

NATIONAL QUALITY FORUM

Stage 1 Concept Submission and Evaluation Worksheet 1.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's concept evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: C 2065 NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
CONCEPT SPECIFICATIONS
De.1 Concept Title: Gastrointestinal Hemorrhage Mortality Rate (IQI #18)
Co.1.1 Concept Steward: Agency for Healthcare Research and Quality
De.2 Brief Description of Concept: Percent of discharges with an in-hospital death among cases with a principal diagnosis of gastrointestinal hemorrhage
2a1.1 Numerator Statement: Number of in-hospital deaths among cases meeting the inclusion and exclusion rules for the denominator
2a1.4 Denominator Statement: All discharges, age 18 years and older, with a principal diagnosis code of gastrointestinal hemorrhage
2a1.8 Denominator Exclusions: Exclude cases: <ul style="list-style-type: none"> • transferring to another short-term hospital • MDC 14 (pregnancy, childbirth, and puerperium) • with missing discharge disposition, gender, age, quarter, year or principal diagnosis
1.1 Concept Type: Outcome 2a1. 25-26 Data Source: Administrative claims 2a1.33 Level of Analysis: Facility 1.2-1.4 Is this concept paired with another measure? No
2a1.1 Numerator Statement (<i>Brief, narrative description of the concept focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome</i>): Number of in-hospital deaths among cases meeting the inclusion and exclusion rules for the denominator
2a1.3 Numerator Details (<i>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</i>) For new concepts , describe how you plan to identify and calculate the numerator. All discharges with a Disposition of Patient (DISP) coded as "died" (20)
2a1.4 Denominator Statement (<i>Brief, narrative description of the target population being measured</i>): All discharges, age 18 years and older, with a principal diagnosis code of gastrointestinal hemorrhage
2a1.5 Target Population Category (<i>Check all the populations for which the concept is specified and tested if any</i>): Adult/Elderly Care
2a1.7 Denominator Details (<i>All information required to identify and calculate the target population/denominator such as definitions,</i>

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 denominator.

ICD-9-CM principal diagnosis code of Gastrointestinal hemorrhage (see below for detail)

Time window may be determined by the user, but is generally a calendar year.

ICD-9-CM Gastrointestinal hemorrhage diagnosis codes:

4560 ESOPHAG VARICES W BLEED
5307 MALLORY-WEISS SYNDROME
53021 ULCER ESOPHAGUS W BLEED
53082 ESOPHAGEAL HEMORRHAGE
53100 AC STOMACH ULCER W HEM
53101 AC STOMAC ULC W HEM-OBST
53120 AC STOMAC ULC W HEM/PERF
53121 AC STOM ULC HEM/PERF-OBS
53140 CHR STOMACH ULC W HEM
53141 CHR STOM ULC W HEM-OBSTR
53160 CHR STOMACH ULC HEM/PERF
53161 CHR STOM ULC HEM/PERF-OB
53200 AC DUODENAL ULCER W HEM
53201 AC DUODEN ULC W HEM-OBST
53220 AC DUODEN ULC W HEM/PERF
53221 AC DUOD ULC HEM/PERF-OBS
53240 CHR DUODEN ULCER W HEM
53241 CHR DUODEN ULC HEM-OBSTR
53260 CHR DUODEN ULC HEM/PERF
53261 CHR DUOD ULC HEM/PERF-OB
53300 AC PEPTIC ULCER W HEMORR
53301 AC PEPTIC ULC W HEM-OBST
53320 AC PEPTIC ULC W HEM/PERF
53321 AC PEPT ULC HEM/PERF-OBS
53340 CHR PEPTIC ULCER W HEM
53341 CHR PEPTIC ULC W HEM-OBS
53360 CHR PEPT ULC W HEM/PERF
53361 CHR PEPT ULC HEM/PERF-OB
53400 AC MARGINAL ULCER W HEM
53401 AC MARGIN ULC W HEM-OBST
53420 AC MARGIN ULC W HEM/PERF
53421 AC MARG ULC HEM/PERF-OBS
53440 CHR MARGINAL ULCER W HEM
53441 CHR MARGIN ULC W HEM-OBS
53460 CHR MARGIN ULC HEM/PERF
53461 CHR MARG ULC HEM/PERF-OB
53501 ACUTE GASTRITIS W HMRHG
53511 ATRPH GASTRITIS W HMRHG
53521 GSTR MCSL HYPRT W HMRG
53531 ALCHL GSTRITIS W HMRHG
53541 OTH SPF GASTRT W HMRHG
53551 GSTR/DDNTS NOS W HMRHG
53561 DUODENITIS W HMRHG
53783 ANGIO STM/DUDN W HMRHG
53784 DIEULAFOY LES,STOM&DUOD
56202 DVRTCLO SML INT W HMRHG
56203 DVRTCCLI SML INT W HMRHG
56212 DVRTCLO COLON W HMRHG

