



STANDARD TREATMENT GUIDELINES ON ACUTE SINUSITIS

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1. INTRODUCTION

1.1 Definitions- Acute sinusitis is an inflammation of the paranasal sinuses and the nasal cavity lasting no longer than 4 weeks *characterized by purulent nasal discharge (anterior, posterior or both) accompanied by nasal obstruction, facial pain-pressure-fullness, or both.* The term Acute sinusitis and Acute rhinosinusitis has been used interchangeably in literature are same entity and hence in the rest of the guidelines term Acute sinusitis is used.

1.2 Burden of disease- Though acute sinusitis is a very common disease and a significant burden on the health services, data on prevalence of acute sinusitis in India could not be obtained by the clinical sub group when a systematic literature search using Pubmed and Google.Twelve percent of US population (nearly 1 in 8 adults) reported being diagnosed with rhino sinusitis in the prior 12 months in a 2012 national health survey¹. Approximately 0.5% of all upper respiratory tract infections are complicated by sinusitis; the incidence of acute sinusitis ranges from 15 to 40 episodes per 1000 patients per year, depending on the setting. It is much more common in adults than it is in children, whose sinuses are not fully developed. Acute sinusitis is the second most common infectious disease seen by General Practitioners (GPs). Most acute sinusitis is caused by the same viruses that cause the common cold (ARI). It is self-limiting disease and most of them can be treated symptomatically. Treatment with antibiotics is required only on cases when the symptoms persist for more than 10 days indicating that there is superadded bacterial infection.

1.3 Morbidity and mortality -

Exact incidence of acute sinusitis in India was not available when a literature search was performed on Pubmed or Google scholar. Whatever data is available is from western population. Rhinosinusitis is an extremely common condition. Incidence rates among adults are higher for women than men (1.9-fold), and adults between 45 and 74 years are most commonly affected.

2. CURRENT PRACTICES IN INDIA

It is common practice for most diagnoses of upper respiratory tract infection to receive prescription for antibiotics from primary care physicianwithout a diagnosis of sinusitis. All patients going to primary care physician receive prescriptions for antibiotics. This occurs despite the fact that natural history of disease is self limiting. Despite the high prevalence and economic impact of sinusitis, considerable practice variations exists across and within the multiple disciplines involved in managing the condition. Currently there are no standard treatment guidelines available for diagnosis and management of acute sinusitis in India.

3. NEED FOR A STG/ GUIDELINE PURPOSE

There is widespread misuse of antibiotics by the general practitioners and primary care physicians to treat even simple upper respiratory tract infection. This indiscriminate use of the antibiotics has led to the development of drug resistance and is an economic burden to the health services. Apart from this there is an additional expense from lost productivity, reduced job effectiveness, and impaired quality of life. All this can be avoided if we have standard treatment guidelines for acute sinusitis. In additionthere is anover of use of various other ancillary treatments like antihistaminics, steroids, pain killers, decongestants, vitamins, mucolytics, steam inhalations, saline douching and saline spray etc. The use of all these ancillary treatment also placesa lot of financial burden on the patients and health services. Use of the all these ancillary treatments must be based on scientific evidence and a standard treatment guideline will streamline this.

Developing a STG on acute sinusitis will help improve quality of care and decrease costs by accurate diagnosis of the condition, appropriate medical therapy, effective radiological imaging and appropriate subspecialist consultation.

4. RECOMMENDATIONS

- **4.1 Diagnosis of Acute Sinusitis**-Up to 4 weeks of purulent nasal drainage (anterior, posterior, or both) accompanied by nasal obstruction, facial pain-pressure-fullness, or both.
- **4.1.1** Acute viral sinusitis (the common cold) is caused by,or presumed to be caused by viral infection. A clinician should diagnose acute viral sinusitis when symptoms or signs of acute rhinosinusitis are present less than 10 days and the symptoms are not worsening.
- **4.1.2** Acute bacterialrhinosinusitis(ABRS) is made on the basis of following any of the three clinical presentation criteria.
 - 1. Onset with persistent symptoms or signs compatible with acute rhinosinusitis, lasting for more than 10 days without any evidence of clinical improvement

- 2. Onset with severe symptoms or signs of high fever (>39°C /102°F) and purulent nasal discharge or facial pain lasting for at least 364 consecutive days at the beginning of illness
- 3. Onset with worsening symptoms or signs characterized by the new onset of fever, headache, or increase in nasal discharge following a typical viral URI that lasted 566 days and were initially improving (::double-sickeningø).
- 4. Rule out allergic rhinitis (AR) which is diagnosed when in addition to nasal obstruction and discharge there is also itchy nose, excessive sneezing, red and watery eyes.*

4.1.3 Clinical features: symptoms and signs

Diagnosis of Acute sinusitis is probable if 2 or more of these major symptoms are present or 1 major symptom along with 2 or more minor symptoms (RI 2004)

Major Symptoms

- Purulent anterior or posterior nasal discharge)
- Nasal blockage/congestion/obstruction
- Facial congestion/ fullness
- Facial pain/pressure/fullness
- Hyposmia/anosmia
- Fever (acute only) high grade more than 39 degree Celsius.

