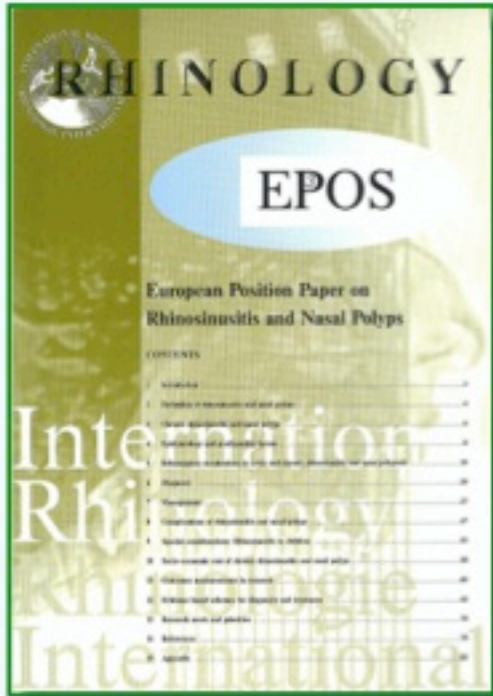


What is new in the 2012 position paper?

EPOS 2012

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Objectives of EP³OS

Update for ENT, non-ENT specialists and GPs:

- Updated review on *rhinosinusitis and nasal polyposis*
- Evidence Based Medicine on *diagnostic tools*
- Evidence Based Medicine on *available treatments*
- *Stepwise approach* on the disease management
- Recommended *definitions* and *result outcomes* for different aspects of *research*

Category of Evidence and Strength of Recommendation

Ia	Evidence from meta-analysis of randomised controlled trials
Ib	Evidence from at least one randomised controlled trial
IIa	Evidence from at least one controlled study without randomisation
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

A	Directly based on Category I evidence
B	Directly based on Category II evidence or extrapolated recommendation from Category I evidence
C	Directly based on Category III evidence or extrapolated recommendation from Category I or II evidence
D	Directly based on Category IV evidence or extrapolated recommendation from Category I, II or III evidence

What is Evidence-based Medicine ?

Evidence-based medicine is the *conscientious, explicit and judicious* use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means *integrating* individual *clinical expertise* with the best available external *clinical evidence* from *systematic research*.

Position paper

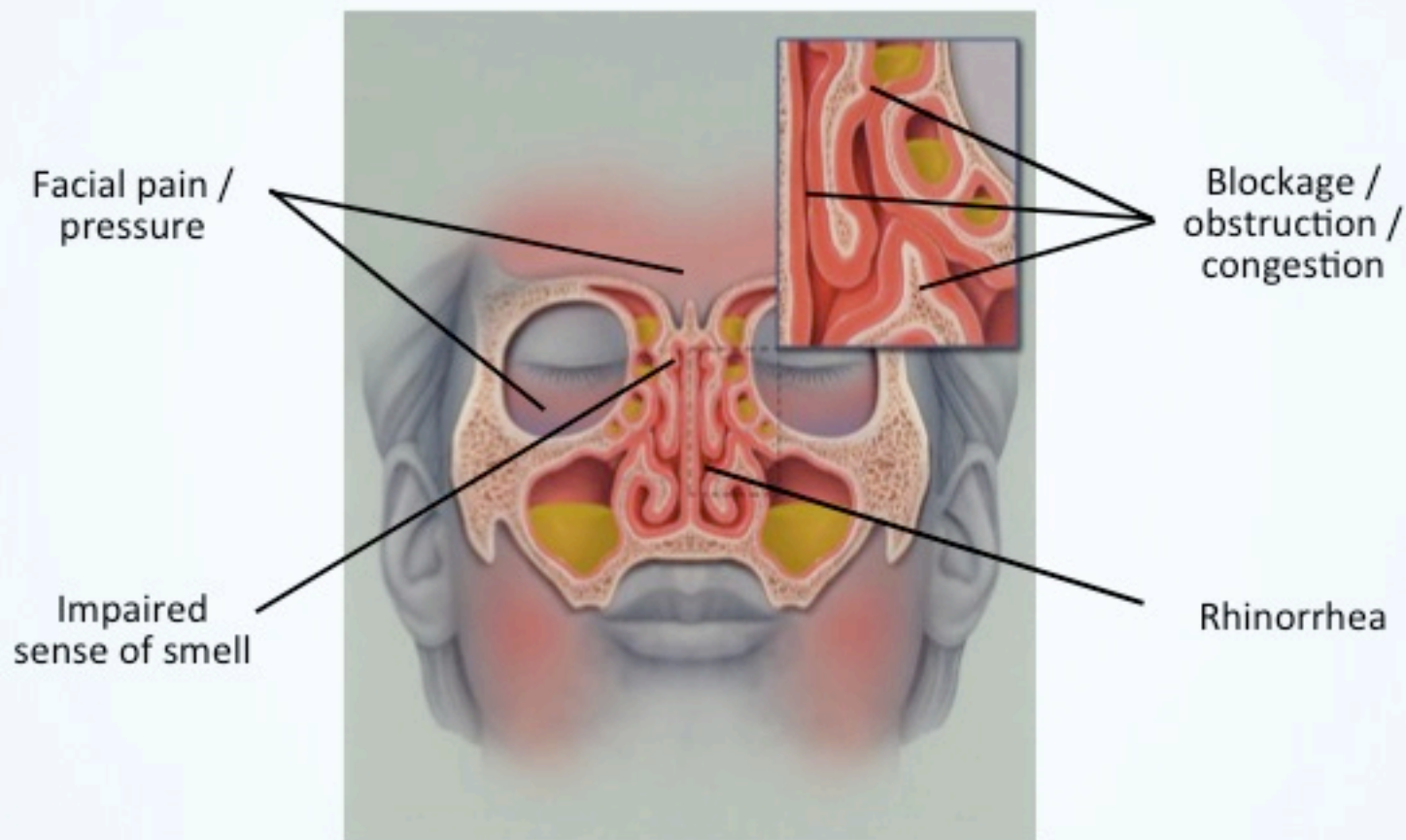
- uses an **Evidence Medicine approach** of selected subjects
- **helps** practitioners to identify and apply the most **efficacious and pertinent** clinical decisions
- points out areas where **additional research** is needed
- helps to determine the most **costeffective** and **appropriate** patient care even if this decision is **not the cheapest one**
- **IS NOT: tell practitioners what to do**
- **IS NOT: a legal document**

Tripod of evidence based medicine

- 1. Best available external *evidence* systematically identified and incorporated in the clinical decisions
- 2. Irreplaceable individual *clinical expertise*
- 3. *Patient preference*

Symptoms of Rhinosinusitis

EPOS 2012



Clinical Definition

Rhinosinusitis in adults

Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / posterior nasal drip):

- ± Facial pain / pressure
- ± Reduction / loss of smell

AND either ENDOSCOPIC SIGNS of

- Polyps and / or
- Mucopurulent discharge primarily from middle meatus and / or
- Edema / mucosal obstruction primarily in middle meatus

AND / OR CT CHANGES

- Mucosal changes within ostiomeatal complex and / or sinuses

General Classification Rhinosinusitis

1. Duration of symptoms:

- Acute > 10 days and < 12 weeks, complete resolution of symptoms
- Chronic > 12 weeks, no complete resolution of symptoms

2. Severity of symptoms (VAS, main symptom or symptom score):

- Mild
- Moderate
- Severe

$VAS \leq 3$

$VAS > 3 - 7$

$VAS \geq 7$



Definitions

Clinical diagnosis

- Symptoms
- Either nasendoscopy or CT scan

- ✓ Severity
- ✓ Duration

Epidemiologic diagnosis

- Symptoms
- Duration

Research diagnosis

- Endoscopic
- Prior surgery

Chronic Rhinosinusitis

Nasal Polyps

Clinical Definition

Rhinosinusitis in children

Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / posterior nasal drip):

- ± Facial pain / pressure
- ± **Cough**

AND either ENDOSCOPIC SIGNS of

- Polyps and / or
- Mucopurulent discharge primarily from middle meatus and / or
- Edema / mucosal obstruction primarily in middle meatus

AND / OR CT CHANGES

- Mucosal changes within ostiomeatal complex and / or sinuses

Epidemiological Definition

Rhinosinusitis

Two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / postnasal drip):

- ± Facial pain / pressure
- ± Reduction or loss of smell

Based on symptoms

Validation by telephone or interview

No need for ENT exam or radiology

Question for allergic symptoms

Acute rhinosinusitis is defined as:

Sudden onset of two or more symptoms, one of which should be either nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip):

- \pm facial pain/pressure,
- \pm reduction or loss of smell
- For <12 weeks;
- With symptom free intervals if the problem is recurrent,
- With validation by telephone or interview.

