# NATIONAL QUALITY FORUM

**Measure Evaluation 4.1**
**January 2010**

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each sub-criterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the* sub-criteria *(yellow highlighted areas)*.

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few sub-criteria as indicated)

(for NQF staff use) **NQF Review** #: ACP-035-10 **NQF Project:** Ambulatory Care - Additional Outpatient Measures 2010

| MEASURE DESCRIPTIVE INFORMATION |
|---|
| De.1 **Measure Title:** Patient(s) with an emergency medicine visit for syncope that had an ECG. |
| De.2 **Brief description of measure**: This measure identifies patients with an emergency medicine visit for syncope that had an ECG done as part of their evaluation. |
| 1.1-2 **Type of Measure:** process<br>De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** Does not apply. |
| De.4 **National Priority Partners Priority Area:** care coordination<br>De.5 **IOM Quality Domain**: effectiveness<br>De.6 **Consumer Care Need:** Getting Better |

| CONDITIONS FOR CONSIDERATION BY NQF | NQF Staff |
|---|---|
| Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards: | |
| **A.** The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.*<br>A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes<br>A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** proprietary measure<br>A.3 **Measure Steward Agreement:** agreement signed and submitted<br>A.4 **Measure Steward Agreement attached:** Measure steward addendum_Ingenix 012510-634000233968213821.doc | **A**<br>**Y**☐<br>**N**☐ |

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| **B.** The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section | **B** Y☐ N☐ |
| **C.** The intended use of the measure includes both public reporting and quality improvement.<br>►**Purpose:** public reporting, quality improvement Payment Incentive, Accountability | **C** Y☐ N☐ |
| **D.** The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.<br>D.1**Testing:** Yes, fully developed and tested<br>D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?**<br>Yes | **D** Y☐ N☐ |
| (for NQF staff use) **Have all conditions for consideration been met?**<br>**Staff Notes to Steward** (*if submission returned*)**:** | **Met** Y☐ N☐ |
| **Staff Notes to Reviewers** (*issues or questions regarding any criteria*)**:** | |
| **Staff Reviewer Name(s):** | |

| | |
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| **TAP/Workgroup Reviewer Name:** | |
| **Steering Committee Reviewer Name:** | |
| **1. IMPORTANCE TO MEASURE AND REPORT** | |
| Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.<br>*Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria)<br>**1a. High Impact** | Eval Rating |
| (for NQF staff use) Specific NPP goal: | |
| **1a.1 Demonstrated High Impact Aspect of Healthcare:** patient/societal consequences of poor quality, affects large numbers<br>**1a.2**<br><br>**1a.3 Summary of Evidence of High Impact:** Syncope is a common presentation to the emergency department (ED) that accounts for 1 to 1.5 percent of emergency department visits every year; it accounts for up to 6% of hospital admissions (1,2). Although most potential causes are benign and self-limited, others are associated with significant morbidity and mortality. During emergency department evaluation, the cause of syncope often remains unclear. Therefore, evaluation and management must focus on risk stratification to distinguish patients who can be safely discharge from patients who require emergent investigation and hospitalization. ECG testing is recommended to identify potentially life-threatening conditions such as prolonged intervals (QRS, QTc), severe bradycardia, preexcitation syndromes, evidence of myocardial infarction, and other abnormalities (3).<br><br>**1a.4 Citations for Evidence of High Impact:** 1. Blanc JJ, L'Her C, Touiza A, et al. Prospective evaluation and outcome of patients admitted for syncope over a 1 year period. Eur Heart J 2002;23:815-820.<br>2. Quinn JV, Stiell IG, McDermott DA, et al. Derivation of the San Francisco syncope rule to predict patients with short-term serious outcomes. Ann Emerg Med 2004;43:224-232.<br>3. American College of Emergency Physicians (ACEP). Clinical policy: critical issues in the evaluation and management of patients presenting to the emergency department with syncope. Ann Emerg Med. 2007;49:431-444. | **1a** C☐ P☐ M☐ N☐ |

**Comment [KP1]: 1a.** The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

**1b. Opportunity for Improvement**

**1b.1 Benefits (improvements in quality) envisioned by use of this measure:** This measure will identify patients with an emergency department visit for syncope who had an ECG as part of their evaluation. This evaluation will identify patients cardiac arrhythmia or ischemia as the cause of syncope.

**1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:**
Using a geographically diverse 15 million member benchmark database (this database represents predominately a commercial population less than 65 year of age) the compliance rate was 77.5 percent, indicating a clear gap in care and opportunity for care improvement.

**1b.3 Citations for data on performance gap:**
Ingenix EBM Connect benchmark results, September 2009

**1b.4 Summary of Data on disparities by population group:**
None

**1b.5 Citations for data on Disparities:**

**1b**
**C☐**
**P☐**
**M☐**
**N☐**

**1c. Outcome or Evidence to Support Measure Focus**

**1c.1 Relationship to Outcomes** (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This measure will identify patients with an emergency department visit for syncope who had an ECG as part of their evaluation. This evaluation will identify patients cardiac arrhythmia or ischemia as the cause of syncope. In one prospective observational study, patients with an ECG showing sinus rhythm and no new abnormal changes compared to prior ECG's had a much lower risk of adverse events during the week following their syncope (1).

**1c.2-3. Type of Evidence:** observational study, evidence based guideline

**1c.4 Summary of Evidence** (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Patients presenting to an emergency room with syncope should have a 12-lead electrocardiogram (ECG) as part of their evaluation. An ECG can be used to identify patients with cardiac arrhythmia or ischemia as the cause of their syncope (2). This is a Level A recommendation from ACEP guidelines (2). In one prospective observational study, patients with an ECG showing sinus rhythm and no new abnormal changes compared to prior ECG's had a much lower risk of adverse events during the week following their syncope (1). Other studies have demonstrated that patients with a normal ECG had a low likelihood of dysrhythmias as a cause of syncope (2). Finally, an abnormal ECG has been associated as being the most important predictor of serious outcomes and a multivariate predictor for arrhythmia or death within a year after the syncopal episode (2).

**1c.5 Rating of strength/quality of evidence (***also provide narrative description of the rating and by whom***):**
Level A, American College of Emergency Physicians

**1c.6 Method for rating evidence:** ACEP levels of recommendation:
Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II
studies that directly address all of the issues).
Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III
studies).
Level C recommendations. Other strategies for patient management that are based on preliminary,

**1c**
**C☐**
**P☐**
**M☐**
**N☐**

**Comment [KP2]: 1b.** Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

**Comment [k3]:** 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

**Comment [k4]: 1c.** The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure … [1]

**Comment [k5]:** 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve … [2]

**Comment [k6]:** 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system … [3]

inconclusive, or conflicting evidence, or in the absence of any published literature, based on panel consensus.

**1c.7 Summary of Controversy/Contradictory Evidence:** Though the diagnostic yield of the ECG is low (less than 5%), the test is noninvasive and relatively inexpensive and can occasionally identify a cardiac cause for the syncope (2). Of note, this measure is similar to an endorsed AMA PCPI and CMS PQRI measure that address this aspect of care.

**1c.8 Citations for Evidence (***other than guidelines***):** 1. Quinn JV, Stiell IG, McDermott DA, et al. Derivation of the San Francisco syncope rule to predict patients with short-term serious outcomes. Ann Emerg Med 2004;43:224-232.

**1c.9 Quote the Specific guideline recommendation (***including guideline number and/or page number***):**
ACEP, page 435

Level A recommendations. Obtain a standard 12-lead ECG in patients with syncope.

Diagnostic Testing Data
In patients for whom a diagnosis of syncope is established, history and physical examination identify the cause in the majority of patients in which an etiology will be established. The yield of the ECG in finding a cause is low (less than 5%), but the test is noninvasive and relatively inexpensive and can occasionally pick up potentially lifethreatening conditions such as preexcitation syndromes, prolonged QT syndromes, or Brugada syndrome in otherwise healthy-appearing young adults. A patient with a normal ECG result has a low likelihood of dysrhythmias as a cause of syncope. The definitions of an abnormal ECG vary from study to study and within specialty guidelines. One study defined an abnormal ECG result as any nonsinus rhythm or an ECG with any new changes compared with a previous ECG and
found it the most important predictor of serious outcomes. Another study found the presence of an abnormal ECG (defined as any abnormality of rhythm or conduction, ventricular hypertrophy, or evidence of previous myocardial
infarction but excluding nonspecific ST-segment and T-wave changes) was a multivariate predictor for arrhythmia or death within 1 year after the syncopal episode.

**1c.10 Clinical Practice Guideline Citation:** 2. American College of Emergency Physicians (ACEP). Clinical policy: critical issues in the evaluation and management of patients presenting to the emergency department with syncope. Ann Emerg Med. 2007;49:431-444.
**1c.11 National Guideline Clearinghouse or other URL:** guideline is attached on the

**1c.12 Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
Level A, American College of Emergency Physicians

**1c.13 Method for rating strength of recommendation** (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:**
The rating system is described in 1c.6. It is equivalent to a USPSTF grade A/B recommendation.

**1c.14 Rationale for using this guideline over others:**
The American College of Emergency Physicians (ACEP) is the largest national medical specialty organization representing physicians who practice emergency medicine. ACEP continually monitors trends in the health care environment and analyzes issues affecting emergency physicians and their patients. This is the only guideline that specifically addresses the evaluation of syncope in patients presenting to an emergency department.

| **TAP/Workgroup: What are the strengths and weaknesses in relation to the** sub-criteria **for** *Importance to Measure and Report?* | **1** |
|---|---|

