

Use of Antipsychotics in Older Patients in the Inpatient Hospital Setting (AP) Measure

Project title

Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance

Dates

- The call for public comment ran from Friday, April 15, 2016, to Sunday, May 15, 2016.
- The public comment summary was submitted to the Centers for Medicare & Medicaid Services on Friday, May 27, 2016.

Project overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Mathematica Policy Research to develop the Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting (AP) measure. The contract name is Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM). The contract number is HHSM-500-2013-13011/HHSM-500-T0003. As part of its measure development process, CMS asks interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project objectives

CMS has contracted with Mathematica Policy Research and its partners to develop, electronically specify, and maintain process and structural clinical quality measures for five CMS hospital quality programs: the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program, and Electronic Health Record (EHR) Incentive Program for Eligible Hospitals. As part of its measure development process, CMS asked interested parties to submit comments on the Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting (AP) measure.

Information about the comments received

The project team used extensive outreach methods to notify stakeholders and the general public about the comment period, including the following:

- Email sent to stakeholders and stakeholder organizations, including:
 - Academy of Psychosomatic Medicine
 - Alzheimer's Association
 - American Academy of Family Physicians
 - American Academy of Physician Assistants

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- American Association for Geriatric Psychiatry (AAGP)
 - American Association of Nurse Practitioners
 - American Board of Internal Medicine
 - American Board of Surgery
 - American College of Physicians
 - American Delirium Society
 - American Geriatrics Society (AGS)
 - American Hospital Association
 - American Medical Association
 - American Medical Group Association
 - American Nurses Association
 - American Osteopathic Association
 - American Psychiatric Association (APA)
 - American Psychological Association
 - Association for Adult Development and Aging
 - Clinical researchers (Drs. Kate Lapane, Jennifer Stevens, Michael Howell, and Shoshana Herzig)
 - Dementia Society of America
 - Gerontological Society of America
 - Health IT Policy Committee Quality Measures Work Group
 - Hospital-MDM Clinical and Measure Development Advisory Board
 - Hospital-MDM Patient and Family Advisory Board
 - Hospital-MDM Technical Expert Panel
 - Institute for Healthcare Improvement
 - National Alliance for Caregiving
 - National Quality Forum eMeasure contacts
 - Pharmacy Quality Alliance
 - Society of Critical Care Medicine
 - Facilitators of the following groups were asked to announce the public comment period during periodic meetings:
 - eMeasures Issue Group (eMIG) work group
 - Weekly governance call for measure developers

- Other communication vehicles/lists:
 - CMS listservs
 - eHealth provider workgroup
 - eHealth vendor workgroup
 - Healthcare Information and Management Systems Society (HIMSS) Electronic Health Record Association
 - HIMSS Clinical Quality Collaboration Center
 - Announcement on the eCQI Resource Center website

We received 22 comments. Most of them addressed multiple topics within a single comment submission. The comments were submitted during the public comment period from the following categories of stakeholders:

- **Six hospital/health systems.** Lexington Health Center, Oklahoma Heart Hospital, Hospital Corporation of America, Kaiser Permanente, Vizient, and Memorial Sloan Kettering Cancer Center
- **Seven professional associations.** Florida Society for Post-Acute and Long-Term Care Medicine, American Health Care Association, Alzheimer’s Association, American Geriatrics Society, American Psychiatric Association, Society of Critical Care Medicine, and Society of Hospital Medicine
- **Two EHR vendors.** Epic (submitted multiple comments) and McKesson
- **Three academic institutions.** The Ohio State University College of Nursing, State University of New York Upstate Medical University, and Thomas Jefferson University
- **Two individuals.** No organization or contact information provided

Stakeholder comments—general and measure specific

Support for the measure

One commenter said the measure is a first step toward improving care by providing an estimate regarding whether the use of antipsychotics is moderate, high, or out of control.

One commenter supported the overall measure concept and addressed inappropriate use of antipsychotic medications as an issue in the inpatient setting, citing the potentially life-threatening side effects of antipsychotics as well as both their safety and efficacy in treating various diagnoses.

One commenter supported the measure as a means to educate hospital staff about problems relating to antipsychotic prescribing practices. The commenter also thought the measure had the capacity to make hospital staff members rethink how they use antipsychotics and promote individualized care.

One commenter stated that the proposed CMS measure, if properly designed and accompanied by clinician education and a team approach to care, could be a very meaningful

quality measure for inpatient settings to help address a known clinical and patient safety problem. The commenter added that antipsychotics are still misused and over-prescribed for older adults in hospitals despite the clear guidance from AGS (Beers Criteria) and AAGP.

Response: Thank you for your comment.

Measure intent

One commenter indicated that although the measure may inadvertently increase the use of other pharmacological treatments, it might result in hospitals implementing protocols that focus on adjusting the physical environment (structural changes, special wards, and so on) which would lessen the need for medications.

Response: Thank you for your comment.

Two commenters questioned whether the intent of the measure was to push clinicians away from prescribing antipsychotics.

Response: This measure is not intended to completely eliminate antipsychotic use, rather to characterize the prevalence of antipsychotic use and to encourage further exploration of underlying medical issues prior to attempting therapeutic approaches that have limited evidence to support their safety and effectiveness. Our experts suggested that antipsychotics are used far too often as a first line of therapy to manage patients who present with disruptive or dangerous behaviors, as opposed to seeking safer and more effective alternatives.

Unintended consequences

One commenter expressed concern about reducing the quality of life for elderly patients with dementia who are admitted to psychiatric units with behavioral dyscontrol.

Response: The measure population does not include patients admitted to inpatient psychiatric facilities or units. We will clarify this in future versions of the specification.

Four commenters raised concerns about the potential use of benzodiazepines as substitutes for antipsychotics if the measure were to be implemented as written. They worried that intensive care unit (ICU) practitioners may revert to other medications to treat delirium and rely more heavily on physical restraints to protect patients and caregivers. Although non-pharmacologic delirium management strategies have proven successful outside the ICU, the safety and effectiveness of these interventions in the intensive care setting has yet to be fully demonstrated.

Response: We appreciate your raising the possible unintended consequences of implementing a measure that discourages antipsychotic medications. Benzodiazepines do pose significant risks to patients and, for those 65 and older, an increased risk for cognitive impairment, delirium, and falls. CMS will consider a complementary measure addressing the use of benzodiazepines in patients 65 and older in future measure development initiatives.

One commenter expressed concern that appropriate use of antipsychotics would be penalized, resulting in under-recognition, under-reporting, and inadequate management of

delirium. The commenter recommended introducing ongoing interdisciplinary education and support so the intent of the measure is not misconstrued.

Response: Thank you for your comment about the importance of interdisciplinary care team education as a means to decrease occurrences of under-recognizing and under-treating delirium. Our expert work group emphasized this very issue and CMS is aware of the importance of addressing delirium assessment and appropriate management as key to addressing overuse of antipsychotics in inpatient facilities.

One commenter expressed concern that the measure could also discourage important applications for the use of antipsychotics. In the oncology setting, antipsychotics are frequently used for the treatment of cachexia and weight loss due to cancer progression and chemotherapy-induced nausea, vomiting, and decreased appetite. Given that the stated measure rationale is to assess off-label treatment of delirium with antipsychotics, we recommend removing from the measure numerator patients with cancer who are being treated for cachexia, weight loss, nausea, vomiting, or loss of appetite.

Response: We appreciate your comments and references on these two topics: (1) the use of antipsychotics in treating delirium for hospitalized patients with cancer and (2) addressing cachexia and weight loss for patients with cancer. The commenter cites a paper from Breitbart et al. (2012) indicating that the prevalence of delirium episodes in cancer patients range from 10 to 30 percent in the hospital. We will share the Breitbart study with our expert work group to examine whether an exclusion for cancer patients presenting with delirium is appropriate. We will make sure to continue to exclude the following antipsychotic medications from the antipsychotic medication value set due to their use in treating cancerous conditions: prochlorperazine (Compazine), promethazine (Phenergan), and metoclopramide (Reglan).

Interpretation of measure-related guidelines

One commenter stated that antipsychotics are an appropriate treatment option for patients with symptoms of dementia. The commenter noted that according to APA guidelines, the minimal effective dose is warranted for patients with dementia. Another commenter noted that the APA's "Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia" suggests that an individualized therapy treatment plan is ideal for improving treatment outcomes. This plan should take into account the patient's personal preferences and values, such as quality of life.

Response: Thank you for your comments. We acknowledge that newly released APA guidance recommends a minimal effective dose of antipsychotics for the shortest period of time for patients with dementia. We will share the May 2016 APA guidance with our expert work group, noting that the AGS Beers Criteria make specific note of the increased risks of antipsychotic use in patients with dementia.

One commenter, citing the Beers criteria, noted that antipsychotics should be used in older patients for whom nonpharmacological options have failed or who pose a threat to self or others.

Response: Thank you for your comment. We agree and note that the proposed measure excludes patients who pose a threat of harm to themselves or others.

One commenter cited National Institute for Health and Care Excellence (NICE) guidelines and noted that patients who are severely distressed are candidates for antipsychotics. This commenter was concerned that an exclusion for severely distressed patients would not be feasible to implement because the symptoms would not be captured in a discrete field, calling into question the validity of the measure.

Response: The Beers Criteria suggest that patients who are “threatening substantial harm to self or others” may merit treatment with antipsychotics. Our intent in excluding these patients is to make sure that situations where patients are experiencing severe distress are not included in this measure, as providers may not have effective alternatives available to them. We will examine the validity of “threatening substantial harm to self or others” through continued field testing of the measure concept.

Measure specifications

Denominator-related comments

One commenter suggested excluding elderly patients with a psychotic disorder, including psychosis secondary to dementia.

Response: The measure currently excludes diagnoses with indications that are approved by the U.S. Food and Drug Administration (FDA) for the use of antipsychotics, including schizophrenia, Huntington’s disease, bipolar disorder, and Tourette’s syndrome. We note that several antipsychotics have FDA black box warnings for increased mortality in elderly patients with dementia-related psychosis.

One commenter suggested that antipsychotic medication prescribed by a psychiatrist should be excluded from the measure.

Response: The measure is focused on hospitalized patients under general medical care and excludes patients admitted to inpatient psychiatric facilities or units who are under the care of a psychiatric service.

One commenter suggested that *pro re nata* (PRN) or “as needed” antipsychotic medication orders should be excluded from the measure.

Response: Our research has suggested that PRN use of antipsychotics is neither effective for the treatment of delirium nor does it contribute to high quality care. We do not currently plan to exclude PRN antipsychotic orders from this measure.

