

NATIONAL QUALITY FORUM

Key Points Sheet – Measure Concept/Importance to Measure and Report Review Submissions for Completeness and Responsiveness

PROCESS

Purpose/Objective: To ensure that all information needed to evaluate the measure against the NQF criteria is available for review and in the correct location to facilitate the ease and efficiency of evaluation by the Steering Committee. Measure submissions that are either incomplete or unresponsive will not be passed on for Steering Committee evaluation.

Definitions

Completeness: All submission questions (items) are answered unless clearly not applicable.

Responsiveness: Information provided in the submission form corresponds to what was asked and is entered in the correct location.

Note: This review does not make a judgment about whether NQF evaluation criteria are met, just whether the requested information is provided and in the correct location of the form.

Who: All NQF Performance Measures staff may review submissions for completeness and responsiveness. Determination that a measure submission does not meet the condition that it is complete and responsive is approved by a Sr. Director.

Timing: Submissions are reviewed as they are submitted. Generally submissions are reviewed for completeness and responsiveness at the same time by the same staff person.

Result of Review:

If the measure submission is:

- Complete and responsive, the measure/concept is ready for Steering Committee review.
- EITHER incomplete OR unresponsive, the measure/concept is not ready for consideration by the Steering Committee. Opportunity for revision depends on timing of submission as follows:
 - If the submission occurs on or before the technical assistance deadline, staff will provide feedback to the developer who will be able to revise the submission prior to the measure submission deadline.
 - If the submission occurs after the technical assistance deadline, there is no guarantee that staff will have time to review and provide feedback for measure developers to make revisions before the measure submission deadline. Submissions that are incomplete or unresponsive are not accepted for consideration in the current project. The reason is given to the developer who may revise and resubmit for a later project for that topic area.

CHECK THAT ALL CONDITIONS ARE MET TO EVALUATE CONCEPTS

Condition A. Is the steward agreement signed or updated?

Steward agreements are required for all non-government organizations even if measure is made publicly and freely available.

Fully specified and tested measures: Signed [measure steward agreement](#) (MSA) OR updated list of measures that includes the additional measure that will be appended to the signed MSA.

Concepts only (when measure not yet fully specified and tested): Signed **concept steward agreement** OR updated list of concepts [under development]

Condition B: Measure maintenance applies to stage 2 measure submissions.

Condition C. Use for accountability/public reporting and improvement – Check that either current or planned use includes both accountability (including public reporting) and performance improvement.

Condition D: Fully specified and tested applies to stage 2 measure submissions.

Condition E. Related and Competing measures addressed – check that the questions on related and competing measures have been answered. Check the NQF measures database to identify potentially related and competing measures to make sure they are completely identified in the submission.

- Check against the list of all previously endorsed measures in the topic area (posted on the project page)
- Check against new concepts and measures submitted for the current review period
- Search strategy: begin with taxonomy terms for subject/topic areas, then keyword search on terms for the subject/topic area and measure focus

Condition F. Measure submission information is **complete and responsive**.

- Refer to examples of what good looks like as needed. The examples are not the only way to respond; and if it's unclear whether an answer is responsive, check with the Sr. Director.
- Answers to questions asking for **data** should include numbers
- For endorsement maintenance, performance gap and disparities data should be provided for the measure as specified. This could be supplemented with data from the literature, but it's not required unless the measure has not been put into use.
- Make sure the **evidence form** is attached and completed properly.

If a **health outcome**

- Requires only 1c.1-1c.2 (A health outcome is an end-result (e.g., mortality, complication, function, health status; or sometimes a proxy for health outcome such as hospital admission))

For all other measures (structure, process, intermediate outcome)

- Some items are required and some may not be needed.

Required:

- 1c.3 relationship of measure focus to desired outcomes
- 1c.8-1c.13 and questions regarding systematic review of body of evidence
- 1c.4 whether or not there is a guideline (if yes, 1c.4.1 -1c.5; If 1c.5 is yes, then 1c.5.1)
- 1c.6 whether or not there is another published systematic review (if yes, 6.2-6.3)

Used only under certain conditions:

- 1c.7-1c.7.3 only if no other systematic review from guideline (1c.5) or other published systematic review (1c.6)

GENERAL PRESENTATION OF SUBMISSIONS

- Make sure all URLs are active and correct
- This review does not focus on spelling and grammar; however, if numerous mistakes impede readability and understanding then the developer should be asked to correct. Staff should not spend time identifying or suggesting specific edits.

EXAMPLE RESPONSES FOR MEASURE SUBMISSION ITEMS

The following examples are only for illustration of the type of information that that would be considered complete and responsive and ready for Steering Committee evaluation. Some of the examples are adapted from actual measure submissions and some were developed only as examples. The key point is to provide substantive information and data in the measure submission so that the Steering Committee can evaluate whether the NQF criteria are met.

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EXAMPLE — HIGH IMPACT (1a) AND OPPORTUNITY FOR IMPROVEMENT (1b)

**NATIONAL QUALITY FORUM—Concept Submission Items
High Impact and Opportunity for Improvement**

EXAMPLE — HIGH IMPACT (1a) AND OPPORTUNITY FOR IMPROVEMENT (1b)

The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of high impact and opportunity for improvement. The key point is to provide substantive information and data in the measure submission.

Note: These items are in the online submission form and responses must be entered into the online form.

EXAMPLE: Adapted from measure about influenza vaccination in healthcare workers (NQF#0431, by CDC)

High Impact (1a)

1a.1

Demonstrated high impact aspect of healthcare

[Selected from List]

EXAMPLE:

affects large numbers; patient/societal consequences of poor quality

1a.2

If "Other", please describe:

1a.3

Provide **epidemiologic or resource use data** that demonstrates the measure addresses a high impact aspect of healthcare. List citations in 1a.4.