**Comment [k7]:** USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

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| **Steering Committee: Was the threshold criterion,** *Importance to Measure and Report*, **met?**<br>**Rationale:** | **1**<br>**Y☐**<br>**N☐** |
| **2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES** | |
| Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria) | Eval Rating |
| **2a. MEASURE SPECIFICATIONS** | |
| **S.1 Do you have a web page where current detailed measure specifications can be obtained?**<br>**S.2 If yes, provide web page URL:**<br><br>**2a. Precisely Specified** | |
| **2a.1 Numerator Statement (***Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**<br>Patients who have an emergency medicine visit for syncope, who had an electrocardiogram (ECG) during the event<br><br>**2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):**<br>During the emergency medicine event, defined as one day prior to the start date of the emergency medicine encounter through one day after the end date of the emergency medicine encounter<br><br>**2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**<br>Patients who fulfilled at least one of the following criteria (A or B) during the following time period: one day prior to the start date of the emergency medicine encounter through one day after the end date of the emergency medicine encounter:<br>A. Patients who had an electrocardiogram (ECG) (code sets PR0304, RV0304, LC0049)<br>B. Patients who had a 12-lead ECG performed (code set PR0305) and NO claim with a procedure code for 12-lead ECG performed that indicated a reason for not obtaining a 12-lead ECG (code set PR0306)<br>1. 1P (Performance Measure Exclusion Modifier due to medical reasons)<br>2. 2P (Performance Measure Exclusion Modifier due to patient reasons)<br><br>Cd. Set Cd. Set Description Procedure Code<br>PR0304 Electrocardiography 0178T<br>PR0304 Electrocardiography 0179T<br>PR0304 Electrocardiography 0180T<br>PR0304 Electrocardiography 89.52<br>PR0304 Electrocardiography 89.53<br>PR0304 Electrocardiography 93000<br>PR0304 Electrocardiography 93005<br>PR0304 Electrocardiography 93010<br>PR0304 Electrocardiography 93015<br>PR0304 Electrocardiography 93016<br>PR0304 Electrocardiography 93017<br>PR0304 Electrocardiography 93018<br>PR0304 Electrocardiography 99350<br><br>Cd. Set Cd. Set Description Procedure Code<br>PR0305 12-lead ECG performed 3120F<br><br>Cd. Set Code Set Description PR Code Modifier<br>PR0306 12-lead ECG performed (exclusion modifier) 3120F 1P<br>PR0306 12-lead ECG performed (exclusion modifier) 3120F 2P | **2a-specs**<br>**C☐**<br>**P☐**<br>**M☐**<br>**N☐** |

**Comment [KP8]: 2a.** The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

| Cd. Set Code Set Description | Revenue Code |
|---|---|
| RV0304 Electrocardiography | 0482 |
| RV0304 Electrocardiography | 0730 |
| RV0304 Electrocardiography | 0739 |

| Cd. Set Code Set Description | LOINC Code |
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| LC0049 Electrocardiography | 10000-8 |
| LC0049 Electrocardiography | 10001-6 |
| LC0049 Electrocardiography | 10002-4 |
| LC0049 Electrocardiography | 10003-2 |
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| LC0049 Electrocardiography | 10005-7 |
| LC0049 Electrocardiography | 10006-5 |
| LC0049 Electrocardiography | 10007-3 |
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| LC0049 | Electrocardiography | 18539-7 |
| LC0049 | Electrocardiography | 18540-5 |
| LC0049 | Electrocardiography | 18541-3 |
| LC0049 | Electrocardiography | 18542-1 |
| LC0049 | Electrocardiography | 18543-9 |
| LC0049 | Electrocardiography | 18544-7 |
| LC0049 | Electrocardiography | 18545-4 |
| LC0049 | Electrocardiography | 18546-2 |
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| LC0049 | Electrocardiography | 18548-8 |
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| LC0049 | Electrocardiography | 18560-3 |
| LC0049 | Electrocardiography | 18561-1 |
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| LC0049 | Electrocardiography | 18564-5 |
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| LC0049 | Electrocardiography | 18566-0 |
| LC0049 | Electrocardiography | 18567-8 |
| LC0049 | Electrocardiography | 18568-6 |
| LC0049 | Electrocardiography | 18569-4 |
| LC0049 | Electrocardiography | 18570-2 |
| LC0049 | Electrocardiography | 18571-0 |
| LC0049 | Electrocardiography | 18572-8 |
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| LC0049 | Electrocardiography | 18578-5 |
| LC0049 | Electrocardiography | 18579-3 |
| LC0049 | Electrocardiography | 18844-1 |
| LC0049 | Electrocardiography | 34534-8 |
| LC0049 | Electrocardiography | 8607-4 |
| LC0049 | Electrocardiography | 8608-2 |
| LC0049 | Electrocardiography | 8609-0 |
| LC0049 | Electrocardiography | 8610-8 |

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| LC0049 Electrocardiography | 8611-6 | |
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| LC0049 Electrocardiography | 8626-4 | |
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| LC0049 Electrocardiography | 9999-4 |

**2a.4 Denominator Statement (***Brief, text description of the denominator - target population being measured***):**
Patients 60 years of age or older who have an emergency medicine encounter with a diagnosis of syncope

**2a.5 Target population gender:** Female, Male
**2a.6 Target population age range:** Patients 60 years of age or older at the end of the report period

**2a.7 Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):**
The following time period will be used to find eligible emergency medicine encounters: one day after the start of the 12-month report period through one day prior to the end of the 12-month report period.

**2a.8 Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Criteria for inclusion in the denominator are as follows:
1. All males or females that are 60 years of age or older at the end of the report period
2. The patient must be continuously enrolled in both medical and pharmacy benefits throughout the emergency medicine event. The event is defined as one day prior to the start date of the emergency medicine encounter through one day after the end date of that encounter. The standard EBM Connect® enrollment break logic allows unlimited breaks in coverage of no more than 45 days and no breaks greater than 45 days.
3. Build an event with a claim during the following window of time: one day after the start of the 12-month report period through one days prior to the end of the 12-month report period, where the diagnosis is syncope (as defined by CMS)(code set DX0306) and the procedure on the claim is emergency medicine service codes (CMS defined) (code set PR0303). The emergency medicine event will encompass the following period of time: one day prior to the emergency medicine encounter through one day after that encounter. EBM Connect® allows multiple emergency medicine events within the time period defined in the "denominator time window" section if denominator requirements are met for all events.

| Cd. Set | Code Set Description | DX Code | Diagnosis Code Description |
|---|---|---|---|
| DX0306 | Syncope (CMS) | 780.2 | SYNCOPE AND COLLAPSE |

| Cd. Set | Code Set Description | Procedure Code |
|---|---|---|
| PR0303 | Emergency medicine service codes (CMS) | 99281 |
| PR0303 | Emergency medicine service codes (CMS) | 99282 |
| PR0303 | Emergency medicine service codes (CMS) | 99283 |
| PR0303 | Emergency medicine service codes (CMS) | 99284 |
| PR0303 | Emergency medicine service codes (CMS) | 99285 |

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| PR0303 Emergency medicine service codes (CMS) 99291 | |
| **2a.9 Denominator Exclusions (***Brief text description of exclusions from the target population***):** 1. Exclude emergency medicine events which included hospitalizations<br>2. Exclude emergency medicine events without a preceding clear window<br>3. Exclude emergency medicine events where the member was less than 60 years of age on the episode end date | |
| **2a.10 Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**<br>1. Exclude the event if, during the following time period: one day prior to the emergency medicine encounter through one day after that encounter, a facility event – confinement/admission (i.e., hospitalization) occurred.<br>2. Exclude the event if, on the event start date (one day prior to the start date of the emergency room encounter), there is a claim where the procedure is emergency medicine service codes (CMS defined) (code set PR0303).<br>3. Exclude the event if the patient was less than 60 years of age on the episode end date (defined as the end date of the emergency medicine encounter).<br><br>Cd. Set Code Set Description Procedure Code<br>PR0303 Emergency medicine service codes (CMS) 99281<br>PR0303 Emergency medicine service codes (CMS) 99282<br>PR0303 Emergency medicine service codes (CMS) 99283<br>PR0303 Emergency medicine service codes (CMS) 99284<br>PR0303 Emergency medicine service codes (CMS) 99285<br>PR0303 Emergency medicine service codes (CMS) 99291 | |
| **2a.11 Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**<br>Does not apply | |
| **2a.12-13 Risk Adjustment Type:** no risk adjustment necessary<br><br>**2a.14 Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**<br><br>**2a.15-17 Detailed risk model available Web page URL or attachment:** | |
| **2a.18-19 Type of Score:** rate/proportion<br>**2a.20 Interpretation of Score:** better quality = higher score<br>**2a.21 Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**<br>1. Exclude members who meet denominator exclusion criteria<br>2. Assign a YES or NO result to remaining members based on numerator response<br>3. Rate = YES/[YES+NO] | |
| **2a.22 Describe the method for discriminating performance** *(e.g., significance testing)***:**<br>Over 1,200 patients met the denominator definition from a geographically diverse 15 million member benchmark database. More than 250 patients did not meet numerator compliance, indicating a significant population with a gap in care. The subsequent compliance rate was 77.5 percent. | |
| **2a.23 Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:<br>A 15 million patient population sample was chosen to analyze the potential patient safety gap in care. The sample was derived from more than 60 million patients based on criteria including national geographic representation, commercial health coverage and patient age less than 65. | |
| **2a.24 Data Source (***Check the source(s) for which the measure is specified and tested***)** | |

**Comment [k9]:** 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

lab data, Electronic adminstrative data/claims

**2a.25 Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
Our data source is a proprietary Ingenix provider database that includes more than 60 million patients, over multiple years. It includes data from multiple payors. This measure specifically uses the following data from this database: member demographics, ICD-9 codes, revenue codes, CPT codes, place of service codes, and LOINC ECG lab results.

**2a.26-28 Data source/data collection instrument reference web page URL or attachment:**

**2a.29-31 Data dictionary/code table web page URL or attachment:** Attachment Input Guide_NQF-634014150078164140.doc

**2a.32-35 Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Individual, Clinicians: Group, Population: states, Population: counties or cities, Program: Disease management, Program: QIO, Facility/Agency, Health Plan, Integrated delivery system, Multi-site/corporate chain, Can be measured at all levels

**2a.36-37 Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Long term acute care hospital, nursing home (NH) /Skilled Nursing Facility (SNF), Rehabilitation Facility, Ambulatory Care: Clinic, Ambulatory Care: Emergency Dept, Ambulatory Care: Hospital Outpatient

**2a.38-41 Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

## TESTING/ANALYSIS

**2b. Reliability testing**

**2b.1 Data/sample** *(description of data/sample and size)***:** Reliability is tested by using multiple databases. There are three primary databases that we use: 1) a customer acceptance (CAT) database that includes approximately 4000 members who satisfy the condition confirmation criteria; 2) a one million member face validity testing (FVT) database that is geographically diverse; and 3) a 15 million member benchmark database that is geographically diverse. All databases represent predominately a commercial population less than 65 year of age.

**2b.2 Analytic Method** *(type of reliability & rationale, method for testing)***:**
Quality assurance of each measure is accomplished through the testing using multiple methods and databases. Types of testing, data samples and volume vary to ensure the integrity of the measure. Rigorous development, analysis and testing processes are deployed for creating measure specifications. Software testing ensures the software is working as designed. Reliability and validity testing of measures is based on differing data samples and volume of members. National benchmarks are created on a large volume set of data representing members throughout the United States. All quality checks for all measure results must have consistent results and meet expected outcomes based on industry knowledge and experience.

Customer Acceptance Testing (CAT) is an important quality process. CAT ensures that the clinical measures are functioning as intended and that they generate accurate results for typical billing patterns. Using actual claims data a team of business analysts, nurses, and health services researchers conducts a detailed analysis of the output. For each clinical condition in the product (e.g., Diabetes Mellitus, Coronary Artery Disease, etc.) there is a set of CAT data with at least 4000 members who satisfy the condition confirmation criteria. This data is extracted from a large (50+ million member) multi-payer benchmark database and contains inpatient, outpatient, pharmacy, and laboratory data. The testing team analyzes claims from individual members and compares the creation of denominators (target population), numerators, and exclusions from this manual review process to output results from the quality measure.

