Supplemental Project To Assess the Transparency of Reporting for Strategies To Improve Mental Health Care for Children and Adolescents



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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by e-mail to epc@ahrq.hhs.gov.

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Background and Objectives for the Systematic Review

The RTI International—University of North Carolina Evidence-based Practice Center (RTI-UNC EPC) used an ongoing review, *Strategies to Improve Mental Health Care for Children and Adolescents* (SIMHC), to generate a report on the additional information gained by including data from clinicaltrials.gov. The purpose of the report was to summarize the evidence on strategies to improve mental health for children, through quality improvement (QI) strategies and interventions with proven effectiveness (e.g., evidence-based practices [EBPs]). The rationale for the topic was to understand how to bridge the gap between observed and achievable processes and outcomes, through strategies that target changes in the organization and delivery of mental health services

Conducting a supplemental transparency project on this review afforded an opportunity to explore additional sources of information on the included strategies, which are generally complex, systems-focused, and underreported. To achieve this goal, we explored the differences between information from published and unpublished sources included in the review and clinicaltrial.gov.

In addition to this primary goal, we had three additional goals. First, we wanted to understand the state of reporting and reporting requirements on a topic of increasing importance: quality improvement (QI), implementation, and dissemination. Despite advances in the evidence base about interventions for treating mental health conditions in children, national health outcomes remain suboptimal, in part because of the failure of systems and providers to adopt QI strategies and interventions with proven efficacy. Given the gap between observed and achievable processes and outcomes, the next critical step is the adoption of effective QI strategies and the development of strategies to implement or disseminate effective interventions. ¹⁻³ These strategies are complex and may include multiple components, caregivers, or systems. Closing the gap requires more information on not just outcomes of these complex interventions: it requires information on study conduct and processes to allow interpretation of results, assessment of their applicability, and enable scale-up. To achieve this goal, we reached out to authors to understand the utility of clinicaltrials.gov and other archives (e.g., the World Health Organization [WHO] International Clinical Trials Registry and NIHReporter) for information on implementation processes.

Second, we wanted to investigate reporting shortcomings for complex study designs, such as cluster randomized controlled trials (cRCTs). cRCTs require advanced analytic methods (hierarchical linear modeling, for example) that account for clustering at each level of recruitment. To date, our investigation has revealed that a substantial proportion of the included studies in the SIMHC review use cRCTs (10 cRCTs of 17⁴⁻²⁰ included studies). However, the published data on these trials have been woefully inadequate and do always not permit an independent assessment of the effects of the intervention. These inadequacies hinder not only higher order analyses, such as risk of bias assessment, but also basic calculations of effect size and precision because of poor reporting of retention at the multiple levels of recruitment in a cRCT. To achieve this goal, we sought information from clinicaltrials gov on more design details, and when they were not available, seek to understand the impediments to reporting through outreach to study authors.

Third, we wanted to understand whether impediments to publication for pragmatic trials and systems interventions exist and if so, why. As noted above, we sought to understand the impediments to publication through outreach to study authors.

Key Questions

Our key questions (KQ) focus on the utility of clinicaltrials.gov for the systematic review. We also explored the additional issues (described above) that are specific to this review, complex interventions and study designs:

- 1. Which studies were in the EPC report alone, clinicaltrials.gov alone or in both?
- 2. For completed studies that were in both sources:
 - a. What were the differences, if any, in pre-specified outcome measures, statistical plan and size of the study reported, retention, study conduct, and other details of study design in the peer reviewed literature vs. clinicaltrials.gov?
 - b. Were results reported in clinicaltrials.gov for any of the studies? If they were, what were the differences, if any, in the results reported in the peer reviewed literature vs. clinicaltrials.gov?
- 3. For studies in clinicaltrials.gov that were not completed or discontinued:
 - a. For the discontinued studies, were there reasons given for discontinuation? If so, what were they?
 - b. For studies that are ongoing but not completed, what was the date of initiation of the studies? Are the studies proceeding according to the original schedule or is there information in clinicaltrials.gov indicating a delay in completion? If there is a delay in completion, what is the reason given?
 - c. For studies that are completed but not published, what are the reasons for delay in or lack of publication?
- 4. For included studies with limited or no information on study processes and conduct in clinicaltrials.gov, what, if any, publicly available sources provide or can provide information on implementation processes? What are the constraints to producing and disseminating this information? What is the perceived utility of clinicaltrials.gov as an archive for such information?
- 5. What is the impact on the conclusions of the EPC report with and without the information from clinicaltrials.gov? What would be the impact on the strength of evidence (including impact of knowledge of outcomes measured in studies but not reported in the peer reviewed literature)?

