



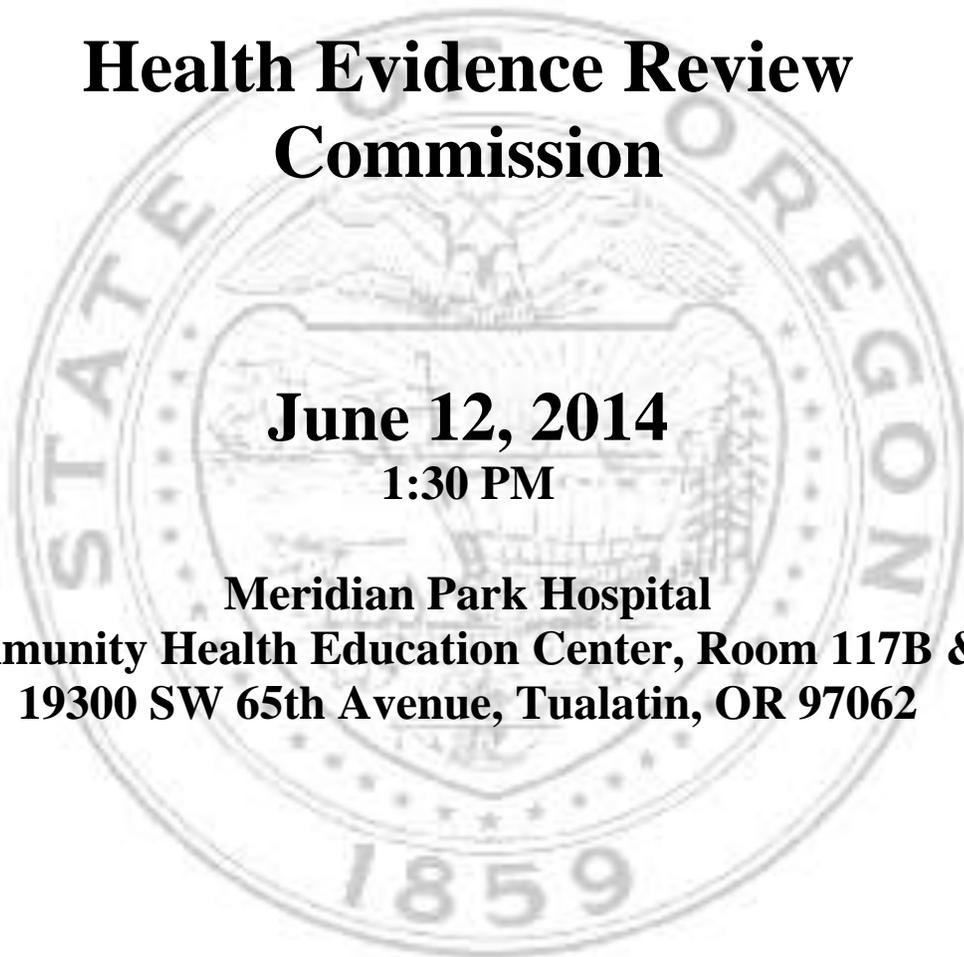
Health Evidence Review Commission

June 12, 2014

1:30 PM

Meridian Park Hospital

**Community Health Education Center, Room 117B & C
19300 SW 65th Avenue, Tualatin, OR 97062**



Section 1.0

Call to Order

AGENDA
HEALTH EVIDENCE REVIEW COMMISSION

Meridian Park Room 117B&C

June 12, 2014

1:30-4:30 pm

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to Order	Som Saha	
2	1:35 PM	Approval of Minutes (March 13, 2014)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1:45 PM	Health Technology Assessment Subcommittee Report 1) CGs for HERC approval · Use of DXA in screening for and monitoring of Osteoporosis	Wally Shaffer Alison Little	X
5	2:30 PM	Topic prioritization review and next topics	Cat Livingston	X
6	2.40 PM	Value-based Benefits Subcommittee Report	Lisa Dodson Ariel Smits Cat Livingston	X
7	3:15 PM	Preliminary findings on HERC assessment and process improvement project	Pam Curtis Valerie King	X
8	4:15 PM	Next Steps · Schedule next meeting – August 14, 2014 Meridian Park Room 117 B&C	Som Saha	
9	4:20 PM	Public Comment		
10	4:30 PM	Adjournment	Som Saha	

Minutes

HEALTH EVIDENCE REVIEW COMMISSION
Meridian Park Hospital
Community Health Education Center Room 117B&C
Tualatin, OR 97062
March 13, 2014

Members Present: Som Saha, MD, MPH, Chair; Lisa Dodson, MD; James Tyack, DMD; Beth Westbrook, PsyD; Vern Saboe, DC (teleconference, arrived at 2:15 pm); Irene Crowell, RPh; Mark Gibson; Gerald Ahmann, MD, PhD.

Members Absent: Susan Williams, MD; Leda Garside, RN, MBA; Wiley Chan, MD.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Wally Shaffer, MD; Jason Gingerich; Denise Taray, RN; Dorothy Allen-Peck.

Also Attending: Shannon Vandegriff, OHSU CeBP; Ron Stock, MD, OHA; Camille Kerr and Deirdre Monroe, Allergan; Jim Murray, Hill-Rom; Tom Jenkins, MD, Legacy Health; Bridget Kiene, American Cancer Society; Dr. E. Michael Lewiecki.

Call to Order

Som Saha, Chair of the Health Evidence Review Commission (HERC), called the meeting to order. Role was called.

Approval of Minutes

MOTION: To approve the minutes of the January 9, 2014 meeting as presented.
CARRIES 7-0 (Absent: Saboe).

Director's Report

New Staff:

Darren Coffman introduced new staff member, Denise Taray. Denise is a registered nurse with over 25-years clinical experience and has most recently been the DMAP liaison to HERC. She will act as lead staff to the Pain Management Commission and as an analyst for HERC with a primary focus on VbBS and the Prioritized List.

Pending Report:

The tentative May 8th meeting was postponed to June 12, when the Commissioners will have an opportunity to discuss and provide feedback to a preliminary the Center for Evidence-based Policy's report analyzing HERC's products and processes.

Commission Membership

The Commission has two vacancies for which we are recruiting for:

- Doctor of Osteopathy

- Consumer Representative

Subcommittee Membership

Coffman noted there appears to be an imbalance in the subcommittee structures with eight on VbBS (six Commissioners) nine on EbGS (five Commissioners), and four on HTAS (with only one Commissioner seated). Members should contact staff if they might consider a different subcommittee.

Coverage Guidance News

- IMRT and SBRT:
HTAS ceased their study of these two topics because the evidence base examined tumor types as opposed to the prevailing Medicare guidelines, which are based on proximity to organs.
- Injections for Cervical Pain:
HTAS would like to expand their investigation of this topic to include additional percutaneous cervical interventions such as radio frequency denervation, including medial branch block, for chronic neck pain, radicular pain of cervical origin and axial pain.

MOTION: To expand the cervical pain coverage guidance topic to include percutaneous cervical interventions. CARRIES 7-0 (Absent: Saboe).

Update on the OHA Transformation Center [Presentation](#)

Dr. Ron Stock gave an overview of the Oregon Transformation Center, OHA's hub for innovation and improvement. Highlights include:

- An overview of the Patient Protection & Accountable Care Act
- Health review efforts in Oregon
 - Coordinated care organizations (CCO)
 - Patient-Centered Primary Care Home (PCPCH)
 - Independence at Home Demonstration
 - Community-based Care Transitions Program
 - Grants, including the State Innovation Model (SIM) grant
- Innovation Center Aims
 - Test new payment and service delivery models
 - Evaluate results and advance best practice
 - Engage a broad range of stakeholders to develop new models
- Transformation Center Work
 - Innovator Agents
 - Community Advisory Councils
 - Learning Collaboratives/Experiences
 - § CCO incentive measures
 - § Complex Care Collaborative
 - PCPCH program support
 - Behavioral Health integration
 - Council of Clinical Innovators

At the conclusion of his presentation, Dr. Stock asked the Commission for their thoughts about collaboration opportunities. Coffman said one of HERC's goals is to support and help the CCOs through the transformation effort. This discussion dovetails with another review process underway, which, in part, is examining HERC's work products and what other tools, or *derivative products* (produced under the SIM grant), would be helpful.

One question to answer is how the Prioritized List fits in the world of CCOs and global budgeting. Staff members are fleshing out some ideas to present at another meeting.

Dr. Vern Saboe shared a time when complementary and alternative medicine (CAM) intersected with behavioral health within his PCPCH to help an individual with substance abuse issues to control their pain to the extent opioids were no longer needed. He asked if there were similar organizations in the state. Stock was unaware of that particular combination but mentioned there is a grant-funded project underway which uses mental health as a primary care home and reverse-integrates primary care.

Saha wondered if HERC's current process of defining what is "covered" or "not covered," both on the Prioritized List and the Coverage Guidances, is a bit antiquated. He expressed we should find out if the CCOs need something different from us.

Stock said the Transformation Center may be able to help by disseminating information through their learning network and rapid communication model. He also thought the HERC could play a role in the incentive metrics project, particularly by identifying what providers could do in the trenches to help "move the needle" towards the goals.

Health Technology Assessment Subcommittee (HTAS) Report
[Meeting materials, pages 93-131](#)

Use of Dual-energy X-ray Absorptiometry (DXA) in Screening for and Monitoring of Osteoporosis

Wally Shaffer presented the proposed coverage guidance from HTAS, including the following evidence summary:

- Bone measurement tests predict short-term risk for osteoporotic fractures (women and men)
- Most appropriate interval for screening unknown
- Repeat bone mineral density (BMD) measurement up to 8 yrs. after initial measurement does not significantly change fracture estimates
- For women with normal BMD, it takes approximately 17 years for 10% of women to transition to osteoporosis
- Drug therapies reduce risk for fractures (primary prevention) in postmenopausal women without previous osteoporotic fracture
 - Bisphosphonates, parathyroid hormone, raloxifene, and estrogen
- Potential harms of screening for osteoporosis
 - False-positive test results causing unnecessary treatment
 - False-negative test results

- Patient anxiety about positive test results
- Women aged 65+ yrs. and younger women with similar estimates of fracture risk
 - At least moderate benefit of treating screening-detected osteoporosis
 - Harms range from small to moderate
 - Net benefit of screening for osteoporosis is at least moderate
- Men without previous fractures
 - Inadequate evidence to assess effectiveness of drug therapies in reducing subsequent fracture rates

Shaffer added that the appointed expert recommended less restrictive coverage criteria based on guidelines, but HTAS rejected that recommendation due to insufficient evidence. He also reported that VbBS recommended adding a diagnostic guideline to the Prioritized List based on the draft coverage guidance.

Discussion:

Shaffer mentioned the numerous handouts on this topic. These letters are last minute public testimony letters sent mostly from the national osteoporosis organizations.

Dr. E. Michael Lewiecki, the appointed expert to HTAS, participated by phone. Dr. Lewiecki explained density testing is inexpensive and vastly under-utilized. He feels if the proposed guidelines go into effect, they would further limit the use of DXA and probably result in fewer patients being diagnosed with osteoporosis, fewer people treated appropriately and more people having fragility fractures. Ultimately, he asserted, this would cost the healthcare system more.

Lewiecki commented on two points of the proposed guidance:

- While there is wide-spread agreement that women over 65 should receive screening, using the U.S. Preventive Services Task Force criteria for others is just not useable in clinical practice. He challenged anyone to tell him what the fracture risk is for a 65-year-old white women with no additional risk factors.
- The recommendation of screening a woman with normal bone density no more than every 15 years is based on the Gourlay paper. This was a limited population study to test solely the rate of change in bone density that would be required to result in a diagnosis of osteoporosis. He asserted this study was never intended to be used for a guideline. In clinical practice, doctors estimate the probability of fracture. He asserts that 50% of hip fracture patients do not have a t-score in the osteoporosis range, but rather in the osteopenia range, when treatment should begin.

Saha confirmed his recollection that patients with osteopenia are not thought to be in the normal range. Shaffer said for those patients, screening would be more frequent, perhaps every two years. Lewiecki countered with the importance of following a patient who has some risk until it is the right time to begin treatment.

Ahmann asked if there are studies showing that treating patients with osteopenia result in reduced risk of fracture. Lewiecki offered there are studies where FRAX is used to identify at-risk patients that show pharmacological therapy is reducing the risk.

Saha asked if the results were normal, is the intent to wait 15 years for another scan. Shaffer explained a physician should look at all the risk factors and reuse the FRAX tool to determine if there is an increased risk. If so, DXA could be used more frequently. Saha remarked there is nothing in the coverage guidance document to indicate that practice, yet there is explicit

language to *not* retest sooner than 15 years. A 65-year-old white woman who had a t-score in the normal range would not be scanned for 15 years. As a woman ages, her t-score might decline. He posited the risk of hip fracture of women with a low score at 65 compared to one with a normal score at 65 but who declined to moderate osteopenia by age 72 would be very similar. Shaffer agreed it was possible, but countered the group of individuals who progress at a rapid rate is relatively rare.

Saha asked if treatment should begin at the osteopenia state, and inquired about the time horizon for decline from normal to osteopenia? Lewiecki asserted that osteopenia is not a recognized term by osteopath societies; the term was coined for the Gourlay study. What we really want to do is identify patients at high fracture risk using all the clinical tools we have.

Gibson posited if a t-score is normal at 65, should FRAX be used as the primary diagnostic tool during routine preventive care? Lewiecki countered that the best way to use FRAX is in combination with bone density testing. Shaffer confirmed. Gibson asked if that information is shown in evidence-based studies. Lewiecki replied yes, many studies, particularly from the World Health Organization.

Dodson asked Lewiecki to identify which group of women need more frequent screening. He stated there is no magic number and chastened the Commission for considering it. He argued for leaving screening decisions to the physician. Saha countered that philosophy is why the United States has the widest variation in the practice of health care and why we spend more money than any other country; we *must* set parameters.

Lewiecki mentioned another study, published in February, 2014, that modeled increased fracture risk over time and showed the doubling time for fracture risk was 5-6 years. Saha proposed we look into the modeling study. Lewiecki will send the study information to the Commission so staff may assess it. There is no need to return the topic to HTAS. The Commission will revisit this issue at the June 12, 2014 meeting.

Evidence-based Guidelines Subcommittee (EbGS) Report
[Meeting materials pages 133-221](#)

Prenatal Genetic Testing

Cat Livingston presented the proposed coverage guidance from EbGS, including the following evidence summary:

Routine Prenatal Care

Three good quality guidelines (generally consistent) recommend:

- General risk assessment
- Aneuploidy screening (including indications for karyotype)
- Screening options for
 - Hemoglobinopathies
 - Cystic fibrosis
 - Structural abnormalities
 - Tay Sachs disease

Specific Genetic Tests

- Generally no evidence in trusted sources
- Recommendations derived from guidelines of variable quality

Aneuploidy Testing

- Gold standard = Karyotyping (amniocentesis or chorionic villus sampling)
 - Invasive procedure, can result in pregnancy loss
 - Requires amniocyte culture (takes time)
- Four alternatives

Aneuploidy Testing – alternatives to karyotype

- Array CGH testing: identifies losses or duplications to genome (copy number variants)
 - Limited by difficulty determining whether copy number imbalance is likely causative or benign
 - Unable to detect balanced rearrangements
 - Detects approximately 5% additional genomic imbalances when conventional karyotyping is normal, if structural malformation on ultrasound
 - Not recommended for low risk pregnancies
 - Recommended when fetal structural abnormalities identified
- QF-PCR: amplifies markers on chromosomes of interest to determine number of copies
 - Advantages: amniocyte culture not required, fast turn around
 - Disadvantages: limited to identifying specific chromosomal abnormalities (number of copies of specific chromosomes)
 - No evidence identified
- FISH testing: similar to QF-PCR, allows detection of the number of specific chromosomes using fluorescent DNA probes
 - Advantages and disadvantages similar to QF-PCR
 - Unable to detect 7% to 11% of potentially harmful chromosome disorders
- Cell-free fetal DNA testing:
 - Isolates fetal DNA from maternal blood, detects excess of chromosome of interest
 - TA including 8 RCTs found
 - § Reduced invasive confirmatory procedures and associated miscarriages
 - § Improved number of detected cases of trisomy 21, compared to standard screening procedures in high-risk populations
 - Same limitations as QF-PCR, FISH
- QF-PCR, FISH testing, and cell-free fetal DNA testing:
 - Amniocyte culture not required
 - More rapid turnaround time
 - Less accurate/complete diagnosis
- Tay-Sachs disease – sufficient evidence to support:
 - Screening by Hex A enzyme testing for individuals at high risk (Ashkenazi Jewish, French-Canadian or with positive family history) or partners of known carriers
 - Additional DNA analysis in individuals with:
 - § Ambiguous Hex A test results
 - § Suspected variant form of TSD
 - § Suspected pseudodeficiency of Hex A
- Cystic fibrosis – sufficient evidence to support:
 - CF carrier screening if results will be used to inform decisions regarding childbearing or need for fetal diagnosis

- Fragile X Syndrome – 3 guidelines recommend carrier screening of women with:
 - A positive personal or family history of Fragile X-rated disorders
 - Unexplained mental retardation or premature ovarian failure
 - Prenatal fetal DNA testing for known carriers
- Heritable thrombophilia – evidence supports:
 - Not screening for heritable thrombophilia in any group
- Fetal skeletal dysplasia – guideline recommends:
 - Determining lethality based on ultrasound measurements
 - Molecular testing of at-risk pregnancies
- Spinal muscular atrophy – conflicting recommendations
 - Carrier screening for all couples vs. only for those with family history of SMA-like disease
- Ethnicities at increased genetic risk
 - 2 guidelines recommend screening those of Ashkenazi Jewish descent for:
 - Tay-Sachs disease
 - Canavan disease
 - Cystic fibrosis
 - Familial dysautonomia
 - Guidelines disagree about screening for 4 additional conditions

Livingston then proceeded to outline the deliberations of the subcommittees, which also considered expert input and public comment.

EbGS Deliberations

- Recommended coverage for genetic counseling only for women with certain risk factors
- Chose not to include coverage for CVS/Amniocentesis for the indication of ‘on maternal request’ as a weak recommendation
- Decided to recommend coverage for Cell-Free Fetal DNA testing for high risk pregnancies based on new evidence from trusted sources which was submitted during public comment
- Changed the recommendation for thrombophilia screening to clarify that it is not recommended for screening, or for women with a history of recurrent pregnancy loss
- Made no recommendation on QF-PCR as the test is not available in the United States
- In Array CGH testing when the karyotype is normal and there is a structural anomaly on ultrasound, the subcommittee decided to remove the recommendation for genetic counseling, as counseling would already have occurred before the CVS/amniocentesis. For Array CGH with stillbirth at >20 weeks gestation, the subcommittee decided to strike the recommendation, as none of the evidence reviewed supports its use in improving future pregnancy outcomes.
- Recommended coverage for spinal muscular atrophy only once in a lifetime with pretest genetic counseling
- Recommended coverage for carrier screening in the Ashkenazi Jewish population for only four conditions rather than eight

VbBS Deliberations

- Added procedures codes
- Allowed use of expanded panel for Ashkenazi Jewish population if lower cost than tests recommended for coverage
- Did not allow expanded carrier screening for other conditions because of concern about results including traits which are clinically irrelevant

Discussion

Tom Jenkins, MD, Director of Prenatal Diagnosis at the Legacy Center for Maternal-Fetal Medicine joined the discussion as an invited guest since this coverage guidance began development before ad hoc experts were being appointed.

Livingston stated there was a lot of public comment submitted. Deliberation led to recommending only women with certain risk factors have genetic counseling and that maternity doctors should be able to provide risk counseling for an otherwise healthy woman.

Livingston mentioned a February 2014 New England Journal of Medicine suggests cell-free DNA aneuploidy testing might be effective in low risk women but the consensus is that it is too soon to tell. Staff recommends waiting until the cyclical two-year review to consider this study.

Members discussed clause #1 of the proposed diagnostic guideline and decided to remove the phrase: "or elevated risk of aneuploidy based on screening as defined in items 5 and 6 below."

MOTION: To approve the proposed coverage guidance for Prenatal Genetic Testing as amended. Carries 8-0.

MOTION: To approve the proposed Prenatal Genetic Testing diagnostic guideline for the Prioritized List as amended. Carries 8-0.

