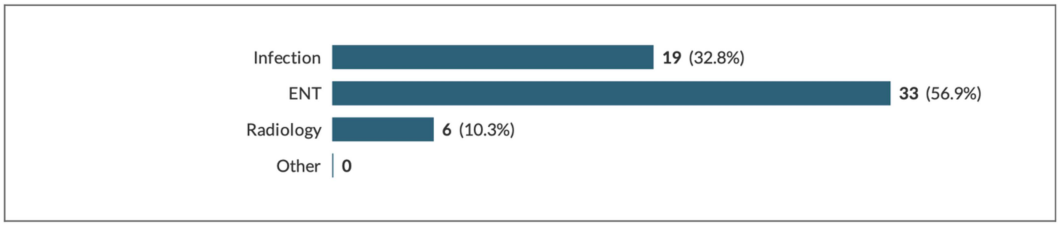
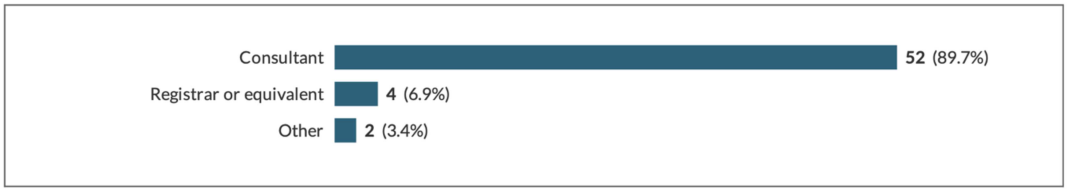
DELPHI ROUND 5 – RESULTS
FEBRUARY 2021
Response Rate: 79% (58/73)

Specialty



Grade



If you selected Other, please specify:

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Question 1

A definite case of NOE is an invasive infection of the external ear canal which has the following characteristics:

- Otalgia and otorrhoea OR otalgia and a history of otorrhoea

AND

- Granulation OR inflammation of the external auditory canal

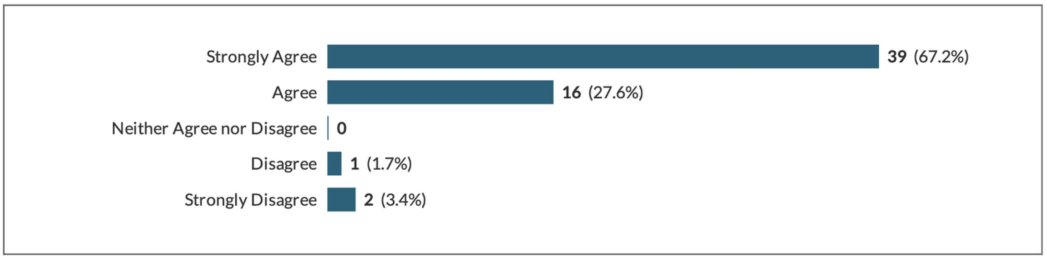
AND

- Histological exclusion of malignancy in cases where this is suspected

AND

- Radiological features consistent with NOE

(This refers to EITHER CT imaging findings of bony erosion of the external auditory canal, together with soft tissue inflammation of the external auditory canal **OR** MRI with changes consistent with NOE, for example bone marrow oedema of the temporal bone with soft tissue inflammation of the external auditory canal).