Regression testing is the part of CAT that verifies the reliability of the product across software releases. For a new release the testing team confirms that every unchanged measure produces the same results as in

**2b**
**C☐**
**P☐**
**M☐**
**N☐**

**Comment [KP10]: 2b.** Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

**Comment [k11]:** 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

previous releases, accounting for systematic changes to the software (e.g., code updates, logic changes, etc). Regression testing is conducted at multiple points throughout the software development cycle.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Given the size of our benchmark database, it is the most reliable source for compliance results. Over 1,200 members from the benchmark database met the denominator definition for this measure. The overall compliance rate was 77.5 percent.

**2c. Validity testing**

2c.1 **Data/sample** *(description of data/sample and size)*: Our data sample for face validity testing includes a geographically diverse one million member database. Our data sample for benchmark testing includes a geographically diverse 15 million member database. Both databases represent predominately a commercial population less than 65 year of age.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Face Validity Testing (FVT) is the final testing step in the software release cycle. One million members are randomly selected from the large multi-payer benchmark database and their claims data is processed through the software. The Medical Director reviews the results to verify that:
1. Prevalence rates for a condition are comparable to nationally published rates
2. Compliance rates for a measure are comparable to the rates reported in the published literature or by other national sources (e.g. HEDIS). If no comparable sources are available, the rates are judged based on what is clinically reasonable.
In addition, all results are reviewed for face validity by members of an external physician clinical consultant panel.

A similar review of benchmark test results occurs in conjunction with a software release. With benchmark testing, 15 million members are randomly selected from the large multi-payer benchmark database and their claims data is processed through the software.

Our claims-based measures have been validated using a chart review comparison process. This validation project is summarized below:
Goal: evaluate the reliability of claims-based measure results using chart review as the gold standard
Methods:
The charts of 100 members from two clinics in one city were reviewed. Results from our claims-based measures were compared to information present in the chart. During this process, 726 measures were evaluated.
Results:
The overall error rate was less than 5%. The error rate varied depending on the type of claim required for numerator compliance and is summarized as follows:
o The error rate was highest with medications, with an 11 percent error rate (2/18). From chart review, it was difficult to tell if this represented a real error, a medication sample was provided, or the prescription was never filled).
o The error rate was 4 percent (14/318) for measures that required labs for numerator compliance. It was noted that a claims-based measure approach sometimes identified labs that were missing in chart review.
o The error rate for office visit and specialty appointments was 2 percent (8/390). Of note, administrative claims was more likely than chart review to identify relevant office and specialty visits, particularly for appointments that occurred outside the clinic or network.
o Errors were found related to coding in claims data, not due to the claims-based measures or methodology. These errors were not quantified.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
Summarized in 2b3

**2c**
**C☐ P☐ M☐ N☐**

**2d. Exclusions Justified**

**2d**

**Comment [KP12]: 2c.** Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

**Comment [k13]:** 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

**Comment [KP14]: 2d.** Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

**2d.1 Summary of Evidence supporting exclusion(s):**
This measure does not include any exclusions.

**2d.2 Citations for Evidence:**

**2d.3 Data/sample** *(description of data/sample and size)***:**

**2d.4 Analytic Method** *(type analysis & rationale)***:**

**2d.5 Testing Results** *(e.g., frequency, variability, sensitivity analyses)***:**

C☐ P☐ M☐ N☐ NA☐

**Comment [k15]:** 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

**2e. Risk Adjustment for Outcomes/ Resource Use Measures**

**2e.1 Data/sample** *(description of data/sample and size)***:** This measure does not include risk adjustment.

**2e.2 Analytic Method** *(type of risk adjustment, analysis, & rationale)***:**

**2e.3 Testing Results** *(risk model performance metrics)***:**

**2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:**

**2e**
C☐ P☐ M☐ N☐ NA☐

**Comment [KP16]: 2e.** For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

**Comment [k17]:** 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

**2f. Identification of Meaningful Differences in Performance**

**2f.1 Data/sample from Testing or Current Use** *(description of data/sample and size)***:** Our benchmark data sample includes a geographically diverse 15 million member benchmark database. The database represents predominately a commercial population less than 65 year of age.

**2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)***:**
During benchmark testing, 15 million members are randomly selected from the large multi-payer benchmark database and their claims data is processed through the software. The Medical Director reviews the results to verify that:
1. Prevalence rates for a condition are comparable to nationally published rates
2. Compliance rates for a measure are comparable to the rates reported in the published literature or by other national sources (e.g. HEDIS). If no comparable sources are available, the rates are judged based on what is clinically reasonable.

In addition, all results are systematically reviewed for face validity by members of an external physician clinical consultant panel.

**2f.3 Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)***:**
Summarized in 2b3

**2f**
C☐ P☐ M☐ N☐

**Comment [KP18]: 2f.** Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

**Comment [k19]:** 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

**2g. Comparability of Multiple Data Sources/Methods**

**2g.1 Data/sample** *(description of data/sample and size)***:**

**2g.2 Analytic Method** *(type of analysis & rationale)***:**

**2g**
C☐ P☐ M☐ N☐ NA☐

**Comment [KP20]: 2g.** If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

| | |
|---|---|
| 2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*: | |
| **2h. Disparities in Care**<br><br>2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*:<br><br>2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** | **2h**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the** sub-criteria **for** *Scientific Acceptability of Measure Properties*? | **2** |
| **Steering Committee: Overall, to what extent was the criterion,** *Scientific Acceptability of Measure Properties*, **met?**<br>**Rationale:** | *2*<br>C☐<br>P☐<br>M☐<br>N☐ |
| **3. USABILITY** | |
| Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria) | Eval Rating |
| **3a. Meaningful, Understandable, and Useful Information**<br><br>3a.1 **Current Use:** in use<br><br>3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*):<br>Health plans, physicians (individuals and groups), care management, and other vendors/customers are using this measure on a national level. However, we do not know if this specific measure is being used as part of a public reporting initiative.<br><br>3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**<br>Health plans, physicians (individuals and groups), care management, and other vendors/customers use many of our measures on a national level for quality improvement, disease management, and physician sharing programs. Customers are able to select their measures depending on their business needs. As such, we do not know which specific measures are used by our customers.<br><br>**Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)<br>3a.4 **Data/sample** *(description of data/sample and size)*: Results are summarized and reported by users/customers depending on their business need - we do not have access to this information. Because of us my multiple users/customers, there is no single data sample, methodology, or public reporting format.<br><br>3a.5 **Methods** *(e.g., focus group, survey, QI project)*:<br><br>3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*: | **3a**<br>C☐<br>P☐<br>M☐<br>N☐ |
| **3b/3c. Relation to other NQF-endorsed measures**<br><br>3b.1 **NQF # and Title of similar or related measures:**<br>0093: Electrocardiogram Performed for Syncope | |
| (for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:** | |

**Comment [KP21]: 2h.** If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

**Comment [KP22]: 3a**. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

**3b. Harmonization**

If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):

**3b.2 Are the measure specifications harmonized? If not, why?**

This measure is harmonized with the endorsed AMA PCPI measure. It uses the same age population, timeframe, and basic code sets. Our measure is enhanced using enriched claims data, as summarized below.

**3b** C☐ P☐ M☐ N☐ NA☐

**3c. Distinctive or Additive Value**

**3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**

The AMA PCPI measure depends on the submission of CPT II codes for numerator inclusion and denominator exclusion. Our measure uses CPT II codes for numerator inclusion and denominator exclusion but, in addition, uses CPT I and LOINC codes for numerator compliance. This dramatically increases the usability of this measure.

**5.1 Competing Measures If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), describe why it is a more valid or efficient way to measure quality:**

The submission of CPT II codes is extremely limited. This challenges the widespread usability and feasibility of the current AMA PCPI measure. Our measure enhances the current AMA PCPI measure by allowing CPT I and LOINC codes for ECG tests to satisfy numerator compliance. This source of enriched claims data dramatically increases the usability and feasibility of this measure.

**3c** C☐ P☐ M☐ N☐

**TAP/Workgroup: What are the strengths and weaknesses in relation to the** sub-criteria **for** *Usability*?

**3**

**Steering Committee: Overall, to what extent was the criterion,** *Usability*, **met?**
**Rationale:**

**3** C☐ P☐ M☐ N☐

## 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

Eval Rating

**4a. Data Generated as a Byproduct of Care Processes**

**4a.1-2 How are the data elements that are needed to compute measure scores generated?**

coding/abstraction performed by someone other than person obtaining original information,

**4a** C☐ P☐ M☐ N☐

**4b. Electronic Sources**

**4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)

Yes

**4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**

**4b** C☐ P☐ M☐ N☐

**4c. Exclusions**

**4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?**

No

**4c.2 If yes, provide justification.**

**4c** C☐ P☐ M☐ N☐ NA☐

**4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences**

**4d**

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable



**Comment [KP23]: 3b.** The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

**Comment [k24]:** 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

**Comment [KP25]: 3c.** Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare).

**Comment [k26]: 5.** Demonstration that the measure is superior to competing measures – new submissions and/or endorsed measures (e.g., is a more valid or efficient way to measure).

**Comment [KP27]: 4a.** For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

**Comment [KP28]: 4b.** The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

**Comment [KP29]: 4c. Exclusions** should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

**Comment [KP30]: 4d.** Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

| | |
|---|---|
| **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.**<br>None anticipated | C☐<br>P☐<br>M☐<br>N☐ |
| **4e. Data Collection Strategy/Implementation**<br><br>**4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:**<br>No modifications have been made based on testing or operational use of the measure.<br><br>**4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:**<br>We do not have access to this information. This would vary based on the customer/vendor, patient population, and programs/interventions associated with measure use.<br><br>**4e.3 Evidence for costs:**<br><br>**4e.4 Business case documentation:** | **4e**<br>C☐<br>P☐<br>M☐<br>N☐ |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the** sub-criteria **for** *Feasibility*? | **4** |
| **Steering Committee: Overall, to what extent was the criterion,** *Feasibility*, **met?**<br>**Rationale:** | **4**<br>C☐<br>P☐<br>M☐<br>N☐ |
| **RECOMMENDATION** | |
| (for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.** | **Time-limited**<br>☐ |
| **Steering Committee: Do you recommend for endorsement?**<br>**Comments:** | Y☐<br>N☐<br>A☐ |

**Comment [KP31]: 4e.** Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

| **CONTACT INFORMATION** |
|---|
| **Co.1 Measure Steward (Intellectual Property Owner)**<br>**Co.1 Organization**<br>Ingenix \| 12125 Technology Drive \| Eden Prairie \| Minnesota \| 55344<br><br>**Co.2 Point of Contact**<br>Kay \| Schwebke, Medical Director \| kay \| 952-833-7154 |
| **Measure Developer If different from Measure Steward**<br>**Co.3 Organization**<br>Ingenix \| 12125 Technology Drive \| Eden Prairie \| Minnesota \| 55344<br><br>**Co.4 Point of Contact**<br>Kay \| Schwebke, Medical Director \| kay.schwebke@ingenix.com \| 952-833-7154 |
| **Co.5 Submitter If different from Measure Steward POC**<br>Kay \| Schwebke, Medical Director \| kay.schwebke@ingenix.com \| 952-833-7154- \|Ingenix |
| **Co.6 Additional organizations that sponsored/participated in measure development**<br>This measure has been reviewed and supported by the American Academy of Family Physicians and the American |

College of Emergency Physicians.