Approved Coverage Guidance:

HERC COVERAGE GUIDANCE

The following are recommended for coverage (*weak recommendation*):

- Genetic counseling for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect
- Genetic counseling prior to consideration of CVS, amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- Validated questionnaire to assess genetic risk in all pregnant women
- Screening high risk ethnic groups for hemoglobinopathies
- Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency]
- Ultrasound for structural anomalies between 18 and 20 weeks gestation
- CVS or amniocentesis for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
- Array CGH when major fetal congenital anomalies apparent on imaging, and karyotype is normal
- FISH testing only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
- Screening for Tay-Sachs carrier status in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
- Screening for cystic fibrosis carrier status once in a lifetime

- Screening for fragile X status in patients with a personal or family history of
 - fragile X tremor/ataxia syndrome
 - premature ovarian failure
 - unexplained early onset intellectual disability
 - fragile X intellectual disability
 - unexplained autism through the pregnant woman's maternal line
- Screening for spinal muscular atrophy once in a lifetime
- Screening those with Ashkenazi Jewish heritage for Canavan disease, familial dysautonomia, Tay-Sachs carrier status and cystic fibrosis carrier status.
- Expanded carrier screening only for those genetic conditions identified above

The following are recommended for coverage (*strong recommendation*):

- Cell free fetal DNA testing for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening)

The following are not recommended for coverage (*weak recommendation*):

- Serum triple screen
- Screening for thrombophilia in general population or for recurrent pregnancy loss
- Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

Approved for OHP implementation:

DIAGNOSTIC GUIDELINE XXX, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women:

- 1) Genetic counseling (CPT 96040, HPCPS S0265) for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, elevated risk of neural tube defect.
- 2) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of CVS, amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- 3) Validated questionnaire to assess genetic risk in all pregnant women
- 4) Screening high risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
- 5) Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511)
- 6) Cell free fetal DNA testing (CPT 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
- 7) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
- 8) CVS or amniocentesis (CPT 59000, 59015) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
- 9) Array CGH (CPT 81228) when major fetal congenital anomalies apparent on imaging, and karyotype is normal
- 10) FISH testing (CPT 88271, 88275) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
- 11) Screening for Tay-Sachs carrier status (CPT 81255) in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
- 12) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
- 13) Screening for fragile X status (CPT 81243, 81244) in patients with a personal or family history of

- a. fragile X tremor/ataxia syndrome
 - b. premature ovarian failure
 - c. unexplained early onset intellectual disability
 - d. fragile X intellectual disability
 - e. unexplained autism through the pregnant woman's maternal line
- 14) Screening for spinal muscular atrophy (CPT 81401) once in a lifetime
 - 15) Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)
 - 16) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

- 1) Serum triple screen
- 2) Screening for thrombophilia in the general population or for recurrent pregnancy loss
- 3) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

Coverage Guidance Topics

[Meeting materials handout-1](#)

Livingston led the discussion about potential new topics, highlighting a new ranking matrix that may help guide topic selection. Scoring criteria includes disease burden, prevalence, uncertainty of efficacy/harm, public interest, relevant subgroup information available and degree of impact (ability to align care with recommendations). The last criterion score is a multiplier and the others additive. Topics scoring above 20 may be considered viable. Saha expressed his admiration for this work and would love to see it published.

The suggested topic of ablation for atrial fibrillation had a score of 30, while stenting for chronic angina had a total of 45. Saha questioned the "uncertain efficacy" score of 3, having read recent studies which may contradict that. Staff will verify that score with Dr. Eric Walsh, who suggested the topic.

Saha suggested conditional approval of Stenting for Chronic Angina pending confirmation that stakeholders are interested in this topic. Ablation for Atrial Fibrillation was approved for future potential development.

Value-based Benefits Subcommittee (VbBS) Report

[Meeting materials handout pages 41-91](#)

Ariel Smits, Cat Livingston and Lisa Dodson reported the VbBS met earlier in the day, March 13, 2014. Each helped to summarize a number of topics discussed.

The October 1, 2014 ICD-10 Prioritized List was finalized. There will be a coding freeze until 4/1/2015 because of the implementation of ICD-10 (changes approved at this meeting will be the last incorporated until the freeze ends). Staff will maintain a webpage listing known issues and the fixes proposed by staff and awaiting HERC consideration or those approved by HERC but awaiting inclusion on the list until after the coding freeze.

VbBS began discussion on:

- Treatment of autism
- Oral health risk assessments
- Transgender hormone therapy

Recommendations for interim changes, effective 10/1/14 include:

- Delete the procedure code for repair of webbed finger from 5 lines (remain on one covered line).
- Add screening for lung cancer among certain high-risk persons to the covered prevention services line with a diagnostic guideline.
- Add a dental risk assessment procedure code to the covered preventive services line with a new guideline.
- Add the procedure code for chemodenervation for migraine to the covered migraine line with a future guideline planned to specify when this procedure is covered.
- Edit the non-genetic testing guideline to specify the training/experience requirements for clinicians who can provide genetic counseling.
- Edit the prophylactic treatment for breast cancer among high risk women guideline to refer to the non-genetic testing guideline specifications for the type of clinician who can provide genetic counseling.

Recommendations for the 2016 biennial list include:

- Create a new line for fibromyalgia which will be located at approximately line 534, with a new guideline associated with the line regarding treatment.

MOTION: To accept the VbBS recommendations as stated. [See the VbBS minutes of 3/14/2014 for a full description. Carries: 7-0 \(Saboe absent\).](#)

Public Comment

There was no additional public comment at this time.

Adjournment

Meeting was adjourned at 4:35 pm. Next meeting will be from 1:30-4:30 pm on Thursday, June 12, 2014 at the Meridian Park Hospital Health Education Center in Conference Room 117 B&C.

Value-based Benefits Subcommittee Recommendations Summary For Presentation to: Health Evidence Review Commission in June 2014

For specific coding recommendations and guideline wording, please see the text of the 05/08/14 VbBS minutes.

CODE MOVEMENT

- A surgical code was added to the colon cancer line
- A surgical code was added to the vascular insufficiency of intestines line
- Open and closed hip fracture diagnoses were combined on the hip fracture line
- Transurethral prostatic implants were added for treatment of benign prostatic hypertrophy
- Multiple surgical codes were removed from the covered sleep apnea line

ITEMS CONSIDERED BUT NO CHANGES MADE

- The addition of cross-sex hormone therapy and sex reassignment surgery as treatments for gender dysphoria were discussed, but no decisions were made. This topic will be readdressed at the June 2014 meeting.
- The fluoride varnish guideline was reviewed but no changes made
- Electronic tumor treatment fields were not added for treatment of recurrent glioblastoma
- A new guideline regarding electroconvulsive therapy (ECT) was discussed, and will be further discussed at an upcoming meeting
- The structure of the low back pain lines was discussed, and will be readdressed at a future meeting
- Changes to the fluoride varnish guideline were discussed but no changes made

GUIDELINE CHANGES

- The rehabilitation guideline was extensively revised to reflect criteria for rehabilitation services rather than limits on the number of visits.
- The sleep apnea guideline was revised to further define daytime sleepiness and to specify that tonsillectomy/adenoidectomy surgical codes on that line are for treatment of children only.
- A new diagnostic guideline was added specifying that computer aided mammography (screening and diagnostic) is not a covered service

BIENNIAL REVIEW

- The diagnosis codes for injuries to the major blood vessels of the neck were moved from one covered line to a more appropriate covered line
- A new lymphedema line was created and prioritized into the covered region of the Prioritized List
- A new line for miscellaneous conditions requiring no treatment was created and prioritized to the last line on the Prioritized List
- The somatization and factitious disorder lines were merged and prioritized into the non-covered region of the Prioritized List

MINUTES

VALUE-BASED BENEFITS SUBCOMMITTEE

Clackamas Community College, Room 111-112
Wilsonville Training Center
29353 SW Town Center Loop E
Wilsonville, Oregon 97070

May 8, 2014

Members Present: Lisa Dodson, MD, Chair; Kevin Olson, MD, Vice-chair (left 1 PM); James Tyack, DMD; David Pollack, MD; Susan Williams, MD (arrived 8:50 AM); Mark Gibson (left 1:15 PM); Irene Crosswell, RPh; Laura Ocker, LAc.

Members Absent: None

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Denise Taray.

Also Attending: Jesse Little, OHA Actuarial Services Unit; Brian Nieubuurt, OHA; Danielle Askini, Peter Molof, Aubrey Harrison and Maura Roche, Basic Rights Oregon; Megan Bird, MD, Legacy Health Systems; Kathleen Klemann, FamilyCare; Bruce Boston, MD, OHSU; Shane Jackson, OR ABA; Brenna Legaard; Tobi Rates, Autism Society of Oregon; Susan Bamberger, Oregon Physical Therapy Association; Bridget Kiene, American Cancer Society; John Beckwith, PT, Sacred Heart Medical Center; Tim Baxter, Lane County Legal Aid.

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 8:35 am and roll was called. Minutes from the March 2014 VbBS meeting were reviewed and approved without changes.

MOTION: To approve the March 2014 VbBS minutes as presented. CARRIES 7-0 (Williams absent).

Action: HERC staff will post the approved minutes on the website as soon as possible.

Smits reported that ICD-10 implementation has been delayed until at least October 1, 2015 by CMS. The October 1, 2014 Prioritized List is in ICD-10 format. Staff has met with HERC leadership and decided to keep the previously adopted October 1, 2014 List and add the ICD-9 codes back to the lines, making the List "bilingual" with both ICD-9 and ICD-10 codes on each line. There was no objection or discussion about this plan.

Smits announced that Dr. Holly Jo Hodges from Trillium Healthcare will be joining the VbBS as the medical director/CCO representative beginning with the June, 2014 VbBS meeting. Dr. Lisa Dodson will be stepping down as Chair and resigning after the June,

2014 VbBS meeting due to a move to Wisconsin. Her service has been exemplary and her leadership will be sorely missed.

Note: All line numbers in these minutes reflect the understanding at the time of this meeting that they would go into effect on October 1, 2014 with the implementation of the new biennial list. At the June 12, 2014 meeting the subcommittee will discuss implementing the biennial list on January 1, 2015 instead, as there is no longer an need to tie it to implementation of the ICD-10-CM codeset on that date and a January 1 effective date would correspond to the contracting period for the Coordinated Care Organizations, as has been done in previous years.

Ø **Topic: Straightforward/Consent Agenda**

Discussion: There was no discussion.

MOTION: To approve the consent agenda as presented. CARRIES 8-0.

Actions:

- 1) Add 45397 (Laparoscopy, surgical; proctectomy, combined abdominoperineal pull-through procedure (eg, colo-anal anastomosis), with creation of colonic reservoir (eg, J-pouch), with diverting enterostomy, when performed) to line 161 Cancer of colon, rectum, small intestine and anus
- 2) Add 44310 (Ileostomy or jejunostomy, non-tube) to line 158 Vascular Insufficiency of Intestine
- 3) Lymphedema, NOS (I89.0) was moved from line 579 LYMPHEDEMA to line 427 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
- 4) I89.1 (Lymphangitis) was moved from 579 LYMPHEDEMA to 209 SUPERFICIAL ABSCESSSES AND CELLULITIS

Ø **Topic: Quality of Evidence Document**

Discussion: Livingston reviewed the documents on quality of evidence and criteria for topic reviewed for VbBS. The subcommittee approved the criteria for topic selection document without changes. On the Quality of Evidence Document, the subcommittee made a few wording changes to the document, clarifying that consistency as well as strength of evidence is important. See Appendix C for the revised text, with meeting edits shown in red text.

Actions: Approved two documents on:

- 1) Criteria for Topic Review (approved as it appeared in the meeting materials.)

2) Quality of Evidence Statement for the Prioritized List of Health Services.
(As shown in Appendix C)

Ø **Topic: Treatments for gender dysphoria**

Discussion: Smits reviewed the literature on the effectiveness and risks of cross-sex hormone therapy and sex reassignment surgery. Based on poor quality evidence, these treatments are effective at improving quality of life and reducing gender dysphoria symptoms. The high morbidity and mortality of gender dysphoria was reviewed, which includes increased deaths due to suicide, accidents, HIV infection, increase suicide attempts, and IV drug abuse.

Testimony was heard from Dr. Bruce Boston, pediatric endocrinologist at OHSU, from Dr. Megan Bird, OB/GYN at Legacy and Danielle Askini from Basic Rights Oregon. The high rate of suicide attempts (44%) among transgendered persons was noted. In a Belgian study, treatment of gender dysphoria with cross-sex hormones, surgery, or some combination, resulted in an 80% reduction in suicide attempts (from 30% to 5%). Transgender individuals also participate in other high risk activities, such as IV drug use, unprotected sex, etc. Hormone/surgical therapy have been found to reduce these risky behaviors as well. The experts testified that hormones and surgery are safe and effective treatments which are considered medically necessary by the American Congress of OB/GYNs, AAFP, APA, and AMA. When questioned about whether hormone treatment alone without surgical options is effective at reducing suicide attempts and other risky behavior, the experts testified that that was not known. All studies have been done on patients who had access to surgical options as well as hormone therapy. In their expert opinion, offering only cross-sex hormone therapy without surgical options would not be very helpful. Boston noted that transgendered young adults who have received appropriate treatment have been found to be better adjusted than age-matched controls. The experts offered to provide citations to HERC staff for the above referenced studies. Dr. Bird will provide HERC staff with the WPATH guidelines, which are proprietary.

Pollack raised concerns about patients with personality disorders and other psychological/psychiatric problems. He states that if surgical treatment of gender dysphoria is added to the Prioritized List, it must be accompanied by a strict guideline about evaluation and treatment of psychiatric co-morbidities. The experts noted that the major guideline in this area, from WPATH, requires psychological evaluation by both an MD/PhD level clinician and from a master's level clinician.

The subcommittee directed staff to work with experts to look at the mortality reduction (from suicide and risky behaviors such as IV drug use) resulting from treatment of gender dysphoria.

The experts noted to staff that some patients cannot take hormones due to medical contraindications. Any guideline should allow for surgical options without hormonal options due to this fact.

There was discussion about the expected costs of covering cross-sex hormone therapy. It is not known how many transgendered persons are in the Oregon Medicaid program or what the cost of treatments might be. There are also possible cost savings from avoiding suicide attempts, etc. The experts noted that Washington, California, Vermont, and DC Medicaid all cover cross-sex hormone therapy and sex reassignment surgery. The California Department of Insurance has done a study on the costs of this treatment in California and found a minimal increase in the costs to the Medicaid program once these therapies were covered. There is also a study from UCLA and data from San Francisco on costs of coverage. The experts will help HERC staff find this data.

The subcommittee asked the experts if there was a black market in cross-sex hormone therapy and were told that there was a considerable market in the Portland area. Such therapy is not medically supervised, not at recommended dosages, etc. Allowing coverage of cross-sex hormones would reduce this black market.

Livingston expressed concern about the possible costs of fertility preservation. The experts testified that there was very little interest among these patients in fertility preservation.

Actions:

- 1) HERC staff will work with experts to find data on harm reduction and on costs for addition of cross-sex hormone therapy and sex reassignment surgery.
- 2) Staff will mock up a separate line for hormone and surgery as treatments for gender dysphoria and suggest prioritization scoring for it. If the scoring results in a line close to the existing line for gender dysphoria (413), then these services will be proposed for addition to the existing line. If not close, the proposal will be to create a separate line on the biennial list tentatively scheduled for April 1, 2017.

Ø **Topic: Applied behavioral analysis for autism spectrum disorder**

Discussion: Livingston reviewed the summary document on ABA therapy for autism spectrum disorder. She noted that staff recently participated in a conference call during which they became aware of potential issues with the current draft due to federal parity rules for mental health care, and asked the subcommittee to defer discussion of the hour and duration limits until the next meeting.

Dr. Larsson, who served as one of three appointed ad hoc experts during the EbGS evaluation of evidence, reviewed the new procedure codes created for ABA. These are temporary codes approved for use after July 1. He said he wasn't sure they added anything over codes currently being used by private payers. He also commented that the hour limits in the draft evaluation are not based on his understanding of the evidence but more on Senate Bill 365 and other factors, as many of the studies included in the source report used more than 25 hours per week of intensive therapy. He also discussed his alternate proposals which have more of a focus on progress evaluation for continued coverage than on limitations on intensity and duration of treatment. Dodson then invited public comment. Tobi Rates testified first, as the executive director of the Autism Society of Oregon and parent of two children with autism. She expressed appreciation for the recommendations for coverage but also expressed concern about the limits of eight hours per month. She said for her 9 year old, 8 hours per month isn't enough to make a difference in quality of life. She said that EbGS didn't adequately consider the impact on healthy life, and mentioned that Dr. Larsson and Dr. Zuckerman (also an appointed expert) disagreed with the hour limits in the draft evaluation of evidence, and expressed concern about compliance with mental health parity laws. She would prefer to have coverage begin as soon as possible, even if it is with pre-existing codes. Brenna Legaard also offered comment. She is the mother of a six year old with autism, and said she had to sue an insurance company in order to get coverage, and argued that waiting for the temporary codes to be approved might delay implementation. She said that parents of children with autism are limited in their ability to have jobs due to care demands, and expressed support for more intensive treatment than the current draft recommendations so as to maximize the chance for parents to return to the workforce and participation in the community.

Shane Jackson, a lobbyist from Oregon Association for Behavior Analysis and the Autism Society of Oregon also spoke, saying that the age and hour limits are inconsistent and will cause problems in the future due to some plans having such limits and others that will not due to federal standards. He also said that he didn't believe that the impact of autism on the society and family as well of the individuals.

Coffman addressed the comments about timing of implementation due to coding changes. The language in Senate Bill 365 was based on an expected ICD-10 implementation on October 1, 2014. ICD-10 has been delayed one year, and staff is still assessing the impact of this delay, along with the new temporary codes. The advocates proposed code H2010 as an appropriate code for ABA. Coffman pointed out that this code does not really relate to ABA services. He said the temporary codes more accurately reflect ABA services and would lead to more appropriate reimbursement.

Olson asked whether there are studies about the impact of autism on families. Legaard stated that the evidence evaluation was focused on efficacy of treatment, but that she believes there are studies on the larger impact. Livingston said that the subcommittee included a rating of “low variability” in the values and preferences column of the GRADE table in the evidence evaluation because it assumed that families would want the therapy and that improvements in these behaviors would be important for families. Legaard said that advocates began to doubt that they were being heard because of the limit of 8 hours per month for older children seems inadequate for children with severe behavioral issues, and the single subject research design literature shows effectiveness for these therapies for many children.

Actions:

- 1) Staff will bring back revised recommendations, including recommendations on self-injurious behavior for children with self injurious behavior.

Ø **Topic: Rehabilitation therapies guideline**

Discussion: Smits reviewed the proposed new rehabilitation therapies guideline. The discussion mainly centered on making the guideline as simple and straightforward as possible. The OHP plans are not finding a need to have specific limits on the number of visits. Taray noted that the wording regarding the need for services, the qualifications of provider, and the need for medical review are very helpful for DMAP and mirror current OHP rules. The subcommittee decided to not specify visit limits and left in wording only specifying medical necessity and review. The line specifying unlimited visits during hospitalization/rehabilitation facility stays was thought to be unnecessary and removed.

Pulmonary rehabilitation was noted to not be included in this guideline. Staff was directed to review whether a guideline should be included regarding pulmonary rehabilitation.

MOTION: To approve the revised guideline as amended. CARRIES 8-0.

Actions:

- 1) The rehabilitation guideline was modified as shown in Appendix A

Ø **Topic: Guideline revision for treatment of sleep apnea**

Discussion: Livingston reviewed the summary of suggested changes for the treatment of sleep apnea line and guideline. The wording of “covered” was changed to “included on this line” in the guideline, and surgical codes which would be removed from the sleep apnea line to align with the guideline. After

brief discussion, the subcommittee approved the recommendation with slight wording changes to correctly indicate that surgery for sleep apnea is “not included on this line” rather than “not covered.”

MOTION: To approve coding changes and the guideline as amended. CARRIES 8-0.

Actions:

- 1) Remove from line 210 SLEEP APNEA AND NARCOLEPSY
 - a. 21193-21199, 21206-21215, 21230, 21235, 30117, 30140, 30520, 42140, 42145, 42160
- 2) Add to line 646
 - a. 21199
- 3) Advise DMAP to add to the Excluded List
 - a. 42140
- 4) Modify GN 27 as shown in Appendix A

Ø **Topic: Fluoride varnish guideline revision**

Discussion: Livingston introduced a summary document regarding suggested changes to the fluoride varnish guideline. The suggestion was to not allow primary care providers to apply fluoride varnish. Livingston reviewed the evidence that allowing PCPs to apply fluoride varnish reduces dental caries and increases referrals to dentists. Tyack said this is controversial among some dentists but agreed that fluoride varnish application in primary care homes should be covered.

Actions:

- 1) No changes made to the current guideline

Ø **Topic: Computer aided mammography**

Discussion: Livingston introduced the summary of evidence and recommendations for mammography with computer-aided detection (CAD). The subcommittee discussed adding 77051 (diagnostic mammography with CAD) to the Excluded List as well as 77052 (screening mammography with CAD) due to the lack of evidence of any benefit and the evidence of harm. The proposed diagnostic guideline note was changed to include both diagnostic and screening CAD mammograms and the wording “for breast cancer screening” was removed to reflect the VbBS desire to not cover CAD for any indication. There was some discussion about adding the CAD codes to the new section of the Prioritized List for items reviewed but not placed on the List; however, it was pointed out that the codes would be in the diagnostic guideline and therefore searchable and that the guidelines carried more weight than the new section due to their reference in statute.

MOTION: To approve the coding changes and the amended diagnostic guideline.
CARRIES 8-0.

Actions:

- 1) Recommend to DMAP to remove 77051 and 77052 from the Diagnostic File and place in the Excluded File
- 2) A new diagnostic guideline was added as shown in Appendix B

Ø **Topic: Electronic tumor treatment fields**

Discussion: Smits reviewed the summary document. The subcommittee agreed with creation of a new section of the Prioritized List for items reviewed but not included. This section will include those technologies or treatments with CPT or HCPCS codes that could be placed on one or more lines on the List, but which the commission does not find evidence of effectiveness or finds to be a much more costly alternative. The subcommittee did not agree on the proposed title for this section and recommended staff work on a more streamlined name and bring back to the June meeting to discuss.

The subcommittee agreed that electronic tumor treatment fields (ETTF) should not be added to the Prioritized List, but rather added to this new section of reviewed but not included items. There was discussion about how the entry for ETTF should be written. The decision was made to not include wording about ETTF being second line therapy as the VBBS did not want it included at all. Wording about coverage was changed to inclusion. HERC staff was directed to work on the final wording for this topic and bring back to the June meeting.

Actions:

- 1) Staff will bring back revised wording of the title for the new reviewed but not included on the List section to the June meeting
- 2) Staff will bring back revised wording on the entry for ETTF to the June meeting

Ø **Topic: Electroconvulsive therapy (ECT)**

Discussion: Smits reviewed the staff evidence review and recommendations regarding ECT. Pollack noted that Dr. George Keepers, a psychiatrist at OHSU who specializes in ECT, objected to the draft guideline. He requested that Dr. Keepers be approached to give input. Pollack also recommended looking at the American Psychiatric Association guidelines for ECT.