Three commenters suggested restricting the measure population to inpatients 65 and older. One commenter added that including younger adults, who are prescribed antipsychotics for psychiatric conditions and acute delirium, would skew measure data. Two commenters wrote that the measure should include all hospitalized patients, pointing out that many patients under age 65 have Alzheimer’s disease and often display dementia-related behaviors. The commenter thought that the administration of antipsychotics to younger individuals should be captured in addition to older patients.

Response: Thank you for your comments about limiting the measure population to adults 65 and older in the acute inpatient setting. We will continue to review testing data and scientific evidence relating to antipsychotic medication use and patient safety for all Medicare-eligible age groups (18 and older).

Two commenters suggested excluding patients with a diagnosis of major depressive disorders from the denominator. One of them noted that patients with schizoaffective disorder should also be removed from the denominator.

Response: We will consider your suggestion to exclude schizo-affective disorder and will further explore the possibility of exclusions for patients with major depressive disorder where specific antipsychotics are used as adjunct therapy consistent with FDA labeling.

Once commenter stated that three accepted indications for antipsychotics are palliative care, end-of-life care, and assistance with management of delirium. The commenter indicated that patients with these indicators should be removed from the denominator.

Response: The measure population does not include individuals in palliative or hospice care. We will further investigate the appropriateness of excluding patients experiencing delirium and the ability to reliably identify such patients.

One commenter recommended excluding patients with fibromyalgia, chronic pain, seizures, panic disorders, Parkinson's disease, and allergic conditions. Also, hypertensive patients being treated with reserpine should be excluded.

Response: The measure currently excludes patients with FDA-approved indications for antipsychotics. We will further investigate whether patients with fibromyalgia, chronic pain, seizures, panic disorders, Parkinson's disease, and allergic conditions should be excluded. We note that Parkinson's is subject to a FDA black box warning for several antipsychotics.

Numerator-related comments

One commenter indicated that delirium is not synonymous with dementia or agitation. The commenter indicated that physicians need to have access to antipsychotics to treat delirium in elderly patients in the hospital setting.

Response: Thank you for your comment. We agree that the presentation, symptoms, and management of delirium, dementia, and agitation are distinctive. This measure is intended to characterize the prevalence of off-label use of antipsychotics for patients 65 and older and encourage exploration of their underlying medical cause. Our research indicates that antipsychotics are used too often as a first line of therapy, without careful consideration of their safety and effectiveness in treating the underlying etiology. We agree, however, that clinicians should still have access to antipsychotics to manage critically ill patients who threatening harm to themselves or others.

A few commenters were concerned about specific language in the measure specification and provided feedback on how to capture "threat to self or others."

One commenter provided feedback on the language used in the measure to capture behaviors that demonstrate a threat to self or others. The commenter stated that patients who have failed alternative therapy for agitation or who have been reported violent and/or self-destructive should be excluded from the measure proportion.

Response: Thank you for your comment. The measure exclusion for “threat to self or others” is intended to remove the population described in your comment who may be violent and/or preventing staff from safely treating the underlying medical condition.

Another commenter questioned the list of exclusion codes included in the measure to define “threat to self or others” and suggested that consistent documentation of these behaviors in a standard fashion was unlikely.

Response: Thank you for your comment. We plan to thoroughly explore the concept of “threat to self or others” in further testing and will consider including the codes you have suggested.

One commenter suggested alternative language to capture “threat to self or others.” The commenter proposed including the following phrases: “verbalized threat toward staff,” “verbalized threat toward other patient,” “verbalized threat toward caregiver,” and “assaulted/struck other person (staff/patient/caregiver).”

Response: We will take under consideration your feedback on language to capture behaviors demonstrating “threat to self or others.”

One commenter didn’t think that the measure provided sufficient criteria to define appropriate use of antipsychotics, resulting in possible unintended consequences.

Another commenter suggested excluding patients who receive antipsychotics as an outpatient prior to hospitalization.

Response: Thank you for your comment. The measure excludes patients with FDA-approved diagnoses indicating appropriate antipsychotic medication treatment. Patients admitted to the hospital on antipsychotics present a challenge as abrupt termination of antipsychotic medication therapy is severely detrimental to a patient’s safety. We are continuing to examine possible methods to specify a measure that accounts for attempts to taper antipsychotic medication dosage or create specific care management plans that promote discontinuation in the shortest possible time frame after discharge.

Measure value sets

Two commenters suggested dropping Compazine from the list of antipsychotics considered in the measure. One of these commenters suggested excluding Compazine because it is commonly used as anti-nausea medication. This commenter also recommended excluding Phenergan and Reglan.

Response: We will make sure not to include prochlorperazine (Compazine) in the value set of antipsychotic medications used in the measure due to its use as a treatment for nausea.

Compazine, along with two other antipsychotics with similar profiles—promethazine (Phenergan), and metoclopramide (Reglan)—were not included in the value set and will not be included in the measure.

One commenter was concerned about codes used to define “threat of harm to self or others,” as Systematized Nomenclature of Medicine (SNOMED) codes used in the measure specifications might not be available at all hospitals.

Response: We will provide hospitals with guidance on the terminology used to identify measure elements, as appropriate. SNOMED is a preferred terminology standard for clinical and medical ontology within CMS eMeasure specifications.

One commenter recommended adding ICD-9 and ICD-10 codes relating to suicidal and homicidal ideations only if an underlying psychiatric diagnosis was present.

Response: Thank you for your feedback on the inclusion of specific ICD-10 codes that relate to suicidal and homicidal ideations. We will consider your suggestions for additions to the value set identifying “threat to self or others.”

Measure logic

One commenter was confused by the possible difference in timing between the occurrence of the “threat to self or others” state and other patient diagnoses. The commenter suggested that the “threat” state could occur at any time during the inpatient stay, whereas other patient diagnoses must be either pre-existing or start within 12 hours of the inpatient stay.

Response: Thank you for your comment. For the exclusions, we wish to capture diagnoses that are present on admission as this will best identify patients who are on long-term therapy. The 12-hour window is to allow hospital admission documentation to be complete with the necessary patient information. “Threat to self or others” may be a transitory state, and it could occur at any point (or at multiple points) during the inpatient encounter.

Addressing quality gaps

One commenter expressed concern over a quality gap in hospital practices. The commenter identified informed consent as a quality gap and stated that decision makers in the hospital need to fully appreciate all of the risks and benefits associated with antipsychotic use.

Response: We appreciate your feedback on addressing the quality gap relating to patient-centered care and informed consent. Although the measure does not address informed consent, we would hope that hospitals will look to this precept in their efforts to reduce antipsychotic use.

Addressing continuum of care

One commenter noted that use of antipsychotics in the inpatient setting is, in part, due to regulatory oversight of antipsychotic use in nursing homes. The commenter noted that antipsychotics are used in the hospital and then are tapered in the aftercare setting, resulting in a cycle of symptom re-emergence and subsequent re-hospitalization.

Response: Antipsychotic use in the inpatient setting is a complex issue and should be carefully monitored, including monitoring for unintended consequences. The proposed measure will encourage a focus on the many negative consequences patients face when receiving antipsychotic medications.

One commenter noted that initiation of antipsychotics often occurs in emergency departments (EDs); patients often stay on antipsychotics upon discharge from the ED to an inpatient unit.

One commenter cited a recent study showing that antipsychotic use is a potential issue during transitions of care, such as when a patient is transferred from the ICU to a medical floor or when a patient is discharged from the hospital to an aftercare center.

Response: We appreciate your feedback on emphasizing the re-examination of antipsychotics during transitions of care. We are currently examining methods to specify caregiver attempts to decrease patients' antipsychotics per best practice guidance.

Preliminary recommendations

We will review the commenter suggestions with CMS and our measure development team to improve the measure by:

- More explicitly specifying “threat to self or others” and connecting this language to a well-defined value set
- Assuring that the language used in the narrative specifications and measure logic are aligned and clear
- Addressing feasibility of data collection from hospital EHRs
- Accounting more clearly for use of benzodiazepines with consideration for recommending a complementary measure addressing the use of these drugs in patients 65 and older in future measure development initiatives
- Examine measurement approaches to patients admitted to the hospital on antipsychotics without FDA label indications for their use, as abrupt termination of therapy presents significant risk to patients.
- Explore the possibility of excluding cancer patients where delirium is present

Overall analysis of the comments and recommendations

Feedback received on the AP measure was highly constructive. Many commenters acknowledged the importance of developing a hospital measure that addresses use of antipsychotics in the inpatient setting. Some of them, however, highlighted the potential unintended consequences of the measure's implementation in critical care settings. Commenters frequently referenced APA, AGS, and NICE guidance characterizing the situations where antipsychotic prescribing met very narrowly defined care standards.

Some of the commenters expressed concern over the overall intent of the measure, suggesting that the measure might unintentionally encourage the use of even less effective

alternatives such as benzodiazepines. These commenters also questioned the ability of the measure to address either appropriate use of antipsychotics or quality care gaps. Responses reinforced the measure's main goal of calling attention to off-label antipsychotic prescribing practices, thereby reducing inappropriate use of antipsychotics.

Commenters provided constructive feedback on the measure definitions, including restricting the population to patients 65 years and older and recommending additional diagnosis and antipsychotic drug exclusion criteria. Some questioned the use of "delirium," "dementia," and "agitation." Several commenters were concerned about the possibility of a measure defining "threat to self or others." Responses cited the use of this phrasing in the AGS 2015 Updated Beers Criteria.