Acute rhinosinusitis

Common cold/ acute viral rhinosinusitis is defined as:

- Duration of symptoms for less than 10 days.

Acute post-viral rhinosinusitis is defined as:

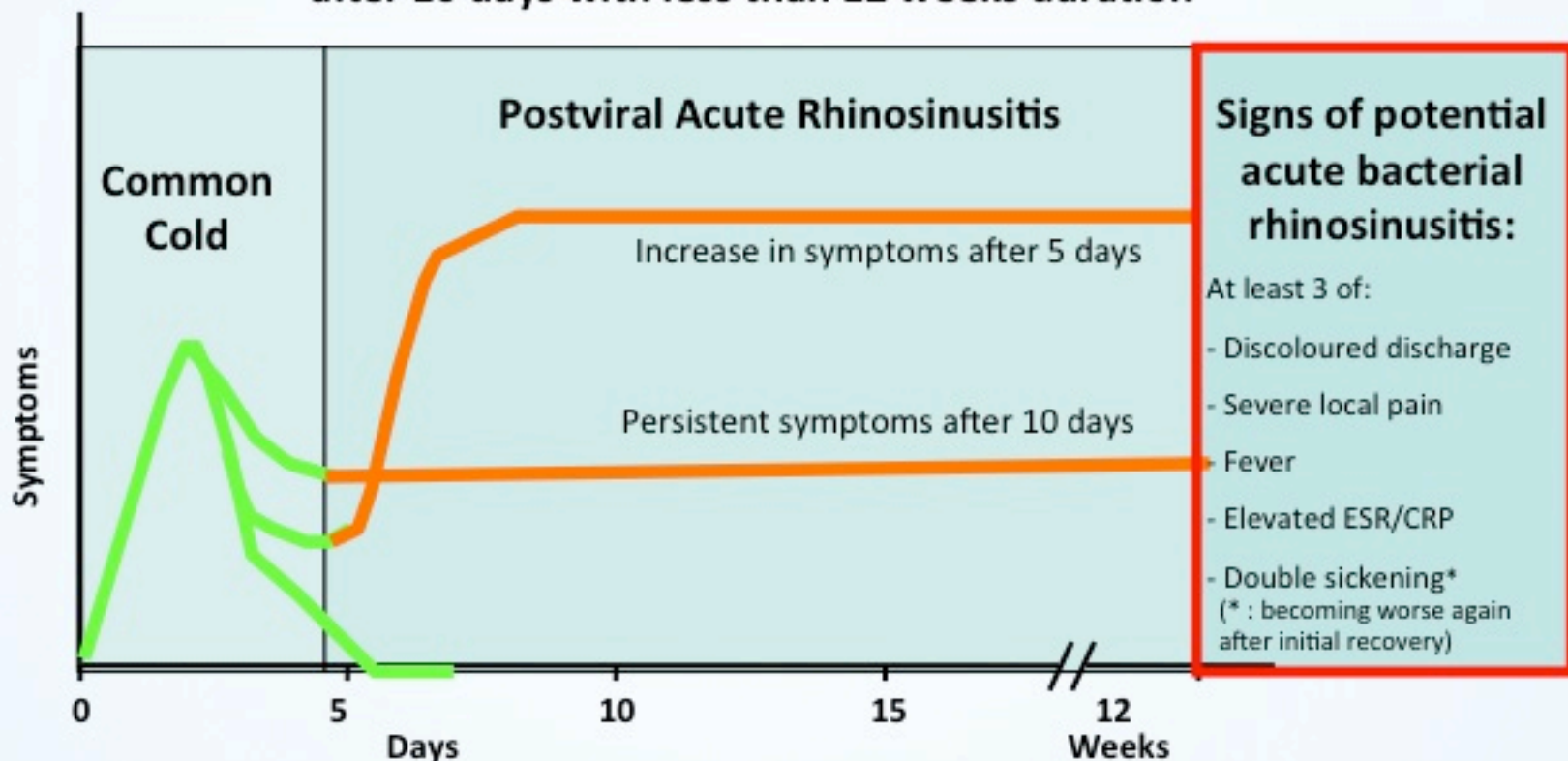
- Increase of symptoms after 5 days or persistent symptoms after 10 days with less than 12 weeks duration.

Acute bacterial rhinosinusitis (ABRS)

- Acute bacterial rhinosinusitis is suggested by the presence of at least 3 symptoms/signs of:
 - Discoloured discharge (with unilateral predominance) and purulent secretion in *cavum nasi*,
 - Severe local pain (with unilateral predominance)
 - Fever ($>38^{\circ}\text{C}$)
 - Elevated ESR/CRP
 - 'Double sickening' (i.e. a deterioration after an initial milder phase of illness).

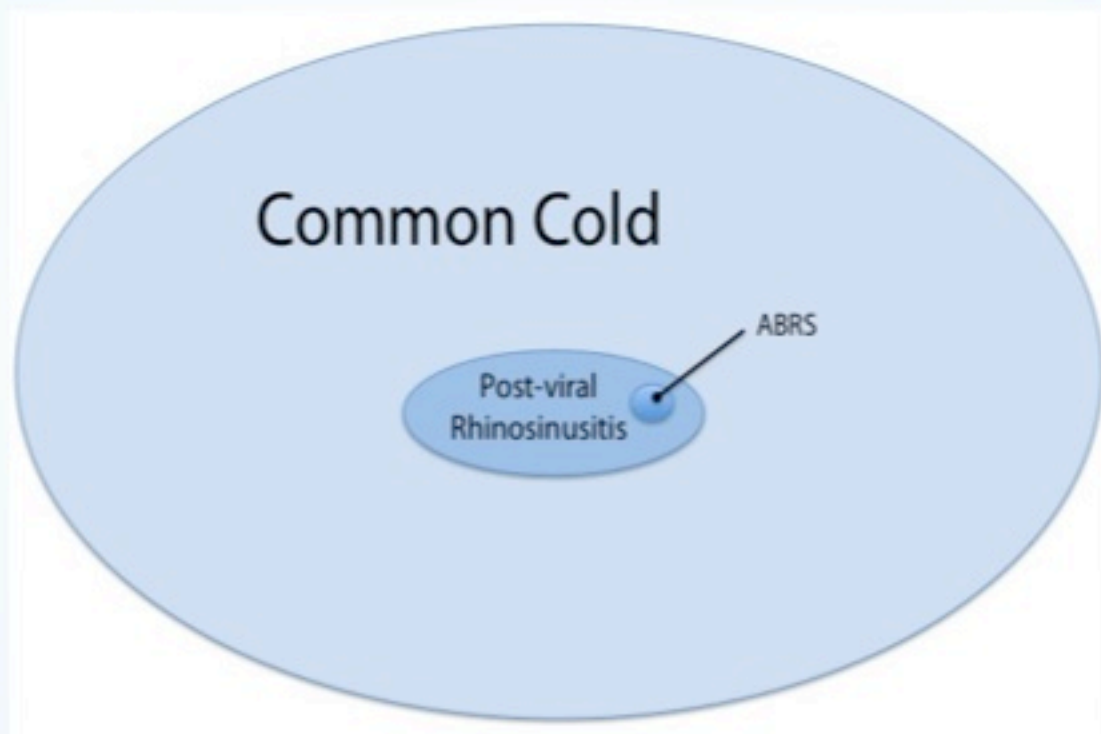
Definition of Acute Rhinosinusitis

Increase in symptoms after 5 days or persistent symptoms after 10 days with less than 12 weeks duration



Acute rhinosinusitis can be divided into:
common cold and **post-viral rhinosinusitis**.