Minor Symptoms

- Headache
- Ear pain/fullness/pressure
- Halitosis
- Dental pain
- Cough
- Fever
- Fatigue

Signs (may be seen but absence of these does not exclude Acute sinusitis)* expert group consensus

- Hypo-nasal speech indicating nasal obstruction
- Swelling, redness of the skin due to congestion of the capillaries (erythema) or abnormally large fluid volume (edema) localized over the involved cheek bone or periorbital area
- Palpable cheek tenderness or percussion tenderness of the upper teeth
- Purulent drainage in the nose or posterior pharynx

• Signs of extra-sinus involvement (orbital or facial cellulitis, orbital protrusion, abnormalities of eye movement, neck stiffness indicating complications.

4.2Role of imaging

4.2.1 Do not use radiographic imaging for patients who have a diagnosis of acute sinusitis, unless a complication such as orbital and intracranial extension or alternative diagnosis is suspected.

4.2.2 If symptoms of sinusitis persist for more than three weeks despite antibiotics or recur more than four times per year, a sinus CT scan should be performed while the patient is symptomatic to reassess diagnosis and determine need for referral (UM).

4.2.3 Plain sinus x-rays, are not at all recommended in management of sinusitis.

4.2.4 Indications of CT scan PNS

• Severe headache associated with facial swelling or cranial nerve palsy or neck rigidity

- Forward displacement or bulging of the eye (proptosis)
- Visual disturbances

4.3Treatment

4.3.1 When should empiric antibiotic therapy be initiated?

Initiate empiric antimicrobial therapy as soon as the clinical diagnosis of ABRS is established as defined in recommendation.

4.3.2 Choice of antibiotic for ABRS

- 1. Amoxicillin-clavulanate is recommended as empiric antimicrobial therapy for ABRS in adults.
- 2. The recommended duration of therapy for uncomplicated ABRS in adults is 567 days.
- 3. For partial but incomplete resolution after an initial course of antibiotics, extend the duration of antibiotic therapy by an additional 7 to 10 days.

Use of High-dose (2 g orally twice daily or 90 mg/kg/day orally twice daily) amoxicillinclavulanate is recommended for patients with acute sinusitis (eg, evidence of systemic toxicity with fever of more than 39 degree C [102 degree F] or higher, and threat of suppurative complications, attendance at daycare, age <2 or >65 years, recent hospitalization, antibiotic use within the past month, or who are immunocompromised.

4.3.3Choice of antibiotic for ABRS in penicillin allergic patients

Use of doxycycline (100mg every 12hr) or a respiratory ł uoroquinolone (levoł oxacin 500mg daily or moxił oxacin 400mg daily) is recommended as an alternative agent for empiric antimicrobial therapy in adults who are allergic to penicillin.

4.3.4 Treatment failure for ABRS

- 1 Reassess the patient after 7 days to confirm ABRS, exclude other causes of illness, and detect complications if the patient fails to improve with the initial management option or worsens during the initial management.
- 2 If ABRS is confirmed in the patient initially managed with observation, the clinician should begin antibiotic therapy.
- 3 The second line antibiotics include high dose amoxicillin/clavulanate combination(2 g orally twice daily or 90 mg/kg/day orally twice daily), levofloxacin (500mg daily), and moxifloxacin (400mg daily) or the combination of clindamycin (300 mg 12 hr) plus a third-generation oral cephalosporin {cefixime(200 mg 12 hr) or cefpodoxime(200 mg 12 hr) }.
- 4 Worsening is defined as progression of presenting signs or symptoms of ABRS or onset of new signs or symptoms. Failure to improve is lack of reduction in presenting signs or symptoms of ABRS by 7 days after diagnosis, which would not apply if the patient had persistent, yet gradually improving, symptoms.
- 5 ABRS may take up to 7 days to improve, persistence or minor worsening prior to 7 days does not necessarily indicate treatment failure, and complete cure (absence of all signs and symptoms) may take 14 days or longer.

4.4 Ancillary therapy

4.4.1 Decongestants (topical- Oxymetazoline and Xylometazoline)

Use of topical decongestants is recommended in case of severe nasal obstruction for short duration. (Maximum of 5 days). These should be used with precautions in patients with hypertension.

4.4.2 Analgesics

Nonsteroidal anti-inflammatory drugs like paracetamol 500 mg tab tds/sosor diclofenac sodium 50 mg tab tds/sos, are recommended for pain relief associated with acute sinusistis.

4.4.3 Antihistamines

Routine administration of antihistamines are not recommended in patients of sinusitis.

4.4.4 Intra nasal corticosteroid spray

Though INCSs are not essential for treatment of ABRS they are recommended as an adjunct to antibiotics in the empiric treatment of ABRS for 10 days. Fluticasone ormometasone intra nasal sprays are recommended twice daily.

4.4.5 Steam inhalation

Steam inhalation is recommended by the expert group twice a day for 5-7 days.

4.4.6 Nasal spray and douching with physiologic/hypertonic saline

Intranasal saline irrigations with either physiologic or hypertonic saline are recommended as an adjunctive treatment in adults with ABRS.