Methods

KQ 1

We updated our searches for SIMHC draft report and then compare the yield with clinicaltrials.gov, using a dual independent review process.

KQ₂

- (a) For studies with information in both peer-reviewed literature and clinicaltrials.gov, we extracted and compared the results, using a dual review process, with a second reviewer checking the first abstractions.
- (b) For studies with differences in reporting by source, we reached out to study authors via email and phone interview, if necessary, to understand the reasons for the differences.

KQ3

- (a) For discontinued studies, we planned to reach out to authors via email to identify reasons for discontinuation.
- (b) For ongoing incomplete studies, we supplemented information in clinicaltrials.gov with additional information from study authors via email.
- (c) For completed and unpublished studies, we planned to reach out to authors of discontinued studies via email to identify reasons for lack of publication

KQ 4

We reached out to authors of included studies on the reasons for use or non-use of clinicaltrials.gov or other archive sites for information on study conduct and processes.

KQ 5

We integrated the information for KQs 1-4, using data from searches; abstraction from clinicaltrials.gov; and email, personal interviews, and any additional information provided by authors. We planned to update the strength of evidence and conclusion of the SIMHC report, if we found relevant results.

Table 1 provides the questions for email or personal interview. These are general questions, to be tailored for each interviewee. We obtained IRB exemption before conducting email interviews. We planned a minimum of two email and two telephone outreach attempts before categorizing investigators as non-responders.

Table 1. Questions for authors of studies identified for the SIMHC report or through clinicaltrials.gov

The RTI-UNC Evidence-based Center is conducting a systematic review of strategies to improve mental health for children and adolescents. In addition, our funder, the Agency for Healthcare Research and Quality, has requested an additional investigation of the validity and reliability of clinicaltrials.gov as a potential additional source of information on study conduct, processes and results. Your study [xxx, has been included/is eligible for inclusion] in this review. We are reaching out to you to obtain some additional details about the reporting of your study. Thank you for agreeing to answer our questions.

[For authors of included clinical trials included in the report that do not have a clinicaltrials.gov listing, N=8^{4, 5, 8, 10, 11, 13-15, 17}]

1. We were unable to find a listing for your study on clinicaltrials.gov. Is the study listed on clinicaltrials.gov?

- If yes, what is the listing number?
- 2. Is the study listed elsewhere on another clinical trials registry? If yes, where and what is the listing number?
- 3. [If the study results are not listed in any clinical trials registry] Did you attempt to list your study in a clinical trials registry? If yes, what barriers did you experience?
- 4. Where can other investigators find supplemental information on your study, such as your experiences with implementing the study or your assessment of critical components necessary for dissemination?
- 5. In abstracting your study, we noted that study arms differed in their use of [list specific components here, tailored for each study]. Which of these elements (or otherwise that we may be unaware of) do you consider to be the critical component(s) of your intervention, for those wishing to replicate your study?

[For authors of clinical trials included in the report that have a listing in clinicaltrials.gov, with no results reported in clinicaltrials.gov at the time of our outreach, N=5^{6, 7, 9, 16, 20}]

- 1. What barriers did you experience or anticipate in presenting your results in a clinical trials registry?
- 2. If other investigators wish to scale up your strategy, where can they find necessary information, for example, on your experience of study conduct and processes or your assessment of critical components?
- 3. What do you consider to be the critical components of your intervention, for those wishing to replicate your study?
- 4. [If such information is not available publicly or in clinicaltrials.gov] What barriers did you experience or anticipate in using a clinical trials registry to make such information available publicly?