56213 DVRTCLI COLON W HMRHG
5693 RECTAL & ANAL HEMORRHAGE
56985 ANGIO INTES W HMRHG
56986 DIEULAFOY LES, INTESTINE
5780 HEMATEMESIS
5781 BLOOD IN STOOL
5789 GASTROINTEST HEMORR NOS

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

Exclude cases:

- transferring to another short-term hospital
- MDC 14 (pregnancy, childbirth, and puerperium)
- with missing discharge disposition, gender, age, quarter, year or principal diagnosis

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the 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.

- transferring to another short-term hospital (Disposition of Patient (DISP) coded as Transfer to Short-term Hospital (2))
- Major Diagnostic Category 14 (pregnancy, childbirth, and puerperium) - note that this exclusion is implied by the fact that the denominator is limited to patients with a principal diagnosis code for gastrointestinal hemorrhage, which maps to MDC 6 (digestive)
- missing discharge disposition (DISP=missing)
- missing gender (SEX=missing)
- missing age (AGE=missing)
- missing quarter (DQTR=missing)
- missing year (YEAR=missing)
- missing principal diagnosis (DX1=missing)

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the 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, if you plan to stratify the measure results, describe the plans for stratification.

Not applicable

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and 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, if an outcome, describe how you plan to adjust for differences in case mix/risk across measured entities.

The predicted value for each case is computed using a two-stage hierarchical model (the first stage is a logistic regression using Generalized Estimating Equations (GEE) to account for clustering of patients within hospitals; the second stage is a reliabi

2a1.25 Data Source (Check all the sources for which the concept is specified and tested). If other, please describe:

Administrative claims

2a1.26 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): HCUP State Inpatient Databases (SID). Healthcare Cost and Utilization Project (HCUP). Agency for Healthcare Research and Quality, Rockville, MD.

Data dictionary and code tables are available at <http://www.qualityindicators.ahrq.gov/Downloads/Software/Win>

2a1.33 Level of Analysis (Check the levels of analysis for which the concept is specified and tested): Facility

2a1.34 Care Setting (Check all the settings for which the concept is specified and tested): Hospital/Acute Care Facility

IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is the criterion that must be met in order to recommend a concept for approval. All three subcriteria must be met to pass this criterion. See [guidance on evidence](#).

1a. High Impact: H M L I

(The concept directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): [Gastrointestinal \(GI\)](#), [Gastrointestinal \(GI\) : Bleeding](#)

De.5 Cross Cutting Areas (Check all the areas that apply):

1a.1 Demonstrated High Impact Aspect of Healthcare: [A leading cause of morbidity/mortality](#)

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

More people are admitted to the hospital for upper GI bleeding than for congestive heart failure or deep vein thrombosis.¹ In the United States, the annual rate of hospitalization for upper GI bleeding is estimated to be 165 per 100,000—equating to more than 300,000 hospitalizations per year, at a cost of \$2.5 billion,^{2,3} with a case-fatality rate of 7 to 10 percent.¹ However, costs are not constant across all bleed types. In a study using the Nationwide Inpatient Sample, researchers reported a fourfold higher cost and LOS attributable to rebleeding for variceal upper gastrointestinal bleeding compared to nonvariceal upper gastrointestinal bleeding.² Hospitalization costs with and without complications were \$5,632 and \$3,402 for non-variceal upper gastrointestinal bleeding, versus \$23,207 and \$6,612 for variceal upper gastrointestinal bleeding, respectively. Mean length of stay was 4.4 and 2.7 days for nonvariceal bleeding, versus 15.2 and 3.8 days for variceal bleeding, respectively.² Acute, massive lower gastrointestinal bleeding has an incidence of 20 to 27 episodes per 100,000 persons annually, with a mortality rate of 4 to 10 percent.³ Mortality rates increase in patients with advancing age and increasing number of associated underlying comorbidities, specifically renal and hepatic dysfunction, heart disease, and malignancies.³⁻⁹ Among community hospitals in the Healthcare Cost and Utilization Project, the risk-adjusted rate of this indicator was 19.363 per 1,000 eligible admissions (1.94%) in 2008. This rate has steadily declined over the past 14 years, from 5.78% in 1994 to 4.57% in 2000 to 3.02% in 2005.