Key Points

- Limit to half page
- Should include quantitative data (e.g., number of persons and percentage affected, dollar amounts), not just statements of conclusion
- Should relate to the target population (e.g., condition, specific procedure, etc.) and category for impact selected in 1a.1
- The online form does not accept formatting such as tables – use narrative or lists

EXAMPLE:

From 1976-2007, influenza virus infections caused an average of 23,607 influenza-related deaths with a wide yearly range of 3,349 to 48,614 deaths over 31 influenza seasons; approximately 90% of these deaths occurred among persons aged 65 and older.(1) Healthcare personnel (HCP) can serve as vectors for influenza transmission because they are at risk for both acquiring influenza from patients and transmitting it to patients and HCP often come to work when ill.(2) One early report of HCP influenza infections during the 2009 H1N1 influenza pandemic estimated 50% of infected HCP had contracted the influenza virus from patients or coworkers in the healthcare setting.(3) Influenza virus infection is

common among HCP: one study suggested that nearly one-quarter of HCP were infected during influenza season, but few of these recalled having influenza.(4) Therefore, all HCP are recommended to receive the seasonal influenza vaccine annually to protect themselves and their patients.(5)

Nosocomial influenza outbreaks in healthcare facilities result in longer stays and greater mortality for patients (6-9) and missed work for HCP.(2,9) Higher influenza vaccination coverage among HCP is associated with reductions in nosocomial influenza among hospitalized patients (8,10) and nursing home residents.(11-13) Influenza vaccination of HCP is also associated with decreased all-cause mortality among nursing home residents.(11-14).

1a.4

Citations for data demonstrating High Impact provided in 1a.3

Key Points

- Limit to one page

EXAMPLE:

1. Thompson MG, Shay DK, Zhou H, et al. Estimates of deaths associated with seasonal influenza – United States, 1976–2007. *MMWR Morb Mortal Wkly Rep.* 2010; 59(33):1057–1062.
2. Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in healthcare professionals: a randomized trial. *JAMA* 1999; 281: 908–913.
3. Harriman K, Rosenberg J, Robinson S, et al. Novel influenza A (H1N1) virus infections among health-care personnel – United States, April–May 2009. *MMWR Morb Mortal Wkly Rep.* 2009; 58(23): 641–645.
4. Elder AG, O’Donnell B, McCrudden EA, et al. Incidence and recall of influenza in a cohort of Glasgow health-care workers during the 1993–4 epidemic: results of serum testing and questionnaire. *BMJ.* 1996; 313:1241–1242.
5. Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Recomm Rep.* 2010; 59(08): 1–62.
6. Cunney RJ, Bialachowski A, Thornley D, Smaill FM, Pennie RA. An outbreak of influenza A in a neonatal intensive care unit. *Infect Control Hosp Epidemiol.* 2000; 21:449–454.
7. Bridges CB, Kuehnert MJ, Hall CB. Transmission of influenza: implications for control in health care settings. *Clin Infect Dis* 2003; 37: 1094–1101.
8. Weinstock DM, Eagan J, Malak SA, et al. Control of influenza A on a bone marrow transplant unit. *Infect Control Hosp Epidemiol.* 2000; 21:730–732.
9. Sartor C, Zandotti C, Romain F, et al. Disruption of services in an internal medicine unit due to a nosocomial influenza outbreak. *Infect Control Hosp Epidemiol* 2002; 23:615–619.
10. Salgado CD, Giannetta ET, Hayden FG, Farr BM. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. *Infect Control Hosp Epidemiol* 2004; 25:923–928.
11. Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *BMJ* 2006; 333: 1241–1246.
12. Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. *J Infect Dis.* 1997; 175:1–6.
13. Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. *J Am Geriatr Soc.* 2009; 57:1580–1586.
14. Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. *Lancet* 2000; 355:93–97.

Performance Gap – Opportunity for Improvement (1b)

1b.1

Briefly explain the rationale for this measure

Key Points

- Limit to half page
- Explain benefits (improvements in quality) envisioned by use of this measure
- Do not repeat information for impact, performance gap, or evidence

EXAMPLE:

Use of this measure to monitor influenza vaccination among HCP is envisioned to result in increased influenza vaccination uptake among HCP, because improvements in tracking and reporting HCP influenza vaccination status will allow healthcare institutions to better identify and target unvaccinated HCP. Increased influenza vaccination coverage among HCP is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, as described above in Section 1a.3.

1b.2

Provide **data** demonstrating performance gap/opportunity for improvement (Variation or overall less than optimal performance across providers). List citations in 1b.3.

For endorsement maintenance, provide performance data on the measure as specified (mean, std dev, distribution of scores by decile, min, max). Describe who was included in the performance data in 1b.3.

Key Points

- Limit to two pages
- The online form does not accept formatting such as tables – use narrative or lists
- Should include quantitative data (e.g., number, percent), not just statements of conclusion
- Should be about the measure focus and target population
- If new concept or measure, data could be from literature, studies, or testing
- If endorsement maintenance, the data should be the performance scores on the measure as specified and for the specified level of analysis
- Should correspond to the level of analysis for the measure (e.g., variation across hospitals, or physicians, etc.)
- If limited variation, should discuss in context of impact or overall less than optimal performance

EXAMPLE:

(data from testing)

Among employees, the median influenza vaccination coverage rate among healthcare institutions participating in the field test was 63% (quartile 1: 44%, quartile 3: 79%).

Among credentialed non-employees, the median influenza vaccination coverage rate was 46% (quartile 1: 8%, quartile 3: 90%).

Among other non-employees, the median influenza vaccination coverage rate was 51% (quartile 1: 29%, quartile 3: 92%).

Reported influenza vaccination coverage rates vary noticeably by denominator group. In addition, all three estimates are substantially lower than the Healthy People 2020 goal of 90% influenza vaccination coverage among HCP, demonstrating substantial room for improvements.

1b.3

Citations for data on performance gap provided in 1b.2.

For endorsement maintenance, describe who was included in the performance results reported in 1b.2, (number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include).

Key Points

- Limit to one page
- Provide citations for data from literature
- For performance scores, describe data source as requested

EXAMPLE:

The measurement testing was conducted from October 2010 to March 2011 among 234 healthcare institutions from four jurisdictions, including 78 acute care hospitals, 59 long-term care facilities, 16 ambulatory surgical centers, 43 dialysis clinics, and 38 physician practices. This represents a 74% response rate from our initially recruited sample of 318 healthcare institutions (92 acute care hospitals, 89 long-term care facilities, 30 ambulatory surgical centers, 51 dialysis clinics, and 56 physician practices). Demographic and policy characteristics of participating institutions are further described in Section 2b5.1.

1b.4

*Provide **data** on disparities by population group. List citations in 1b.5.*

For endorsement maintenance, provide performance data by population group on the **measure as specified** (e.g., mean, std dev). Describe who was included in the performance data in 1b.5.

Key Points

- Limit to two pages
- The online form does not accept formatting such as tables – use narrative or lists
- Should include quantitative data (e.g., number, percent), not just statements of conclusion
- Should be about the measure focus and target population
- If new concept or measure, data could be from literature, studies, or testing
- If endorsement maintenance, the data should be the performance scores on the measure as specified and for the specified level of analysis

EXAMPLE:

Data on influenza vaccination in healthcare workers by population group is not available. Data on influenza vaccination rates by population group in general obtained from the Behavioral Risk Factor Surveillance System are as follows.

