Intermountain Healthcare, Proven Imaging:

Process for Imaging AUC Development and Maintenance

Introduction:

Intermountain Healthcare, through its ***Proven Imaging*** initiative is dedicated to the development, maintenance, and deployment of evidence-based standards for imaging in support of its mission of helping people live the healthiest lives possible. The appropriate use of imaging must be defined and understood within the specific clinical context in which it occurs. This context can be very complex and include factors such as demographics, prior medical history, signs and symptoms, prior diagnostic test results and current therapies. Further, a full understanding of context includes the anticipated downstream impacts of the imaging service result on therapy and ultimately on outcome. The ***Proven Imaging*** guidelines are framed within a population health management model where evidence-based preventative, diagnostic, therapeutic, and palliative standardized care processes are interwoven to form evidence-based care pathways across the continuum of care.

Multidisciplinary clinical teams called Clinical Programs are organized within Intermountain to develop and oversee implementation of evidence-based standards of care for defined sub-populations. Current Intermountain Clinical Programs include Behavioral Health, Cardiovascular, Intensive Medicine, Musculoskeletal, Oncology, Pediatric, Primary Care, Surgical Services, and Women & Newborn. Experts in imaging including radiologists and cardiologists serve within the Clinical Programs as domain knowledge experts in imaging. The main work of the clinical programs is to develop Care Process Models (CPMs) for the key processes of care provided within their clinical domain. Imaging services are component services within the CPMs. This architecture allows for very complex clinical context to be specified for the imaging service and very importantly links the outcome of the imaging service to other downstream diagnostic and/or therapeutic services. In addition to providing guidelines for care, CPMs also include the collection and analysis of data metrics that allow objective assessment of CPM impacts on outcome and on the total cost of care. CPMs functionally serve as a portfolio of dynamic Quality Improvement initiatives that are the essence of a Learning Healthcare System.

The ***Proven Imaging*** initiative leverages the Clinical Program infrastructure to develop Imaging Appropriate Use Criteria (AUC), generally in a CPM architecture. The steps to AUC development include; 1- Identification of Priority Clinical Areas as defined by CMS and assignment to the most appropriate Clinical Program and development of a project plan, 2- Constitution of a development team to build and maintain the AUC, 3- Performance of evidentiary review, 4- Creation of AUC in most appropriate format,

5- Testing and validation, 6- Publishing AUC to Intermountain's ***Proven Imaging*** website, and 7- Annual review of published AUC.

Step 1: Identify Priority Clinical Area and assign to the most appropriate Clinical Program for AUC development and management and establish a general project plan.

On an annual basis, as CMS designates Priority Clinical Areas (PCAs), the medical director of Imaging Services collaborates with the medical directors of the Clinical Programs to determine which Clinical Program is most appropriate to lead out in developing and managing CPM or CPMs relevant to the PCAs. The appropriate scope of the project is established. At a minimum, the scope will include the development of appropriate use criteria sufficient to encompass the breadth of advanced imaging use (MR, CT, NM, PET) for the entire PCA. Scope may be extended to include upstream and downstream content. Upstream content would include requirements and processes for acquiring needed history, physical exam, laboratory or other diagnostic studies, etc. used to guide the clinician to the appropriate ordering of an advanced imaging procedure (Diagnostic CPM). Downstream content would include determinations as to how the imaging study results would impact further diagnostic or therapeutic interventions (Comprehensive CPM).

In collaboration with operational leaders, a project plan is developed, where the proposed scope of the project is discussed and defined. Anticipated resource requirements are estimated. Project plans include a determination of what AUC architecture(s) are to be used. The project plan is approved by Clinical Program and Imaging Service leadership.

Step 2: Constitute development team

Intermountain leverages its Clinical Program Infrastructure to develop CPMs. For each project, a development team is convened. Development teams include physicians, operational support, and statistical support. In developing and managing CPMs for the PCAs, development team membership at a minimum includes the following:

- At least 1 practicing clinician who is an expert in the PCA
- At least 1 practicing provider who is an expert in the relevant imaging procedures
- At least 1 primary care provider where a primary care provider is defined in section 1861 of the Social Security Act as a physician who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, pediatric medicine or is a nurse practitioner, clinical nurse specialist, or physician assistant.
- At least 1 expert in statistical analysis
- At least 1 expert in clinical trial design

One clinical member of the development team is designated as the development team leader. All participating team members are screened for conflicts of interest in accordance with Intermountain's conflict of interest (COI) policy. A copy of Intermountain's general COI policy is attached as "Intermountain COIPolicy v1.pdf". In this policy, employees and contracting medical providers are required to annually complete a general COI screening survey (see attached documents "Intermountain EmployeeCOI Disclosure v1.pdf" and "Intermountain AffiliatedCOI Disclosure v1.pdf"). In order to fully comply with PAMA regulations, more specific screening questions will need to be included for AUC development team members. Intermountain is currently developing these amended questions and will update this document and associated COI attachments once completed. Participation of development team members with any potential COI identified by screening must be approved by Clinical Program and Imaging Services executive leadership. Upon request, Intermountain discloses all COI information required by regulation to outside parties.