Actions:

- 1) Staff will work with Drs. Pollack and Keepers to revised the proposed guideline and seek APA or other guidelines for additional input. This topic will be readdressed at the June meeting.

Ø **Topic: Hip fractures**

Discussion: There was minimal discussion.

MOTION: To approve the changes to placement of hip fractures as presented.
CARRIES 8-0.

Actions:

- 1) Move open hip fracture ICD-9 and ICD-10 codes from line 136 to line 85
 - a. ICD-9 820.x (open fracture of neck of femur)
 - b. ICD-10 S72.0xxx (open fracture of head or neck of femur)
- 2) Remove hip fracture repair CPT codes from line 136
 - a. 27236 (Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement)
 - b. 27267 (Closed treatment of femoral fracture, proximal end, head; without manipulation)
 - c. 27268 (with manipulation)
- 3) Rename line 85 FRACTURE OF HIP, ~~CLOSED~~

Ø **Topic: Transurethral prostatic implants for benign prostatic hypertrophy**

Discussion: There was minimal discussion.

MOTION: To approve the placement of the new HCPCS codes as presented.
CARRIES 8-0.

Actions:

- 1) Add HCPCS C9739 (Cystourethroscopy with transprostatic implant; 1 to 3 implants) and C9740 (4 or more implants) to line 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

Ø **Topic: Lymphedema**

Discussion: Smits introduced the summary of a suggested reorganization and rescoring of the lymphedema line. The subcommittee was in agreement that the lymphedema diagnoses be combined on a line with scoring that would place it in the funded region.

The HSC placed the post-mastectomy lymphedema and other lymphedema codes on a line for complications of a procedure. The intention was to cover the lymphedema that resulted as a complication of a surgery, radiation, etc. Taray informed the subcommittee that DMAP is currently interpreting the placement on the complications line as requiring the lymphedema itself to have a complication, such as ulceration, to allow treatment. This is not HSC/HERC intent. HERC desires lymphedema treatment as a preventive service to avoid such complications.

John Beckwith, PT, testified about his experiences working with patients with lymphedema. He noted that many lymphedema patients have lymphedema that does not arise as a complication from surgery, chemotherapy, etc. He also advocated for covering treatment of patients with severe venous insufficiency to prevent ulceration, etc. Venous insufficiency not related to lymphedema is not currently covered.

The subcommittee heard that DMAP determines coverage of DME, as there are decisions about vendor, type of product, etc. which is too much detail for HERC to determine. Pollack requested that this information be placed on the HERC organizational chart.

The subcommittee reiterated that the HERC intends that lymphedema treatment should be covered when the lymphedema has not resulted in any complications such as ulcerations. The HERC intends that appropriate DME be covered for treatment of lymphedema, such as compression sleeves.

Actions:

- 1) HERC staff to evaluate adding a sentence about DME to the current lymphedema guideline
- 2) HERC staff to review possible coverage of some types of preventive treatment for venous insufficiency
- 3) Move the following ICD-9 codes to the lymphedema line and remove from all other lines as part of the current biennial review
 - a. 457.0 Postmastectomy lymphedema syndrome
 - b. 457.1 Other lymphedema
- 4) Move the following ICD-10 codes to the lymphedema line and remove from all other lines as part of the current biennial review
 - a. Postmastectomy lymphedema (I97.2)
 - b. Lymphedema, NOS (I89.0)
- 5) Move 457.1/I89.1 (lymphangitis) to line 214/209 SUPERFICIAL ABSCESSSES AND CELLULITIS and remove from line 598/579 as part of the current biennial review
- 6) Reprioritize the lymphedema line as shown below as part of the current biennial review

Line XXX
Condition: LYMPHEDEMA
Treatment: MEDICAL THERAPY, OTHER OPERATION ON LYMPH
CHANNEL
ICD-9: 457.0-457.9, 757.0
ICD-10: I89.0, I89.8, I89.9, Q82.0
CPT codes: same as current lymphedema line

Scoring

Category : 7
HL: 4
Suffering: 1
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 3
Need for service: 0.8
Net cost: 3
Score: 288
Approximate line placement: line 470

Ø **Topic: Somatization/factitious disorder line merge**

Discussion: Smits introduced a summary of the Behavioral Health Advisory Panel's (BHAP) recommendation to merge lines 462 FACTITIOUS DISORDERS and 497 SOMATIZATION DISORDER; SOMATOFORM PAIN DISORDER, CONVERSION DISORDER. BHAP had charged staff with devising proposed scoring for this new line. The subcommittee agreed with merging these lines, but had considerable debate on the scoring of this new line. It was noted that line 462 had been given a category score of "6" which includes fatal illnesses, which had resulted in its relatively high priority line placement. This condition is not fatal, and the appropriate category for the combined line is "7." Scores between 0.8 and 1.0 for "need for service" were proposed, with the final decision being 0.9. Net cost was given a 3, because correct treatment of these conditions involves only office visits and should have some cost savings due to reduced ER visits, testing, etc.

MOTION: To approve the new combined line as presented with amended scoring. CARRIES 8-0.

Actions:

- 1) Merge lines 462 FACTITIOUS DISORDERS and 497 SOMATIZATION DISORDER; SOMATOFORM PAIN DISORDER, CONVERSION DISORDER with line details and scoring as shown below

Line XXX

Condition: SOMATIC SYMPTOMS AND RELATED DISORDERS

Treatment: CONSULTATION

ICD-9: 300.16, 300.19, 300.7-300.9, 301.51, 306.x, 307.8x

ICD-10: F68.1x, F44.x, F45x, F52.5

CPT: from line 462 + 96150-96154

HCPCS: from line 497

Scoring

Category: 7

HL: 2

Suffering: 2

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 0

Effectiveness: 1

Need for service: 0.9

Net cost: 3

Score: 72

Approximate line placement: 556

Ø **Topic: Restructuring of low back pain lines**

Discussion: Smits introduced a summary document outlining a proposed change of the low back pain lines from distinguishing the two lines based on radiculopathy/neurologic symptoms to distinguishing them based on effective vs ineffective treatments. In general, the subcommittee liked the general idea of change to effective/ineffective treatments. However, there was discussion that effective treatments are a “moving target” and therefore would require a large amount of continuous review. There was also concern that some therapies may not be effective for a large population, but might be very effective for an individual.

Susan Bamburger, PT, past president of the OR PT association, gave testimony. She testified that most patients with radicular pain started with non-radicular pain, which was not adequately managed and therefore progressed to radicular pain. Treating the patient earlier in the course of the disease, before radicular symptoms or other complications develop, is more effective. She urged treatments to be chosen that are right for the individual patient rather than best in an RCT. She thought the lines should be distinguished based on signs and symptoms rather than cause of the pain.

Further discussion in the subcommittee included a discussion that surgical care is very much determined by neurological symptoms. Any change in how the List

is structured would have a significant financial impact based on changing surgical indications. Williams requested that the two spinal deformity lines be included in a review of the low back pain lines. Taray suggested also including the dysfunction lines in this review.

There was a sense that a larger review of the back pain lines should be done, and that such a review would take time. It is unlikely to be completed by August to be a part of the current biennial review. However, the new lines could be modifications of the existing lines and therefore be a non-biennial review change.

The subcommittee requested that staff create a task force to review the low back pain lines as well as the spinal deformity lines and come up with a proposal restructuring these lines. The dysfunction lines should be reviewed and some diagnoses and treatments moved to the back pain lines as well. This task force would be charged with determining how to determine when a diagnosis or treatment would be on the covered line. Task force membership should include a physical therapist, an acupuncturist or other alternative medicine practitioner, a spinal surgeon, a primary care provider, a member of the Oregon Pain Management Commission, physical medicine and rehabilitation, and other members as staffs sees fit.

Actions:

- 1) HERC staff will convene a taskforce on low back pain as outlined above

Ø **Topic: Miscellaneous Conditions with No or Minimally Effective Treatments or No Treatment Necessary**

Discussion: There was minimal discussion.

MOTION: To approve the new line as presented. CARRIES 8-0.

Actions:

- 1) Rename line 669 GASTROINTESTINAL CONDITIONS ~~AND OTHER MISCELLANEOUS CONDITIONS~~ WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
- 2) Create a new line for miscellaneous conditions with no treatment necessary or no effective treatment with scoring as shown below
 - a. Remove all included ICD-9 and ICD-10 diagnoses from their current lines
- 3) Move the following ICD-9 diagnoses from current lines to line 684 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
 - a. 256.0 (Hyperestrogenism), 272.6 (Lipodystrophy), 272.8 (Other disorders of lipid metabolism)

Line XXX

Condition: MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Treatment: EVALUATION

ICD-9: 744.5, 744.8x and 744.9, 748.1, 754.0, 994.5

ICD10: E66.3, E67.2, E67.8, Q18.3, Q18.4, Q18.5, Q18.6, Q18.7, Q18.8, Q18.9, Q30.x, Q67.x, T73.3

CPT: 98966-98969,99051,99060,99070,99078,99201-99215,99281-99285, 99341-99355,99358-99378,99381-99404,99408-99412,99429-99449, 99487-99496,99605-99607

HCPCS: G0396,G0397,G0463

Scoring

Category: 9

HL: 0

Suffering: 0

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 0

Effectiveness: 0

Need for service: 0

Net cost: 0

Score: 0

Line placement: 670 (last line of the list)

Ø Topic: Injuries to blood vessels of the neck

Discussion: There was discussion about whether a new line was needed for injuries to blood vessels of the neck. The subcommittee decided to add these diagnoses to the existing injury to major blood vessels of the extremities line and change the line title to include the neck. This was thought to be a simpler solution and the line priority appropriate for the seriousness of these injuries.

MOTION: To approve the movement of the injury to blood vessel in the neck codes to line 82. CARRIES 8-0.

Actions:

- 1) Move ICD-9 (900.xx) and ICD-10 (S15.xxx) codes for injuries to the blood vessels of the neck from Line 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME to line 82 INJURY TO MAJOR BLOOD VESSELS OF EXTREMITIES
- 2) Move the CPT codes for repair of neck vessels from line 135 to line 82
 - a. 35201 Repair blood vessel, direct; neck
 - b. 35231 Repair blood vessel with vein graft; neck

- c. 37615 Ligation, major artery (eg, post-traumatic, rupture); neck
 - d. 37565 Ligation, internal jugular vein
- 3) Rename line 82 INJURY TO MAJOR BLOOD VESSELS OF EXTREMITIES
[AND NECK](#)

Ø **Public Comment:**

No additional public comment was received.

Ø **Next Steps**

Issues for next meeting:

- Continued discussion of treatments for gender dysphoria:
 - Cross-sex hormone therapy
 - Sex reassignment surgery
- Continued discussion of ABA therapy for autism spectrum disorders
- Hearing loss issues
 - Biennial review deletion of audiant bone conductor for conductive hearing loss line
 - Unilateral hearing loss
 - Bone anchored hearing aids
- Physical therapy for urinary incontinence
- Electronic tumor treatment fields
- Electroconvulsive therapy (ECT) guideline
- Potential new guidelines on:
 - Treatment of hepatitis C
- Potential revisions to existing guidelines on:
 - Bariatric surgery (clarification)
 - Lymphedema
- Treatments for venous insufficiency
- Microwave thermoplasty for benign prostatic hypertrophy
- Physical therapy for urinary incontinence
- Pairing of diagnoses with osteopathic manipulation

Ø **Next meeting:**

June 12, 2014 at Meridian Park Hospital Health Education Center, Conference Room 117B&C in Tualatin, OR

Ø **Adjournment**

The meeting was adjourned at 1:40 pm.

Appendix A

Revised Guidelines

GUIDELINE NOTE 6, REHABILITATIVE THERAPIES

Lines 37,50-52,64,74-76,78,80,85,89,90,94,95,98-101,108,109,115,116,122,129,139,141-143,145,146,158,161,167,179,184,185,189,190,192,194,195,201,202,208,209,216,226,237,239,270,271,273,274,279,288,289,293,297,302,304,307-309,318,336,342,349,350,363,367,369,375,376,378,382,384,385,387,400,406,407,434,441,443,448,455,467,478,489,493,507,516,535,549,562,580,597,619,638

Physical, occupational and speech therapy, and cardiac and vascular rehabilitation are only included on these lines when the following criteria are met:

- 1) therapy is provided by a licensed physical therapist, occupational therapist, speech language pathologist, physician, or other practitioner licensed to provide physical, occupational, or speech therapy.
- 2) there is objective, measurable documentation of progress toward the therapy plan of care goals and objectives.
- 3) the therapy plan of care requires the skills of a therapist, and
- 4) the client and/or caregiver cannot be taught to carry out the therapy regimen independently.

~~Physical, occupational and speech therapy, and cardiac and vascular rehabilitation, are covered for diagnoses paired with the respective CPT codes, depending on medical appropriateness, for up to 3 months immediately following stabilization from an acute event.~~

~~Following the 3 month stabilization after an acute event, or, in the absence of an acute event, the following number of combined physical and occupational therapy visits are allowed per year, depending on medical appropriateness:~~

- ~~• Age < 8: 24~~
- ~~• Age 8-12: 12~~
- ~~• Age > 12: 2~~

~~And the following number of speech therapy visits are allowed per year, depending on medical appropriateness (with the exception of swallowing disorders, for which limits do not apply):~~

- ~~• Age < 8: 24~~
- ~~• Age 8-12: 12~~
- ~~• Age > 12: 2~~

~~Whenever there is a change in status, regardless of age, such as surgery, botox injection, rapid growth, an acute exacerbation or for evaluation/training for an assistive communication device, the following additional visits are allowed:~~

- ~~• 6 visits of speech therapy and/or~~
- ~~• 6 visits of physical or occupational therapy~~

Appendix A

~~No limits apply while in a skilled nursing facility for the primary purpose of rehabilitation, an inpatient hospital or an inpatient rehabilitation unit.~~

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA IN ADULTS

Line 210

CPAP is covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour; or if between 5 and 14 events with additional symptoms including one or more of the following:
 - excessive daytime sleepiness defined as either an Epworth Sleepiness Scale score >10 or daytime sleepiness interfering with ADLs that is not attributable to another modifiable sedating condition (e.g. narcotic dependence), or
 - documented hypertension, or
 - ischemic heart disease, or
 - history of stroke;
- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks is based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.

Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Tonsillectomy and adenoidectomy codes are included on this line only for children who meet criteria according to Guideline Note 118 OBSTRUCTIVE SLEEP APNEA DIAGNOSIS AND TREATMENT IN CHILDREN.

Appendix B
New Guidelines

DIAGNOSTIC GUIDELINE DXX COMPUTER-AIDED MAMMOGRAPHY

Computer-aided mammography (CPT code 77051 and 77052) is not a covered service.

DRAFT

Appendix C

Health Evidence Review Commission

Quality of Evidence Statement

HERC relies heavily on high quality evidence and evidence-based guidelines in making prioritization decisions.

The following source list illustrates how HERC and the Value-based Benefits Subcommittee (VbBS) view various types of evidence for prioritization decisions. The existence of evidence in the form of a high-quality study design does not necessarily mean that the overall evidence on that topic will be considered high quality. For instance, a high quality systematic review might find that the available studies have significant potential for bias and may conclude there is a low strength of evidence or insufficient evidence to support an intervention.

Lower quality evidence may sometimes be considered in situations where higher quality evidence is difficult to obtain (for example, in rare clinical conditions).

The commission **also** includes other factors into its decision making process, such as harms, treatment alternatives, health equity and the needs of specific subgroups when relevant data exists.

HERC may consider various factors in evaluating a particular study, including:

- Potential for bias
- Clinical significance of outcomes studied
- Strength **and consistency** of evidence, not just **study** quality
- Study relevance based on population and health system characteristics
- Conflicts of interests of the authors

The following sources generally produce high quality evidence and are preferred by HERC:

- Agency for Healthcare Research and Quality (AHRQ) <http://www.ahrq.gov/clinic/>
- Blue Cross Blue Shield Technology Evaluation Center (TEC) <http://www.bcbs.com/blueresources/tec/>
- British Medical Journal (BMJ) Clinical Evidence <http://www.clinicalevidence.com>
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA) <http://www.cadth.ca/index.php/en/hta>
- Cochrane Database of Systematic Reviews <http://www2.cochrane.org/reviews/>
- Evidence-Based Practice Centers (EPC) www.ahrq.gov/clinic/epc
- Health Technology Assessment Programme - United Kingdom <http://www.hta.nhsweb.nhs.uk/ProjectData>
- National Institute for Clinical Excellence (NICE) - United Kingdom <http://guidance.nice.org.uk/>
- Scottish Intercollegiate Guidelines Network (SIGN) <http://www.sign.ac.uk/guidelines/index.html>
- University of York <http://www.york.ac.uk/inst/crd/>

The following types of study designs can be considered high quality and are preferred by HERC:

- Systematic reviews of randomized controlled trials

Appendix C

- Systematic reviews of prospective cohort studies
- Evidence-based guidelines from trusted sources

The following types of study designs/documents can be considered lower quality and are often reviewed by HERC:

- Guidelines issued by professional societies and advocacy organizations (e.g. American Heart Association)
- Coverage decisions by private health plans (e.g. Aetna)
- Well-conducted, peer-reviewed individual studies (experimental or observational)

The following types of evidence can be considered very low quality and are seldom reviewed by HERC:

- Case reports, case series
- Unpublished studies (posters, abstracts, presentations, non-peer reviewed articles)
- Individual studies that are poorly conducted, do not appear in peer-reviewed journals, are inferior in design or quality to other relevant literature, or duplicate information in other materials under review by the Commission

DRAFT

MINUTES

Evidence-based Guidelines Subcommittee
Holiday Inn, Candlewood Room
25425 SW 95th Ave, Wilsonville, OR
March 20, 2014
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Beth Westbrook, PsyD; John Sattenspiel, MD, MPH; Som Saha, MD, MPH; Bob Joondeph, JD, Leda Garside, RN (by phone).

Members Absent: Steve Marks, MD, Vice-Chair; Vern Saboe, DC, MBA, Eric Stecker, MD, MPH.

Staff Present: Darren Coffman; Wally Shaffer, MD, MPH; Jason Gingerich.

Also Attending: Eric Larsson, PhD, LP, BCBA-D, Eric Fombonne, MD; Katharine Zuckerman, MD, MPH, FAACP; Alison Little, MD and Shannon Vandergriff (CEBP); Jenny Fischer and Shane Jackson (ORABA), Tobi Rates (Autism Society of Oregon), Jessie Little (OHA Actuarial Services).

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:00 pm.

2. MINUTES REVIEW

No changes were made to the November 7, 2013 minutes.
Minutes approved 5-0, Garside absent.

3. REVIEW OF PUBLIC COMMENTS

Topic: Applied Behavior Analysis (ABA) for Autism Spectrum Disorder

Darren Coffman provided a summary of the process to date and the status of the evaluation of evidence. He clarified some points about the process and how the Health Evidence Review Commission and its subcommittees evaluate evidence. In particular he explained how a single source of evidence may be of a type considered high quality (e.g., a systematic review), but can still be considered to provide poor evidence (e.g., the review only includes case series or randomized control trials showing no treatment effect). He also noted that the HERC and its subcommittees do not interpret law, as this is not the Commission's area of expertise. He clarified that this meeting is to review public comments and references submitted by experts and interested parties.

Livingston reviewed the changes (on page 37-38 of the meeting materials) made to the evidence evaluation since the November meeting, including a new draft update of the Warren report.

Little reviewed the public comments and related references, and how they were reviewed by staff. Many of the studies were single subject research designs (SSRD), but there were also systematic reviews and meta-analyses as well as other research designs and legal opinions and guidelines.

Livingston reviewed the public comment disposition document. Staff pulled together some of the comments related to issues which require decisions into a summary document to guide discussion.

The subcommittee discussed whether the age for coverage should include children below the age of two. Little said that the Warren update included several trials including children as young as 18 months, but did not break out results for patients younger than 24 months versus older. Larsson said that some techniques including the Early Start Denver Model are designed specifically for children at the younger ages. Zuckerman said that diagnosis at younger ages is no longer rare, and that established diagnostic tools now include modules for use with toddlers. Diagnosis at younger ages is, however, less reliable. The subcommittee discussed the concern that using treatments based on evidence for a different population can result in overtreatment. Yet there was also reluctance to set a coverage limit simply because a study had a specific age cutoff. After discussion, the subcommittee decided to recommend coverage of Early Intensive Behavior Intervention (EIBI)/comprehensive ABA for children aged 1-12 to allow for the treatment of younger children, as there was no evidence that treatment is less effective in this population.

Livingston asked for confirmation that the quality of evidence for EIBI interventions on cognitive and language skills should be upgraded to moderate based on the draft update to the Warren report. Members agreed that it should.

The subcommittee discussed whether SSRD designs should be included as evidence. After discussion, the group decided to review the summary provided by Little in the meeting materials. Livingston noted that the Warren criteria would have allowed inclusion of studies using at least 10 patients under a SSRD design, but that no studies were identified which met these criteria. Members found the evidence insufficient on the effectiveness of ABA in individuals over age 12, as the populations were in institutional and educational settings, and the subcommittee's concerns about reproducibility and publication bias could not adequately addressed. The subcommittee also determined that randomized controlled trials would be reasonable, as they have been conducted for other interventions (including drugs) in these populations. The subcommittee discussed inviting an SSRD methodology expert to discuss these studies, as current staff does not have this expertise. In the end however, the group agreed that it would work towards developing a recommendation including some limited coverage of focused ABA in children over 12 and adults based on values and preferences informed by expert opinion and clinical judgment.

The subcommittee also discussed the health disparities and equity issues that might result from a recommendation against coverage that goes against a state insurance mandate, especially since children from disadvantaged groups are vulnerable to

misdiagnosis and underdiagnosis and may face additional barriers accessing care. Coffman clarified that Senate Bill 365 only mandates coverage for children who initiate treatment before the age of 9, so the current draft recommendation would not create such inequities even if services are not available to OHP patients over the age of 12.

