). Later, the Food and Drug Administration Amendments Act of 2007 (FDAAA) required that many trials of regulated products report results on [clinicaltrials.gov](https://www.fda.gov/clinicaltrials) (<https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007>). Alongside the Final Rule that implemented the FDAAA requirements on clinical trials registration and results information submission (<https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>), the National Institutes of Health (NIH) adopted a policy requiring all trials funded by NIH to register prospectively and to report results on [clinicaltrials.gov](https://www.fda.gov/clinicaltrials).

In addition to these efforts, the Office of Planning, Research and Evaluation (OPRE) has demonstrated support for open science practices through multiple avenues. First, the majority of the funding distributed for research and evaluation at OPRE is through contracts. In the standard contract language, the office requires projects to prospectively register studies, archive data (when appropriate), publicly share measures and analysis plans through the Paperwork Reduction Act process, share all results on public reports, and declare conflicts of interest on research teams. Second, OPRE focused on Promoting Open Science in Social Policy Research for a recent annual methods meeting (<https://opremethodsmeeting.org/meetings/2019/>), sending a clear signal to the social policy research and evaluation community on the importance of the

topic. Lastly, in response to our TRUST Initiative comment on 85 FR 47376, the Home Visiting Evidence of Effectiveness (HomVEE) Reporting Guide for Authors recently added recommendations for authors to clearly indicate details related to eight open science practices (see Table 5: https://homvee.acf.hhs.gov/sites/default/files/2020-12/HomVEE_Reporting_Guide.pdf). Given this broader support and acknowledgement of the importance of open science, we believe that encouraging (if not requiring) open science practices is crucial for high-stakes reviews such as those conducted by the Clearinghouse.

TOP Guidelines for Evidence Clearinghouses

Based on the Transparency and Openness Promotion (TOP) Guidelines—which have been endorsed by thousands of journals publishers and societies (<https://www.cos.io/top>)—we have identified a set of open science practices for clearinghouses to consider as part of their reviews of evidence (see Table 1). We believe that the Clearinghouse has a strong rationale to consider each of these practices, and we note where the Clearinghouse is already doing so:

- **Study Registration**: To ensure that all relevant studies can be identified by the Clearinghouse, studies should be included in a structured, web-based, publicly accessible registry (e.g., ClinicalTrials.gov, other registries on the International Clinical Trials Registry Platform, the Society for Research on Educational Effectiveness' Registry of Efficacy and Effectiveness Studies, the American Economic Association's registry for randomized trials).
 - When there are more than 15 eligible studies for an intervention, the Clearinghouse currently assigns points in a manner that prioritizes studies that have been registered.
- **Protocol and Statistical Analysis Plan**: To prevent program and service designations from being based on false-positive results, study methods and analytical procedures should be established prior to starting data collection.
 - When there are more than 15 eligible studies for an intervention, the Clearinghouse currently assigns points that prioritize studies with published study protocols. We did not identify any policies, procedures, or practices related to statistical analysis plans.
- **Data, Code, and Materials Sharing**: Data, code, and research materials should be made publicly available to ensure that the Clearinghouse and other stakeholders can reproduce study results and use these products in subsequent research.
 - We did not identify any standards or procedures for data, code, and materials sharing.

- Design and Analysis Transparency: To ensure that the Clearinghouse can assess risk of bias and the applicability of eligible studies, study methods and results should be reported according to discipline- and design-specific standards.
 - The Clearinghouse recently has developed a Reporting Guide for Study Authors.
- Public Availability of Results: To ensure that all eligible results can be included in the Clearinghouse, and that Clearinghouse conclusions and transparent and verifiable, summary information on study outcomes should be freely available to the public.
 - The Clearinghouse currently shares outcome-level data using a standardized, tabular format for each intervention entry on its website.
- Replication: To mitigate the effects of reporting bias on program and service designations, and to demonstrate that conclusions are reproducible, original studies showing beneficial effects should be repeated on new analytic samples.
 - The Clearinghouse requires at least two studies for a “well-supported” rating.
- Investigator Conflicts of Interest: To allow Clearinghouse users to evaluate investigator conflicts of interest, study reports should include declarations of interest that could influence the validity of research.
 - We did not identify any standards or procedures for investigator conflicts of interest.
- Citation Standards: To allow the Clearinghouse to validate the results of studies based on previously collected information, data, code, and research materials should be cited appropriately in the references section of reports.
 - We did not identify any standards or procedures for citation standards on data, code, or research materials.

