**DRAFT E-Recommendation Template and Breast Cancer Screening E-Recommendation**

Version of 1/6/10 [external review version w/edits to Implementation Considerations]

1. **Header Information**

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| E-Recommendation Name | USPSTF SCREENING FOR BREAST CANCER (B Recommendation on mammography only) | E-Recommendation Id | USPSTF-MAMMO-B-REC |
| Version number | 2 (revision of 2002 guidelines) | Set Id | USPSTF-A-B-RECS |
| Rule set | USPSTF A and B Recommendations |
| eMeasure on which rule is based (if applicable) | PQRI112:Preventive Care and Screening: Screening Mammography [PQRI age range40 69] |
| Available Date | 17 Dec 2009 | Effective Date Range | 17 Dec 2009 – 17 Dec 2011 |

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| Author | Structured Recommendations Team on AHRQ contract |

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| Verified by | Agency for Healthcare Research and Quality (AHRQ); United States Preventive Services Task Force (USPSTF) *[?]* |

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| Maintained by | Agency for Healthcare Research and Quality (AHRQ) and United States Preventive Services Task Force (USPSTF) |
| Description/ Purpose | U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for breast cancer in the general population converted into standardized e-Recommendation statement. (recommendation version of 2009) |

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| Prose statement of guideline recommendation | “The USPSTF recommends biennial screening mammography for women between the ages of 50 and 74 years. (Grade B recommendation)… This recommendation statement applies to women … who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation.” |
| Potentially pertinent settings | Inpatient, Emergency Department, Outpatient  |
| Rule classification | Screening: primary prevention |
| Rationale | **Importance**Breast cancer is the second-leading cause of cancer death among women in the United States. Widespread use of screening, along with treatment advances in recent years, have been credited with significant reductions in breast cancer mortality.**Detection**Mammography, as well as physical examination of the breasts (CBE and BSE), can detect pre-symptomatic breast cancer. Because of its demonstrated effectiveness in randomized, controlled trials of screening, film mammography is the standard for detecting breast cancer; in 2002, the USPSTF found convincing evidence of its adequate sensitivity and specificity.**Benefits of Detection and Early Intervention:**There is convincing evidence that screening with film mammography reduces breast cancer mortality, with a greater absolute reduction for women aged 50 to 74 years than for women aged 40 to 49 years. The strongest evidence for the greatest benefit is among women aged 60 to 69 years. |
| Reference | Clinical Guidelines: Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. U.S. Preventive Services Task ForceAnn Intern Med November 17, 2009 151:716-726 |

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| **2. Data and Logic Specification**[[1]](#footnote-2) |
| **2.a** [**Data definitions**](http://www.hl7.org/v3ballot/html/domains/uvqm/POQM_EX000001.xml#toc)[[2]](#footnote-3) |
| Eligibility/Inclusion-related data | **Demographic*** Target Gender: F
* Target Age low limit: 50
* Target Age high limit: 74[[3]](#footnote-4)

**Condition*** [*not relevant to mammography example*]

**Risk*** [*not relevant to mammography example*]
 |
| Patient data | Patient AgePatient Gender |
| Intervention interval | Screening interval: 2 years *[See Section 3. Implementation Considerations below for details on operational exclusion criteria and related logic where screening interval is used ]* |
| Exclusion criteria-related data | **High risk patients**[[4]](#footnote-5)<Value set: History of chest radiation >* Code set: CPT 4
* Code list: 77401 Radiation treatment delivery, superficial and/or ortho voltage; 77402 Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks, up to 5 MeV; 77403 Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks, 6-10 MeV; etc.
* Quality data type: Procedure history

<Value set: Known genetic mutation, BRCA1, BRCA2, [possibly others]>* Code set: (LOINC, SNOMED)
* Code list: \_\_\_\_,\_\_\_\_,\_\_\_\_
* Quality data type: Laboratory test result