Public comment verbatim report

| Date Posted | Name/ Organization | Measure Name | Comment | Recommendation/Actions Taken |
|-------------|---------------------|---|--|--|
| 4/24/2016 | Robert Cohen | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>I am very concerned that the approach being proposed will have the unintended consequence of reducing the quality of life of the elderly patient with dementia who is admitted to a psychiatric unit with behavioral dyscontrol. As we are routinely willing to use pain killers (e.g. opiates) that we recognize have the unintended consequences of increasing morbidity and mortality in all patients, but particularly the elderly why do we not consider quality of life in these patients as well.</p> <p>Elderly patients coming into psychiatric hospitals from either home or ALF or nursing facilities are individuals who cannot be cared for in a way that fosters their quality of life. Currently, there are no medications that have been FDA approved for treatment of dementia with behavioral dyscontrol. Clinicians should not be discouraged from using the broad spectrum of medications available to them to determine whether on an individual basis a particular medication is helpful.</p> <p>While we would all love to have behavioral interventions that would serve this purpose there is no convincing data that treating behavioral dyscontrol with non-pharmacological means is effective in the vast majority of patients even under the ideal conditions of a research study never mind in the typical clinical setting. These patients are typically suffering as demonstrated by their obvious fearfulness and agitation. In many instances they are unable to give voice to their emotions either because of cognitive impairments, but also because of a disconnection between their emotions and mental ideation.</p> <p>The unintended consequences of restricting use of one class of medications will lead to the use of other medications that also likely to increase morbidity and mortality due to dyscontrol, balance problems, greater cognitive impairment and falls, e.g., high doses of benzodiazepines, antidepressants, antiepileptic drugs.</p> <p>One final comment. Should you continue along this path which I don't believe is a good idea I would suggest that you, at least, allow a category of reasonable use of antipsychotics for augmentation of antidepressants in elderly patients suffering from major depressive disorder, particularly those in anxious distress.</p> | <p>Thank you for your comment.</p> <p>The measure is not intended for use in inpatient psychiatric facilities or units. We will clarify this in future versions of the specification.</p> <p>The prevalence of antipsychotic use in the inpatient setting is not well understood. Expert input to date has suggested that the use of these medications varies widely. The intent of this measure is to better understand the prevalence and variation.</p> <p>We understand that literature supporting behavioral interventions for these patients is currently limited but that new models of care are under study.</p> <p>We appreciate the importance of potential unintended consequences of implementing this measure and plan to explore these, in particular the issue of substituting other drug classes that may present risks to patients.</p> <p>We will explore adding an exclusion for major depressive disorder to this measure.</p> |
| 4/28/2016 | Howard Bregman/Epic | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Two factors are considered in determining whether the antipsychotic treatment is valid or invalid: whether the patient has an exclusionary diagnosis, and whether the patient is a threat. However, the threat state can occur at any time during the encounter, while the diagnosis must be pre-existing or start within 12 hours of the encounter start.</p> <p>There doesn't seem to be any justification in the measure description for this difference. Why not just treat the diagnosis in the same way,</p> | <p>Thank you for your comment. We have heard during early development of this measure that a potential unintended consequence of measuring the rate of antipsychotic use may be that inaccurate diagnoses are documented (e.g., bipolar disorder). Our intent in requiring a different timing for the exclusion diagnoses is to capture diagnoses that are present on admission, allowing a window for hospitals to document that information after admission. "Threat to</p> |

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| | | | so that any overlap with the encounter is enough to exclude the patient? | self or others" is a short term state which could occur at any point during the inpatient encounter. |
| 4/28/2016 | Howard Bregman/Epic | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>The NICE guidance as referenced in the clinical recommendation statement states that patients who are severely distressed are candidates for antipsychotics. But there is no exclusion allowed for this indication.</p> <p>Even if present in an individual patient, practically it would be hard to find "severe distress" in discrete documentation, it would be written into a note. And if a clinician can't adequately document this reasonable exclusion in a way that counts for the measure, the overall validity of the measure should be questioned.</p> | <p>Thank you for your comment.</p> <p>The measure intent is to exclude patients in situations where they represent harm to self or others. This is consistent, in part, with the NICE guidelines. The American Geriatrics Society Beers Criteria suggests that patients who are "threatening substantial harm to self or others" may merit treatment with antipsychotics, and as such be excluded from the measure. We plan to discuss the concept of "threatening substantial harm to self or others" with hospital staff in order to explore the validity and feasibility of identifying these patients. We will also examine the extent to which this "severe distress" occurs in the absence of "threatening harm to self or others."</p> |
| 4/28/2016 | Howard Bregman/Epic | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>There are a number of diagnosis codes that could appear in the record that have the meaning of "threat to self and others" that would not count as a valid exclusions. Since it's already rather infeasible to document this fact discretely in the record (as opposed to in a note) the fact that these are not counted magnifies the false negative rate for exclusions.</p> <p>ICD-10 codes: R45.5 Hostility R45.6 violent behavior R45.850 homicidal ideations R45.851 suicidal ideations (not an exhaustive list)</p> | <p>Thank you for your comment. We plan to explore the concept of "threat to self or others" with hospital staff and will seek input on additional codes that may be useful to identify patients, including the codes that you have suggested.</p> <p>Thank you for your feedback on the inclusion of specific ICD-10 codes that relate to suicidal and homicidal ideations.</p> |
| 4/28/2016 | Howard Bregman/Epic | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>The measure does not exclude patients who receive anti-psychotics as an outpatient prior to hospitalization and are given even a single dose as an inpatient.</p> <p>Certainly any patients in this category would not have their outpatient meds discontinued "cold turkey" when they were admitted to the hospital, whether the outpatient therapy was or wasn't given for a qualifying reason.</p> <p>Ideally these patients would be excluded.</p> | <p>Thank you for your comment. The measure currently excludes patients with FDA-approved indications for antipsychotics. We will examine further in testing the appropriateness of removing patients who are admitted with an active antipsychotics prescription.</p> |
| 4/29/2016 | Melanie Lobel, MD, PharmD/ Lexington Medical Center | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Delirium is separate from agitation in many respects in the inpatient setting. The neuropsychiatric symptoms of dementia are also very different from delirium. Please understand that when trying to stabilize patients on the inpatient setting both can also be happening. Medical issues need to be ruled out first, of course and delirium treated by treating the medical issue causing this and symptoms of delirium as well. The drug of choice for delirium is an antipsychotic, i.e. haldol. Elderly patients are at greater risk of delirium based on age alone. Clinicians need access to</p> | <p>Thank you for your comment.</p> <p>We understand that the symptoms of dementia and delirium may differ, but these may be difficult to distinguish in the inpatient setting.</p> <p>This measure is intended to characterize the prevalence of use of antipsychotics in the inpatient setting and encourage exploration of underlying medical issues. Expert feedback has suggested that antipsychotics are too often used as a first line of therapy, and are not used consistently or in a</p> |

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| | | | antipsychotics in an inpatient setting to stabilize these patients and not to prolong hospital stays. | way that has demonstrated effectiveness in treating these symptoms. We agree, however, that clinicians should still have access to antipsychotics for FDA approved use and in patients threatening harm to self or others in an inpatient setting. |
| 5/6/2016 | Michele Balas | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>As outlined in the supporting documents, there is reason to believe that antipsychotic medications may be inappropriately utilized in the in-patient setting. Because these medications have many, important and often life-threatening side effects and their safety and efficacy in treating various disorders and syndromes such as delirium has yet to be fully established, the proposed CMS measure may help us better understand the extent to which these medications are being used in the older adult population.</p> <p>As an expert in the field of critical care and geriatric nursing, while supporting the measure, I do have some concerns regarding potential unintended consequences. First, I am not sure where you received feedback suggesting “benzodiazepines may be substituted for antipsychotics to control behavior of patients experiencing delirium or behavioral or psychological symptoms of dementia.” This statement is NOT congruent with many current evidence-based guidelines and may serve to further elevate hospitalized older adults’ risk of iatrogenic injury. Similar to antipsychotics, this class of medications is on the updated Beers Criteria of Potentially Inappropriate Medications for the Elderly because of the increased risk of cognitive impairment, delirium, falls, and fractures seen in older adults when these medications are used. Importantly, the American Geriatrics (AGS) Society Clinical Practice Guideline of Postoperative Delirium in Older Adults also strongly recommends that practitioners should avoid medications (like benzodiazepines) that induce delirium postoperatively in older adults to prevent delirium. The AGS makes similar statements regarding the treatment of agitation and delirium. For example, they strongly recommend that “practitioners should not use benzodiazepines as a first line treatment of the agitated post-operative delirious patient who is threatening substantial harm to self and/or others to treat postoperative delirium except when benzodiazepines are specifically indicated (including but not limited to treatment of alcohol or benzodiazepine withdrawal). Treatment with benzodiazepines should be at the lowest effective dose for the shortest possible duration, and should be employed only if behavioral measures have failed or are not possible and ongoing use should be evaluated daily with in-person examination of the patient.” The Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium in Adult Patients in the Intensive Care Unit, laid forth by the Society of Critical Care Medicine, also suggests that sedation strategies using nonbenzodiazepine sedatives may be preferred over sedation with benzodiazepines to improve clinical outcomes in mechanically</p> | <p>Thank you for your comment.</p> <p>Our statement regarding the use of benzodiazepines was not intended to mean that it is an acceptable substitution, but rather that implementing a measure of inpatient antipsychotic use could have unintended consequences (e.g., an increased use of benzodiazepines). We agree that antipsychotic use in the inpatient setting is a complex issue and should be monitored carefully, which includes potential unintended consequences.</p> <p>We agree that future measurement should explore behavioral interventions, and should encourage improved care protocols for patients experiencing or at risk for developing delirium.</p> |

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| | | | <p>ventilated adult ICU patients and that in mechanically ventilated adult ICU patients at risk of developing delirium.</p> <p>Admittedly, antipsychotic use in the ICU setting is a particularly complex issue. While the treatment of delirium should be focused on identify and removing the cause of delirium, antipsychotics are frequently used in the ICU to treat, prevent, and manage this complex syndrome. Moreover, antipsychotics are sometimes used to treat bothersome and distressing symptoms (e.g., hallucinations) and for their sedative properties. Should ICU practitioners perceive that antipsychotic medication use is being restricted, I fear that they may turn to other medication classes to prevent and treat delirium that are as equally non-evidenced based. They may also rely more heavily on physical restraint use (another hazard of hospitalization for older adults) in an effort to protect the critical lines and tubes used in this population. While nonpharmacologic delirium management strategies have proven successful outside the ICU, the safety and effectiveness of these interventions in the setting of complex illness has yet to be fully demonstrated. Moreover, these strategies often take more education and time than simply administering a medication. My hope is that CMS and other federal agencies will invest in future initiatives aimed at generating, disseminating, and implementing effective behavioral management interventions in the future.</p> | |
| 5/9/2016 | Brooke Villarreal/ Hospital Corporation of America (HCA) | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Are there unintended consequences of this measure?</p> <ul style="list-style-type: none"> • The oversight of antipsychotic use in nursing homes has led to a revolving door of readmissions of patients with dementia who become agitated or psychotic. Antipsychotics are used in the hospital and then tapered in the aftercare setting resulting in re-emergence of symptoms and re-hospitalization. • Benzodiazepines (BZDs) are associated with worsening of delirium and cognitive impairment. Benzodiazepines increase the risk of falls and can lead to dependence. They may also cause a paradoxical agitation and disinhibited behavior in elderly patients that can increase risk of injury or harm to the patient and/or healthcare provider. <ul style="list-style-type: none"> - The American Geriatric Society 2015 Updated Beers Criteria provide a strong recommendation to avoid the use of benzodiazepines in senior adult patients especially those with dementia or cognitive impairment, delirium or high risk of delirium, and history of falls or fractures. • Guidelines for delirium focus on first on prevention, early recognition and non-pharmacologic nursing strategies for management of patients with delirium rather than pharmacological treatment (as there are no FDA-approved medications for the management of delirium). Treatment of | <p>Thank you for your comment.</p> <ul style="list-style-type: none"> • Antipsychotic use in the inpatient setting is a complex issue and should be monitored carefully, which includes potential unintended consequences such as the issue you describe in the nursing home setting. • Our statement regarding the use of benzodiazepines was not intended to mean that it is an acceptable substitution, but rather that implementing a measure of inpatient antipsychotic use could have unintended consequences (e.g., an increased use of benzodiazepines that may increase risk to patients). • The measure currently excludes diagnoses with FDA-approved indications for the use of antipsychotics. We will seek further feedback from stakeholders on whether patients with psychotic disorders, including psychosis secondary to dementia, should be excluded. • The measure does not identify prescribing clinicians or their specialty. However, the measure is not intended for use in inpatient psychiatric facilities or units, which may help address this concern. We will clarify this in future versions of the specification. |