- 1a.4 Citations for Evidence of High Impact cited in 1a.3:**
1. Albeldawi M., Qadeer MA, Vargo JJ. Managing acute upper GI bleeding, preventing recurrences. *Cleveland Clin J Med.* 2010; 77(2):131-142.
 2. Viviane A, Alan BN. Estimates of costs of hospital stays for variceal and nonvariceal upper gastrointestinal bleeding in the United States. *Value Health* 2008; 11:1–3.
 3. Yavorski RT, Wong RK, Maydonovitch C, Battin LS, Furnia A, Amundson DE. Analysis of 3,294 cases of upper gastrointestinal bleeding in military medical facilities. *Am J Gastroenterol* 1995; 90:568–573.
 4. Manning-Dimmitt LL, Dimmitt SG, Wilson GR. Diagnosis of gastrointestinal bleeding in adults. *Am Fam Physician.* 2005; 71(7):1339-46.
 5. Wilcox CM, Clark WS. Causes and outcome of upper and lower gastrointestinal bleeding: the Grady Hospital experience. *South Med J.* 1999;92:44–50.
 6. Vreeburg EM, Snel P, de Bruijne JW, Bartelsman JF, Rauws EA, Tytgat GN. Acute upper gastrointestinal bleeding in the Amsterdam area: incidence, diagnosis, and clinical outcome. *Am J Gastroenterol.* 1997;92:236–43.
 7. Hussain H, Lapin S, Cappell MS. Clinical scoring systems for determining the prognosis of gastrointestinal bleeding. *Gastroenterol Clin North Am.* 2000;29:445–64.
 8. Zuccaro G Jr. Management of the adult patient with acute lower gastrointestinal bleeding. American College of Gastroenterology. Practice Parameters Committee. *Am J Gastroenterol.* 1998;93:1202–8.
 9. Longstreth GF. Epidemiology and outcome of patients hospitalized with acute lower gastrointestinal hemorrhage: a population-based study. *Am J Gastroenterol.* 1997;92:419–24.

1b. Opportunity for Improvement: H M L I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this concept:

[Providers may adopt the processes of care or structures of care of the best performing providers or consumers may select the best](#)

performing providers in order to improve overall outcomes.

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. **In regard to figures below:**

1st figure: estimate per 1,000, risk adjusted rates

2nd figure: standard error

3rd figure: p value relative to marked group (marked group = "c")

4th figure: p value: current year relative to prior year

Key:

"c": Reference for p-value test statistics

***: Data do not meet criteria for statistical reliability, data quality, or confidentiality

HCUPNet: <http://hcupnet.ahrq.gov>

Hospital characteristic:

Location of inpatient treatment:

Northeastc	20.844	0.405	c.ccc	0.000
Midwest	17.614	0.367	0.000	0.000
South	19.539	0.288	0.009	0.000
West	19.688	0.437	0.052	0.000

Ownership/control:

Private, not-for-profitc	18.405	0.208	c.ccc	0.000
Private, for-profit	21.746	0.495	0.000	0.001
Public	22.779	0.528	0.000	0.000

Teaching status:

Teaching	17.346	0.333	0.000	0.000
Nonteachingc	20.192	0.214	c.ccc	0.000

Location of hospital (NCHS):

Large central metropolitan	18.404	0.317	0.857	0.000
Large fringe metropolitanc	18.315	0.379	c.ccc	0.000
Medium metropolitan	18.742	0.377	0.424	0.000
Small metropolitan	22.087	0.578	0.000	0.008
Micropolitan	22.245	0.568	0.000	0.000
Noncore	24.739	1.193	0.000	0.000

Bed size of hospital:

Less than 100	22.932	0.596	0.000	0.000
100 - 299c	20.285	0.284	c.ccc	0.000
300 - 499	18.548	0.347	0.000	0.000
500 or more	17.257	0.371	0.000	0.000

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*)

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2009, and AHRQ Quality Indicators, modified version of 4.1.