Influenza vaccination coverage, * by race/ethnicity† --- Behavioral Risk Factor Surveillance System 2009-2010

Seasonal (only) influenza vaccination coverage

Reported in this order:

- 1) Children aged 6 mos--17 yrs (n = 159,652)
- 2) Adults at high-risk§ aged 18--49 yrs (n = 21,821)
- 3) Adults aged 50--64 yrs (n = 117,267)
- 4) Adults aged ≥65 yrs (n = 112,752)
- 5) All aged ≥6 mos (n = 514,785)

Reported as % (95% CI)

All:

- 1) Children aged 6 mos--17 yrs 43.7 (42.8--44.6)
- 2) Adults at high-risk§ aged 18--49 yrs 38.2 (36.9--39.5)
- 3) Adults aged 50--64 yrs 45.0 (44.4--45.6)
- 4) Adults aged ≥65 yrs 69.6 (69.0--70.2)
- 5) All aged ≥6 mos 41.2 (40.8--41.6)

White, non-Hispanic:

- 1) Children aged 6 mos--17 yrs 43.2 (42.3--44.1)
- 2) Adults at high-risk§ aged 18--49 yrs 39.9 (38.3--41.5)
- 3) Adults aged 50--64 yrs 46.5 (45.9--47.1)
- 4) Adults aged ≥65 yrs 71.7 (71.2--72.2)
- 5) All aged ≥6 mos 43.9 (43.5--44.3)

Black, non-Hispanic:

- 1) Children aged 6 mos--17 yrs 37.0¶ (34.4--39.6)
- 2) Adults at high-risk§ aged 18--49 yrs 34.8¶ (31.5--38.1)
- 3) Adults aged 50--64 yrs 40.3¶ (38.3--42.3)
- 4) Adults aged ≥65 yrs 55.2¶ (52.9--57.5)
- 5) All aged ≥6 mos 33.7¶ (32.5--34.9)

Hispanic:

- 1) Children aged 6 mos--17 yrs 46.9¶ (44.3--49.5)
- 2) Adults at high-risk§ aged 18--49 yrs 35.5 (31.6--39.4)
- 3) Adults aged 50--64 yrs 40.6¶ (37.9--43.3)
- 4) Adults aged ≥65 yrs 56.1¶ (52.8--59.4)
- 5) All aged ≥6 mos 33.6¶ (32.4--34.8)

Other, non-Hispanic**:

- 1) Children aged 6 mos--17 yrs 53.6¶ (50.5--56.7)
- 2) Adults at high-risk§ aged 18--49 yrs 41.3 (35.5--47.1)
- 3) Adults aged 50--64 yrs 44.1 (40.6--47.6)
- 4) Adults aged ≥65 yrs 68.1 (64.9--71.3)
- 5) All aged ≥6 mos 42.4 (40.8--44.0)

Abbreviation: CI = confidence interval.

* Coverage estimates are for persons with reported vaccination during August 2009--May 2010 who were interviewed during October 2009--June 2010.

† Race/ethnicity categories are mutually exclusive.

§ High-risk conditions include asthma, other lung problems, diabetes, heart disease, kidney problems, anemia, and weakened immune system caused by a chronic illness or by medicines taken for a chronic illness.

¶ Statistically significant difference at $p < 0.05$ (t-test) in estimated vaccination coverage. Referent group was non-Hispanic whites.

** Because of limited sample sizes, respondents who self-identified as Asians, American Indians/Alaska Natives, Native Hawaiians, Pacific Islanders, and persons of multiple races were classified in the non-Hispanic Other group.

1b.5

Citations for data on Disparities provided in 1b.4

For endorsement maintenance, describe who was included in the performance results reported in 1b.4, (number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include).

Key Points

- Limit to one page
- Provide citations for data from literature
- For performance scores, describe data source as requested

EXAMPLE:

Truman, B.I., et al. CDC Health Disparities and Inequalities Report, United States 2011. *MMWR Morb Mortal Wkly Rep.* 2011 Jan 14; Supplement **60(01);38-41.**

<http://www.cdc.gov/mmwr/preview/mmwrhtml/su6001a7.htm#tab>

EXAMPLE — EVIDENCE, HEALTH OUTCOME

NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

EXAMPLE — EVIDENCE, HEALTH OUTCOME

The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of the evidence. The key point is to provide substantive information and data in the measure submission form so it is clear about the evidence that does or does not exist to support the measure focus.

Measure Title: 30-day unplanned hospital readmission

Date of Submission: [5/31/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- Contact NQF staff for examples and resources, or questions.

STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

1c.1. This is a measure of:

Outcome

- Health outcome: [30-day unplanned hospital readmission](#)
- Intermediate clinical outcome: [Click here to name the intermediate outcome](#)
- Process: [Click here to name the process](#)
- Structure: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

HEALTH OUTCOME MEASURE **If not a health outcome, skip to 1c.3**

If the measure focus identified in 1c.1 is a [health outcome](#), answer 1c.2 and 1c.2.1.

1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

Key Points

- A health outcome is an end-result (e.g., mortality, complication, function, health status; or sometimes a proxy for health outcome such as hospital admission).
- Should indicate the causal pathway – not just a general statement.
- Multiple processes may influence a health outcome – not all need to be included – focus on those with the strongest rationale.
- Do not include rationale or evidence in this item.

EXAMPLE

Hospital readmission is considered a proxy for the health outcome of deterioration in health status.

Multiple care processes can influence deterioration in health status after discharge resulting in hospital readmission (e.g., appropriate treatment/intervention, medications, clinical stabilization, care coordination/transition).

Comprehensive care transition management/care coordination can lead to decreased hospital readmissions as described below.

Comprehensive care transition management/ care coordination

Leads to ↓

Early reconnection to primary care; appropriate level of follow-up care; patient understanding of self-monitoring, self-management, & follow-up care

Leads to ↓

Continuity of treatment plan; early identification & intervention for adverse changes

Leads to ↓

Stable/improved health status

Leads to ↓

Decreased likelihood of readmission

1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

Key Points

- The rationale should support linkages described in 1c.2 above.
- The rationale should be based on evidence to the extent possible and/or logical conceptual relationships.
- If a health outcome, not required to complete other items about body of evidence.