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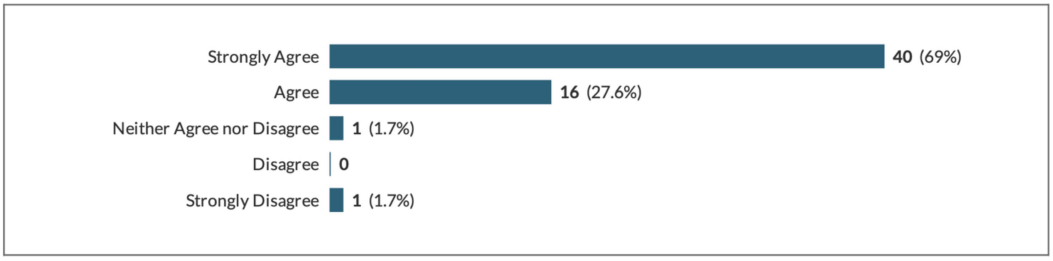
This definitely works for me. These are the 4 things that would seal a diagnosis of NOE for me, and more so if patient was diabetic.
CT scans in early NOE can be very misleading due to the lag of bony demineralization. MRI far more helpful in particular BM oedema and oedema around the TMJ and soft tissue of the infratemporal fossa structures therefore should read CT and/or MRI
if granulation/ inflammation is part of the diagnostic criteria why would you not biopsy this?
Until excluded malignancy can cause same symptoms - histological exclusion is the only definitive way of proving it.
Soft tissue oedema of the ear canal is a common finding in just OE. I think perhaps it should say something like: evidence of soft tissue inflammation extending beyond and including the external auditory canal. For me extension into retrocondylar fat is very classic for NOE.
addition of "in cases where this is suspected" makes this a workable CD
I would say that the histological exclusion of malignancy is a must if there is granulation tissue in the canal. As the symptoms and signs of NOE is sufficient to suspect malignancy.
I have found opacity in mastoid cells without gross bony erosion
should we consider having something around presdisposing factors - or do you think that is covered with the "histological exclusion of malignancy". essentially NOE without underlying immunosuppression of some sort is vanishingly rare
There are often no signs in the ear canal at the time of presentation
good.
For both CT and MRI after soft tissue inflammation of the external auditory canal.. Also consider adding ... or adjacent soft tissues outside the EAC (caudal to the lateral and central skull base/TMJ etc.)
Whilst otorrhoea occurs in many cases it is not universal and I don't think this needs to be part of the diagnostic criteria. I think that malignancy needs to be excluded in all cases. It should be suspected in every case. MRI features of NOE aren't just about bone marrow oedema. There is often oedema of the soft tissues around the skull base, especially the masticator space

Question 2

A case of NOE may be classified as 'complex' if any of the following are present:

- Facial nerve palsy or other lower cranial nerve palsy
- Cerebral venous thrombosis seen on MRI or contrast enhanced CT
- Extensive bone involvement as demonstrated by any of the following;
    - CT showing bone erosion in other skull base locations in addition to the external ear canal wall, e.g: around stylomastoid foramen, clivus, petrous apex, temporomandibular joint.
    - MRI showing bone marrow oedema extending to central skull-base.
    - CT or MRI showing extensive soft tissue oedema or inflammation or fluid collection below the skull base.
- Intracranial spread of the disease (dural thickening, extradural or subdural empyema, cerebral/cerebellar abscess)



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No issues here. Agreed.
CT or MRI showing extensive soft tissue oedema or inflammation or fluid collection. Its very common in almost all of our NOE to see oedema/inflammation in the soft tissue below the skull base. This is not necessary a poor prognostic indicator or sign of complex disease. I agree totally once disease involves neurovascular structures or crosses the mid-line then it is severe and more complex
I think "extensive soft tissue oedema" is inexact. How do you define "extensive2. I would have thought that soft tissue changes below skull base around the tympanic ring or at the osseocartilagenous junction would be common in 'simple' NOE. What about clarifying by stating that the soft tissue changes have progressed BEYOND the tympanic ring?? I am sure better answered by a neuroradiologist.
I would suggest using the word "Advanced" or "Complicated". The word complex does not necessarily indicate progression of the original disease.
I don't like the term phlegm on at all!
good definition.
I'm not keen on the term 'complex'. Perhaps 'advanced' would be better. With regards to imaging definition of 'advanced' disease, how do you define 'extensive'?
Not sure how 'extensive' soft tissue oedema under the skull base will be defined - would definitely agree re collection though.

