Comparative Effectiveness Research Review Disposition of Comments Report

Research Review Title: *Interventions for Adult Offenders With Serious Mental Illness*

Draft review available for public comment from September 13, 2012 to October11, 2012.

Research Review Citation: Fontanarosa J, Uhl S, Oyesanmi O, Schoelles KM. Interventions for Adult Offenders With Serious Mental Illness. Comparative Effectiveness Review No. 121. (Prepared by the ECRI Institute Evidence-based Practice Center under Contract No. 290-2007-10063-I.) AHRQ Publication No. 13-EHC107-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2013. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Comments to Research Review

The Effective Health Care (EHC) Program encourages the public to participate in the development of its research projects. Each comparative effectiveness research review is posted to the EHC Program Web site in draft form for public comment for a 4-week period. Comments can be submitted via the EHC Program Web site, mail or email. At the conclusion of the public comment period, authors use the commentators' submissions and comments to revise the draft comparative effectiveness research review.

Comments on draft reviews and the authors' responses to the comments are posted for public viewing on the EHC Program Web site approximately 3 months after the final research review is published. Comments are not edited for spelling, grammar, or other content errors. Each comment is listed with the name and affiliation of the commentator, if this information is provided. Commentators are not required to provide their names or affiliations in order to submit suggestions or comments.

The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

Source: http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1644
Published Online: August 21, 2013

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Introduction	b. Introduction: Introduction provided a framework for the importance of the questions being addressed. I liked the delineations of the interventions. Could add a bit more on the policy issues given the intended audience.	Thank you. We clarified throughout the report that it is intended for a broad audience (e.g., patients, clinicians, and, possibly, policy makers).
Peer Reviewer #1	Methods	c. Methods: The inclusion and exclusion criteria are clearly delineated and are justifiable. The search strategies are quite comprehensive, well specified, including all the grey literature sources and all the data bases and the list of search terms used. These all seemed quite appropriate and whenever I thought of a source or term I found that it was listed. The review is extremely comprehensive – although there may be a few omissions which I will note below for which there may be a valid reason for non-inclusion. There is a clear list of outcomes and they are defined operationally in terms of the specific studies included. They did indicate how they assessed the studies under the heading of data synthesis. They did not conduct a meta-analysis, but they did do a good job of justifying the lack of available instruments for synthesizing the evidence due to the methodological problems. As result of a number of methodological issues that are well specified on pages 22-23 of the report they did a narrative review. It would have been helpful if the investigators were more specific as to how this narrative assessment was actually conducted. Was any reliability checks conducted, for example?	As indicated in the report, we conducted a narrative review due to limitations of the available data. Two researchers worked on each of the Key Questions, verifying the data extraction and interpretation of the results. Thank you for your thoughtful review.
Peer Reviewer #1	Results	d. Results: The major findings are clearly stated. The strength of the evidence and the potential bias in the studies were well specified. However, they did not discuss the fidelity of the interventions, high attrition rates, and potential power problems of the studies they did include (extremely high attrition rates were exclusion criteria for studies). Fidelity of interventions are particularly important and for example, the Solomon and Draine study noted that their fidelity to ACT was low. (Also in Solomon & Draine study the report in some places noted subjects were serving 9.5 years and other place 9.5 months – it was 9.5 months – given that it was jail study 9.5 years does not make logical sense). The tables were clear and well delineated. The report provided more of a global assessment of the strengths and weaknesses of the studies rather than much in terms of	We generally do not discuss power problems of individual studies as our goal is to conduct meta-analysis, making individual study sample sizes irrelevant. We did discuss high attrition in this report. For example, on p. 38: “Further, as evidenced by the high attrition rate of patients assigned to the R & R group in the Cullen et al. study, certain treatments may not be easily adaptable to inmates with SMI. The R & R program was originally developed for incarcerated individuals without mental illness. It was adapted for use in offenders with mental disorders on the basis that they demonstrate

Commentator & Affiliation	Section	Comment	Response
		specific strengths and weaknesses, such as sample size, outcome measures, and fidelity assessment, etc. The following article was not listed (looked for it under no mental health outcomes – was not listed)Cusack, Morrissey, Cuddleback, Prime & Williams (2010) Criminal justice involvement, behavioral health service use, and cost of Forensic Assertive Community Treatment: A randomized tria. Community mental Health Journal, 46, 356-363. For reviews I did not find the following – part of this review covered the domain of the report – another review by some of the same authors which was less relevant to the topic was listed. Heilbrun, Dematteo, Yasuhara, Brooks-Holliday et al (2012). Community-based alternatives for justice-involved individuals with severe mental illness. Criminal Justice and Behavior 39, 351-419. Also in the area of pending research on p. 65– they did not note Critical Time Intervention study of prisoners leaving jails in New Jersey funded by NIMH and PI Jeffrey Draine. The reviewers do note the limitations and some areas of future direction, but I do think they could be stronger in the need for more research. For example, FACT and CTI for re-entry is being implemented in a number of places – this is a major policy issue, but the evidence for these is not very strong. Since the intended audience is policy makers – may need to be clearer about the evidence lacking and the need for further research in these areas. In other words it would be helpful given the intended audience if the recommendations are stated in terms of major practice and policy questions – what do we know (very little) and what specific of study questions need to be addressed. Also add to list on pages 63-65 the need for RCTs to be conducted with high fidelity interventions. The studies need not only to be concerned with greater specificity of the control condition, but ensuring the well specified experimental intervention is what was	similar patterns of criminal thinking and behavior as offenders without mental disorders. However, as Cullen et al. point out, the program as it currently stands may be too demanding or may not meet the needs of offenders with SMI, particularly those who have a history of violence and antisocial behavior." Fidelity was also discussed in various places throughout the report. See p. 66 Methodological Considerations: Treatment fidelity was not consistently reported by study authors, and when it was reported, it was often found to be inadequate. Going forward, researchers may attempt to closely monitor and maintain fidelity throughout the trial, so the treatments' maximum benefit potentials can be determined. Once a program is established, researchers can attempt to implement it with some variations to see if the treatment effect remains constant. Thank you for noting the inconsistencies in reporting average length of jail stay, which was 9.5 months as you indicated. We made the correction. The Cusack et al. 2010 article was in the Excluded Studies Table but was categorized under the heading "Not a Criminal Justice Setting of Interest". Thank you for pointing this out. We added the Heilbrun review and the ongoing Draine study to the report. Thank you for pointing these out. We clarified throughout the report that it is intended for a broad audience (e.g., patients, clinicians, and, possibly, policy makers).