EXAMPLE (adapted from NQF # 1789, CMS)

Randomized controlled trials have shown that improvement in the following areas can directly reduce readmission rates: quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Evidence that hospitals have been able to reduce readmission rates through these quality-of-care initiatives illustrates the degree to which hospital practices can affect readmission rates. Successful randomized trials have reduced 30-day readmission rates by 20-40% [4-14].

Since 2008, 14 Medicare Quality Improvement Organizations have been funded to focus on care transitions, applying lessons learned from clinical trials. Several have been notably successful in reducing readmissions. The strongest evidence supporting the efficacy of improved discharge processes and enhanced care at transitions is a randomized controlled trial by Project RED (Re-Engineered Discharge), which demonstrated a 30% reduction in 30-day readmissions. In this intervention, a nurse was assigned to each patient as a discharge advocate, responsible for patient education, follow-up, medication reconciliation, and preparing individualized discharge instructions sent to the patient's primary care

provider. A follow-up phone call from a pharmacist within 4 days of discharge was also part of the intervention [4].

Given that studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, it is reasonable to consider an all-condition readmission rate as a quality measure.

References:

1. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *New England Journal of Medicine* 2009;360(14):1418-28.
2. Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. *Archives of Internal Medicine* 2000;160(8):1074-81.
3. Medicare Payment Advisory Commission (U.S.). Report to the Congress promoting greater efficiency in Medicare. Washington, DC: Medicare Payment Advisory Commission, 2007.
4. Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med* 2009;150(3):178-87.
5. Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. *J Am Geriatr Soc* 2004;52(11):1817-25.
6. Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. *J Am Geriatr Soc* 2009;57(3):395-402.
7. Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomised controlled trial. *BMC Public Health* 2007;7:68.
8. Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. *J Hosp Med* 2009;4(4):211-218.
9. Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic metareview. *BMC Health Serv Res* 2007;7:47.
10. Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. *Ann Intern Med* 1994;120(12):999-1006.
11. Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. *Jama* 1999;281(7):613-20.
12. van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during post-discharge visits on hospital readmission. *J Gen Intern Med* 2002;17(3):186-92.
13. Weiss M, Yakusheva O, Bobay K. Nurse and patient perceptions of discharge readiness in relation to postdischarge utilization. *Med Care* 2010;48(5):482-6.
14. Krumholz HM, Amatruda J, Smith GL, et al. Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. *J Am Coll Cardiol*. Jan 2 2002;39(1):83-89.

Note: For health outcome measures, no further information is required

STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).

1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes No
If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes No **If no, skip to #1c.6**

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)
Yes No **If no, skip to #1c.7**

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes No

If yes, answer 1c.7.1-1c.7.3. (**Note:** Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS
(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [Click here to enter date range](#)

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes No **If no, stop**

If yes,

1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review

Example-Process #1 xxxx Women with urinary incontinence who receive pelvic floor muscle training

EXAMPLE — EVIDENCE, PROCESS #1

NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

EXAMPLE — EVIDENCE, PROCESS #1

The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of the evidence. The key point is to provide substantive information and data in the measure submission form so it is clear about the evidence that does or does not exist to support the measure focus.

Measure Title: [Women with urinary incontinence who receive pelvic floor muscle training](#)

Date of Submission: [5/31/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

1c.1. This is a measure of:

Outcome

- Health outcome: [Click here to name the health outcome](#)
- Intermediate clinical outcome: [Click here to name the intermediate outcome](#)
- Process: [pelvic floor muscle training for urinary incontinence](#)
- Structure: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

HEALTH OUTCOME MEASURE *If not a health outcome, skip to 1c.3*

If the measure focus identified in 1c.1 is a [health outcome](#), answer 1c.2 and 1c.2.1.

1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

Note: *For health outcome measures, no further information is required*

STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

If the measure focus identified in 1c.1 is a [structure](#), [process](#), or [intermediate outcome](#) answer all the following questions (except as indicated by skip pattern).

Key Points

- See NQF [guidance on evaluating evidence](#) and criteria for rating [Quantity, quality, consistency of body of evidence](#)

- A **systematic review** is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include quantitative synthesis (meta-analysis), depending on available data ([IOM,2011](#)).
- A body of evidence includes all the evidence for a topic, which is systematically identified, based on pre-established criteria for relevance and quality of evidence.
- Expert opinion is not considered empirical evidence, but evidence is not limited to randomized controlled trials
- There is variability in evidence reviews, grading systems, and presentation of the findings; however, the information should be reported as requested in this form so the Steering Committee can evaluate it according to NQF criteria and guidance.

1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)

Key Points

- Should indicate the causal pathway – not just a general statement
- Do not discuss evidence in this item

EXAMPLE

Pelvic floor muscle training (PFMT) >>

Increases strength (the maximum force generated by a muscle in a single contraction); endurance (ability to contract repetitively, or sustain a single contraction over time); coordination of muscle activity or to suppress urge, or a combination of these lead to>>

Decreased urine leakage

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes No
If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

1c.4.1. Guideline citation (including date): Incontinence in women. In: Schröder A, Abrams P, Andersson KE, Artibani W, Chapple CR, Drake MJ, Hampel C, Neisius A, Tubaro A, Thüroff JW. Guidelines on urinary incontinence. Arnhem, The Netherlands: European Association of Urology (EAU); 2009 Mar. p. 28-43.

1c.4.2. URL (if available online):

Key Points

- Make sure URL is active and correct

EXAMPLE

<http://www.uroweb.org/gls/pdf/Urinary%20Incontinence%202010.pdf>

<http://www.guideline.gov/content.aspx?id=16386&search=urinary+incontinence#Section424>

1c.4.3. Identify guideline number and/or page number:

Key Points

- If guideline recommendation is one of many from a single document, the specific guideline number

and/or page number is necessary.

EXAMPLE

Guideline 5.2 Initial treatment of UI in women. p.29

1c.4.4. Quote **verbatim**, the specific guideline recommendation:

Key Points

- Do not summarize, paraphrase, or shorten

EXAMPLE

PFMT should be offered as first-line conservative therapy to women with stress, urgency, or mixed UI

1c.4.5. Grade assigned to the recommendation with definition of the grade:

Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for a recommendation

EXAMPLE

A - Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes No **If no, skip to #1c.6**

If **yes**, answer 1c.5.1. (**Note:** Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence
- If specific details regarding systematic review of evidence for guideline not available, will need to identify another review of the body of evidence

EXAMPLE

The guideline document states that the recommendation is based on a systematic review of evidence, but the specific grade and summary of the body of evidence was not provided.