A small subgroup of the post-viral rhinosinusitis is caused by bacteria:
acute bacterial rhinosinusitis (ABRS)



Treatment evidence and recommendations for adults with acute rhinosinusitis

Therapy	Level	Grade of recommendation	Relevance
antibiotic	1a	A	yes in ABRs
topical steroid	1a	A	yes mainly in post viral ARS
addition of topical steroid to antibiotic	1a	A	yes in ABRs
addition of oral steroid to antibiotic	1a	A	yes in ABRs
saline irrigation	1a	A	yes
antihistamine analgesic-decongestion combination	1a	A	yes in viral ARS
ipratropium bromide	1a	A	in viral ARS
probiotics	1a	A	to prevent viral ARS
zinc	1a	C	no
vitamine C	1a	C	no
echinacea	1a	C	no
herbal medicine (pelargonium sidoides, Myrtol)	1b	A	yes, in viral and postviral ARS
aspirin / NSAID's	1b	A	yes, in viral and postviral ARS
acetaminophen (paracetamol)	1b	A	yes, in viral and postviral ARS
oral antihistamine added in allergic patients	1b (1 study)	B	no
steam inhalation	1a(-)\$	A(-)**	no
cromoglycate	1b(-)*	A(-)	no
decongestion	no data for single use	D	no
mucolytics	no data	D	no

*1b (-): 1b study with negative outcome

\$ 1a(-) 1a level of evidence that treatment is not effective.

**A(-): grade A recommendation not to use

**Acute Postviral Rhinosinusitis is
a self limiting disease**

No value of Antibiotics in the management of ARS in GP

THE LANCET

Primary-care-based randomised placebo-controlled trial of antibiotic treatment in acute maxillary sinusitis

F L van Buchem, J A Knotterma, V J J Scheijnsmaekers, M F Posters

Summary

Background The value of antibiotics in acute rhinosinusitis is uncertain. Although maxillary sinusitis is commonly diagnosed and treated in general practice, no effectiveness studies have been done on unselected primary-care patients. We used a randomised, placebo-controlled design to test the hypothesis that there would be an improvement associated with amoxicillin treatment for acute maxillary sinusitis patients presenting to general practice.

Methods Adult patients with suspected acute maxillary sinusitis were referred by general practitioners for radiographs of the maxillary sinus. Those with radiographic abnormalities (n=214) were randomly assigned treatment with amoxicillin (750 mg three times daily for 7 days; n=108) or placebo (n=106). Clinical course was assessed after 1 week and 2 weeks, and reported relapses and complications were recorded during the following year.

Findings After 2 weeks, symptoms had improved substantially or disappeared in 83% of patients in the study group and 77% of patients taking placebo. Amoxicillin did not influence the clinical course of maxillary sinusitis nor the frequency of relapses during the 1-year follow-up. Radiographs had no prognostic value, nor were they an effect modifier. Side-effects were recorded in 28% of patients given amoxicillin and in 5% of those taking placebo (p<0.01). The occurrence of relapses was similar in both groups (21 vs 17%) during the follow-up year.

Interpretation Antibiotic treatment does not improve the clinical course of acute maxillary sinusitis presenting to general practice. For these patients, an initial radiographic examination is not necessary and initial management can be limited to symptomatic treatment. Whether antibiotics are necessary in more severe cases warrants further study.

Lancet 1997; 349: 683-87

Introduction

In the management of patients presenting to general practice with common colds, the question often arises of whether acute maxillary sinusitis is also present. It is widely accepted that acute maxillary sinusitis is a more serious condition than the common cold alone and requires additional treatment with antibiotics. Whether this view is accurate has not been studied in a population representative of primary-care patients.

All published studies about the presence of acute maxillary sinusitis have been done in selected groups of patients who were referred to ear, nose, and throat (ENT) clinics after the discovery of empyema (pus and pathogenic bacteria in the sinus). For such patients, puncture of the sinus is generally thought to be the gold standard for diagnosis. In one study the effectiveness of antibiotic treatment of patients with acute maxillary sinusitis was compared with placebo.¹ Antibiotics seemed to accelerate resolution of abnormalities seen on the radiograph, but the differences between antibiotic and placebo resolution rates were small. Other investigators have compared various antibiotics and found no differences.²⁻⁴ In a study of the course of acute maxillary sinusitis without antibiotic treatment, 80% of the patients were found to have completely recovered after 14 days.⁵

These investigations do not, however, answer the question of whether, in unselected primary-care patients, acute maxillary sinusitis requires antibiotic treatment. Despite the lack of evidence in favour of antibiotic therapy, throughout the world many primary-care patients with acute maxillary sinusitis are treated with antibiotics. For these patients, it is important to bear in mind that clinical and prognostic spectra, and, consequently, treatment efficacy may differ from those in patients referred to ENT clinics.⁶

It is difficult in general practice to distinguish clearly between a common cold and acute maxillary sinusitis with only case history and physical examination.⁷

However, in a primary-care-based study, in patients presenting with a new episode of acute rhinosin-

Antibiotic treatment did not improve the clinical course of acute maxillary sinusitis presenting to general practice. For these patients, an initial radiographic examination is not necessary and initial management can be limited to symptomatic treatment. Whether antibiotics are necessary in more severe cases warrants further study.

Antibiotics for Acute Maxillary Sinusitis

Meta analyses

Table 3.4.1. Evidence from systemic review or meta-analysis for antibiotics in treatment of Acute Rhinosinusitis (ARS).

Authors, year, ref.	Inclusion criteria	Number of		Conclusion
		Studies	Patients/ placebo	
Falagas, et al. 2009 ⁽²⁹⁾	RCTs	12	4,430	Short-course antibiotic treatment had comparable effectiveness to a longer course of therapy
Falagas, et al. 2008 ⁽¹⁵⁾	RCTs	17	2,648	Antibiotics should be reserved for carefully selected patients with a higher probability for bacterial disease
Burton, et al. 2008 ⁽¹⁶⁾	Extracts from the Cochrane library	NA	NA	A small treatment efficacy in patients with uncomplicated ARS
Ahovuo-Saloranta, et al. 2008 ⁽²⁰⁾	RCTs	5	631	Antibiotics have a small treatment efficacy in patients with uncomplicated ARS. 80% patients improve within two weeks without antibiotics
Young, et al. 2008 ⁽²⁶⁾	RCTs	9	2,547	Antibiotics are not justified even if a patient reports symptoms for longer than 7-10 days
Williams JW Jr, et al. 2008 ⁽²⁹⁾	RCTs	49	13,660	For acute maxillary sinusitis confirmed radio-graphically or by aspiration, current evidence is limited but supports the use of penicillin for 7 to 14 days
Rosenfeld, et al. 2007 ⁽¹⁰⁾	DBPC randomized trials	13	NA	Over 70% of patients with ARS are improved after 7 days, with or without antimicrobial therapy
Arroll B. 2005 ⁽²⁸⁾	Review of the Cochrane reviews	4	NA	The use of antibiotics for acute purulent rhinitis and acute maxillary sinusitis seems to be discretionary rather than prohibited or mandatory, at least for non-severe cases
Stalman, et al. 1997 ⁽²⁹⁾	DBPC randomized trials	3	NA	The effectiveness of antibiotic treatment in acute maxillary sinusitis in a general practice population is not based sufficiently on evidence

RCTs: randomized controlled trials; DBPC: double-blind, placebo-controlled; NA: not applicable

Why do we use antibiotics?

