

# Health Benchmarks® Program

## Clinical Quality Indicator Specification 2011

<b>Measure Title</b>	ANNUAL MONITORING FOR MEMBERS ON PERSISTENT MEDICATIONS: DIGOXIN		
<b>Disease State</b>	Congestive Heart Failure, Atrial Fibrillation	<b>Indicator Classification<sup>1</sup></b>	Medication Monitoring
<b>Strength of Recommendation<sup>2</sup></b>	B		
<b>Organizations Providing Recommendation</b>	United States Food and Drug Administration		
<b>Clinical Intent</b>	To ensure that all members who received digoxin undergo appropriate laboratory monitoring (i.e., serum potassium and BUN or creatinine) at least annually.		
<b>Background</b>	<p><b>Disease Burden</b></p> <ul style="list-style-type: none"> <li>• Approximately one third of patients with Congestive Heart Failure (CHF) in the United States are treated with digoxin.[1]</li> <li>• Around 5 million people in the United States have heart failure. About 550 thousand new cases are diagnosed each year. More than 287 thousand people in the United States die each year with heart failure. [2]</li> <li>• In 2004, there were approximately 1.1 million hospitalizations nationwide for CHF, adding to nearly \$29 billion in hospital charges.</li> <li>• CHF was the second most common reason for hospital admission in 2003.[3]</li> </ul> <p><b>Reason for Indicated Intervention or Treatment</b></p> <ul style="list-style-type: none"> <li>• Digoxin possesses a narrow window between toxicity and therapeutic efficacy. Toxic effects include induction of arrhythmia and conduction disturbances.[4]</li> <li>• Digoxin clearance is reduced among patients with CHF, and particularly so among those with renal impairment.[5]</li> <li>• Digoxin therapy for CHF is associated with a large increase (OR = 2.39, CI 1.37, 4.18) in risk of primary cardiac arrest among patients with moderate renal impairment (serum creatinine 1.5 – 3.5 mg/dL).[6]</li> <li>• A 2004 study published by the Digoxin Intervention Group reported that all-cause mortality (mean observation time 3 years) was inversely proportional to glomerular filtration rate, however, the effect of digoxin did not differ by level of renal function.[7]</li> <li>• Hyperkalemia may indicate digitalis toxicity, and is a predictor of morbidity and mortality.[8] A classic paper by Bismuth <i>et al.</i> demonstrated among patients with acute digoxin toxicity, those with potassium levels less than 5.0 meq/dL had a 0% mortality rate while</li> </ul>		

those with potassium levels between 5.0 and 5.5 had a 50 percent mortality rate, and those with potassium levels above 5.5 meq/dL had a 100 percent mortality rate.[8]

- Hypokalemia has been associated with digoxin induced cardiac arrhythmia. [9]

**Clinical Recommendations**

- FDA labeling for Digoxin recommends that patients have their “serum electrolytes and renal function assessed periodically.”[10]

**Source** Healthcare Effectiveness Data and Information Set (HEDIS®) 2011 Technical Specification for Physician Measurement

**Denominator**

**Denominator Definition** Continuously enrolled members ages 18 years or older by the end of the measurement year who received at least a 180 day supply of digoxin during the measurement year.

*Note: Members may switch therapy within any medication listed in digoxin\_den\_medlist\_2011\_v1.xls during the measurement year and have the days supply for those medications count towards the total 180 days supply.*

**Denominator Index Date** N/A

**Denominator Encounters/Claims Criteria** *Note: Members may switch therapy within any medication listed in digoxin\_den\_medlist\_2011\_v1.xls during the measurement year and have the days supply for those medications count towards the total 180 days supply.*

Drug list: Digoxin

**Denominator Exclusion**

**Denominator Exclusion Definition** Members who had an acute/nonacute inpatient stay during the measurement year.

**Denominator Exclusion Claims Criteria** CPT-4 code(s): 99221-99223, 99231-99233, 99238-99239, 99251-99255, 99261\*-99263\*, 99291-99300, 99356-99357, 99431\*-99440\*, 99460-99465, 99468-99476, 99477-99480

UB revenue code(s): 010x, 0110-0114, 0119, 0120-0124, 0129, 0130-0134, 0139, 0140-0144, 0149, 0150-0154, 0159, 016x, 020x-022x, 072x, 080x, 0987

\*Code range was retired but is still appropriate for retrospective analysis.

