**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 1879

**Measure Title**: Adherence to Antipsychotic Medications for Individuals with Schizophrenia

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/2/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name what is being measured

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

**1a.3** **Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not Applicable. This is not a patient-reported measure.

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

X Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

X Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | National Institute for Clinical Excellence- Psychosis and Schizophrenia in Adults: The NICE Guideline on Treatment and Management  National Collaborating Centre for Mental Health  2014  The National Institute for Clinical Excellence and the National Collaborating Centre for Mental health. Psychosis and Schizophrenia in Adults: Prevention and Management. Pages 301-379. Retrieved from https://www.nice.org.uk/guidance/cg178/evidence/full-guideline-pdf-490503565 |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | For people with first episode psychosis offer:   * oral antipsychotic medication in conjunction with psychological interventions (family intervention and individual cognitive behavioral therapy).   For people with an acute exacerbation or recurrence of psychosis or schizophrenia, offer:   * oral antipsychotic medication in conjunction with psychological interventions (family intervention and individual cognitive behavioral therapy).   Consider offering depot /long-acting injectable antipsychotic medication to people with psychosis or schizophrenia:   * who would prefer such treatment after an acute episode. * where avoiding covert non-adherence (either intentional or unintentional) to antipsychotic medication is a clinical priority within the treatment plan. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The guideline developers used the GRADE system but did not provide independent grades for each recommendation’s evidence. The recommendations rely on randomized control trials and meta-analyses, suggesting a high level of quality. |
| Provide all other grades and definitions from the evidence grading system | Randomized control trials (RCT) without important limitations provide high quality evidence.  Observational studies without special strengths or important limitations provide low quality evidence.  For each outcome, quality may be reduced depending on five factors: methodological limitations, inconsistency, indirectness, imprecision and publication bias. |
| Grade assigned to the **recommendation** with definition of the grade | The Guidelines did not provide independent grades to each recommendation. |
| Provide all other grades and definitions from the recommendation grading system | The Guidelines did not provide independent grades to each recommendation. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | For the review of initial treatment with antipsychotic medication: 9 RCTs.  For the review of treatment with antipsychotics in people with an acute exacerbation of recurrence of schizophrenia: 72 RCTs.  For the review of depot/long-acting injectable antipsychotics: meta-review of five Cochrane reviews. |
| Estimates of benefit and consistency across studies | There is well-established evidence for the efficacy of antipsychotics in both the treatment of acute psychotic episodes and relapse prevention over time. |
| What harms were identified? | Side effects of antipsychotics identified include lethargy, sedation, weight gain, sexual dysfunction, and movement disorders. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Practice Guidelines for the Treatment of Patients With Schizophrenia Second Edition  American Psychiatric Association  2010  Lehman, A. F., Lieberman, J. A., Dixon, L. B., McGlashan, T. H., Miller, A. L., Perkins, and D. O. Kreyenbuhl, J. (2004). Practice Guidelines for the Treatment of Patients with Schizophrenia. American Psychiatric Association. Reprieved from https://psychiatryonline.org/pb/assets/raw/sitewide/practice\_guidelines/guidelines/schizophrenia.pdf |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | It is recommended that pharmacological treatment be initiated promptly, provided it will not interfere with diagnostic assessment, because acute psychotic exacerbations are associated with emotional distress, disruption to the patient’s life, and a substantial risk of dangerous behaviors to self, others, or property [Recommendation Grade - I].  While most patients prefer oral medication, patients with recurrent relapses related to nonadherence are candidates for a long-acting injectable antipsychotic medication, as are patients who prefer this mode of administration [Recommendation Grade - II].  If the patient is not improving, it may be helpful to establish whether the lack of response can be explained by medication nonadherence, rapid medication metabolism, or poor absorption [Recommendation Grade - II]. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The attributing evidence is not clearly linked to each recommendation. Each rating of clinical confidence considers the strength of the available evidence and is based on the best available data. When evidence is limited, the level of confidence also incorporates clinical consensus with regard to a particular clinical decision. |
| Provide all other grades and definitions from the evidence grading system | The following coding system is used to indicate the nature of the supporting evidence in the summary recommendations and references:  [A] Double-blind, randomized clinical trial. A study of an intervention in which subjects are prospectively followed over time; there are treatment and control groups; subjects are randomly assigned to the two groups; both the subjects and the investigators are blind to the assignments.  [A–] Randomized clinical trial. Same as above but not double-blind.  [B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally; study does not meet standards for a randomized clinical trial.  [C] Cohort or longitudinal study. A study in which subjects are prospectively followed over time without any specific intervention.  [D] Case-control study. A study in which a group of patients is identified in the present and information about them is pursued retrospectively or backward in time. |
| Grade assigned to the **recommendation** with definition of the grade | See brackets after each recommendation above for specific recommendation grades. Overall the grades were:  [I] Recommended with substantial clinical confidence.  [II] Recommended with moderate clinical confidence. |
| Provide all other grades and definitions from the recommendation grading system | The other grade in the recommendation grading system is:  [III] May be recommended on the basis of individual circumstances |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | 1,272 clinical trials and meta-analyses were screened by using title and abstract information. The Cochrane Database of Systematic Reviews was also searched by using the keyword schizophrenia. Additional, less formal literature searches were conducted by APA staff and individual members of the work group on schizophrenia. |
| Estimates of benefit and consistency across studies | Nearly all studies found that the antipsychotic medication was superior for treating schizophrenia compared to placebo. These studies demonstrated the efficacy of antipsychotic medications for every subtype and subgroup of patients with schizophrenia. Effectiveness of specific medications will vary by patient symptoms and history. |
| What harms were identified? | There are numerous side effects to use of both first-generation and second-generation antipsychotics. Antipsychotics are associated with extrapyramidal effects, sedation, orthostatic hypotension and tachycardia, anticholinergic and antiadrenergic effects.  Other side effects include weight gain and metabolic effects, and sexual side effects. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | No |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**