4.5 Alternative Diagnoses

ÉAllergic rhinitis ÉHeadache, migraine or tension ÉNasal drying (sicca patients) ÉGastroesophageal reflux ÉAtrophic rhinitis ÉTemperomandibular joint pain, dental pain ÉAtypical facial pain

4.6 When to refer to ENT specialist? Any symptoms orsigns suggestive of complications

Refer to an ENT specialist if any of the following indications are present: (IDSA 2012 guidelines)

- 1. Severe infection (high persistent fever with temperature >39 degree C [>102 degree F]
- 2. Orbital edema, severe headache, visual disturbance, altered mental status, meningeal signs)
- 3. Recalcitrant infection with failure to respond to extended courses of antimicrobial therapy
- 4. Immunocompromised host
- 5. Multiple medical problems that might compromise response to treatment (eg, hepatic or renal impairment, hypersensitivity to antimicrobial agents, organ transplant)
- 6. Unusual or resistant pathogens
- 7. Fungal sinusitis or granulomatous disease
- 8. Nosocomial infection.
- 9. Anatomic defects causing obstruction and requiring surgical intervention

- 10. Multiple recurrent episodes of acute bacterial rhinosinusitis (ABRS) (364 episodes per year) suggesting chronic sinusitis
- 11. Chronic rhinosinusitis (with or without polyps or asthma) with recurrent ABRS exacerbations.

4.7 Summary



5. Patient Information Sheet

5.1 Diagnosis of Acute Sinusitis

Question 1. What are sinuses?

Answer 1. Sinuses are hollow spaces in the bones around the nose that connect to the nose through small, narrow channels. The sinuses stay healthy when the channels are open, which allows air from the nose to enter the sinuses and mucus made in the sinuses to drain into the nose.

Question 2. What is sinusitis?

Answer2. Sinusitis, also called Acute sinusitis or rhinosinusitis, affects about 1 in 8 adults annually and generally occurs when viruses or bacteria infect the sinuses (often during a cold) and begin to multiply. Part of the bodyøs reaction to the infection causes the sinus lining to swell, blocking the channels that drain the sinuses. This causes mucus and pus to fill up the nose and sinus cavities.

Question 3. How can I tell if I have acute sinusitis?

Answer 3. You have acute sinusitis when there has been up to 4 weeks of cloudy or colored (not clear) drainage from the nose plus one or both of the following: (a) a stuffy, congested, or blocked nose or (b) pain, pressure or fullness in the face, head, or around the eyes.

Question 4. How can I tell if my sinusitis is caused by viruses or bacteria?

Answer 4. Acute viral sinusitis is likely if you have been sick less than 10 days and are not getting worse. Acute bacterial sinusitis is likely when you do not improve at all within 10 days of getting sick or when you get worse within 10 days after beginning to get better.

Question 5 Why is it important to tell if my sinusitis is caused by bacteria?

Answer 5. Because sinusitis is treated differently based on cause: acute viral sinusitis does not benefit from antibiotics, but some patients with acute bacterial sinusitis may get better faster with an antibiotic.

5.2 Treating Acute Bacterial Rhinosinusitis (ABRS)

Question 1. How long will it take before I feel better?

Answer 1. Most patients with ABRS feel better within 7 days, and by 15 days, about 90% are cured or improved.

Question 2. Is there anything I can do for symptomatic relief?

Answer 2. There are several ways to relieve sinusitis symptoms that should be discussed with your doctor to decide which are best for you: 1. Acetaminophen or ibuprofen can relieve pain and fever. 2. Saline irrigations, or washing out the nose with salt water, can relieve symptoms and remove mucus that is hard to blow out. 3. Nasal steroid sprays can reduce symptoms after 15 days of use, but the benefit is small (about 14 people must use them to get 1 person better), and side effects include headache, nasal itching, and nosebleeds. Decongestants may help you breathe easier and can be taken as a nasal spray (for no more than 3 days in a row to avoid worsening congestion) or by mouth.

Question 3. Is there anything I should not do?

Answer 3. Antihistamines and oral steroid medicines should not be used routinely because they have side effects and do not relieve symptoms. If I have ABRS, do I have to take an antibiotic? No, both watchful waiting and antibiotic therapy are proven ways to treat ABRS. Most people get better naturally, and antibiotics only slightly increase symptom relief (about 10 to 15 people must use antibiotics to get 1 more person better after 7-15 days).

Question 4.Is there any downside to using antibiotic?

Answer 4. Antibiotics have side effects that include rash, upset stomach, nausea, vomiting, allergic reactions, and causing resistant germs.

Question 5. What is õwatchful waitingö for ABRS?

Answer 5. Watchful waiting means delaying antibiotic treatment of ABRS for up to 7 days after diagnosis to see if you get better on your own.

Question 6. How is watchful waiting done?

Your doctor can give you an antibiotic prescription, but you should only fill the prescription and take the antibiotic if you do not get better after 7 days or if you get worse at any time. If you do use the antibiotic, contact your doctorøs office and let them know.

Question 7.If I use an antibiotic, for how many days should I take it?

Answer 7. Antibiotics are usually given for 10 days to treat ABRS, but shorter courses may be equally effective. Ask your doctor about a 5- to 7-day course of antibiotics since side effects are less common.

6. How this guideline was developed

1) Acute sinusitis STG Subgroup established

Background

December 2014: A Task Force was constituted to guide the development of Standard Treatment Guidelines (STG) in India. The Task Force subsequently approved the draft STG development manual of India (Part 1) for development of adapted guidelines. In addition, it approved a list of 14 topics recommended by a subgroup of the task force appointed to select prioritized topics for STG development. These 14 topics are from 10 clinical specialties for which the first set of STGs will be developed. The topic of Acute sinusitis was included in this first list and was the dealt with by the ENT clinical subgroup.

