



**Treatment for
Acute Inflammation
of the
middle Ear**

CONSENSUS STATEMENT

Consensus Development Conference

May 10 – 12, 2000

Treatment for Acute Inflammation of the Middle Ear

Consensus Statement

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The Swedish Medical Research Council

Box 7151

103 88 Stockholm

e-mail: mfradmin@mfr.se

website: <http://www.mfr.se>

Treatment for acute inflammation of the middle ear in children

Acute inflammation of the middle ear (also referred to below as “acute otitis media”) is generally defined as acute, short-term, clinically confirmed inflammation in the middle ear. Second to the common cold, acute otitis media is the most common infectious disease among children. Mainly small children are affected; prior to 2 years of age, approximately 50% of children have at least one episode of acute otitis media. The disease is treated by several categories of specialists, mainly general practitioners, pediatricians, and ear, nose, and throat (ENT) specialists.

In Sweden, the recommended treatment for purulent, acute otitis media has included antibiotic treatment for all acute ear infections. This practice has been questioned in recent years, in part because resistance to antibiotics has increased among the targeted bacteria.

The Swedish Medical Research Council, the Federation of Swedish County Councils, and the National Swedish Board of Health and Welfare arranged a consensus development conference on May 10 - 12, 2000 to reach a consensus on the treatment of acute otitis media in children. The aim of the conference was to agree on recommendations that could be given to all physicians who treat acute otitis media as regards the use of antibiotics and the requirements that should be placed on diagnosis and followup.

The questions addressed at the conference were:

1. What causes acute otitis media?
2. How should acute otitis media be diagnosed?
3. How should acute otitis media be managed and followed up?
4. What are the economic consequences of different treatment routines?
5. What information is most urgently needed in research and education?

Scope

The consensus conference addressed single episodes of acute otitis media in children below 16 years of age. The group of otitis-inclined children, ie, children with recurring acute middle ear infections, was not included.

Definitions

Acute inflammation of the middle ear (acute otitis media) is defined in this document as a purulent inflammation of the middle ear which has a sudden onset, is of short duration, and can be clinically verified.

Mastoiditis refers to the spread of infection beyond the mucous membrane in the middle ear and the cell system with development of osteitis (inflammation in bone tissue).

Otitis-inclined child refers to a child who has experienced three or more episodes of acute middle ear inflammation during a 6-month period.

Relapse (recurrence) in acute otitis media refers to a new episode within 30 days that occurs after a symptom-free interval.

Secretory otitis media (SOM) also referred to as otitis positioned and mobile eardrum without signs of fluid in the middle ear.

Therapy failure refers to no change, or deterioration, or re-inflammation in the middle ear despite at least 3 days of treatment.

A panel, similar to a court jury, jointly responded to the five questions listed above to form the consensus statement presented here. Their answers were based solely on the facts that were either presented by experts or emerged during discussions among the experts, the panel, and the other participants during the conference.

Question 1: What causes acute otitis media?

Microbiologic etiology and resistance

Bacteria can be found in 50% to 70% of all acute middle ear infections. Since the mid-1950s, *Streptococcus pneumoniae* (referred to here as pneumococci) has been a common cause of acute otitis media, while *Streptococci pyogenes* (referred to here as Group A streptococci), previously a dreaded etiological agent, is now seldom found. *Hemophilus influenzae* and *Moraxella catarrhalis* are other common contagions while other types of bacteria, including anaerobic bacteria, are uncommon causes of ear inflammation.

Pneumococci are not only the most common cause of acute otitis media (40% of culture-verified ear infections), but also of mastoiditis and meningitis emanating from the middle ear. They can cause acute otitis media at all ages, but dominate mainly in younger children. The most important virulence factor is the polysaccharide capsule. Spontaneous elimination of bacteria from the middle ear within 2 to 7 days is poor (20%). There is a positive correlation between spontaneous elimination of bacteria from the middle ear and clinical recovery within 7 to 14 days. Even with deficient bacteriological elimination clinical recovery is reported in approximately 60% of the cases. Pneumococci are usually sensitive to penicillin. Since the late 1960s, however, strains that are less sensitive (ie, with greater resistance) have been found. Such strains are usually treatable by amoxicillin. The frequency of resistant strains in some European countries is 50% to 60%. In these countries, multiresistant strains also appear, ie, strains resistant to three or more antibiotics.