The subcommittee discussed the public comments which said that a randomized trial was not reasonable for ethical reasons. Larsson said that it is more difficult to do randomized studies for focused interventions as there are not standardized broad assessment skills for focused behaviors. Fombonne said that recruiting a homogenous group of patients in a single geographic area would be difficult. However, in light of testimony that randomized controlled trials for drugs for self injurious behavior as well as EIBI had occurred, the subcommittee concluded that such a study was reasonable.

The subcommittee discussed options for coverage language for the recommendation. Livingston said that the current draft language does not recommend coverage for children 13 and over. She also reviewed current coverage under the Oregon Health plan, which includes 8 hours per month for behavioral treatments (excluding ABA) for children with autism.

Livingston presented an option which would recommend coverage of focused ABA for children over the age of 12. One option would be to cover behavioral interventions including focused ABA for up to 8 hours per month. Saha asked about the reason for the 8 hour limit, and asked the experts about this limit. Fombonne said 8 hours makes sense. Larsson said that the research numbers are all over the map because of the individualization, and suggested that 8 hours would be reasonable for the behavior analyst's time doing treatment and the planning and supervision of other providers with less training. In Minnesota, they also provide 6 to 25 hours of behavioral services provided by personal care attendants. These assistants don't perform ABA and are paid little more than minimum wage but a behavioral analyst may be able to perform the analysis and train the parents and care team in 8 hours per month. However, he said there would be some cases where that would be inadequate and recommended base level of coverage for 8 hours per week of analyst time, which would be authorized with little scrutiny, with additional hours available if there is evidence in the behavior assessment that a higher level of analysis would be effective. He also presented another option, that 40 total hours of initial assessment and treatment planning by a trained professional (plus additional time by an assistant) might be covered without prior authorization. After that, analysis would be limited to 8 hours per month unless authorized.

Coffman noted that the Prioritized list contains a separate line for self-injurious behavior. So the List could include different parameters for self-injurious behaviors. Zuckerman asked whether a higher limit might also be needed for aggressive behaviors as well. Fombonne said that this could occur but that need for a higher limit would apply to a very tiny proportion of patients.

Livingston asked whether we need to have language about the evaluation hours versus treatment hours. Larsson said that evaluation and assessment are integral parts of the treatment. However in order to control costs, he recommends allowing a certain number of hours of services during which a payer would expect a more sophisticated evaluation. Based on that assessment there would be data to justify a request for additional treatment hours if they are needed. Livingston asked Sattenspiel whether this sort of

parameter would be helpful. He said it may be helpful but he's not sure how it would work in practice. Livingston proposed that each expert could submit suggested language in response to the language reviewed at the meeting. Then the various drafts could be reviewed at the next meeting. Subcommittee members agreed.

Chan asked about requiring an initial evaluation for EIBI for children 1-12. He asked whether coverage should require a 40-hour initial evaluation. Little said that there would be nothing in the literature to support this. Saha said that if ABA is an assessment as well as therapy, it may be like physical therapy, occupational and speech therapy where there is an acute phase and maintenance phase. Coffman said that the new CPT codes include separate codes for the initial evaluation and ongoing therapy. The subcommittee did not make a decision on whether to address evaluation.

Next steps: Staff and experts to collaborate to bring several options for coverage recommendations to the subcommittee at its next meeting.

5. PUBLIC COMMENT

Chan invited public comment. Jenny Fischer testified. She is a behavior analyst and owner of Cascade Behavioral Intervention, which serves children with autism and other conditions. She is also Policy Chair at the Oregon Association for Behavioral Analysis. She told the story of a man named Derek, who is now 21. He was diagnosed at the age of three with autism. He has had insurance for comprehensive ABA since the age of three. He made progress through the age of twelve, but he still had significant difficulties with aggression, elopement, self-injurious behavior, property destruction and compliance with medical treatment. He has not engaged in any of these behaviors in six years. She reported that he lives with his parents and does self care, is safe going out in the community and undergoes medical procedures without special assistance, despite the fact that his parents were once told he would likely require long-term care. She showed a SSRD for a different patient from 1997 as an example. It included the functional analysis of when the behaviors occur, a treatment plan and measurement of the behavior.

Shane Jackson also spoke. He is the registered lobbyist for the Autism Society of Oregon, Autism Speaks, and the Oregon Association of Behavioral Analysts. He read a letter from Tobi Rates, executive director of the Autism Society of Oregon. The letter requested coverage of ABA for patients over the age of 12 due to absence of evidence of harm from the treatment and the risks associated with the condition. The letter referenced the Guidance Development Framework and argued for a strong recommendation for coverage because of factors including that a trial would be unreasonable.

6. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for April 24, 2014 from 2:00-5:00 pm in Room 117B&C of the Meridian Park Hospital Community Health Education Center in Tualatin.

MINUTES

Evidence-based Guidelines Subcommittee
Oregon Dental Association
Conference Center
8699 SW Sun Place
Wilsonville, OR 97070
April 24, 2014
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Vice-Chair; Vern Saboe, DC; Beth Westbrook, PsyD; John Sattenspiel, MD, MPH; Bob Joondeph, JD; Eric Stecker, MD, MPH (participated by phone from approximately 3:15-4:30).

Members Absent: Steve Marks, MD; Leda Garside, RN, MBA; Som Saha, MD, MPH;

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Alison Little, MD (CEBP); Shannon Vandergriff (CEBP); Paul Terdal (Autism Speaks), Barbara Morrow (Astellas).

1. CALL TO ORDER

The meeting lacked a quorum until 2:30 p.m. Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:30 pm.

2. MINUTES REVIEW

No changes were made to the March 20, 2014 minutes.
Minutes approved 5-0 (Stecker not present).

3. EVALUATION OF EVIDENCE: APPLIED BEHAVIOR ANALYSIS (ABA) FOR AUTISM SPECTRUM DISORDERS

A) Update on ABA process and implementation

Coffman provided a review of the process to date and said that in order to meet the legislative timeline, the EbGS needs to approve the document today. Chan invited public testimony.

B) Public comment

Paul Terdal gave public testimony and also introduced Vera, who spoke about her experience with her son, who will soon be thirteen and who has an autism spectrum disorder and is covered under OHP. She said that her son has symptoms including insomnia, toe-walking, hair pulling and he is almost entirely nonverbal. She believes he

has feeling and thoughts but cannot express them. She is concerned about the proposed limits on therapy for children over the age of 12, because she is hoping that expanded coverage of ABA can make a difference for her son.

Terdal said that he appreciates the work of the subcommittee but disagrees with the subcommittee's choices about the sufficiency of evidence and reasonableness of a trial in the population of children over the age of 12. He referenced several studies referenced in the subcommittee's evidence sources which did include some children over 12. He said there is no evidence for decline of effectiveness by age. Changing either of these two factors would change the recommendation according to the HERC Guidance Development framework to a strong recommendation for coverage. He also referenced legal decisions about the reasonableness of a trial. He said that Vera's child would not be here to day if he had received therapy, either because ABA had been effective or because it hadn't and he had sought other treatments.

C) Discussion and approval of modified Evidence Review to send to VbBS/HERC

Livingston reviewed the changes since the last meeting, as described in the [meeting materials](#) on page 12 of the PDF document. During the discussion, the group asked that the remaining references to the age range of 2 to 12 be changed to 1 to 12 per the discussion at the subcommittee's previous meeting. In addition, the group decided to use the proposed new pathway in the coverage guidance development framework for ABA treatments for children aged 1 to 12, including EIBI and other less intensive interventions, though the recommendation is still a strong recommendation for coverage. In addition, the group decided to change the language in the GRADE-informed framework from "Comprehensive ABA" to Early Intensive Behavioral Interventions.

For adolescents and young adults, the group made no changes to the guidance development framework, though Joondeph expressed concern that the cutoff was arbitrary. Sattenspiel said that without evidence of global benefit for the broader therapy, the limited coverage shown in this draft makes sense for older children. Westbrook said she also struggles with how it may feel unfair, but said we need to be consistent with how we've treated the evidence in other reviews. Chan noted that in medicine, similar decisions are frequently made based on inclusion criteria for studies. For instance, the use of statins is not well-studied in patients over the age of 75. Joondeph said that he finds the single-subject research design studies submitted by members of the public compelling, even if they do not meet the Commission's normal criteria for sufficient evidence. Westbrook noted, however, that many of these studies used different populations, including people without autism spectrum disorders, and that SSRDs are subject to bias.

After more discussion the group decided to ask Livingston to add language reflecting the subcommittee's differing opinions about the evidence for older individuals.

The group then moved on to discuss the summary conclusions. Though there is no good evidence on which to base decisions about limits on the number of hours, the group decided to use a maximum intensity of 25 hours per week for a maximum of 3 years, using the rationales from the meeting materials.

Larsson expressed concern that these numbers were based on averages and may not accommodate the needs of some patients. His recommendation for coverage for EIBI,

submitted with the packet materials, recommended an average of 20 hours of behavior technician time and an average of 7 hours of behavior analyst services for a maximum of 3 years. Joondeph said that setting a limit based on the average from studies didn't make sense to him. Livingston explained that the evidence included studies with various intensities, above and below 25 hours, and that we lack evidence that the more intensive interventions are more effective. The 25 hour limit would be the same as commercial payers. She said she sees no evidence against a 25 hour limit and does see some reasons to support it. Westbrook asked for clarifications about the exceptions and appeals processes, and Sattenspiel explained that CCOs are required to allow for exceptional circumstances, but are not reimbursed for providing those services. If CCOs deny coverage, patients have the right to appeal the decision.

After reviewing an emailed comment provided by Dr. Fombonne, an appointed expert for this review, the group decided to change the references to "comprehensive ABA" to reference EIBI and clarify that the UCLA Lovaas and ESDM models referenced are examples. The listed standardized assessments are also examples.

The group also discussed the language for less intensive ABA-based interventions, which has been added to the draft. The subcommittee changed the recommendation for duration to allow for an initial six months of coverage, with ongoing coverage based on demonstrated progress towards meaningful predefined objectives or the emergence of new problem behaviors.

For individuals 13 and older the subcommittee clarified the rationale regarding the need for meaningful progress towards predefined goals and changed the phrase "medical necessity" to "medical appropriateness." In addition, the group clarified that coverage for training of parents and other caregivers is appropriate.

The group also made changes to the duration and frequency after broad agreement that reauthorizations more often than every six months don't make sense, as assessment and post-treatment evaluation would take up some of the time.

After further discussion, the group voted to approve the draft evaluation of evidence as modified during the meeting and with additional language by Livingston to reflect disagreement among subcommittee members about strength of evidence in children over the age of 12. **Motion approved 5-0** (Stecker absent)

4. REVIEW OF NEW DRAFT COVERAGE GUIDANCES ON NUCLEAR CARDIAC IMAGING

Discussion deferred to the next meeting as there was no time to discuss the topic.

5. PUBLIC COMMENT

Chan invited additional public comment, but no one chose to testify.

6. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for June 5, 2014 from 2:00-5:00pm in Room 117B/C of the Meridian Park Hospital Community Health Education Center in Tualatin.

DRAFT

MINUTES

Health Technology Assessment Subcommittee
Meridian Park Community Health Education Center
19300 SW 65th Avenue, Tualatin, OR
April 28, 2014
1:00-4:00pm

Members Present: James MacKay, MD, Vice-Chair; Gerald Ahmann, MD, PhD; George Waldmann, MD

Members Absent: Timothy Keenen, MD

Staff Present: Darren Coffman; Wally Shaffer, MD, MPH; Jason Gingerich, Rae Seltzer, (Preventive Medicine resident at OHSU)

Also Attending: Alison Little, MD (CEBP); Shannon Vandegriff (CEBP); Alejandro Perez, MD (Providence); Ann Demaree (Oregon Biotech); Enoch Huang, MD (Adventist Medical Center); Bridget Kiene (American Cancer Society); David Sibell (OHSU), MD; Noshad Rahimi (PSU); Liliya Hogaboam (PSU).

1. CALL TO ORDER

Jim MacKay, chair pro tem, called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:00 pm.

2. MINUTES REVIEW/STAFF REPORT

No changes were made to the draft February, 2014 minutes.

Minutes approved 3-0.

Coffman announced that Dr. Muday has resigned from the subcommittee and the group discussed potential new members. Coffman said that the group does need new members, but that because of the process review currently underway at HERC, the subcommittee structure may be changing in the coming months, and this may impact selection of new members.

3. DRAFT COVERAGE GUIDANCES

A) Percutaneous interventions for cervical spine pain

Seltzer reviewed the coverage guidance and the additional sources reviewed at the subcommittee's request, along with the updated recommendations, which recommend coverage for interlaminar injections for some patients, but do not recommend transforaminal injections due to safety concerns. In addition she reviewed other payer policies from the Washington HTA project and Medicare, which specify indications and

limitations for coverage for neck injections and ablation and appear as appendices in the updated draft.

Seltzer reviewed the changes. The GRADE table has a new rationale column, and column header titles were changed to more accurately reflect the contents. The Epidural Steroids row and Radiofrequency Neurotomy rows were changed to weak recommendations for coverage with certain conditions. The recommendations are based on other policies, supplemental sources and expert input.

Waldmann asked whether (in the epidural steroid injection section) the pain should be consistent with the dermatomal distribution of the herniated disk (that is, the pain is in the part of the body associated with nerves which exit the spine near the affected disk). Sibell said that the guidance refers to neck pain, but should really be upper extremity pain. In addition he said that pain usually follows this distribution but sometimes people have two problems, such as shoulder injuries resulting in pain in additional areas. In addition some people have slightly different dermatomal distributions than the averages used in medical charts, or two nonconsecutive herniated discs resulting in pain in two locations. The group agreed to change the coverage guidance to reference chronic cervical pain with radiculopathy. The subcommittee agreed not to require objective findings but to require that the pain correspond to a dermatomal distribution, though plans such as the Oregon Health Plan may require neurologic deficit. Seltzer noted that neurologic deficit was among the exclusion criteria for one of the studies.

Sibell asked for one additional correction. He said that there are three types of radiofrequency denervation, standard, pulsed and cooled. Seltzer agreed to correct this. He also wanted to ensure that coverage for RF neurotomy would include the coverage of diagnostic medial branch blocks, since therapeutic medial branch blocks are not recommended for coverage. Shaffer suggested clarifying that only “therapeutic” medial branch blocks were not recommended for coverage. The group agreed that diagnostic medial branch blocks would need to be covered as a part of the workup prior to RF neurotomy.

Shaffer raised an additional suggestion, requiring two different local anesthetic agents be used for the two diagnostic medial branch block injections, as per the Institute for Clinical Systems Improvement guideline. Sibell agreed this would be the most evidence-based way to proceed. On Sibell’s advice, the group agreed to require that the agents used be commonly-used agents with different anticipated durations of action.

Waldmann asked Sibell about a patient with a herniated disc and documented neurologic deficit. A pain center might want to try an injection. He wonders if it would be better to send the patient straight to surgery. Sibell agreed in the case of a patient with documented weakness. Still, Sibell said he can’t predict whether surgeons want to operate. He said this is a judgement call. After discussion the group did not require certain patients to be referred directly to surgery.

MacKay invited public comment but no one chose to testify.

A motion was made to approve the draft coverage guidance as modified and open it for public comment. **Motion approved 3-0.**

B) Topic: Indications for Hyperbaric Oxygen Therapy

Shaffer reviewed the changes to the draft coverage guidance made based on the additional resources provided by Dr. Huang.

For the indication of diabetic wound care, MacKay asked about adequate arterial blood supply. Shaffer said this is one of the criteria. Huang said there is a study which showed effectiveness in patients with vascular disease not amenable to surgery but they were able to document oxygenation using transcutaneous oximetry (using an electrode placed on the foot). Physicians can show response during hyperbaric treatment using oximetry before and during treatment, and at certain levels a response predicts that hyperbaric oxygen will benefit patients. After discussion the group decided to add language requiring arterial assessment before treatment. Huang advocated for immediate inpatient hyperbaric treatment after amputation but the subcommittee didn't add this language. Huang said there is only one study of this; most of the studies waited 30 days after amputation and did not show success. The group also discussed adding a requirement for glycemic control but on discussion did not add that, as waiting for glycemic control would delay urgently needed treatment.

For venous ulcers, surgical reconstruction without flaps and grafts, compromised flaps and grafts, and crush injuries there was no discussion. Shaffer noted that these decisions were consistent with Medicare and Washington HTA.

Huang acknowledged the low quality evidence for used in refractory osteomyelitis because of lack of randomized controlled trials, but said that it can be effective along with antibiotics and surgical therapy, according to the Undersea and Hyperbaric Medical Society (UHMS), and suggested that it might be covered when provided in conjunction with these other therapies. Seltzer asked about comparing surgical debridement and antibiotics with triple therapy. Huang and Perez mentioned studies showing arrest rates of 60 and 70 percent, which would imply that triple therapy has an advantage over surgery plus antibiotics. Subcommittee members requested that this information be provided during public comment period, if available, and left the recommendation unchanged[JDG1].

The group next discussed carbon monoxide poisoning. Huang read from the transcript of the Washington HTA meeting where the topic was specifically chosen not to be reviewed. Shaffer reviewed the evidence from the coverage guidance. Huang explained the issues surrounding treatment and said that the Weaver study is higher quality than the others, which were underdosed, not controlled or had too long of a delay before treatment. He said the second and third treatments are for sequelae for carbon monoxide poisoning including mitochondrial poisoning. MacKay suggested simply ignoring the topic and not making a recommendation. After discussion, the group agreed to be silent on carbon monoxide poisoning in terms of the recommendation, but to leave the information in the report for others who may benefit from the summary. Coffman noted that hyperbaric oxygen is covered for carbon monoxide poisoning on the Oregon Health Plan.

For acute traumatic brain injury, Shaffer said there is moderate quality evidence but of uncertain clinical significance. Though the risk of death was lower, many of the patients still ended up severely limited in function. Huang said UHMS doesn't recommend this, as it may leave more patients in a vegetative state despite the reduced risk of death. After

discussion the group agreed to recommend against coverage for both acute traumatic brain injuries and brain injuries other than acute traumatic brain injuries and updated the coverage guidance development framework.

For sensorineural hearing loss, Shaffer reviewed the updated draft. Huang said there was a statistically significant improvement for patients with acute sensorineural hearing loss, but the Cochrane source reports questioned the clinical significance. However, the degree of improvement reported by Cochrane would make hearing aids unnecessary. Huang said this is a new recommendation from the UHMS and there is still some controversy in the field. After brief discussion, subcommittee members left the recommendation against coverage unchanged but asked Little to further investigate the issue of clinical significance during the public comment period.

MacKay offered an opportunity for public comment but no one wished to testify.

A motion was made to approve the draft coverage guidance as written and open it for public comment. **Motion approved 3-0.**

6. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for July 28, 2014 from 1:00-4:00pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

Section 2.0

Previously Discussed Items

Coverage Guidance Prioritization Changes

Use of DXA in screening for and monitoring of osteoporosis

VbBS Recommendations (modified draft language for 6-12-2014 HERC):

1) Adopt a new diagnostic guideline

DIAGNOSTIC GUIDELINE XX OSTEOPOROSIS SCREENING AND MONITORING IN ADULTS

Osteoporosis screening by dual-energy X-ray absorptiometry (DXA) is covered only for women aged 65 or older, and for men or younger women whose fracture risk is equal to or greater than that of a 65 year old white woman who has no additional risk factors.

Fracture risk should be assessed by the World Health Organization's FRAX tool or similar instrument.

~~Repeat osteoporosis screening by DXA, for women with normal bone density, is not covered more frequently than once every fifteen years.~~

Routine osteoporosis screening by DXA is not covered for men.

The frequency of subsequent monitoring for development of osteoporosis should not be based on DXA scores alone. If rapid change in bone density is expected, more frequent DXA scanning is appropriate (for example, in patients taking glucocorticoids, those with a history of rapid weight loss, those with medical conditions that could result in secondary osteoporosis, etc.).

~~Unless~~ If there has been no significant change in ~~an~~ the individual's risk factors, ~~such that rapid changes in bone density are expected,~~ monitoring ~~of individuals with low bone density~~ by repeat DXA scanning is covered only at the following frequencies:

- once every two years for those with osteoporosis or advanced osteopenia (T-score of -2.00 or lower)
- once every four years for moderate osteopenia (T-score between -1.50 and -1.99)
- once every ~~fifteen~~ ten years for mild osteopenia (T-score between -1.01 and -1.49).
- once every fifteen years for those with normal bone density.

Repeat testing is only covered if the results will influence clinical management. For purposes of monitoring osteoporosis medication therapy, testing at intervals of less than two years is not covered.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: OSTEOPOROSIS SCREENING AND MONITORING BY DUAL-ENERGY X-RAY ABSORPTIOMETRY (DXA)

DRAFT for HERC meeting materials 6/12/2014

HERC COVERAGE GUIDANCE

Osteoporosis screening by dual-energy X-ray absorptiometry (DXA) is recommended for coverage only for women aged 65 or older, and for men or younger women whose fracture risk is equal to or greater than that of a 65 year old white woman who has no additional risk factors. Fracture risk should be assessed by the World Health Organization's FRAX tool or similar instrument (*strong recommendation*).

~~Repeat osteoporosis screening by DXA, for women with normal bone density, is not recommended for coverage more frequently than once every fifteen years (*weak recommendation*).~~

Routine osteoporosis screening by DXA is not recommended for coverage in men (*weak recommendation*).

The frequency of subsequent monitoring for development of osteoporosis should not be based on DXA scores alone. If rapid change in bone density is expected, more frequent DXA scanning is appropriate (for example, in patients taking glucocorticoids, those with a history of rapid weight loss, those with medical conditions that could result in secondary osteoporosis, etc.).