## ADDITIONAL INFORMATION

**Workgroup/Expert Panel involved in measure development**

Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**

We have an external consultant panel that participates in the original literature search process, measure development, code set review, testing review, and maintenance processes. Panel members include the following:

NAME & Title Employer/Position
Alexander, Beth Pharm D, BCPS Assistant Professor, Augsburg College
Ayenew, Woubeshet, MD Hennepin Faculty Associates; Hennepin County Medical Center
Becker, Keith, MD Fairview Medical Center
Betcher, Susan, MD Allina Medical Clinic
Bruer, Paul, MD Comprehensive Ophthamology, LLC
Capecchi, Joseph, MD Allina Medical Clinic
Giesler, Janell, MD Allina Medical Clinic
Grabowski, Carol, MD Allina Medical Clinic
Hansen, Calvin, MD Iowa Health Physicians
Hargrove, Jody, MD Arthritis and Rheumatology Consultants
Hermann, Richard, MD Tufts - New England Medical Center
Jemming, Brian, Pharm D CentraCare Health System
Kohen, Jeffrey, MD Veterans Affairs Medical Center
McCarthy, Teresa, MD University of Minnesota, Department of Family Medicine & Community Health
McEvoy, Charlene, MD, MPH HealthPartners & HealthPartners Research Foundation; Assistant Professor of Medicine, University of Minnesota
McGee, Deanna, Pharm D, BCPS Retail Pharmacy
Ogle, Kathleen, MD Hennepin Faculty Associates; Hennepin County Medical Center: Assistant Professor of Medicine, University of Minnesota Medical School
Peter, Kathleen, MD Park Nicollet Medical Center
Pieper-Bigelow, Christina, MD Allina Medical Clinic
Redmon, Bruce, MD University of Minnesota Physicians
Scharpf, Steven, MD Mountain Valleys Health Centers
Weitz, Carol, MD Independent

Ad.2 **If adapted, provide name of original measure:**
Ad.3-5 **If adapted, provide original specifications URL or attachment**

**Measure Developer/Steward Updates and Ongoing Maintenance**

Ad.6 **Year the measure was first released:** 2008
Ad.7 **Month and Year of most recent revision:** 2007-12
Ad.8 **What is your frequency for review/update of this measure?** every three years at minimum
Ad.9 **When is the next scheduled review/update for this measure?** 2010-04

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**Ad.11 -13 Additional Information web page URL or attachment:** Attachment Syncope ACEP 2007.pdf

**Date of Submission** (*MM/DD/YY*)**:** 02/15/2010

**Page 3: [1] Comment [k4]** **Karen Pace** **10/5/2009 8:59:00 AM**

**1c.** The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

**Page 3: [2] Comment [k5]** **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

**Page 3: [3] Comment [k6]** **Karen Pace** **10/5/2009 8:59:00 AM**

3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

INGENIX®

# Input Guide

Release 7.0, Technical Guide for Windows, February 2008



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# What Input Files to Prepare

The following list specifies what input files you prepare for processing:

- The claims data file (required)
- The member data file (required)
- The member term data file (required)

# Field Type Definitions and Input File Requirements

This chapter lists the field requirements for your input files. One of the attributes listed among the requirements is defined as "Type". There are four field types used to describe a field's value, and they are defined below.

| Field Type | Definition |
|---|---|
| AlphaNum | A value made of letters and/or numbers. If a value of this type is made of numbers only, it will not be a value that can be operated on mathematically. For example, it would be inappropriate to subtract one procedure code from another procedure code even though both values may contain only numbers. |
| Num | A value made of numbers only, and which can logically be operated on mathematically. Age is an example of this type.<br>One particular field, while not used in mathematical calculations, is defined in the EBM Connect software as such that it accepts only numeric values. (To enter a non-numeric value would cause EBM Connect processing to stop.) Therefore, this field is defined as Num. It is the Case ID field in the optional disease registry input file. |
| Date | A value which can be interpreted as a date value. Values should always use four-digit years but the format may vary otherwise. |
| DecNum | A value made of numbers and a decimal point. These values can also logically be operated on mathematically. |

# Claims Input File

The claims file contains detailed information on services that were billed or performed or otherwise rendered. The claims file includes:

- Medical claims, including medical services, facility services and clinic services
- Pharmacy claims, including billed prescriptions and drugs
- Lab claims, including lab test and results information

| Field Name | Type | Length | Required or Optional |
|---|---|---|---|
| Family ID | AlphaNum | 1-30 | Always required for all claims |
| Patient ID | AlphaNum | 0-2 | Optional |
| Amount Paid | DecNum | 1-11 | Required for all claims |
| Amount Allowed | DecNum | 0-11 | Required for all claims |
| Procedure Code | AlphaNum | 5 | Required if there is no revenue code, NDC, or LOINC® code |
| Procedure Code Modifier | AlphaNum | 2 | Required for medical claims |
| Revenue Code | AlphaNum | 0 or 4 | Optional (applies to medical claims when used) |
| First Diagnosis Code | AlphaNum | 5 or 6 | Required for medical claims |
| Second Diagnosis Code | AlphaNum | 0, 5 or 6 | Optional (applies to medical claims when used) |
| Third Diagnosis Code | AlphaNum | 0, 5 or 6 | Optional (applies to medical claims when used) |
| Fourth Diagnosis Code | AlphaNum | 0, 5 or 6 | Optional (applies to medical claims when used) |
| First Date of Service | Date | 8 or 10 | Always required for all claims |
| Last Date of Service | Date | 8 or 10 | Required for all claims |

| | | | |
|---|---|---|---|
| Paid Date | Date | 0, 8 or 10 | Optional |
| Type of Service | AlphaNum | 0-10 | Optional |
| Provider ID | AlphaNum | 1-20 | Required for medical claims |
| Ordering Provider ID | AlphaNum | 0-20 | Optional |
| Provider Type | AlphaNum | 1-10 | Required for medical claims |
| Provider Specialty Type | AlphaNum | 1-10 | Required for medical claims |
| Provider Key | AlphaNum | 1-20 | Required for medical claims |
| NDC | AlphaNum | 0 or 11 | Required for Rx claims |
| Day Supply | Num | 0-4 | Required for Rx claims |
| Quantity Count | DecNum | 0-10 | Required for Rx claims |
| LOINC® | AlphaNum | 0 or 7 | Required for lab claims |
| Lab Test Result | AlphaNum | 0-18 | Required for lab claims |
| Place of Service | AlphaNum | 1-10 | Required for medical claims |
| Unique Record ID | AlphaNum | 1-28 | Required for all claims |
| Claim Number | AlphaNum | 1-28 | Required for all claims |
| Bill Type Frequency Indicator | Num | 0 or 1 | Optional |
| Patient Status | AlphaNum | 1-2 | Required for facility claims (involving admission or confinement). |
| Facility Type | AlphaNum | 0-2 | Optional |
| Bed Type | AlphaNum | 0-1 | Optional |
| First ICD-9 Procedure Code | AlphaNum | 0, 4 or 5 | Optional, but will impact results (applies to medical claims when used) |
| Second ICD-9 Procedure Code | AlphaNum | 0, 4 or 5 | Optional (see above) |
| Third ICD-9 Procedure Code | AlphaNum | 0, 4 or 5 | Optional (see above) |
| Fourth ICD-9 Procedure Code | AlphaNum | 0, 4 or 5 | Optional (see above) |

# Field Descriptions

Instructions for each input field are as follows:

## Family ID

This field identifies all members of a family and can be any alphanumeric string.

***Note***: Remember that each Family ID (and Patient ID) listed in your claims input file must have a corresponding record in your member input data file and your member term data file.

## Patient ID

This field identifies individual members within a family. If present, this field must be sorted within Family ID, so that all records for an individual are contiguous. If the Family ID uniquely identifies an individual, this field need not be specified (that is, its length in the dictionary will be zero).

## Amount Paid

The amount paid for this claim line.

## Amount Allowed

The allowed amount for this claim line. This amount typically represents the total amount reimbursed including deductibles, copays, coinsurance, insurer paid, etc.

## Procedure Code

The procedure code must be one of:

- A procedure code specified in the Physician's Current Procedure Terminology, 4th Edition (CPT®-4 codes) defined by the American Medical Association, for the years 1997 and later.
- A procedure code specified by the HCFA Common Procedure Coding System, Level II code (HCPCS) defined by the Centers for Medicare and Medicaid Services (CMS) for the years 1999 and later.
- A National Uniform Billing Committee (NUBC) revenue code.

***Note***: When the NUBC code is entered in the Procedure Code field, it should be padded to the right with blanks because the Procedure Code field always occupies five characters.

- If your organization defines its own procedure codes and/or revenue codes, they must be mapped to standard procedure and revenue codes.

## Procedure Code Modifier

Use this field to specify any procedure code modifier that accompanies the procedure code.

## Revenue Code

The revenue code, if one was entered for the claim. Supported values in this field are NUBC revenue codes. If your organization defines its own revenue codes, they must be mapped to standard revenue codes.

The revenue code is an optional field, allowing you to define your input records so that you can place an NUBC revenue code and a CPT/HCPCS procedure code on a single record line.

For claim records that do not have a revenue code, leave the revenue code field blank.

### First Diagnosis Code Through Fourth Diagnosis Code

Up to four diagnoses may be entered for each claim, but only the first is required.

If your organization defines its own diagnosis codes, they must be mapped to standard ICD-9 diagnosis codes.

### First Date of Service and Last Date of Service

The first date and last date represented by the claim line. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/ YYYY, and DD/MM/YYYY, where the separator can be any character.

### Paid Date

This field is optional. This is the date the claim was paid. The format of the paid date must be the same as that used in the First and Last Date of Service.