Clinical Subgroup on ENT

Disease Condition ó Sinusitis in Adults

Dr. A. K. Agrawal ó Director Professor MAMC, New Dehi	None
DrAvani Jain, Senior resident, MAMC, New Delhi	of the
Dr Sunil Kumar Dhanda, Professor and Head, LHMC, New	memb
Delhi	ers
Dr Ravi Meher, Professor, MAMC, New Delhi	report
	report
Dr Sanjay Sachdeva, Chairman ENT, Max Hospital, Saket,	
New Delhi	confli
Dr V K Monga, Leading private practitioner	ct of
	interes
	Dr. A. K. Agrawal ó Director Professor MAMC, New Dehi DrAvani Jain, Senior resident, MAMC, New Delhi Dr Sunil Kumar Dhanda, Professor and Head, LHMC, New Delhi Dr Ravi Meher, Professor , MAMC, New Delhi Dr Sanjay Sachdeva, Chairman ENT, Max Hospital, Saket, New Delhi Dr V K Monga, Leading private practitioner

t in the development of this guideline and have all signed their declarations.

May 2015: NHSRC with technical support from NICE international carried out a training workshop to guide the STG group members and chairs on the methodology to follow in developing adapted STGs suitable for the Indian context. This workshop was conducted on 29th & 30th May, 2015 and two members (Ravi Meher and Sunil Dhanda) of the ENT STG team attended.

2) Scope of the STG

The task group decided to concentrate on the Acute sinusitis and exclude chronic sinusitis altogether since the aetiology, diagnosis of chronic sinusitis is different and may involve surgical treatment. The task group excluded the children because they have very small, underdeveloped sinuses and acute sinusitis in children is rarely seen in general practice. The scope of the STG on acute sinusitis was initially drafted by the three experts i.e. Dr A K Agarwal, Dr Sunil Kumar and Dr Ravi Meher. It was subsequently reviewed and approved by the STG sub group in the first meeting held on 12 Oct 2015 from 2.00 pm to 4.30 pm in Dr A K Agarwal chamber at MAMC. In the meeting it was decided that the scope will include the clinical diagnosis, the indication and choice of antibiotics, when to get radiological investigations and when to refer to an ENT specialist. There was a consensus on developing these guidelines for the general practitioners who are the first contact with the patients of sinusitis in India. Also there was intent to give clear cut guidelines for use and choice of antibiotics for treating acute sinusitis.

3) Search & select guidelines

A search for guidelines on Acute sinusitis was performed on the National Guideline Clearinghouse (NGC) website and following three guidelines were retrieved.

- 1. IDSA Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults.
- 2. Clinical Practice Guideline (Update): Adult Sinusitis by American Academy of Otolaryngologyô Head and Neck Surgery Foundation 2015.
- 3. Acute Rhinosinusitis in Adults by University of Michigan.

Following are the web links to the above guidelines

- <u>https://www.idsociety.org/uploadedFiles/IDSA/Guidelines-</u>
 <u>Patient_Care/PDF_Library/IDSA%20Clinical%20Practice%20Guideline%20for%20</u>
 <u>Acute%20Bacterial%20Rhinosinusitis%20in%20Children%20and%20Adults.pdf</u>
- http://www.med.umich.edu/1info/FHP/practiceguides/Rhino/rhino.pdf
- <u>http://oto.sagepub.com/content/152/4/598.full.pdf+html</u>

Overview

The STG on Acute Sinusitis was developed by a team of experts and relevant stakeholders.

4) Compare & shift guidelines

After going through the available guidelines, the group selected all the above three guidelines as source guidelines. Since all the three guidelines are from the National Guideline Clearinghouse, we did not need perform the AGREE instrument to check their quality. The selected three guidelines were subsequently approved as source guidelines by the STG sub group on acute sinusitis.

The First Face - to - face Meeting - The STG sub group on acute sinusitis met on 12 Oct 2015 from 2.00 pm to 4.30 pm in DrA K Agarwal chamber at MAMC, New Delhi. All the members of the STG sub group declared that they do not have any conflict of interest/ financial interest in the development of the STG. DrAvani Jain was introduced to all the members of the group as Rapporteur.

- 1. The group discussed the various guidelines in detail and found that the IDSA Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adult is the most comprehensive guideline available and majority of the recommendations may be adopted as such.
- 2. Also there was discussion on finding some good Indian studies on acute sinusitis which can identify the common organism causing sinusitis in India and also the antibiotic sensitivity pattern.
- 3. Dr Agarwal stressed the need of including the Transillumination test as one of the diagnostic criteria of acute sinusitis. There was no consensus on the issue among the members and hence further literature search on Transillumination test was advised by Dr Agarwal.
- 4. The rough draft of the STG on acute sinusitis to be mailed to all the members before the next meeting.

5) Search & select recommendations

IDSA guidelines were the most comprehensive and appropriate among all the guidelines and hence majority of the recommendations were selected from it. The STG subgroup met again on 1st Dec at 2.00 pm in Maulana Azad Medical College in which all the major recommendations in the rough draft were discussed point wise.

The third meeting was held on 27th Jan 2016 again at the same venue. All the recommendations were discussed at length and modifications suggested by Dr Abhaand the NICE team were incorporated in the STG.