Question 3

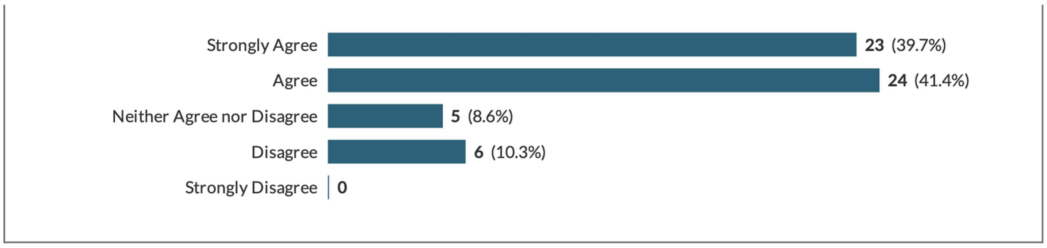
Possible NOE is a severe infection of the external ear canal which does not show bony erosion of the external auditory canal on CT scan OR does not show changes consistent with NOE on MRI if this is performed (for example bone marrow oedema of the temporal bone) AND which has the following characteristics:

Otalgia and otorrhoea OR otalgia and a history of otorrhoea

AND Granulation OR inflammation of the external auditory canal

AND any of the following features:

- immunodeficiency
- night pain
- raised inflammatory markers (ESR/CRP) in absence of other plausible cause
- failure to respond to >2 weeks of topical anti-infectives and aural care



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is this not severe otitis externa
I agree with this but for some reason not as strongly as with the definite case, though I cannot really add anything to the definition that would strengthen it in my mind. Overall, it is a more than fair definition for a possible case.
NOE is either present or not so it is NOE or severe AOE. AOE left unchecked in the right patient profile is probably a continuum and may lead to NOE. If CT and or MRI shows no extension of inflammation beyond the auditory canal then it is severe AOE not a possible NOE this is too ambiguous and will lead to heterogenicity in future studies
Night pain and raised inflammatory markers could still be an issue in severe otitis externa
I would think MRI would show early changes of NOE so I disagree with this statement.
I would prefer to see this definition in the last section as "AND and 2 or more of the following features" as the definition above with just raised inflammatory markers is not enough in my opinion
I think chronicity or failure to respond should be and AND nont just included in any of the follwoing features
I really think that key population needs to be in this group. Will this definition include that immunodeficiency includes frail or elderly patients. For example simple OE is extremely painful and many younger fit patients present at night with severe pain so I think there needs to be something to reflect this otherwise the definition will not be very 'specific' at all. I think in the 'possible NOE' group it is even more important to ensure this reflects our clinical suspicion that NOE does not occur in the young and healthy.
Note - some also consider this as severe OE and will admit patients for symptom control.
failure to respond to oral cipro and drops as many severe OE's take longer than 2 weeks to settle.
If an MRI scan is performed and does not show any evidence of bone marrow oedema I would not consider it possible NOE since lack of bone
marrtow oedema on MRI has a higher negative predictive vallue in my view than lack of bone erosion on CT
I would consider if immunodeficiency needs any definition - is is worth specific mention of diabetes? does extreme age/frailty count as 'immunodeficiency'?
immunodeficiency -Clearly that is easy if present but NOE is often seen in those with multiple morbidities (DM, obesity, Heart failure etc etc) and might be worth considering having 'multiple medical morbidities' as a feature

If a patient has severe Otalgia, Otorrhea, Granulations, Immunodeficient, Night pain, raised ESR and failing to respond to AB for 2 weeks, would the patient still be a possible NOE!!. I think not having the radiological features while fulfilling the rest of the criteria should be an early NOE.
2 weeks is a short time frame to consider a case of OE non-responsive. I would suggest 4-6 weeks.
need histology to rule out other causes in absence on imaging evidence.
good.
If immunodeficiency includes DM
See above re: otorrohoea
night pain is not a feature I have traditionally related specifically to NOE. happy to be outvoted on this point

Question 4

A relapsed case of NOE is a serious, invasive infection which occurs **after the initial infection was considered to be treated and cured** and is characterised by:

Recurrence of local disease

- Recurrent otalgia OR recurrent otorrhoea

AND

- Recurrent granulation OR inflammation

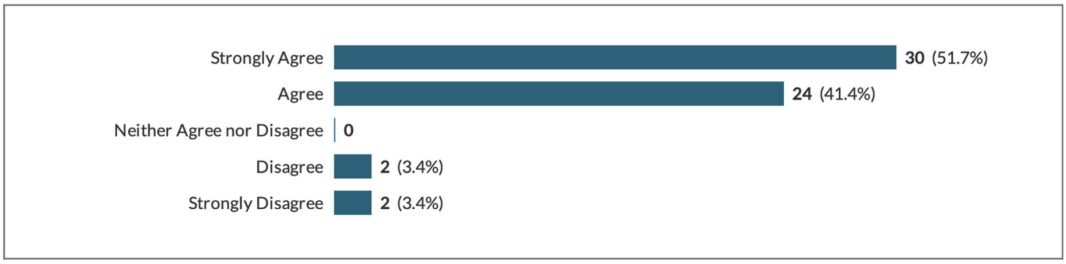
AND

- Unchanged or progression of bony erosion of the external auditory canal on CT OR unchanged or progression of MRI changes such as bone marrow oedema of the temporal bone and soft tissue changes of the external auditory canal.

AND/OR

Development or recurrence of complex disease

- Development or worsening of a lower cranial nerve palsy, base of skull osteomyelitis or development or worsening of other intracranial complication deemed a consequence of NOE and supported by radiological imaging.



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Yes, agreed.
That is fine
I am unclear how the radiological component of 'unchanged' in the definition of recurrence would allow differentiation between a case of O.E. following resolved NOE versus recurrence of NOE. This part of the definition may give rise to an overdiagnosis of recurrent NOE when in fact the patient may have a resolved NOE followed by simple OE.
But you need to define what is "treated" or "cure" before you define relapse- I would define a relapse as one within 6 months of start of first infection and recurrence as reoccurrence of symptoms beyond 6 months.
Some cases will relapse without Ear canal signs (granulations) so stipulating the re-appearance of granulations by using "and" will exclude the most serious cases of relapse, which relapse with CN palsy. Also, most radiological changes of NOE especially the CT ones tend to last for long time and some of them will never re-mineralize or normalise so adding unchanged picture of radiology is not helpful. I would suggest relapse to be recurrence of Otalgia and any of the other 3 (granulations, Progression of Radiology or complications e.g. CN palsy etc...)
CT and MRI findings often remain "unchanged" for many months even in treated cases (although we don't really know the natural history of these changes).
Not so happy with insistence on primary ear symptoms - some of these patients have their ear symptoms cured by initial treatment and this represents skull base disease.
unchanged bone erosion requires a timeframe to be meaningful - even if treated radiological resolution lags by several months
good, includes all relevant considerations.
What's the definition of cure? is it symptoms gone only or does it require change/reversal on radiology?
My only difficulty is the unchanged appearance on CT/MRI
I would remove 'serious and invasive' from the definition of 'relapsed NOE' as all types of NOE are serious and invasive and, if they have been defined as having NOE previously then by definition they must have NOE as the cause of the relapse. I think you need a time scale in the definition of 'relapsed NOE' ie. if they had NOE 10 years ago and they have another episode now that would not be regarded as the same infection. I would say 'within 6 months' of the original infection being regarded as settled. See above re: otorrhoea

Any additional final comments about the 'NOE: Setting the foundations' process / any specific issues?

Showing all 10 responses
The additions are all valuable and pertinent
see Q3 - I think this is v important so that you dont include lots of patients with simple OE.
These definitions have improved a great deal through this iterative process - well done!
I agree the diagnostic criteria is much tighter with these additions to the definitions.
the definitions nearly make it compulsory to perform both CT and MRI
well done - thank you!
So need a definition of cure! and then define difference between a relapse versus a reoccurrence. well done though nearly there !
Well done, a difficult challenge but we have succeeded in achieving a solid consensus that works in the clinical setting. Thank you, Fiona.
These are good definitions