[For authors of studies included in the report that are NOT clinical trials, N=4^{4, 12, 18, 19}]

- 1. If other investigators wish to scale up your strategy, where can they find information on your experience of study conduct and processes or your assessment of critical components necessary for dissemination?
- 2. In abstracting your study, we noted that study arms differed in their use of [list specific components here, tailored for each study]. Which of these elements (or otherwise that we may be unaware of) do you consider to be the critical component(s) of your intervention, for those wishing to replicate your study?
- 3. [If such information is not available publicly] Are you aware of public registries for observational or non-randomized studies that might be relevant to your effort? If yes, what are these registries?
- 4. What barriers did you experience or anticipate in using registries to make information on study conduct and processes available publicly?

[For authors of ongoing incomplete studies identified via clinicaltrials.gov, not included in the SIMHC review, N=3]

- 1. We identified your ongoing study through a search of clinicaltrials.gov as potentially meeting our eligibility criteria for inclusion in our SIMHC review. [If clinicaltrials.gov does not provide this information] What is the anticipated date of completion for this study?
- 2. We identified your study through a search of clinicaltrials.gov as potentially meeting our eligibility criteria for inclusion in our SIMHC review. Are there plans to publish the findings? If yes, where will you attempt to publish the material? If no, why not?
- 3. Is there any addition information or data that you could share with us that is not currently included on clincaltrials.gov for this study? [If relevant]
- 4. Your experience of study conduct and processes may be valuable to others attempting a similar strategy. Where can other investigators find such information?
- 5. [If relevant] What barriers did you experience or anticipate in using a clinical trials registry to make such information available publicly?

We also constructed questionnaires in three additional categories but did not find studies in these categories (studies with different results reported in clinicaltrials.gov and published results, eligible discontinued studies identified via clinicaltrials.gov, and complete but unpublished studies identified via clinicaltrials.gov)

Results

Table 2 provides the results of the outreach.

Table 2. Transparency of reporting: summary of results of outreach to study investigators

Author	Available on clinical- trials.gov	on other	on registry		Barriers to presenting information on critical components on registries	Availability of materials for replication	Critical components for replication as identified by study authors
Beidas et al., 2012 ⁵	No	No	NA	Not a traditional clinical trial in that it focused on changing clinician behavior and did not enroll patients; therefore did not attempt to include it on the clinical trials registry.	NA	In existing publications on the trial	Augmented training: focus on principles of treatment and use of experiential learning; the ongoing support and consultation
Bickman et al., 2011 ¹⁶	Yes	No	No	None	Not perceived as necessary because author did not experience barriers in dissemination through routine outlets such as publications and presentations	NA	Feedback
Carroll et al., 2013 ⁶	Yes	NR	Yes	NR	NR	NR	NR
Epstein et al., 2011 ⁷		No	No	clinicaltrials.gov is made for pharmaceutical clinical trials and was very difficult to complete some of the fields for this non-pharmaceutical study. It required an extended call with tech support at clinicaltrials.gov to get results posted correctly.	clinicaltrials.gov	NA	an internet based platform through which parents, teachers, and pediatricians all input information about the target child during initial ADHD assessment and treatment, which then resulted in a report change in office flow
Epstein et al., 2007 ⁸		No	NA	No barriers noted but the authors did not attempt registration because it was not mandated at the start of the trial	NA	Published materials or contact authors	Recruitment of patients from community-based pediatric practices.
Garner et al., 2012 ⁹	Yes	No	No	None given that clinicaltrials.gov automatically indexed publications via the ClinicalTrials.gov Identifier	A study registry could serve as a repository but unclear whether it could be used for this purpose.	None	Financial incentives provided to the staff delivering the intervention