Commentator & Affiliation	Section	Comment	Response
		really implemented.	
Peer Reviewer #1	Discussion	e. Discussion/ Conclusion: I did find the report well-structured and organized. Main points are clearly made for researchers more so than for practitioners and policy-makers. Limitation of the evidence and future research directions could be done more in terms of key policy and practice questions. This will be more helpful for the intended audience. It requires some interpretation as presented – the report is written more so for researchers then for whom the intended audience is noted to be. I believe researchers can more easily translate this report into new research.	There is no primary intended audience for this report. It was not directed to researchers over other readers. It just seems that given the limitations of the data, the next logical step for people interested in the field is to conduct more research targeted at some of the interventions and populations we pointed out in the report.
Peer Reviewer #1	Conclusion	See above (Discussion Section)	NA
Peer Reviewer #1	General	f. Clarity and Usability: The report is quite clear, main points clearly stated. given the limited nature of the findings it is more about what not to do rather than about to do. There is little to take away in terms of actually doing in terms of policy and practice. it is much more about the need for more research to fill the gaps. given intended audience, as noted above the intro and conclusion can be reconfigured with practitioners and policymakers in mind. a. General Comments: The report attempts to be clinically meaningful, but the directions offered for either providers or policy makers is very narrow and extremely limited. However, it is evident that the research that is available to answer these questions is rather limited and the quality of these studies was also of a moderate level of risk of bias. None were at a low level of risk of bias. Furthermore, the studies were rated in terms of strength of the evidence as insufficient. The number of studies of relevance and of the quality, i.e., meeting study review criteria, to enter the review was extremely few. Only 14 studies were reviewed. The key questions are the appropriate ones and the process by which the reviewers refined the questions was logical and rigorous. The target population is well defined and the audience is clearly specified as health care providers and policy makers. A few reviews have been conducted that overlap with this	Thank you for your careful review of the document. Reports developed for AHRQ's EPC Program synthesize available evidence and assess its strength, but intentionally do not make recommendations for action. However, EPCs are asked to reflect on gaps in the evidence and to make suggestions for future research. Policymakers reviewing this report will have to decide for themselves how to act on this information. We updated the searches while the report was out for peer review and identified two new studies. One of the studies was graded as low risk of bias. The inclusion of these studies did not alter our conclusions.

Commentator & Affiliation	Section	Comment	Response
		review and have come to similar conclusions – that the evidence is generally weak and that there are a limited number of studies to address these and related questions, e.g., Morrissey, Meyer, & Cuddleback, 2007. The final overall conclusion is that the review was well conceived, searched the appropriate sources, engaged in a careful and thoughtful review, but there is clearly a need for more research, particularly rigorous RCTs, to answer these questions. If there is a fault with the review document is the need to be stronger in terms of indicating the limited information of relevance to both practice and policy in this arena and to be more specific as to the research that needs to be conducted. There may be a few review articles and studies that may have been omitted from the review (see below). However, it is unlikely that the inclusion of these would substantially change the bottom line that is apparent from this review – the available evidence is limited and there are major research gaps that need to be filled with rigorous research.	
Peer Reviewer #2	General Comments	a. General Comments: 1. General Comment: The focus of this paper on detained and transitioning populations omits the large literature on various jail diversion interventions as well as literature pertaining to community corrections (e.g. probation and parole). Would a more accurate paper title be "Interventions for Adults With Serious Mental Illness Undergoing Incarceration, Forensic Hospitalization, and Community Re-Entry?" f. Clarity and Usability: The report is clearly written and well organized. However, the usefulness of this report in guiding policy and/or practice decisions is somewhat limited by the current state of the literature which is insufficient to support firm conclusions.	Thank you for this comment. During calls with Key Informants the scope of the report was discussed at length. It was decided to limit the focus of the report to the incarceration and incarceration-to-community settings but not put limits on the types of mental health interventions that would be assessed. These decisions were made, in part, based on time limitations. We, too, were sorry to see that there were not more comparative trials to be assessed in this report. Thank you.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	Executive Summary	2. Executive Summary Comment: On page ES-14, lines 19-25, the authors point out shortcomings of the clozapine trials, including the lack of information about the dose of the comparator drug. However, the most critical issue in these trials is likely to be whether or not they enrolled drug refractory subjects. If study subjects were drug responsive, then it is not surprising that no differences were found between clozapine and the comparator drugs.	We reviewed the two clozapine drug trials again to determine if the authors reported on responsivity of enrolled subjects. Both Balbuena et al. and Martin et al. were retrospective nonrandomized comparative studies. Balbuena used data from all patients on clozapine for a minimum of 6 weeks and Martin et al. enrolled all patients admitted to the unit during the specified study period. Neither study indicated that a lack of responsivity to medication was a reason for exclusion.
Peer Reviewer #2	Introduction	b. Introduction: 1. On page 4, lines 29-43, the authors refer to "first generation" and "next-generation or atypical antipsychotics". For consistency, consider using the terms "first generation" and "second generation". Also, the authors state that medications like clozapine and olanzapine "have a lower risk for developing movement disorders and other unpleasant side effects". Since those medications actually have a much higher risk for metabolic side effects such as weight gain, hyperglycemia and hyperlipidemia, please consider revising that sentence. 2. On page 5, the authors reference a Minnesota Department of Health website as an example of IDDT used within correctional settings (reference #32), but the website presents IDDT in very general terms. It seems like a more appropriate reference or perhaps an additional reference for Integrated Dual Diagnosis Treatment would be from SAMHSA. For instance, the IDDT toolkit itself can be found there: http://store.samhsa.gov/product/Integrated-Treatment-for-Co-Occurring-Disorders-Evidence-Based-Practices-EBP-KIT/SMA08-4367 3. The terminology "Assertive Case Management" is confusing (on page 6, line 40). I am not aware of a major form of case management called "assertive case management", nor does the article that is referenced on line 38 mention even "assertive case management". To avoid confusing "Assertive Case Management" with "Assertive Community Treatment", please consider changing the heading "Assertive Case Management" to simply "Case Management".	We changed all next-generation references to second generation for consistency. Thank you for noticing this. We also revised the statement about side effects as you suggested. We will add the reference to IDDT as you suggested. Thank you. We changed assertive case management to standard case management to avoid confusion with assertive community treatment, as you suggested. Thank you. We were unable to obtain the Lamberti chapter in a timely manner for inclusion in the report.