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| | | | <p>delirium with benzodiazepines is no longer recommended, even in hyperactive or agitated patients, since BZDs may cause excessive sedation, disinhibition, and worsen delirium.</p> <p>Are there other patients who should be removed from the denominator?</p> <ul style="list-style-type: none"> Exclude elderly patients with any psychotic disorder including psychosis secondary to dementia <p>Are there antipsychotic medications that should not be included in the measure?</p> <ul style="list-style-type: none"> Exclude antipsychotic medication prescribed by a psychiatrist Exclude “prn” antipsychotic medication orders <p>We welcome feedback on the language in the measure specification and are seeking recommendations on how to capture behaviors that demonstrate a threat to self or others.</p> <ul style="list-style-type: none"> Exclude any elderly patient who has failed alternative therapy for agitation or who has been repeated violent and/or self-destructive off of antipsychotic therapy <p>We seek feedback on whether the proposed measure will:</p> <ul style="list-style-type: none"> Shed light on the magnitude of antipsychotics prescribed and administered in the inpatient setting <ul style="list-style-type: none"> If the measure specifically targets inappropriate or frivolous use of antipsychotics for indications such as insomnia or non-specific anxiety, then it may be useful in determining the prevalence of such usage. If the measure is overly inclusive of appropriate indications, it may reveal high levels of prescribing practices but not impact true patient safety and quality of care. Promote improvement in prescribing practices in the hospital <ul style="list-style-type: none"> Every patient is unique, as is every treatment plan. Prescribing decisions should be thoughtful, patient-centered discussions between the physician, patient and/or caregiver or family members in order to ensure the risks versus benefits of antipsychotic use in elderly are being addressed. This practice is consistent with the updated 2016 “American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia” (APA, <i>Am J Psych</i> 173:5) which suggest individualized therapy ultimately be made in collaboration with the patient whenever possible to incorporate patient’s personal preferences and values (such as quality of life) to improve treatment outcomes. | <ul style="list-style-type: none"> Expert input received to date has suggested that PRN use of antipsychotics is not effective for the treatment of delirium and may be an unsafe practice. We do not currently plan to exclude PRN antipsychotic orders from this measure. Expert input received to date has suggested that, while behavioral interventions are a valuable first step in preventing delirium, this is not currently documented in a structured fashion and would not likely be captured by a quality measure. The measure exclusion for “threat to self or others” is intended to remove the population described in your comment about this language, who may be violent and preventing staff from treating their underlying medical condition. Thank you for your comment regarding frivolous and inappropriate uses of APs for insomnia and anxiety. While we are not in a position to study these in detail, our testing may reveal when these conditions are cited for use of APs and we will seek additional feedback from hospital staff and stakeholders. We appreciate your feedback on the need for patient-centered care. We hope the measure will result in hospitals focusing on staff education regarding antipsychotic prescribing. In particular, the need to include the patient and family in discussions about behavioral and environmental approaches as well as pharmacological interventions. We acknowledge that some guidance documents indicated that antipsychotics might be appropriate for patients with dementia, at a minimal effective dose for shortest period of time. This measure is focused on hospitalized patients 65 and older prescribed APs without an FDA-approved indication or representing a threat to self or others. In testing, we will attempt to determine the extent to which patients with dementia are included in the numerator. |

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| | | | <ul style="list-style-type: none"> - Our concern would be that the measure may have a negative impact on patient outcomes due to an overzealous attempt to eliminate antipsychotic utilization in the elderly. • Address a quality gap that justifies changing hospital practices and procedures around antipsychotic use <ul style="list-style-type: none"> - The true quality gap is in the realm of informed consent that allows decision makers to fully appreciate the risks and benefits of antipsychotic medication use in this patient population. The measure would need to be reconfigured in order to address that gap. • Provide information that indicates appropriate, patient-centered care <ul style="list-style-type: none"> - Antipsychotic therapy is an appropriate treatment option in patients who experience behavioral or psychological symptoms of dementia. Consistent with the APA guidelines, antipsychotics drug at a minimal effective dose is reasonable in this patient population both acutely and for maintenance treatment. - Additionally, in the non-demented elderly population, antipsychotics should be used sparingly and only when clearly indicated (schizophrenia, psychotic depression, bipolar disorder or agitation in autistic spectrum). The use of certain atypical antipsychotics as adjuncts for the treatment of major depressive disorder may be too risky given the many other alternatives for treatment of depression and the increased risk of all-cause mortality in the elderly exposed to antipsychotics. | |
| 5/9/2016 | Katie Thomas/ Thomas Jefferson University | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>There are unintended consequences of this measure. The use of antipsychotics in palliative care and EOL care and to assist with management of delirium. These are three accepted indications of use that do not fall into the descriptions.</p> <ul style="list-style-type: none"> • The age range should not be expanded to include all adults. • Patients with delirium or being used for palliative or EOL care should be removed from the denominator. • Haldol is the medication used most commonly in palliative and EOL care. Although other antipsychotics are often uses – the exclusions should be more based on reason for use rather than drug. | <p>Thank you for your response.</p> <p>The measure population does not include individuals in palliative care or EOL care. Instead, the measure population is limited to adults 65 and older in the acute inpatient setting.</p> <p>The measure currently excludes patients with FDA-approved indications for antipsychotics from the denominator population.</p> <p>We appreciate your feedback on the age range for the measure denominator and note the measure applies to adults 65 and older.</p> <p>Currently, measure exclusions are based on reasons for use. Patients with FDA approved indications for antipsychotics are excluded from the denominator population while inpatient hospitalizations for patients with a documented indication of “threat to self or others” are</p> |

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| | | | | excluded from the numerator based on the AGS Beers Criteria. |
| 5/9/2016 | Lynn Baldwin | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Denominator Exclusions:</p> <p>\$ExclusionDiagnosis overlaps "Occurrence A of Encounter, Performed: Encounter Inpatient. What is intent of "overlap"? What time period would this represent if \$ExclusionDiagnosis addressed time evaluated before encounter and during encounter.</p> <p>Numerator:</p> <p>Only Medication, Order: antipsychotic Medications is included in measure logic however we see multiple references to the actual administration of the medication (both in Description on human readable document and framing document). Please clarify if intent is to evaluate only order and not administration.</p> <p>Numerator Exclusions:</p> <p>Is there a need for a more general Medical Reason exclusion? If the physician feels the medication is needed but no risk to self or others, and not one of the conditions listed in \$ExclusionDiagnosis</p> <p>Guidance on use of Symptom (we didn't see this in the Implementation Guide – but may have missed it). We can comment that this seems to fit more with the "Physical Exam, Performed". category, state</p> | <p>The intent of the logic statement \$Exclusion diagnosis overlaps "Occurrence A of Encounter, Performed: Encounter Inpatient" is to indicate that the exclusion diagnoses must be present at the start of the encounter.</p> <p>The numerator logic, as currently written, is only intended to evaluate an order of antipsychotics during the inpatient hospitalization and not administration of antipsychotics.</p> <p>An unspecified medical exclusion is not possible in an eMeasure. Reasons to exclude patients from this measure must be specified using existing terminology standards (e.g., ICD, LOINC).</p> |
| 5/10/2016 | Anne Coultas/ McKesson | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Thank you for the opportunity to comment on this measure while it is in development.</p> <p>We agree with the population being restricted to inpatients aged 65 and over.</p> <p>In response to the question: are there other patients who should be removed from the denominator?</p> <p>Yes. Identifying the appropriate population may be difficult. We agree with excluding patients with the diagnosis of schizophrenia, Tourette's syndrome, bipolar disorder, or Huntington's disease. There are additional diagnoses to consider for exclusion such as: fibromyalgia, chronic pain, seizures, panic disorders, Parkinson's, and allergic conditions. Some hypertension patients are appropriately treated reserpine and should not be included in the numerator. We agree with other comments suggesting exclusion based on reporting antipsychotics as home medications. While these medications may be ordered to continue during their admission, it is not a new medication for a problem occurring while in the hospital.</p> <p>We agree with excluding inpatient psychiatric patient and notice there is no logic for this exclusion. Accurately identifying those patients may be difficult – is there a proposed methodology?</p> | <p>Thank you for your comment.</p> <p>We appreciate your feedback on the age range and support for the 65 and older population.</p> <p>The measure currently excludes diagnoses with FDA-approved indications for the use of antipsychotics.</p> <p>We will seek further feedback from stakeholders on whether patients with fibromyalgia, chronic pain, seizures, panic disorders, allergic conditions, and Parkinson's disease should be excluded. The measure currently excludes patients with FDA-approved indications for antipsychotics. We will examine further in testing the appropriateness of removing patients who are admitted with an active antipsychotics prescription.</p> <p>The value set that identifies eligible encounters intentionally does not include inpatient psychiatric patients.</p> <p>We appreciate your feedback suggesting additional numerator exclusions. The medications listed (e.g., fluoxetine) are not antipsychotics and are not referenced in the measure. We will explore exclusions for patients with</p> |