Proposed Standards and Procedures on Open Science for the Clearinghouse Handbook

While we appreciate that the Clearinghouse does not have direct control over researcher behavior, the Clearinghouse Handbook of Standards and Procedures likely will influence how prevention researchers design future impact studies. **At a minimum, we recommend that the Clearinghouse document the use of open science practices in studies on programs and services to move future research in the field toward greater transparency, openness, and reproducibility.** That said, certain open science practices may already be ready for more stringent requirements. As such, we propose three ways (of increasing stringency) in which the Clearinghouse could integrate each open science practice into their evidence review process:

1. Collect data on and report whether intervention evaluations used open science practices (e.g., through the use of Open Science Badges);
2. Include open science practices in standards of evidence related to ratings of programs and services; and
3. Verify that evaluations used open science practices for study eligibility or model designation of “well-supported” (e.g., for studies initiated after a future date, to be specified by the Clearinghouse).

We provide recommendations below on how these open science practices can be considered at specific steps of the Prevention Services Clearinghouse systematic review process:

- Reporting Guide for Study Authors: The Clearinghouse should **update its Reporting Guide for Study Authors to include recommendations on open science practices** (see Table 5: https://homvee.acf.hhs.gov/sites/default/files/2020-12/HomVEE_Reporting_Guide_.pdf).
- Select and Prioritize Programs and Services: The Clearinghouse should **prioritize the inclusion of programs and services with open access books, manuals, implementation**

resources, or other documentation available at no cost to program adopters.

- Literature Search: The Clearinghouse should consider **adding study registers (e.g. ClinicalTrials.gov) and preprint servers (e.g., <https://osf.io/preprints/>) to its search strategy** as their use becomes more common by evaluators of social programs and services.
- Study Eligibility Screening and Prioritization: As it does with study registration and protocol sharing, the Clearinghouse should **include additional open science practices in its study review prioritization criteria**. Namely, the Clearinghouse should consider whether there is (1) a registered analysis plan; (2) publicly available data; (3) publicly available code; (4) publicly available research materials; (5) publicly available summary results (e.g., in a registry like ClinicalTrials.gov); (6) a completed checklist for an appropriate reporting guideline (e.g., CONSORT-SPI); (7) an investigator conflicts of interest statement; and (8) citations to data, code, and materials in the references section.
- Evidence Review: The Clearinghouse should **use open science practices when determining the design and execution ratings** for each contrast in eligible studies. The below suggestions could influence the rating itself (high, moderate, low), or could be a separate output or “badge” (<https://www.cos.io/our-services/badges>) reported alongside the rating.
 - First, to combat concerns about selective outcome reporting, the Clearinghouse should always **compare the reported analysis for a finding with the study registration, protocol, and/or statistical analysis plan** to see (a) if the analysis was prospectively registered and, if it was prospectively registered, (b) whether the reported analysis matches the pre-registered analysis.
 - Second, to combat concerns about errors in the reported result, the Clearinghouse should **use the underlying data and code to attempt to computationally reproduce the**

reported findings (<https://bitss.github.io/ACRE/>).

- Program or Service Ratings: The Clearinghouse should **use open science practices as part of the process of translating design and execution ratings from one or more studies of a program or service into ratings for that program or service**. Designations of programs and services as “well-supported” have the greatest credibility when the evidence base underpinning that rating consists of **pre-registered analyses that are computationally reproducible and have been replicated in a second sample**. As we understand that the language for “well-supported” in The Family First Prevention Services Act is unmalleable, we recommend the Clearinghouse to consider piloting (or examining the impact of) the following adjustments to these criteria:

- At least one of the studies described in sub-clause (I) demonstrates favorable impacts using **prospectively-registered, computationally-reproducible analyses**.
- Both of the studies described in sub-clause (I) report **prospectively-registered, computationally-reproducible analyses with favorable impacts that replicate across both of studies**.

- Procedures for Reviewing Programs and Services: The Clearinghouse should **report information on its website about the use of open science practices by studies reviewed**.

Specific recommendations include reporting whether:

- The study was registered, including whether it was registered prospectively
- The analysis plan was registered, including whether it was registered prospectively
- The study protocol is publicly available
- The study manuscript adheres to an appropriate reporting guideline
- Data, code, and research materials are publicly available

- Data, code, and research materials are cited in manuscript references sections
- Each study included an investigator conflict of interest statement
- A study is a replication of a previous study
- The analysis underpinning a finding from moderate- and high-rated manuscripts:
 - Match a pre-registered outcome and analysis
 - Are computationally reproducible using the underlying data and code
- An open access manuscript is available for each study
- The program or service has an open access book, manual, implementation resource, or other documentation at no cost to program adopters

Follow-up Discussions

We write as members of the Transparency of Research Underpinning Social intervention Tiers (TRUST) Initiative, which aims to increase the transparency of social intervention research used to support evidence-based policy-making (<https://www.trustinitiative.org/>). We would be delighted to further discuss open science with the Clearinghouse, and to assist with any piloting or implementation of our current proposals.

