

Imaging for Rhinosinusitis

Draft Key Questions: Public Comment & Response

November 19, 2014

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Imaging for Rhinosinusitis

Response to Public Comments on Topic and Key Questions

November 19, 2014

Prepared by:

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Response to Public Comments, Topic and Key Questions***Imaging for Rhinosinusitis***

Hayes, Inc. is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document.

Draft key questions for each WA HTA report are posted online in order to gather public input and any additional evidence to be considered in the evidence review. Since key questions guide the evidence report, WA HTA seeks input on whether the questions are appropriate to address its mandate to gather evidence on safety, efficacy, and cost-effectiveness relevant to coverage determinations. Input about the following is especially helpful:

- Are appropriate populations or indications identified?
- Are appropriate comparators identified?
- Are appropriate patient-oriented outcome measures included?
- Are there special policy or clinical considerations that could affect the review?

Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only. When comments cited evidence, the vendor was encouraged to consider inclusion of this evidence in the report.

This document responds to comments from the following parties:

- Harrison Peery; Health Policy Analyst, American Academy of Otolaryngology - Head and Neck Surgery
- R. Christopher Miyamoto, MD, FACS, FAAP; Chairman of the Imaging Committee;, American Academy of Otolaryngology - Head & Neck Surgery
- Danielle E. Jarchow, Esq.; Health Policy Analyst, American Academy of Otolaryngology—Head & Neck Surgery

Table 1 provides a summary of comments with responses.

Table 1. Public Comments on Topic and Key Questions, Imaging for Rhinosinusitis

Comment and Source	Response
Comments on Topic	
March 17, 2014 Letter from Harrison Peery	
<p>“The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) represents approximately 12,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical ailments treated by this specialty are the most common that afflict all Americans, old and young, including hearing loss, balance disorders, chronic ear infections, rhinological disorders, snoring and sleep disorders, swallowing disorders, facial and cranial nerve disorders, and head and neck cancer.</p> <p>After reviewing the Washington Healthcare Authority’s (WHA’s) most recent selections for health technologies to undergo review in 2015, we have identified several AAO-HNS resources that are directly relevant to WHA’s review of two topics: 1) Imaging for Rhinosinusitis and 2) Tympanostomy Tubes. We hope that WHA will consider the following AAO-HNS resources as evidence for consideration during review of these two important topics.”</p> <p>Several resources were cited.</p>	<p>Thank you for your comments and for the helpful links to several resources regarding imaging for rhinosinusitis. The references will be considered for inclusion in the report.</p>
Comments on Draft Key Questions	
October 22, 2014 Letter from R. Christopher Miyamoto, M.D.	
<p>“I serve as the Chairman of the Imaging Committee for the American Academy of Otolaryngology-Head & Neck Surgery. Our committee has reviewed your Draft Questions for the Imaging of Rhinosinusitis. We think they are reasonable. We would like to participate/make comments on your draft report when it is available during open comment period in early 2015. I note that one of our Academy members, Dr. Seth Schwartz, serves on your HTA advisory committee. I wanted to pass along references regarding imaging of chronic rhinosinusitis which we feel are relevant and important for patient care. They will answer some of the issues in draft questions.”</p>	
<p>Several resources were cited, including 2 clinical consensus statements published by the American Academy of Otolaryngology-Head & Neck Surgery</p>	<p>Thank you for these references. The references will be considered for inclusion in the report.</p>
October 22, 2014 Letter from Danielle Jarchow, Esq.	
<p>“Thank you for the opportunity to provide comments on the draft questions for the Authority’s technology review on Imaging for Rhinosinusitis. We appreciate this opportunity and look forwarding to participating and/or providing comments on the draft report when it is available in early 2015. Please find below comments from Dr. Joseph Han, Chair of the Rhinology & Paranasal Sinus Committee of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) for your consideration.”</p>	