~~Unless~~ If there has been no significant change in ~~the~~ an individual's risk factors, such that rapid changes in bone density are expected, monitoring of individuals with low bone density by repeat DXA scanning is recommended for coverage (*weak recommendation*) only at the following frequencies:

- once every two years for those with osteoporosis or advanced osteopenia (T-score of -2.00 or lower)
- once every four years for moderate osteopenia (T-score between -1.50 and -1.99)
- ~~once every fifteen~~ ten years for mild osteopenia (T-score between -1.01 and -1.49).
- once every fifteen years for those with normal bone density

Repeat testing should only be covered if the results will influence clinical management. For purposes of monitoring osteoporosis medication therapy, testing at intervals of less than two years is not recommended for coverage (*weak recommendation*).

Note: Definitions for strength of recommendation are provided in Appendix A GRADE Element Description

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Trusted Sources

Gourlay, M.L., Fine, J.P., Preisser, J.S., May, R.C., Li, C., Lui, L., et al. (2012). Bone-density testing interval and transition to osteoporosis in older women. *New England Journal of Medicine*, 366(3), 225-233.

National Clinical Guideline Center. (2012). *Osteoporosis: Assessing the risk of fragility fracture*. London: National Clinical Guideline Center. Retrieved May 10, 2013, from <http://guidance.nice.org.uk/CG146/Guidance>

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The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

Additional Sources

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SUMMARY OF EVIDENCE

Clinical Background

Osteoporosis is characterized by low bone mineral density (BMD) and a resultant increased risk for fractures. It is estimated that as many as 1 in 2 women and 1 in 5 men are at risk for an osteoporosis-related fracture during their lifetime. Osteoporosis is more common in women than men and is more common in white persons than in any other racial group. For all demographic groups, the rates of osteoporosis increase with age. Elderly patients have increased susceptibility to fractures because they commonly have additional risk factors for fractures, such as poor bone quality and an increased tendency to fall. Hip fractures in particular can result in significant morbidity and mortality. Fractures at other sites also can lead to significant illness, causing chronic pain or disability and negatively affecting functional ability and quality of life. Direct medical care costs of osteoporotic fractures were estimated to be \$12.2 to \$17.9 billion per year in 2002 U.S. dollars; these estimates do not include indirect costs associated with lost productivity of patients and caregivers.

Many different risk assessment instruments have been developed to predict risk for low BMD or fractures. Multiple studies have validated these tools; however, few of these studies have included men. Despite various risk factors and variables included in the different risk assessment tools, none of the tools has consistently superior performance. The FRAX tool, developed by the World Health Organization and the National Osteoporosis Foundation, is one of the most widely used instruments to predict risk for fractures. This tool was derived from data on 9 cohorts in Europe, Canada, the United States, and Japan. Seven of these cohorts included men. The FRAX tool was validated in 11 cohorts, but only 1 of these cohorts included men. Because a large and diverse sample was used to develop and validate the FRAX tool and this instrument includes a publicly available risk calculator, the USPSTF used the FRAX tool to determine which individuals would exceed the baseline risk threshold for fractures on the basis of their age or other risk factors (such as low BMI, parental history of hip fracture, smoking status, and daily alcohol use). Considering a 65-year-old white woman who has no other risk factors to be the baseline risk case (a 10-year risk for any osteoporotic fracture of 9.3%), women as young as 50 years may have a 10-year risk for any

osteoporotic fracture of 9.3% or greater, depending on the type and number of risk factors present.

Bone mineral density (BMD) criteria were developed by the World Health Organization (WHO) from epidemiologic data that describe the normal distribution of BMD in a young healthy reference population. Osteoporosis is diagnosed when the BMD at the spine, hip, or wrist is 2.5 or more standard deviations (SD) below the reference mean. Low bone density or mass (sometimes referred to as osteopenia) is diagnosed when BMD is between 1.0–2.5 SD below the reference mean. The number of standard deviation units above or below the young healthy mean is called the T-score. Although intended for epidemiologic purposes, T-scores have been used as selection criteria for trials of therapies. They are now used to identify individuals with low BMD and to make treatment decisions.

Evidence Review

USPSTF

Detection

The USPSTF found convincing evidence that bone measurement tests predict short-term risk for osteoporotic fractures in women and men. The most commonly used tests are dual-energy x-ray absorptiometry (DXA) of the hip and lumbar spine and quantitative ultrasonography of the calcaneus. Adequate evidence indicates that clinical risk assessment instruments have only modest predictive value for low bone density or fractures.

Benefits of Detection and Early Intervention

No controlled studies have evaluated the effect of screening for osteoporosis on fracture rates or fracture related morbidity or mortality. In postmenopausal women who have no previous osteoporotic fractures, the USPSTF found convincing evidence that drug therapies reduce the risk for fractures. In women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors, the USPSTF judged that the benefit of treating screening-detected osteoporosis is at least moderate. Because of the lack of relevant studies, the USPSTF found inadequate evidence that drug therapies reduce the risk for fractures in men who have no previous osteoporotic fractures.

Accuracy of Screening Tests

DXA

Measurement of bone density using DXA has become the gold standard for the diagnosis of osteoporosis and for guiding decisions about which patients to treat. Although it is not a perfect predictor of fractures, DXA of the femoral neck is considered

the best predictor of hip fracture and is comparable with DXA measurements of the forearm for predicting fractures at other sites. Previous studies evaluating the accuracy of DXA for predicting fractures have focused mainly on women; studies have only recently assessed the predictive ability of DXA in men. A large prospective cohort study in the Netherlands that included men and women older than 55 years reported the incidence of vertebral and nonvertebral fractures approximately 6 years after baseline DXA measurements of the femoral neck were obtained. For each SD reduction in BMD at the femoral neck, the hazard ratio for vertebral and non-vertebral fractures increased to a similar degree in both men and women. Other studies of the performance of DXA in men have reported similar findings.

Quantitative Ultrasonography

The most commonly used test in the United States after DXA is quantitative ultrasonography (US) of the calcaneus. Quantitative US is less expensive than DXA, does not involve radiation, and can feasibly be implemented in primary care settings. Recent studies demonstrate that quantitative US of the calcaneus can predict fractures as effectively as DXA in postmenopausal women and in men. Quantitative US seems to be equivalent to DXA for predicting fractures and has other potential advantages, but also a few distinct disadvantages. The current diagnostic criteria for osteoporosis use DXA measurements as cutoffs, and the measurements obtained from quantitative US are not interchangeable with those obtained from DXA. Also, all trials evaluating drug therapies for osteoporosis use DXA measurements as inclusion criteria. Thus, for quantitative US to be relevant and clinically useful, a method for converting or adapting results of quantitative US to the DXA scale will need to be developed.

One meta-analysis examined 25 studies to assess the accuracy of quantitative US compared with DXA in identifying patients with osteoporosis. When various quantitative US index parameter cutoffs were used, the results varied widely in sensitivity and specificity for identifying individuals with a T-score of -2.5 or less on DXA. No quantitative US cutoff existed at which sensitivity and specificity were both high.

Frequency of Monitoring

The USPSTF did not make any specific recommendations regarding screening interval or frequency. The systematic review conducted to support the recommendation reported on only one study that addressed this question, a large good-quality prospective cohort study of 4,124 women age ≥ 65 years from the Study of Osteoporotic Fractures. This study found that repeating a BMD measurement up to 8 years after an initial measurement did not significantly change estimates for non-vertebral, hip, or vertebral fractures. No studies of screening intervals have been conducted in men or other groups of women.

Because of the limited evidence supporting frequency of monitoring, an additional search of the literature was undertaken from the end date of the Nelson review (December 2009). One study was identified that addressed frequency of monitoring (Gourlay et al. 2012). This NIH funded study evaluated women with normal or osteopenic BMD who were older than 66 years of age and had no history of hip or vertebral fracture. Osteopenia was categorized as mild (T-score -1.01 to -1.49), moderate (T-score -1.50 to -1.99) or advanced (T-score -2.0 to -2.49). They were followed prospectively for 15 years and the BMD testing interval, defined as the estimated time for 10% of women to make the transition to osteoporosis, was calculated. The estimated BMD testing interval was 16.8 years (95% CI, 11.5 to 24.6) for women with normal BMD, 17.3 years (95% CI, 13.9 to 21.5) for women with mild osteopenia, 4.7 years (95% CI, 4.2 to 5.2) for women with moderate osteopenia, and 1.1 years (95% CI, 1.0 to 1.3) for women with advanced osteopenia.

Effectiveness of Early Detection and Treatment

No controlled studies have evaluated the effect of screening for osteoporosis on rates of fractures or fracture related morbidity or mortality. Drug therapies for osteoporosis can be for primary prevention (prevention of an osteoporotic fracture in patients with low BMD who have no previous fractures) or secondary prevention (prevention of an osteoporotic fracture in patients who have a known previous osteoporotic fracture). Primary prevention trials are more applicable to the screening population addressed in this recommendation. Drug therapies include bisphosphonates, parathyroid hormone, raloxifene, estrogen, and calcitonin. For primary prevention in postmenopausal women, bisphosphonates, parathyroid hormone, raloxifene, and estrogen have been shown to reduce vertebral fractures. The evidence is strongest and most consistent for bisphosphonates and raloxifene.

In a meta-analysis of 7 trials, the relative risk (RR) for vertebral fractures for bisphosphonates compared with placebo was 0.66 (95% CI, 0.50 to 0.89). Two large placebo controlled trials of raloxifene reported reduced vertebral fractures, with a combined RR for raloxifene of 0.61 compared with placebo (CI, 0.55 to 0.69). A pooled analysis of 9 trials demonstrated a non-statistically significant trend toward a reduction in non-vertebral fractures with bisphosphonates compared with placebo (RR, 0.83 [CI, 0.64 to 1.08]). In the largest trial of bisphosphonates, the Fracture Intervention Trial of alendronate, fractures were significantly reduced only in women with baseline femoral neck T-scores less than -2.5. Evidence of the effectiveness of treatment of osteoporosis in men is limited. There are no primary prevention trials of bisphosphonates in men and only 2 secondary prevention trials of alendronate. When the 2 trials were pooled, alendronate was associated with a reduced risk for vertebral fractures (odds ratio [OR], 0.35 [CI, 0.17 to 0.77]), and the effect on non-vertebral fractures was not statistically

significant (OR, 0.73 [CI, 0.32 to 1.67]). A single primary prevention trial of parathyroid hormone in men reported a non-statistically significant trend toward a reduction in vertebral and non-vertebral fractures. None of the other therapies for osteoporosis in men has been evaluated in randomized trials.

Potential Harms of Screening and Treatment

Potential harms of screening for osteoporosis include false-positive test results causing unnecessary treatment, false-negative test results, and patient anxiety about positive test results. No studies that addressed the potential harms of screening were identified during this review. The harms of drug therapy for osteoporosis have been studied most extensively for bisphosphonates, raloxifene, and estrogen. For bisphosphonates, the evidence demonstrates no definitive increase in the risk for serious gastrointestinal adverse events (for example, perforations, ulcers, bleeding, esophagitis, or esophageal ulceration) in persons who use these medications appropriately. The evidence on the risk for atrial fibrillation with bisphosphonates is conflicting. One large case-control study in Denmark showed an increased risk for atrial fibrillation with any use of alendronate compared with no use of this agent (OR, 1.86 [CI, 1.09 to 3.15]), but a smaller case-control study in Washington showed no increased risk for atrial fibrillation with any use of etidronate (RR, 0.95 [CI, 0.84 to 1.07]) or any use of alendronate (RR, 1.04 [CI, 0.90 to 1.21]) compared with no use of either agent.

Osteonecrosis of the jaw has been associated with bisphosphonates in case reports, but this condition typically develops in patients with cancer who receive higher doses than those normally used for osteoporosis treatment or prevention. Case reports also have described severe musculoskeletal symptoms associated with all of the bisphosphonates. In October 2010, the U.S. Food and Drug Administration issued a warning about a possible elevated risk for midfemur fractures in patients receiving bisphosphonates, especially for patients who have received them for more than 5 years.

Raloxifene and estrogen are associated with higher rates of thromboembolic events than placebo. Estrogen increases the risk for stroke, and estrogen with progestin increases the risk for coronary heart disease and breast cancer. Evidence is limited on the harms associated with use of calcitonin and parathyroid hormone for osteoporosis.

Overall, the USPSTF found no new studies that described harms of screening for osteoporosis in men or women. Screening with DXA is associated with opportunity costs (time and effort required by patients and the health care system). Harms of drug therapies for osteoporosis depend on the specific medication used. The USPSTF found adequate evidence that the harms of bisphosphonates, the most commonly prescribed therapies, are no greater than small. Convincing evidence indicates that the harms of estrogen and selective estrogen receptor modulators are small to moderate.

Estimate of Magnitude of Net Benefit

The USPSTF found convincing evidence that drug therapies reduce subsequent fracture rates in postmenopausal women. For women aged 65 years or older and younger women who have similar estimates of fracture risk, the benefit of treating screening-detected osteoporosis is at least moderate. The harms of treatment were found to range from no greater than small for bisphosphonates and parathyroid hormone to small to moderate for raloxifene and estrogen. Therefore, the USPSTF concludes with moderate certainty that the net benefit of screening for osteoporosis in this group of women is at least moderate. For men, the USPSTF concludes that evidence is inadequate to assess the effectiveness of drug therapies in reducing subsequent fracture rates in men who have no previous fractures. Treatments that have been proven effective in women cannot necessarily be presumed to have similar effectiveness in men. Thus, the USPSTF could not assess the balance of benefits and harms of screening for osteoporosis in men.

Overall USPSTF Assessment

The USPSTF concludes that for women aged 65 years or older and younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors, there is moderate certainty that the net benefit of screening for osteoporosis by using DXA is at least moderate. The USPSTF concludes that for men, evidence of the benefits of screening for osteoporosis is lacking and the balance of benefits and harms cannot be determined.

[\[Evidence Source\]](#)

NICE GUIDELINE

The NICE guideline makes the follow recommendations pertaining to assessing the risk of fragility fractures:

Targeting risk assessment

1. Consider assessment of fracture risk:

- in all women aged 65 years and over and all men aged 75 years and over
- in women aged under 65 years and men aged under 75 years in the presence of risk factors, for example:
 - previous fragility fracture,
 - current use or frequent recent use of oral or systemic glucocorticoids,
 - history of falls,
 - family history of hip fracture,

- other causes of secondary osteoporosis¹,
- low body mass index (BMI) (less than 18.5 kg/m²),
- smoking,
- alcohol intake of more than 14 units per week for women and more than 21 units per week for men.

2. Do not routinely assess fracture risk in people aged under 50 years unless they have major risk factors (for example, current or frequent recent use of oral or systemic glucocorticoids, untreated premature menopause or previous fragility fracture), because they are unlikely to be at high risk.

3. Estimate absolute risk when assessing risk of fracture (for example, the predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage).

4. Use either FRAX² (without a bone mineral density [BMD] value, if a dual-energy X-ray absorptiometry [DXA] scan has not previously been undertaken) or QFracture³, within their allowed age ranges, to estimate 10-year predicted absolute fracture risk when assessing risk of fracture. Above the upper age limits defined by the tools, consider people to be at high risk.

5. Interpret the estimated absolute risk of fracture in people aged over 80 years with caution, because predicted 10-year fracture risk may underestimate their short-term fracture risk.

6. Do not routinely measure BMD to assess fracture risk without prior assessment using FRAX (without a BMD value) or QFracture.

7. Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD with DXA in people whose fracture risk is in the region of an

¹ Causes of secondary osteoporosis include endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatological (rheumatoid arthritis; other inflammatory arthropathies), haematological (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility (due for example to neurological injury or disease).

² FRAX, the WHO fracture risk assessment tool, is available from www.shef.ac.uk/FRAX. It can be used for people aged between 40 and 90 years, either with or without BMD values, as specified.

³ QFracture is available from www.qfracture.org. It can be used for people aged between 30 and 84 years. BMD values cannot be incorporated into the risk algorithm.

intervention threshold⁴ for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.

8. Consider measuring BMD with DXA before starting treatments that may have a rapid adverse effect on bone density (for example, sex hormone deprivation for treatment for breast or prostate cancer).

9. Measure BMD to assess fracture risk in people aged under 40 years who have a major risk factor, such as history of multiple fragility fracture, major osteoporotic fracture, or current or recent use of high-dose oral or systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer).

10. Consider recalculating fracture risk in the future:

- if the original calculated risk was in the region of the intervention threshold⁵ for a proposed treatment and only after a minimum of 2 years, or
- when there has been a change in the person's risk factors.

11. Take into account that risk assessment tools may underestimate fracture risk in certain circumstances, for example if a person:

- has a history of multiple fractures
- has had previous vertebral fracture(s)
- has a high alcohol intake
- is taking high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer)
- has other causes of secondary osteoporosis.⁶

⁴ An intervention threshold is the level of risk at which an intervention is recommended. People whose risk is in the region from just below to just above the threshold may be reclassified if BMD is added to assessment. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

⁵ An intervention threshold is the level of risk at which an intervention is recommended. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

⁶ Causes of secondary osteoporosis include: endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatological (rheumatoid arthritis; other inflammatory arthropathies), haematological (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility (due for example to neurological injury or disease).

12. Take into account that fracture risk can be affected by factors that may not be included in the risk tool, for example living in a care home or taking drugs that may impair bone metabolism (such as anti-convulsants, selective serotonin reuptake inhibitors, thiazolidinediones, proton pump inhibitors and anti-retroviral drugs).

[\[Evidence Source\]](#)

Evidence Summary

Bone measurement tests predict short-term risk for osteoporotic fractures in women and men. The most appropriate interval for screening has not been identified, but repeating a BMD measurement up to 8 years after an initial measurement does not significantly change fracture estimates, and transition to osteoporosis occurs for most women with normal BMD no sooner than 17 years. In postmenopausal women who have no previous osteoporotic fractures, drug therapies reduce the risk for fractures (primary prevention). Bisphosphonates, parathyroid hormone, raloxifene, and estrogen have all been shown to reduce vertebral fractures in this population. Potential harms of screening for osteoporosis include false-positive test results causing unnecessary treatment, false-negative test results, and patient anxiety about positive test results.

For women aged 65 years or older and younger women who have similar estimates of fracture risk, the benefit of treating screening-detected osteoporosis is at least moderate, while the harms range from small to moderate. Therefore, the net benefit of screening for osteoporosis in this group of women is at least moderate. For men, the evidence is inadequate to assess the effectiveness of drug therapies in reducing subsequent fracture rates in men who have no previous fractures.

GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource Allocation	Values and preferences	Coverage Recommendation
Screening for osteoporosis in women aged 65 or over, or with equivalent risks	Small to moderate net benefit	High	Moderately high on a population-wide basis, but with significant offsets if effective fracture prevention	Low variability (most people would prefer screening and fracture prevention)	Recommended for coverage (strong recommendation)
Screening for osteoporosis in men aged 70 or over	Unknown	Very low	Moderately high	Moderate variability (some would prefer availability of screening even if benefit not established)	Not recommended for coverage (weak recommendation)
Repeat DXA < 2 years for monitoring osteoporosis or advanced osteopenia	Likely no net benefit	Very low	Moderately significant cost associated with more frequent monitoring	Low variability	Not recommended for coverage (weak recommendation)

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource Allocation	Values and preferences	Coverage Recommendation
Repeat DXA < 4 years for monitoring moderate osteopenia	Likely no net benefit	Very low	Moderately significant cost associated with more frequent monitoring	Low variability	Not recommended for coverage (weak recommendation)
Repeat screening DXA < 15 years in women with normal BMD or mild osteopenia	Likely no net benefit	Very low	Moderately significant cost associated with more frequent monitoring	Low variability	Not recommended for coverage (weak recommendation)

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

Choosing Wisely[®] is part of a multi-year effort of the ABIM Foundation to help physicians be better stewards of finite health care resources. Originally conceived and piloted by the [National Physicians Alliance](#) through a [Putting the Charter into Practice grant](#), nine medical specialty organizations, along with Consumer Reports, have identified five tests or procedures commonly used in their field, whose necessity should be questioned and discussed. The American College of Rheumatology makes the following recommendation:

Don't routinely repeat DXA scans more often than once every two years.

Initial screening for osteoporosis should be performed according to National Osteoporosis Foundation recommendations. The optimal interval for repeating Dual-energy X-ray Absorptiometry (DXA) scans is uncertain, but because changes in bone density over short intervals are often smaller than the measurement error of most DXA scanners, frequent testing (e.g., <2 years) is unnecessary in most patients. Even in high-risk patients receiving drug therapy for osteoporosis, DXA changes do not always correlate with probability of fracture. Therefore, DXAs should only be repeated if the result will influence clinical management or if rapid changes in bone density are expected. Recent evidence also suggests that healthy women age 67 and older with normal bone mass may not need additional DXA testing for up to ten years provided osteoporosis risk factors do not significantly change.

Five quality measures were identified pertaining to BMD testing when searching the [National Quality Measures Clearinghouse](#). All five were developed by the National Committee for Quality Assurance, and four of the five are endorsed by the NQF:

- Osteoporosis management in women who had a fracture: percentage of women 67 years of age and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six months after the fracture.
- Osteoporosis testing in older women: the percentage of Medicare women 65 years of age and over who report ever having received a bone density test to check for osteoporosis.
- Osteoporosis: percentage of patients aged 50 years and older with a fracture of the hip, spine or distal radius who had a central DXA measurement ordered or performed or pharmacologic therapy prescribed.
- Osteoporosis: percentage of female patients aged 65 years and older who have a central DXA measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.

The fifth measure has not been endorsed by the NQF:

- Osteoporosis: percentage of patients aged 18 years and older with one of the following conditions or therapies: receiving oral glucocorticosteroid therapy for greater than 3 months OR hypogonadism OR fracture history OR transplant history OR obesity surgery OR malabsorption disease OR receiving aromatase therapy for breast cancer who had a central dual-energy X-ray absorptiometry ordered or performed or pharmacologic therapy prescribed within 12 months.