Commentator & Affiliation	Section	Comment	Response
		4. On page 7, line 4-5, FACT is correctly described as involving modification of the ACT model. However, the statement includes a reference to a "fidelity scale" that has not been properly tested or validated to my knowledge (reference #40). In addition, this scale says nothing about how the ACT model is actually modified. Instead, it lists several activities that fall well within the scope of traditional ACT teams, such as providing intensive case management services, securing housing and assisting with benefits. To more accurately describe the FACT model, please consider the following citation: Lamberti JS, Weisman RL. "Forensic Assertive Community Treatment: Origins, Current Practice and Future Directions. In: Reentry Planning for Offenders with Mental Disorders: Policy and Practice. Dlucacz, H, Ed. Civic Research Institute, Kingston, NJ. Chapter 7:1-24, 2010	
Peer Reviewer #2	Methods	c. Methods: The authors did a good job of detailing the focus of this review, the method of obtaining relevant literature, and the criteria for study inclusion and exclusion.	Thank you.
Peer Reviewer #2	Results	Results: 1. On page 33, line 32, the authors state that "Risperidone has effects similar to clozapine, but is associated with less serious side effects". This statement suggests that risperidone is equally effective compared to clozapine which is incorrect. Since clozapine is the only antipsychotic drug with an indication for treatment-resistant schizophrenia, please consider revising the statement.	We revised the sentence as you suggested. Thank you for clarifying this point.
Peer Reviewer #2	Discussion/Conclusion	e. Discussion/ Conclusion: No Comments	NA