Comment and Source	Response
<p>Key Question 1 “The role for US and MRI has questionable value for diagnosing sinusitis, and nasal endoscopy is not an imaging tool. There should, however, be no role for x-ray for evaluation or diagnosis of sinusitis. Perhaps a rewording of the question to, “Under which conditions should a patient get imaging study for sinusitis?”</p>	<p>Thank you for this comment. A review of several Practice Guidelines found mention of CT, MRI, x-ray and ultrasound as options for imaging.</p> <p>No change to the Key Question except for elimination of nasal endoscopy, because it is not considered a form of imaging.</p>
<p>Key Question 2 “A very complicated question. What outcomes are being measured and who will measure them?”</p>	<p>Please refer to the PICO statement for a summary of outcome measures to be assessed.</p> <p>These include “diagnostic performance (accuracy) in terms of sensitivity/specificity, positive/negative predictive value, and positive/negative likelihood ratios; change in clinical management decisions or utilization; health outcomes such as improvement in symptoms, reduced incidence of episodes, improved quality of life (QOL), and prevention of complications; adverse events associated with imaging (e.g., radiation exposure, puncture by endoscopic tube) or with imaging-guided treatment; cost and cost-effectiveness.”</p> <p>No change in the Key Question.</p>
<p>Key Question 3 “The first part of the question is appropriate, but the second part of the question is unclear. More specifically, what is “imaging guided treatment of rhinosinusitis”? There is image guidance surgery used with endoscopic sinus surgery (ESS) but technically it is not a separate procedure so it cannot have its own adverse effects. It would be complications associated with ESS and how IGS affects the complication rate.”</p>	<p>Thank you for this question. This Key Question concerns potential adverse effects of treatment for rhinosinusitis that is <i>informed by</i> diagnostic imaging.</p> <p>The Key Question wording has been modified to increase clarity.</p>

Comment and Source	Response
<p>Key Question 4 “This question is difficult to understand, as it is unclear as to what is being asked. There are certain imaging performed with certain type of sinus disease. Such as a MRI and CT should be performed in patient with a sinonasal tumor.”</p>	<p>Thank you for this question. This Key Question concerns potential patient histories/characteristics that <i>may</i> be found in the analysis of the literature to affect outcomes (e.g., comorbidities, subtypes of rhinosinusitis).</p> <p>The Key Question wording has been modified by providing examples to increase clarity.</p>
<p>Key Question 5 “This question is difficult to understand. More specifically, what type of repeated imaging is the question referring to? Repeat CT? Or is the repeat imaging of another image modality such as an MRI or PET scan? “</p>	<p>Thank you for this comment.</p> <p>We will address any of the possibilities mentioned in the comment if they are represented in the research literature. However, if relevant data are found, this question will be covered in the findings for Key Question #2.</p> <p>The Key Question has been removed, as data will be covered in the findings for Key Question #2.</p>
<p>Key Question 6 “What is cost? Just the dollar amount of the various imaging modality? Or does cost include complications/adverse effects from the imaging study, disease process, pain, time off from work, length in OR procedure, etc.”</p>	<p>Thank you for this question. We will consider evidence related to any costs but will focus on costs pertinent to a payer perspective.</p> <p>No change in the Key Question.</p>

Subject: FW: WHA Topics for Review in 2015: Imaging for Rhinosinusitis and Tympanostomy Tubes

Importance: High

From: Peery, Harrison [<mailto:Hpeery@entnet.org>]

Sent: Monday, March 17, 2014 12:31 PM

To: HCA ST Health Tech Assessment Prog

Cc: Kappel, Jenna; Minton, Jenna; Jarchow, Danielle; Brereton, Jean; Masters, Christine V. (HCA)

Subject: Re: WHA Topics for Review in 2015: Imaging for Rhinosinusitis and Tympanostomy Tubes

Importance: High

Dear Ms. Masters:

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) represents approximately 12,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical ailments treated by this specialty are the most common that afflict all Americans, old and young, including hearing loss, balance disorders, chronic ear infections, rhinological disorders, snoring and sleep disorders, swallowing disorders, facial and cranial nerve disorders, and head and neck cancer.