There are 630 hospitals with a least 1 denominator case for IQI 18 in the NIS; this represents all such hospitals in the NIS, which is a 20% stratified random sample of all community hospitals.

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.

In regard to figures below:

1st figure: estimate per 1,000, risk adjusted rates

2nd figure: standard error
 3rd figure: p value relative to marked group (marked group = "c")
 4th figure: p value: current year relative to prior year

Key:

"c": Reference for p-value test statistics

"*": Data do not meet criteria for statistical reliability, data quality, or confidentiality

HCUPNet: <http://hcupnet.ahrq.gov>

Patient characteristic:

Age groups for conditions affecting any age

18-44c	04.395	0.308	c.ccc	0.111
45-64	18.300	0.345	0.000	0.000
65 and over	22.989	0.238	0.000	0.000

Age groups for conditions affecting primarily elderly

65-69c	13.675	0.503	c.ccc	0.000
70-74	14.911	0.452	0.068	0.023
75-79	15.322	0.470	0.017	0.000
80-84	21.815	0.495	0.000	0.000
85 and over	38.483	0.597	0.000	0.000

Gender:

Malec	22.153	0.259	c.ccc	0.000
Female	18.005	0.250	0.000	0.000

Median income of patient's ZIP code:

First quartile (lowest income)	20.311	0.329	0.000	0.000
Second quartile	20.089	0.352	0.000	0.000
Third quartile	18.554	0.376	0.296	0.000
Fourth quartile (highest income)c	17.985	0.395	c.ccc	0.000

Location of patient residence (NCHS):

Large central metropolitan	18.732	0.338	0.225	0.000
Large fringe metropolitan	18.129	0.364	c.ccc	0.000
Medium metropolitan	19.466	0.405	0.014	0.000
Small metropolitan	21.911	0.639	0.000	0.013
Micropolitan	20.531	0.524	0.000	0.000
Noncore	21.007	0.662	0.000	0.000

Expected payment source:

Private insurancec	21.381	0.510	c.ccc	0.176
Medicare	18.374	0.204	0.000	0.000
Medicaid	22.228	0.799	0.372	0.000
Other insurance	30.117	1.379	0.000	0.003
Uninsured / self-pay / no charge	25.447	1.094	0.001	0.020

Race/ethnicity (observed rates, not risk-adjusted):

White 0.14554
 Black 0.09087
 Hispanic 0.11465
 Asian and NH/PI 0.19054
 Amer Indian/AN 0.17424
 Other 0.16857

1b.5 Citations for Data on Disparities Cited in 1b.4:

Sources:

Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2009, and AHRQ Quality Indicators, modified version of 4.1.

Race/ethnicity data are from the Healthcare Cost and Utilization Project, State Inpatient Databases, 2008, Agency for Healthcare Research and Quality, Rockville, MD.

There are 630 hospitals with a least 1 denominator case for IQI 18 in the NIS; this represents all such hospitals in the NIS, which is a 20% stratified random sample of all community hospitals.

1c. Evidence (*Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the concept focus a health outcome? Yes No **If not a health outcome, rate the body of evidence.**

Quantity: H M L I Quality: H M L I Consistency: H M L I

Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the concept pass subcriterion1c?
Yes IF rationale supports relationship

Please see the attached Evidence Submission Worksheet for evidence specifications.

Was the concept approval criterion, *Importance to Measure and Report*, met?
(1a & 1b must be rated moderate or high and 1c yes) Yes No
Provide rationale based on specific subcriteria:

3. USABILITY

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)

Current Use:

Planned Use:

5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

5.1 If there are related measures (*either same measure focus or target population*) or competing measures (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

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

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

Not Applicable

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s):

Describe why this concept 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*):

Not Applicable

CONTACT INFORMATION
Co.1 Concept Steward (Intellectual Property Owner): Agency for Healthcare Research and Quality, 540 Gaither Road Rockville Maryland 20850
Co.2 Point of Contact: John Bott, AHRQ Quality Indicators Senior Analyst John.Bott@AHRQ.hhs.gov 301-427-1317-
Co.3 Concept Developer if different from Concept Steward: Agency for Healthcare Research and Quality 540 Gaither Road Rockville Maryland, 20850
Co.4 Point of Contact: John Bott, AHRQ Quality Indicators Senior Analyst John.Bott@AHRQ.hhs.gov 301-427-1317-
Co.5 Submitter: John Bott, AHRQ Quality Indicators Senior Analyst John.Bott@AHRQ.hhs.gov 301-427-1317- Agency for Healthcare Research and Quality
Co.6 Additional organizations that sponsored/participated in concept development: Battelle Memorial Institute, Stanford University and the University of California-Davis
Co.7 Public Contact: John Bott, AHRQ Quality Indicators Senior Analyst John.Bott@AHRQ.hhs.gov 301-427-1317- Agency for Healthcare Research and Quality