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #3	General	a. General Comments: Report does a good job in defining target populations, etc. Sparcity of evidence undermines concerns about clinical relevance. Text should make clear, however, that the large preponderance of people in the criminal justice system are in community (probation and parole) vs. institutional settings so that the focus on incarcerated populations is only considering a segment of the total. There is a diffuse range of studies on psychiatric treatments in community corrections but most do not meet the rigor of RTCs. Further explanation should be provided about why this review was limited to incarcerated offenders. f. Clarity and Usability: Yes, this report is very well done and makes a clear case that there is a paucity of evidence about what treatments work for the many thousands of persons with SMI who are incarcerated in prisons and detained in jails throughout US. Much more efficacy research is needed in these areas. The policy implication is also clear--correctional and mental health authorities have a huge research agenda that needs to be focused and adequately funded.	Thank you. The review was limited in scope during the Key Informant process, in part due to time limitations. Narrowing the included settings permitted our review to incorporate data from trials on all mental health interventions. We made a note of the limitations of the scope of this review in the report. Thank you for your comment. Thank you for noting the clarity and usability of the report.
Peer Reviewer #3	Executive Summary	None	NA
Peer Reviewer #3	Introduction	b. Introduction: Very clear and concise statement about purposes, procedures, and findings.	Thank you.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #3	Methods	c. Methods: Scope and parameters of this report are well-described and justified. Sparcity of evidence warrants qualitative review. Excellent profile of included studies, measures, biases, strength of evidence, etc. Pharmacotherapy applicability section p. 35--prisons/forensic hospitals are special settings -- treatment outcomes here are different than treatment outcomes in the community -- predictors of treatment success likely to be different in these two settings -- some recognition of this should be acknowledged in this section Not clear why Cusack et al. study of forensic ACT was excluded from consideration in Question 2 (re-entry)?	We discussed which outcomes to assess with TEP members. Generally, they felt that the same outcomes were important to both the incarceration and incarceration-to-community settings. For example, adherence to treatment is an issue in both settings as pointed out by one TEP member who served as the medical director for a large prison system in the U.S. The Cusack et al. 2010 article was in the Excluded Studies Table categorized under the heading "Not a Criminal Justice Setting of Interest." We re-reviewed the article and again deemed it out of scope for this particular report. It compared those diverted from jail to FACT or TAU in the community. Diversion was not a setting of interest for this report. We assessed interventions administered in the incarceration setting as well as those initiated during incarceration and continued upon release. Thank you.
Peer Reviewer #3	Results	d. Results: Presentation and associated tables are clear and concise. Compilation of evidence in this report will be a great aid to the research and policy communities.	Thank you.
Peer Reviewer #3	Discussion/Conclusion	e. Discussion/ Conclusion: Discussion and observations about gender bias in included studies (p. 64) is a bit naive--fails to acknowledge that prison populations are 80-90% male--so women are not under-represented in these studies although they are a growing proportion of incarcerated populations. Discussion should return to suggestion above about making it clear that this report does not address the treatment effectiveness of interventions for the large majority of persons with mental illness in the criminal justice system. Acknowledgements should be offered about the need for studies of clinical interventions for the larger population of SMI folks who are justice-involved in community settings.	We wanted to be sensitive to all subpopulations of offenders. The researchers who studied female offenders pointed out that they may have some additional, special needs that limit the applicability of findings from studies conducted in male offenders. We made a note of the limitations of the scope of this review in the report. Thank you again for your comment.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #1	Introduction	b. Introduction: The Key questions are clearly described. A brief discussion contrasting the abundance of evidence based treatment (e.g., medication for persons with a SMI, cognitive therapy for depression etc.) with the purpose of this review would be helpful. In other words, this study does imply that evidence based treatment (from noncorrectional/forensic settings) is not applicable to these settings. This paper is attempting to assess the impact the setting exerts on the particular treatments being used (i.e., more or less effective?).	We added some information about treatments known to be effective in other settings to give the report more context.
TEP Reviewer #1	Methods	c. Methods: yes to the above questions. Please note my expertise does not include analyzing the statistical methods used. Caution should made more explicitly re: treatment positively impacting recidivism for reasons similar to effective treatment for diabetes or hypertension not being correlated with impacting recividism.	We added a sentence indicating that a treatment may be effective for one type of outcome and not have a positive impact on another, as was the case with Sacks et al.
TEP Reviewer #1	Results	d. Results: yes to all of the above except the last question.	Thank you.
TEP Reviewer #1	Discussion	e. Discussion/ Conclusion: The implications and limitations of the findings should be expanded. The following publication, Ethical Considerations for Research Involving Prisoners (Edited by Lawrence O Gostin, Cori Vanchieri, and Andrew Pope. Institute of Medicine (US) Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research. Washington (DC): National Academies Press (US); 2007) should be cited along with a summary of the barriers to research in these settings that have contributed to the dearth of studies pertinent to the 2 key questions. No to the last question because overcoming the barriers to such research has not been adequately addressed in this paper.	We did cite the Gostin et al. article and pointed out some of the requirements for conducting research on incarcerated individuals.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #1	General	a. General Comments: yes to all of the above questions. However, the clinical usefulness of the report is very limited due to the findings that essentially state that research applicable to the key questions is so limited that Key Question 1 can not be answered and Key question 2 can only be minimally answered. f. Clarity and Usability: yes, yes, and partially yes. I have some concern that this report could be misinterpreted by nonmental health policy makers to conclude that evidence based practices are not applicable to these settings.	Thank you for your comment. We were also disappointed by the paucity of the available evidence.
TEP Reviewer #2	General Comments	a. General Comments: While the target audience is not formally specified (unless I missed it) I would think it would be quite broad and, once made available, the report would be useful to a broad range of policymakers, researchers and administrators. f. Clarity and Usability: I'm not sure, frankly, how much these findings will affect policy. Certainly they arm administrators with data to use as they go before legislators to obtain more funding, but the nature of the problem is so great that one wonders if even as comprehensive a job as this will have the desired effect!	Thank you for your comment. We clarified that the target audience for the report is broad, as you indicated.
TEP Reviewer #2	Introduction	b. Introduction: Personally I thought the introductory discussion of the importance of the issue targeted in the report could have been more comprehensive, but, that said, it was not the reports purpose to serve as a book on mental health issues in criminal justice. Certainly the point of the article is made strongly enough.	Thank you.
TEP Reviewer #2	Methods	c. Methods: I think the inclusion criteria serve a very useful purpose. I think one function of this report will be as a resource for researchers in constructing arguments for future research. Having this kind of organization available will be of tremendous value.	Thank you.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #2	Results	Results: I thought the methodology generally and inclusion/exclusion criteria were very well described. This specificity will be extremely useful; to researchers who will wish to cite appropriate studies. I do think the level of detail may be a bit "over the top," and could perhaps be included in an appendix. On the other hand, given the stringency of the analysis, it's useful to have it right there as one reads. There may be other studies that could have been included, although many might have fallen outside the inclusion criteria. I saw nothing I felt warranted exclusion.	Thank you.
TEP Reviewer #2	Discussion/Conclusion	e. Discussion/ Conclusion: The implications of the findings are well stated, and the limitations well described. Whether the future research section, while quite clear, will result in future research, remains an open question. Who will fund such research is an even greater question!	Thank you.
TEP Reviewer #3	General Comments	a. General Comments: The questions are clear and explicit. I believe key question 1 is too broad to be meaningful or useful. Saying you are comparing the effectiveness without specifying on what outcomes is problematic. Then you are comparing VERY different interventions - that do not have direct applicability to each other as they address different aspect of mental health. I think the better way is to identify key outcomes that you want to know how to impact and then identify problems targeting them - and evaluate the extent to which they are successful. The same problem is present in question 2- especially as it relates to the "comparative effectiveness" analysis- the report says it this is accessed across release mechanisms - when it should be addressed across release mechanism BY OUTCOME. Assessments outside of outcomes offer practitioners little direction on what intervention to choose. The question is not what works best generally - it is what works best when I am trying to work with clients with problem X or trying to work with clients to change Y. These overly broad questions did not provide information to help providers with this question or build research around them	We formulated the questions and determined the list of outcomes with the assistance of experts in the field. All outcomes listed in the analytic framework were assessed for each Key Question. We understand that the report could have been organized by outcome rather than by intervention type, as you suggest. However, none of the results would have changed. Thank you for giving us a different perspective on ways to organize research reports in the future.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #3	Introduction	b. Introduction: The introduction's discussion of recidivism among people with smi needs work. It misuses citation 8 in its discussion of reasons for high recidivism rates. Cloyes et all - looks at time to readmission - this analysis can not provide reasons for the rates. The review also fails to include recent research on recidivism in jail that identified differential rates of recidivism among people with smi and points to the important role substance use plays recidivism among this population. Also on line 40 to 44 authors use this term "assertive case management" which they differential from Assertive community treatment teams. I am unaware of any case management models other than ACT that use the term "assertive" in it. Then they use a definition that says this case management does not use assertive outreach. This seems unclear and unnecessarily complex. From the definition provided they appear to be referring to a case management style known as "intensive case management"- there are many resources that lay out the different types of case management used in mental health settings. I suggest they be consulted. Phyllis Solomon, Gary Bond are 2 good sources.	We revised the discussion on recidivism based on your comments and some of the other reviewers as well. Thank you. We also changed the heading from "assertive case management" to "standard case management" per your review and one other expert in the field. Thank you.
TEP Reviewer #3	Methods	c. Methods: All of these issues were clearly explained. The problem is the overly broad focus of the questions.	Thank you for your comment.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #3	Results	d. Results: It is not clear that at least one study in Key question 1 fits the criteria. The report states between line 14 and 19 of this section that " The R & R cognitive skills program was developed on the premise that many offenders, with and without mental illness, "have failed to develop core social cognitive skills and are therefore non-reflective, impulsive, egocentric, concrete in their thinking, and tend to externalize blame for their actions."49 The program targets cognitive deficits and maladaptive thinking styles and encourages offenders to develop prosocial skills and behaviors." There seems to be a misunderstanding of the target of this intervention - which is criminogenic thinking/behaviors/attitudes - NOT psychiatric symptoms. The measure they report as the reason for inclusion - based on its assessment of psychiatric symptoms is related to the criminogenic behaviors- not psychiatric symptoms. This makes me think this study was misclassified and should not be included.	The participants in the trial in question (Cullen et al. 2011) were offenders with SMI (>80% with schizophrenia). We understand your concern that the reported "psychiatric" outcome was social problem solving but nonetheless this was an intervention applied in a setting of interest to individuals with SMI and it did report a measure of mental health. Therefore, we believe it should be included in this report. You may be correct that some interventions are more interested in improving criminal behavior than mental health, but we wanted to capture the interventions if they reported a measure that could be categorized as mental health. AHRQ is interested in healthcare/clinical outcomes. We reported criminal justice outcomes only for those trials that also reported a healthcare outcome, as this was the focus of the report. Thank you.
TEP Reviewer #3	Discussion/Conclusion	e. Discussion/ Conclusion: see response to f f. Clarity and Usability: The report is clearly written. The issue goes back to the questions. The results do not report any new information or useful guidelines for practice. While this might be challenging in a relatively new area of research - the decision to choice intervention strategies a priori combined with the lack of focus on clear outcomes of interest - makes the results overly broad - which limits their utility and relevance. I am honestly not sure what new information is gained at all from this review due to the limited scope of interventions included and the lack of assurance related to the level of evidence available in the included studies.	We did not choose interventions a priori. We were willing to assess all interventions that attempted to improve mental health. The outcomes, like the Key Questions, were discussed at length with a group of experts before being finalized.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #4	Introduction	This systematic review of interventions for adults with serious mental illness who are or were incarcerated addresses an important issue and clearly establishes the serious gaps in our knowledge base. There are many aspect of this review that were well executed, such as the detailed coding and extensive search. However, I do have concerns with how the overall assessments of effectiveness were determined. I will address my concerns below. In the introduction (page 28, lines 44-45), the authors claim that poor coordination of services and insufficient community-based services are the reason for the high recidivism among the SMI offender population. This may well be the case but the existing evidence does not establish this conclusion. The high recidivism among the SMI population is actually not much worse than the general offender population. We know that recidivism rates are high and we know that service coordination and service availability are low. We don't yet have the evidence to establish that providing these services will be effective. Isn't determining this the focus of key question 2?	We modified the paragraph that discussed SMI offenders having high recidivism rates due to a poor availability of transitional services. We also added some information on recidivism rates among offenders without SMI. Thank you for making this point.
TEP Reviewer #4	Methods	Although the search was thorough and well document, clearly reflecting the methods and goals of a systematic review, I disagree with the authors decision to exclude dissertations. Dissertations are a good source of grey literature studies and are often thoroughly reported. Dissertations completed within the past 10-years or so can often be obtained for free in electronic version from the author. Given the small number of eligible studies, purchasing a few dissertations from UMI would not have been a serious budgetary issue. I also disagree with the authors inclusion criteria that restricted studies to those that were "peer reviewed". By definition this will exclude many grey literature studies and will only increase the likelihood of publication selection bias in the review. Methodological quality should be assessed by the systematic review team and not presumed based on a proxy measure such as peer-review. The key questions for this review articulate the focus of the review but are silent on the outcomes for which effectiveness is to be established. That is, effectiveness for	We excluded dissertations because we anticipated that we would need to review an extremely large number of reports, with very few, if any, studies being identified for inclusion. We did not list all of the outcomes of interest in the Key Questions because they are already quite wordy and the outcomes are spelled out just after the Key Questions in the analytic- and PICOTS frameworks. Thank you for this comment. For continuous outcomes we calculated effect sizes given the data available. In some cases that was pre-post standardized means; in others only post-intervention data was available. We would have had less data to work with if we had not used all available data in our analysis. As we included only trials that were randomized or employed some technique to insure group comparability, we do not see the

