Healthcare Quality Page Blog

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Exclusions and exceptions in quality-of-care measures — Can we standardize calculations to improve the validity of measurement done for quality improvement purposes?

Why definitions are important

We have been measuring the quality of healthcare services for over fifty years through various forms of measures called standards, criteria, indicators, key performance indicators, performance measures and healthcare quality measures. Most measures are expressed as a percentage of patients who receive care consistent with the care described in the measure. Therefore, measures have been defined through a component that makes up the numerator and a component that makes up the denominator used in the calculation of the percentage of compliance with the measure.

However, the precise definitions of what makes up the numerator and the denominator vary across programmes that measure the quality of healthcare services. The variation in definitions affects the usefulness of data resulting from the measurement of clinical practice and the ability to reach valid conclusions about the quality of clinical practice, whether in an individual healthcare organization or across healthcare organizations nationally. The variation in definitions inevitably affects the validity of the measurement.

Exclusions and exceptions — Definitions

Definitions of exclusions and exceptions in quality measures vary. Some sources explain exclusions in relation to the population to be included in the measurement process and exceptions in relation to factors that account for the aspect of care specified in a measure not being delivered.[1–2] Some refer to the terms being used interchangeably, although there are subtle differences.[3] Still other sources refer to an exclusion being identified in advance of data capture and an exception being recognized only after data capture when it is clear that a patient's care has not been consistent with the aspect of care specified in the numerator.[4]

Some sources have identified categories of exceptions as reasons for which a patient may be excluded from a measure including the following:[5]

- Medical reasons, including the care specified in the measure not being indicated (already received or performed or other explanation) or contraindicated (patient allergic history, potential adverse drug reason, etc)
- Patient reasons, including the patient declined; economic, social or religious reasons; or other patient reasons

- System reasons, including resources to perform the services not being available; insurance coverage or payer-related limitations; or other reasons attributable to health care delivery systems.

Definitions of these terms depend on the purpose of the measurement of quality of health care.[6–12] If the purpose is quality improvement or accountability, exceptions to individual measures are essential to allow for clinical judgement in responding to specific clinical or patient circumstances. Improvements in practice are limited to acting on the reasons why patients did not have care consistent with the measures, including defined exceptions. If the purpose is pay-for-performance, the measure is likely to include a minimum threshold of a percentage of patients that must have the care specified in order for a provider to receive a defined level of payment; exceptions may or may not be recognized in individual measures, which could affect the amount paid to providers.

If the purpose is practitioner or organization payment-related, for example, exceptions could recognize systems limitations in the delivery of care. However, if the purpose of measurement is quality improvement, the distinctions of terms should be those described in the box.

Exclusions and exceptions — Who decides

An issue that pervades explanations of healthcare quality measures is who defines exclusions and exceptions — the organization managing the measuring, such as a national organization conducting a national clinical audit or quality improvement project, or local clinicians. When realistic exceptions are not recognized in national measures, the quality of clinical performance may be underestimated.[13]

On the other hand, studies have demonstrated variation in specifying exclusions or exceptions when these cases can be defined locally by clinicians. Depending on the 'stakes' involved in the findings of measurement, there can be considerable variation by healthcare organization.[14–15] If the stakes are high, for example, to prevent financial penalties for a clinical service, it is possible that local clinicians could use exceptions as a gaming mechanism.[15] However, in usual clinical practice, with locally-based peer review of exceptions, peers may support up to 94% of exceptions named by colleagues.[16]

When local clinicians are able to specify their own exclusions or exceptions, some have suggested that the number and type of exclusions or exceptions used by local clinicians should be reported publicly

Term	Meaning
Exclusion	Relates to the **population** to which the measure is to be applied A patient or group of patients or circumstances that are removed from the group of patients to which the quality measure is being applied Exclusions require very careful specification of the population, for example, exact diagnostic or procedure codes, age ranges of patients, complex cases or co-morbidities, time of onset of condition, length of illness, or other factors to be excluded from application of the measure.
Exception	Relates to the **justification** for the aspect of **care** being measured **not** being **provided for an individual patient** Exceptions require very careful specification of the rationale for the aspect of care being measured to not apply to individual patients who may be in the population, for example, patient declining the care, patient-specific contraindications, patient-specific circumstances for the care not being appropriate.

as part of a report of performance.[14, 17] Such reporting would allow judgement about the nature of the exclusions or exceptions and would enable learning about the circumstances or situations in which processes may or may not be associated with outcomes.[17]