Glisson et No al., 2012 ^{10,}	No	NA	Did not attempt registration so no barriers noted	NA	Publications, website, intervention training materials	The ARC intervention strategies depend on trained specialists who work at all levels of a service system to: (a) embed guiding principles for improving services, (b) develop shared mental models among organizational members to support the improvement effort, and (c) enact organizational tools (e.g., feedback) for identifying and addressing service barriers.
Glisson et No al., 2010 ¹⁷	No	NA	Did not attempt registration so no barriers noted	NA	Publications, website, intervention training materials	The ARC intervention strategies depend on trained specialists who work at all levels of a service system to: (a) embed guiding principles for improving services, (b) develop shared mental models among organizational members to support the improvement effort, and (c) enact organizational tools (e.g., feedback) for identifying and addressing service barriers.
Gully et No al., 2008 ⁴ (study 1)	NR	NR	NR	NR	NR	NR
Gully et No al., 2008 ⁴ (study 2)	NR	NR	NR	NR	NR	NR
Henggeler No et al., 2008 ¹²	NR	NR	NR	NR	NR	NR
Henggeler No et al., 2013 ¹³	NR	NR	NR	NR	NR	NR
Lester et No al., 2009 ¹⁴	NR	NR	NR	NR	NR	NR

Lochman et al., 2009 ¹⁵	No	No	NA	Did not attempt registration so no barriers noted	NA	Contact authors	Audit and feedback components where trainers reviewed the rate of completion of session objectives and provided individualized supervisory feedback
Ronsely et al., 2012 ¹⁹	No	NR	NR	NR	NR	NR	NR
Sterling et al., 2015	No	No	NA	No barriers noted but the authors did not attempt registration because it was not mandated	A registry could be of use if it included very specific protocols to assist people in replicating procedures, either for other studies or for implementation in program settings	NA	Brief training in how to deliver SBIRT in the pediatrician-only arm; embedding a BHCP in the BHCP arm
Wildman et al., 2012 ¹⁸	No	NA	NA	NA	NA	Contact authors	Creating easy referral procedures for primary care providers to use for behavioral health care.

Abbreviations: NA = not applicable; NR = not reported

Proportion of Studies Reported in Clinicaltrials.gov (KQ 1)

We identified 17 studies, reported in 17 articles⁴⁻¹⁹ (including two studies in a single article,⁴ and one study reported in two articles.^{10, 11} Of these, ten are cRCTs,^{6-11, 13-16, 20} three are parallel-group^{4, 5} or two-stage trials,¹⁷ and the remaining four are nonrandomized studies.^{4, 12, 18, 19} Only 4—all cRCTS^{6, 7, 9, 16}—of the 13 trials appeared in a trials registry (clinicaltrials.gov). All other studies (9 trials^{4, 5, 8, 10, 11, 13-15, 17, 20} and 4 nonrandomized studies^{4, 12, 18, 19}) did not appear in a study registry. Additionally, we found three ongoing trials in clinicaltrials.gov that have not yet published results (NCT02097355, NCT01829308, NCT02271386).

Comparing Data Between Clinicaltrials.gov and Published Sources (KQ2)

Three of four studies that had been registered in clinicaltrials.gov did not report results (NCT01308879, 16 NCT01016704, 9 and NCT010560167). One study updated the clinicaltrials.gov registry with results after we sent out a query to the authors (NCT013510646). The results did not differ between the publication and the registry, with one exception. In the publication, the authors present an adjusted odds ratio for the use of structured diagnostic assessments, of 8.0 (95% CI, 1.6 to 40.6). In clinicaltrials.gov, the authors provide raw data rather than adjusted results. Using these data, we calculated an unadjusted odds of 6.9 (95 CI%, 2.6 to 18.6).

Incomplete, Discontinued, or Unpublished Studies (KQ 3)

We reached out to investigators of three ongoing studies (NCT02097355, NCT01829308, and NCT02271386). Two did not note barriers to registering their trials, but a third noted difficulties arising from the required data entry fields in clinicaltrials.gov, which are not designed for implementation trials.

We found no discontinued or unpublished studies.