After reviewing the Washington Healthcare Authority's (WHA's) most recent selections for health technologies to undergo review in 2015, we have identified several AAO-HNS resources that are directly relevant to WHA's review of two topics: 1) Imaging for Rhinosinusitis and 2) Tympanostomy Tubes. We hope that WHA will consider the following AAO-HNS resources as evidence for consideration during review of these two important topics:

Imaging for Rhinosinusitis:

- Clinical Practice Guideline on Adult Sinusitis (Update in Progress): http://www.entnet.org/guide_lines/Adult-Sinusitis.cfm
- Clinical Consensus Statement on Imaging for Paranasal Sinus Disease: <http://oto.sagepub.com/content/147/5/808.abstract>
- Clinical Indicator Adult Sinus Surgery: <http://www.entnet.org/Practice/Endoscopic-Sinus-Surgery-Adult.cfm>
- Clinical Indicator Pediatric Sinus Surgery: <http://www.entnet.org/Practice/Endoscopic-Sinus-Surgery-Pediatric.cfm>
- Clinical Indicator Diagnostic Nasal Endoscopy: <http://www.entnet.org/Practice/Diagnostic-Nasal-Endoscopy.cfm>
- Position Statement on Intra-Operative Use of Computer Guided Imagery <http://www.entnet.org/Practice/policyIntraOperativeSurgery.cfm>
- Position Statement on Sinus Endoscopy: <http://www.entnet.org/Practice/policySinusEndoscopy.cfm>
- Position Statement on Point of Care Imaging: <http://www.entnet.org/Practice/policyReimburseImagingStudies.cfm>
- Patient Fact Sheet on Allergic Rhinitis, Sinusitis and Rhinosinusitis: <http://www.entnet.org/HealthInformation/rhinitis.cfm>

Tympanostomy Tubes:

- Clinical Practice Guideline: Tympanostomy Tubes in Children: <http://www.entnet.org/guidelines/Tubes.cfm>
- Clinical Indicator on Myringotomy and Tympanostomy Tubes: <http://www.entnet.org/Practice/Myringotomy-and-Tympanostomy-Tubes.cfm>
- Position Statement on Middle-Ear Ventilation Tube Placement: <http://www.entnet.org/Practice/policyMidEarVentPlacement.cfm>

If you have further information regarding the schedule and process of these two reviews, please feel free to forward on and keep us posted as we would like to submit additional comments and potentially have one of our physician leaders attend the meetings as we have done in the past. Please let me know if you have any questions about any of the above listed resources.

Best Regards,

Harrison Peery
Health Policy Analyst
American Academy of Otolaryngology - Head and Neck Surgery
P: 703-535-3728
E: hpeery@entnet.org

From: [Miyamoto, Richard](#)
To: [HCA ST Health Tech Assessment Prog](#)
Cc: [Jarchow, Danielle](#); [Gavin Setzen, MD](#)
Subject: comments on imaging for rhinosinusitis from AAO-HNSF
Date: Tuesday, October 21, 2014 9:52:30 PM

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Hello:

I serve as the Chairman of the Imaging Committee for the American Academy of Otolaryngology-Head & Neck Surgery . Our committee has reviewed your Draft Questions for the Imaging of rhinosinusitis. We think they are reasonable. We would like to participate/make comments on your draft report when it is available during open comment period in early 2015. I note that one of our Academy members ,Dr Seth Schwartz, serves on your HTA advisory committee.

I wanted to pass along references regarding imaging of chronic rhinosinusitis which we feel are relevant and important for patient care. They will answer some of the issues in draft questions.