Commentator & Affiliation	Section	Comment	Response
		what? The reader learns a bit later that a very broad range of outcomes are of interest. This should be incorporated into the key questions. The discussion around the computation of effect sizes seems to conflate two, different issues. For continuous outcomes the authors seem to imply that they only computed pre-post standardized mean differences. Examining the table in the appendix clearly indicates that some of the standardized mean difference effect sizes were based on the difference between the treatment and comparison groups whereas others were based on the pre-post differences within each group (these two types of "d" effect sizes are not directly comparable). Why were these latter effect size computed? They are almost impossible to interpret in the context of two groups. What is of interest is the difference between the change between the two groups, not the individual within group change. A single effect size that represents the treatment and comparison contrast (possibly adjusted for pre-test differences when these are available) is far more meaningful and consistent with the design types included in this review. The strength-of-evidence grade is problematic in its ambiguity. Coders would interpret "narrow cinfidence interval" rather differently. An important goal of a good systematic review is replicability and I'm not convinced that the application of this grading system is replicable. Also, the categorization is not exhaustive. For example, how would two studies with consistent findings but high risk of bias be categorized? Also, how is consistency established? Related to the above is that the body of the report ignores effect sizes and their associated confidence intervals. These should be incorporated in the main tables that summarize the findings, such as Tables A and B in the executive summary. Even better would be forest plots that graphically represent this data. Furthermore, meta-analysis should be applied to situations where there are 2 or more studies the same intervention-outcome combination. According to Tables A and B, there are five such instances. Using meta-analysis may well change the interpretation. For	use of between-group comparisons of outcome data as problematic. For the strength of evidence grading system, we had two raters review the results and agree on a final grade for the overall evidence base. We would have categorized two high risk of bias trials with consistent findings as "low", but would have warned the reader that the studies carried a high potential for bias. We have tried to be more explicit about how the strength of evidence was graded. We counted studies as consistent if their findings were in the same direction. For example, both studies reported that treatment A was better than treatment B. There was too much heterogeneity in outcomes reported and populations for Key Question 1 to perform meta-analyses of the medication trials. Table A and B were our attempt to summarize the data for the reader. We removed the following bullet point: "When the evidence consists of multiple studies, how would the applicability of different studies be synthesized to reach a general conclusion about the applicability of the evidence? We did not identify any validated instrument for this type of synthesis." It was poorly worded. Meta-analysis is not designed to synthesize applicability, by which we mean "the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under 'real-world' conditions."[Atkins D, Chang S, Gartlehner G, Buckley DI, Whitlock EP, Berliner E, Matchar D. Assessing the Applicability of Studies When Comparing Medical Interventions. Agency for Healthcare Research and Quality; December 2010. Methods Guide for Comparative Effectiveness Reviews. AHRQ Publication No. 11-EHC019-EF. Available at