ADDITIONAL INFORMATION
<p>Concept Developer/Steward Updates and Ongoing Maintenance</p> <p>Ad.3 Year the concept was first released:</p> <p>Ad.4 Month and Year of most recent revision:</p> <p>Ad.5 What is your frequency for review/update of this measure?</p> <p>Ad.6 When is the next scheduled review/update for this measure?</p>
Ad.7 Copyright statement: Not applicable
Ad.8 Disclaimers: Not applicable
Ad.9 Additional Information/Comments:
Date of Submission (MM/DD/YY): Jul 16, 2012

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

Measure Title: Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

Date of Submission: [7/9/2012](#)

- 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: [Inpatient mortality](#)
- Intermediate clinical outcome: [2T](#)
- Process: [2T](#)
- Structure: [2T](#)
- Other: [2T](#)

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.

Admission for gastrointestinal hemorrhage is fairly common (circa 100/100,000 adults/year). Mortality is generally regarded as an undesirable outcome of hospital care for this condition, as for many other conditions and procedures (e.g., acute myocardial infarction, heart failure, pneumonia, stroke), although there is a small subset of patients for whom death may be the expected outcome.

Multiple care processes can influence the course of a patient during a hospital stay for gastrointestinal hemorrhage, including but not limited to:

1. Prompt recognition of gastrointestinal hemorrhage as the cause of a patient's symptoms, necessitating inpatient admission for further evaluation and treatment.
2. Prompt assessment of the severity of the patient's hemorrhage and the associated risk of mortality, to guide initial decisions about where to admit the patient and how much nursing care to provide.
3. Appropriate stabilization of acutely ill patients with prompt but safe administration of fluids, blood products, vasopressors, and other resuscitative maneuvers.
4. Appropriate diagnostic and evaluation processes to identify the source of bleeding and to characterize the risk of rebleeding.
5. Appropriate monitoring by nurses, physicians, and other health professionals to identify early warning signs of clinical deterioration and to implement "rapid response" as appropriate.

6. Appropriate treatment of high-risk bleeding sources with pharmacologic and procedural interventions that have been demonstrated to reduce the risk of rebleeding and transfusion requirements.
7. Appropriate timing of transfer from the intensive care setting to the regular unit setting, with appropriate handoffs to ensure that all important information is transmitted and that the care plan is continued and modified as needed.

Mortality rates for GI hemorrhage vary greatly, and lower mortality has been associated with more use of treatments such as early endoscopy (within 24-48 hours of presentation), though the strength of this relationship has not been established, with some studies failing to find significant relationships. Mortality rates in large population based databases have not changed since the 1940s, though there have been increases in the ages and comorbidities of patients that may have offset mortality rate declines due to better quality of care.

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

A number of medical treatments have been shown to be associated with bleeding control among patients admitted with acute GI hemorrhage, although evidence on mortality is more limited. One meta-analysis showed a slight advantage for early endoscopy versus medical management among unselected patients with acute nonvariceal upper GI hemorrhage,⁸ although some individual studies have failed to find significant associations in multivariate analyses.²