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)

Yes No **If no, skip to #1c.7**

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date): Dumoulin C, Hay-Smith J; Pelvic floor muscle training versus no treatment or inactive control treatments for urinary incontinence in women; Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD005654, DOI: 10.1002/14651858.CD005654.pub2.

1c.6.2. URL (if available online):

Key Points

- Make sure URL is active and correct

EXAMPLE

<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005654.pub2/abstract;jsessionid=5B59498CFC062003F250C00B2B8CEEEE.d01t03>

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence

EXAMPLE

An overall grade of methodological quality was not assigned. In the systematic review, individual study quality was graded on a scale for risk of bias – see section 8.

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

- Key Points**
- Responses to the following items should NOT include a description of each individual study – the responses should include quantitative data from a synthesis of the entire body of evidence. If there is more than one systematic review, each should be reported separately (not combined by the submitter).
 - May copy relevant sections from source(s) of systematic reviews cited in 11c.5, 1c.6, or 1c.7; include page number if possible; make sure it includes substantive, quantitative information not just conclusions

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)
1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [1989-2008](#)

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

- Key Points**
- Only enter number and type of study design here — discuss in 1c.10
 - NQF does not require evidence be only randomized controlled trials
 - Study design relates to quality of evidence but is insufficient by itself to judge quality

EXAMPLE

14 randomized controlled trials

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

- Key Points**
- Do not discuss each study individually — categorize by quality

EXAMPLE

The systematic review identified quality of evidence based on risk of bias. System for determining risk of bias was explained in Chapter 8 of Cochrane Handbook for Systematic Reviews for Interventions, 5.0.2, updated September 2009 <http://www.mrc-bsu.cam.ac.uk/cochrane/handbook502> .

| Risk of bias | Interpretation | Within a study | Across studies |
|-------------------|-------------------------|--------------------------|--------------------------|
| Low risk of bias. | Plausible bias unlikely | Low risk of bias for all | Most information is from |

| | | | |
|-----------------------|--|---|--|
| | to seriously alter the results. | key domains. | studies at low risk of bias. |
| Unclear risk of bias. | Plausible bias that raises some doubt about the results. | Unclear risk of bias for one or more key domains. | Most information is from studies at low or unclear risk of bias. |
| High risk of bias. | Plausible bias that seriously weakens confidence in the results. | High risk of bias for one or more key domains. | The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results. |

Based on the reported adequacy of allocation concealment and blinding, two trials appeared to be at low risk (Bø 1999; Castro, 2008), six at moderate risk (Bidmead 2002; Burgio 1998; Burns 1993; Kim 2007; Miller 1998; ; Yoon 2003;), and six at high or possible high risk of bias (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990; Lagro-Janssen 1991; Wells 1999). Interestingly, the more recent trials tended to be of lower risk for bias based on the trial reports.” (p. 20)

Methodological quality was evaluated from the trial reports. Therefore, the quality of reporting might have affected the judgement of methodological quality. Two of the included studies were published only as abstracts (Bidmead 2002; Henalla 1990). Limited methodological detail was given, which made it particularly difficult to judge the quality of these trials. In addition, few data were reported. In one way, it was disappointing that only two trials sufficiently described the randomisation process so that the review authors could be sure there was adequate concealment. On the other hand, it was encouraging, given the difficulties of blinding participants and treatment providers to PFMT, that eight of the 14 studies used blinded outcome assessors. Generally, the proportion of dropout and withdrawals was in the region of 0 to 20%. Sample sizes were small to moderate in 12 of the 14 studies, and only three trials reported an a priori power calculation. Two trials stated that intention to treat principles were used for the primary analysis, and one stated that intention to treat analysis did not change the findings of the primary analysis.

Sensitivity analysis on the basis of trial quality was not considered appropriate in view of the small number of trials contributing to each comparison. It is not known to what extent the variable quality of the trials has affected the findings of the review. It is interesting to note that of all the studies contributing data to the analysis, the largest treatment effect (for cure and improvement, and leakage episodes) was observed in a trial at the high risk of bias. This might be an example of the apparent overestimation of treatment effect (about 30%) observed in trials with inadequate or unclear concealment of random allocation (Egger 2002).” (p. 20)

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

| |
|---|
| <p>Key Points</p> <ul style="list-style-type: none"> Do not discuss each study individually — categorize by outcome studied |
|---|

EXAMPLE

Meta-analysis was not possible due to study heterogeneity.

Comparison of PFMT versus no treatment, placebo, or control was studied for a variety of outcomes as follows:

Outcome: Patient Perceived Cure – 2 studies with consistent direction in favor of PFMT but differences in magnitude of effect (risk ratio 2.34-16.80)

Outcome: Patient Perceived Cure or Improvement – 3 studies with consistent direction in favor of PFMT but differences in magnitude of effect (risk ratio 2.26-20.0). The authors concluded “Overall, the differences in likelihood of cure or improvement after PFMT compared to control suggested by the review are sufficient to be of interest to women.” (p.18)

Outcome: QoL – 2 studies

Hopkins Symptom Checklist, for psychological distress (SCL-90-R)

Global severity: 50.8 (12.8) vs. 51.4 (10.9); mean difference -0.6, 95% CI -5.3 to 4.1

Norwegian Quality of Life Scale

90.1 (9.5) vs. 85.2 (12.1); mean difference 4.9, 95%CI -1.1 to 10.9

The authors concluded “Based on evidence from single trials, there is improved condition specific QoL in women treated with PFMT compared to controls, but there might be less or no effect on generic QoL.” (p.18)

Outcome: Leakage Episodes – 5 studies with consistent direction in favor of PFMT but differences in magnitude of effect. “there were statistically significantly fewer leakage episodes (-0.77 to -2.92) with PFMT” (p.18)

Outcome: Number of Voids per Day – 1 study with significantly fewer (-3.1) with PFMT

Outcome: Number of Voids per Night – 1 study with no significant difference

Outcome: Short pad Test Number Cured – 3 studies with consistent direction in favor of PFMT but differences in magnitude of effect (risk ratios 5.54-16.24)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

Key Points

- Information on harms may come from different studies than the treatment effectiveness studies, often from observational studies

EXAMPLE

Three of four studies that reported adverse events stated there were none with PFMT. The other trial recorded a few minor effects of PFMT (for example discomfort with training), and all of which were reversible with cessation of training. Although randomized trials are probably not the most appropriate way to address safety, neither these data nor the content of PFMT suggest that PFMT is likely to be unsafe. (p. 19)

The authors concluded that “PFMT is better than no treatment, placebo, drug, or inactive control for women with stress, urge, or mixed incontinence. Women treated with PFMT were more likely to report cure or improvement, report better QoL, have fewer leakage episodes per day and have less urine leakage on short pad tests than controls. (p.21)

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes No *If no, stop*

If yes,

1c.13.1. For **each** new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

EXAMPLE — EVIDENCE, PROCESS #2

NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

EXAMPLE — EVIDENCE, PROCESS #2

The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of the evidence. The key point is to provide substantive information and data in the measure submission form so it is clear about the evidence that does or does not exist to support the measure focus.