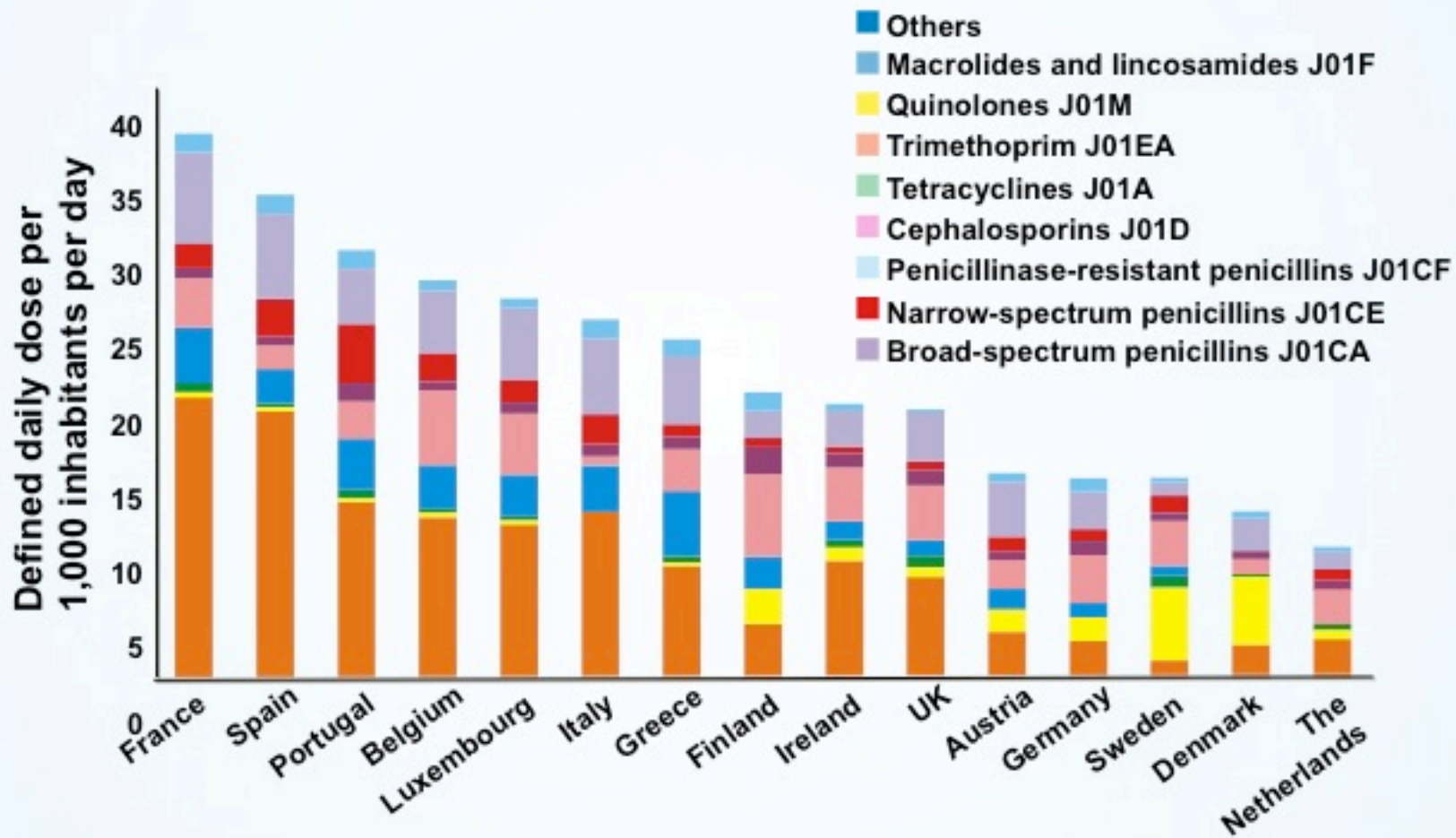
- Acute rhinosinusitis is sometimes a bacterial disease but antibiotics have very little effect
- Acute rhinosinusitis can lead to severe complications but antibiotics do not seem to prevent them

Can more liberal use of antibiotics prevent complications?

France 3 times more antibiotics than **The Netherlands**

- ▣ estimated studied population: 12 milion (age 14 – 60)
 - ▣ complications: 30 /year (11 intracranial)
 - ▣ 37% no indication of ARS before complication
 - ▣ 44% had antibiotics before complication (70% of the patients with proven bacterial ARS)
- ▣ Adult population: 12,7 milion
 - ▣ complications: 22 / year (11 intracranial)
 - ▣ 40% no indication of ARS before complication
 - ▣ 43% had antibiotics before complication