- Dr Agarwal stressed the need of including the Transillumination test. The issue of dark room and availability of a strong light source to perform the test was deliberated. It was decided that since the test is a simple one and has high predictive value it should be included in the guidelines and must be done if the facility of performing it are present.
- Regarding ancillary treatment there was a general consensus that the local nasal decongestants should be recommended only in cases of severe nasal obstruction though the guidelines does not approve its use in acute sinusitis. This is because it does provide symptomatic improvement in case of nasal obstruction to the patient though it might not alter the natural course of the disease. It was also discussed that the nasal decongestant must not be given for more than 5 days and should be used with precautions in case of hypertensive patients.

• Similarly the INCSs have been recommended as an adjunct to the treatment of acute sinusitis as they have good anti-inflammatory effects but they are not essential part of the treatment as addition of INCSs therapy will increase the cost of the treatment. They must be always given in case there is an associated history of suggestive of allergic rhinitis.

There is an anticipated barrier to the diagnosis of Acute Sinusitis is the differentiation of VRS from ABRS in a busy clinical setting. This is facilitated by the clear, unambiguous criteria for diagnosing ABRS on the history and time course of illness, without invasive tests or imaging studies. Patient education may also help address this barrier, as mentioned in patient information sheet. When diagnosed with VRS, patients may pressurize clinicians for prescribing antibiotics, in addition to symptomatic therapy. This can be overcome by educational handout of patient information. Some clinicians might object to amoxicillin with clavulanate as first-line therapy for ABRS, based on assumptions that newer, more expensive alternatives õmust beö more effective. Most favourable clinical outcomes for non severe ABRS, however, result from natural history, not antibiotics, and randomized controlled trials of comparative efficacy do not support superiority of any single agent for initial empiric therapy. Education about the use of antibiotics, their efficacy and possibility of drug resistance may help in dispelling these myths.

MoHFW guideline	Adopted/ Adapted	Original Guideline	Remarks	
Definitions		I		
Acute sinusitis is an inflammation of the paranasal sinuses and the nasal cavity lasting no longer than 4 weeks characterized by purulent nasal discharge (anterior, posterior or both) accompanied by nasal obstruction, facial pain- pressure-fullness, or both.	Adapted	UMHS guidelines 2011	Addition of the symptoms characterized by purulent nasal discharge (anterior, posterior or both) accompanied by nasal obstruction, facial pain-pressure- fullness, or both.	
Diagnosis of Acute sinusitis				
Acute Sinusitis- Up to 4 weeks of purulent nasal drainage (anterior, posterior, or both)	Adopted	IDSA 2012 guidelines		

6) Adopt/ adapt recommendations

accompanied by nasal			
obstruction, facial pain-pressure-			
fullness, or both.			
Acute viral sinusitis			
Acute viral sinusitis or the	Adopted	AAO 2015	
common cold is caused by virus			
and symptoms or signs of acute			
rhinosinusitis are present less			
than 10 days and the symptoms			
are not worsening.			
Acute bacterial rhinosinusitis(A)	BRS)		
Diagnosis of ABRS is made on	Adopted	IDSA 2012	
the basis of following criteria.		guidelines	
• Onset with persistent			
symptoms or signs			
compatible with acute			
rhinosinusitis, lasting for			
more than 10 days			
without any evidence of			
clinical improvement			
• Onset with severe			
symptoms or signs of			
high fever (>39°C			
$/102^{\circ}$ F) and purulent			
nasal discharge or facial			
pain lasting for at least			
364 consecutive days at			
the beginning of illness			
• Onset with worsening			
symptoms or signs			
characterized by the new			
onset of fever, headache,			
or increase in nasal			
discharge following a			
typical viral URI that			
lasted 566 days and were			
initially improving			
(∺double-sickeningø).			
Rule out allergic rhinitis (AR)	New	Expert group	Important to rule our
which is diagnosed when in	recommendat	consensus	allergic rhinitis as it
addition to nasal obstruction and	ion		may have similar
discharge there is also itchy			presentation.
nose, sneezing, red and watery			

eyes.					
Clinical features: symptoms and signs					
Diagnosis of ARS is probable if	Adopted	IDSA 2012			
2 or more of these major		guidelines			
symptoms are present or 1 major		0			
symptom along with 2 or more					
minor symptoms.					
Signs (may be seen but	Adapted	Expert group			
absence of these does not	1	consensus			
exclude Acute sinusitis)					
• Hypo-nasal speech					
indicating nasal obstruction					
• Swelling redness of the					
skin due to congestion of the					
capillaries (erythema) or					
abnormally large fluid					
volume (edema) localized					
over the involved cheek bone					
or periorbital area					
• Palpable cheek					
tenderness or percussion					
tenderness of the upper teeth					
• Purulent drainage in the					
nose or posterior pharvnx					
• Signs of extra-sinus					
involvement (orbital or facial					
cellulitis orbital protrusion					
abnormalities of eve					
movement neck stiffness					
indicating complications.					
indicating complications.					
When should empiric antibiotic	therapy be init	iated?			
We recommend that empiric	Adopted	IDSA 2012			
antimicrobial therapy be		guidelines			
initiated as soon as the clinical					
diagnosis of ABRS is					
established as deLned in					
recommendation.+					
Choice of antibiotic for ABRS			1		
Amoxicillin-clavulanate rather	Adopted	IDSA 2012			
than amoxicillin alone is		guidelines			
recommended as empiric					
antimicrobial therapy for					
ABRS in adults.					
Duration of therapy					