Measure Title: [Periconception folic acid supplementation](#)

Date of Submission: [5/31/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

1c.1. This is a measure of:

Outcome

- Health outcome: [Click here to name the health outcome](#)
- Intermediate clinical outcome: [Click here to name the intermediate outcome](#)
- Process: [Folic acid supplements for women who may become pregnant and in early pregnancy to prevent neural tube defects](#)
- Structure: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

HEALTH OUTCOME MEASURE *If not a health outcome, skip to 1c.3*

If the measure focus identified in 1c.1 is a [health outcome](#), answer 1c.2 and 1c.2.1.

1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

Note: *For health outcome measures, no further information is required*

STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

If the measure focus identified in 1c.1 is a [structure, process, or intermediate outcome](#) answer all the following questions (except as indicated by skip pattern).

Key Points

- See NQF [guidance on evaluating evidence](#) and criteria for rating [Quantity, quality, consistency of](#)

body of evidence

- A **systematic review** is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include quantitative synthesis (meta-analysis), depending on available data ([IOM,2011](#)).
- A body of evidence includes all the evidence for a topic, which is systematically identified, based on pre-established criteria for relevance and quality of evidence.
- Expert opinion is not considered empirical evidence, but evidence is not limited to randomized controlled trials
- There is variability in evidence reviews, grading systems, and presentation of the findings; however, the information should be reported as requested in this form so the Steering Committee can evaluate it according to NQF criteria and guidance.

1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)

Key Points

- Should indicate the causal pathway – not just a general statement
- Do not discuss evidence in this item

EXAMPLE

Folic acid supplementation in women planning, or capable of becoming pregnant, and continued during the early weeks of pregnancy reduces the occurrence of neural tube birth defects.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes No

If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

1c.4.1. Guideline citation (including date):

U.S. Preventive Services Task Force. Folic Acid for the Prevention of Neural Tube Defects: U.S. Preventive Services Task Force Recommendation Statement. AHRQ Publication No. 09-05132-EF-2, May 2009.

<http://www.uspreventiveservicestaskforce.org/uspstf09/folicacid/folicacidrs.htm>

Folic Acid for the Prevention of Neural Tube Defects: U.S. Preventive Services Task Force

Recommendation Statement U.S. Preventive Services Task Force Ann Intern Med May 5, 2009 150:626-631.

American College of Obstetricians and Gynecologists (ACOG). Neural tube defects. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Jul. 11 p. (ACOG practice bulletin; no. 44). [81 references]

The American College of Obstetricians and Gynecologists (ACOG) reaffirmed the currency of the guideline in 2008.

1c.4.2. URL (if available online):

Key Points

- Make sure URL is active and correct

EXAMPLE

USPSTF: <http://www.uspreventiveservicestaskforce.org/uspstf/uspnrfol.htm>

ACOG: <http://www.guideline.gov/content.aspx?id=3994&search=folic+acid+supplement>

1c.4.3. Identify guideline number and/or page number:

Key Points

- If guideline recommendation is one of many from a single document, the specific guideline number and/or page number is necessary.

EXAMPLE

USPSTF: no numbering provided; date is May 2009

ACOG: practice bulletin no. 44

1c.4.4. Quote **verbatim, the specific guideline recommendation:**

Key Points

- Do not summarize, paraphrase, or shorten

EXAMPLE

USPSTF: The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.

ACOG: Periconceptional folic acid supplementation is recommended because it has been shown to reduce the occurrence and recurrence of neural tube defects (NTDs).

1c.4.5. Grade assigned to the recommendation with definition of the grade:

Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for a recommendation

EXAMPLE

USPSTF: A recommendation - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Offer or provide this service.

ACOG: Level A - Recommendation is based on good and consistent scientific evidence

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes No **If no, skip to #1c.6**

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence
- If specific details regarding systematic review of evidence for guideline not available, will need to identify another review of the body of evidence

EXAMPLE

USPSTF: High Certainty of Net Benefit - The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.

ACOG: The National Guideline Clearinghouse states recommendation based on systematic review of evidence, but the specific grade and summary not provided.

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)

Yes No **If no, skip to #1c.7**

If yes, answer 1c.6.1-1c.6.3. (**Note:** Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. **Citation** (including date): Wolff T, Witkop CT, Miller T, Syed SB. Folic Acid Supplementation for the Prevention of Neural Tube Defects: An Update of the Evidence for the U.S. Preventive Services Task Force. Evidence Synthesis No. 70. AHRQ Publication No. 09-051132-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality. May 2009.

1c.6.2. **URL** (if available online):

Key Points

- Make sure URL is active and correct

EXAMPLE

<http://www.ncbi.nlm.nih.gov/books/NBK43412/>

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence

EXAMPLE

The evidence synthesis did not provide one overall grade. See prior section for USPSTF grade for the recommendation. See next section for summary of evidence.

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

Key Points

- Responses to the following items should NOT include a description of each individual study – the responses should include quantitative data from a synthesis of the entire body of evidence. If there is more than one systematic review, each should be reported separately (not combined by the submitter).
- May copy relevant sections from source(s) of systematic reviews cited in 1c.5, 1c.6, or 1c.7; include page number if possible; make sure it includes substantive, quantitative information not just conclusions

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: 1992-2009

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

Key Points

- Only enter number and type of study design here — discuss in 1c.10
- NQF does not require evidence be only randomized controlled trials

- Study design relates to quality of evidence but is insufficient by itself to judge quality

EXAMPLE

USPSTF: Initially 1 large randomized, controlled trial (RCT) for the 1996 review.

The recent evidence synthesis included 4 studies published since 1996: 1 cohort study, 2 case control studies, and 1 meta-analysis.

1c.10. What is the overall quality of evidence across studies in the body of evidence? (*discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

Key Points

- Do not discuss each study individually — categorize by quality

EXAMPLE

USPSTF:

One cohort study rated as fair quality.