### Type of Service

This is an optional code which represents the type of service (TOS) performed for this claim. If no specific value is available for this field, it should be filled with blanks. If this field is not used (i.e., its length is set to zero in the configuration), non-pharmaceutical claims with no procedure code will be treated as ancillary records.

### Provider ID

Provider identification number from the claim. Used to identify who performed the service.

### Ordering Provider ID

This is an optional field. This is the identification number of the provider who ordered the service.

### Provider Type

This code represents the type of provider who performed the service. Examples of provider types would be chiropractor, nurse practitioner, medical doctor, counselor, pharmacy, hospital or treatment facility.

### Provider Specialty Type

This code represents the specialty of the provider who performed the service.

### Provider Key

Unique number or code for a physician who has multiple provider IDs or specialties. A single health care provider may have multiple provider IDs in your input claims data, but this person or entity should have only one provider key.

## NDC

If this is a pharmaceutical claim, this field should contain the drug's NDC code. For non-pharmaceutical claim records, the NDC field should be filled with blanks.

## Day Supply

For pharmacy records, the number of days a filled prescription is expected to last. If you have no pharmacy records, the Days Supply is an optional field.

## Quantity Count

Quantity of drug dispensed in metric units:

Each - solid oral dosage forms (tablet, capsule), powder filled (dry) vials, packets, patches, units of use packages, suppositories, bars.

Milliliter - (cc) liquid oral dosage forms, liquid filled vials, ampules, reconstituted oral products.

Grams - ointments, bulk powders (not IV).
If you have no pharmacy records, the Quantity Count is an optional field.

## LOINC®

Logical Observation Identifiers Names and Codes (LOINC®). The LOINC Code is a universal identifier for a lab test for a particular analyte. The LOINC User's Guide and database can be found at www.regenstrief.org.

Enter a LOINC code if the record is a lab record. For non-lab records, leave the LOINC field blank.

If you have no lab records in your claims input, the LOINC code is optional.

Notes:

(1) When using lab results data that has not been mapped to a LOINC code, map the comparable vendor-specific test number provided by the laboratory vendor(s) to one of these default codes.

(2) This is a retired code which may be present on historical data, or which some laboratories may be continuing to use. Input record data with this code is included in the definition of this test.

## Lab Test Result

If the record is a lab record, use this field to enter the result value of lab test. For non-lab records, this field should be blank.

If you have no lab records in your claims input, the Lab Test Result is optional.

## Place of Service

Place of service (POS). You must map your internal POS codes to Centers for Medicare and Medicaid Services (CMS) standard POS codes.

## Unique Record ID

This required field contains a unique identifier representing the service line from the claim. For medical services, this ID typically represents the service row from the CMS 1500 or CMS 1450/UB92 claim form.

## Claim Number

A unique identifier used to link service lines for a specific claim submitted for a member. If a claim has multiple service lines, each service will have a unique record ID and the same claim number to represent the claim.

## Bill Type Frequency Indicator

This optional field is used to indicate the disposition of confinements.

## Patient Status

This field is required for facility claims. The contents will be the patient status indicator field from the NUBC UB-92 form. This field can denote whether the member died during a confinement.

## Facility Type

This field is optional. Space for it is provided to allow for additional post grouping analysis. The contents will typically be the UB-92 facility type data value. This would allow records to be easily selected for diagnosis related grouping (DRG) based on the facility type.

## Bed Type

If a value is present, this field acts as an additional discriminator in determining whether a Facility record extends an existing confinement or starts a new confinement.

## First ICD-9 Procedure Code Through Fourth ICD-9 Procedure Code

If your claims have ICD-9 procedure codes, include them in your claims input file.

If a decimal point will appear in this field in your claim records, the length should be given as 5. If the decimal separator is not used, the length is 4. If these fields are unused, the length is zero.

# Member Input File

The member data file contains the most current information about the member.

## Field Descriptions

| Field | Type | Length | Required or Optional |
|---|---|---|---|
| Family ID | AlphaNum | 1-30 | Required |
| Patient ID | AlphaNum | 0-2 | Optional |
| Patient Gender | AlphaNum | 1 | Required |
| Date of Birth | Date | 8 or 10 | Required |
| Member Beginning Eligibility Date | Date | 0, 8 or 10 | Optional |
| Member Ending Eligibility Date | Date | 0, 8 or 10 | Optional |

Instructions for each input field are as follows:

### Family ID

This field identifies all members of a family and can be any alphanumeric string. The records in the member file must be sorted first on the Family ID (together with Patient ID, if available) so that all records for an individual are contiguous.

### Patient ID

This field identifies individual members within a family. If present, this field must be sorted within Family ID, so that all records for an individual are contiguous. If the Family ID uniquely identifies an individual, this field need not be specified (that is, its length in the dictionary will be zero).

### Patient Gender and Date of Birth

The member's gender (F or M) and date of birth. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid date formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY, where the separator can be any character.

### Member Beginning Eligibility Date and Ending Eligibility Date

The first date on which the member became covered under the plan and the last date of the member's coverage. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY, where the separator can be any character.

# Member Term Input File

The member term data file contains member coverage and term activity information. Plan coverage begin and end dates are required in order to correctly calculate the other fields in the member term file. There may be more than one record per individual member.

## Field Descriptions

| Field | Type | Length | Required or Optional |
|---|---|---|---|
| Family ID | AlphaNum | 1-30 | Required |
| Patient ID | AlphaNum | 0-2 | Optional |
| Member Beginning Eligibility Date | Date | 8 or 10 | Required |
| Member Ending Eligibility Date | Date | 8 or 10 | Required |
| Primary Care Provider | AlphaNum | 20 | Required |
| Provider Specialty Type | AlphaNum | 1-10 | Required |
| Medical Flag | AlphaNum | 1 | Required |
| Pharmacy Flag | AlphaNum | 1 | Required |

Instructions for each input field are as follows:

### Family ID

This field identifies all members of a family and can be any alphanumeric string. The records in the member term file must be sorted first on the Family ID (together with Patient ID, if available) so that all records for an individual are contiguous.

### Patient ID

This field identifies individual members within a family.

### Member Beginning Eligibility Date and Member Ending Eligibility Date

The first date on which the member became covered under the plan and the last date of the member's coverage. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY, where the separator can be any character.

### Primary Care Provider

The provider key for the member's primary care physician. A single health care physician may have multiple provider IDs in your input claims data, but this person should have only one provider key.

## Provider Specialty Type

This code represents the specialty of the primary care physician.

## Medical Flag

Identifies whether the member has medical coverage (Y or N).

## Pharmacy Flag

Identifies whether the member has pharmacy coverage (Y or N).

# Clinical Policy: Critical Issues in the Evaluation and Management of Adult Patients Presenting to the Emergency Department with Syncope

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## INTRODUCTION

Syncope is a symptom complex that is composed of a brief loss of consciousness associated with an inability to maintain postural tone that spontaneously and completely resolves without medical intervention. It is distinct from vertigo, seizures, coma, and states of altered consciousness. Syncope is a common presentation to the emergency department (ED) that accounts for 1% to 1.5% of ED annual visits and up to 6% of hospital admissions.[1,2] The ED evaluation of patients with syncope may be problematic for several reasons. Accurate historical information is often lacking or there may be conflicting historical information from observers. Furthermore, patients are often asymptomatic when they arrive in the ED and may have no recall of the event.

Any process that transiently reduces cerebral perfusion may be the precipitant of syncope. Concerns that well-appearing patients are at risk for sudden death often fuel extensive clinical evaluations or hospital admissions because the large differential diagnosis includes some processes that may be life-threatening. Many studies have demonstrated the low yield of nondirected diagnostic testing.[3-6] From the available literature, it is unclear whether admitting asymptomatic syncope patients for observation and inpatient evaluation affects patient outcome. Additionally, it is estimated that more than $2 billion a year is spent in the United States on hospitalization of patients with syncope.[7] An analysis of the 2001 American College of Emergency Physicians (ACEP) clinical policy on syncope found that by applying the Level B recommendations, all patients with cardiac causes of syncope were identified, and the admission rate would be reduced from 57.5% to 28.5%.[8] These facts must lead to a reassessment of the role of the emergency physician in evaluation of the patient presenting with syncope.

The emergency physician must still identify those relatively few patients with life-threatening processes (eg, dysrhythmias, pulmonary embolism, aortic dissection, subarachnoid hemorrhage, acute coronary syndromes) and other patients who may benefit from intervention (eg, patients with bradycardia, medication-induced orthostatic hypotension). Frequently, however, the ED evaluation of a patient presenting with syncope does not reveal a clear etiology. The emergency physician must then determine which of these patients require further diagnostic evaluation and monitoring and in what setting that should occur. The role of the emergency physician in evaluating the patient with syncope has moved from efforts to determine a specific diagnosis of syncope type to that of risk stratification, similar to the process of chest pain evaluation.

Symptoms and complaints associated with syncope should be fully evaluated. A careful history should be obtained, considering other associated symptoms, whether cardiac, neurologic, abdominal, or respiratory, because it may lead to a diagnosis of an underlying medical condition such as an acute coronary event, aortic dissection, pulmonary embolism, seizure, ectopic pregnancy, or gastrointestinal hemorrhage.

This document does not attempt to outline the evaluation of patients presenting with syncope associated with specific diagnoses but rather focuses on assisting the emergency physician in addressing 3 critical questions:

1. What history and physical examination data help to risk-stratify patients with syncope?
2. What diagnostic testing data help to risk-stratify patients with syncope?
3. Who should be admitted after an episode of syncope of unclear cause?

This policy is an update of the 2001 ACEP clinical policy on syncope.[9] Other professional societies have developed guidelines for evaluation of syncope but this policy is designed to reflect recommendations focused on the practice of emegency medicine.[10,11]

## METHODOLOGY

This clinical policy was created after careful review and critical analysis of the medical literature. MEDLINE searches for articles published between March 1998 and May 2005 were performed using a combination of key words, including "syncope" and variations of "risk," "risk stratification," "admission," "outcomes," "emergency department," "prognosis," "differential diagnosis," "physical examination," and "diagnostic evaluation." Searches were limited to English-language sources. Additional articles were reviewed from the bibliographies of studies cited. Subcommittee members also supplied articles from their own knowledge and files.

The reasons for developing clinical policies in emergency medicine and the approaches used in their development have been enumerated.[12] This policy is a product of the ACEP clinical policy development process and is based on the existing literature; where literature was not available, consensus of emergency physicians was used. Expert review comments were received from individual emergency physicians, individual members of the American College of Cardiology, members of ACEP's Observation Section, Geriatric Section, and Quality and Performance Committee. Their responses were used to further refine and enhance this policy. Clinical policies are scheduled for revision every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly.