Hemophilus influenzae can be found in encapsulated and non-encapsulated forms. Most infections are caused by non-encapsulated strains with low virulence. National vaccination programs have nearly eliminated infections caused by the more virulent H. influenzae with capsule type B. H. influenzae has a lower sensitivity to penicillin, but is spontaneously eliminated from the middle ear to a much greater extent (50%) than pneumococci. In Sweden, approximately 10% of H. influenzae strains are penicillin-resistant

due to the production of betalactamase or changes in penicillin-binding proteins.

Moraxella catarrhalis causes acute otitis media mainly in younger children. It has low virulence and complications are rare. Spontaneous elimination in the middle ear is high (80%). In Sweden, betalactamase production is found in approximately 90% of *M. Catharralis* cases. Hence, in practice, the bacteria are assumed to be resistant to penicillin V and ampicillin.

Group A streptococci can give rise to relatively severe acute ear inflammation. In terms of complications it is similar to pneumococci infection. In Sweden, Group A streptococci can be found in approximately 5% of children with acute otitis media. The bacteria are always sensitive to betalactamase antibiotics, while resistance to erythromycin is found in approximately 3%.

Viruses. It is well known that an acute otitis media often follows upper airway infections. Hence, viruses are a recognized cause of acute otitis media, often in combination with bacteria. It has been estimated that up to 75% of all patients with acute otitis media have a simultaneous viral infection, and virus in the middle ear can be demonstrated in up to 50% of patients. Viral infections affect the ability of the epithelial cells to keep the bacteria from attaching, and also modify the patient's inflammatory response in a negative direction. RS-viruses (respiratory syncytial) and influenza viruses are important in this context.

Average resistance status of airway pathogen bacteria studied in Sweden.

Note that wide local variations are possible.

PBP = Penicillin-binding proteins

Bacteria	Penicillin resistant				
	Betalactamase	Altered PBP	Peroral cephalosporin	Erythromycin	Trimethoprim sulfamethoxazole
Pneumococci	0%	5%	5%	2-4%	4-7%
H. influenzae	10%	1-3%	1-3%	se fotnot	7-10%
M. catarrhalis	89-95%	?	?	<5%	<1%
Group A streptococci	0%	0%	0%	2-5%	0%

Footnote: Erythromycin shows poor activity against H. influenzae.

Age, gender, and other factors that influence onset

Acute otitis media often affects children, and is most common among children under 2 years of age. Children who fall ill prior to 1 year of age are more often affected by recurrent acute middle ear infections. Acute otitis media is somewhat more common among boys than among girls.

Meta-analyses in industrialized nations suggest the following risk factors:

Heredity is a major risk factor. This concerns immunological factors and/or the anatomy in the nasopharynx, cranial base, Eustachian tube, and middle ear.

The type of child daycare and **size of children's group** are obvious risk factors. The more siblings or the more children in the same group where a child is cared for, the greater the risk for developing acute otitis media. Several studies show that daycare attendance is a risk factor for children below 2 years of age.

Breast-feeding has a protective effect during the first 12 months of life. Little or no breast-feeding constitutes a risk factor for acute otitis media.

Bottle-feeding is a risk factor.

Pacifier use is associated with an increased risk for acute otitis media, but it is unclear whether the same applies to thumb sucking.

Smoking. Recurrent acute middle ear infections are more common in children who receive care at home by a mother who smokes heavily. Smoking during pregnancy also constitutes a risk factor.

Seasonal variation. Acute otitis media and upper airway infections are closely associated. Both are most common during the winter months.

Other studies indicate the following associations:

Open bite is a risk factor for acute otitis media.

Allergies have not been unequivocally shown to constitute a risk factor.

Nose blowing has traditionally been viewed to contribute to bacteria finding their way through the ear to the middle ear, but no studies could be found to confirm this.

Disease course and complications

As a rule, acute otitis media is expressed as sudden ear pain, often in conjunction with an upper airway infection. Discharge from the ear may appear as a sign of a perforated tympanic membrane. During the first days, ear pain, fever, general distress, anxiety, and sleep problems are common. The infections often affect both ears. The symptom profile and clinical findings may vary depending on the bacterial etiology. Generally, pneumococci and group A streptococci have a less favorable clinical profile than other pathogens. The rate of spontaneous clinical recovery from acute otitis media is high, but varies by etiology and is lower for pneumococci and Group A streptococci.