Studies will be graded "fair" if any or all of the following problems occur, without the fatal flaws noted in the "poor" category : Generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention to treat analysis is done for RCTs.

Two case control studies – one rated fair quality and one rated good quality.

Good: Appropriate ascertainment of cases and nonbiased selection of case and control participants; exclusion criteria applied equally to cases and controls; response rate equally to or greater than 80 percent; diagnostic procedures and measurements accurate and applied equally to cases and controls; and appropriate attention to confounding variables.

Fair: Recent, relevant, without major apparent selection or diagnostic work-up bias but with response rates less than 80 percent or attention to some but not all important confounding variables.

One meta-analysis rated fair quality.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (*e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance*)

Key Points

- Do not discuss each study individually — categorize by outcome studied

EXAMPLE

USPSTF: The Czeizel cohort study reported that 1 NTD and 9 NTDs occurred in the supplemented and unsupplemented women, respectively, for an adjusted odds ratio (aOR) of 0.11 (95% CI, 0.01–0.91); the odds ratio (OR) was adjusted for birth order, chronic maternal disorders, and history of previous fetal

death or congenital abnormality. The meta-analysis also found a protective effect of folic acid-containing multivitamins in NTDs with an OR of 0.67 (95% CI, 0.58–0.77) in case-control studies and an OR of 0.52 (0.39–0.69) in RCTs and cohort studies. Both the Czeizel study and the meta-analysis found a statistically significant association between folic acid supplementation and a reduction in cardiovascular congenital abnormalities. In addition, there was a significant effect of folic acid-containing multivitamin use on congenital limb defects in the meta-analysis. No consistent effect of folic acid-containing multivitamins, either on orofacial clefts or on urinary tract congenital abnormalities, was seen in the Czeizel study or the meta-analysis.

The 1995 case-control study reported an OR of 0.65 (95% CI, 0.45–0.94) for use of folic acid-containing supplements in the 3 months before conception, and an OR of 0.60 (95% CI, 0.46–0.79) for supplement use in the 3 months after conception. The 2003 study by Thompson and colleagues reported an OR of 0.55 (0.25–1.22) for regular use, and an OR of 0.92 (0.55–1.55) for some use of folic acid-containing supplements, but neither of these findings was statistically significant. Several differences in these case-control studies may explain differences in results. The 2003 Thompson study was smaller and adjusted for dietary folate intake. Additionally, the exposure timeframes were different: the Shaw study measured exposure in 2 time frames, 3 months before and 3 months after conception, while the Thompson study combined these same 6 months of periconception time into one measure of exposure.

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

Key Points

- Information on harms may come from different studies than the treatment effectiveness studies, often from observational studies

EXAMPLE

USPSTF: The recommendation statement concluded: “Adequate evidence suggests that folic acid from supplementation at usual doses is not associated with serious harms. In its current review, the USPSTF found no evidence on drug interactions, allergic reactions, or carcinogenic effects.”

The evidence synthesis found one fair quality retrospective cohort study that addressed whether folic acid supplementation in women of childbearing age increases the risk of harmful outcomes for either the woman or the infant. After adjusting for age and parity, the authors reported an OR of 1.59 (95% CI 1.41–1.78) for twin delivery after preconceptional folic acid supplementation. In a subgroup analysis of women who did not report IVF, the risk of twinning was lower and non-significant (OR 1.13, 95% CI 0.97–1.33), as expected given the increase in multiple gestation associated with IVF and other assisted reproductive technologies. The odds of having twins of unlike sex, an outcome used as a proxy for dizygotic twinning, were increased in women taking folate, (OR 1.43, 95% CI 1.12–1.83). The authors then adjusted for both a 45% underreporting of supplementation as well as an estimated 12.7% of unidentified IVF pregnancies. When the likely underreporting for folic acid use and IVF were accounted for, the OR for twin delivery after preconceptional supplementation fell to 1.02, and was no longer statistically significantly greater than the risk for women who did not take folic acid (95% CI, 0.85–1.24).

ACOG: Risks of folic acid supplementation. The risks of higher levels of folic acid supplementation are believed to be minimal. Folic acid is considered nontoxic even at very high doses and is rapidly excreted in the urine. There have been concerns that supplemental folic acid could mask the symptoms of pernicious anemia and thus delay treatment. However, folic acid cannot mask the neuropathy typical of this diagnosis. Currently, 12% of patients with pernicious anemia present with neuropathy alone. With

folic acid supplementation, this proportion may be increased, but there is no evidence that initiating treatment after the development of a neuropathy results in irreversible damage. A small number of women taking seizure medication (diphenylhydantoin, aminopterin, or carbamazepine) may have lower serum drug levels and experience an associated increase in seizure frequency while taking folic acid supplement. Monitoring drug levels and increasing the dosage as needed may help to avert this complication.

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes No *If no, stop*

If yes,

1c.13.1. For **each** new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

EXAMPLE — MEASURE CONCEPT SPECIFICATIONS

NATIONAL QUALITY FORUM—Concept Submission Items
Measure Concept Specifications

Key Points

- Measure concepts should be sufficiently specified so that it is clear how the concept will be measured

De.1. Measure Title

Key Points

- Briefly convey as much information as possible about the measure focus and target population

SUGGESTED FORMAT

[target population] who received/had [measure]

EXAMPLE

Patients with diabetes who received an eye exam

De.2. Brief description of measure (*including type of score, measure focus, target population, timeframe, e.g., percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year*)

Key Points

- Briefly describe the type of score (e.g., percentage, proportion, number) and the target population and focus of measurement.

SUGGESTED FORMAT

[type of score] of [target population] who received/had [measure focus]

EXAMPLE

Percentage of adult patients age 18-75 with diabetes who received a foot exam

De.4. Subject/Topic Areas (Check all the areas that apply): **[Taxonomy - select from list]**

De.5. Cross Cutting Areas (Check all the areas that apply): **[Taxonomy - select from list]**

Measure Specifications (Measure evaluation criterion 2a1)

2a1.1. Numerator Statement (*Brief, narrative description of the measure focus or what is being measured the target population, i.e., cases from the target population with the target process, condition, event, or outcome*)

Key Points

- Describe the measure focus—cases from the target population with the target process, condition, event, or outcome based on the evidence.
- If the time frame is different than for identifying the target population, it should be specified.