COMMITTEE DELIBERATIONS – HTAS

At its meeting 11/25/2013, the HTAS reviewed public comments. After brief discussion, the subcommittee referred the draft coverage guidance to VbBS and HERC for implementation and approval.

COMMITTEE DELIBERATIONS – VBBS

At its meeting 1/9/2013, the VbBS reviewed the draft coverage guidance and an associated diagnostic guideline for implementation in the Oregon Health Plan. The diagnostic guideline was approved for review by the HERC.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Appendix A. GRADE Element Descriptions

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality of evidence across studies for the treatment/outcome

High = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low = Any estimate of effect is very uncertain.

Appendix B. Applicable Codes

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
733.0	Osteoporosis
733.90	Disorder of bone and cartilage, unspecified
V82.81	Special screening for osteoporosis
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
76977	Ultrasound bone density measurement and interpretation, peripheral sites, any method
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
HCPCS Level II Codes	
None	

Note: Inclusion on this list does not guarantee coverage

Appendix C. HERC Guidance Development Framework

Screening for osteoporosis in women aged 65 or over, or with equivalent risks



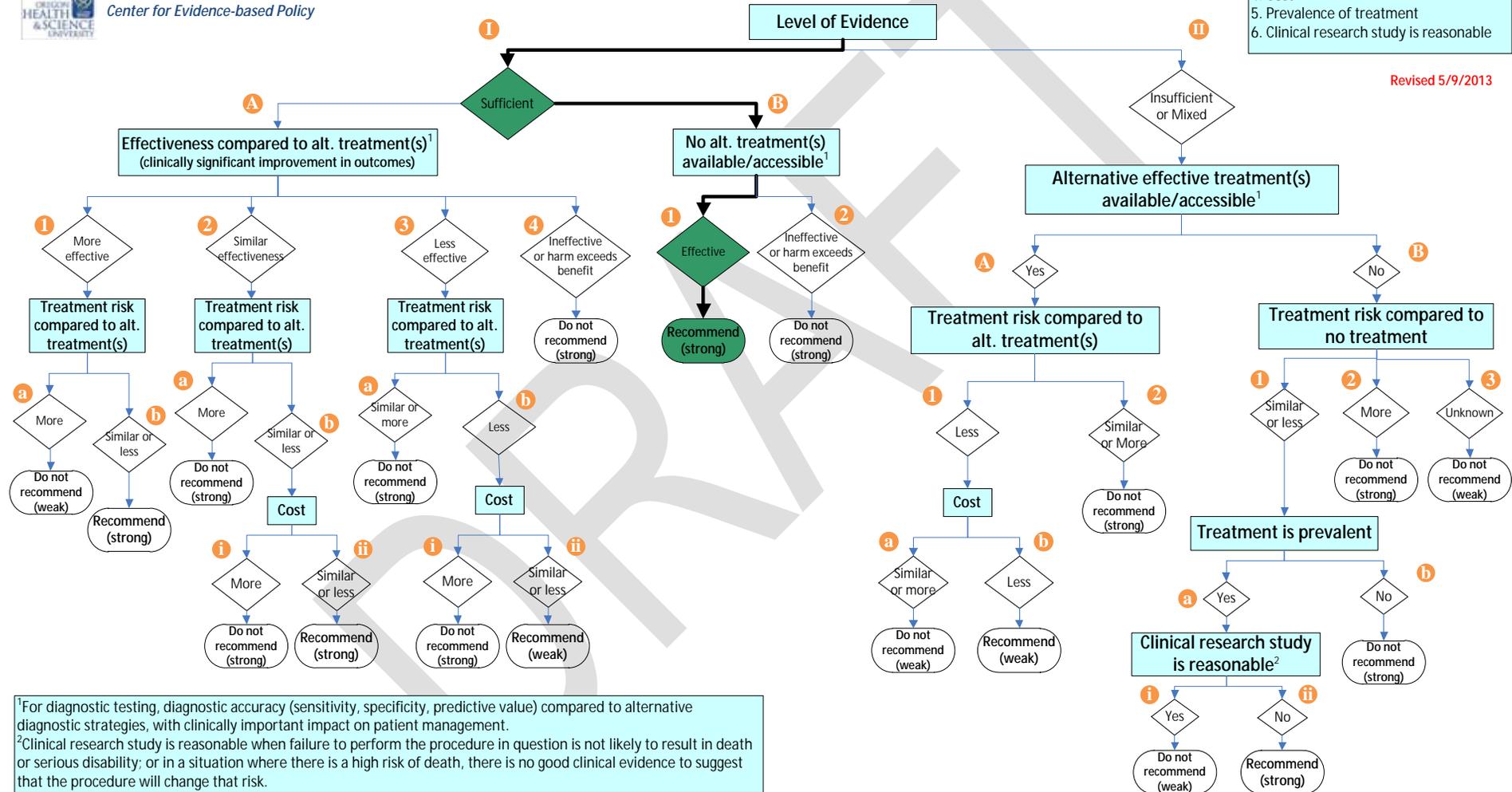
HERC Guidance Development Framework

Refer to HERC Guidance Development Framework Principles for additional considerations

Decision Point Priorities

1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 5/9/2013



Screening for osteoporosis in men without additional risk factors



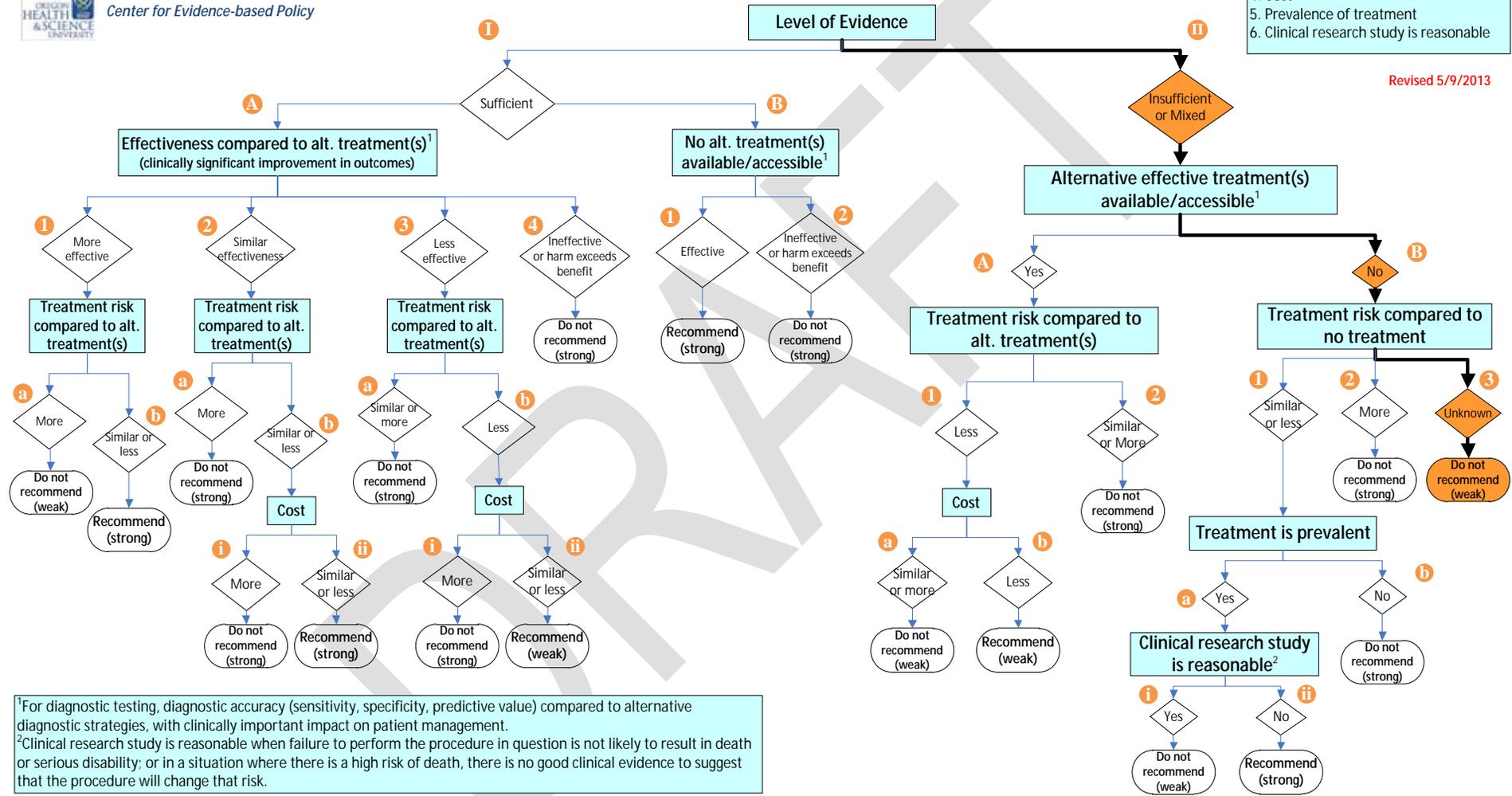
HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**

 1. Level of evidence
 2. Effectiveness & alternative treatments
 3. Harms and risk
 4. Cost
 5. Prevalence of treatment
 6. Clinical research study is reasonable

Revised 5/9/2013



¹For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
²Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Repeat DXA for monitoring osteoporosis or advanced osteopenia < 2 years; Repeat screening <4 years for moderate, Repeat screening DXA < 15 years in women with normal BMD or mild osteopenia



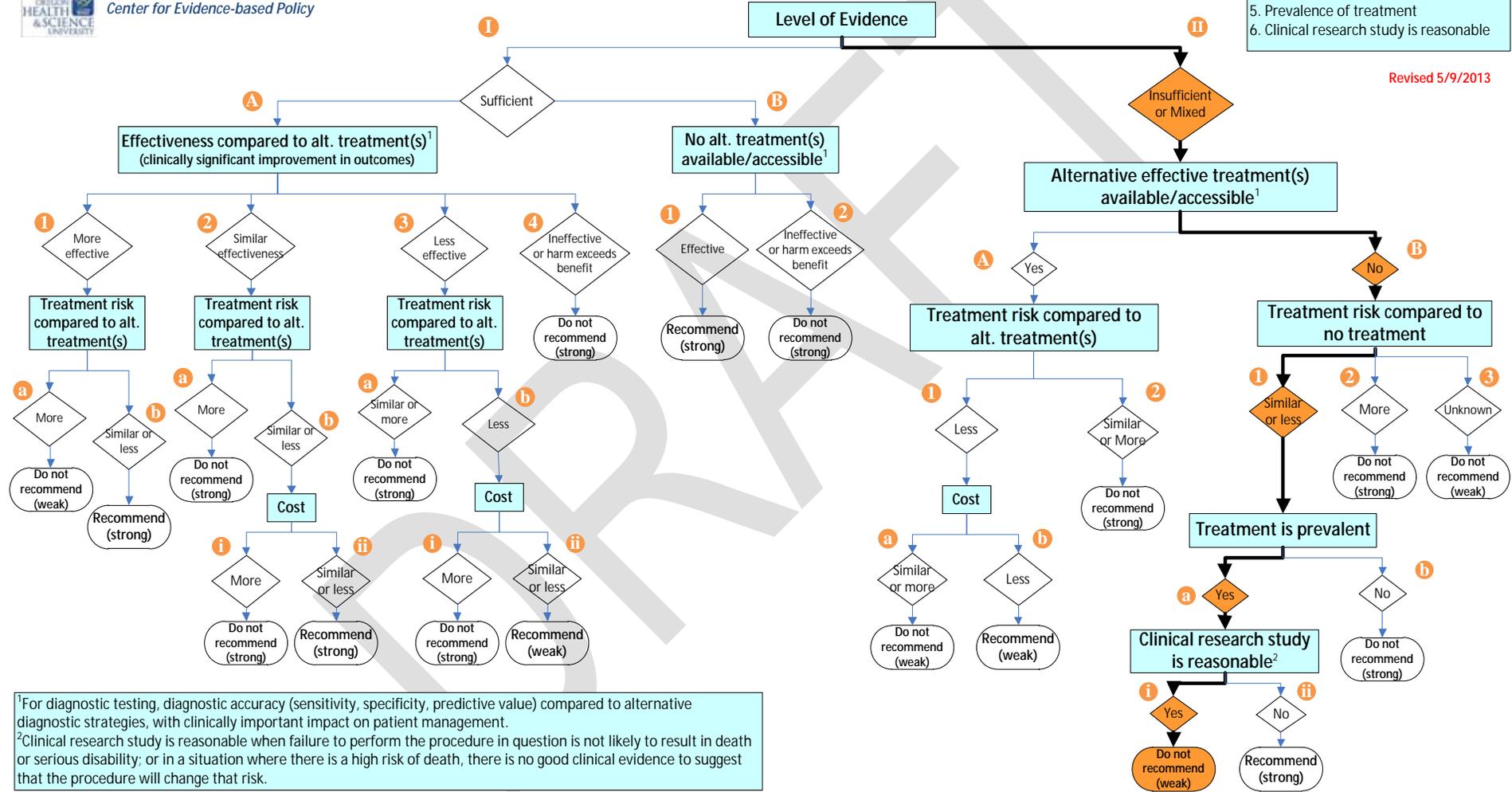
HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**

 1. Level of evidence
 2. Effectiveness & alternative treatments
 3. Harms and risk
 4. Cost
 5. Prevalence of treatment
 6. Clinical research study is reasonable

Revised 5/9/2013



HERC Coverage Guidance – Osteoporosis Screening And Monitoring By Dual-Energy X-Ray Absorptiometry (DXA) Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	E. Michael Lewiecki, MD, FACP, FACE Osteoporosis Director, New Mexico Clinical Research & Osteoporosis Center, Inc., Albuquerque, NM <i>HERC-appointed Expert [Submitted during public comment period June 2013]</i>
B	National Bone Health Alliance, Washington, DC <i>[Submitted at HERC meeting March 2014]</i>
C	American Association of Clinical Endocrinologists, Jacksonville, FL <i>[Submitted at HERC meeting March 2014]</i>
D	Osteoporosis Research Center at Creighton University, Omaha, NE <i>[Submitted at HERC meeting March 2014]</i>

HERC Coverage Guidance – Osteoporosis Screening And Monitoring By Dual-Energy X-Ray Absorptiometry (DXA) Disposition of Public Comments

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A	1	<p>Background. Osteoporosis, defined as low bone strength that increases the risk of fractures (1), is a common skeletal disorder that has been identified by the US Surgeon General as a major public health concern (2). About one of every two women and one of every five men will have an osteoporotic fracture in their lifetimes. Osteoporotic fractures are associated with an increase in morbidity and mortality, as well as high healthcare expenses (2). We are fortunately able to easily and inexpensively measure bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) (3), assess fracture risk (4), and treat with pharmacological agents to reduce fracture risk (5). However, osteoporosis continues to be underdiagnosed (6) and undertreated (7), with those for whom treatment is started commonly failing to take medication correctly or long enough to achieve the expected benefit (8). This “treatment gap,” the difference between the number of patients who could benefit from treatment and those who actually receive it (9), has created the need for better strategies to reduce the burden of osteoporotic fractures.</p>	Thank you for this background information.
	2	<p>Clinical applications of DXA. DXA is used to measure BMD, predict fracture risk, and monitor the skeletal effects of osteoporosis treatment (10). The National Osteoporosis Foundation (NOF) has developed evidence-based clinical practice guidelines, endorsed by numerous profession societies and updated in 2013, that provide clinicians with indications for BMD testing, treatment of osteoporosis, and monitoring treatment (11). The NOF guidelines state that BMD testing is indicated in the following individuals:</p> <ul style="list-style-type: none"> • Women age 65 and older and men age 70 and older, regardless of clinical risk factors • Younger postmenopausal women, women in the menopausal transition and men age 50 to 69 with clinical risk factors for fracture • Adults who have a fracture after age 50 • Adults with a condition (e.g., rheumatoid arthritis) or taking a medication (e.g., glucocorticoids in a daily dose \geq 5 mg prednisone or equivalent for \geq three months) associated with low bone mass or bone loss 	HTAS is aware of the NOF guideline. Methodology for production of the guideline is not described. Funding of the NOF includes a substantial number of industry donors, including Pfizer, Medtronic, Novartis and 15 others.
	3	<p>The NOF guidelines also describe the use of DXA to monitor osteoporosis therapy, as follows:</p> <ul style="list-style-type: none"> • Serial central DXA testing is an important component of osteoporosis management. • Measurements for monitoring patients should be performed in accordance with medical necessity, expected response and in consideration of local regulatory requirements. NOF recommends that repeat BMD assessments generally agree with Medicare guidelines of 	See comment #2. There is no discussion in the NOF guideline about test characteristics (i.e., precision) of DXA; retesting too soon may result in the margin of error of the test being larger than the actual change in the value of the bone density. USPSTF recommendation states: “Because of limitations in

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		<p>every two years, but recognizes that testing more frequently may be warranted in certain clinical situations.</p> <p>Clinical situations for which testing more frequently (e.g., one year interval) is helpful includes patients started on treatment or changing treatment in order to evaluate for treatment effect, and patients on glucocorticoid therapy who are at risk for rapid bone loss.</p>	<p>the precision of testing, a minimum of 2 years may be needed to reliably measure a change in BMD; however, longer intervals may be necessary to improve fracture risk prediction.” Current coverage recommendations allow for more frequent testing in patients for whom there has been a significant change in risk factors other than medication therapy.</p>
	4	<p>Although concerns have been raised that some screening prevention programs for other chronic diseases do not result in healthcare savings (12), this is not the case for BMD testing in appropriately selected patients. The experience of healthcare systems suggests that increases in BMD testing reduce fracture rates and save money. A 5-year observational study evaluated the clinical and fiscal outcomes of the Geisinger Health System Osteoporosis Disease Management Program from 1996 to 2000 (13). It was found that implementation of osteoporosis guidelines that included increases in BMD testing and treatment was associated with a significant decrease in the age-adjusted incidence of hip fractures and an estimated \$7.8 million reduction in healthcare costs during this 5-year period.</p>	<p>This observational study projected cost savings of this screening program in women over 65, but projected additional expense in the population between 55 and 65. Guidance document recommends screening on all women 65 and over.</p>
	5	<p>At Kaiser Southern California, an osteoporosis disease management program (“Healthy Bones Program”) was fully implemented in 2002, with a goal of reducing hip fractures by increasing BMD testing rates and treatment in patients at high risk of hip fracture (14;15). It was estimated that in 2006, 935 hip fractures, with an average cost of \$33,000 each, were prevented, resulting in savings of over \$30.8 million for Kaiser (16). Multiple osteoporosis screening strategies have been found to be clinically effective and cost-effective as well (17-19).</p>	<p>Ref #14 not available through OHSU library. Ref #15 is a clinical summary article that includes a brief description of Ref #16, which is a prospective observational study of the “Healthy Bones” program. This included screening of all women over 65, men over 70, patients with history of hip or fragility fracture or on steroids. Ref #17 is a CEA of a variety of different screening strategies. While they report the best strategy with ICER < \$50,000 was initiation of screening at age 55 with DXA and rescreening every 5 years, they note that several strategies using SCORE (a screening tool similar to FRAX) for prescreening were more cost effective, with ICERs < \$30,000. Ref #18 is a position statement of the American College of Preventive Medicine, which states: “All adult patients age ≥ 50 years should be evaluated for risk factors for osteoporosis. Screening with BMD testing for osteoporosis is recommended in women aged 65</p>

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			years and in men aged 70 years. Younger postmenopausal women and men aged 50–69 years should undergo screening if they have at least one major or two minor risk factors for osteoporosis.” Ref #19 is also a CEA that concludes “bone densitometry of post-menopausal women who have not had a prior fracture is reasonable from 65-70 years of age, and is perhaps reasonable for men without a prior fracture after the age of 80 years depending on drug costs, the direct medical costs of fractures, fracture disutility, underlying fracture rates in the population and the societal willingness to pay for health benefits.”
	6	Comments on HERC coverage guidance. Three sources of medical evidence were used in the development of the coverage guidance: 1. USPSTF recommendations for screening for osteoporosis (20;21); 2. a posthoc subgroup analysis of a single observational study in postmenopausal women (22); and the NICE guidelines from the UK (23). There are serious concerns with each of these that limit their applicability in setting rules for DXA coverage in the US.	HTAS acknowledges that these are the source documents, but disagrees that there are serious concerns regarding their use.
	7	USPSTF recommendations- The USPSTF recommended screening for osteoporosis “in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.” This was taken almost verbatim for inclusion in the HERC Guidance. However, the proposal very difficult to implement in clinical practice, as it would involve using FRAX without the benefit of BMD, which is not as good a predictor of fracture risk as FRAX with BMD, and assumes that physicians have the time and knowledge to use FRAX regularly and correctly. A 65 year-old Caucasian woman of average height and weight with no risk factors has a FRAX 10-year probability of major osteoporotic fracture of 9.4% and a 10-year probability of hip fracture of 1.4%. If she has low body weight, the numbers are 11% and 3.0%, respectively. If she is Hispanic, it is 6.0% and 1.7%, respectively. If she is Asian, it is 5.9% and 1.7%, respectively. If she is Black, it is 4.7% and 1.3%, respectively. If another fracture risk calculator, such as Garvan, is used for a 65-year old Caucasian woman with no risk factors, there is a 1.2% 5-year risk of hip fracture, a 2.4% 10-year risk of hip fracture, a 6.7% 5-year risk of any fragility fracture, and a 13.9% 10-year risk of any fragility fracture. There are other calculators as well that would generate different numbers. It is simply not feasible in a	The USPSTF selected the FRAX tool because “this tool relies on easily obtainable clinical information, such as age, body mass index (BMI), parental fracture history, and tobacco and alcohol use; its development was supported by a broad international collaboration and extensively validated in 2 large U.S. cohorts; and it is freely accessible to clinicians and the public.” HTAS does not agree that it is not feasible for a physician to utilize this tool and believes that there are many who do. Compliance is an issue of implementation and does not impact the recommendations.