**Other exclusion-related data*** [*not relevant to mammography example*]
 |
| Operational exclusion criteria-related data[[5]](#footnote-6)  |  [*Will depend on implementation considerations/choices: See Section 3. Implementation Considerations for examples*] |

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| **2.b Logic Statement**  | **If** <Eligibility/Inclusion Criteria> **AND NOT** (<Exclusion Criteria> OR <Operational Exclusion Criteria>) **THEN** <Action> |
| <Eligibility/Inclusion Criteria> | Patient Gender = Target Gender AND: <Patient Age >= Target Age Low Limit>AND<Patient Age <= Target Age High Limit>*AND:* *<Evidence of condition/risk = non-null ]>* [[6]](#footnote-7) |
| <Exclusion Criteria>  | **<Patients for whom a different intervention protocol may be warranted>*** <Value set: History of chest radiation > = non-null
* OR: <Value set: Known genetic mutation > = non-null

**<Patients that have already received intervention within recommended interval>*** <Value set: mammogram results documented within 2 years >[[7]](#footnote-8) = non-null
 |
| <Operational exclusion criteria> | [*Will depend on implementation considerations/choices: See Section 3. Implementation Considerations for examples*] |
| <Action> | **<Recommended Action: Perform Intervention: procedure/test/medication/counseling/etc.>*** <Bilateral mammogram>
	+ <Code set: CPT/HCPCS
	+ Code list: 77057 Screening mammography, bilateral (2-view film study of each breast); G0202 screening mammography, producing direct digital image, bilateral, all views
	+ Quality data type: Diagnostic Study Order>
 |

**3. [Implementation](http://www.hl7.org/v3ballot/html/domains/uvqm/POQM_EX000001.xml%22%20%5Cl%20%22toc%22%20%5Co%20%22http%3A//www.hl7.org/v3ballot/html/domains/uvqm/POQM_EX000001.xml#toc) Considerations**

Successfully implementing the generic logic statement above as a useful CDS rule requires careful attention to many additional rule development and deployment details. These are typically specific to local circumstances, and relate to clinical policies, information system capabilities, availability of electronic/coded data, workflow considerations and the like.

 To assist with adapting the logic statement above into a valuable and well accepted CDS rule, several key implementation considerations are outlined below.

**OPTIMIZING RULE SPECIFICITY**: Taken by itself, the logic from the guideline underlying this e-Recommendation would cause rule firing in many circumstances where the recommendation would not be appropriate. For example, guideline logic typically doesn’t explicitly exclude individuals for whom the recommended intervention has already been accomplished, is pending, or has been rejected by the clinician or patient.

Such ‘operational exclusion criteria’ must be considered in rule development to minimize false positive notifications and the problems they can cause (e.g., information overload, recipient dissatisfaction, etc.). Below are some data, criteria and logic issues to consider, among others, in developing operational exclusion criteria for this e-Recommendation.

Operational data

* + Notification fired
		- Provider, date
	+ Acknowledgment
		- Provider, date, type (to be done, refused by provider, refused by patient, already done, etc.)
	+ Screening interval
		- 2 years
	+ Alerting interval
		- 2 months

Operational exclusion criteria data

* + Tests for diagnosis or problem in process or done within specified screening interval

Mammogram completed within past 2 years: Record of the patient having received a mammogram in the previous 2 years (by history or by stored data)

* + - By history
			* Mammogram externally as per patient history or need for such request to be asked in CDS
		- By data
			* Completed mammography encounter: Notation of previous encounter in a mammography setting
			* Mammogram completed: Mammogram noted in patient record
			* Mammogram already ordered or scheduled but not yet completed
			* MRI, ultrasound or other procedure of breast done or ordered. (e.g. women with dense breasts by mammogram may be followed subsequently by these means instead of mammogram)
			* <Value Set: evidence of the screening procedure or related procedures having been done>: <Bilateral mammogram>
				+ <Code set: CPT/HCPCS
				+ Code list: 77057 Screening mammography, bilateral (2-view film study of each breast); G0202 screening mammography, producing direct digital image, bilateral, all views
				+ Quality data type: Diagnostic Study Result>

