

Imaging for Rhinosinusitis

Draft Evidence Report: Comment & Response

April 3, 2015

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Imaging for Rhinosinusitis Response to Public Comments on Draft Report

April 3, 2015

Prepared by:

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Response to Public Comments, Draft Report

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.

Comments related to program decisions, processes, or other matters not pertaining to the evidence report are acknowledged through inclusion only. When comments cite evidence, the information is forwarded to the vendor for consideration in the evidence report.

This document responds to comments from the following parties:

- The American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS); Rhinology and Paranasal Sinus (RPS) Committee
- The American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS); Imaging Committee

Table 1 provides a summary of the comments with corresponding responses.

Table 1. Public Comments on Draft Report, Imaging for Rhinosinusitis

Key: AAO, American Academy of Otolaryngology; HNS, Head and Neck Surgery; RPS, Rhinology and Paranasal Sinus

Comment and Source	Response
March 16, 2015 e-mail from Danielle Jarchow (AAO-HNS, RPS Committee)	
Comment: "The Committee is concerned with the authors' consideration of CRS as a bacterial disease. The authors appear to be weighing how CT affects antibiotic usage in CRS. This is an outdated approach. CRS is an inflammatory disease and the examination needs to address CT's impact appropriately. "	Thank you for this comment. We have modified the Clinical Background section to stress that CRS is an inflammatory disease and that bacterial infection is one of several variations.
	It should be noted that a search of the literature for Key Question #2 (regarding the impact of imaging on clinical management decisions and utilization) produced 3 studies, 2 of which had primary findings that CT prior to medical treatment may reduce the use of antibiotics in patients with persistent symptoms but a negative endoscopy. (The third study assessing clinical utility found that CT may be an important factor in surgeons' decision to offer surgery in patients with refractory CRS.) Published review articles also reflect an interest in reduction of antibiotic use by upfront CT. Thus, it is necessary to maintain some emphasis on the utility of CT for this indication.
Comment: "We recommend inclusion of AAO-HNS' Clinical Practice Guideline: Adult Sinusitis (update currently in process; publication expected April 2015) as a reference and resource for the WSHA's report."	Thank you for your comment. Because the Final Report must be completed prior to the date of publication of the updated guideline, an assessment and description of the updated guideline cannot be included in this report. However, we will refer to the imminent publication of the updated guideline in the Summary of Practice Guidelines table (Appendix V) and familiarize ourselves with the new guidelines prior to the public meeting.

Comment and Source	Response
March 16, 2015 e-mail from Danielle Jarchow (AAO-HNS, Imaging Committee)	
 Key Question #3 Comment: "Key Question #3 (and elsewhere where low dose point-of-care (POC) CT imaging is reference, we would recommend providing additional language for a better understanding of safety issues associated with different forms of imaging technologies. As written, the report notes the safety/lower radiation dose that point-of-care (POC) imaging can provide but these comments are location/site specific and do not reference cone beam CT (CBCT) specifically, which is the imaging technology that makes this low radiation dose imaging option possible. It is important to make this specific distinction because POC imaging includes both cone beam CT (CBCT) technologies and/or conventional CT technologies. The FDA has approved CBCT technologies and CMS and third party payers consider both conventional and CBCT appropriate for imaging of the paranasal sinuses, skull base and temporal bones in the office (POC) setting. CBCT provides greater spatial resolution at a significantly lower level of radiation than a conventional CT scanner [2]; an important distinction to make between CBCT and conventional CT. In other words, CBCT is the only modality available to provide this lower dose of radiation. As such, the AAO-HNS encourages the WSHA to consider revising the language under Key Question #3 to make this distinction apparent." [2] Miracle, A.C., Mukherji, S.K. (2009). Conebeam CT of the Head and 	Thank you for this comment. The content under Key Question #3 has been modified accordingly to clarify the safety issues associated with different CT imaging technologies. Additional background information on CBCT has been added to the Clinical Background section, citing the Miracle and Mukherji (2009) study.
Neck, Part 1: Physical Principles, AJNR, 30	

From:	Jarchow, Danielle
To:	HCA ST Health Tech Assessment Prog
Cc:	Jarchow, Danielle
Subject:	Draft Evidence Report for Imaging Rhinosinusits
Date:	Friday, March 13, 2015 2:24:24 PM
Attachments:	image001.png

To Whom It May Concern:

Thank you for the opportunity to provide comments on the draft report for the Authority's technology review on Imaging for Rhinosinusitis. The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) appreciates this opportunity and looks forward to continuing our participation. Please find below comments from Imaging Committee of the AAO-HNS for your consideration.