Recent attention has focused on patients with hemorrhage due to bleeding esophageal varices, who have a particularly high risk of death. A meta-analysis of 12 randomized trials of beta blockers showed a 21% improvement in the percentage of patients free of rebleeding (RR 1.42), a 5.4% improvement in the mean survival rate (RR 1.27), and 7.4% improvement in the mean percentage of patients free of bleeding death (RR 1.50).⁹ Eight trials evaluated the effects of antibiotic prophylaxis compared with placebo or no antibiotic prophylaxis in 864 cirrhotic patients with upper gastrointestinal hemorrhage; significant beneficial effects on mortality (RR 0.73 [95% CI, 0.55 to 0.95]) and the incidence of bacterial infections (RR 0.40 [95% CI 0.32 to 0.51]) were observed.¹⁰ Vasoactive agents such as terlipressin also significantly reduce mortality (RR 0.66 [95% CI, 0.49 to 0.88]) relative to placebo,¹¹ but not relative to endoscopic sclerotherapy.¹² A meta-analysis of 23 randomized trials, with 1860 patients, comparing endoscopic plus beta-blocker therapy with either therapy alone, showed that combination therapy reduced overall rebleeding, variceal bleeding, and variceal recurrence more than either endoscopic or beta-blocker therapy alone. Mortality after combination therapy was nonsignificantly lower than that after endoscopic (odds ratio, 0.78 [95% CI, 0.58 to 1.07] or drug therapy alone (odds ratio, 0.70 [95% CI, 0.46 to 1.06]).¹³

These findings from randomized controlled trials and meta-analyses have been incorporated into recent practice guidelines from the American College of Gastroenterology and the American Association for the Study of Liver Diseases.¹⁴ Their Class 1 recommendations include:

1. Acute GI hemorrhage in a patient with cirrhosis is an emergency that requires prompt attention with intravascular volume support and blood transfusions, being careful to maintain a hemoglobin of 8 g/dL (Class I, Level B).

2. Short-term (maximum 7 days) antibiotic prophylaxis should be instituted in any patient with cirrhosis and GI hemorrhage (Class I, Level A)....
3. Pharmacological therapy (somatostatin or its analogues octreotide and vapreotide; terlipressin) should be initiated as soon as variceal hemorrhage is suspected and continued for 3-5 days after diagnosis is confirmed (Class I, Level A).
4. EGD, performed within 12 hours, should be used to make the diagnosis and to treat variceal hemorrhage, either with EVL or sclerotherapy (Class I, Level A).
5. TIPS is indicated in patients in whom hemorrhage from esophageal varices cannot be controlled or in whom bleeding recurs despite combined pharmacological and endoscopic therapy (Class I, Level C).
6. Balloon tamponade should be used as a temporizing measure (maximum 24 hours) in patients with uncontrollable bleeding for whom a more definitive therapy (e.g., TIPS or endoscopic therapy) is planned (Class I, Level B).

Similarly, from the World Gastroenterological Association's evidence-based guidelines: "Management of Acute Variceal Hemorrhage in Patients with Cirrhosis"

Resuscitation measures include:

1. Intravenous (IV) volume support
2. Blood transfusion
3. Correct severe coagulation/platelet deficits
4. Antibiotic prophylaxis (up to 7 days):
5. Oral norfloxacin (400 mg twice daily [BID]), or
6. IV ciprofloxacin (400 mg BID), or
7. IV ceftriaxone (1 g/day) in advanced cirrhosis

Pharmacological therapy includes:

1. Continue 3-5 days after confirmed diagnosis
2. Somatostatin (terlipressin or octreotide, vapreotide)

Within 12 hours:

1. Confirm diagnosis with EGD
2. Treat variceal hemorrhage with EVL or sclerotherapy

In uncontrollable bleeding or recurrence:

1. TIPS indicated

In uncontrollable bleeding while waiting for TIPS or endoscopic therapy:

1. Balloon tamponade as temporizing measure for 24 hours maximum."¹⁵

Many of the deaths reported among GI hemorrhage are not associated with bleeding per se. One study found that only one such death was directly related to bleeding, and that patient had several severe comorbidities.³ In many cases, deaths among patients with a principal diagnosis of gastrointestinal hemorrhage are due to infectious or cardiovascular complications of the hemorrhage or the underlying condition (e.g., chronic liver disease, cancer) and not primarily due to the acute hemorrhage itself. Among patients with bleeding from esophageal varices, death rates are higher and appear to be more closely related to blood loss and interventions to minimize blood loss.^{7,16} However, appropriate risk stratification, early stabilization, ongoing monitoring, and measures to prevent infectious and cardiovascular complications (e.g., central line bundle to prevent central line associated bloodstream

infections, sepsis bundle to detect early signs of sepsis and respond appropriately) appear to have favorable effects on all hospitalized patients at risk, including patients with GI hemorrhage.

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15. World Gastroenterology Organisation (WGO). Esophageal varices. Munich (Germany): World Gastroenterology Organisation (WGO); 2008 Jun. 17 p.
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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.)

Not applicable

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: 21

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.