* + Pre-existing condition diagnosis or problem

Note: Implementer may want to expand the definition of “high risk patients for which appropriate treatment differs from recommendation” based on local protocols/decisions. For example, in some systems, a local CDS rule may be in place to deal with patients at higher than average risk for breast cancer (when high risk is defined by criteria beyond those in the USPSTF, such as those with prior premalignant biopsy result, etc.). If so, it may be advisable to exclude such patients from the screening rule. If such a local CDS rule is not in place, however, it may not be advisable to exclude such patients from the screening rule.

* + - Patient has condition being screened (thus being managed, not in primary prevention mode)
			* problem list or diagnosis of breast cancer or premalignant lesion, e.g., in one breast
				+ <Value set: Diagnosis of breast cancer> e.g.,
				+ Code set: ICD9-CM
				+ Code list: V10.3 Personal history of malignant neoplasm, breast
				+ Quality data type: Diagnosis past history
		- Indirect evidence of diagnosis or problem already made
			* Recurrent tests or procedures implying diagnosis
				+ Pathology diagnoses, cytology, etc.
			* Treatments implying diagnosis or problem
				+ Radiation, chemotherapy, surgery etc., e.g.

19301 Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy);

19302 Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy

19303 Mastectomy, simple, complete

19304 Mastectomy, subcutaneous

19305 Mastectomy, radical, including pectoral muscles, axillary lymph nodes

19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation)

19307 Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle

These codes would have a modifier-50, or –RT and –LT to indicate bilateral

* + - * Related or derivative diagnoses or problems
				+ Post radiation or chemo illnesses without other primary disease explanation – need to alert
	+ Rule having fired within specified alerting interval
		- Intervention recommended has been acknowledged, action pending
			* Notification indication of rule having been triggered within past XX interval (e.g., past 2 months)
	+ Reason noted for not following rule recorded within specified alerting interval
		- Patient or clinician declined recommendation
			* Acknowledgment having been made of reason for refusal or deferral within past XX interval (e.g., past 2 months)

Operational exclusion criteria logic

* + - * AND NOT: Tests for diagnosis or problem in process

AND NOT: Pre-existing condition diagnosis or problem

* + - * ELSE AND NOT: Rule having fired within specified alerting interval

OR NOT: Reason noted for not following rule recorded within specified alerting interval

**DETERMINING RULE TRIGGERING:** There are many different ways that the logic statement can be triggered as a CDS rule within various health/healthcare workflows. To achieve desired results, the logic may be deployed in several different ways simultaneously within an organization or practice – e.g. as a real-time/interactive reminder for clinicians, a real-time/interactive reminder for patients, and as a batch-mode rule for the practice/hospital. Issues and options to consider include:

* + - Is operation interactive/real time?
		- Batch mode, e.g. through clinic/practice administration?
		- Can information be obtained from patient at time of rule firing?
		- Where you might get the data from (e.g. ask the patient if the data is not available in the EMR).
		- Is rule fired by visit, by elapsed time interval, as result of a search finding eligible patients, or by query initiated by provider or patient? Potential Rule Forms to consider:
			* Alert on data-trigger
			* Reminder on time-trigger
			* Interactive recommendation on user request
			* Search evaluation list
		- Scenarios might include:
			* Encounter with potentially eligible patient
			* Reminder of due date for test for patient already having been identified (e.g., in a registry or based on previous test)
			* Search for eligible patients (e.g., those to be seen, or periodically for those in a panel or database)
			* Inquiry by provider
			* Inquiry by patient

**DEFINING NOTIFICATION APPROACH**: Workflows related to how rule output recipients will be presented with, and respond to, rule-triggered notifications must be handled carefully in order for the rule to support the desired clinical actions and results. Below are some issues to consider regarding rule notification.