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| | | | <p>In response to the question: Are there antipsychotic medications that should not be included in the measure?</p> <p>Yes, there some used for antidepressant use and also other uses. Our search in VSAC did not find Antipsychotic Medications with the OID of 2.16.840.1.113883.3.464.1003.196.12.1255. A search by “Antipsychotic Medications” found OID 2.16.840.1.113883.3.464.1003.196.11.1265. We do not know what the differences may be between the 2.</p> <p>Our recommendations for the value set used in the measure, (based on a review of Antipsychotic Medications with OID 2.16.840.1.113883.3.464.1003.196.11.1265 and not OID 2.16.840.1.113883.3.464.1003.196.12.1255) are to remove or not include the following:</p> <ul style="list-style-type: none"> • • Amitriptyline – chronic pain • • Clonazepam – panic disorders, seizures • • Fluoxetine – bulimia, fibromyalgia, panic disorders • • Reserpine – hypertension; including the combination products listed in the value set • • Cyproheptadine – allergic conditions • • Selegiline – parkinsons | <p>major depressive disorder where specific antipsychotics are used as adjunct therapy consistent with FDA labeling</p> <p>This measure is currently under development. As such, the VSAC is not always up to date with current OIDs. Thus, we encourage the commenter to check the VSAC periodically.</p> |
| 5/12/2016 | Julianna Belelieu/ Memorial Sloan Kettering Cancer Center | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Caution in the use of antipsychotics in older adults in the inpatient hospital setting is warranted, particularly for patients with dementia as opposed to acute delirium. However, assessing the rate of antipsychotic use in older adults in this setting without fully assessing criteria for appropriate use may result in negative and unintended consequences.</p> <p>As noted in the “feedback on measure component to date” for the measure rationale, this measure holds the unfortunate potential to incentivize the preferential substitution of benzodiazepines for antipsychotics in delirium in older patients. This is directly at odds with consensus guidelines and peer-reviewed literature. For example, the Delirium Guidelines of the American Psychiatric Association recommend against the use of benzodiazepines in delirium, as do Cochrane Evidence and the American Geriatrics Society guidelines on management of postoperative delirium in older adults, noting the potential for adverse effects.</p> <p>This measure could also discourage important applications for the use of antipsychotics. In the oncology setting, antipsychotics are frequently used for the treatment of cachexia and weight loss due to cancer progression and chemotherapy-induced nausea, vomiting, and decreased appetite. Given that the stated measure rationale is to assess off-label treatment of delirium with antipsychotics, we recommend removing patients with cancer who are being treated for</p> | <p>Thank you for your comment.</p> <p>We appreciate the importance of potential unintended consequences of implementing this measure. Antipsychotic use in the inpatient setting is a complex issue and should be monitored carefully, including the issue you describe regarding cancer progression treatment.</p> <p>We appreciate your feedback on additional numerator exclusions.</p> <p>We acknowledge that some guidance documents indicated that antipsychotics might be appropriate for patients with dementia, at a minimal effective dose for shortest period of time. This measure is focused on hospitalized patients 65 and older prescribed APs without an FDA-approved indication or representing a threat to self or others. In testing, we will attempt to determine the extent to which patients with dementia are included in the numerator.</p> <p>We appreciate the additional literature that you provided regarding the use of antipsychotics in treating delirium for patients with cancer and nonpharmacological interventions for cancer patients in palliative care settings. To clarify, the measure population does not include individuals in palliative care or hospice care. Instead, the measure</p> |

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| | | | <p>cachexia, weight loss, nausea, vomiting, or loss of appetite from the measure numerator.</p> <p>Moreover, this proposed measure does not accurately reflect the AGS guidelines on management of postoperative delirium in older adults. The AGS guidelines recommend that the prescribing practitioner may use antipsychotics at the lowest effective dose for the shortest possible duration to treat patients who are severely agitated or distressed, and are threatening substantial harm to self and/or others. Based on that recommendation and the current evidence on the use of antipsychotics in cancer patients with delirium, we recommend removing cancer patients with delirium who present with severe agitation, distress, risk of substantial harm to self/others from the measure numerator.</p> <p>A synthesis of the best available recommendations on the use of antipsychotics in delirium in patients with cancer is attached for your reference (see William Breitbart and Yesne Alici. (2012). Evidence-based treatment of delirium in patients with cancer. Journal of Clinical Oncology, 30:1206-1214). A study failing to demonstrate a positive effect for nonpharmacological interventions in the prevention of delirium or reduction of delirium severity among cancer patients in palliative care settings is also attached (see Gagnon, P. et al. (2012). Delirium prevention in terminal cancer: Assessment of a multicomponent intervention. Psychooncology, 21(2):187-94).</p> | <p>population is limited to adults 65 and older in the acute inpatient setting.</p> |
| <p>5/12/2016</p> | <p>Holly Harmon/ American Health Care Association</p> | <p>Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting</p> | <p>Thank you for the opportunity to comment. Below are our comments on the New EHR Measure: Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting</p> <p>We support a measure on antipsychotic use in the hospital setting. Appropriate use of antipsychotics is important across the healthcare continuum.</p> <p>We support the exclusions of FDA approved diagnoses.</p> <p>We support dropping Compazine from list of antipsychotics since it is used commonly as anti-nausea medication.</p> <p>We would not support using antipsychotic if a person is at risk of harm to themselves. These medications take time to be effective for psychoses and acute effect is sedation.</p> <p>We would like to submit corrections to the statement made that this hospital measure is harmonized with long term care. This is not the case for these reasons:</p> <ul style="list-style-type: none"> • Long term care measure does not exclude bipolar. Please note we have advocated for bipolar to be an exclusion in long term care measure. | <p>Thank you for your comment.</p> <p>We appreciate your feedback on the general measure concept and exclusions of FDA-approved diagnoses.</p> <p>We appreciate your feedback on antipsychotic medications that should not be included in the measure.</p> <p>The measure is currently aligned with both the AGS Beers Criteria and, in part, with the NICE guidance.</p> <p>Thank you for your feedback on harmonization of the proposed measure with the measure used in long-term care settings. We've examined this and have attempted to align the hospital-based measure with the long-term care measure; however, we have crafted the hospital measure so it moves beyond a utilization measure only.</p> |

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| | | | <ul style="list-style-type: none"> • Long term care does not have a diagnosis on admission restriction, which this document on the hospital measure states diagnoses are excluded if present on admission. • The hospital measure is restricted to patients 65 and older, unlike the long term care measure which does not have an age restriction. • Last, the hospital measure excludes if there is documentation of patient as harm to self or others, the long term care measure does not have an exclusion like this. <p>Thank you for considering these comments.</p> | |
| 5/13/2016 | Laura Thornhill/ Alzheimer's Association | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>The Alzheimer's Association appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed quality measure, Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting.</p> <p>The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support, and research. Today, there are more than 5 million Americans living with Alzheimer's disease. As the size and proportion of the United States population age 65 and older continue to increase, the number of Americans with Alzheimer's disease and other dementias will grow. Studies have found that more than 90 percent of people with dementia develop at least one dementia-related behavior, like hallucinations and aggression, and a significant percentage of these individuals have serious clinical implications. Although use of antipsychotic medications is associated with an increased mortality risk, there are instances in which dementia-related behaviors pose a greater risk to individuals and families than the medications themselves. We appreciate CMS's effort to measure and ensure their safe and appropriate use.</p> <p>Historically, antipsychotic medications have been used appropriately and inappropriately to address some of the behavioral and psychological symptoms of dementia. Psycho-social interventions (non-pharmacologic) should be a first-line alternative to pharmacologic therapies. However, psychotropic medications may need to be considered when non-pharmacologic interventions do not address the behavior. We refer CMS to the Alzheimer's Association position statement on dementia-related behavior and offer feedback on the measure's elements and CMS's additional areas of concern below.</p> <p>While this measure is designed to capture information in inpatient settings, the Association believes that the initiation of antipsychotics often occurs in emergency departments (EDs) and they are carried over to an inpatient stay or upon discharge from an ED. Without knowing when the antipsychotic was prescribed, this measure may not provide the appropriate guidance as a quality indicator for</p> | <p>Thank you for your comment.</p> <p>We recognize that antipsychotics initiation may occur outside of the inpatient hospital setting. The intent of the measure is to reduce inappropriate use of antipsychotics in the inpatient hospital setting.</p> <p>We appreciate your feedback on additional data collection and dissemination considerations prior to implementing this measure.</p> <p>Our statement regarding the use of benzodiazepines was not intended to mean that it is an acceptable substitution, but rather that implementing a measure of inpatient antipsychotic use could have unintended consequences (e.g., an increased use of benzodiazepines).</p> <p>We appreciate your feedback on the age range for the measure denominator.</p> <p>We appreciate your feedback on the measure. We agree that use of these medications varies widely. The intent of this measure is to reduce inappropriate use of antipsychotics in the inpatient hospital setting.</p> |

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| | | | <p>hospital care (e.g., the need for better inpatient staff training). With regard to short hospital stays, recommendations to use antipsychotics in the lowest dose for the shortest possible amount of time may not be feasible to implement prior to discharge, leaving dose titration and discontinuation to non-hospital based care providers. Furthermore, this measure may or may not recognize hospitals working to reduce antipsychotic use in patients with longer lengths of stays (LOSs). Consistent with the Government Accountability Office's 2015 report and recommendation, the Alzheimer's Association respectfully requests that the Department of Health and Human Services (HHS) collect and share data on antipsychotic use in hospitals and emergency departments and per LOS for hospitalized patients prior to implementing a measure. Such data can inform measure development.</p> <p>Comments on Measure Specifications</p> <p>Rationale</p> <p>The Alzheimer's Association does not recommend the use of benzodiazepines in place of antipsychotics. Both benzodiazepines and antipsychotics may both contribute to cognitive decline, particularly when used over long periods of time. Antipsychotics should only be used when non-pharmacologic interventions have failed. When they are used, they should be used for the briefest possible period. We urge CMS to monitor and disseminate the most recent literature on the risks and benefits of these medications to providers.</p> <p>Denominator</p> <p>The Alzheimer's Association supports expanding the application of this measure to all hospital inpatients. Approximately 200,000 individuals under the age of 65 have younger-onset Alzheimer's disease, often experience dementia-related behaviors, and may receive antipsychotics if aggressive or threatening behavior results in hospitalization. The administration of antipsychotics to these individuals should be captured in addition to older persons. CMS should also capture the number of all persons admitted through emergency departments and their lengths of stays.</p> <p>Denominator Exclusions</p> <p>The Association appreciates CMS's exclusion of individuals with disorders for which antipsychotics are indicated.</p> <p>Additional Considerations</p> <p>Implementation of this measure is likely to shed light on the magnitude of antipsychotic use in the inpatient setting. We are concerned, however, that hospitals and prescribers may interpret implementation of the measure as CMS discouraging antipsychotic use. As noted, the Association and persons with dementia and their</p> | |