Step 3: Perform evidentiary data review

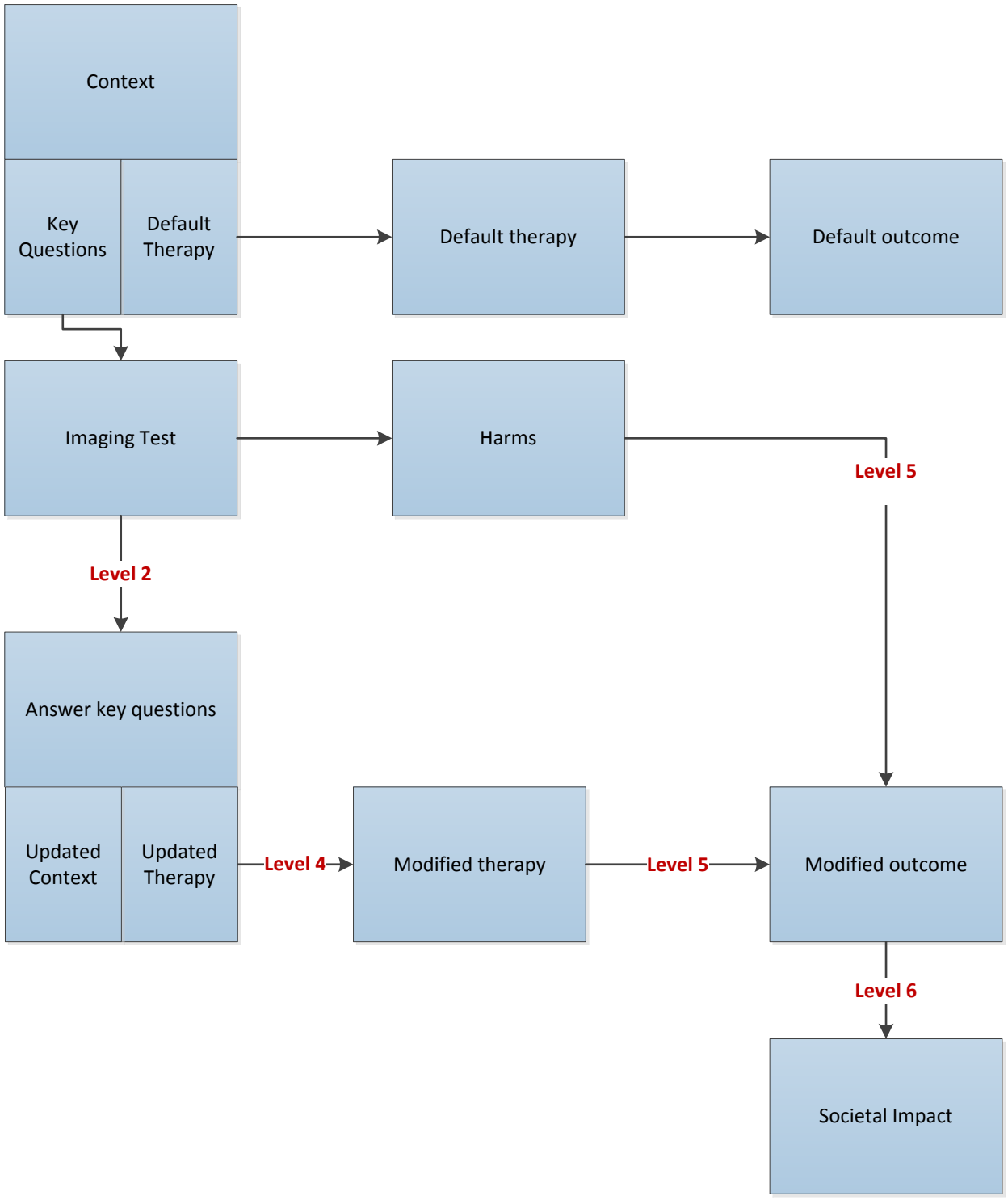
Evidence Background

Before delineating the evidentiary data review process, a conceptual framework for evidentiary review of imaging used by Intermountain is given. Several rating systems have been established to rank the strength of medical evidence. The 2011 revision of the Oxford Centre for Evidence-Based Medicine (OCEMB) 2011 Levels of Evidence standard includes categorical levelling grades relevant to diagnostic studies (OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence". Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 * *OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson*). This system can be used to rate individual sources of evidence (published papers or other research data) on a 5-point scale. OCEBM levels for diagnostic studies are given in the following table.