Of particular importance are our two clinical consensus statements published by our Academy:

1) *Clinical Consensus Statement: Appropriate Use of Computed Tomography for Paranasal Sinus Disease*

Setzen, G et al. Otolaryngol Head Neck Surg November 2012 vol. 147 no. 5 808-816

2) Clinical Consensus Statement: Pediatric Chronic Rhinosinusitis *Otolaryngol Head Neck Surg October 1, 2014 151: 542-553*

The longer list of references is listed at the bottom of the email.
Thank you for your attention. We hope to be of assistance to your organization during the public comment period.

Sincerely
Chris Miyamoto

[R. Christopher Miyamoto,MD, FACS, FAAP](#)
Pediatric Otolaryngology
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Diagnosis and management of rhinosinusitis: a practice parameter update.
Peters AT, Spector S, Hsu J, Hamilos DL, Baroody FM, Chandra RK, Grammer LC,
Kennedy DW, Cohen NA, Kaliner MA, Wald ER, Karagianis A, Slavin RG.
Ann Allergy Asthma Immunol. 2014 Oct;113(4):347-85. doi:
10.1016/j.anai.2014.07.025.

The prevalence of bacterial infection in acute rhinosinusitis: A Systematic review and meta-analysis.

Shintani Smith S, Ference EH, Evans CT, Tan BK, Kern RC, Chandra RK.
Laryngoscope. 2014 Apr 9. doi: 10.1002/lary.24709. [Epub ahead of print]
PMID:

. A review of current evidence regarding several key sinonasal disorders.
Chandra R.

Am J Rhinol Allergy. 2013 Sep-Oct;27(5):343-4. doi: 10.2500/ajra.2013.27.0013. No abstract available.

Effect of symptom-based risk stratification on the costs of managing patients with chronic rhinosinusitis symptoms.

Tan BK, Lu G, Kwasny MJ, Hsueh WD, Shintani-Smith S, Conley DB, Chandra RK,
Kern RC, Leung R.
Int Forum Allergy Rhinol. 2013 Nov;3(11):933-40. doi: 10.1002/alr.21208. Epub 2013 Sep 5.

National burden of antibiotic use for adult rhinosinusitis.

Smith SS, Evans CT, Tan BK, Chandra RK, Smith SB, Kern RC.
J Allergy Clin Immunol. 2013 Nov;132(5):1230-2. doi:
10.1016/j.jaci.2013.07.009. Epub 2013 Aug 26.

Primary care and upfront computed tomography scanning in the diagnosis of chronic rhinosinusitis: a cost-based decision analysis.

Leung RM, Chandra RK, Kern RC, Conley DB, Tan BK.
Laryngoscope. 2014 Jan;124(1):12-8. doi: 10.1002/lary.24100. Epub 2013 Aug 5.

Chronic rhinosinusitis: epidemiology and cost.

Halawi AM, Smith SS, Chandra RK.
Allergy Asthma Proc. 2013 Jul-Aug;34(4):328-34. doi: 10.2500/aap.2013.34.3675.
Review.

Chapter 4: Chronic rhinosinusitis.

Settipane RA, Peters AT, Chandra R.
Am J Rhinol Allergy. 2013 May-Jun;27 Suppl 1:S11-5. doi:
10.2500/ajra.2013.27.3925. Review.

Advances in endoscopic instrumentation and visualization, as well as radiologic imaging, have facilitated earlier diagnosis and lesser morbidity from therapeutic intervention.

Chandra R, Chiu A, Carr W, Settipane R.
Am J Rhinol Allergy. 2013 May-Jun;27 Suppl 1:S1. doi: 10.2500/ajra.2013.27.3933.

No abstract available.

Incidence and associated premorbid diagnoses of patients with chronic rhinosinusitis.

Tan BK, Chandra RK, Pollak J, Kato A, Conley DB, Peters AT, Grammer LC, Avila PC, Kern RC, Stewart WF, Schleimer RP, Schwartz BS.

J Allergy Clin Immunol. 2013 May;131(5):1350-60. doi:

10.1016/j.jaci.2013.02.002. Epub 2013 Mar 28.