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		busy medical practice for any physician to sort through all of this and not possible for a regulatory agency to monitor for compliance.	
	8	The USPSTF addressed only screening DXA in women; they do not provide guidance on the use of DXA other than screening (e.g., monitoring) or DXA in men. It should be noted that men age 70 and older are at high risk for fracture, and the consequences of fractures in men (morbidity and mortality) are more grave than in women. The adoption of the USPSTF recommendation would serve to reduce the use of DXA in evaluating patients (especially postmenopausal women under age 65 and men) for fracture risk, when the current problem is quite the opposite- too few patients are being screened for osteoporosis.	HTAS is aware that the USPSTF does not address the use of DXA in monitoring, and therefore includes the Gourlay study in the guidance document to address this void. The USPSTF <u>does</u> address the use of DXA in men, stating that the evidence is insufficient to recommend for or against screening. .
	9	Gourlay et al study- This analysis of a subset of subjects in the Study of Osteoporotic Fractures (SOF) concluded quite reasonably that older women with very good BMD were unlikely to develop osteoporosis for many years, if ever. However, it was widely misinterpreted in the media, and by some healthcare providers, to mean that DXA is an expensive overused technology that was increasing medical expenses with little benefit. There was a firestorm of protest from many physicians and professional societies to set the story straight, including two where I was an author (24;25). Gourlay et al correctly identified limitations of the study that preclude its applicability to a wider patient population. The study cohort was restricted to pre-selected women ≥ 67 years of age and did not include men or younger postmenopausal women. It is particularly important to note that women in their early postmenopausal years are likely to experience accelerated bone loss that may require short testing intervals (e.g., 1-2 years) to assess. Also excluded from the trial were nearly 50% of the SOF study participants who had a previous diagnosis of osteoporosis (based on a prior hip or clinical vertebral fracture or densitometric evidence of osteoporosis) or who were already on treatment for osteoporosis.	HTAS is aware of the limitations of the Gourlay study. However, no other evidence has been identified or provided that provides evidence supporting a different testing interval. The cited reference #24 is an editorial that is verbatim to the comment provided here. Reference #25 is a letter to the editor. The author's (Gourlay's) response is as follows: "We strongly agree with Lewiecki and colleagues that too few initial BMD tests are performed in older women. An appropriate response to our results would be for primary care physicians to substantially increase the number of initial tests in older women, then to tailor the subsequent BMD screening interval according to BMD T-score and age."
	10	There were other limitations not noted by the authors. Only clinical vertebral fractures were considered in the analysis, although undiagnosed morphometric vertebral fractures are common in patients with densitometric evidence of osteopenia and are associated with high morbidity (26).	Ref #26 is a prospective case series that followed women > 65 over 4 years and reported incidence of vertebral fracture and back pain/disability. It found that approx. 2/3 of new fractures were not diagnosed clinically, yet those patients still reported increased pain and disability. These fractures were diagnosed by lateral spine radiographs, which would not be indicated in the general population. Unclear how this relates to the recommended guidance, or how this suggests the need for more frequent monitoring.
	11	In a prospective cohort study of 671 postmenopausal women undergoing periodic spine imaging,	Ref #27 is a prospective case series of 671 post-

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		48% of vertebral fractures were found in women with T-scores between -1.0 and -2.5. With a morphometric vertebral fracture, they would be reclassified as having a clinical diagnosis of osteoporosis (27). Many of these patients would not have been identified in the study of Gourlay et al.	menopausal women followed over 9 years. This study found that women who were osteopenic had an increased risk of fracture over that time period, and risk was also increased with age, prior fracture and high bone turnover markers. There is no comment in the article regarding reclassification of these women as having osteoporosis. WHO criteria and NOF guideline list only T-score as criteria.
	12	In making treatment decisions in clinical practice, it is imperative to consider risk factors for fracture in addition to the femoral neck and total hip T-score. Gourlay et al., for example, did not measure lumbar spine BMD. Low lumbar spine BMD is associated with increased fracture risk at all skeletal sites (28). Moreover, lumbar spine T-score may be ≤ -2.5 even if the femoral neck or total hip T-score is > -2.5 . Without tracking lumbar spine BMD, Gourley et al. may have underestimated the number of individuals who progressed to osteoporosis during the study. Most importantly, with its singular focus on BMD, the study did not capture those patients with osteopenia who by the FRAX fracture risk assessment would have been at high risk for fracture and therefore warrant drug therapy. It would be grossly inappropriate to use the Gourlay et al study to set guidelines for frequency of BMD testing in the vast majority of clinical practice patients.	The abstract of Ref #28 states this was a prospective case series of 8,134 women > 65 followed 0.7 years and found the risk of fracture inversely related to BMD at all sites of measurement (proximal femur, spine, calcaneus, distal radius, proximal radius), and that none were more predictive than others. Does not appear to support contention that spine BMD needs to be tracked in addition to or instead of hip BMD. While the Gourlay article only evaluated hip BMD, again, no other evidence has been identified or provided that provides evidence supporting a different testing interval.
	13	NICE guidelines- These guidelines were developed through economic modeling of circumstances in the UK, where healthcare priorities and resources are quite different than in the US. This modeling used economic assumptions, including fracture-related medical expenses, that are uncertain even in the UK, and clearly not applicable in the US. FRAX in the UK was calibrated using country-specific fracture prevalence rates and mortality statistics that are not the same as in the US. There is controversy regarding the NICE guidelines amongst healthcare providers in the UK. As with all guidelines, NICE recognize that healthcare decisions should be individualized according the needs each patient.	HTAS does not disagree that modeling and economic assumptions in the UK may not apply perfectly to the US setting, but evidence to support an alternative testing schedule has not been provided. HTAS is familiar with controversy over testing guidelines, and while it is ideal for healthcare decisions to be individualized, that does not eliminate the need for a population-based coverage decision.
	14	Recommendations. It is my opinion that the proposed HERC Coverage Guidance, while well intentioned, is not sufficiently clear for clinical use, and that it would not be in the best interests of the citizens of Oregon to implement as it is. I think Oregon could do no better than to adopt the NOF guidelines for BMD testing and frequency of testing, allowing for physicians to individualize patient care decisions as needed. There are a number of minor formatting issues that should be corrected according to standard nomenclature established by the International	Some formatting corrections have been made, thank you. The use of 2 decimal points has been preserved, as this is directly from the evidence source. "Advanced osteopenia" is not deleted, as it is a helpful description of the T-score value 2.0 to 2.49. HTAS does not believe the NOF guidelines are

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		Society for Clinical Densitometry (29). Change “DEXA” to “DXA,” which is the preferred acronym. Be consistent in using “T-score” and not other forms, such as “T score,” and express T-scores to one decimal place not two. Note that “advanced osteopenia” is not a recognized diagnostic category and should not be used; it was presented by the authors of the Gourlay et al study for use in their publication but has no established definition.	sufficiently evidence-based for adoption.
B	15	<p>I’m writing on behalf of the National Bone Health Alliance (www.nbha.org), a public-private partnership on bone health established in 2010 that brings together the expertise and resources of its 52 members from the non-profit and private sectors (as well as four government liaisons) to promote bone health and prevent disease; improve diagnosis and treatment of bone disease; and enhance bone research, surveillance and evaluation.</p> <p>It is our understanding that the Oregon Health Evidence Review Commission (HERC) is considering new osteoporosis testing frequency guidelines for use in the Oregon Medicaid population, per the document “Health Evidence Review Commission (HERC) Coverage Guidance: Osteoporosis Screening and Monitoring By Dual-Energy X-Ray Absorptiometry (DXA)” as posted for public comment on June 27, 2013 (accessed at http://www.oregon.gov/oha/OHPR/HERC/docs/CG/DXA%20Screening%20for%20osteoporosis%2006-24-13.pdf). Based on our review of that document, we have the following feedback:</p> <p><i>Duplicate comments submitted by commenters B, C, and D. Additional comments grouped below.</i></p>	Your comments were submitted outside the allowed timeframe for public comment on this document, which closed on July X, 2013.
C	16	<p>The American Association of Clinical Endocrinologists (AACE) is pleased to have the opportunity to comment on the newly proposed osteoporosis testing frequency guidelines for use in the Oregon Medicaid population that are under review by the Oregon Health Evidence Review Commission (HERC).</p> <p>As you may know, AACE is the largest association of clinical endocrinologists, representing over 6,500 endocrinologists in the United States and in over 90 countries. The great majority of AACE members are certified in Endocrinology and Metabolism and concentrate on the treatment of patients with endocrine and metabolic disorders including diabetes, thyroid disorders, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension and obesity. AACE has 36 members practicing in the State of Oregon.</p> <p>AACE is also a member of the National Bone Health Alliance, a public-private partnership on bone health that includes 56 organizational participants from the public, non-profit and private sectors.</p> <p>Our comments on the proposed guidelines contained in the document “Health Evidence Review</p>	Your comments were submitted outside the allowed timeframe for public comment on this document, which closed on July X, 2013.

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		<p>Commission (HERC) Coverage Guidance: Osteoporosis Screening and Monitoring by Dual-Energy X-Ray Absorptiometry (DXA)" as posted for public comment on June 27, 2013, are the following:</p> <p><i>Duplicate comments submitted by commenters B, C, and D. Additional comments grouped below.</i></p>	
D	17	<p>I'm writing on behalf of the Osteoporosis Research Center at Creighton University, a proud member of the National Bone Health Alliance (www.nbha.org), a public-private partnership on bone health that includes 56 organizational participants from the public, non-profit and private sectors. The Osteoporosis Research Center has created an international center of excellence in bone research for over 40 years.</p> <p>It is our understanding that the Oregon Health Evidence Review Commission (HERC) is considering new osteoporosis testing frequency guidelines for use in the Oregon Medicaid population, per the document "Health Evidence Review Commission (HERC) Coverage Guidance: Osteoporosis Screening and Monitoring By Dual-Energy X-Ray Absorptiometry (DXA)" as posted for public comment on June 27, 2013 (accessed at http://www.oregon.gov/oha/OHPR/HERC/docs/CG/DXA%20Screening%20for%20osteoporosis%2006-24-13.pdf). Based on our review of that document, we have the following feedback:</p> <p><i>Duplicate comments submitted by commenters B, C, and D. Additional comments grouped below.</i></p>	Your comments were submitted outside the allowed timeframe for public comment on this document, which closed on July X, 2013.
B, C, D	18	<p>1. An incorrect definition of osteoporosis is being used, which results in a set of guidelines that are fundamentally flawed. HERC disputes the statement that women with T-scores between -1.0 and -2.5 with a morphometric vertebral fracture in the Gourlay study should have been reclassified as having a clinical diagnosis of osteoporosis. Please see attached a position paper just published in <i>Osteoporosis International</i> by the NBHA Clinical Diagnosis of Osteoporosis Working Group on the clinical definition of osteoporosis.</p>	See comment #11. Position statement from the National Bone Health Alliance Working Group was authored by 15 individuals, most with multiple industry relationships. NOF and WHO criteria remain unchanged.
	19	<p>2. HERC's reliance on Gourlay, et al ("Bone Density Testing Interval and Transition to Osteoporosis in Older Women", <i>New England Journal of Medicine</i>, January 19, 2012) to establish these osteoporosis screening and monitoring frequency guidelines are inappropriate as follows:</p> <p>a. The Gourlay study population consisted of post-menopausal women age 67 and over and did not address testing intervals in recently post-menopausal women where rates of bone loss are much more rapid or women with additional illnesses or requiring medications that adversely affect bone in whom more frequent testing may be appropriate. In adopting these proposed frequency rates, HERC ignored the study author's warning that "...our analysis was limited to women 67 years of age or older; different results might have been obtained from analyses that</p>	See comment #9. No evidence provided to suggest an alternative screening frequency.

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		included younger postmenopausal women or men.”	
	20	2b. The study cohort in Gourlay also excluded nearly 50% of the SOF study participants who had a previous diagnosis of osteoporosis (based on a prior hip or clinical vertebral fracture or densitometric evidence of osteoporosis) or who were on treatment. In other words, the study focused only on the healthiest patients.	See comment #9. HERC is interested in determining screening frequency for those who are healthy, since those with current osteoporosis are allowed screening every two years as the guidance is currently written, or more frequently with a change in risk factors.
	21	2c. Gourlay study findings underestimate time intervals because they excluded the likely majority of vertebral fractures by only including clinical vertebral fractures. Unappreciated, asymptomatic vertebral compression fractures are common in patients with low bone mass based solely on bone mineral density (BMD). A sizable percentage of postmenopausal women who have low bone mass based on BMD (48% in the Sornay-Rendu study) had morphometric vertebral body compression fractures. Many of these patients would have been identified in the Gourlay study as continuing to have low bone mass with lengthy intervals between testing even though by virtue of the vertebral fracture, they should have been classified as having osteoporosis.	See comment #10.
	22	2d. The categories Gourlay has proposed (mild osteopenia with T-score of lower than -1.0 and higher than -1.5, moderate osteopenia with T-score of lower than -1.5 and higher than -2.0, and severe osteopenia with T-score of lower than -2.0 and higher than -2.5) are not recognized by any medical societies nor the World Health Organization. This classification completely ignores the role of FRAX in determining fracture risk for the osteopenic patient and places risk solely based on BMD. There is no scientific rationale for adhering to this risk assessment strategy.	See comment #14.
	23	2e. Gourlay further underestimated the length of time for women to transition from one category to another because the study did not consider women with low spine BMD. As low lumbar spine BMD is associated with increased fracture risk, clinicians must consider this site in making recommendations to minimize fracture risk.	See comment #12.
	24	2f. Gourlay focused on the estimated interval for 10% of the participants to make the transition from normal BMD or osteopenia to osteoporosis before a hip or clinical vertebral fracture occurred or before treatment for osteoporosis was started. While that may have been an acceptable threshold for that study, it is completely inappropriate to develop testing thresholds that assumes 10% of patients will transition to osteoporosis or have a hip or clinical fracture. Osteoporosis testing and treatment thresholds are designed to avoid fracture and osteoporosis before they occur, not after.	The Gorley study outcome is that 10% of the population transition to osteoporosis <u>before</u> a fracture occurs; commenters statement that it is inappropriate to develop testing thresholds that assume 10% of patients will have a fracture is an inaccurate representation of the Gorley study.

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Commenter	References
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B	<p>1) Siris ES, Adler R, Bilezikian J, Bolognese M, Dawson-Hughes B, Favus MJ, Harris ST, Jan de Beur SM, Khosla S, Lane NE, Lindsay R, Nana AD, Orwoll ES, Saag K, Silverman S, Watts NB. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. <i>Osteoporos Int</i>. 2014 Feb 28. [Epub ahead of print] Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24577348</p>

Dual Energy X-ray Absorptiometry Screening for Osteoporosis

This topic was reviewed by the Health Technology Assessment Committee of the HERC in February, who made the following recommendations:

Osteoporosis screening by dual-energy X-ray absorptiometry (DXA) is recommended for coverage only for women aged 65 or older, and for men or younger women whose fracture risk is equal to or greater than that of a 65 year old white woman who has no additional risk factors. Fracture risk should be assessed by the World Health Organization's FRAX tool or similar instrument (strong recommendation).

Repeat osteoporosis screening by DXA, for women with normal bone density, is not recommended for coverage more frequently than once every fifteen years (weak recommendation).

Routine osteoporosis screening by DXA is not recommended for coverage in men (weak recommendation).

Unless there has been significant change in the individual's risk factors, such that rapid changes in bone density are expected, monitoring of individuals with low bone density by repeat DXA scanning is recommended for coverage (weak recommendation) only at the following frequencies:

- once every two years for those with osteoporosis or advanced osteopenia (T-score of 2.00 or lower)
- once every four years for moderate osteopenia (T-score between 1.50 and 1.99)
- once every fifteen years for mild osteopenia (T-score between 1.01 and 1.49).

Repeat testing should only be covered if the results will influence clinical management. For purposes of monitoring osteoporosis medication therapy, testing at intervals of less than two years is not recommended for coverage (weak recommendation).

HERC reviewed this recommendation on March 13, 2014, and after additional comments from the appointed expert Dr. Lewiecki, requested additional information, outlined below:

1. Review the article submitted to the HERC on the day of their review by Dr. Lewiecki (Reid 2014)
2. Complete an additional MedLine search for articles that address population screening intervals that may have been published after the last MedLine search, which was from 2010 (end search date of the Nelson systematic review that informed the USPSTF guideline) to April 2013.

3. Add the additional comments received the day before the HERC meeting, along with responses, to the public comment disposition document.

1. Reid 2014

This paper reports the output of a model that uses the FRAX calculator to predict hip and osteoporotic fracture risk using baseline BMD level. It is not a study per se, therefore there is no quality assessment tool that can be applied to it. The article calculates fracture risk at 5 year intervals for a hypothetical woman using BMD T scores of -1.0, -1.5 and -2.0. The authors calculate doubling times using an exponential function (presumably meaning the time required for the risk of a hip fracture to double, although this is not specifically defined in the article). They report that hip fracture risk rises progressively over 15 years, with doubling times of approximately 5 years for all three baseline BMD levels. If the threshold for treatment used by the National Osteoporosis Foundation of a 3% risk of hip fracture or a 20% risk of any osteoporotic fracture is used, the hypothetical woman with no risk factors and a baseline BMD of -1.0 will cross the threshold for treatment after 10 years. For a baseline BMD of -1.5, that time is around 7 years and for a baseline BMD of -2.0 it is around 4 years. In this model, women reach the treatment threshold sooner when considering hip fracture risk than when considering any osteoporotic fracture risk.

Authors conclude the following:

“Gourlay has already shown that women with marked osteopenia (ie, T-score<-2.0) will cross the osteoporotic threshold within 1 to 2 years, so require much closer follow-up. They have also demonstrated that those who are not osteopenic (ie, T-score>- 1.0) do not require follow-up for a period of >17 years. The present data provide useful guidance for the large number of women who lie between these two extremes, and who account for the majority of postmenopausal fractures.”

And:

“The observation that the doubling time for hip fracture risk is consistent across the range of osteopenic BMDs is of immediate relevance to clinical practice, and can be used to determine how long to wait before reassessing fracture risk in women whose other risk factors are unchanged. For instance, a woman with a risk of 1% at baseline (middle line in Fig. 1) would be expected to reach a 2% risk at 4 years and the 3% threshold at about 6 years, so should be reassessed at about that time. In contrast, a baseline risk of 0.6% (lowest line in Fig. 1) will only reach the 3% threshold a decade later, so retesting should be timed appropriately. This

knowledge can avert the waste associated with too frequent BMD testing during follow-up and allow patients to have clear expectations of when intervention is likely to be needed.”

2. MedLine Results (January 2013 through April 2014)

Two potentially relevant studies were identified. Jiang 2013 identified 615 women receiving DXA over a 26 month period of time, who were contacted to determine inputs to the FRAX tool and North American Menopause Society algorithms (age, weight, race, etc), as well as whether they had experienced a fragility fracture. They then compared the likelihood of identifying fractures based on FRAX, the NAMS guidelines from both 2006 and 2010, or age alone. Authors then calculated the area under the curve analysis using logistic regression for each risk prediction strategy, and found the following results:

Predictive Values of Fracture Risk-Prediction Models

Model	AUC	95% CI	P value*
Age alone	0.79	0.67 to 0.91	<0.001
NAMS 2010	0.77	0.66 to 0.88	<0.001
FRAX	0.76	0.64 to 0.89	<0.001
NAMS 2006	0.72	0.60 to 0.85	<0.001

AUC = area under the curve; CI = confidence interval. * Compared with chance (AUC = 0.50).

The authors conclude that all current screening modalities are effective in predicting fracture but not significantly better than age alone.

Berry 2013 included a sample of 802 individuals from the Framingham cohort who had 2 BMD tests between 1987 and 1999. Individuals who had experienced a hip fracture before the second measurement were excluded. Mean time between BMD measurements was 3.7 years. Fracture risk (FRAX) was calculated using updated clinical characteristics and baseline BMD. Mean age was 75. The mean change in BMD was -0.6% per year (mean absolute change in BMD was -0.005 for those without a hip fracture, and was -0.008 for those with a hip fracture).

Throughout a median follow-up of 9.6 years, 76 participants experienced an incident hip fracture and 113 participants experienced a major osteoporotic fracture. In receiver operating characteristic (ROC) curve analyses, the addition of BMD change to a model with baseline BMD did not meaningfully improve performance. The area under the curve (AUC) was 0.71 (95%CI, 0.65 to 0.78) for the baseline BMD model compared with 0.68 (95%CI, 0.62 to 0.75) for the BMD percent change model. Moreover, the addition of BMD change to a model with baseline BMD did not meaningfully improve performance (AUC, 0.72 [95%CI, 0.66 to 0.79]). The authors

conclude that a second BMD measure after 4 years did not meaningfully improve the prediction of hip or major osteoporotic fracture in this population.

Disposition of Comments Received March 12, 2014

Please see separate Public Comment Disposition document.