Question	Step/Level 1	Step/Level 2	Step/Level 3	Step/Level 4	Step/Level 5
Diagnosis	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards	Case-control studies, or poor or non-independent reference standard	Mechanism-based reasoning

The performance of an imaging test should never be viewed as an isolated event. It always takes place in a clinical context and will have an impact on downstream events. A simple depiction of the Imaging Value Chain is given in the following graphic.

Intermountain Proven Imaging Value Chain



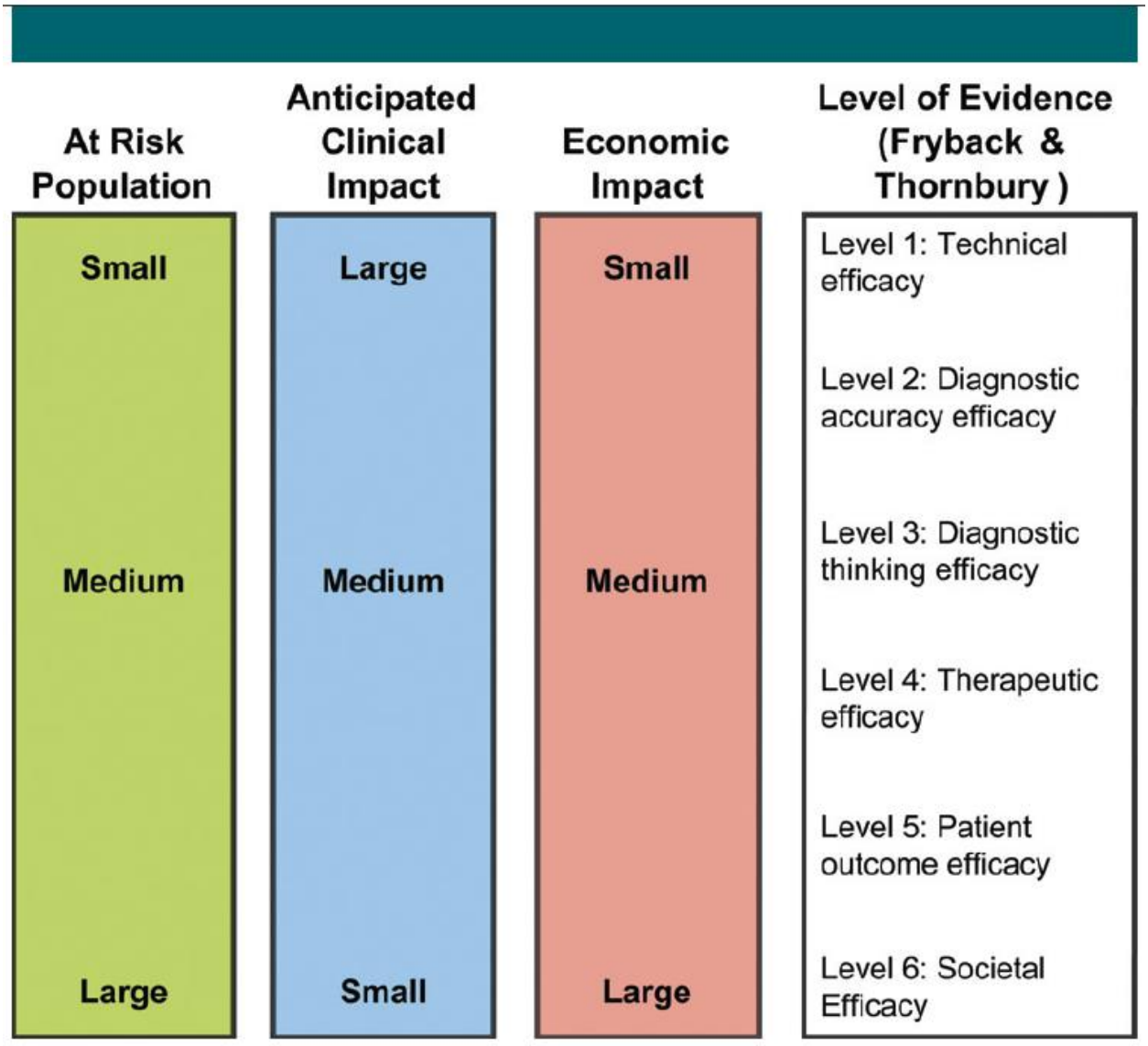
In this model, patients present in common clinical contexts where their medical condition is associated with a default plan for therapy. Where there are unanswered key questions, diagnostic tests may be ordered before instituting the default therapy. Imaging tests are ordered with the primary objective of answering the key questions in the anticipation that the answers will change the therapeutic plan. Further, it is anticipated that this change in therapy will ultimately improve patient outcome. The decision to order an imaging test must, however, include consideration of the possible harms that could negatively impact outcome. In the aggregate, based on the use of the test in a population of patients, the aggregated outcomes will have a global societal impact.