Most children in whom acute otitis media has been confirmed by a physician have been treated with antibiotics. Therefore, we have limited knowledge about the natural course and complications in cases not treated with antibiotics. Meta-analyses suggest that ear pain is somewhat less pronounced 2 to 7 days after symptom onset in children who have received antibiotics, ie, 1 in 8 to 17 treated children report less pain. Fewer children develop acute otitis media in the second year compared to those who have not received antibiotics. Some studies have even shown a slight difference in duration in other symptoms in favor of antibiotic treatment. Diarrhea, nausea, vomiting, and skin outbreaks occur nearly at twice the rate in children treated with antibiotics.

Secondary conditions and complications from acute otitis media include secretory otitis, tympanic membrane (eardrum) perforation, mastoiditis, meningitis with or without permanent neurological problems, epidural abscess (collection of pus within the skull), facial paresis (paralysis of the face), labyrinthitis (inflammation of the internal ear that can cause hearing loss and tinnitus), and sinus thrombosis (blood clot in a major cerebral vessel). Younger children are more often affected by complications than older children. Secretory otitis is common after acute otitis media regardless of antibiotic treatment. Long-term secretory otitis media results in hearing loss. There is some relationship between long-term secretory otitis and chronic middle ear diseases such as severe eardrum retraction and cholesteatoma, conditions which can lead to osteomyelitis and permanent hearing damage. Permanent perforation occurs and can result in recurring ear discharge and hearing loss.

Perforation can be reason for surgery (tympanoplasty).

Of the serious and acute complications, mastoiditis is the most common. The prevalence is estimated at less than 1 per 10 000 diagnosed cases of acute otitis media. Approximately half of mastoiditis cases develop despite antibiotic treatment of acute otitis media. Some studies show that these cases have less obvious symptomatology and therefore can be difficult to detect. Mastoiditis is most common among children under 2 years of age. Pneumococci and Group A streptococci are the most common etiological causes.

The most serious complications require acute medical and/or surgical management. Today, they are rarely seen compared to the situation during the first half of the 1900s. This is probably due to a combination of several factors: the introduction of antibiotics, the higher socioeconomic standard of living that has contributed to better public health and immune defense, changes in the virulence characteristics in the pathogenic flora, and greater accessibility to medical treatment. It has not been scientifically proven that serious complications are more common in non-antibiotic treatment of acute

Question 2: How should otitis media be diagnosed?

Strictly scientifically, acute otitis media is an infection in the middle ear where perforation of the tympanic membrane reveals fluid with infectious agents. In practical usage, it is necessary to apply a different definition based on medical history, symptoms, and status of the tympanic membrane.

Diagnostic criteria

Acute otitis media can be identified when findings reveal symptoms of infection and a bulging tympanic membrane or discharge of purulent secretion into the auditory canal.

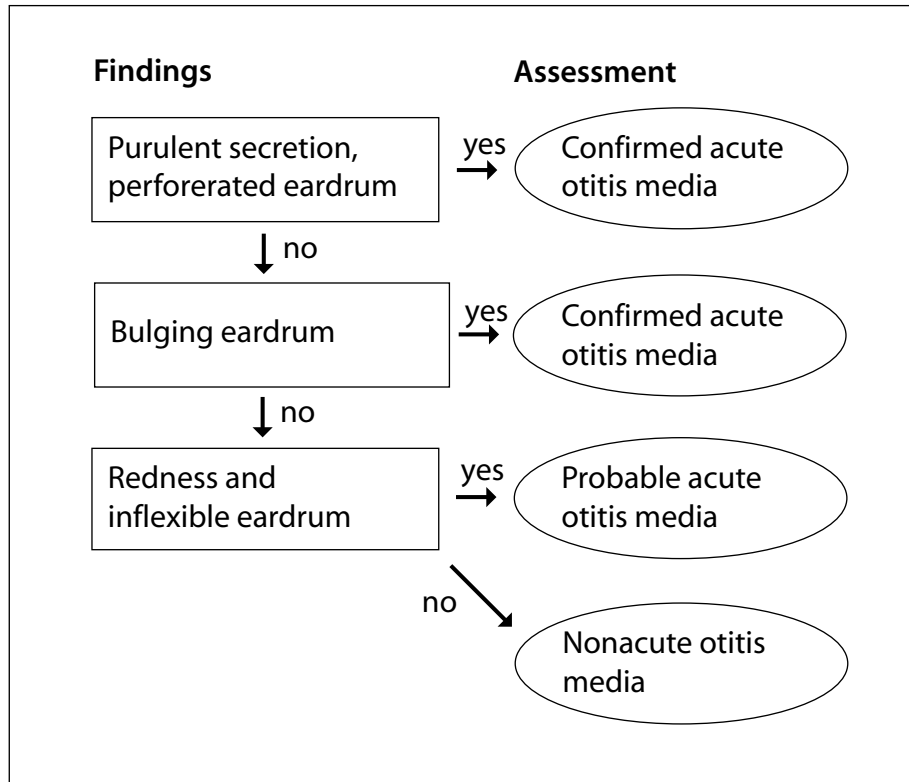
If the eardrum does not bulge, but examination reveals changes in color and structure, then flexibility must be assessed to determine if secretion is found in the middle ear.