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members for strength of evidence and classified by the subcommittee members into 3 classes of evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic clinical reports respectively (Appendix A). Articles were then graded on 6 dimensions thought to be most relevant to the development of a clinical guideline: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (eg, selection, detection, transfer), external validity (ie, generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula taking into account design and quality of study (Appendix B). Articles with fatal flaws were given an "X" grade and not used in formulating recommendations in this policy. Evidence grading was done with respect to the specific data being extracted, and the specific critical question being reviewed. Thus, the level of evidence for any one study may vary according to the question, and it is possible for a single article to receive different levels of grading as different critical questions are answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of this policy.

Clinical findings and strength of recommendations regarding patient management were then made according to the following criteria:

***Level A recommendations.*** Generally accepted principles for patient management that reflect a high degree of clinical certainty (ie, based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

***Level B recommendations.*** Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (ie, based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

***Level C recommendations.*** Other strategies for patient management that are based on preliminary, inconclusive, or conflicting evidence, or in the absence of any published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

This policy is not intended to be a complete manual on the evaluation and management of adult patients with syncope but rather a focused look at critical issues that have particular relevance to the current practice of emergency medicine.

It is the goal of the Clinical Policies Committee to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain enough quality information to answer a critical question, the members of the Clinical Policies Committee believe that it is equally important to alert emergency physicians to this fact.

Recommendations offered in this policy are not intended to represent the only diagnostic and management options that the emergency physician should consider. ACEP clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the crucial questions addressed in this policy.

***Scope of Application.*** This guideline is intended for physicians working in hospital-based EDs.

***Inclusion Criteria.*** This guideline is intended for adult patients presenting to the ED with syncope.

***Exclusion Criteria.*** This guideline is not intended for children or for patients in whom the episode of syncope is thought to be secondary to another disease process. Among the clinical conditions specifically excluded are patients with seizures, chest pain, headache, abdominal pain, dyspnea, hemorrhage, hypotension, or a new neurologic deficit.

## CRITICAL QUESTIONS

**1. What history and physical examination data help to risk-stratify patients with syncope?**

***Level A recommendations.*** Use history or physical examination findings consistent with heart failure to help identify patients at higher risk of an adverse outcome.

***Level B recommendations.***

1. Consider older age, structural heart disease, or a history of coronary artery disease as risk factors for adverse outcome.
2. Consider younger patients with syncope that is nonexertional, without history or signs of cardiovascular disease, a family history of sudden death, and without comorbidities to be at low risk of adverse events.

***Level C recommendations.*** None specified.

The traditional approach of focusing on establishing an etiology of syncope in the ED is often of limited utility. Multiple studies have demonstrated a diagnostic rate of only 20% to 50% in the initial evaluation of the syncope patient.[1,13,14] Even in subspecialty studies with patients undergoing extensive diagnostic evaluations, 15% to 30% of patients remain without a definitive cause.[15-18] Review of the syncope literature reveals that because of the lack of a criterion standard, the final diagnosis given to a syncope patient is difficult to validate and subject to variability.

Few studies have directly evaluated risk stratification of syncope patients in the ED. In a Class I study, Martin et al[5] studied 252 syncope patients to develop a risk classification system and then tested the system in a validation cohort of 374 patients. Predictors of arrhythmia or 1-year mortality in the validation cohort were found to be: (1) abnormal ECG result, (2) history of ventricular arrhythmia, (3) history of congestive heart failure, or (4) age more than 45 years. The event rate (clinically significant arrhythmia or death) at 1 year in the validation cohort ranged from 0% for those with none of the 4 risk factors to 27% for those with 3 or 4 risk factors. In a similarly designed Class I study from Italy, Colivicchi et al[19] derived risk factors for 1-year mortality (not arrhythmias) in 270 patients and then validated them on 328 patients and found an abnormal ECG result, a history of cardiovascular disease, lack of prodrome, and age older than 65 years to predict all deaths in the 2 cohorts. These studies have determined that age, abnormal ECG result, lack of a prodrome, a history of cardiovascular disease, especially ventricular arrhythmia, and heart failure all appear to have predictive value in assessing 1-year risk of adverse outcomes in patients with syncope.

A Class I study by Quinn et al,[2] the San Francisco Syncope Study, examined short-term serious events in 684 ED patients presenting with syncope. Recursive partitioning techniques identified the following characteristics associated with a higher likelihood of an adverse event within 7 days of ED presentation: abnormal ECG result, shortness of breath, systolic blood pressure less than 90 mm Hg after arrival in the ED, hematocrit level less than 30%, and congestive heart failure by history or examination. This derivation set has now been prospectively

validated.[20] A prospective Class III study by Sarasin et al[21] also found that an abnormal ECG result, history of congestive heart failure, and age more than 65 years were all risk factors for experiencing a serious arrhythmia.

Little literature exists to guide the clinician in cases of exertional syncope in young patients (age <35 years). This is an uncommon occurrence, usually with a very different etiology than syncope in an older patient. Possible etiologies include hypertrophic cardiomyopathy, coronary artery abnormalities, conduction abnormalities (long QT, preexcitation syndromes), and arrythmogenic cellular dysplasias. Cardiology consultation may be considered either as an inpatient or outpatient.

**History and Physical Examination Data**

History and physical examination are the defining factors in syncope risk stratification. Often the patient may not have accurate recall of the event; thus, eyewitness accounts, are an important part of the history, which includes estimation of duration of loss of consciousness and evidence of seizure activity. Mild, brief, tonic-clonic activity may commonly accompany syncope of any etiology ("convulsive syncope"). Witnesses also may report falls or other trauma during the episode. Postsyncopal history, also best obtained from eyewitnesses, includes duration of confusion or lethargy after the episode or evidence of focal neurologic deficits. After an episode of syncope, patients may briefly appear disoriented or confused, but this resolves within moments and is often shorter than the postictal period associated with generalized seizures. Absent or brief prodrome (less than 5 seconds) may be present with dysrrhythmias, whereas neurally mediated syncope (synonyms include neurocardiogenic syncope and "vasovagal" syncope) may be characterized by longer prodromes and associated nausea or vomiting. Obvious precipitating events or stress with a consistent history may be sufficient to diagnose neurally mediated syncope, which is important because the diagnosis of neurally mediated syncope is consistently associated with a good prognosis.[22] However, it is problematic that prodromal symptoms are subjective, and agreement on the presence of "vagal" symptoms and the eventual diagnosis is inconsistent among physicians.[2] Syncope that occurs while the patient is seated or reclining is more likely to have a cardiac etiology,[23] whereas syncope that occurs within 2 minutes of standing may suggest orthostatic hypotension.[24,25]

Medications and drug interactions may cause syncope. Many drugs prolong the QT interval and are associated with life-threatening dysrhythmias. Vasoactive drugs such as antihypertensive agents, vasodilators used for angina, and those used for erectile dysfunction may lead to syncope. In one study, antihypertensive agents, other cardiovascular drugs, diuretics, and central nervous system agents were most frequently cited as a cause of syncope. Drug-related syncope was especially common in elderly patients taking multiple medications.[26]

Though less well established in the literature, a family history of premature sudden cardiac death should alert the clinician to the possibility of serious congenital conduction abnormalities, including preexcitation syndromes, long QT syndromes, or Brugada syndrome.[27-29]

The demographic variables of age, sex, and race are potential risk factors for cardiovascular disease. Epidemiologic and cohort studies have confirmed the importance of age,[3,5,22] though of course age alone is a marker for increased mortality. Although increasing age is accompanied by an increased risk of poor outcome, there is no single age cutoff but rather a continuum of gradually increasing risk.

Cardiovascular diagnoses and older age do increase the risk of sudden death in patients with syncope. In a prospective cohort study, in patients older than 60 years, those with a cardiovascular diagnosis regardless of age had an increase in sudden death within 2 years.[30] Two Class II studies found cardiovascular risk to be the only predictor of 1-year mortality and also found that cardiovascular risk, not syncope, was the best predictor of mortality and cardiovascular events.[31,32] According to Class I and Class II studies, patients younger than 45 years, in the absence of other symptoms or examination findings, tend to be of lower risk, whereas older patients are at greater risk for adverse outcomes. There is no discrete cutoff age for assessing age-related risk, and the ability to make any firm age-based recommendation about risk stratification is confounded by the arbitrary choice of age thresholds in different studies. Patients with a history of poor left ventricular function, which appears to be best predicted by a diagnosis of heart failure, are consistently at greater risk of sudden death in almost every study assessing risk,[2,5,19,21] which is not just due to the fact that a history of heart failure alone has a poor prognosis. Syncope in the patient with heart failure is a poor prognostic sign. Middlekauff et al[33] showed in a Class II study that even if patients with heart failure are diagnosed with a noncardiac etiology for their syncope, these patients appeared to be at risk of sudden death. Exertional syncope raises special concerns about structural heart lesions producing fixed cardiac output.

***Vital signs.*** Loss of consciousness with syncope is transient, and the hypoperfusion or hypotension usually is transient as well. Persistent hypotension is concerning and should suggest the possiblity of another disease process. Tachycardia and hypotension may represent ongoing hemodynamic instability or volume depletion, and a cause for persistent hypotension (sepsis, hemorrhage, cardiac failure) should be sought.

Orthostatic hypotension is usually defined as a decrease in systolic blood pressure with standing of 20 mm Hg or greater. This finding may identify some patients with syncope related to volume depletion, autonomic insufficiency, or medications. Recurrence of symptoms such as light-headedness or even syncope on standing is more significant than any numeric change in blood pressure. Orthostatic hypotension is common in patients with syncope of unknown etiology, as well as in patients with other documented diagnoses such as cardiac disease, and is detected in most patients within 2 minutes after standing. This finding is also present in up to 40% of asymptomatic patients older than 70 years, and 23% of those

younger than 60 years.[24] Relying on the diagnosis of orthostatic hypotension as a cause of syncope should be symptom-related and a diagnosis of exclusion in otherwise low-risk patients, with the realization that many high-risk patients will have orthostasis.[34]

***Cardiopulmonary.*** Physical examination findings of congestive heart failure are indicators of high risk of sudden death or early mortality after syncope, as shown in a Class I study.[2] Murmurs indicative of valvular heart disease or outflow obstruction should prompt further evaluation for structural heart disease.

***Head and face.*** Tongue biting, particularly if it is lateral, has a high specificity for convulsive seizures. Because of low sensitivity, absence of tongue bites has no diagnostic significance.[35] Head trauma resulting from syncope is not associated with any particular type of syncope or short-term outcome,[2] although syncope and resultant head injury have been associated with 1-year death.[19]

***Abdominal.*** Abdominal pain or tenderness associated with syncope should be investigated. It may be a marker of significant pathology or hemorrhage. Rectal examination with observation and testing for bleeding is recommended if gastrointestinal hemorrhage is suspected.