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Section 3.0

New Discussion Items



OREGON HEALTH EVIDENCE REVIEW COMMISSION

ASSESSMENT & IMPROVEMENT PROJECT

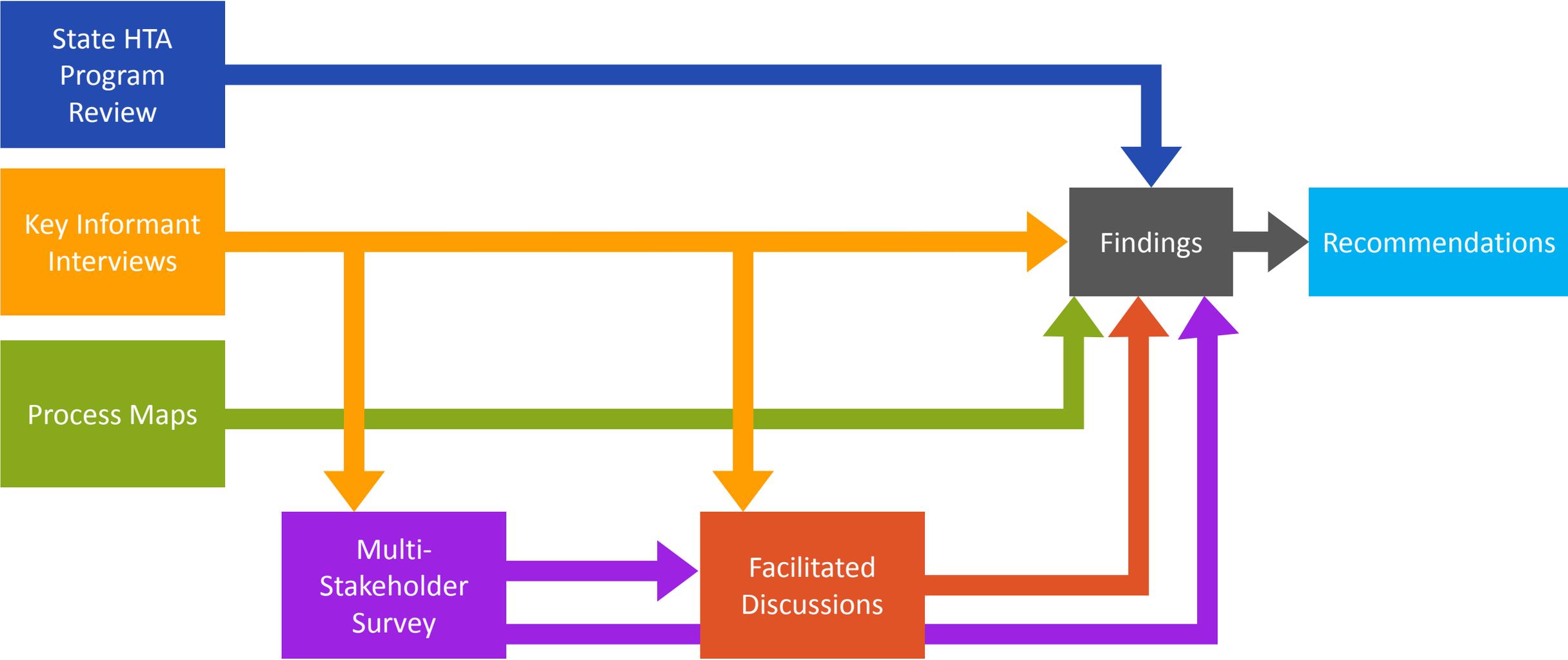
BACKGROUND

- OHA contracted the Center for Evidence-based Policy at OHSU to:
 - Assess current HERC processes
 - Make recommendations based on assessment findings



Identify potential steps to make
HERC products more *relevant*,
accessible, and *useful* to decision
makers

PROJECT DESIGN





State HTA Program Review

Identify best practices

STATE HTA PROGRAM REVIEW

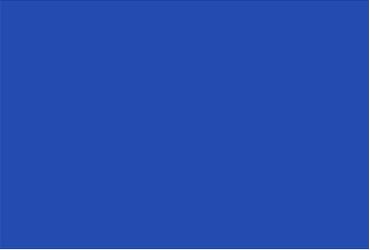
METHODS

- Organizations' websites
- MED report, *Health Technology Assessment* (Pinson, 2011)
- Direct communication

STATE HTA PROGRAM REVIEW

METHODS CONT.

- Summarize key components of 5 state HTA programs
 - California Technology Assessment Forum
 - Minnesota Health Services Advisory Council
 - New York Medicaid Redesign Team – Evidence-based Benefits Review Advisory Committee
 - Oregon Health Evidence Review Commission
 - Washington Health Technology Assessment Program
- Reviewed 5 areas, including 14 key components

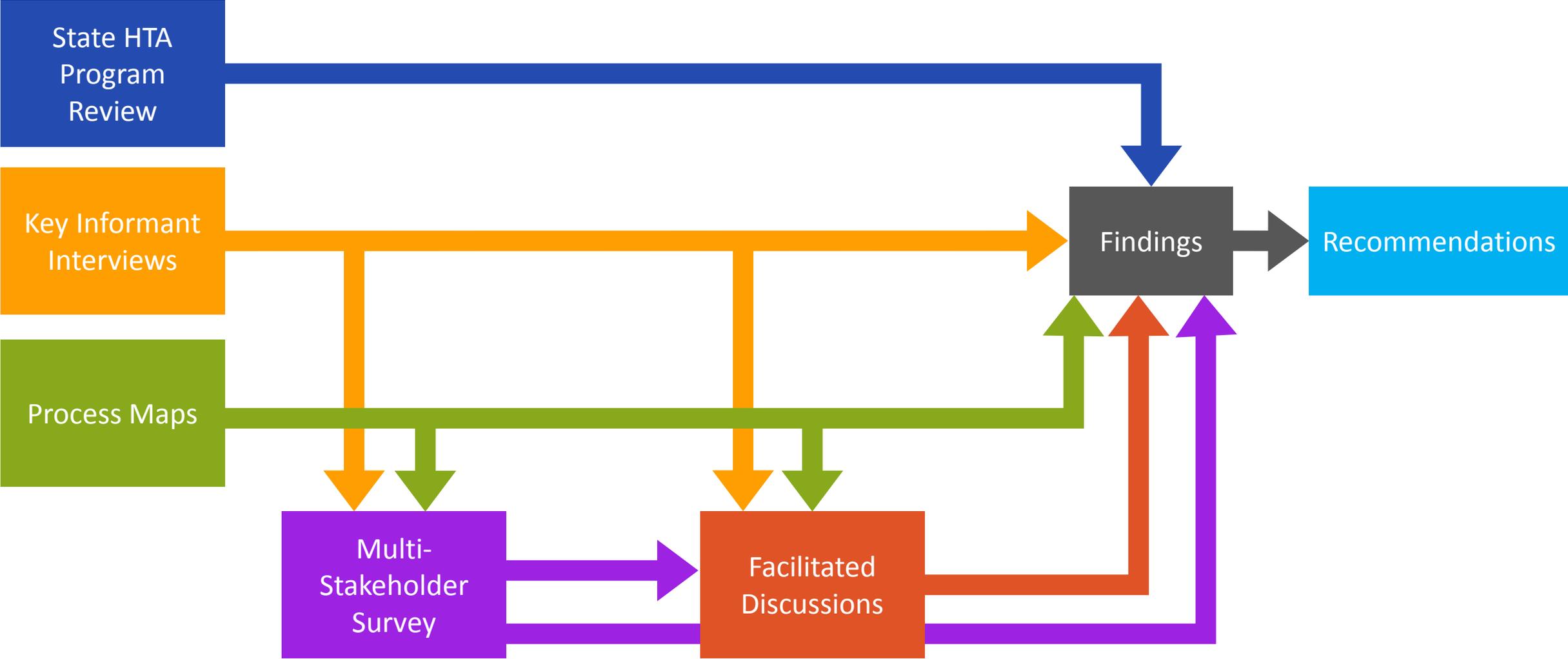


STATE HTA PROGRAM REVIEW

FINDINGS

- HERC is similar to other programs
- Alternative practices identified for:
 - Organization & structure
 - Topic nomination & selection
 - Stakeholder engagement
 - Product dissemination

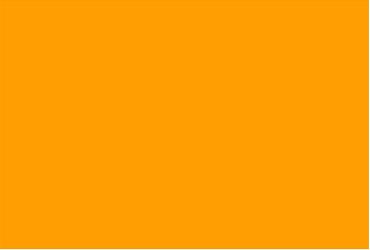
PROJECT DESIGN





Key Informant Interviews

Inform how the process of creating HERC products can be improved



KEY INFORMANT INTERVIEWS

METHODS

- Semi-structured, qualitative interviews
- 18 interviews of staff & HERC committee members
 - December 2013-January 2014
- 10 questions, 30-60 minutes

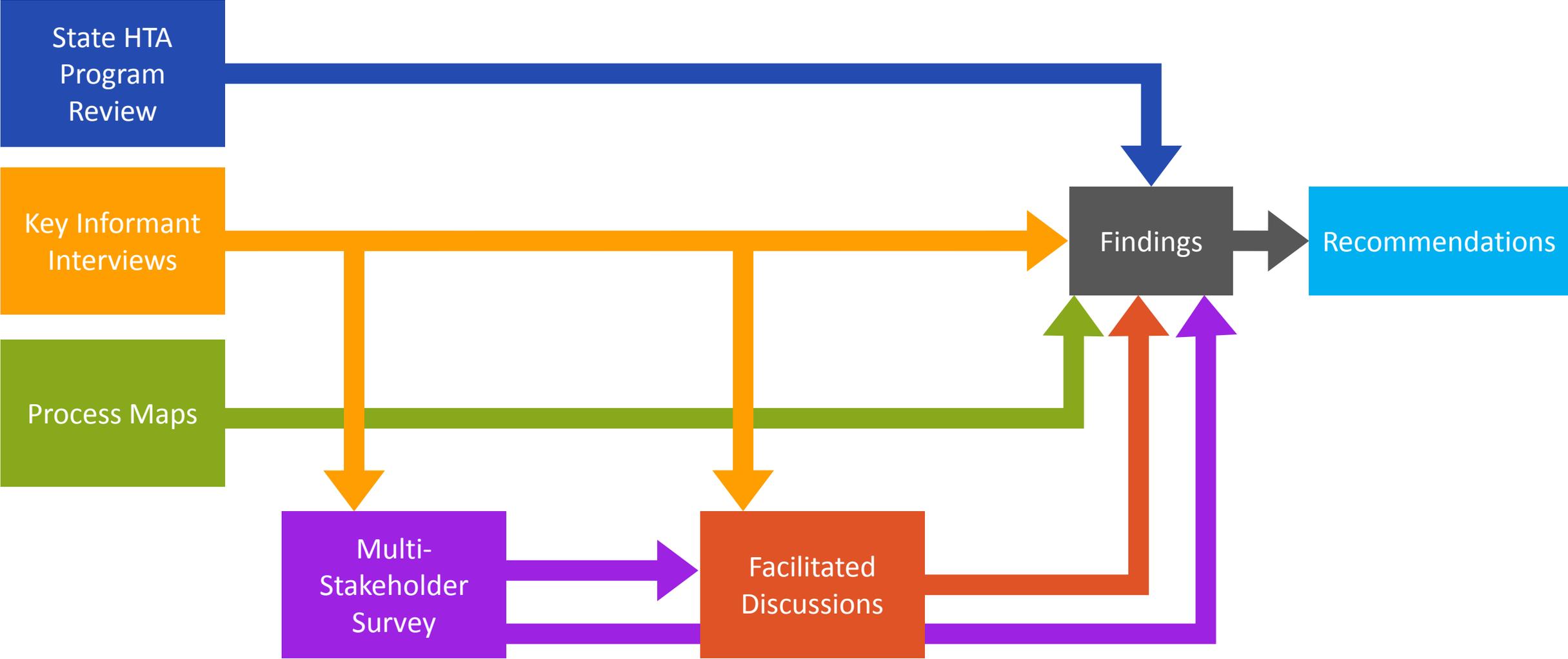


KEY INFORMANT INTERVIEWS

FINDINGS

- Depth of knowledge of processes is highly variable
- HERC staff are “amazing”
- Opportunities for improvement:
 - Meeting structure & processes
 - Internal communication
 - Stakeholder engagement

PROJECT DESIGN





Process Maps

Depict the course that Coverage Guidances took after a topic was selected, and identify areas of preventable delays and related barriers



PROCESS MAPS

METHODS

- 15 Coverage Guidance process maps
- Four phases:
 - I. Development
 - II. Review
 - III. Application
 - IV. Final Approval

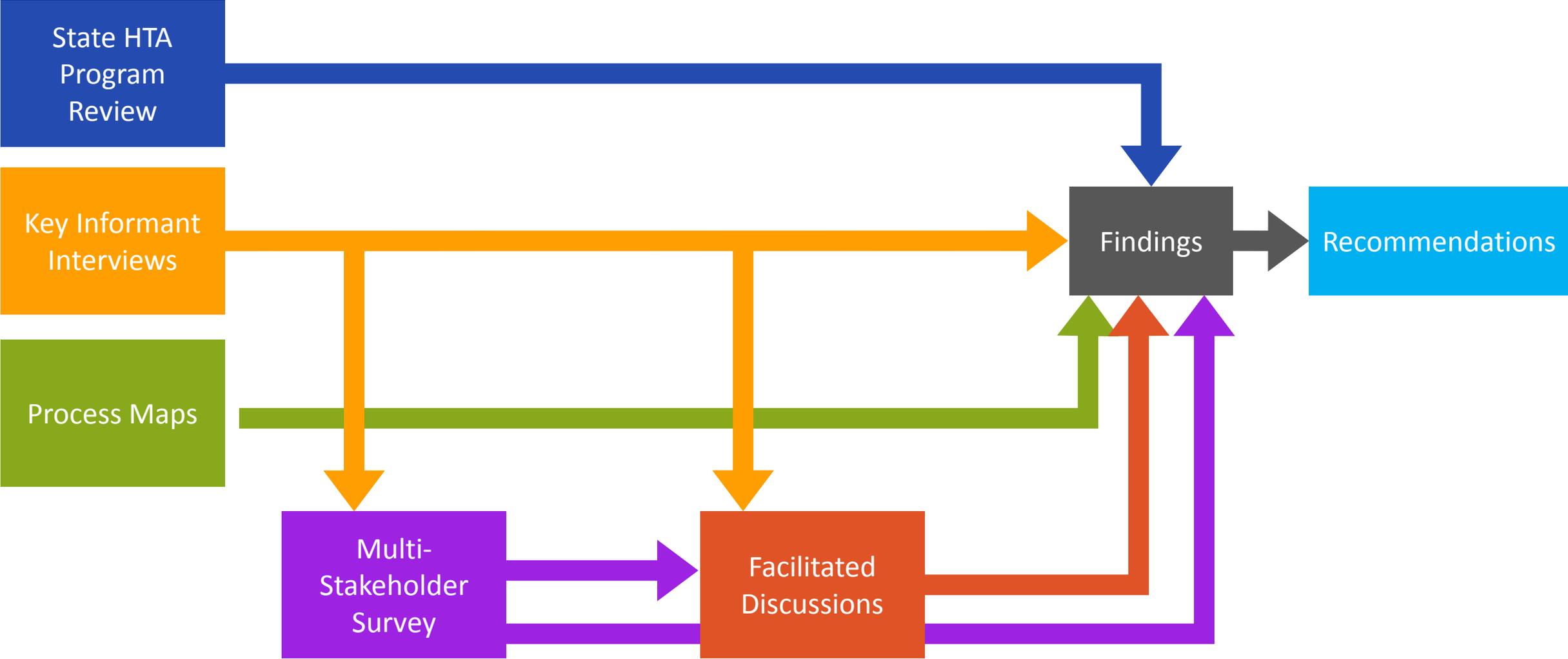


PROCESS MAPS

FINDINGS

- Average completion time = 44 weeks
- 9 extra weeks per delay (mode)
- Significant causes of delay:
 - Insufficient meeting time to cover agenda
 - Requests for additional research
 - Topic returned to subcommittee

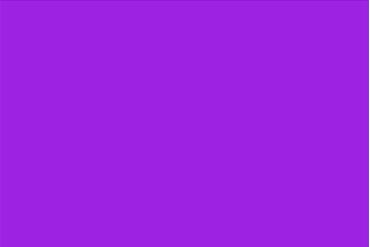
PROJECT DESIGN





Multi-Stakeholder Survey

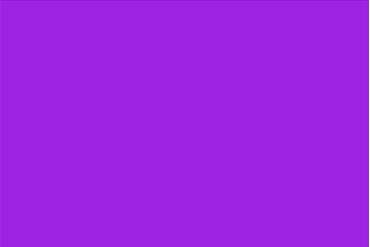
Gather feedback from stakeholders on HERC processes & products



MULTI-STAKEHOLDER SURVEY

METHODS

- 27 question, online survey
 - Quantitative & open-ended questions
 - March 9 – April 27, 2014
- Recruitment through professional networks/organizations, listserves, etc.
- 274 participants

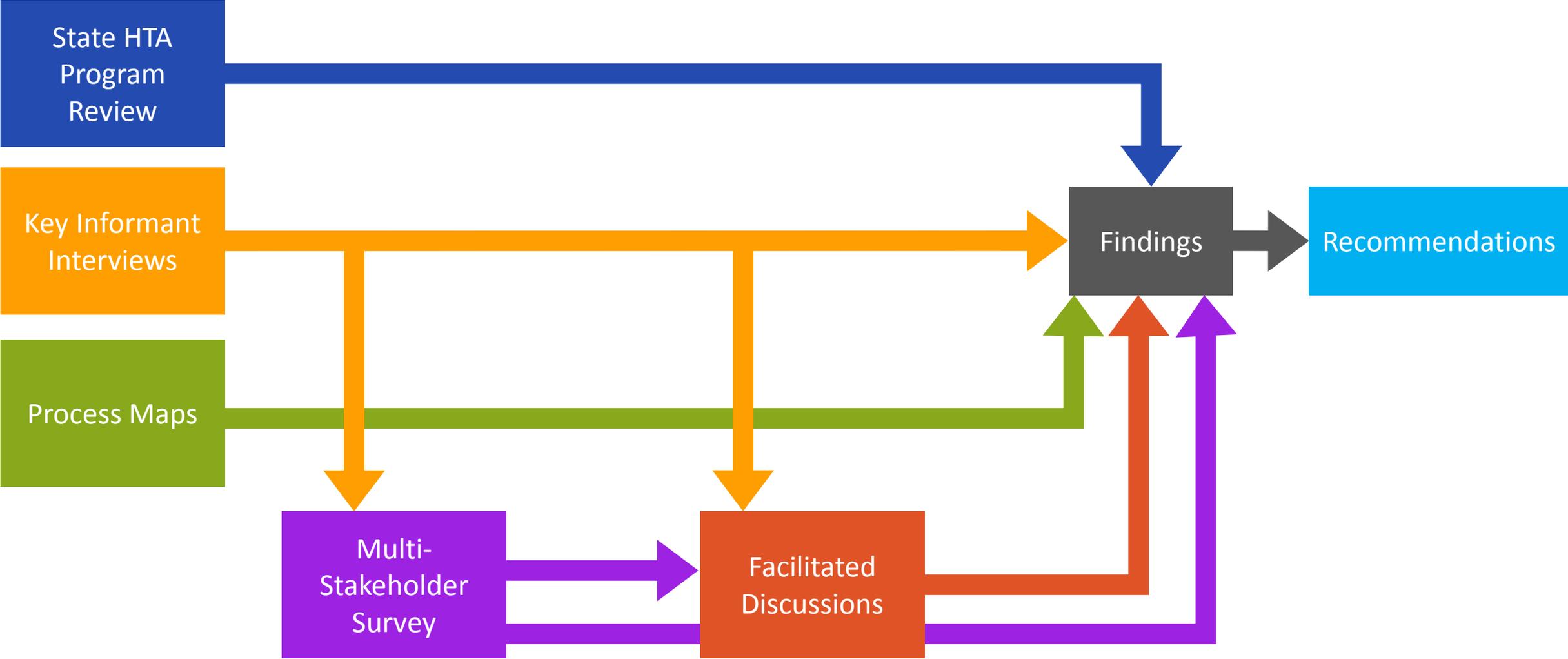


MULTI-STAKEHOLDER SURVEY

FINDINGS

- Many stakeholders are unfamiliar with HERC & its products
 - Stakeholders that are familiar with HERC products rate them highly
 - There is interest in understanding & engaging with HERC
 - Some processes are not well understood by stakeholders
 - Stakeholders are likely to participate in HERC processes
 - There are opportunities to make products more useful & applicable to stakeholders
- 

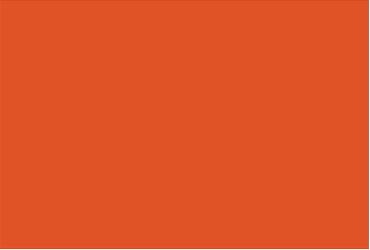
PROJECT DESIGN





Facilitated Discussions

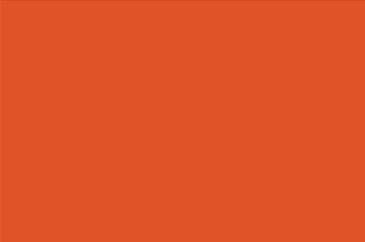
Validate findings to date & solicit additional feedback on processes, product dissemination & utilization



FACILITATED DISCUSSIONS

METHODS

- 3 discussions
 - QHOC
 - CCO Innovator Agents
 - OHLC
- Focus on topic identification, product dissemination & derivative products



FACILITATED DISCUSSIONS

PRELIMINARY FINDINGS

- HERC products used across stakeholder groups
- Accessing HERC information/products can be challenging
- Opportunities to coordinate with commercial payers exist
- High interest in engaging with HERC, particularly on identification of topics
- High interest in derivative products



NEXT STEPS

- Synthesize findings
- Develop recommendations
- Produce final report for OHA



Questions & Feedback

Initial reactions?

Is anything missing?

What does this mean for you?

What should be done to act on the findings?

FOR MORE INFORMATION

Pam Curtis

Director, Center for Evidence-based Policy

Oregon Health & Science University

curtispa@ohsu.edu

Randy Evans

Project Manager, Center for Evidence-based Policy

Oregon Health & Science University

evansr@ohsu.edu

THANK YOU!



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