Medical history may reflect a varied profile of colds, fever, reduced appetite, poor sleep, and general irritation. Earache in children under 2 years of age suggests acute otitis media (high positive predictive value) but the absence of pain does not eliminate the possibility of acute otitis media (low sensitivity).

Assessing the tympanic membrane

To establish a diagnosis, the tympanic membrane must be inspected. This may be done by otoscopy or ear microscopy. If the eardrum does not bulge, but reveals color and structural changes, flexibility should be assessed by pneumatic otoscopy or tympanometry to enhance diagnostic reliability. Redness of the tympanic membrane, but good flexibility, speaks against purulent secretion in the middle ear.

Situations may arise where it is impossible to remove wax and inspect the eardrum. If the auditory canal is not completely blocked, tympanometry can provide information on the flexibility of the eardrum. Medical history and symptoms alone yield an uncertain basis for diagnosis. If the child's condition permits, it may be appropriate to delay antibiotic therapy, dissolve the wax, and schedule time for a new assessment within 24 hours.



Medical history flowchart for diagnosing acute otitis media.

Question 3: How should acute otitis media be managed and followed up?

Background

Meta-analyses of placebo-controlled studies of treatment, with or without antibiotics, for acute otitis media have not shown any decisive differences in the resolution of acute otitis media in groups of otherwise healthy children over 2 years of age. Published studies do not provide a sufficient basis for corresponding conclusions in children under 2 years of age. In this age group, diagnosis is more difficult and complications are more common. If the eardrum is perforated, the data suggest that this results more often from infection by a more virulent agent, with some increase in the risk for complications. A reduced use of antibiotics can be expected to have a positive effect on the development of resistance. Furthermore, antibiotic treatment is associated with some side effects.

Initial contact

The first contact with the health services is often made by telephone. Seldom are there medical reasons to examine a child with suspected acute otitis media during the evening or at night. An appointment with a physician should be offered within 24 hours. An examination is not needed if the child improves and symptoms disappear during the waiting period.

If the clinician is uncertain about the nature of the symptoms, or if the child is generally distressed, then the child should be examined as soon as possible.

Initial examination

All treatment should be provided in consultation with the patient and parents. Analgesics are administered as needed. An elevated position and nasal drops have no verified effects on acute otitis media, but may relieve nasal congestion.

If the child is generally distressed and findings from the ear examination do not explain the problem, then further examination is necessary, and contact with an ENT specialist or pediatrician should

be considered. If the child is not affected, and there are difficulties in establishing a certain diagnosis, then the child should be re-examined within 24 hours.

Treating children with acute otitis media

Children under 2 years of age: Antibiotic treatment is recommended in these children. Another assessment by a physician should take place to reassess diagnosis and treatment if the child does not improve after 3 days. If the condition deteriorates, the child should be examined further.

Children over 2 years of age: Children with perforated acute otitis media or acute otitis media with general distress are recommended antibiotic treatment. In other children, the scientific information presented at the conference suggests two alternatives:

Alternative 1: If the child does not suffer from general distress, information is provided and the physician recommends holding off on administering antibiotics. Parents are recommended to contact a physician again (possibly by telephone) if the problem persists after 2 days following symptom onset. If the problem remains unchanged, the physician may agree to prescribe antibiotics in conjunction with this contact without re-examining the child. Furthermore, if the situation appears to be stable, it is possible to wait yet another day and agree to a new contact. If symptoms persist for 3 days following symptom onset, the child should be examined again, and antibiotics should be prescribed if the diagnosis is verified. Should the condition deteriorate, the child should be examined earlier.