**2. What diagnostic testing data help to risk-stratify patients with syncope?**

***Level A recommendations.*** Obtain a standard 12-lead ECG in patients with syncope.

***Level B recommendations.*** None specified.

***Level C recommendations.*** Laboratory testing and advanced investigative testing such as echocardiography or cranial CT scanning need not be routinely performed unless guided by specific findings in the history or physical examination.

**Diagnostic Testing Data**

In patients for whom a diagnosis of syncope is established, history and physical examination identify the cause in the majority of patients in which an etiology will be established. The yield of the ECG in finding a cause is low (less than 5%),[3,4,36,37] but the test is noninvasive and relatively inexpensive and can occasionally pick up potentially life-threatening conditions such as preexcitation syndromes, prolonged QT syndromes, or Brugada syndrome in otherwise healthy-appearing young adults.[27,28] A patient with a normal ECG result has a low likelihood of dysrhythmias as a cause of syncope.[2,21,38] The definitions of an abnormal ECG vary from study to study and within specialty guidelines. One study defined an abnormal ECG result as any nonsinus rhythm or an ECG with any new changes compared with a previous ECG and found it the most important predictor of serious outcomes.[2] Another study found the presence of an abnormal ECG (defined as any abnormality of rhythm or conduction, ventricular hypertrophy, or evidence of previous myocardial infarction but excluding nonspecific ST-segment and T-wave changes) was a multivariate predictor for arrhythmia or death within 1 year after the syncopal episode.[5]

***Cardiac monitoring.*** Continuous cardiac monitoring in the ED occasionally detects an arrhythmia not evident on a single 12-lead tracing. A strong suspicion of arrhythmias may prompt inpatient or ambulatory monitoring. For most patients, monitoring longer than 24 hours is not likely to increase the detection of significant arrhythmias. One study found 4 factors that identified patients likely to have an abnormality with prolonged monitoring of up to 72 hours: (1) age older than 65 years, (2) male sex, (3) history of heart disease, and (4) nonsinus rhythm on initial ECG. However, none of the patients with arrhythmias detected in the second and third 24-hour periods were symptomatic.[39]

***Laboratory testing.*** In an evaluation of syncope, laboratory tests rarely yield any diagnostically useful information, and their routine use is not recommended.[3,36,37] However, in an unselected group of patients presenting to the ED with syncope from any cause, Quinn et al[2] found hematocrit level less than 30% to be a useful predictor of adverse events.

***Advanced tests and imaging.*** There is no evidence to suggest that routine screening of syncope patients with advanced imaging (such as CT), testing such as functional cardiac echocardiography, or electrophysiologic testing is indicated. In a Class II study on echocardiography and syncope, Sarasin et al[40] found that the only added clinically useful information was in those patients with a history of cardiac disease, an abnormal ECG result, or when aortic stenosis was suspected. The use of advanced testing must be guided by the patient's history and physical examination results, shaping the physician's overall impression of likelihood that any of the rare, life-threatening conditions that can present with syncope might exist.

**3. Who should be admitted after an episode of syncope of unclear cause?**

***Level A recommendations.*** None specified.

***Level B recommendations.***

1. Admit patients with syncope and evidence of heart failure or structural heart disease.
2. Admit patients with syncope and other factors that lead to stratification as high-risk for adverse outcome (Figure).

***Level C recommendations.*** None specified.

The primary reason for admitting patients with syncope to an inpatient unit, observation unit, or other monitored area should be that the physician's risk assessment indicates that a patient may be at risk for significant dysrrhythmia or sudden death and that observation might detect that event and enable an intervention. Problematic is the definition of short-term outcome, which is subjective and not clearly defined. Which patients will benefit from a 24- to 48-hour hospital admission or observation unit admission is not adequately described in the medical literature, nor has the value of admission in preventing a later adverse outcome been demonstrated. Endpoints for patients followed up after an episode of syncope are typically

Older age and associated comorbidities*
Abnormal ECG†
Hct <30 (if obtained)
History or presence of heart failure, coronary artery disease, or structural heart disease

*Different studies use different ages as threshold for decisionmaking. Age is likely a continuous variable that reflects the cardiovascular health of the individual rather than an arbitrary value.

†ECG abnormalities, including acute ischemia, dysrhythmias, or significant conduction abnormalities.

**Figure.** Factors that lead to stratification as high-risk for adverse outcome.

reported at intervals of 6 months to 1 year or even longer. Only the San Francisco Syncope Rule, which used an endpoint of 7 days, has evaluated short-term risk of patients discharged from the ED. Other studies of ED patients have patient numbers that are too small for firm conclusions.[41] The most rational approach to admission is to understand the specific risks for patients as stated in critical question 1, and make the admission decision in light of available literature. High-risk patients require hospital admission. However, one should also realize that the decision to admit patients often takes into consideration other symptoms, other medical problems, and social factors. Admission may also be initiated for additional testing and consultation or for anticipated therapy.

**Future Directions**

A small number of studies have explored a clinical decision or observation unit, with testing or consultation as an alternative to inpatient admission in patients stratified as neither high-risk nor low-risk for adverse outcomes (ie, intermediate-risk patients). Further studies are needed to identify distinct subgroups that might benefit from this strategy.[42] The distinction between ED evaluation and admission is blurring with the availability of additional diagnostic resources, the opportunity for longer observation periods, and the reality of prolonged ED stays.

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**Evidentiary Table.**

| Study | Year | Design | Intervention(s)/ Test(s)/Modality | Outcome Measure/ Criterion Standard | Results | Limitations/Comments | Class |
|---|---|---|---|---|---|---|---|
| Blanc et al[1] | 2002 | Prospective cohort, observational, with retrospective review of charts | Review of all patients (37,475) presenting to the ED from June 1999 to June 2000; with syncope: 454 had definite syncope | 454 (1.2%) were diagnosed as having syncope; for 296 patients, it was the first episode; 169 were discharged from the ED; 285 were admitted; in 76% of patients, a discharge diagnosis was reported but evaluation was inadequate to explain a syncopal episode in 16% | Syncope is a frequent symptom, but its cause often remains unknown partly because of inadequate management | Study looked at the evaluation and diagnostic findings of patients admitted to a hospital in France; definition of syncope not clear in patient notes | III |
| Quinn et al[2] | 2004 | Prospective cohort study | Physicians prospectively completed a structured data form when evaluating patients with syncope; serious outcomes were defined at the start of the study; all patients were followed up to determine whether they had experienced a serious outcome within 7 days of their ED visit | 684 ED visits for syncope, with 79 of these visits resulting in patients experiencing serious outcomes; of the 50 predictor variables considered, 26 were associated with a serious outcome on univariate analysis | The San Francisco Syncope Rule derived in this cohort of patients appears to be sensitive for identifying patients at risk for short-term serious outcomes | Prospective derivation study of San Francisco Syncope Rule | I |
| Kapoor et al[3] | 1983 | Prospective cohort study | Followed 204 patients with syncope to determine how often a cause of syncope could be established and to define the prognosis of patients | A cardiovascular cause was established in 53 patients and a noncardiovascular cause in 54 patients; the cause remained unknown in 97 patients | Patients with syncope can be separated into diagnostic categories that have prognostic importance; patients with a cardiovascular cause have a strikingly higher incidence of sudden death than patients with a noncardiovascular, unknown cause | Study of diagnosis and outcome in 204 syncope patients, demonstrating increased mortality in those with cardiac etiology; correction made for patient subgroups with no change in results | II |

**Evidentiary Table (continued).**

| Study | Year | Design | Intervention(s)/ Test(s)/Modality | Outcome Measure/ Criterion Standard | Results | Limitations/Comments | Class |
|---|---|---|---|---|---|---|---|
| Martin et al[5] | 1997 | Prospective studies | Two prospective studies were carried out at a large urban teaching hospital ED; a cohort of 252 patients with syncope presenting to the ED was used to develop the risk classification system; a second cohort of 374 patients with syncope was used to validate the system | Multivariate predictors of arrhythmia or 1-y mortality; arrhythmias or death within 1 y | Historical and ECG factors available at presentation can be used to stratify risk of arrhythmias or mortality within 1 y in ED patients presenting with syncope; multivariate predictors of arrhythmia or 1-y mortality were: an abnormal ED ECG result, history of ventricular arrhythmia, history of CHF, or age >45 y; arrhythmias or death within 1 y occurred in 7.3% (derivation cohort) to 4.4% (validation cohort) of patients without any risk factors and in 80.4% (derivation) to 57.6% (validation) of patients with 3 or 4 risk factors | All potential predictors were included during derivation; the decision rule has been validated in this study; the derivation and validation data are set independent in 2 cohorts; 1 for derivation, 1 for validation; outcomes were defined at the start of the study; more ECG abnormalities/cardiac morbidity in derivation cohort; multivariate regression analysis post-study for subgroups with variables known to have different prognostic value; assessment of outcomes not blinded | I |
| Crane[13] | 2002 | Retrospective | Study applied ACP risk stratification/admit guidelines to 208 patients evaluated with syncope; 43% of cohort was not assigned a diagnosis after their assessment in ED; 47 (22%) were placed in ACP group 1; 63 (30%) in ACP group 2; and 100 (48%) in ACP group 3 | 36% of those in group 1, 14% of those in group 2, and none in group 3 died within a y | It is possible to risk-stratify syncope patients presenting to an ED by using ACP guidelines for managing syncope | Risk stratification successful based on 1-y mortality; no blinding | III (risk stratification) |
| Kapoor et al[14] | 1982 | Retrospective | 121 patients hospitalized for syncope of uncertain cause | The definitive cause for syncope was diagnosed in only 13 of 121 patients after average hospitalization of 9 days | Findings suggest that an extensive evaluation of syncope of unknown origin is cost-ineffective and that prospective goal-directed approaches should be developed | Low diagnostic yield and high cost of inpatient evaluations were noted findings in patients without evident diagnosis on initial evaluation | III |
| Ammirati et al[17] | 2000 | Simplified 2-step diagnostic algorithm was developed and prospectively implemented in 9 community hospitals in Lazio region of Italy | 195 consecutive patients presenting with syncopal spells to EDs throughout a 2-mo period | Improvement in clinical decisionmaking rated by percentage of cases remaining as "undiagnosed" after evaluation | The systematic implementation of the proposed diagnostic algorithm resulted in a striking reduction of undiagnosed cases | Study examines the use of a diagnostic algorithm to determine the cause/ diagnosis of syncope; a prior study is used as a "control" group; lack of risk stratification, and no separate derivation (consensus through literature) and validation set of data; it is unclear how diagnoses were reached and how diagnoses were validated | III (risk stratification) |