Utility of Trial Registries for Disseminating Information on Study Outcomes and Processes (KQ 4)

As noted in Table 2, three investigators (lead investigators on two studies and one proxy for two studies with a deceased principal investigator) did not respond to our repeated outreach attempts. A fourth respondent refused because of lack of time and a fifth responded to us but was unable to provide us with information because the principal investigator (lead on two studies) was deceased. Of the remaining ten investigators who completed the questionnaires, six did not attempt to register the study on clinicaltrials.gov and therefore noted no barriers. Three of four respondents who registered their study noted no barriers, with one noting that clinicaltrials.gov automatically indexed publications via the ClinicalTrials.gov Identifier. A fourth noted barriers arising from a mismatch between the nature of the trial and the purpose of clinicaltrials.gov, which was designed for pharmaceutical trials. We asked these four respondents about the utility of adding information on critical components to registries. Two expressed doubts about the utility of clinicaltrials.gov for housing such information, and one did not perceive a need for clinicaltrials.gov to house such information.

Discussion

Impact of Results on EPC Report (KQ 5)

Table 2 lists the critical components of the study, as identified by study authors. As noted previously, a significant constraint in understanding the results of studies of complex interventions is that they frequently involve complex designs and multiple components. Outreach to study investigators can potentially shed light on critical components that are not otherwise identified in the literature. Ideally, this information can be used to cluster and analyze studies in a systematic review to generate insights and effect estimates from the overall body of evidence. Although we were able to update the report with additional information on critical components in the study descriptors table, our efforts did not result in sufficient information to alter the EPC report materially, for a few reasons. First, despite multiple attempts to reach out to investigators, we had a 59 percent completion rate (we received responses for 10 of 17 studies). Second, among those who responded, use of clinicaltrials.gov was very limited. Only one author posted results in clinicaltrials.gov, and those results did not differ substantively from what was otherwise available to us. Third, investigators who responded may have interpreted our questions in varying ways. Fourth, because of the email format of our outreach, we could not ask followup questions.

Utility of Clinicaltrials.gov for Systems Interventions

The limited utility of clinicaltrials.gov for supplementing information in this report arises from three sources. First, clinicaltrials.gov is not designed or a good fit for the types of complex designs typified by implementation, dissemination or quality improvement studies. Authors who attempt to register studies on their own reported difficulties. Second, authors did not generally report findings on clinicaltrials.gov. Third, authors do not perceive a need for using clinicaltrials.gov to house information vital to the next generation of implementation studies on the critical components of their interventions.

Next Steps

Implementation, dissemination, and quality improvement studies such as those covered by this systematic review urgently require substantial documentation of design, processes, and outcomes. Current methods of dissemination simply do not provide sufficient detail at the present time to fully understand or synthesize these strategies and replicate them. As research teams splinter or change trajectories, this information is potentially lost forever (as we inferred from our attempts to reach some authors). At the present time, clinicaltrials.gov does not appear to offer a viable solution to house such information for two reasons: first, the site is not designed for implementation studies and second, authors do not perceive that their audience will seek such information from clinicaltrials.gov. The most viable alternative to enhancing transparency of reporting for these strategies appears to be through journal requirements such as TIDieR. Recent changes to clinicaltrials.gov specifying that eligible clinical trials include an FDA-regulated device product are likely to deter any further reporting of implementation, dissemination, and quality improvement trials, which often do not include such products. 22

In the short term, enhanced searches of clinicaltrials.gov and outreach to authors appear to offer limited utility for systematic reviews of implementation, dissemination, and quality improvement trials. However, as the main body of our report indicates, we found that studies of

related publications ("sibling" studies of the same intervention, or searches of authors of included interventions) can substantially enhance the descriptions and interpretation of studies. These sibling studies are not available, however, for all included studies and cannot serve as comprehensive and universal sources of information. Future systematic reviews of implementation, dissemination, and quality improvement should anticipate using a combination of citation mining of included studies and searches of sibling studies in order to capture all relevant studies.

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