Commentator & Affiliation	Section	Comment	Response
		example, using the effect sizes reported in the appendix (and converting the odds-ratio to a standardized mean difference using well established methods), the overall mean effect size for clozapine versus other antipsychotics for psychiatric symptoms is .30 with a 95% CI of -.03 to .64 (p = .08). The effects are homogeneous and actually quite similar (.29 and .33). Table A states the consistency is unknown. This is incorrect. These effects are highly consistent. They are still somewhat imprecise (I'm still not clear on the threshold for precision) but of a clinically meaningful size. To claim that you can't combine effect sizes such as this but still arrive at an overall assessment such as those reported in Tables A and B is contradictory. Tables A and B essentially perform "mental" meta-analyses. If the studies are two heterogenous to be combined meta-analytically, then they shouldn't be combined mentally either. (I do agree with the authors that combining effect sizes across the different types of treatments and outcomes present in Tables A and B would not make sense.) On page 50 of the PDF, lines 17-20, the authors state "When the evidence consists of multiple studies, how would the applicability of different studies be synthesized to reach a general conclusion about the applicability of the evidence? We did not identify any validated instrument for this type of synthesis." This is exactly what meta-analysis was designed to do.	http://effectivehealthcare.ahrq.gov/.] Applicability is essentially in the "eye of the user." Our discussion of applicability is intended to assist users in deciding whether the evidence is applicable to their specific populations and settings.
TEP Reviewer #4	Results	None	N/A
TEP Reviewer #5	General	a. General Comments: The report is meaningful. It's unfortunate to put this much work into it to find very weak conclusions. But this is the fault of the literature, not the researchers. Hopefully, it will help frame future questions and guide funding.	Thank you. We too were disappointed by the lack of comparative trials available for inclusion in the report.
TEP Reviewer #5	Executive Summary	Note: Most of my comments, referenced to the Executive Summary section, are, of course, also applicable to the corresponding section of the main report. p ES1, line 24-30 You report that recidivism rates are high for SMIs. Some readers may not know what the "normal" recidivism rate is, and, in fact, it varies considerably from	Based on your comment and those from other reviewers, we have revised those sentences dealing with recidivism among offenders with SMI. Thank you. We added the National Commission on Correctional Health Care standards reference to