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| | | | <p>families acknowledge the potential benefits of appropriately-used antipsychotics. These medications should be an option that is weighed by informed prescribers and consumers alike. CMS must fully communicate the underlying intent of the measure and how it will be used in the future.</p> <p>As written, the measure is not likely to improve prescribing practices or address quality gaps on its own. Little is known about antipsychotic use in settings other than nursing homes or the impact of transitioning between settings, which experts agree affects usage. Again, we urge HHS and CMS to collect data on antipsychotic use in various settings to better understand where and how they are used. CMS can then use this information to design measures to improve prescribing practices and address quality gaps.</p> <p>The Alzheimer’s Association would be pleased to serve as a resource to CMS as it considers these important issues and how they relate to individuals living with Alzheimer’s and related dementias. Please contact Laura Thornhill, Manager of Regulatory Affairs, at 202-638-7042 or lthornhill@alz.org if you have questions or if we can be of additional assistance.</p> | |
| 5/13/2016 | Anna Mikhailovich/ American Geriatrics Society | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>The American Geriatrics Society (AGS) appreciates the opportunity to provide the following feedback on the Centers for Medicare & Medicaid Services’ (CMS’) proposed quality measure, “Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting”:</p> <p>Rationale</p> <p>In response to the feedback that CMS has received to date, we note that benzodiazepines should not be a first line agent for delirium since there is data to suggest an increase in delirium with the use of this type of medication.</p> <p>As outlined in the “AGS Beers Criteria Update,” antipsychotics should only be used to control symptoms in older patients for whom nonpharmacological options have failed or who pose a threat to themselves or others.</p> <p>The AGS would also like to highlight new data (https://www.ncbi.nlm.nih.gov/pubmed/26582298) showing that antipsychotic use is a potential issue during transitions of care (i.e. from the ICU to the medical floor or discharged from the hospital) in addition to the inpatient setting.</p> <p>Denominator exclusions</p> <p>The AGS recommends removing patients with a diagnosis of major depressive disorders from the denominator as well as patients with hyperactive delirium.</p> <p>Increase our understanding of the magnitude of antipsychotics prescribed and administered in the inpatient setting?</p> | <p>Thank you for reviewing comments provided to CMS. We agree that the use of benzodiazepines is not an acceptable substitution for antipsychotics. We also recognize that implementing this measure could have unintended consequences such as an increased use of benzodiazepines.</p> <p>Thank you for the new data that highlights antipsychotic use as a potential issue during transitions of care.</p> <p>We will further explore exclusions for patients with a diagnosis of major depressive disorder or hyperactive delirium.</p> <p>We appreciate your feedback on emphasizing the re-examination of antipsychotics during transitions of care. The intent of the proposed measure is to reduce inappropriate use of antipsychotics in the inpatient hospital setting.</p> <p>Thank you for your feedback on additional data elements that would be useful for the measure to collect.</p> |

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| | | | <p>Yes, the AGS believes that the proposed measure will shed light on this largely understudied area. However, in addition to the magnitude of this issue, much is unknown about where antipsychotics are prescribed within the inpatient setting and their continued use in the community and long-term care setting. Therefore, it would be particularly helpful if the measure could record service of origin (e.g. in-patient psychiatry unit, ICU, etc.) and whether the medication was prescribed at discharge.</p> <p>Promote improvement in prescribing practices and reduce variation in use of antipsychotics?</p> <p>The AGS believes that an emphasis on the re-examination of antipsychotics during transitions of care would be helpful.</p> <p>Provide information that is a useful indicator of appropriate, patient-centered care?</p> <p>The AGS notes that it is difficult at this point to measure appropriate patient-centered care with high levels of accuracy, however, we believe that the proposed measure is a first step towards improvement by providing an estimate regarding whether the use of antipsychotics is moderate, high, or out of control.</p> | |
| 5/13/2016 | Samantha Shugarman/ American Psychiatric Association | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>APA appreciates the opportunity to weigh in and share our opinion on this measure concept as this population is often times over prescribed antipsychotic medication.</p> <p>Are there any unintended consequences of this measure? The use of physical restraints could increase. Not only could benzodiazepines be substituted, but also highly anticholinergic meds (such as hydroxyzine and benztropine) and antidepressants (which have been associated with falls). Violence towards nursing staff could also increase, resulting in higher rates of injury, and an avoidance of these types of patients, which would interfere with their medical care. It could also become very difficult to discharge these patients to home or to community nursing homes if behavior could not be adequately managed. This would result in extended and inappropriately lengthy acute hospital admissions.</p> <p>Are there other patients who should be removed from the denominator? Schizoaffective disorder, major depression with psychotic features</p> <p>Are there antipsychotic medications that should not be included in the measure? Compazine, Phenergan and reglan</p> <p>We welcome feedback on the language in the measure specification and are seeking recommendations on how to capture behaviors that demonstrate a threat to self or others.</p> <ul style="list-style-type: none"> -Verbalized threat towards staff | <p>Thank you for your comment.</p> <p>We appreciate the importance of potential unintended consequences of implementing this measure including benzodiazepine substitution to control the behavior of patients experiencing delirium or behavioral or psychological symptoms of dementia.</p> <p>Antipsychotic use in the inpatient setting is a complex issue and should be monitored carefully, including the issues you described.</p> <p>We will consider your suggestion to exclude schizoaffective disorder and will explore exclusions for patients with major depressive disorder where specific antipsychotics are used as adjunct therapy consistent with FDA labeling.</p> <p>We appreciate your feedback on exclusions of FDA approved diagnoses.</p> <p>We will take your feedback on language to capture behaviors demonstrating “threat to self or others” under consideration.</p> |

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| | | | <ul style="list-style-type: none"> • -Verbalized threat towards other patient • -Verbalized threat towards caregiver • -Assaulted/struck other person (staff/patient/caregiver) | |
| 5/13/2016 | Lori Harmon/ Society of Critical Care Medicine | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Please accept our comment regarding the CMS Quality Measure Proposal, "Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting" Specifically, we would like to comment on the effect of this measure in the ICU. We strongly believe that this CMS quality measure, as currently proposed, could have important, and unintended, consequences on the ability of ICU clinicians to safely and appropriately manage critically ill, older adults under their care.</p> <p>There are a number of important issues that are unique to the ICU that influence antipsychotic therapy use in the critical care setting. These issues are numerous and we suggest that it is inappropriate and likely not possible to develop an antipsychotic-related quality measure that applies to both ICU and non-ICU patients. We urge CMS to consider the unique aspects of antipsychotic use in the ICU (versus that outside of the ICU) and develop a separate quality measure for the critically ill population. Until these changes are considered, we request that CMS exclude ICU patients from the current proposed quality measure.</p> <p>Several key issues surrounding the use of antipsychotics in the ICU should be noted:</p> <ul style="list-style-type: none"> • It is premature to strictly limit antipsychotic use in the ICU for either the treatment or prevention of delirium before the definitive studies evaluating their safety and efficacy are published. <ul style="list-style-type: none"> - The current published evidence in the critically ill is based on relatively small studies that have enrolled heterogeneous patient populations and suffer from important methodological limitations. In many of these studies, a protocolized ABCDEF approach to patient care, that emphasizes non-pharmacologic strategies like early mobilization shown to reduce delirium, was not used. Until large RCTs evaluating the role of antipsychotics for the prevention and/or treatment of delirium in the ICU are published (two of which have nearing completion), the specific role for antipsychotics in the ICU cannot be clearly defined. • ICU patients may have delirium symptoms that require treatment with an antipsychotic who are not severely agitated. <ul style="list-style-type: none"> - In the context of a patient with delirium in the ICU, a short course of any antipsychotic may be indicated when the patient exhibits bothersome delirium symptoms (i.e. hallucinations, delusions or fear) regardless of whether agitation is present. | <p>Thank you for your comments.</p> <p>The overall intent of the measure is to reduce inappropriate use of antipsychotics in the inpatient hospital setting. We are continuing to explore antipsychotic use by location.</p> <p>We recognize there are a number of important issues unique to the ICU setting that impact antipsychotic use. We will consider the unique aspects of antipsychotic use in the ICU and potential unintended consequences for critically ill patients.</p> |

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| | | | <ul style="list-style-type: none"> The proposed CMS criteria for antipsychotic use may not always fit the criteria for their use in an ICU patient with delirium who is agitated. <ul style="list-style-type: none"> The definition of antipsychotic appropriateness being used in the proposed quality measure (i.e., documentation that the patient is threatening harm to themselves or others) may only account for a small proportion of ICU patients with delirium-associated agitation and where a short trial of low-dose antipsychotic therapy may be warranted. Antipsychotics are often administered to ICU patients on a short-term basis for their sedative properties, regardless of whether delirium is present. <ul style="list-style-type: none"> Antipsychotics, particularly IV haloperidol, can be an effective short-term, intermittent sedative (in patients with agitation not related to pain) who do not require a sedative continuous infusion in an effort to avoid the administration of intermittent benzodiazepine therapy (a proven cause for delirium). There may be a role for an antipsychotic at night in patients who report not being to fall asleep when other nonpharmacologic interventions like ear plugs have been offered and have not worked. <p>Thank you for considering our concerns. Please be assured that SCCM is committed to reducing inappropriate antipsychotic use in both ICU and post-ICU settings, but the quality measure, as currently proposed, is far too restrictive for ICU practice.</p> | |
| 5/13/2016 | Joshua Lapps/ Society of Hospital Medicine | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>SHM appreciates the opportunity to provide comments on the draft measure for use of antipsychotics.</p> <p>Feedback on Use of Antipsychotics Measure</p> <p>Measure Rationale: This measure examines the potentially inappropriate use of antipsychotic medications, similar to the approach used in nursing homes (CMS 2015). Measuring the use of antipsychotics among older adult patients could help reduce inappropriate use.</p> <p><i>Input sought: Are there any unintended consequences of this measure?</i></p> <p><i>SHM Comments:</i> One of the greatest potential unintended consequences is the potential increase in use of benzodiazepines to control the behavior of patients who experience delirium or behavioral or psychological symptoms of dementia. Benzodiazepines are also classified as medications to “avoid” in the updated Beers’ criteria—increasing risk of cognitive impairment, delirium, falls, fractures, and motor vehicle crashes (2015 AGS). These are not generally recommended in delirium or dementia and</p> | <p>Thank you for your comment.</p> <p>Our statement regarding the use of benzodiazepines was not intended to mean that it is an acceptable substitution, but rather that implementing a measure of inpatient antipsychotic use could have unintended consequences (e.g., an increased use of benzodiazepines). Antipsychotic use in the inpatient setting is a complex issue and should be monitored carefully, including the potential consequences you described.</p> <p>We appreciate your feedback on the age range and support for the 65 and older population.</p> <p>The measure currently excludes diagnoses for FDA-approved indications for the use of antipsychotics. We will consider your suggestion to exclude schizoaffective disorder and other psychotic disorders from the measure and also investigate the potential exclusion of patients undergoing emetogenic chemotherapy.</p> |