Alternative 2: The child is treated with antibiotics in the same way as children under 2 years of age.

Check-up

Children with confirmed acute otitis media are recommended a followup visit, which normally takes place 3 months after onset. It is particularly important to followup on the youngest children. The purpose of the check-up is to assure a normalization of hearing and tympanic membrane status.

Children who should be exempted from these general recommendations

In assessing children with acute otitis media it is important to know if the child in question belongs to a group with a higher sensitivity to infection, which can carry a risk for a complicated disease course.

These groups include children with immune deficiencies, malformation syndromes, and chromosomal disorders. Children with serious primary diseases – and who receive immunosuppressive treatment – also comprise a risk group. A third group includes children with anatomic changes in the ear region, eg, skeletal malformations or residual conditions following fracture of the cranial base. Yet another group would be children who have had ear surgery, particularly if foreign material has been implanted (not including plastic grommets).

It is preferable if the total continuity of care for these children helps them avoid the need to visit an emergency department. This also applies to children with recurring otitis media.

Choice of antibiotic

First choice: PcV (Phenoxymethyl penicillin) for 5 days.

Dose: 50 mg/kg body weight/day at 2 or 3 doses per day.

On relapse: PcV for 10 days, or amoxicillin 50 mg/kg body weight/day at 2 or 3 doses per day for 10 days.

If therapy fails: Amoxicillin 50 mg/kg body weight/day at 2 or 3 doses per day for 10 days.

If penicillin allergy is confirmed: Erythromycin for 7 to 10 days.

Dose: 40 mg/kg body weight/day at 2 or 3 doses per day.

For penicillin allergy and failed therapy: Trimethoprim / sulfamethoxazole.

If therapy fails, lab cultures and consultation by an ENT specialist may be of value in pursuing further treatment.

Question 4: What are the economic consequences of different treatment routines?

There are no reliable estimates of incidence and cost in Sweden. However, if the incidence estimates compiled in Finland are applied to Sweden, approximately 750 000 cases of acute otitis media would be diagnosed annually. If the estimates are based on epidemiological studies from Norway the figure would be approximately 500 000 annually.

Based on the epidemiological studies performed in Malmö, the total socioeconomic costs in Sweden for acute otitis media are estimated to be approximately one billion SEK in 1999 monetary value. Of this sum, healthcare costs represent 43% (whereof antibiotics account for slightly over 2%) and production loss (parents caring for sick children) represents 57%. The management of acute otitis media proposed in the answer to Question 3 reflects an unchanged treatment strategy in children under 2 years of age, and for problem groups over 2 years of age, including children who relapse repeatedly. These groups are assumed to account for approximately one half of the total number of physician visits. Hence, the proposed strategy does not represent any change in the costs for these cases.

The proposed change in the management of children over 2 years of age probably implies some increase in the number of physician visits. This mainly concerns visits resulting from children who visit a physician again following the initial contact. Given the other uncertainties in the economic estimates, the change in the number of visits is assumed to be so limited that it has not been taken into account.

Health economics may be affected as a result of:

1. Fewer prescriptions for antibiotics.
2. Reduction in side effects from antibiotics.
3. Reduced spread of resistance.
4. Changes in lost productivity resulting from changes in the disease course.

The economic impact from a change in treatment routines for acute otitis media are difficult to estimate, and probably differ in the short and the long term. Currently, there is insufficient data to determine how costs would be influenced by the proposed treatment routines, and therefore these data were not considered.

Question 5: What information is most urgently needed in research and education?

Research

In Sweden, most children presenting with otitis media are seen by a general practitioner. We feel this is appropriate since it offers good continuity and accessibility for many patients. A consequence of this approach is that the primary care services form an important base for developing knowledge and systematic research and development activities. More scientific studies should therefore be grounded in primary care, and collaborative research by general practitioners, pediatricians, and ENT specialists should be encouraged.

Epidemiology

There is a need for more knowledge about the prevalence and incidence of acute otitis media in different parts of Sweden and in different population groups. Another urgent area for research concerns the incidence of complications in relation to geography, demography, and therapy.