Overall, the Imaging Committee finds the report to be very thorough and detailed with a robust reference base of quality evidence. Despite not having problems with the document as a whole the Committee feels there are areas where greater clarification is warranted. More specifically, under Key Question #3 (and elsewhere where low dose point-of-care (POC) CT imaging is reference, we would recommend providing additional language for a better understanding of safety issues associated with different forms of imaging technologies. Under Key Question #3 the report currently reads, "As noted in the SUMMARY OF CLINICAL BACKGROUND section, the risks associated with CT, MRI, x-ray, and US scans are minimal. These are all established technologies that have long been used for many applications. However, unnecessary repeated use of CT and x-ray in a patient would be of concern because of the radiation exposure." The report here goes on to note that one of the modeling studies reviewed as evidence for Key Question #5 estimated that upfront CT, compared with empiric medical therapy, for CRS would result in an increased radiation exposure of 0.09 millisieverts (mSv) or 0.48 mSv, depending on whether point-of-care (POC) or only conventional CT were available.

As written, the report notes the safety/lower radiation dose that point-of-care (POC) imaging can provide but these comments are location/site specific and do not reference cone beam CT (CBCT) specifically, which is the imaging technology that makes this low radiation dose imaging option possible. It is important to make this specific distinction because POC imaging includes **both** cone beam CT (CBCT) technologies <u>and/or</u> conventional CT technologies. The FDA has approved CBCT technologies, and CMS and third party payers consider both conventional and CBCT appropriate for imaging of the paranasal sinuses, skull base and temporal bones in the office (POC) setting. **CBCT provides greater spatial resolution at a significantly lower level of radiation than a conventional CT scanner** [2]; an important distinction to make between CBCT and conventional CT. In other words, CBCT is the only modality available to provide this lower dose of radiation. As such, the AAO-HNS encourages the WSHA to consider revising the language under Key Question #3 to make this distinction apparent.

In addition, we recommend inclusion of AAO-HNS' Clinical Practice Guideline: Adult Sinusitis (update currently in process; publication expected April 2015) as a reference and resource for the WSHA's report. Our regard for providing an unparalleled quality of care to patients with disorders of the ears, nose, throat, and other related head and neck structures cannot be overstated. We strive to provide the highest quality of care to our patient, which is why the AAO-HNS/F routinely works collaboratively with other specialties when producing many of its guidance documents, including its Clinical Practice Guidelines (CPG). Use of our Clinical Practice Guidelines (CPG) is one way that the AAO-HNS/F, more specifically our members, increases implementation of evidence into practice. They serve as guides to best practices, a framework for clinical decision making, and a benchmark for evaluating performance. Our Clinical Practice Guideline: Adult Sinusitis was developed via a multidisciplinary approach, including radiology, and serves as an invaluable resource to many providers. As such, we respectfully request WSHA consider its inclusion as a reference and resource.

[2] Miracle, A.C., Mukherji, S.K., Conebeam CT of the Head and Neck, Part 1: Physical Principles, AJNR 30, June-July 2009

We thank you for the opportunity to provide comment on the draft report. Should you have any questions or concerns, please do not hesitate to contact Danielle Jarchow, Esq. Health Policy Analyst, AAO-HNS, via email at <u>djarchow@entnet.org</u> or via telephone at (703) 535 3729.

Warmest Regards,

Danielle

Danielle E. Jarchow, Esq. *Health Policy Analyst*

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Overall, the RPS Committee finds the report to be very detailed and appears to have looked at the appropriate evidence. However, despite not having problems with the document as a whole, the Committee is concerned with the authors consideration of CRS as a bacterial disease. The authors appear to be weighing how CT affects antibiotic usage in CRS. This is an outdated approach. CRS is an inflammatory disease and the examination needs to address CT's impact appropriately.

We recommend inclusion of AAO-HNS' Clinical Practice Guideline: Adult Sinusitis (update currently in process; publication expected April 2015) as a reference and resource for the WSHA's report. Our regard for providing an unparalleled quality of care to patients with disorders of the ears, nose, throat, and other related head and neck structures cannot be overstated. We strive to provide the highest quality of care to our patient, which is why the AAO-HNS/F routinely works collaboratively with other specialties when producing many of its guidance documents, including its Clinical Practice Guidelines (CPG). Use of our Clinical Practice Guidelines (CPG) is one way that the AAO-HNS/F, more specifically our members, increases implementation of evidence into practice. They serve as guides to best practices, a framework for clinical decision making, and a benchmark for evaluating performance. Our Clinical Practice Guideline: Adult Sinusitis was developed via a multidisciplinary approach, including radiology, and serves as an invaluable resource to many providers. As such, we respectfully request WSHA consider its inclusion as a reference and resource.

We thank you for the opportunity to provide comment on the draft report. Should you have any questions or concerns, please do not hesitate to contact Danielle Jarchow, Esq. Health Policy Analyst, AAO-HNS, via email at <u>djarchow@entnet.org</u> or via telephone at (703) 535 3729.

Warmest Regards, Danielle

Danielle E. Jarchow, Esq. *Health Policy Analyst*



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