The recommended duration of	Adopted	IDSA 2012	
therapy for uncomplicated		guidelines	
ABRS in adults is 567 days.			
-			
For partial but incomplete	Adopted	IDSA 2012	
resolution after an initial	naoptea	guidelines	
course of antibiotics extend		guidennes	
the dynation of antibiotics			
the duration of antibiotic			
therapy by an additional / to			
10 days.			
Use of High-dose (2 g orally	Adopted	IDSA 2012	
twice daily or 90 mg/kg/day		guidelines	
orally twice daily) amoxicillin-			
clavulanate is recommended			
patients with ABRS, those with			
severe infection (eg. evidence			
of systemic toxicity with fever			
of more than 30 degree C [102			
dagraa El or higher and threat			
of supportion complications			
of suppurative complications,			
attendance at day care, age <2			
or >65 years, recent			
hospitalization, antibiotic use			
within the past month, or who			
are immunocompromised.			
Choice of antibiotic for ABRS	in penicillin allergi	c patients	
Use of doxycycline (100mg	Adopted	IDSA 2012	
12hr) or a respiratory		guidelines	
ł uoroquinolone (levoł oxacin			
500mg daily or moxil oxacin			
400mg daily) is recommended			
as an alternative agent for			
empiric antimicrobial therapy			
in adults who are allergic to			
penicillin			
Treatment failure for ABRS			
1 Reassess the nation after 7	Adopted	ΔΔΟ 2015	
days to confirm ADDS	Auopicu	auidalinas	
avaluda other courses		guidennes	
exclude other causes of			
niness, and detect			
complications if the patient			
tails to improve with the			
initial management option			

	an manage during the			
	or worsens during the			
	initial management.			
2	If ABRS is confirmed in			
	the patient initially			
	managed with observation,			
	the clinician should begin			
	antibiotic therapy.			
3	The second line antibiotics			
5	include high dose			
	amovicillin/clavulaneto			
	amoxicitim/clavulanate			
	combination (2 g orany			
	twice daily or 90			
	mg/kg/day orally twice			
	daily), levofloxacin			
	(500mg daily), and			
	moxifloxacin (400mg			
	daily) or the combination			
	of clindamycin plus a third-			
	generation oral			
	cephalosporin (cefixime or			
	cefpodoxime)			
4	Worsening is defined as			
1	progression of presenting			
	signs or symptoms of			
	ADDS on exact of new			
	ABRS or onset of new			
	signs or symptoms. Failure			
	to improve is lack of			
	reduction in presenting			
	signs or symptoms of			
	ABRS by 7 days after			
	diagnosis, which would not			
	apply if the patient had			
	persistent, yet gradually			
	improving, symptoms.			
5	ABRS may take up to 7			
	days to improve			
	persistence or minor			
	worsening prior to 7 days			
	does not necessarily			
	indicate treatment failure			
1	indicate treatment failure,			
1	and complete cure (absence			
	of all signs and symptoms)			
1	may take 14 days or longer.			
Ro	ole of imaging			
Cl	inicians should not obtain	Adopted	AAO 2015	

radiographic imaging for patients who meet diagnostic criteria for acute rhinosinusitis, unless a complication or alternative diagnosis is suspected. Indications of Imaging		guidelines	
If symptoms of rhinosinusitis persist for more than three weeks despite antibiotics or recur more than four times per year, a sinus CT scan should be performed. Plain sinus x-rays	Adapted	UMHS guidelines 2011	Reframing of the sentence
Plain sinus x-rays, are not at all recommended in management of sinusitis.	Adapted	UMHS guidelines 2011	Reframing of the sentence
Decongestants (topical- Oxyme	tazoline and Xylo	metazoline)	
Use of topical decongestants is recommended in case of severe nasal obstruction for short duration. (Maximum of 5 days). These should be used with precautions in patients with hypertension.	Adapted	AAO 2015 guidelines and Expert group consensus	
Analgesics			
Nonsteroidal anti- inflammatory drugs like paracetamol 500 mg tab tds/sos or diclofenac sodium 50 mg tab tds/sos, are recommended for pain relief associated with acute sinusistis	Adapted	AAO 2015 guidelines	
Antinistamines Poutine administration of	Adapted	AAO HNS 2015	
antihistamines are not recommended in patients of sinusitis.	лиариеи	guidelines	
Intra nasal corticosteroid spra	y(INCS)		
Though INCSs are not essential for treatment of ABRS they are recommended as an adjunct to antibiotics in	Adapted	UMHS guidelines 2011	These are notessentialfortreatmentofABRSuntil

the empiric treatment of ABRS			is an element of
for 10 days. Fluticasone			allergic rhinitis
ormometasone intra nasal			also
sprays are recommended twice			
daily.			
Steam inhalation			
	NT		
Steam inhalation is	New	Expert group	
recommended by the expert	recommendation	consensus	
group twice a day for 5-7 days.			
Nasal spray and douching with	physiologic/hyper	tonic saline	<u> </u>
		1	
Intranasal saline irrigations	Adopted	IDSA 2012	
with either physiologic or		guidelines	
hypertonic saline are			
recommended as an adjunctive			
treatment in adults with ABRS			
When to refer to ENT specialis	it?		r
Refer to an ENT specialist if	Adapted	IDSA 2012	
any of the following		guidelines	
indications are present:			
1. Severe infection (high			
persistent fever with			
temperature >39 degree			
C [>102 degree F]			
2. Orbital edema, severe			
headache, visual			
disturbance, altered			
mental status,			
meningeal signs)			
3. Recalcitrant infection			
with failure to respond			
to extended courses of			
4 Immuno compromised			
4. Initiatiocompromised			
IIOSt 5 Multiple medical			
3. Multiple medical			
problems that might			
to treatment (ac			
henotio or romal			
impairment			
hypersensitivity to			
nypersensurvity to			