Outpatient Antibiotic Sales in the European Union

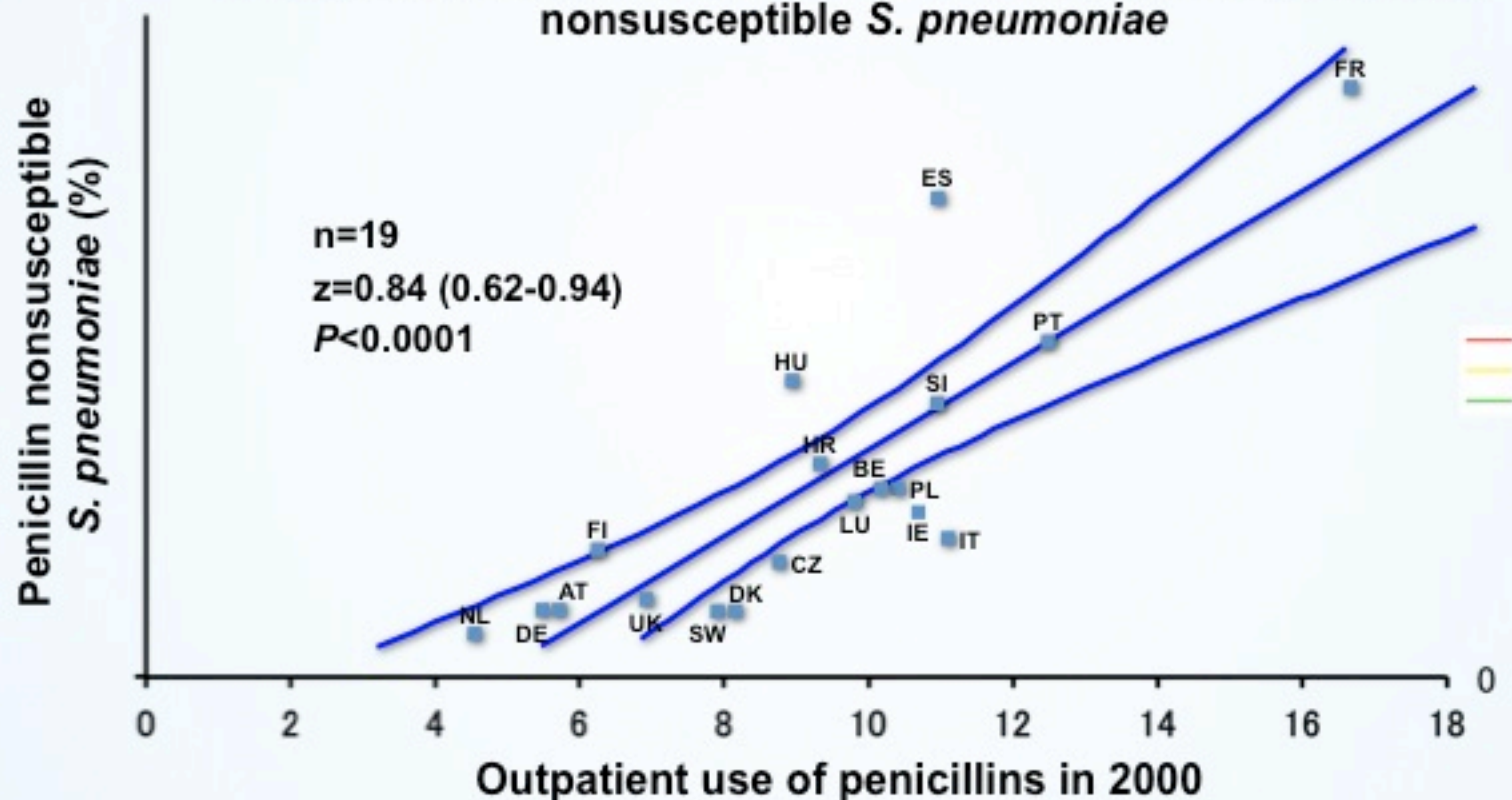


Increasing Prevalence of Antimicrobial Resistance



Increased Penicillin Resistance of *S. pneumoniae* Correlates With Higher Penicillin Use

Correlation between penicillin use and prevalence of penicillin nonsusceptible *S. pneumoniae*



Acute rhinosinusitis in adults Management scheme for Primary Care

2 symptoms: one of which should be nasal obstruction or discoloured discharge
 +/- frontal pain, headache
 +/- smell disturbance
 examination: anterior rhinoscopy
 X-ray/CT not recommended

Immediate referral:

- periorbital oedema/erythema
- displaced globe;
- double vision;
- ophthalmoplegia
- reduced vision acuity;
- severe unilateral or bilateral frontal headache;
- frontal swelling;
- signs of meningitis or
- neurologic signs

symptoms less than 5 days or improving thereafter

common cold

symptomatic relief:
 analgesics, nasal saline irrigation, decongestants, selected herbal compounds

no effect after 10 days of treatment

consider referral to specialist

symptoms persistent after 10 days or increasing after 5 days

moderate (post viral)

+ topical steroids

no effect after 14 days of treatment

continue treatment for 7 - 14 days

severe* (including bacterial)

topical steroids consider antibiotics

effect in 48 h

no effect in 48 h

refer to specialist

* = at least 3 of:
 discoloured discharge
 severe local pain
 fever
 elevated ESR/CRP
 double sickening

Treatment evidence and recommendations for children with acute rhinosinusitis

Therapy	Level	Grade of recommendation
antibiotic	1a	A
topical steroid	1a	A
addition of topical steroid to antibiotic	1a	A
mucolytics (erdosteine)	1b (-)*	A(-)**
saline irrigation	IV	D
oral antihistamine	IV	D
decongestion	IV	D

*1b (-): 1b study with negative outcome

**A(-): grade A recommendation not to use

Clinical Definition

Chronic Rhinosinusitis in adults

Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / posterior nasal drip) for at least 12 weeks :

- ± Facial pain / pressure
- ± Reduction / loss of smell

AND either ENDOSCOPIC SIGNS of

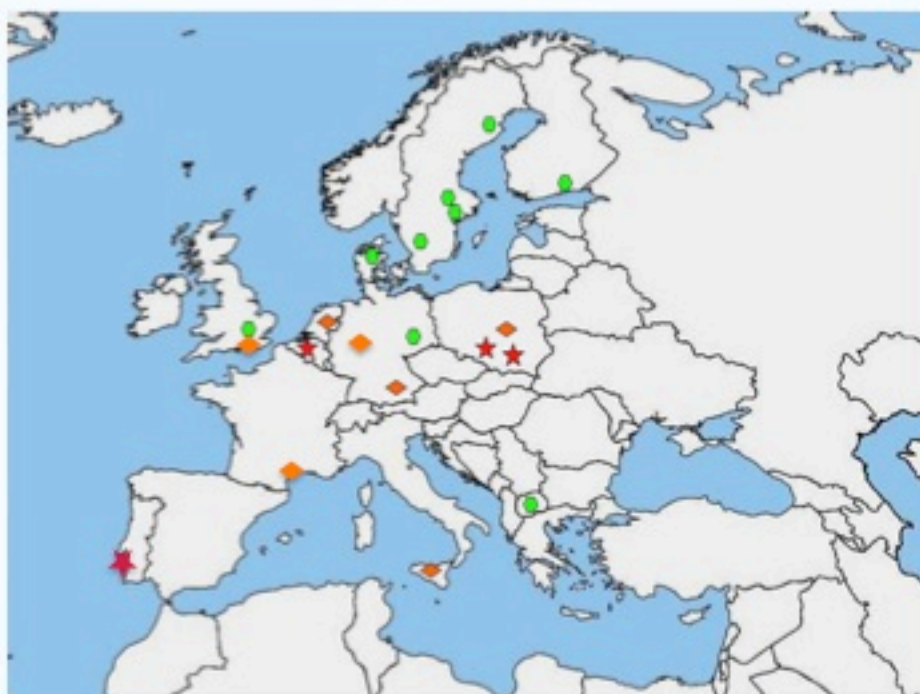
- Polyps and / or
- Mucopurulent discharge primarily from middle meatus and / or
- Edema / mucosal obstruction primarily in middle meatus

AND / OR CT CHANGES

- Mucosal changes within ostiomeatal complex and / or sinuses

Prevalence CRS

11%



- ★ > 15%
- ◇ 10% - 15%
- < 10%

Map of prevalence of CRS. Symbols indicate prevalence categories of $\geq 15\%$ (red stars), $\geq 10\%$ and $< 15\%$ (orange diamonds) and $< 10\%$ (green hexagons)

Associations

- Prevalence of CRS associated with:
 - AR (OR 3.1) especially persistent rhinitis (OR **6.0**)
 - Current Asthma (OR **2.2**)
 - Current smoking and ex-smoking significantly associated with CRS (OR **2.1** and **1.3**)
- Association between CRS, AR and CA persisted after correction for smoking, and if analyses were restricted to non-smokers
- In all age groups, men and women, and irrespective of smoking behaviour, asthma was associated with CRS

Definition of difficult-to-treat rhinosinusitis

Patients who have persistent symptoms of rhinosinusitis despite appropriate treatment (recommended medication and surgery). Although the majority of CRS patients can obtain control, some patients will not do so even with the maximal medical therapy and surgery.

- Patients who do not reach an acceptable level of control despite adequate surgery, intranasal corticosteroid treatment and up to 2 short courses of antibiotics or systemic corticosteroids in the last year can be considered to have difficult-to-treat rhinosinusitis.

Control of disease

The goal of CRS treatment is to achieve and maintain clinical control. Control is defined as a disease state in which the patients does not have symptoms or the symptoms are not bothersome, if possible combined with a healthy or almost healthy mucosa and only the need for local medication. We do not know what percentage of patients with CRS actually can achieve control of disease.