Commentator & Affiliation	Section	Comment	Response
		place to place. So, this would be a more effective statement if you put it in context, i.e. made (appropriate) comparisons to non-SMI recidivism rates. p ES1, line 48-50 The Baillargeon reference (11) is okay, but a stronger reference is the National Commission on Correctional Health Care standards (Standard J or P-G-04) p ES1, line 32 Drug courts are intended to divert from ANY incarceration, not necessarily a LENGTHY one. p ES3 flow diagram (and related text) An additional Patient-Oriented Outcome is all-cause mortality (not just from suicide). We know the rate of death is high upon release from prison, and at least some of that is related to mental illness and drug abuse. (let me know if you need a reference) If there was no literature found on mortality (other than suicide), I think the report should distinguish between the Analytical Framework and the Results. In other words, "framework" suggests the optimal or theoretical way of looking at the issue. It's something you design a priori to guide the research, in which case, mortality should be part of it. That no literature was found on mortality would be a result. I think this distinction is important, because someone else may refer to your framework for doing additional research. p ES3, line 55 "found guilty of a crime" – Make sure this is so. In general it would inconsistent with being incarcerated "a minimum of 24 hours" in that most people incarcerated for that short period are pre-trial, so have not yet been found guilty. p ES7, line 54 The concept of Applicability Assessment needs a little more development/explanation. It appears for the first time here and is addressed in such a way that assumes the reader already knows what you're doing and why. A couple of sentences more would be enough.	the ES and the main document as you suggested. Thank you. In the scope of the report section, we removed the words " a lengthy" from the sentence dealing with diversion. Thank you for clarifying this point. Regarding all-cause mortality, we did not assess that outcome. We only looked at suicide/suicide attempts/dangerousness to others. We recognize it is important and perhaps we should have examined that outcome as well. None of the included trials, however, reported that outcome. The trials included in our report do describe their subjects as "offenders" with SMI. We reviewed the inclusion criteria for the studies included in our review and all enrolled individuals who had committed a crime. Thank you. We added a sentence to further explain Applicability Assessment. Thank you. Both modified therapeutic community trials reported substance use as an outcome. It was measured as any substance use in a specified time frame. Yes, our switch from PICOTS to PICOS was intentional. In this section we reported research gaps. We could have said there was not enough long term followup in the studies identified by our searches, but most studies that were excluded were not excluded because the followup period was too short.

Commentator & Affiliation	Section	Comment	Response
		p ES8, line 50 "Both trials reported substance abuse" – This could be worded a little more clearly. Do you mean relapse to SA? Stopping SA? Something else? pES13, line 52 Did you mean to switch from the PICOTS approach, addressed in Methods, to the PICOS approach here?	
TEP Reviewer #5	Main report	p2, line 48 "constituted 19 percent of the prison population.1" – Are you sure about the reference? You're talking about Washington State, but this reference is about a national survey. Further, the link doesn't work. Lastly, I tried finding the article a different way. If I found the correct article, the reference is actually a "second hand" reference. I think it's improper in this case to cite the secondary source rather than the primary source. When I tried finding the primary source using the link in the Survey, it doesn't work either. Finally, and most importantly, the evidence you cite doesn't support the logic flow of the preceding statement. You are trying to argue that SMI stay incarcerated longer. The evidence you use is that they have more rule violations/infractions. While these two MAY be correlated, that's not a given. For instance, if the violations are minor, they may not impact release time. Or, even if they do affect release time, if they're minor, they may still have a lesser effect on release time, than, perhaps, non-SMIs, who might have fewer violations, but of greater severity (and therefore greater ultimate impact on release time).	We wrote "According to a report by the Treatment Advocacy Group, the main reason inmates who are mentally ill stay incarcerated longer than inmates who are not is that many find it difficult to understand and follow jail and prison rules.[1] Thus, inmates with mental illness are more likely to be charged with facility rule violations or infractions. For instance, in Washington State prisons, inmates with mental illnesses accounted for 41 percent of infractions but constituted 19 percent of the prison population.[1] "That is an accurate reference. This report is based on primary research of administrative databases. However, the link did not work as you indicated. We have corrected the link.
TEP Reviewer #5	Main report	p3, line 28 "Prisons, which are correctional facilities that hold sentenced inmates for more than a year" – This is not accurate. It would be best to say "…typically hold." In Washington State, for example, parole violators got to prison, not jail. This population is held anywhere from a few days to a few months. While this is not the most common arrangement, there are some other states with the same model, e.g. California.	Thank you for clarifying this point. We made the word changes you suggested.
TEP Reviewer #5	Main report	p3, line 29 (and elsewhere) Minor point: are you sure "State" is capitalized when not referring to a particular state?	Thank you

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #5	Main report	p4, line 23 "must be included in the medication formulary." – Be cautious with this statement and the related reference. First of all, that is not a source document that has much penetration into the operation of prisons and jails nor is it part of an accreditation process. Second, even if it were, there are no requirements for jails and prisons except 1. what has been determined by case law, 2. if the facility voluntarily seeks accreditation, or 3. in some states where there are state level requirements.	We decided to keep this reference as it was written by a reputable source.
TEP Reviewer #5	Main report	p4, line 24 "However, special conditions in correctional facilities such as high rates of substance use disorders require that formularies limit or exclude medications that have a high potential for misuse or abuse." This doesn't make sense or is not true (I can't tell). No medication should be restricted from pharmacy solely on the basis of a population with high SA histories. The facilities are still required to provide all medically necessary care. Some facilities DO restrict their formularies for these reasons. When I find that during an investigation, say, for the Department of Justice, I recommend that they be dinged.	We reworded that paragraph to say that some correctional facilities limit their formulary rather than "require that formularies limit or exclude medications."
TEP Reviewer #5	Main report	p4, line 46-57 I'm getting more nervous about your reliance on reference 26. This is not a mainstream reference in correctional health care. It is not peer reviewed. And the facts you're citing from hit here are wrong. TCAs and MAOIs are not contraindicated in correctional facilities. TCAs at least, are used a lot. Further, there is no authority I know of that contraindicates any medication in corrections. Again, they must use what is medically necessary. If the med presents operational challenges, then the facility must find a way to overcome those challenges.	We reworded the text to present results of a study conducted on the Texas prison system's prescribing patterns and added that reference (Baillargeon et al. 2002, a study funded by the US Department of Justice). Thank you for your detailed review of this report.
TEP Reviewer #5	Main report	p10, line 38 Be consistent w caps.	We reviewed the document and corrected the inconsistencies. Thank you.