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| | | | <p>can have a paradoxical effect of worsening the behavioral disturbance.</p> <p>SHM is also concerned about a range of possible unintended consequences of delayed treatment of agitated delirium as a result of the measure and/or increase use of physical restraints which could lead to patient harm.</p> <p>Denominator: Inpatient hospitalizations for patients ages 65 and older.</p> <p><i>Input sought: We welcome feedback on the age range for this measure and whether it should be expanded to include all adults.</i></p> <p>SHM Comments: No comments- agree with the age range as this is consistent with the Beers criteria.</p> <p>Denominator Exclusions: Patients with a diagnosis of schizophrenia, Tourette's syndrome, bipolar disorder, or Huntington's disease at the time of admission.</p> <p><i>Input sought: Are there other patients who should be removed from the denominator?</i></p> <p>SHM Comments: The updated Beers criteria gives the following as possible indications for antipsychotic use: "schizophrenia, bipolar disorder, or short-term use as antiemetic during chemotherapy." SHM would support an exclusion for antipsychotic use during emetogenic chemotherapy. SHM also asks for clarification if the stated exclusion for schizophrenia would also include schizoaffective disorder--that is also a psychiatric diagnosis that could need antipsychotic medications.</p> <p>SHM recommends consider adding more specified psychotic disorders to this list of exclusions: depression with psychosis, cocaine abuse disorder with psychotic reaction, etc. Unspecified psychotic disorders may be difficult to separate from a behavioral consequence of delirium or dementia (and the code may in fact indicate one of those conditions as the reason for treatment).</p> <p>The measure should also be able to exclude patients who come in to the hospital on these medications as hospitalists often don't stop them as it may be that the patient needs them for other reasons.</p> <p>Numerator: Patients who received an order for an antipsychotic medication during the inpatient encounter.</p> <p><i>Input sought: Are there antipsychotic medications that should not be included in the measure?</i></p> <p>SHM Comments: No comment- not enough information in measure framework. Beers list includes all first and second generation antipsychotics.</p> | <p>We recognize that antipsychotics initiation may occur outside of the inpatient hospital setting. The intent of the measure is to reduce inappropriate use of antipsychotics in the inpatient hospital setting.</p> <p>We will further consider your feedback on language to capture behaviors demonstrating "threat to self or others."</p> <p>Your comments on the Additional Questions for Feedback that we posed regarding the measure are helpful. We will take your feedback under consideration.</p> <p>We appreciate the additional literature you provided regarding delirium in older persons.</p> |

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| | | | <p>Numerator exclusions: Patients with documented indication that they are threatening harm to self or others.</p> <p>Input sought: <i>We welcome feedback on the language in the measure specification and are seeking recommendations on how to capture behaviors that demonstrate a threat to self or others.</i></p> <p>SHM Comments: Threat of harm to self or others is an incredibly wide-ranging category and would need to be defined in order to consider how best to document justification. There are numerous behaviors and actions that could be considered threat of harm and it would be difficult to narrow or tailor the list appropriately.</p> <p>Threat to self or others could be captured by physician or nursing documentation, or perhaps an alert override or order checkbox/order set during prescription order entry. Examples could include documentation of inability to redirect agitated patient, patient with command hallucinations to harm self/others, patient attempting to harm self/others, patient climbing out of bed/at severe risk of falling despite restraints or redirection, etc. Documentation could be similar to that required for use of restraints, which is standardized per Joint Commission standards. Documentation could also include what monitoring patient will undergo after receiving the antipsychotic medication (cardiac monitoring, EKG for QTc measurement, oxygenation/respiratory status, neurologic status, etc.) if or when these are indicated. However, SHM notes that increased documentation requirements necessary to justify the use of antipsychotics would represent a clear increase in burden to physician workflow and hospital systems. We recommend identifying a pathway that would have the smallest burden possible.</p> <p><u>Additional Questions for Feedback:</u> Does the measure: <i>Increase our understanding of the magnitude of antipsychotics prescribed and administered in the inpatient setting?</i></p> <p>- Yes, this would provide that information. We would need to understand the prescribing practice as continuation of a home medication versus prescribing in the hospital for an acute indication.</p> <p><i>Promote improvement in prescribing practices and reduce variation in use of antipsychotics?</i></p> <p>O Perhaps. As discussed earlier, this measure may inadvertently increase the use of other pharmacologic treatments, such as benzodiazepine, for delirium, which may be problematic as an alternative. On the other hand, hospitals could be more likely to implement protocols to lessen use of these medication--e.g. increase use of less binding restraints such as soma beds, improve utilization of environmental rather than pharmacologic protocols to reduce incidence of delirium and lessen severity of/shorten delirium.</p> | |

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| | | | <p><i>Collect data that is feasible to obtain from electronic data sources without undue burden?</i></p> <ul style="list-style-type: none"> • This will be challenging. The measure specifically states (and reasonably so) that the medications should be used in patients at risk of harming themselves/others. Defining threat of harm and its documentation tied with indication for the medication would be difficult. • It is also difficult to identify within many EHR systems whether a patient was on the medication at home when administered in the acute inpatient setting so being able to exclude those patients who were already on the medication would be challenging. <p><i>Address a quality gap that is important enough to justify potential changes in workflow to enable discrete measurement of antipsychotics and non-pharmacologic interventions?</i></p> <ul style="list-style-type: none"> • SHM agrees the anecdotal prevalence of antipsychotic to treat delirium or other behavioral issues in the inpatient setting is concerning. • It would be also be interesting to explore how many patients are discharged on these medications when they were prescribed in the hospital for delirium and they weren't taking it prior to admission. If there was a relatively high rate then instituting this or a similar measure may be meaningful in order to prevent inappropriate prescribing of these medications at discharge. <p><i>Provide information that is a useful indicator of appropriate, patient-centered care?</i></p> <ul style="list-style-type: none"> • As above, it could hopefully stimulate hospitals to institute more stepwise approaches to managing the delirious patient where pharmacologic therapy is not appropriate as first-line treatment. Some institutions have already instituted order sets for restraining patients with delirium and at risk for harming themselves, but may not necessarily focus on reducing antipsychotic use in a structured way. <p>Other guidelines for CMS to consider: Delirium in Older Persons: Evaluation and Management - American Family Physician</p> | |
| 5/15/2016 | Helene Martel/ Kaiser Permanente | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>There is agreement and understanding of the concept that improper use of antipsychotic medication in older hospitalized adults is generally not appropriate. As with all things, though, the devil is in the details. There is a need to identify and understand the underlying cause of the aggressive behavior – be it delirium or dementia – in the hospitalized patient. A lack of anticipation of delirium in high risk patients, for example, can result in poor emphasis on implementation of non-pharmacological interventions. Injudicious use of sedating agents such as benzodiazepines, opiates and</p> | <p>Thank you for your detailed comments. We appreciate the need to assess the underlying cause of the aggressive behavior.</p> <p>We are examining in detail scenarios around which a quality measure of antipsychotic use affects the facilities, processes, education, and training of clinical staff in managing patients in the critical care setting.</p> |

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| | | | <p>muscle relaxants in this population further predisposes them to develop delirium.</p> <p>The worry with the metric as it is set up is that it is an incomplete representation of the clinical scenario that may be occurring in the facility, given that it is a pure numbers based calculation with no regard for other measures that have been attempted. It will highlight true outliers, but it could punish those hospitals that are embarking on appropriate measures, given the individual clinical situation. This would be especially true if/when CMS draws the line for "quality" at "x" percent for grading or star purposes. What is the appropriate percentage of usage of antipsychotics in this situation? Does the mean or median indicate appropriateness? Are hospital populations equivalent? A hard and fast number or percentage, given the current proposed methodology is short sighted, and could lead to untoward outcomes and potential patient and staff harm. Given the methodology of the proposed measure, there would not be any way to gain insight into non-pharmacologic approaches.</p> <p>Consider a tempered approach and measure that weighs the processes and systems that hospitals have put in place to manage delirium and agitation - step wise clinical pathways that start with various non-pharmacologic means and escalate with rational lowest effective dose antipsychotics when those non-pharmacologic measures have failed. In this manner, those high performing facilities are rewarded, rather than potentially punished.</p> <p>At the very least, this proposed metric has the potential to push facilities to look for alternative ways to manage their agitated patients with medications that aren't being measured, with the potential for more benzodiazepine use which is possibly worse - more lethargy, aspiration risk etc.</p> <p>Some specific issues as well - if a patient came in on pre-existing doses of anti-psychotic medications without one of the exclusionary diagnoses, shouldn't that be excluded as well, given that it is likely the medication will be continued during their hospitalization? How is the threat of harm to self or others going to be defined (and thus documented for exclusion) and will that add a layer of inefficiency to the workflows of hospitals who are providing appropriate care (and also an avenue for those who aren't to game the system)? Even if this proposal did limit the population to only those with delirium, looking at the use of an antipsychotic for only aggressive behavior "unless they present a threat to themselves or their caregivers" would disregard the extremely paranoid patient, for example.</p> <p>Would there be a way to sort out the use of antipsychotics (both "standard" e.g., haldol and atypical, e.g., olanzapine) for nausea and vomiting (anti-dopaminergic medications are a mainstay in the treatment of n/v), which are used in palliative care patients? In</p> | <p>Our statement regarding the use of benzodiazepines was not intended to mean that it is an acceptable substitution, but rather that implementing a measure of inpatient antipsychotic use could have unintended consequences (e.g., an increased use of benzodiazepines).</p> <p>We will investigate the appropriateness of excluding specific antipsychotics whose principle use is controlling nausea and vomiting.</p> |

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| | | | <p>addition, what about the use of haloperidol for pre-terminal agitation in EOL/comfort care patients?</p> <p>One option would be to create a second measure that includes the same denominator but a numerator that is the number of inpatient hospitalizations for patients who received an order for non-pharmacological delirium prevention and/or management protocol or intervention (with a set definition for the protocol or intervention).</p> | |
| 5/15/2016 | Beth Godsey/ Vizient Inc. | Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting | <p>Vizient, Inc., the largest member-owned health care company in the country, is dedicated to serving members & customers through innovative data-driven solutions, expertise & collaborative opportunities that lead to improved patient outcomes & lower costs.</p> <p>Vizient appreciates the opportunity to comment on this measure as it is an important to assess potentially inappropriate use of antipsychotics in elderly patients that are at higher risk of poor outcomes associated with the administration of these agents.</p> <p>In relation to the measure denominator, Vizient agrees with the recommended restriction to focus on inpatient hospitalizations for patients ages 65 and older and exclusion of the FDA approved indications: diagnosis of schizophrenia, Tourette's syndrome, bipolar disorder, or Huntington's disease at the time of admission.</p> <p>Given the body of evidence supporting an increased risk of mortality for elderly patients diagnosed with dementia or delirium who are prescribed antipsychotics, Vizient recommends further refinement of the denominator to only include patients ages 65 and older with a diagnosis of dementia or delirium, while applying the same exclusions highlighted above (patients with a diagnosis of schizophrenia, Tourette's syndrome, bipolar disorder, or Huntington's disease at the time of admission). These inclusion criteria would improve the accuracy of this measure by allowing organizations to focus on cases where antipsychotic use can result in poor outcomes and further exclude appropriate use for other mental health and behavioral issues. In relation to the numerator, we recommend the same refinement for the base population: only include patients ages 65 and older with a diagnosis of dementia or delirium, while applying the same exclusions highlighted above (patients with a diagnosis of schizophrenia, Tourette's syndrome, bipolar disorder, or Huntington's disease at the time of admission) that have received not only an order for an antipsychotic medication, but evidence of administration during the inpatient encounter. In reviewing the list of antipsychotics included in file 2.16.840.1.113883.3.464.1003.196.12.1265, we recommend the exclusion of NDCs related to the following agents so that only typical and atypical antipsychotics associated with this higher risk in elderly patients with dementia are included:</p> <p>amitriptyline amitriptyline / chlordiazepoxide</p> | <p>Thank you for your comment.</p> <p>We appreciate your feedback on the age range and support for the 65 and older population.</p> <p>We appreciate your feedback on the measure denominator, specifications, and exclusions. The numerator logic, as currently written, is only intended to evaluate an order of antipsychotics during the inpatient hospitalization and not administration of antipsychotics. There is widespread concern that overuse of antipsychotics is in part driven by reliance of PRN orders. We therefore focused our measure on orders and not administration.</p> <p>We have listed available codes to provide hospitals with guidance on their use for the purpose of identifying exclusions, as appropriate.</p> <p>Thank you for your feedback on the inclusion of specific ICD-10 codes that relate to suicidal and homicidal ideations. We will review these codes and include them in the measure specification, as appropriate.</p> <p>The measure is not intended for use in inpatient psychiatric facilities or units. We will clarify this in future versions of the specification.</p> |