Variations in antibiotic prescribing of acute rhinosinusitis in United States ambulatory settings.

Smith SS, Kern RC, Chandra RK, Tan BK, Evans CT.

Otolaryngol Head Neck Surg. 2013 May;148(5):852-9. doi:

10.1177/0194599813479768. Epub 2013 Mar 5.

Identifying clinical symptoms for improving the symptomatic diagnosis of chronic rhinosinusitis.

Hsueh WD, Conley DB, Kim H, Shintani-Smith S, Chandra RK, Kern RC, Tan BK.

Int Forum Allergy Rhinol. 2013 Apr;3(4):307-14. doi: 10.1002/alr.21106. Epub 2012 Nov 5.

Patient level decision making in recurrent acute rhinosinusitis: a cost-benefit threshold for surgery.

Leung R, Almassian S, Kern R, Conley D, Tan B, Chandra R.

Laryngoscope. 2013 Jan;123(1):11-6. doi: 10.1002/lary.23504. Epub 2012 Sep 5.

Cost effectiveness of magnetic resonance imaging in the workup of the dysosmia patient.

Decker JR, Meen EK, Kern RC, Chandra RK.

Int Forum Allergy Rhinol. 2013 Jan;3(1):56-61. doi: 10.1002/alr.21066. Epub 2012 Jul 11.

Medical therapy vs surgery for chronic rhinosinusitis: a prospective, multi-institutional study with 1-year follow-up.

Smith TL, Kern R, Palmer JN, Schlosser R, Chandra RK, Chiu AG, Conley D, Mace JC, Fu RF, Stankiewicz J.

Int Forum Allergy Rhinol. 2013 Jan;3(1):4-9. doi: 10.1002/alr.21065. Epub 2012 Jun 26.

PMID:

Comparison of Intraoperative Portable CT Scanners in Skull Base and Endoscopic Sinus Surgery: Single Center Case Series.

Conley DB, Tan B, Bendok BR, Batjer HH, Chandra R, Sidle D, Rahme RJ, Adel JG, Fishman AJ.

Skull Base. 2011 Jul;21(4):261-70. doi: 10.1055/s-0031-1280681.

Medical therapy vs surgery for chronic rhinosinusitis: a prospective, multi-institutional study.

Smith TL, Kern RC, Palmer JN, Schlosser RJ, Chandra RK, Chiu AG, Conley D, Mace JC, Fu RF, Stankiewicz JA.

Int Forum Allergy Rhinol. 2011 Jul-Aug;1(4):235-41. doi: 10.1002/alr.20063. Epub 2011 Jun 6.

A randomized trial examining the effect of pretreatment point-of-care computed tomography imaging on the management of patients with chronic rhinosinusitis symptoms.

Tan BK, Chandra RK, Conley DB, Tudor RS, Kern RC.

Int Forum Allergy Rhinol. 2011 May-Jun;1(3):229-34. doi: 10.1002/alr.20044. Epub 2011 Mar 16.

Factors associated with computed tomography status in patients presenting with a history of chronic rhinosinusitis.

Abrass LJ, Chandra RK, Conley DB, Tan BK, Kern RC.

Int Forum Allergy Rhinol. 2011 May-Jun;1(3):178-82. doi: 10.1002/alr.20015. Epub 2011 Feb 8.

Establishing a threshold for surgery in recurrent acute rhinosinusitis: a productivity-based analysis.

Leung R, Kern RC, Conley DB, Tan BK, Chandra RK.

Otolaryngol Head Neck Surg. 2012 May;146(5):829-33. doi: 10.1177/0194599811434709. Epub 2012 Jan 18.

PMID:

Age-related differences in the pathogenesis of chronic rhinosinusitis.

Cho SH, Hong SJ, Han B, Lee SH, Suh L, Norton J, Lin D, Conley DB, Chandra R, Kern RC, Tan BK, Kato A, Peters A, Grammer LC, Schleimer RP.