Assessment of current clinical control of CRS (in the last month)

Assessment of current clinical control of CRS (in the last month)			
Characteristic	Controlled (all of the following)	Partly controlled (at least one present)	Uncontrolled
Nasal blockage	Not present or not bothersome	Present on most days of the week	Three or more features of partly controlled CRS
Rhinorrhoea/ Postnasal drip	Little and mucous	Mucopurulent on most days of the week	
Facial pain/headache	Not present or not bothersome	Present	
Smell	Normal or only slightly impaired	Impaired	
Sleep disturbance or fatigue	Not impaired	Impaired	
Nasal endoscopy (if available)	Healthy or almost healthy mucosa	Diseased mucosa (nasal polyps, mucopur. secretions, inflamed mucosa)	
Systemic medication needed to control disease	Not needed	Need of a course of antibiotics or systemic corticosteroids in the last three months	Need of long term antibiotics or systemic corticosteroids in the last month

Clinical Definition

Chronic Rhinosinusitis in adults

Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / posterior nasal drip) for at least 12 weeks :

- ± Facial pain / pressure
- ± Reduction / loss of smell

AND either ENDOSCOPIC SIGNS of

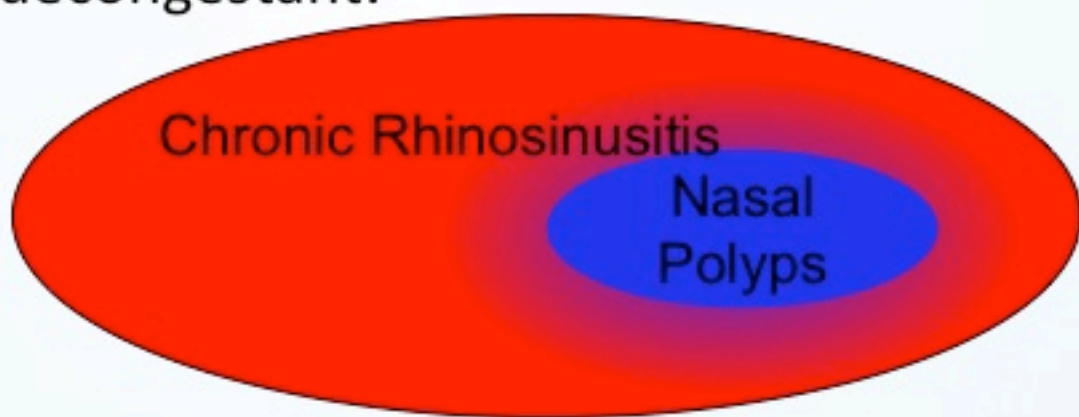
- Polyps and / or
- Mucopurulent discharge primarily from middle meatus and / or
- Edema / mucosal obstruction primarily in middle meatus

AND / OR CT CHANGES

- Mucosal changes within ostiomeatal complex and / or sinuses

Treatment of Chronic Rhinosinusitis with or without nasal polyps

- Chronic rhinosinusitis with nasal polyps (CRSwNP): bilateral, endoscopically visualised in middle meatus.
- Chronic rhinosinusitis without nasal polyps (CRSsNP): no visible polyps in middle meatus, if necessary following decongestant.



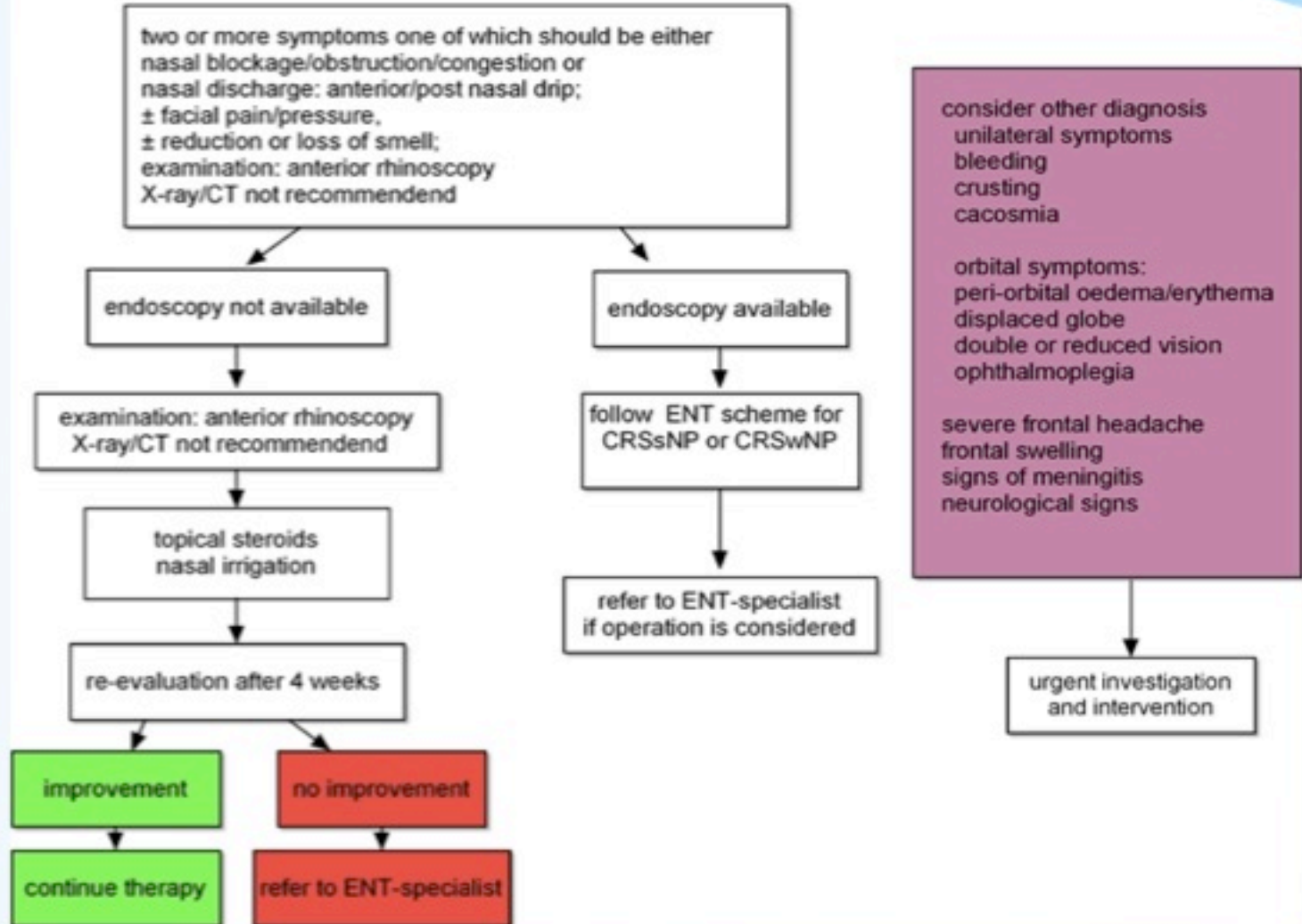
Treatment evidence and recommendations for adults with chronic rhinosinusitis without nasal polyps

Therapy	Level	Grade of recommendation	Relevance
steroid – topical	Ia	A	yes
nasal saline irrigation	Ia	A	yes
bacterial lysates (OM-85 BV)	Ib	A	unclear
oral antibiotic therapy short term < 4 weeks	II	B	during exacerbations
oral antibiotic therapy long term ≥12 weeks**	Ib	C	yes, especially if IgE is not elevated
steroid – oral	IV	C	unclear
mucolytics	III	C	no
proton pump inhibitors	III	D	no
decongestant oral / topical	no data on single use	D	no
allergen avoidance in allergic patients	IV	D	yes
oral antihistamine added in allergic patients	no data	D	no
herbal en probiotics	no data	D	no
immunotherapy	no data	D	no
probiotics	Ib (-)	A(-)	no
antimycotics – topical	Ib (-)	A(-)	no
antimycotics - systemic	no data	A(-)	no
antibiotics – topical	Ib (-)	A(-)\$	no