Fryback and Thornbury (Fryback DG, Thornbury JR. The Efficacy of Diagnostic Imaging. Med Decis Making 1991;11:88-94) published a conceptual framework for the assessment of the efficacy of diagnostic imaging that has been used extensively. Levels of efficacy in their model are given in the following table. Fryback & Thornbury levels of efficacy can also be linked to discrete steps in the imaging value chain and are annotated in red on the value chain graphic above.

Level	Type of efficacy	Meaning
1	Technical efficacy	Physical capabilities to produce images of adequate quality. i.e. Contrast resolution, spatial resolution, etc.
2	Diagnostic accuracy efficacy	Efficacy in making a diagnosis. i.e. Sensitivity/specificity, etc.
3	Diagnostic thinking efficacy	Efficacy in changing clinicians subject assessment of the probably of disease or appropriate therapeutic course. i.e., expert opinion, etc.
4	Therapeutic efficacy	Efficacy in changing the course of treatment. i.e. Changes in drug therapy, surgical therapy, need for additional diagnostic tests, etc.
5	Patient outcome efficacy	Improvement or decline in morbidity, mortality, or quality of life attributable to the test.
6	Societal efficacy	Benefit-cost or cost-effectiveness benefit from societal viewpoint

Most diagnostic imaging research has focused on levels 1 through 3. Level 4, 5, and 6 studies are much harder to conduct. They require multidisciplinary engagement and the reality is that it is unusual to rare for specific imaging questions to be included within what are primarily therapeutic studies. Consequently, when viewed from within the framework of the imaging value chain, evidentiary support for the use of imaging is often weak. A recent publication by Gazelle et.al. (Gazelle, GS, et.al. A

Framework for Assessing the Value of Diagnostic Imaging in the Era of Comparative Effectiveness Research, Radiology 2011;261(3):692- 698) details an approach to assessing the aggregate of available evidence to yield an overall assessment of appropriateness of imaging for a clinical context. In this model, the clinical context is classified in 3 primary domains or pillars. The framework's 3 pillars are; 1- size of the at-risk population, 2- anticipated clinical impact, and 3- economic impact. In this framework, the impacts of the imaging in the three pillar domains are each classified on a 3-point scale (large, medium and small). This assessment is then used as a basis to designate the appropriate Fryback & Thornbury level of evidence that must be satisfactorily demonstrated by scientific data in order for the imaging exam to be deemed "appropriate" as depicted in the following graphic.



Dimensions of an evidence strategy.

Evidentiary review procedure

Intermountain's evidentiary review process uses the concepts described above to determine whether the use of an imaging test is adequately supported by medical evidence. Although clerical and administrative staff resources are used to compile and organize inputs, the development teams are charged to assess the quality, relevance, and to ultimately objectively determine the evidentiary support for the appropriate use of imaging by completing the following process steps.

- Step 1: Performance of a literature search by use of medical search engines, identifying references within key review articles, identifying reference sources from other published AUCs and imaging guidelines.
  - Every effort is made to assure that this search includes publications from the imaging literature and from the literature from the relevant clinical services.
  - Assure that evidence on harms has been included.
- Step 2: Collection of applicable internal Intermountain data. This can include both clinical data and financial data.
- Step 3: Identification of consensus statements of national professional medical societies. Search for recommendations from all relevant medical societies.
- Step 4: From the assembled evidence, identify key sources that are most relevant and that will be thoroughly reviewed.
- Step 5: For each key evidence source
  - Rate of evidence level using "The Oxford 2011 Levels of Evidence" methodology
  - Assign evidence source to the most relevant step(s) in imaging value chain and designate the Fryback & Thornbury level for the evidence source
- Step 6: Review the aggregated quality of evidence and Fryback & Thornbury levels of the key evidence sources. Determine the aggregate Fryback & Thornbury level of evidentiary support for the use of imaging.
- Step 6: Determine the required level of Fryback & Thornbury efficacy required to confirm appropriateness of imaging by
  - Applying the 3-point scale of grading for each of the 3 Gazelle pillars for the clinical context
  - Determining the required Fryback & Thornbury level using the Gazelle framework
- Step 7: Make a final assessment of the appropriateness of the imaging test use in the clinical context (appropriate, inappropriate).