J Allergy Clin Immunol. 2012 Mar;129(3):858-860.e2. doi:

10.1016/j.jaci.2011.12.002. Epub 2012 Jan 10. No abstract available.

Advancements in computed tomography management of chronic rhinosinusitis.

Leung R, Chaung K, Kelly JL, Chandra RK.

Am J Rhinol Allergy. 2011 Sep-Oct;25(5):299-302. doi: 10.2500/ajra.2011.25.3641. Review.

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From: [Jarchow, Danielle](#)
To: [HCA ST Health Tech Assessment Prog](#)
Cc: [Han, Joseph K.](#); [Jarchow, Danielle](#); [Kappel, Jenna](#); [Peery, Harrison](#)
Subject: Comments on Draft Questions Re Imaging for Rhinosinusitis from AAO-HNS
Date: Wednesday, October 22, 2014 2:44:56 PM
Attachments: [image001.png](#)
[image002.png](#)

To Whom It May Concern:

Thank you for the opportunity to provide comments on the draft questions for the Authority's technology review on Imaging for Rhinosinusitis. We appreciate this opportunity and look forward to participating and/or providing comments on the draft report when it is available in early 2015. Please find below comments from Dr. Joseph Han, Chair of the Rhinology & Paranasal Sinus Committee of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) for your consideration.

[DRAFT KEY QUESTIONS FOR TECH ASSESSMENT ON IMAGING RHINOSINUSITIS](#)

1. What is the diagnostic performance (accuracy) of imaging technologies such as x-ray, US, MRI, CT, and nasal endoscopy for evaluation of rhinosinusitis or related complications?

a. Does the diagnostic performance vary by imaging modality or technique?

Comment: The role for US and MRI has questionable value for diagnosing sinusitis, and nasal endoscopy is not an imaging tool. There should, however, be no role for x-ray for evaluation or diagnosis of sinusitis. Perhaps a rewording of the question to, "Under which conditions should a patient get imaging study for sinusitis?"

2. What is the impact of diagnostic imaging for rhinosinusitis on outcomes?

a. On clinical management decisions and utilization?

b. On health outcomes?

c. According to different imaging modalities?

Comment: A very complicated question. What outcomes are being measured and who will measure them?

3. What is the safety to patients of different forms of imaging technologies and what are the potential adverse effects of imaging-guided treatment of rhinosinusitis?

Comment: The first part of the question is appropriate, but the second part of the question is unclear. More specifically, what is "imaging guided treatment of rhinosinusitis"? There is image guidance surgery used with endoscopic sinus surgery (ESS) but technically it is not a separate procedure so it cannot have its own adverse effects. It would be complications associated with ESS and how IGS affects the complication rate.

4. Does the diagnostic performance, impact on clinical management, impact on health outcomes, or incidence of adverse events vary by clinical history or patient characteristics?

Comment: This question is difficult to understand, as it is unclear as to what is being asked. There are certain imaging performed with certain type of sinus disease. Such as a MRI and CT should be performed in patient with a sinonasal tumor.

5. Has repeated imaging been shown to have an impact on clinical management decisions or health outcomes?

Comment: This question is difficult to understand. More specifically, what type of repeated imaging is the question referring to? Repeat CT? Or is the repeat imaging of another image modality such as an MRI or PET scan?

6. What are the cost and cost-effectiveness of imaging modalities in the diagnosis of sinusitis, including comparative costs and incremental cost-effectiveness when comparing modalities?

Comment: What is cost? Just the dollar amount of the various imaging modality? Or does cost include complications/adverse effects from the imaging study, disease process, pain, time off from work, length in OR procedure, etc.

Should you have any questions or concerns regarding the aforementioned comments, please do not hesitate to contact Dr. Han at HanJK@evms.edu or Danielle Jarchow at djarchow@entnet.org. Thank you again for the opportunity to provide comments and feedback on the draft questions.

Warmest Regards,

Danielle E. Jarchow, Esq.