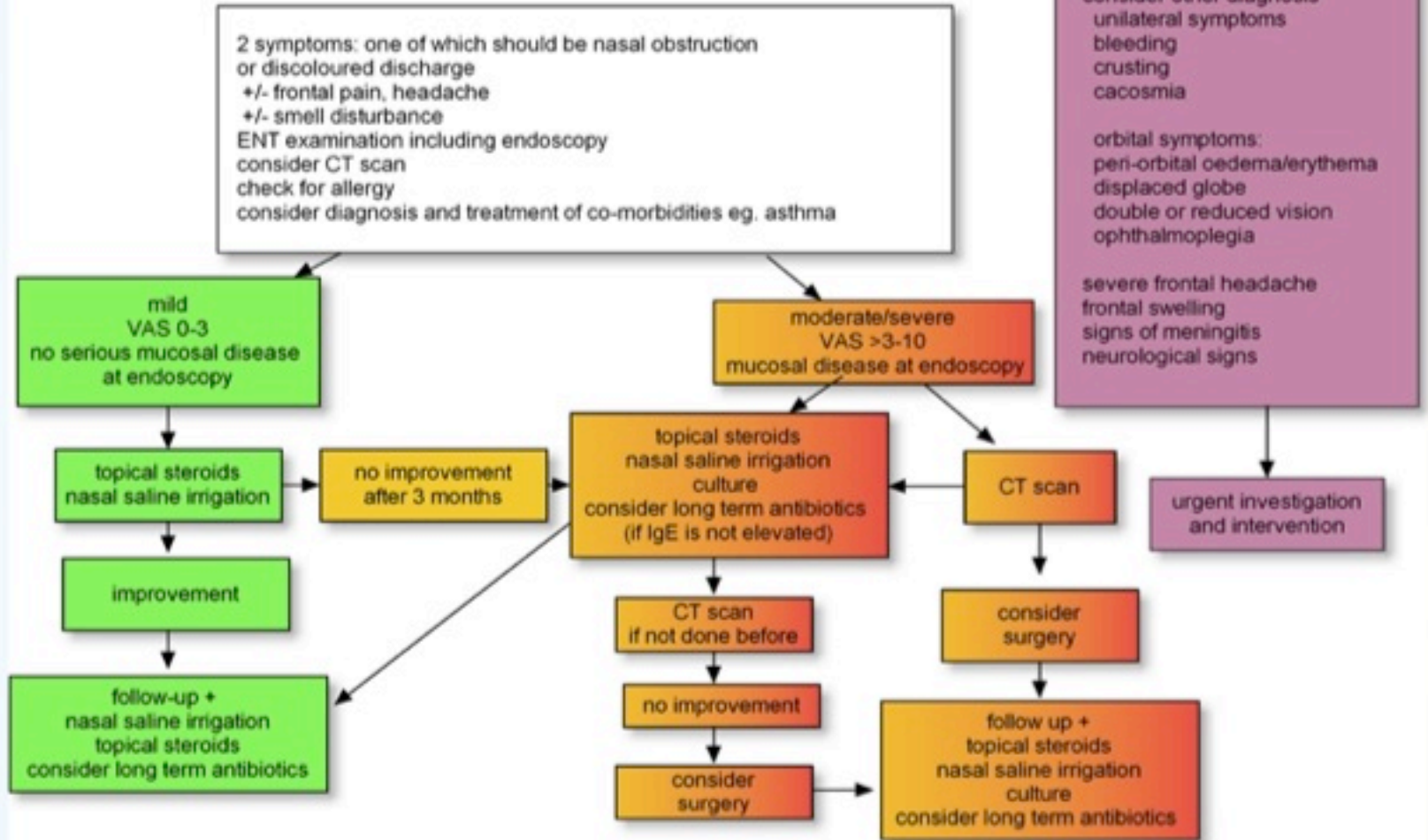
Ib (-): Ib study with a negative outcome

\$ A(-): grade A recommendation not to use

CRS in adults management scheme for Primary Care and non-ENT-specialists



CRSsNP in adults management scheme for ENT-specialists



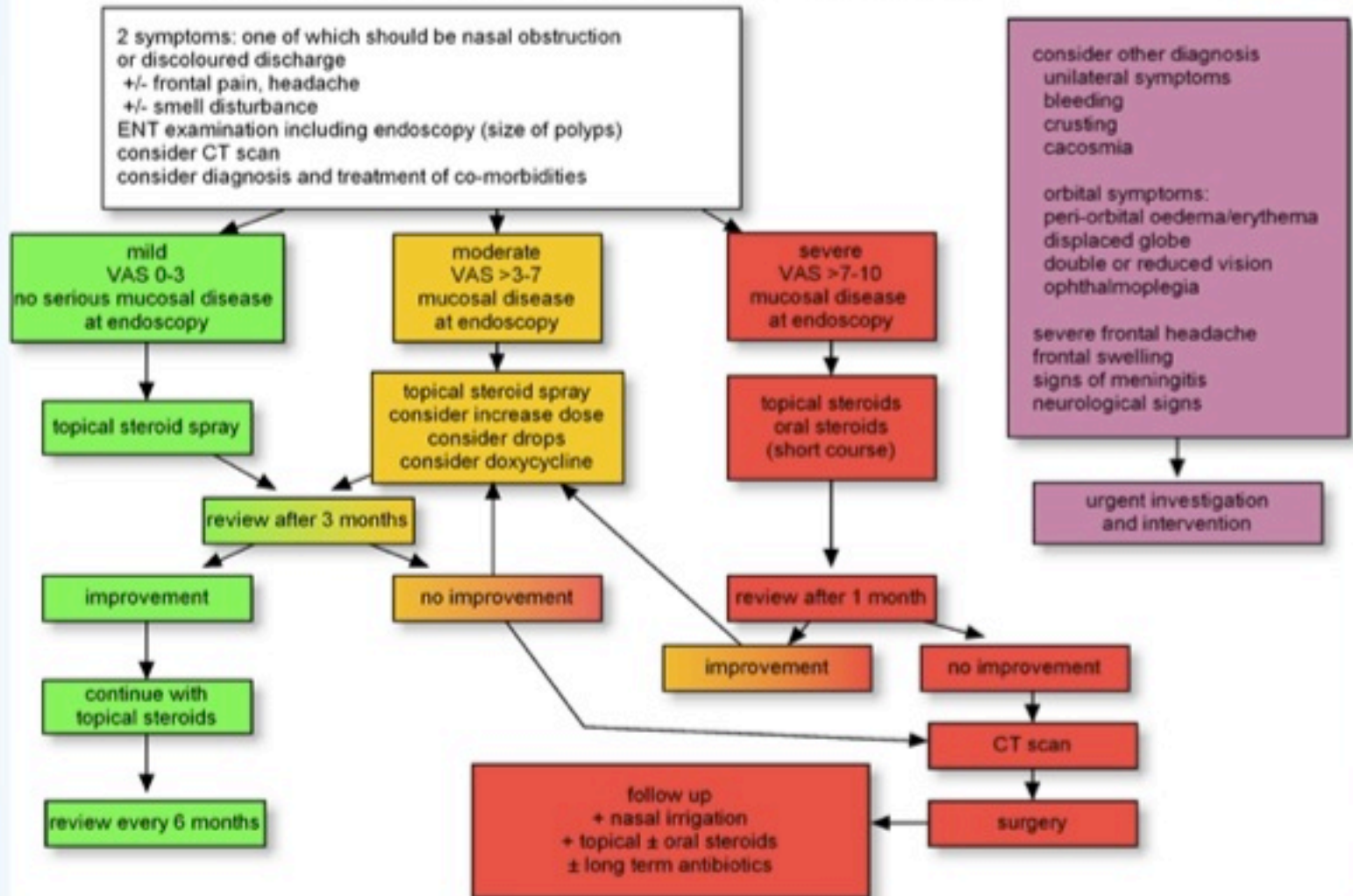
Treatment evidence and recommendations for adults with chronic rhinosinusitis with nasal polyps