A point also raised is the importance of reliable data collection to represent exclusions and exceptions as accurately as possible. Erroneous conclusions about true clinical performance can be drawn if important exclusions or exceptions are not captured accurately through the data collection process.[18]

Exclusions and exceptions — To add or subtract — from the numerator or the denominator

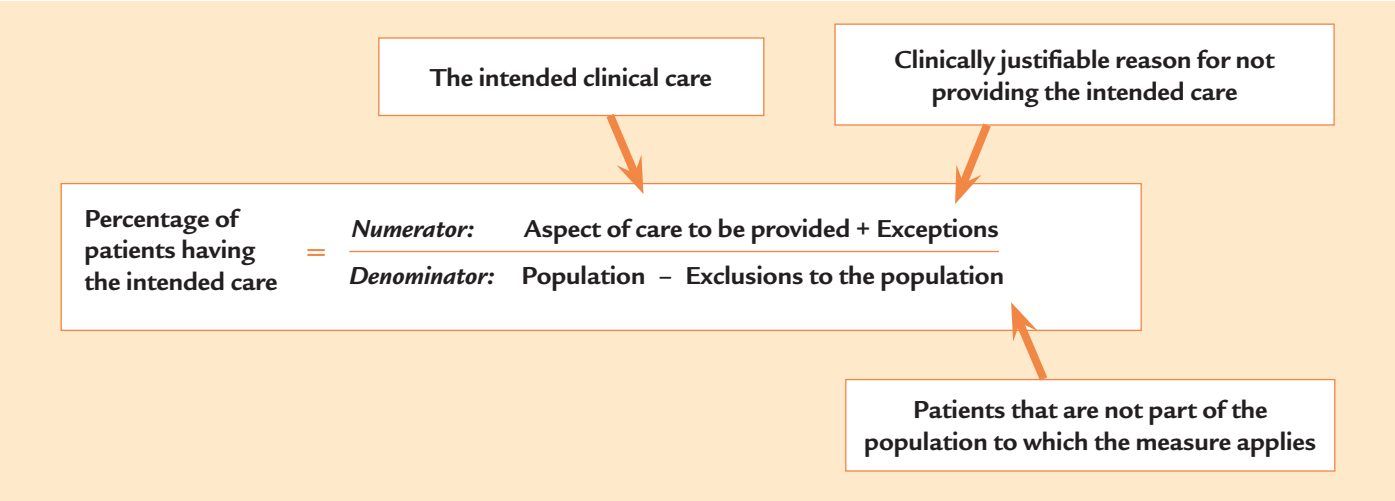
Typical practice appears to be to constrain the numerator in a quality measure to the number of patients who received the care described in the numerator, and to subtract from the denominator both exclusions and exceptions. However, one group suggests adding exceptions, both medical and patient exceptions, to the numerator.[19] The justifications for this practice are: (1) from a shared-decision making perspective, it allows for patient preferences without penalizing clinicians, (2) it reflects the realities of day-to-day clinical practice with clinical variation in presentation among patients, (3) it bolsters clinician engagement with measurement of the quality of care and quality improvement initiatives, and (4) it produces an improvement in compliance with quality measures.[19]

Exceptions added to the numerator in quality measures preserves clinicians' judgement but still enables them to strive for high levels of performance. Without the use of explicit exceptions, and the addition of exceptions to the numerator, the gap between actual performance and 100% can seem insurmountable to clinicians who want to deliver excellent clinical care. When exceptions are added to the numerator of a quality measure, clinicians and those who hold them accountable for meeting the measures could expect a level of performance that is much closer to 100%.[16]

The way to interpret what is an exception is to give credit to a clinician for recognizing that the measure does not apply to an individual patient. Good clinical practice is to provide the aspect of care intended in the measure; good clinical practice is also not to provide the intended aspect of care if it is not appropriate for the patient for medical or patient-related reasons. Good clinical decision-making for both alternatives is positively acknowledged, and the measure structure reflects this recognition of sound clinical practice.

A model of exclusions and exceptions in a quality measure

When a quality measure is used for quality improvement purposes only, a model of providing the most valid representation of clinical practice and clinical judgement in a quality measure is in the box.



The value of the model — The fairest representation of the 'true' quality of care

When an aspect of care does not apply to all patients, there are theoretically three ways to handle the circumstance:

- Use **no exclusion or exception** —
  - In the numerator, include the patients for whom care is consistent with the intended aspect of care.
  - In the denominator, include all patients to which the measure applies without any exclusions or exceptions.
- Use **an exclusion** —
  - In the numerator, include the patients for which care is consistent with the intended aspect of care.
  - In the denominator, **subtract** from all patients to which the measure applies any cases where circumstances would make the patient exempt from receiving the specified care or service.
- Use **an exception** —
  - In the numerator, include the patient for which care is consistent with the intended aspect of care **plus** the patients for whom there is a clinically justifiable circumstance that would make the patients exempt from receiving the care specified in the evidence of quality.
  - In the denominator, include all patients to which the measure applies.