Commentator & Affiliation	Section	Comment	Response
TEP Reviewer #5	Main report	p38, line 27 to 36 This sounds a little like you're contradicting yourself. Early in the paragraph, you opine that the two studies represent the heterogeneity of the target population, but then you go on to describe limited generalizability. To me, at first blush, this is contradictory. If this is what you intended, I think you need to provide a little more explanation of how despite heterogeneity, they're nongeneralizable.	We attempted to emphasize the similarities in the populations and settings studied by the pharmacotherapy studies in the Applicability Section. We were reluctant to combine the pharmacotherapy studies in any sort of analysis, qualitative or quantitative initially because of overall poor reporting about the treatment (dosage provided), comparator (what medications and dosage were given to controls), and because different outcome measures (BPRS and CGIS) were reported. We reconsidered, based on your comment and some other reviewers' comments. The final version of this report qualitatively combined results from the two trials of clozapine.
Kathleen Gans-Brangs, PhD AstraZeneca	General	Highlights of Prescribing Information for Seroquel and SeroquelXR attached.	Thank you
Mark Gale	Structured Abstract	Regarding the Structured Abstract section, specifically: "Results. We included 16 publications describing 14 comparative trials. The studies were conducted in the United States, Canada, United Kingdom, New Zealand and Australia. The risk of bias was moderate for all reported outcomes. For all of the incarceration-based interventions assessed, pharmacotherapy, cognitive therapy, and modified therapeutic community, there was insufficient evidence to draw a conclusion. For individuals transitioning from the incarceration-to-community setting, low strength of evidence supported discharge planning with benefit application assistance and intensive dual disorder treatment compared with standard of care for increasing mental health service use and/or reducing psychiatric hospitalizations. The evidence was insufficient to draw a conclusion about the effectiveness of intensive dual disorder treatment for reducing psychiatric symptoms, substance abuse, and institutional infractions and for improving functioning and medication adherence.	Thank you for your very thoughtful response to our report.

Commentator & Affiliation	Section	Comment	Response
		The evidence was also insufficient for comparing generalist- to forensic specialist-administered interventions for offenders transitioning from incarceration to the community. Conclusions. We identified some promising incarceration-to-community treatments for individuals with serious mental illness. Discharge planning with Medicaid application assistance and intensive dual disorder treatment programs appear to be effective interventions for seriously mentally ill offenders transitioning back into the community. Health care providers and policymakers can use this evidence review to improve the treatment of offenders with serious mental illness. The applicability of our findings is limited to the types of populations and settings in the included studies." **My comments**: The conclusion above does get straight to the point. If we paid the cost of social workers who could assist soon-to-be discharged inmates with benefits eligibility coupled with substance abuse programs in both incarceration settings and upon discharge into the community, we could get a drop in recidivism. We also need real substance abuse treatment that is integrated with mental health treatment instead of clinic appointments for coping with the challenges of serious mental illness and AA/12 Step meetings for the challenges of substance abuse delivered separately. Everyone acknowledges that this should be the highest standard of care, but try finding this integrated treatment in the community. It is almost impossible to find and what few programs there are (that have also suffered large decreases in capacity from budget cuts) have 4-6 month waiting lists unless you are able to pay privately exorbitant sums of money. From my own personal experience in watching individuals I have known engage in 12 Step programs while transitioning back to the community from incarceration in the county jail, I found many of these programs to be ineffective in reducing recidivism. These programs did help some people and for those who fully embraced the 12 Step Method and were able to find consistency in their sobriety, they were an invaluable tool.	

Commentator & Affiliation	Section	Comment	Response
		Yet there seemed to be far greater numbers who could not sustain their sobriety no matter how many meetings they went to. This is anecdotal evidence, but the numbers of negative outcomes far exceeded the numbers of people who attained sobriety successfully. Nonetheless, our courts continue to rely on ineffective 12 step programs (cause that's all they have to work with) where oftentimes a person with a serious mental illness is criticized and stigmatized for taking medication as a breaking of the pledge of sobriety. This is sheer ignorance being spread by some 12 Step facilitators. Where is the outcome data for these programs that our courts continue to utilize? There is no critical evaluation of the effectiveness of these 12 Step programs and no measurement of success or failure of the participants. Just a continuing revolving door as persons are thrown out of these programs for failure and forfeiting the money they have paid in the process. I tried contacting some people within AA who seemed to be at a higher level of the organization. I wanted to reach out to a centralized hierarchy that could spread the truth that taking psychiatric medication had nothing to do with sobriety and, in fact, would help keep a person with serious mental illness stabilized so they could focus on the challenges of their substance abuse. This hierarchy does not exist either on a state or national level. There is no centralized organizational structure that I could find, nor any structured continuing education program updating the premises used by 12 Step meeting facilitators. This level of intolerance of others, stigmatizing and discriminatory behavior, or persons supposed to be leaders to others would never be tolerated in any other behavioral health setting, yet we continue to give AA a "pass" because we have nothing else to replace it with. Surely we can do better. It is time to put our money where our research is. Integrated dual diagnosis care must not be the exception but the rule, especially for people whose substance abuse and mental illness led to entanglements with our criminal justice system resulting in incarceration in our jails and prisons. It is	

Commentator & Affiliation	Section	Comment	Response
		incumbent upon our mental health system to develop true integrated care (mental health treatment joined with substance abuse treatment and delivered by the same clinical team) or this problem will never be solved.	