antimicrobial agents,		
organ transplant)		
6. Unusual or resistant		
pathogens		
7. Fungal sinusitis or		
granulomatous disease		
8. Nosocomial infection.		
9. Anatomic defects		
causing obstruction and		
requiring surgical		
intervention		
10. Multiple recurrent		
episodes of acute		
bacterial rhinosinusitis		
(ABRS) (364 episodes		
per year) suggesting		
chronic sinusitis		
11. Chronic rhinosinusitis		
(with or without polyps		
or asthma) with		
recurrent ABRS		
exacerbations.		

Recommendations selected from various source guidelines are considered adaptations of existing guidelines and should maintain the standards (evidence) used in the original guideline. A systematic approach was followed to ensure high quality of the process. The STG clinical sub group was required to make a series of judgments on the new STG recommendations. There was clear documentation of the deliberations and the reasons for each recommendation being adapted in the process in order to maintain quality assurance. This led to several options:

a) <u>Adopted recommendation</u> - this entailed transferring a recommendation verbatim to the new STG.

<u>b) Adapted a recommendation</u> - This included adapting the recommendation to ensure local compatibility with India or adding precisions to the wording to clarify the recommendation or changing of wording to active phrasing in order to ensure language consistency was maintained throughout the document. It was ensured while adapting a recommendation that the evidence underpinning the recommendation remained intact.

7) Writing the STG: All the recommendations (adopted/ adapted) were compiled and implementation tools were developed.

Dr AbhaMehndiratta and her colleague Dr Laura Downey from NICE group helped in giving important feedback on the rough draft we sent on mail. The suggestions were well taken by all the group members and were incorporated in the final draft.

7. Research needs

There are still knowledge gaps in existing practice patterns and the quality of supporting literature. We present these gaps below to highlight areas for future research and investigation.

- Determine incidence and disease burden of ABRS in India
- Determine organisms commonly responsible for ABRS in India
- Clinical differentiation of bacterial from viral acute rhinosinusitis
- Determine whether 7- or 10-day symptom duration is more likely to be associated with ABRS.
- Assess the validity of diagnosing ABRS before 10 days based on persistent fever plus concurrent purulent nasal discharge.
- Conduct randomized controlled trials (RCTs) to determine the efficacy of an õobservation optionöfornonsevere ABRS, by randomizing patients to immediate vs delayed antibiotics and assessing clinical outcomes.
- Perform RCTs of antibiotics vs placebo using strict diagnostic criteria and stratify by clinical severity (ie, mild, moderate, or severe).
- Perform RCTs to assess the comparative efficacy of different antibiotics for initial management of uncomplicated ABRS.
- Assess the benefits of various symptomatic therapies for ABRS in properly conducted RCTs.
- Determine optimum salinity, pH, and regimen for administering nasal saline irrigation.
- Determine whether there is a difference in efficacy between isotonic and hypertonic concentrations for intranasal saline irrigations.
- Devise strategies or treatment regiments to avoid the rebound effect of topical nasal decongestants.
- Conduct RCTs to determine the efficacy of adjuvant therapy (nasal steroids, antihistamines, decongestants) in combination with antibiotics.

8. Annexure

1. How to do saline irrigations?

The expert group recommends using boiled and cooled water for irrigation. One table spoon of salt (around 9 gm.) can be added to a liter of water for making irrigation solution. There are commercial preparations also available of normal and hypertonic saline which may be used. Nasal saline irrigations can be done using a neti pot or commercially available squeeze bottle. The saline irrigation is done by inserting the neti pot or the nozzle of the squeeze bottle in one of the nostril and allowing the flow of saline from one nostril and

comes our via the opposite nostril while patient keeps saying $\exists K \emptyset \exists K \emptyset \exists K \emptyset \exists K \emptyset d H \emptyset$ This helps in closing the nasopahyrynx by soft palate and thus prevent any risk of saline going into the oropharynx and airway. It is recommended by the group to be done for twice a day for 5-7 days.

2. Role of CT scan

CT scans provide much better definition than a plain sinus x-ray hence plain sinus x-rays, are not at all recommended in management of sinusitis. In general, more advanced imaging modalities such as CT or MRI should be reserved for recurrent or complicated cases or when suppurative complications such as orbital or intracranial extension are suspected. In general, CT is considered the gold standard for assessing bony and anatomical changes associated with acute or chronic sinusitis, whereas MRI is useful to further delineate the extent of soft tissue abnormalities and inf ammation. CT is also necessary for surgical planning and for intraoperative image guided surgical navigation.