The natural course in acute otitis media under the conditions that prevail in Sweden needs to be defined since the evidence supporting the positive effects from antibiotic treatment in uncomplicated acute otitis media is weak. A more differentiated approach to therapy needs to be found. This should be thoroughly assessed in prospective studies.

One of the main reasons for a more restrictive approach to antibiotic treatment is the increased risk for developing resistance. The resistance status for airway pathogens should be monitored over time in several defined cohorts of children geographically distributed throughout Sweden.

The importance of virus as an etiological agent and the clinical profile of the otitis virus in acute otitis media need to be surveyed.

What factors influence the prevalence of otitis media in children?

Some risk factors are known, such as heredity, gender, and type of childcare. What other factors influence the incidence of otitis media? Do factors other than breast-feeding reduce the risk? What habits and behaviors in addition to tobacco smoking in the child's environment influence the risk for acquiring otitis media? Can salutogenic (health-promoting) factors be identified? Are "outdoor daycare centers" an example of such a factor?

How should pain be managed in otitis media?

Pain is often the reason that children with otitis media are taken to a physician. A motive for prescribing medication is the hope that pain should subside more quickly. What is the best way to treat earache? Does treatment provide better and/or quicker relief than the natural course, and what is appropriate treatment?

Followup

Currently, a 3-month check-up is recommended to verify normalization of hearing and tympanic membrane status. Different ways of conducting this check-up should be assessed. In particular, the opportunity to use new technology and the delegation of work to specially trained staff, should be addressed.

Family medicine perspective

As a complement to biomedical knowledge there is a need to study the importance of non-medical factors in otitis media. This includes psychosocial, behavioral, and community medicine effects. For example, there is some evidence that a sense of security during the consultation improves the clinical course. Finding ways to mobilize health resources in sick children and their families can provide benefits such as greater compliance and less uncertainty, and thereby reduce care utilization.

National coordination

To facilitate the implementation of the recommendations presented here and assure a systematic assessment of their effects, we propose that a national multidisciplinary reference group conduct research on

otitis media aimed at initiating and coordinating the development of knowledge, research, and education.

An initial task could be to initiate a prospective health economic assessment of the costs and effects associated with applying the proposed guidelines.

Education

Basic medical education should emphasize the early development of skills necessary in consultation and examination methods for airway infections. Training at ENT departments should be included both in specialist residencies and in the continuing medical education of general practitioners and pediatricians. Likewise, it should be equally as important for ENT specialists to train at community health centers or similar settings.

An approach based on collaboration and delegation of certain tasks assumes a well-functioning system for developing skills of the members in the work team.

Parent education and the development of informational material should be promoted in collaboration with other actors in the health field, eg, medical information and pharmacies, preschools, and schools.

Experts

Karin Prellner, Professor (Chair)
Institute for Ear, Nose, and Throat Diseases
University Hospital
221 85 LUND
e-mail: Karin.Prellner@onh.lu.se

Christer Andersson, M.D.
Department of Family Medicine
Umeå University
901 85 UMEÅ
e-mail: Christer.Andersson@fammed.umu.se

Ingrid Augustsson, Medical Director
ENT Department
Regional Hospital
701 85 ÖREBRO
e-mail: ingrid.augustsson@orebroll.se

Dan Bagger-Sjöbäck, Professor
ENT Department
Karolinska Hospital
171 76 STOCKHOLM
e-mail: dbs@ent.ks.se

Anita Bylander Groth, M.D.
CURA Clinic, Malmö
Erikslustvägen 22
Box 200 37
200 74 MALMÖ
e-mail: groth.medical@lund.mail.telia.com

Margaretha L. Casselbrant, Professor
Department of Otolaryngology
University of Pittsburgh School of Medicine
Children's Hospital of Pittsburgh
PA 15213 USA
e-mail: casselm@chplink.chp.edu

Henrik Harder, M.D.
Ear Clinic
University Hospital
581 85 LINKÖPING
e-mail: henha@inr.liu.se

Sten Hellström, Professor
Institute for Clinical Science
ENT Department
Umeå University
901 85 UMEÅ
e-mail: Sten.Hellstrom@ent.umu.se

Claes Hemlin, M.D.
ENT Department
Danderyd Hospital
182 88 DANDERYD
e-mail: claes.hemlin@oron.ds.sll.se