SUGGESTED FORMAT

Patients [in the target population] who received/had [measure focus] {during [time frame] if different than target population}

EXAMPLE

Patients age 18-75 with diabetes in ambulatory care who received a foot exam

2a1.3. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

For new concepts, describe how you plan to identify and calculate the numerator.

Key Points

- Define all key concepts
- Identify code/value sets (e.g., ICD-10) or standard data collection items (e.g., Minimum Data Set (MDS) that are or will be used for concepts
- Note that lists of individual codes with descriptors or specific data items and responses should be submitted with stage 2 measure submission

EXAMPLE

Identification of foot exam will require review of the medical record. The foot examination must include all the following: inspection, assessment of foot pulses, and testing for loss of protective sensation (LOPS) (10-g monofilament plus testing any one of: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold).

2a1.4. Denominator Statement *(Brief, narrative description of the target population being measured)*

Key Points

- Designate the broadest population based on the evidence for which the target process, condition, event, outcome is applicable target population should indicate age, setting, and time frame for identifying the target population.

SUGGESTED FORMAT

Patients [age] with [condition] in [setting] during [time frame]

EXAMPLE

Patients age 18-75 with diabetes in ambulatory care during a 12-month measurement period

2a1.5. Target Population Category *(Check all the populations for which the measure is specified and tested if any): [Taxonomy - select from list]*

2a1.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format stage 2 measure submission)*

For new concepts, describe how you plan to identify and calculate the denominator.

Key Points

- Define all key concepts
- Identify code/value sets (e.g., ICD-10) or standard data collection items (e.g., Minimum Data Set (MDS) that are or will be used for concepts
- Note that lists of individual codes with descriptors or specific data items and responses should be submitted with stage 2 measure submission

EXAMPLE

Diabetes is/will be identified using ICD-10 codes

2a1.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Key Points

- Identify patients who would be in the target population, but who should not receive the process or are not eligible for the outcome for some other reason, particularly as indicated by the evidence

SUGGESTED FORMAT

Patients in the [target population] who [have some additional characteristic, condition, procedure]

EXAMPLE

Patients with diabetes who have gestational or steroid-induced diabetes

2a1.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

For new concepts, describe how you plan to identify and calculate the exclusions.

Key Points

- Define all key concepts
- Identify code/value sets (e.g., ICD-10) or standard data collection items (e.g., Minimum Data Set (MDS) that are or will be used for concepts
- Note that lists of individual codes with descriptors or specific data items and responses should be submitted with stage 2 measure submission

EXAMPLE

Gestational or steroid-induced diabetes is or will be identified using ICD-10 codes

2a1.10. Stratification Details/Variables *(All information required to stratify the measure results including stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

For new concepts, describe how you plan to stratify the measure results.

Key Points

- Do not describe development and testing of stratification approach here – this item is for specifications
- Identify stratification variables
- Define all key concepts
- Identify code/value sets used for concepts but lists of individual codes and descriptors should be submitted with stage 2 measure submission

EXAMPLE

In addition to overall hospital score compute score for each racial group.

Stratification categories: white, black, Hispanic, and other.

2a1.13. Statistical risk model method and variables *(Name the statistical method - e.g., logistic regression, list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)*

For new concepts, describe how you plan to adjust for differences in case mix/risk across measured entities

Key Points

- Do not describe risk model development and testing here – this item is for specifications
- Identify statistical method for risk adjustment
- Identify risk factor variables but the coefficients and code lists should be provided in Excel file with stage 2 measure submission
- Define all key concepts
- Identify code/value sets used for concepts but lists of individual codes and descriptors should be submitted with stage 2 measure submission

EXAMPLE

Logistic regression model

Risk Factors:

Age

Functional status

Prior hospitalization

Co-morbid conditions of diabetes, CHF, CAD

2a1.25. Data Source *(Check only the sources for which the measure is specified and tested)*

If other, please describe in 2a1.26.

For new concepts, check the planned data sources. **[Taxonomy - select from list]**

2a1.26. Data Source or Collection Instrument (*Identify the specific data source or data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.)*)

EXAMPLES

Outcome and Assessment Information Set (OASIS)
MedPAR database

2a1.33. Level of Analysis (*Check only the levels of analysis for which the measure is specified and tested*):
For new concepts, check the planned levels of analysis. **[Taxonomy - select from list]**

2a1.34. Care Setting (*Check only the settings for which the measure is specified and tested*):
For new concepts, check the planned settings. **[Taxonomy - select from list]**

EXAMPLE — USABILITY AND USE

NATIONAL QUALITY FORUM—Concept Submission Items
Usability and Use

4.1. Current and Planned Use

Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).

(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)

[Taxonomy - select from list]

Key Points

- NQF endorses measures for use in accountability/public reporting, in addition to performance improvement
- Measures do not need to be in use at the time of initial endorsement
- Only check an applications is planned when there is or will be a specific plan for implementation (plan must be submitted with measure submission for stage 2)
- See [Usability Task Force report](#)

EXAMPLE — RELATED AND COMPETING MEASURES/CONCEPTS

**NATIONAL QUALITY FORUM—Concept Submission Items
Related and Competing Measures**

Relation to Other NQF-endorsed® Measures (Measure evaluation criterion 5)

5.1. If there are related measures (either same measure focus or target population) or competing measures with the same measure focus and same target population), list the NQF # and title of all related and/or competing measures. NOTE: Can search and select measures.

Key Points

- Measure harmonization and competing measures must be resolved by developers prior to measure submission in stage 2
- Related and competing measures include those from other developers
- Check the list of all previously endorsed measures in the topic area posted to the project page

Harmonization (Measure evaluation criterion 5a)

5a.1. If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

For new concepts, skip to 5a.2.

Yes

No

Key Points

- Completely harmonized means exactly the same specifications

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

For new concepts, describe why another measure is needed and plans to harmonize measure specifications

Key Points

- Measure harmonization must be resolved by developers prior to measure submission in stage 2
- NQF prefers to endorse measures with the broadest applicability supported by the evidence. Explore the possibility of combining measures.
- Describe actions taken to achieve harmonization including developers contacted and result of that communication
- See [Measure Harmonization report](#).

Competing Measure(s) (Measure evaluation criterion 5b)

5b.1. If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

For new concepts, describe how a new measure will be superior to existing endorsed measures or why additional measure is needed.

Key Points

- Competing measures must be resolved by developers prior to measure submission in stage 2
- NQF prefers to endorse measures with the broadest applicability supported by the evidence. Explore the possibility of combining measures
- Describe actions taken to prevent multiple measures including developers contacted and result of that communication
- See [Competing Measures report](#).