CT findings that correlate with ABRS are

- Sinus opacification
- Air fluid levels (> minimal)
- Marked mucosal thickening
- Polyps

Refer the patient to ENT specialist when following on CT findings are present

- Unilateral disease
- Sinus expansion
- Bony erosion

3. Empiric antibiotic therapy

- BeneŁts: Prompt antimicrobial therapy for patients more likely to have acute bacterial rather than viral rhinosinusitis should shorten the duration of illness, provide earlier symptom relief, restore quality of life, and prevent recurrent infection or suppurative complications.
- Harms: Prompt antimicrobial therapy may result in overuse of antibiotics, enhanced cost, and risk of adverse effects in those patients who do have true bacterial infection but mild disease. However, the patient selection criteria speciLed in recommendation make this possibility less likely.
- A systematic review of 12 randomized controlled trials with radiologically confirmed ABRS found no difference in clinical success for antibiotics given for 3 to

7 days vs a 6- to 10-day course of therapy. Adverse events are more common with antibiotic therapy with 10 days of therapy compared to shorter courses. An average event rate of 15% to 40% is observed, with the most frequent complaints being nausea, vomiting, diarrhea, abdominal pain, headache, skin rash, photosensitivity, and vaginal moniliasis. Adverse events rarely are of sufficient severity to cause a change in therapy. Conversely, the incidence of adverse events is lower when antibiotics are given for 5 days instead of 10 so short courses should be considered for patients with less severe illness.

- For partial but incomplete resolution after an initial course of antibiotics, extend the duration of antibiotic therapy by an additional 7 to 10 days for a total of 3 weeks of antibiotics.
- Benefit: Clinical outcomes that are comparable to broader spectrum antibiotics for initial therapy; potential reduced bacterial resistance by using a narrow-spectrum antibiotic as first-line therapy; cost-effectiveness of amoxicillin vs other antibiotic choices. The addition of clavulanate to amoxicillin substantially improves the coverage for both ampicillin-resistant H. influenzae and M. catarrhalis in ABRS.
- Risks/ Harms: Potential increased gastrointestinal adverse effects with amoxicillinclavulanate compared with other antibiotics and adverse effects from penicillin allergy.

Treatment failures

If the patient does not have the symptom cluster of purulent nasal drainage • accompanied by nasal obstruction, facial pain-pressure fullness, or both but instead has individual symptoms, alternate diagnoses should be explored. Migraines, tension headaches, cluster headaches, and temporomandibular joint disorder are common causes of facial pain that can be mistaken for ABRS. Similarly, nasal discharge or congestion can arise from common noninfectious causes that include allergic rhinitis, vasomotor rhinitis, deviated nasal septum, and nasal valve collapse. Imaging studies are not indicated for uncomplicated ABRS but may be appropriate to orule outo ABRS (eg, a misdiagnosis) if the patient does not respond to therapy. Patients with a reconfirmed diagnosis of ABRS who fail treatment, especially those with a worsening pattern of illness, should be examined for complications that include orbital or intracranial spread of infection. Suggestive findings on physical examination include proptosis, visual changes, severe headache, abnormal extraocular movements, changes in mental status, and periorbital inflammation, edema, or erythema. Acute frontal sinusitis typically causes severe headache localized to the forehead over the orbits, with tenderness produced by pressure on the floor of the frontal sinus. Sphenoidal sinusitis typically causes a dull ache in the back of head, specifically over the occiput with radiation to the frontal and retroorbital regions. Culture of nasal secretions may help guide subsequent antibiotic

therapy and is best performed by direct sinus aspiration rather than by nasopharyngeal swab. Endoscopically guided cultures of the middle meatus are an alternative in adults.

4. Intranasal corticosteroids

- Benefits: The beneŁcial effect of INCSs could be attributed to their antiinł ammatory properties, which may reduce mucosal swelling and promote drainage.
- Risks/Harms. Short-term risks of INCSs are minimal but may include susceptibility to oral candidiasis. Routine administration of INCSs will clearly increase the cost of treating ABRS. However, in patients with concurrent allergic rhinitis, INCS should be routinely administered.

5. Steam inhalation

• Steam inhalation moistens the mucosa and improves ciliary action thereby improving the drainage and providing symptomatic relief. Inhaled steam may soften secretions and provide symptomatic relief, but again, little objective evidence exists regarding their use.

6. Intranasal saline irrigations

- Intranasal saline irrigations with either physiologic or hypertonic saline are recommended as an adjunctive treatment in adults with ABRS (IDSA). It has been postulated that saline irrigation improves nasal symptoms by enhancing mucociliary function, decreasing mucosal edema, mechanically clearing inspissated mucus, and decreasing inł ammatory mediators. Several studies evaluated the role of hypertonic vs physiologic saline on nasal airway patency and mucociliary clearance in patients with symptomatic rhinosinusitis. Both saline preparations signiŁcantly improved mucociliary clearance compared with pretreatment values; however, only physiologic saline signiŁcantly improved nasal airway patency. In other studies, as compared with isotonic saline, hypertonic saline may have a superior anti-inflammatory effect and better ability to thin mucous and transiently improve mucociliary clearance.
- Benefits: Nasal saline irrigation, alone or in conjunction with other adjunctive measures, may improve quality of life, decrease symptoms, and decrease medication use for ABRS, particularly in patients with frequent sinusitis.
- Risks/harms: Nasal burning, irritation, and nausea were the most frequently reported adverse effects from intranasal saline irrigation (7%632% in various studies). In addition, saline irrigants should be prepared from sterile or bottled water in light of recent reports of primary amebic encephalitis from contaminated tap water used for saline nasal irrigation.

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