Ann Hermansson, Associate Professor
Institute for Ear, Nose, and Throat Diseases
University Hospital
221 85 LUND
e-mail: Ann.Hermansson@onh.lu.se

Birgitta Hovelius, Professor
Institute for Community Medicine
Lund University
205 02 MALMÖ
e-mail: Birgitta.Hovelius@smi.mas.lu.se

Leif Ingvarsson, Associate Professor
ENT Department
University Hospital MAS
205 02 MALMÖ
e-mail: Leif.Ingvarsson@oron.mas.lu.se

Gunnar Kahlmeter, Associate Professor
Department of Clinical Microbiology
Central Hospital
351 85 VÄXJÖ
e-mail: gunnar.kahlmeter@ltkronoberg.se

Mats Kalin, Associate Professor
Infectious Disease Unit
Karolinska Hospital
171 76 STOCKHOLM
e-mail: kal@ks.se

Kaj Lundgren, Associate Professor
Andvägen 20
291 43 KRISTIANSTAD
e-mail: kaj.lundgren@swipnet.se

Åsa Melhus, M.D.
Department of Clinical Microbiology
University Hospital MAS
205 02 MALMÖ
e-mail: Asa.Melhus@mikrobiol.mas.lu.se

Ulf Persson, Fil lic
Institute of Health Economics
Box 2127
220 02 LUND
e-mail: up@ihe.se

Kristian Roos, Associate Professor
ENT Department
Lundby Hospital
Wieselgrensplatsen 2A
417 17 GÖTEBORG
e-mail: kristian.roos@lundbyHospital.se

Britta Rynnel Dagöö, Associate Professor
ENT Department
Huddinge Hospital
141 86 HUDDINGE
e-mail: britta.rynnel@ent.hs.sll.se

Margareta Söderström, Associate Professor
Central Research Unit for Family Practice
Panum Institute
Blegdamsvej 3
DK-2200 Copenhagen N, Denmark
e-mail: Margareta.Soderstrom@smi.mas.lu.se

Panel

Sigvard Mölsted, Associate Professor (Chair)
Primary Care R&D Unit
Community Health Center
595 30 MJÖLBY
e-mail: sigvard.molstad@lio.se

Ragnar Asplund, Associate Professor
Center for Studies on Health and the Quality of Life
Community College
831 25 ÖSTERSUND
e-mail: r.asplund@telia.com

Håkan Bengtsson, Medical Journalist
Box 1150
121 15 ENSKEDEDALEN
e-mail: hb@ordslojd.se

Marie Bunne, M.D.
ENT Unit
Sunderby Hospital
971 80 LULEÅ
e-mail: Marie.Bunne@nll.se

Otto Cars, Adj. Professor
Strama
Institute for Prevention of Infectious Disease
171 82 SOLNA
e-mail: otto.cars@smi.ki.se

Ingvar Eliasson, M.D.
Department of Clinical Microbiology
County Hospital
391 85 KALMAR
e-mail: ingvar.eliasson@ltkalmar.se

Ingemar Engstrand, Medical Director
ENT Clinic
Lindesberg Hospital
711 82 LINDESBERG
e-mail: ingemar.engstrand@orebroll.se

Margareta Eriksson, Associate Professor
Institute for Women's and Children's Health
Pediatric Unit
Karolinska Hospital
171 76 STOCKHOLM
e-mail: margareta.eriksson@kbh.ki.se

Stig Holm, Professor Emeritus
Sprängkullsgatan 13
411 23 GÖTEBORG
e-mail: holm.st@telia.mail.se

Stefan Håkansson, Associate Professor
National Swedish Board of Health and Welfare
106 30 STOCKHOLM
e-mail: stefan.hakansson@sos.se

Anders Paperin, Dir. of Primary Care
Federation of Swedish County Councils
Box 7049I
107 26 STOCKHOLM
e-mail: anders.paperin@lf.se

Åke Schwan, M.D.
Kungsgärdet Community Health Center
St Johannesg 28
752 33 UPPSALA
e-mail: ake.schwan@hml.pv.lul.se

Roland Sennerstam, Associate Professor
Pediatrics Clinic
Handen Hospital
136 25 HANINGE
e-mail: rolestam@telia.com

Johan Wiström, Associate Professor
Department of Infectious Diseases
Norrland University Hospital
901 85 UMEÅ
e-mail: Johan.Wistrom@infdis.umu.se