Therapy	Level	Grade of recommendation	Relevance
topical steroids	Ia	A	yes
oral steroids	Ia	A	yes
oral antibiotics short term <4 weeks	1b and 1b(-)	C%	yes, small effect
oral antibiotic long term ≥ 12 weeks	III	C	yes, especially if IgE is not elevated, small effect
capsaicin	II	C	no
proton pump inhibitors	II	C	no
aspirin desensitisation	II	C	unclear
furosemide	III	D	no
immunosuppressants	IV	D	no
nasal saline irrigation	Ib, no data in single use	D	yes for symptomatic relief
topical antibiotics	no data	D	no
anti-IL5	no data	D	unclear
phytotherapy	no data	D	no
decongestant topical / oral	no data in single use	D	no
mucolytics	no data	D	no
oral antihistamine in allergic patients	no data	D	no
antimycotics – topical	Ia (-) **	A(-)	no
antimycotics – systemic	Ib (-)#	A(-) \$	no
anti leukotrienes	Ib (-)	A(-)	no
anti-IgE	Ib (-)	A(-)	no

Ib (-): Ib study with a negative outcome

\$ A(-): grade A recommendation not to use

CRSwNP management scheme for ENT-specialists



Clinical Definition

Chronic Rhinosinusitis in children

Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / posterior nasal drip) for at least 12 weeks :

- ± Facial pain / pressure
- ± Cough

AND either ENDOSCOPIC SIGNS of

- Polyps and / or
- Mucopurulent discharge primarily from middle meatus and / or
- Edema / mucosal obstruction primarily in middle meatus

AND / OR CT CHANGES

- Mucosal changes within ostiomeatal complex and / or sinuses

Paediatric CRS

- The inflammatory reaction in the sinus tissues of children with CRS is rich in lymphocytes and exhibits less eosinophilia and epithelial disruption compared to adults
- Not any CT scan abnormality indicates relevant clinical CRS in children
- Adenoidectomy is successful in improving in 50% of operated children. Whether this is due to the fact that the symptoms were related to adenoiditis per se or to the elimination of the contribution of the adenoids to sinus disease is not clear

Treatment evidence and recommendations for children with chronic rhinosinusitis

Therapy	Level	Grade of recommendation	Relevance
nasal saline irrigation	Ia	A	yes
therapy for gastro-oesophageal reflux	III	C	no
topical corticosteroid	IV	D	yes
oral antibiotic long term	no data	D	unclear
oral antibiotic short term <4 weeks	Ib(-)#	A(-)*	no
intravenous antibiotics	III(-)##	C(-)**	no

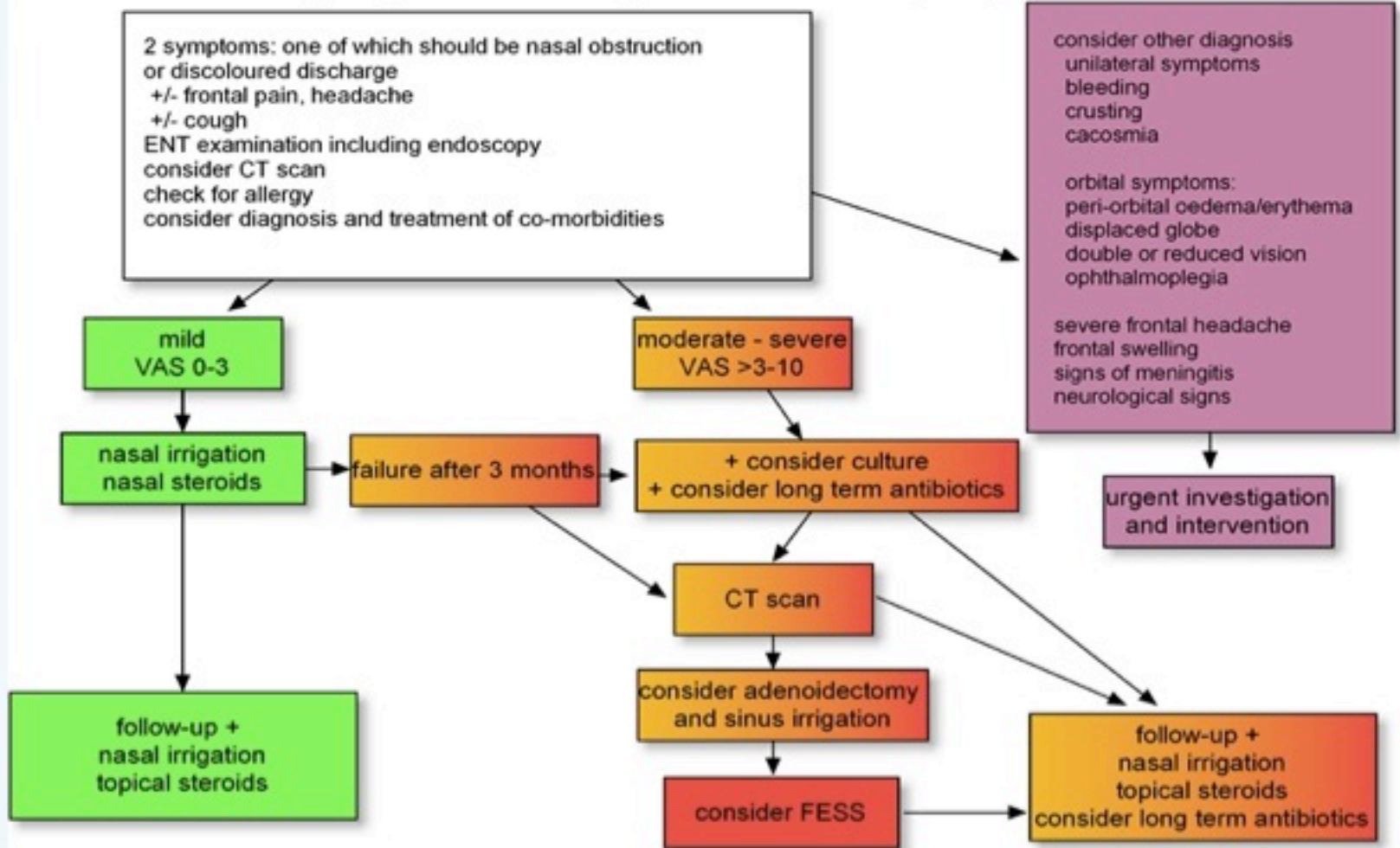
Ib (-): Ib study with a negative outcome

*A(-): grade A recommendation not to use

##III(-): level III study with a negative outcome

**C(-): grade C recommendation not to use

CRSsNP in young children management scheme for (ENT-) specialists



European Position Paper on rhinosinusitis and nasal polyps

FREE DOWNLOAD:

www.rhinologyjournal.com

www.ep3os.org

endorsed by EAACI and ERS

Fokkens, Lund, Mullol et al. *Rhinology*
2012, vol 50 (Suppl 23): 1-198