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| | | | <p>amitriptyline / diclofenac / lidocaine chlorthalidone / reserpine clonazepam cyproheptadine fluoxetine hydralazine / hydrochlorothiazide / reserpine lithium methylothiazide / reserpine selegiline</p> <p>Vizient also recommends a further evaluation of the proposed numerator exclusion: patients with a documented indication that they are threatening harm to self or others; most of the codes provided are SNOMED finding codes. Vizient requests further clarification on whether these SNOMED codes are available across all hospitals and if these codes are consistently and accurately assigned. Vizient recommends that the ICD-9 and ICD-10 codes that were selected relating to suicidal and homicidal ideations be only included (currently being excluded) if an additional underlying psychiatric diagnosis is present. Vizient also requests further clarification on the methodology that will be used to exclude use in the inpatient psychiatric setting for both the numerator and the denominator.</p> <p>Overall, Vizient feels these proposed changes and clarifications will provide this measure additional focus on measuring those elderly patients that are at higher risk for poor outcomes with administration of antipsychotic agents and for which there is no underlying psychiatric condition that is precipitating their use.</p> | |
| <p>5/14/2016</p> | <p>Diane Sanders/ The Florida Society for Post-Acute and Long Term Care Medicine</p> | <p>Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting</p> | <p>In response to the question - Are there any unintended consequences of this measure?</p> <p>With the introduction of any new clinical quality measures there will be a tendency to find alternative means to circumvent the proposal. Given that antipsychotics and anxiolytics are both used to control behaviors in the inpatient setting this could result in an increased in anxiolytic utilization. This unfortunate and expected consequence has to be combated with intense education as many of the behaviors that are often encountered in this age population are a direct result of being in an inpatient setting.</p> <p>In response to the question - Age range and whether it should be expanded to include all adults</p> <p>It is appropriate to target the age population of 65 and older as antipsychotics are often utilized (and over utilized) in this age population to control behaviors, and treat delirium .</p> <p>Inclusion of all adults would unfortunately would not be appropriate as many younger adults are being managed for psychiatric conditions or acute delirium, and this would skew any data this</p> | <p>Thank you for your comment on potential unintended consequences from measure implementation.</p> <p>We appreciate your feedback on the age range and support for the 65 and older population.</p> <p>The measure is not intended for use in inpatient psychiatric facilities or units. We will clarify this in future versions of the specification.</p> <p>We appreciate your feedback on the measure numerator and denominator exclusions as well as medications that should not be included in the measure.</p> <p>Thank you for your comments recommending the measure for use in hospitals for patients 65 and older. We appreciate your reflections on the challenges faced by both patients and hospital staff in addressing delirium appropriately. As you suggest, we believe the measure represents an important first step in improving care for vulnerable patients.</p> |

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| | | | <p>measure would be collecting. Furthermore, adults in the inpatient psychiatric setting should not be included in this measure.</p> <p>In response to question - are there other patients who should be removed from the denominator?</p> <p>It is agreeable to exclude all patients with FDA-approved indications for the use of antipsychotics.</p> <p>In response to question - are there antipsychotic medications that should not be included in the measure?</p> <p>All antipsychotics should be included in the measure.</p> <p>In response to the question regarding Numerator exclusions-</p> <p>It is important that initially we include patients who lack an FDA-approved indication for use of the antipsychotic and are documented to be a threat to themselves or others. Unfortunately, many of the behaviors we are using antipsychotics for are subjective to the person reporting the behavior. Therefore, there needs to be caution before excluding these patients.</p> <p>Overall -</p> <ul style="list-style-type: none"> • Antipsychotics are often overutilized in the hospitalized Geriatric patient. Unfortunately, most hospitals are ill equipped to meet the needs of the Senior patient. We have had the benefit of having an increased number of acute care of the elderly units developed in hospitals, but the high patient to nursing ratio, and overburdened inpatient clinical providers counteracts these developments. This problem then leads to high percentage of patients being transferred to Skilled Nursing Facilities on antipsychotics that are used to control behaviors and act as chemical restraints. • This measure will serve to educate the hospital administration and clinical providers of the vastness and severity of the problem • This measure will demonstrate that our approach to the elderly Hospitalized patient is often based on the comfort of the staff and not on the treatment of the patient, which represents a tremendous gap in quality. Furthermore, this measure can show that there is a true lack of antipsychotic stewardship in the hospital as most of these patients are prescribed these medications even when the observed behavior has dissipated. Finally, this measure will result in a change in prescribing behavior by the clinical providers given that there will be oversight. • This measure will cause hospitals, clinical providers, nursing staff, and pharmacist to reconsider how we are using | |

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| | | | <p>antipsychotics and truly individualize the care of the patient while inpatient - that in itself is the beginning of patient- centered care.</p> | |
| <p>5/13/2016</p> | <p>Joyce Mackessy /Upstate Medical University</p> | <p>Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting</p> | <p>Thank you for the opportunity to respond to this measure during its development.</p> <p>In response to if there are any unintended consequences of this measure? Yes we believe there are consequences even to the extent of actually increasing benzodiazepine use if not addressed through education. In addition this measure could wind up being an essential first step toward establishing additional measures being developed in the future. This measure proposed now is really only addressing the tip of the iceberg in terms of prescribing practices, esp as it relates to delirious patients and the measure cannot address the bigger picture when it comes to benzo use and/or institution of delirium protocols.</p> <p>The real utility of the measure is in defining the scope of the problem (which we predict the prevalence will be higher than anticipated). Once the scope has been defined (and someone has published the results), additional future measures can be built on the defined gap in care for the delirious patient (especially in the use of nonpharmacologic approaches), overuse measures related to antipsychotic use in the elderly, and potentially even outcome measures related to delirium prevention or institution of protocols.</p> <p>If appropriate use is misconstrued as being penalized there could be the concern that under-recognition, under-reporting and inadequate management of delirium. This measure will need to be concurrently introduced with ongoing interdisciplinary education and supports so its intent is not misconstrued.</p> <p>In respect to if there are antipsychotic medications that should not be included in the measure we need to consider that we could risk by our exclusion the unintended consequences of influencing prescription choice. The numerator is simple and straightforward now and seems reasonable to start with but it really only addresses the tip of the iceberg in terms of prescribing practices, esp as it relates to delirious patients.</p> <p>In response to feedback on the age range for this measure and whether it should be expanded to include all adults, the denominator (inpatient hospitalizations for >65) is reasonable and the age range is consistent with current geriatric guidelines. It would be too onerous to expand this to all adults and we don't know how this might impact (negative and positive) clinical care. It does seem better to start with those most at risk for adverse drug reactions. We also agree with excluding inpatient psychiatric units. The denominator exclusions could be improved by including all FDA-approved indications for the use of antipsychotics. For example, the measure doesn't exclude schizoaffective or psychotic depression.</p> | <p>Thank you for your comment.</p> <p>We recognize that implementing a measure of inpatient antipsychotic use could have unintended consequences (e.g., an increased use of benzodiazepines).</p> <p>Thank you for your feedback on the utility of the measure.</p> <p>We appreciate your feedback on the measure numerator.</p> <p>We appreciate your feedback on the age range and support for the 65 and older population.</p> <p>Patients with FDA approved indications for antipsychotics are currently excluded from the denominator population.</p> <p>We appreciate your feedback on whether the measure will promote improvement in hospital prescribing practices.</p> <p>The intent of the measure is to reduce inappropriate use of antipsychotics in the inpatient hospital setting.</p> |

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| | | | <p>A similar measure for older adults in nursing homes and long term care settings has been very helpful in highlighting the problems and reducing inappropriate use of antipsychotics, especially in patients with dementia. Using the nursing home prescribing guidelines, it now takes prescribers more time to document the indication for use of antipsychotics, but in the end it seems to have made a positive difference on the appropriate clinical application of the medications being used.</p> <p>In response to whether the measure will increase our understanding of the magnitude of antipsychotics prescribed and administered in the inpatient setting it is felt that this proposal will probably not improve clinical prescribing practices much unless it is accompanied by a team approach to managing agitation and delirium, which is the most frequent reasons antipsychotics are used in older adults. This means each hospital needs to have a protocol for preventing and managing delirium in the hospital setting. There also has to be ongoing educational program focused on nursing (who often initiate calls to physicians for these meds) and physicians (including all house staff) who likely had little training in this area. It is believed that the majority of antipsychotics in older adults are started by providers with very little psychiatric training and even less formal training in geriatric medicine.</p> <p>A team approach to this issue is going to be needed to address these concerns and should include nursing, physicians, and pharmacists working together.</p> <p>In addition it would also be helpful to track trends in prescription of benzos, other potentially harmful hypnotics (ie zolpidem, diphenhydramine) and the usage of physical restraints in hospitals to assess if more restraints are a potential unintentional consequences of these prescriptions.</p> <p>Overall if properly designed, this measure could be a very meaningful quality measure for inpatient settings to help address a known clinical problem. At the national and global levels, antipsychotics in older adults are still misused and over-prescribed in hospital settings despite the numerous guidelines from AGS (Beers Criteria) and AAGP. In addition to measuring antipsychotic use during acute hospitalization, it would be also be useful to quantify the number of antipsychotics continued at discharge and the consequences of this practice.</p> | |