The decision will affect the picture of performance provided by the measure. Examples are in the box.

Effect of subtracting from the denominator or adding to the numerator

Timeliness of access to the lung cancer service

Numerator	The number of people whose request for an appointment was received in the months of April to June and whose clinic appointment was 10 working days after the request to see the person is received **Exception:** The people who chose to wait longer for the appointment
Denominator	The number of people whose request for referral for an appointment was received in the months of April to June

Findings from data collection

- 100 people were included in the audit, that is, the measure of an appointment with a specialist being requested applied to all 100 people.
- 68 people had an appointment in 10 working days after the request was received.
- 14 people chose to wait longer than 10 working days for an appointment.
- 18 people did not have an appointment 10 working days after the request was received and did not choose to wait longer.

Calculation of compliance making no provision for an exception

$$\frac{\text{68 people had an appointment ⩽10 working days after the request was received}}{\text{100 people were referred for an appointment}} = \frac{68}{100} = 68.0\%$$

Calculation of compliance treating an exception as an exclusion

$$\frac{\text{68 people had an appointment ⩽10 working days after the request was received}}{\text{100 people were referred for an appointment } \textbf{minus} \text{ 14 people who chose to wait longer for an appointment}} = \frac{68}{86} = 79.1\%$$

Calculation of compliance recognizing an exception as valid clinical decision-making

$$\frac{\text{68 people had an appointment ⩽10 working days after the request was received } \textbf{plus} \text{ 14 people who chose to wait longer for an appointment}}{\text{100 people were referred for an appointment}} = \frac{82}{100} = 82.0\%$$

Conclusions about the three approaches to calculations when an aspect of care does not apply to all patients are as follows.

- Using **no exclusion or exception** can result in **underestimation** of the level of compliance with the measure.
- Using an **exclusion** when some cases are exempt from receiving the care specified can result in **underestimation** of the level of compliance with the measure.
- Using an **exception** presents **a more valid picture** of quality by allowing for clinical judgement and unusual circumstances that happen in the provision of patient care.

When are exceptions identified — Before or after data collection

When exceptions can be specified in advance of data collection, the data capture or collection process actually can find and count exceptions, which may help local clinical teams interpret findings from data capture or collection. However, it is possible that a clinical group may not think of all exceptions in advance of data capture. Cases which were not consistent with the quality measure should be reviewed to identify any further exceptions. Examples of possible 'additional' exceptions are in the box below.[2]

The way forward for exclusions and exceptions

In quality measurement systems that are entirely reliant on electronic patient record (EPR) systems, the specifications for the numerator and denominator for individual measures are dependent on the structure of the systems.

However, for clinical audit or quality improvement studies that are not dependent on standardized specifications dependent on the structure of an EPR system for the numerator and denominator, it is important for local clinical peer groups to:

Term	Meaning
Forgotten exception	A common exception to the aspect of quality of care that you simply **overlooked** in drawing up a measure, such as the patient declined the treatment
Rare exception	An exception to the aspect of quality of care that occurs so **rarely** that you would not ordinarily think of including it in a measure. Rare exceptions tend to consist of unusual patient diagnoses or conditions. It is more efficient to identify rare exceptions during review of cases than to determine all the possible rare exceptions when drawing up measures.
Complex exception	A **combination of clinical circumstances** that together create an exception to the aspect of quality. A complex exception tends to be a patient with several diagnoses or problems in which the management of one condition may influence management of another.
State-of-the-art exception	Patient conditions for which there is **no generally accepted effective** prevention or **treatment** or for which the **evidence is in conflict**, which may justify not providing the aspect of care.

Agree in advance of data capture or collection on both the **cases to be excluded** from the population in the study **and** the **clinical and patient exceptions** in quality measures to be applied locally.

- **Add exceptions to the numerator** and **subtract exclusions from the possible population in the denominator**.
- Following data collection, review cases that are not consistent with quality measures as a peer group to **identify any additional exceptions**, such as rare exceptions or complex cases.
- **Adjust the percentage of compliance** with a quality measure to add additional exceptions agreed by a clinical peer group.