Sincerely,

Sean Grant, Indiana University Richard M. Fairbanks School of Public Health—Indianapolis

Evan Mayo-Wilson, Indiana University School of Public Health—Bloomington

Lauren H. Supplee, William T. Grant Foundation

Transparency of Research Underpinning Social Intervention Tiers (TRUST) Initiative

<https://www.trustinitiative.org/>

Table 1. Proposed implementation of Transparency and Openness Promotion Guidelines by evidence clearinghouses

Practice	Definition	Levels of implementation (from least to most effort)
Study Registration	Studies should be included in a structured, web-based, publicly accessible registry	<ol style="list-style-type: none"> 1. Report whether studies were registered, and whether they were registered completely and prospectively 2. Rating is influenced by study registration status (e.g., prospective registration improves intervention rating) 3. Verify complete, prospective study registration (e.g., confirm all registered outcomes are reported as registered, or deviations are adequately described, to obtain “well-supported” rating)
Protocol and Analysis Plan Registration	Study methods and analytical procedures should be established prior to starting data collection	<ol style="list-style-type: none"> 1. Report whether studies publicly shared a protocol and registered their analysis plan 2. Rating is influenced by protocol and analysis plan sharing (e.g., publishing a protocol or analysis plan improves intervention rating) 3. Verify quality of protocol sharing and analysis plan (e.g., confirm protocols and analysis plans match study reports, or deviations are adequately described to obtain “well-supported” rating)
Data, Code, and Materials Sharing	Data, code, and research materials should be made publicly available	<ol style="list-style-type: none"> 1. Report whether data, code, and research materials are publicly available (e.g., provide links to data, code, and materials if available) 2. Rating is influenced by data, code, and materials sharing (e.g., sharing in trusted repositories improves intervention rating) 3. Verify findings by reproducing the results using data, code, and materials (e.g., verification required to obtain “well-supported” rating)
Design and Analysis Transparency	Study methods should be reported according to discipline- and design-specific standards	<ol style="list-style-type: none"> 1. Report whether study reports adhered to reporting guidelines (e.g., articles include completed CONSORT-SPI checklist) 2. Rating is influenced by adherence to reporting guidelines (e.g., recommended information improves intervention rating) 3. Verify study reports contain minimum recommended information (e.g., confirm information is present to obtain “well-supported” rating)

Practice	Definition	Levels of implementation (from least to most effort)
Public Availability of Results	Summary information on study outcomes should freely available to the public	<ol style="list-style-type: none"> 1. Report whether study results are publicly available in a database using a standardized, tabular format 2. Rating is influenced by public availability of results (e.g., entry in ClinicalTrials.gov results database improves intervention rating) 3. Verify all study results are publicly available (e.g., confirm whether all results included in ratings are in the ClinicalTrials.gov results database to obtain “well-supported” rating)
Replication	Original studies showing beneficial effects should be repeated on a new sample	<ol style="list-style-type: none"> 1. Report whether favorable intervention effects were replicated with non-overlapping samples 2. Rating is influenced by replication of intervention effects (e.g., an independent replication improves intervention rating) 3. Verify replication of effects (e.g., confirm consistency through systematic reviews and meta-analyses to obtain “well-supported” rating)
Investigator Conflicts of Interest	Interests that could influence the validity of research should be declared in study reports	<ol style="list-style-type: none"> 1. Report whether study investigators had conflicts of interest 2. Rating is influenced by investigator conflicts of interest (e.g., declarations of interest improve intervention rating) 3. Verify all conflicts of interest are declared (e.g., confirm information required by ICMJE Disclosure Forms is declared to obtain “well-supported” rating)
Citation Standards	Data, code, and research materials should be cited appropriately in references section of reports	<ol style="list-style-type: none"> 1. Report whether studies cited the data, code, and research materials used to produce their results 2. Rating is influenced by data, code, and research material citations (e.g., appropriate citations improve intervention rating) 3. Verify adequate data, code, and material citations (e.g., confirm that DOIs and URLs lead to these items to obtain “well-supported” rating)

Source: Mayo-Wilson, E., Grant, S. & Supplee, L.H. (2021). Clearinghouse standards of evidence on the transparency, openness, and reproducibility of intervention evaluations. *Prevention Science*. doi: 10.1007/s11121-021-01284-x. Retrieval from: <https://link.springer.com/article/10.1007/s11121-021-01284-x>