**Numerator**

**Numerator Definition** Members who received at least 1 of the following:

- A lab panel test during the measurement year

- A serum potassium and a serum creatinine during the measurement year
- A serum potassium and a blood urea nitrogen during the measurement year

**Numerator Claims Criteria**

CPT-4 code(s): 80047, 80048, 80050, 80051, 80053, 80069, 82565, 82575, 84132, 84520, 84525

LOINC code(s): 2160-0, 2163-4, 2164-2, 2823-3, 2824-1, 3094-0, 6298-4, 6299-2, 11041-1, 11042-9, 11064-3, 11065-0, 12195-4, 12812-4, 12813-2, 12964-3, 12965-0, 12966-8, 13441-1, 13442-9, 13443-7, 13446-0, 13447-8, 13449-4, 13450-2, 14682-9, 14937-7, 16188-5, 16189-3, 21232-4, 22760-3, 26752-6, 29349-8, 31045-8, 32713-0, 33558-8, 35203-9, 35591-7, 35592-5, 35593-3, 35594-1, 38483-4, 39789-3, 39790-1, 39955-0, 39956-8, 39957-6, 39958-4, 39959-2, 39960-0, 39961-8, 39962-6, 39963-4, 39964-2, 39965-9, 39966-7, 39967-5, 39968-3, 39969-1, 39970-9, 39971-7, 39972-5, 39973-3, 39974-1, 39975-8, 39976-6, 40112-5, 40113-3, 40114-1, 40115-8, 40116-6, 40117-4, 40118-2, 40119-0, 40120-8, 40121-6, 40122-4, 40123-2, 40124-0, 40125-7, 40126-5, 40127-3, 40128-1, 40248-7, 40249-5, 40250-3, 40251-1, 40252-9, 40253-7, 40254-5, 40255-2, 40256-0, 40257-8, 40258-6, 40264-4, 40265-1, 40266-9, 40267-7, 40268-5, 40269-3, 40270-1, 40271-9, 40272-7, 40273-5, 41656-0, 44734-2, 44784-7, 49071-4, 50380-5, 50381-3, 51618-7, 51619-5, 51620-3, 59570-2, 59826-8, 59834-2 (if available)

**Physician Attribution**

**Physician Attribution Description**

**If client data contains prescribing provider:**

Score the physician(s) who prescribed the member a denominator medication.

**If client data does not contain prescribing provider:**

Score all physicians who saw the member during the measurement year.

**References**

1. Stafford, et al., *National patterns of angiotensin-converting enzyme inhibitor use in congestive heart failure*. Arch Intern Med, 1997. **157**(21): p. 2460-4.
2. American Heart Association. *Heart Disease and Stroke Facts, 2006 Update*. Dallas, Texas: AHA, 2006.
3. A, E. and O. P., *Reasons for Being Admitted to the Hospital Through the Emergency Department, 2003.*, in *HCUP Statistical Brief*, HCUP, Editor. 2006, Agency for healthcare research and quality: Rockville, MD.
4. Smith and T. W., *Digitalis. Mechanisms of action and clinical use*. N Engl J Med, 1988. **318**(6): p. 358-65.
5. Naafs, et al., *Decreased renal clearance of digoxin in chronic congestive heart failure*. Eur J Clin Pharmacol, 1985. **28**(3): p. 249-52.
6. Rea, et al., *Digoxin therapy and the risk of primary cardiac arrest in patients with congestive heart failure: effect of mild-moderate renal*

- impairment*. J Clin Epidemiol, 2003. **56**(7): p. 646-50.
7. Shlipak, et al., *Creatinine levels and cardiovascular events in women with heart disease: do small changes matter?* Am J Kidney Dis, 2004. **43**(1): p. 37-44.
  8. Bismuth, et al., *Hyperkalemia in acute digitalis poisoning: prognostic significance and therapeutic implications*. Clin Toxicol, 1973. **6**(2): p. 153-62.
  9. Surawicz and B., *Factors affecting tolerance to digitalis*. J Am Coll Cardiol, 1985. **5**(5 Suppl A): p. 69A-81A.
  10. *FDA labeling for Lanoxicaps*.  
[http://www.fda.gov/cder/foi/nda/pre96/18118\\_LANOXICAPS\\_PRNTLBL.PDF](http://www.fda.gov/cder/foi/nda/pre96/18118_LANOXICAPS_PRNTLBL.PDF) accessed December 17, 2008. [cited].