* + - * User Notification: Is it desirable to set an indicator that a notification has been delivered, e.g. to avoid redundant firing?
			* Notification Acknowledgment: Is it desirable to document notification response, e.g., for rejection of recommended action?

**OBTAINING KEY DATA**: In many deployments, getting key data needed for proper rule functioning will be problematic – even the most basic data elements. The basic data criteria in Section 2.a above needed for the generic logic statement in 2.b. includes data elements that may be difficult to obtain, not to mention more robust data needed for optimal rule functioning. Below are some considerations around potential minimum data requirements needed to locally implement the eRecommendation as well more robust elements needed for a more nuanced implementation of the eRecommendation.

* + - * Minimum Data Set
			* Extended Data Set

**ACCOMODATING LOCAL CLINICAL POLICIES**: The data definitions and logic statement outlined above are intended to be starting points for local adaptation and implementation into CDS rules; incorporating local clinical policies is an important component of this work. For example, individual sites may wish to modify the elements such as ages at which interventions should begin and end, intervals at which they should be offered, and specific approaches to achieving the recommended intervention (e.g. through related methodologies). These modifications should be made with due attention to evidence-based information and practices, as appropriate. For this logic statement, this may include:

* + - * Target Age Limit High
			* Target Age Limit Low
			* Screening interveal

**ADDITIONAL WORKFLOW/OTHER CONSIDERATIONS**: [placeholder for other issues TBD]

* + - …
1. These data criteria and logic statement elements are a generalized first approximation to consider in implementing a CDS rule for the purpose outlined above based on this eRecommendation statement. They are based where pertinent on a corresponding performance measure specification to assist in using the rule to support local performance excellence on the measure. They leverage NQF’s Quality Data Set to the greatest extent possible. In some cases, these data points may not be readily accessible electronically for automated rule processing and will have to be adapted to local needs, workflows and data availability (e.g. accept lower notification specificity vs. query user for needed data vs. reconfigure information system to gather needed data). [↑](#footnote-ref-2)
2. Definitions, code sets, data elements used in logic statement [↑](#footnote-ref-3)
3. For PQRI 112 to which this logic statement is related, Age Limit High = 69 [↑](#footnote-ref-4)
4. High risk patients may require a different screening protocol. The USPSTF recommendation states that a known genetic mutation or a history of chest radiation puts a woman at an increased risk for breast cancer and excludes this group from the screening recommendation. The recommendation ***implies*** that a different screening/treatment recommendation/protocol applies to this high risk group, although it does not make explicit such a recommendation/protocol.

Therefore, it might be appropriate for implementers to consider if there a recommendation/protocol for the screening/treatment of the given high risk group in place in the system:

If there is a protocol, and if there is evidence that a high risk patient is already on such a protocol, **exclude** this patient from the recommendation.

If there is a protocol, and a high risk patient is not on it, **recommend** that the patient be put on the protocol

If there is no protocol, but if there is evidence that the patient is on such a protocol elsewhere (e.g., having had BRCA1/2 testing), **exclude** this patient.

Otherwise, **do not exclude** this high risk patient. [↑](#footnote-ref-5)
5. Optional element: implementer may define and use operational exclusion criteria pertinent to local needs and constraints. For example, if the intervention recommended is addressed/pending, or if patient has condition being screened and is already undergoing treatment, etc. then implementers may wish to suppress the intervention recommendation to minimize false positive notifications. See implementation consideration section for further details and examples. [↑](#footnote-ref-6)
6. This is a template placeholder for other rule types: not pertinent to this breast cancer screening sample [↑](#footnote-ref-7)
7. See section 3, subsection on Optimizing Rule Specificity for further details on operational exclusion criteria, e.g. related to pertinent pending interventions, etc. [↑](#footnote-ref-8)