Step 4: Build AUCs in most appropriate architecture

The development team develops AUC(s) sufficient to cover the entire Priority Clinical Area. AUCs sufficient to cover the required scope may be developed in one or a number of pieces using any of 3 AUC types. There are 3 types of Intermountain ***Proven Imaging*** AUCs (image order guideline, diagnostic CPM, comprehensive CPM). AUC types, description of architectures, applicable scopes, and examples are given in the following table.

AUC type	Architecture	Applicable Scope	Example
Image order Guideline	Specific clinical context (age, sex, reason for exam, etc.), exam code, appropriateness rating (y/n)	Well-defined clinical context, single imaging exam	AUC designating appropriateness of non-contrast head CT use in context of chronic recurrent but uncomplicated headaches in an adult.
Diagnostic CPM	Broad clinical context, algorithms leading to context refinement and linkage to one or more imaging exams.	Broad context with diagnostic end-points	Diagnostic CPM guiding clinician to choose appropriate imaging test for patient presenting to the ED with symptoms suspicious for pulmonary embolus.
Comprehensive CPM	Broad clinical context, algorithms leading to context refinement and linkage to one or more imaging exams. Downstream logic leading to therapeutic interventions.	Broad context with therapeutic and diagnostic end-points	Comprehensive standards for diagnosis and management of patients with low back pain.

In general, the architecture of the AUC(s) is defined up front in the project plan (step 1) but may be modified as the work of evidentiary review and AUC building proceeds. Results of evidentiary review form the foundation for building all 3 types of AUCs. CPM types also require significant attention to operational workflows and strategies for integration into clinical workflows and therefore require extensive vetting of flow diagrams and other content across multiple teams. Prototypes are developed, input is received, and models are revised as needed. Rigorous attention to the evidentiary base is maintained and assured by the development team as successive versions are advanced. The degree of design iteration and required testing and validation is determined by the complexity of the AUC (the number of provider types and provider settings impacted for example).

Where there is inadequate evidence for the use of imaging within a specific clinical context encompassed within the Priority Clinical Area, the gap is discretely identified and no AUC is produced. These gaps serve as opportunities for further research and data gathering.

Step 5: Testing and validation

AUCs are tested and validated using classical PDSA (plan-do-study-act) cycles or other similar methodology within a controlled clinical environment. Steps 4 and 5 are really iterative, with feedback from a testing/validation cycle being used in refinement and improvement of the AUC. After clinical and operational viability of the AUC is demonstrated in the controlled environment, Intermountain expands

implementation to a broader group of providers, ultimately resulting in enterprise-wide implementation and validation of the CPM.

Step 6: Publish AUC to public website including

AUCs that have been developed using this evidence-based methodology and validated clinical and operationally are approved by Imaging Services and Clinical Program leadership for publication to the ***Proven Imaging*** Website. This public-facing website includes the following information for each AUC published.

- AUC/CPM guideline
- Names, credentials, institutional affiliation, and a designation of disciplinary expertise of development team members
- Designation of Priority Clinical Areas
- Key evidence sources, evidentiary rank for each source, aggregated Fryback & Thornbury level, required Fryback & Thornbury level determined using the Gazelle framework
- Date AUC last reviewed
- Disclosure of parties external from Intermountain who participated in AUC development
- Designation whether AUC was derived from an AUC produced by another qPLE
- A unique identifier for the AUC that includes versioning information

Step 7: Annually review process

On an annual basis, Intermountain Imaging Services and associated Clinical Programs review published AUCs. In the event that new information is available that requires revision/updating of the AUC, the AUC is revised and as needed tested and validated. The degree of re-work is managed and Intermountain does not "build from scratch" every time new versioning is required. However, any revising of an AUC requires that the revisions be developed by a properly constituted multi-specialty team (step 2) and adhere to the same evidentiary rigor defined in step 3. AUCs that are updated are given a new unique identifier and published to the website (step 6).