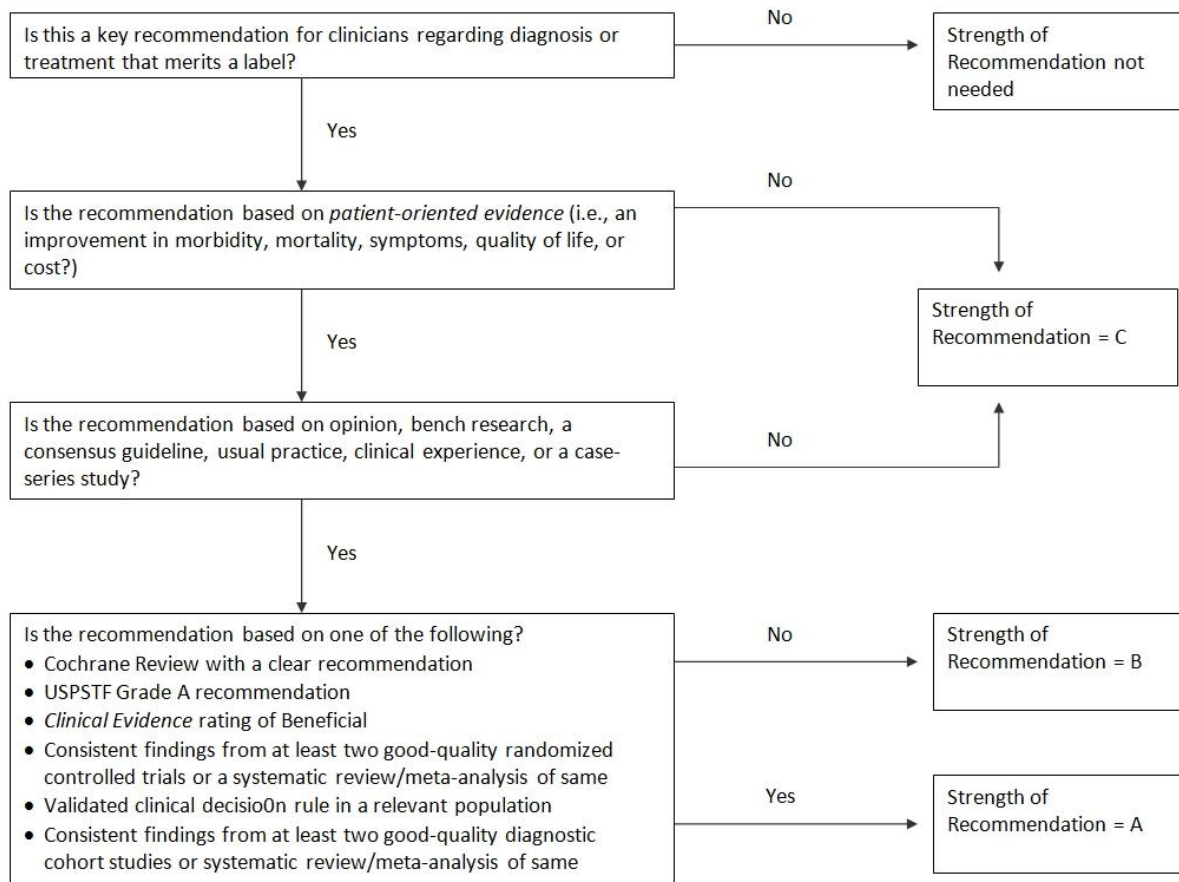
CONFIDENTIAL

---

<sup>1</sup> **Indicator Classification** (Adapted from Health Plan Employer Data Information Set (HEDIS®) technical specifications)

<b>Diagnosis</b>	Measures applicable to patients receiving diagnostic workups for a symptom or condition that delineate appropriate laboratory or radiological testing to be performed (e.g., evaluation of thyroid nodule; pregnancy test in patients with vaginal bleeding or abdominal pain).
<b>Effectiveness of Care</b>	
<b>Prevention</b>	Measures applicable to asymptomatic individuals that are designed to prevent the onset of the targeted condition (e.g., immunizations).
<b>Screening</b>	Measures applicable to asymptomatic patients who have risk factors or pre-clinical disease, but in whom the condition has not become clinically apparent (e.g., pap smears; screening for elevated blood pressure).
<b>Disease Management</b>	Measures applicable to individuals diagnosed with a condition that are part of the treatment or management of the condition (e.g., cholesterol reduction in patients with diabetes; radiation therapy following breast conserving surgery; appropriate follow-up after acute event).
<b>Medication Monitoring</b>	Measures applicable to patients taking medications with narrow therapeutic windows and / or potential preventable significant side effects or adverse reactions (e.g., thyroid stimulating hormone (TSH) testing after levothyroxine dose change; hepatic enzyme monitoring for patients using antimycotic pharmacotherapy).
<b>Medication Adherence</b>	Measures applicable to patients taking medications for chronic conditions that are designed to assess patient adherence to medication (e.g., adherence to lipid lowering medication).
<b>Utilization</b>	Measures applicable to patients receiving treatment for a symptom or condition that advocate appropriate utilization of laboratory and pharmaceutical resources (e.g., conservative use of imaging for low back pain; inappropriate use of antibiotics for viral upper respiratory infection).

### Strength of Recommendation Based on a Body of Evidence



**FIGURE 2.** Algorithm for determining the strength of a recommendation based on a body of evidence (applies to clinical recommendations regarding diagnosis, treatment, prevention, or screening). While this algorithm provides a general guideline, authors and editors may adjust the strength of recommendation based on the benefits, harms, and costs of the intervention being recommended. (USPSTF = U.S. Preventive Services Task Force)