**Evidentiary Table (continued).**

| Study | Year | Design | Intervention(s)/ Test(s)/Modality | Outcome Measure/ Criterion Standard | Results | Limitations/Comments | Class |
|---|---|---|---|---|---|---|---|
| Sarasin et al[18] | 2001 | Prospective | Consecutive patients who presented to the ED with syncope as a chief complaint were enrolled | A diagnosis of etiology of syncope or syncope subtype | The diagnostic yield of a standardized evaluation of syncope was 76%, including the use of specialized cardiovascular tests in selected patients | Lack of criterion standard to validate diagnosis | II |
| Colivicchi et al[19] | 2003 | Prospective multicenter | 270 consecutive patients presenting with syncope to the EDs of 6 community hospitals was used as a derivation cohort for the development of the risk classification system; data from the baseline clinical history, physical examination, and ECG were used to identify independent predictors of total mortality within the first 12 mo after the initial evaluation; risk classification scoring was prospectively confirmed in a validation cohort of 328 consecutive patients | Multivariate predictors of death within 1 y | Clinical and ECG factors available at presentation can be used to stratify risk of mortality within 1 y in patients presenting with syncope | Multivariate analysis showed the following predictors of mortality: (1) age >65 y; (2) cardiovascular disease in clinical history; (3) syncope without prodromes; and (4) abnormal electrocardiogram; mortality increased significantly as the score increased in the derivation cohort (0% for a score of 0, 0.8% for 1 point; 19.6% for 2 points; 34.7% for 3 points; 57.1% for 4 points) | I |
| Quinn et al[20] | 2006 | Prospective cohort study to validate previous derivation set | Physicians prospectively completed a structured data form when evaluating patients with syncope; serious outcomes were defined at the start of the study; all patients were followed up to determine whether they had experienced a serious outcome within 7 days of their ED visit | 791 visits for syncope; 53 (6.7%) resulted in bad outcomes | The rule was 98% sensitive (95% CI 89%-100%) and 56% specific (95% CI 52%-60%) to predict adverse outcomes; LR (+) 2.2; LR (-) 0.04 | Single institution | I |

**Evidentiary Table (continued).**

| Study | Year | Design | Intervention(s)/ Test(s)/Modality | Outcome Measure/ Criterion Standard | Results | Limitations/Comments | Class |
|---|---|---|---|---|---|---|---|
| Sarasin et al[21] | 2003 | Prospective validation and retrospective derivation | 175 patients with unexplained syncope (Geneva, Switzerland) were used to develop and cross-validate the risk score; a second cohort of 269 similar patients (Pittsburgh) was used to validate the system; data from patient's history and 12-lead emergency ECG were used to identify predictors of arrhythmias; risk-score performance was measured by comparing the proportions of patients with arrhythmias at various levels of the score and ROC curves | The prevalence of arrhythmic syncope was 17% in the derivation cohort and 18% in the validation cohort; predictors of arrhythmias were abnormal ECG result, a history of CHF, and age older than 65 y | In patients with unexplained syncope, a risk score based on clinical and ECG factors available in the ED identifies patients at risk for arrhythmias | Derivation group 10 y later than validation group; very selected patient group | III (risk stratification) |
| Soteriades et al[22] | 2002 | Retrospective Framingham database 1971-1998 | | Study evaluating population-based incidence and outcome of syncope | Of 7,812 patients participating in the study, 822 had syncope; incidence 6.2/1,000; 36.6% syncope unknown cause | Those with syncope had higher mortality rates, and even more so when it was cardiogenic syncope; selected population; inclusion criteria of basic study population unclear in this article | II (risk stratification) |
| Graham and Kenny[25] | 2001 | Prospective | 62 patients with >2 episodes of syncope in the past y referred for additional testing; those who had a positive tilt table test and no other identified cause for syncope were assigned a diagnosis of vasovagal syncope | Tilt-table testing was performed using a standard protocol | Patients identified as vasodepressor syncope by virtue of positive tilt test were given a questionnaire; up to one third lacked traditional symptoms associated with vasodepressor syncope; atypical presentations of vasovagal syncope occur in many patients referred to a tertiary referral center; knowledge of the clinical characteristics of unexplained syncope for which vasovagal syncope was the determined diagnosis should assist in appropriate management of such patients | Selection/referral bias; no true criterion standard for diagnosis | III |

**Evidentiary Table (continued).**

| Study | Year | Design | Intervention(s)/ Test(s)/Modality | Outcome Measure/ Criterion Standard | Results | Limitations/Comments | Class |
|---|---|---|---|---|---|---|---|
| Oh et al[31] | 1999 | Prospective cohort | Interview and review of chart to obtain information on 19 symptoms and comorbidities | Arrhythmias, mortality, or recurrent syncope | 497 patients enrolled; in 222 cause of syncope established by history and physical examination; in the other 275, the absence of nausea and vomiting or presence of eletrocardiographic abnormalities were predictive of arrhythmic syncope; underlying cardiac disease was the only predictor of 1-y mortality; symptoms were not useful in risk stratification | Selection bias by study population from tertiary syncope center | II |
| Kapoor and Hanusa[32] | 1996 | Prospective case control | 470 syncope patients and 470 matched patients without syncope | The characteristics of 470 patients with syncope were similar, except that the patients without syncope had more cardiac diseases than those with syncope | Syncope itself is not a risk factor for overall and cardiac mortality or cardiovascular events; underlying heart diseases were risk factors for mortality regardless of whether the patient had syncope or not | For subgroups with important prognostic differences, adjustments were made for these factors; assessment of outcomes was blinded; follow-up was sufficiently long and complete; survival curves are presented | II |
| Middlekauff et al[33] | 1993 | Population with advanced heart failure prospectively identified; retrospective review of historical information and diagnostic tests | The relation of syncope to sudden death was evaluated in 491 consecutive patients with advanced heart failure, no history of cardiac arrest, and a mean left ventricular ejection fraction of 0.20±0.07; syncope patients (60) and nonsyncope patients (431) with CHF class III-IV were compared | 60 patients (12%) had a history of syncope; syncope had a cardiac origin in 29 (48%) and was due to other causes in 31 (52%); sudden death was primary endpoint | Patients with advanced heart failure are at especially high risk for sudden death regardless of the etiology of syncope | Control group much larger than reference group; all patients in same stage of disease (NYHA 3-4, no history of cardiac arrest and LVEF 0.20±0.07); selected group | II |
| Sarasin et al[34] | 2002 | Prospective | Orthostatic blood pressure changes were measured in a standardized fashion for up to 10 min, or until symptoms occurred, in consecutive patients with syncope as a chief complaint | Orthostatic blood pressure changes | According to diagnostic criteria, orthostatic hypotension was considered to be the cause of syncope in 156 patients (24%); 58 patients (37%) had drug-induced hypotension; 33 (21%) had hypovolemia; 19 (12%) had post-prandial hypotension; and 46 (29%) had idiopathic hypotension | 788 patients with syncope seen, but because of refusal or incomplete data, only 650 included in the study; 579 (89%) had standardized measurements of systolic blood pressure with other exclusions including inability to stand up | III |

**Evidentiary Table (continued).**

| Study | Year | Design | Intervention(s)/ Test(s)/Modality | Outcome Measure/ Criterion Standard | Results | Limitations/Comments | Class |
|---|---|---|---|---|---|---|---|
| Eagle and Black[36] | 1983 | Retrospective | 100 patients admitted to the hospital for evaluation of syncope | | In 39 patients, no etiology for syncope was found, and another 18 were thought to have had a vasovagal episode; 12 patients had arrhythmias as the cause for syncope | Study includes hospital testing but no follow-up beyond initial evaluation; no standard evaluation; difficult to use for risk stratification because of selection bias | III |
| Sarasin et al[40] | 2002 | Prospective | 650 consecutive patients with syncope and clinical suspicion of an obstructive valvular, or with syncope not explained by history, physical examination, or ECG underwent echocardiography | The causes of syncope were assigned using published diagnostic criteria | Echocardiography was useful only in patients with abnormal ECG results, history of cardiac disease, or symptoms and signs of aortic stenosis | Small sample size of patients with unexplained syncope | II (risk stratification) |
| Morag et al[41] | 2004 | Prospective, short-term outcomes study | 45 patients met inclusion criteria: nondiagnostic ED evaluation; 67% were hospitalized on monitored bed | Intervention for arrhythmia during hospitalization; interviews at 1 mo | This pilot study suggests that a negative-structured ED evaluation may identify patients ≥50 y of age who may be safely discharged from the ED; none of the patients experienced a life-threatening event or required significant therapeutic interventions during hospitalization; no patient had a new diagnosis relevant to syncope | Study raises question: is hospitalization necessary; however, sample size too small to assess; no control group used; outcomes defined at the start of the study; patients in different stages in their disease | III |
| Shen et al[42] | 2004 | Prospective | Patients were randomly allocated to 2 treatment arms: syncope unit evaluation and standard care; 103 consecutive patients entered the study | Presumptive diagnosis, hospitalization rate, and patient hospital days | 103 consecutive patients with syncope; 51 patients were randomized to the syncope unit; for syncope unit patients, the presumptive diagnosis was established in 34 (67%) vs 5 (10%) of standard care patients; total patient hospital days were reduced from 140 to 64 | Randomized trial for ED observation unit for intermediate risk syncope; small numbers and fairly sophisticated evaluations in the ED limit generalizability; selection bias: selected intermediate risk group | II (risk stratification) III (admission) |

*ACP*, American College of Physicians; *CHF*, congestive heart failure; *ECG*, electrocardiogram; *ED*, emergency department; *LVEF*, left ventricular ejection fraction; *LR*, likelihood ratio; *min*, minute; *mo*, month; *NYHA*, New York Heart Association; *ROC*, receiver operating characteristic; *y*, year.

**Appendix A.** Literature classification schema.*

| Design/Class | Therapy† | Diagnosis‡ | Prognosis§ |
|---|---|---|---|
| 1 | Randomized, controlled trial or meta-analyses of randomized trials | Prospective cohort using a criterion standard | Population prospective cohort |
| 2 | Nonrandomized trial | Retrospective observational | Retrospective cohort<br>Case control |
| 3 | Case series<br>Case report<br>Other (eg, consensus, review) | Case series<br>Case report<br>Other (eg, consensus, review) | Case series<br>Case report<br>Other (eg, consensus, review) |

*Some designs (eg, surveys) will not fit this schema and should be assessed individually.
†Objective is to measure therapeutic efficacy comparing ≥2 interventions.
‡Objective is to determine the sensitivity and specificity of diagnostic tests.
§Objective is to predict outcome including mortality and morbidity.

**Appendix B.** Approach to downgrading strength of evidence.

| | Design/Class | | |
|---|---|---|---|
| **Downgrading** | **1** | **2** | **3** |
| None | I | II | III |
| 1 level | II | III | X |
| 2 levels | III | X | X |
| Fatally flawed | X | X | X |