References

1. Stroke and Stroke Rehabilitation Work Group. *Stroke and Stroke Rehabilitation. Quality Measurement Set Update*. American Academy of Neurology; 2017. https://www.aan.com/siteassets/home-page/policy-and-guidelines/quality/quality-measures/15strokeandrehabmeasureset_pg.pdf. Accessed Dec 2023.
2. Dixon N. *Getting Clinical Audit Right to Benefit Patients*. Romsey: Healthcare Quality Quest; 2023.
3. Quality Measures. American Academy of Family Practice. https://www.aafp.org/family-physician/practice-and-career/managing-your-practice/quality-measures.html. Accessed Dec 2023.
4. Interpreting Performance Report Fields. NRDR. National Radiology Data Registry. https://nrdrsupport.acr.org/support/solutions/articles/11000038822-interpreting-performance-report-fields. Accessed Dec 2023.
5. 2016 GPRO Web Interface Quality Reporting Questions and Answers. Centers for Medicare and Medicaid Services, November 21, 2016. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/QandA_2016DataCollection.pdf. Accessed Dec 2023.
6. Uses of Quality Measurement. Agency for Healthcare Research and Quality. https://www.ahrq.gov/patient-safety/quality-resources/tools/chtoolbx/uses/index.html. Accessed Dec 2023.
7. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM. Accountability measures — Using measurement to promote quality improvement. *N Eng J Med* 2010;363(7):683–8. https://www.doi.org/10.1056/NEJMsb1002320
8. Davies H. Measuring and Reporting the Quality of Health Care: Issues and Evidence from the International Research Literature — A Discussion Paper. NHS Quality Improvement Scotland, November 2005. https://www.semanticscholar.org/paper/Measuring-and-reporting-the-quality-of-health-care-Davies/83da02784680d8e39e3cab2d76a8c237c4afe31c. Accessed Dec 2023.
9. Palmer RH. Measuring clinical performance to provide information for quality improvement. *Qual Manag Health Care* 1996;4(2):1–6. https://www.doi.org/10.1097/00019514-199600420-00001
10. Pringle M, Wilson T, Grol R. Measuring 'goodness' in individuals and healthcare systems. *BMJ* 2002;325:704–7. https://www.doi.org/10.1136/bmj.325.7366.704
11. Raleigh VS, Foot C. *Getting the Measure of Quality. Opportunities and Challenges*. The King's Fund, 2010. https://www.kingsfund.org.uk/publications/getting-measure-quality. Accessed Dec 2023.
12. Solberg LI, Mosser G, McDonald S. The three faces of performance measurement: improvement, accountability and research. *Jt Comm J Qual Improv* 1997;23(3):135–47. https://www.doi.org/10.1016/s1070-3241(16)30305-4
13. Walter LC, Davidowitz NP, Heineken PA, Covinsky KE. Pitfalls of converting practice guidelines into quality measures: lessons learned from a VA performance measures. *JAMA* 2004;291:2466–70. https://www.doi.org/10.1001/jama.291.20.2466
14. Bruckel J, Liu X, Hohmann SF, Karson AS, Mort E, Shahian DM. The denominator problem: national hospital quality measures for acute myocardial infarction. *BMJ Qual Saf* 2017;26(3):189–99. https://www.doi.org/10.1136/bmjqs-2015-004888
15. Campbell S, Hannon K, Lester H. Exception reporting in the Quality and Outcomes Framework: views of practice staff – a qualitative study. *Br J Gen Pract* 2011;61(585):183–9. https://www.doi.org/10.3399/bjgp11X567117
16. Persell SD, Dolan NC, Friesema EM, Thompson JA, Kaiser D, Baker DW. Frequency of inappropriate medical exceptions to quality measures. *Ann Intern Med* 2010;152(4):225–31. https://www.doi.org/10.7326/0003-4819-152-4-201002160-00007
17. Marang-van de Mheen PJ, Nallamothu BK. Exclusions in the denominators of process based quality measures: the missing link in understanding performance or ecological fallacy? *BMJ Qual Saf* 2017;26(3):169–73. https://www.doi.org/10.1136/bmjqs-2016-005254
18. Murdock DK, Engelmeier RS, Logemann T, Schlund A, Haehlke R. Medicare's Cooperative Cardiovascular Project: can we trust our MetaStar report cards? *WMJ* 1999;98(6):44–8.
19. Bowen ME, Bhat D, Fish J, Moran B, Howell-Stampley T, Kirk L, Persell SD, Halm EA. Improving performance on preventive health quality measures using clinical decision support to capture care done elsewhere and patient exceptions. *Am J Med Qual* 2018;33(3):237–45. https://www.doi.org/10.1177/1062860617732830

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