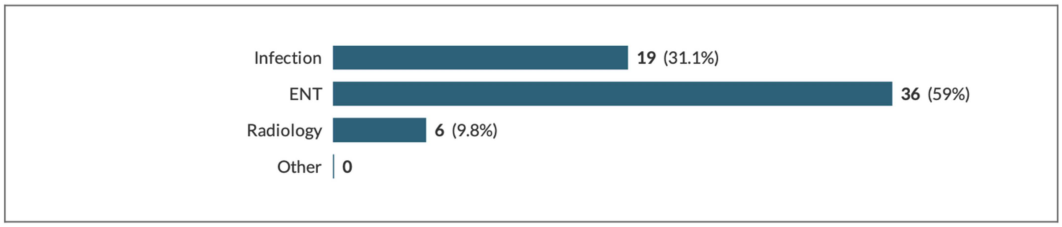
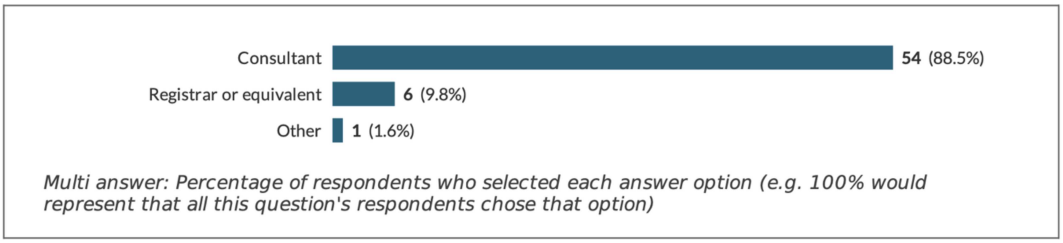
DELPHI ROUND 4 – RESULTS
NOVEMBER 2020
Response Rate: 76% (61/80)

Specialty



Grade



Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option)

If you selected Other, please specify:

Showing 1 response	
Senior Otology and Implant Fellow	662153-662144-67468810

The following definitions have already received consensus:

I. Defining a true case of Necrotising Otitis Externa (NOE)

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

- CT imaging findings of bony erosion of the external auditory canal, together with soft tissue inflammation of the external auditory canal

AND

-is confirmed by exclusion of malignancy on histology

Hodgson SH, *et al. BMJ Open* 2023; 13:e061349. doi: 10.1136/bmjopen-2022-061349

Comments:

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I agree apart from the final one. If there is no granulation tissue, no biopsy will be taken. Generalised swollen ear canal would not be biopsied but would be NOE so I think this needs to at least have a qualifying footnote to say (if granulation tissue/polyp present)
I would say that you don't just have to have bone erosion, you need soft tissue invovlement beyond the external auditory canal (TMJ/skull base)
Entirely agree
Agreed
Should 'a history of otorrhoea' be defined as 'a recent history'? (If so, then we need to define 'recent', but this could be reasonably broad/vague). I think the imaging should be defined as CT or MRI - if the patient happens to have had MRI as first line (without a CT) they shouldn't be excluded from the case definition.
'is confirmed by exclusion of malignancy on histology' in practice is aspirational. Our ENT surgeons very rarely send histology samples
Agree
We have seen a few cases of little or no pain, but with clear bony destruction of EAC bone. We are not certain why these are painless. Diabetic neuropathy has been suggested.
'confirmed by exclusion of malignancy on histology' although correct in my experience occurs <50% time.
Not all cases have samples sent for histology. Whilst it is preferable to have malignancy excluded if possible, I don't think this is a requisite for making a diagnosis fo NOE.
in our institute 40% CT false negative in early NOE. MRI with contrast far more sensitive and specific
Agree
Bony erosion may not be evident on CT in early cases so this needs to be highlighted
I think this is good that we have opted for a gold standard definition albeit in practice histology is rarely performed in my experience
not all cases can get a biopsy
The last point suggests that ALL patients must be biopsied and also raises the question as to where to biopsy from as the superficial inflammatory appearances may mask a deeper seated neoplasm. I am not sure biopsy is mandatory in all cases?
Agree with above definition.
Agree
Agree
Imaging - if CT normal but MR shows inflammation of marrow I would still deem that to be a true case.
Does a biopsy HAVE to be done to call it a true case. If so I am going to struggle to include the majority of our cases!
Seems reasonable, but where does this leave the patient with a persistent area of exposed bone in the floor of the external ear canal, but no bone erosion confirmed by CT. Can we say 'ideally CT imaging findings of bony erosion'?
Severe intractable pain not responding to topical treatment, not just otalgia, is a key symptom. Sometimes there is just soft tissue involvement on MRI without bony erosion on CT. it may be better to make this AND/OR. The presence of diabetes or immunocompromisr is not pathognomic but if present certainly makes NOE much more likely.
We have a problem of cases where the patient presents with complications of NOE eg. cranial nerve palsy but does not have bony erosion of the temporal bone. How should these cases be classified?
Very reasonable
agreed
Agree
Does it have to have bone erosion. What if there is extensive inflammatory soft tissue change and marrow signal change on MR?
yes
"true case" or confirmed case?
Patients will often present with a normal ear canal, local infection there having resolved as it spread medially
Tissue biopsy for histology is not commonly done in my centre, rather only done if poor response to antibiotic or relapse. It isn't always easy to do a biopsy.
Agree, but CT finding can be subtle in terms of bone erosion, in which case if clinically NOE, treat as such if CT equivocal / soft tissue only

II. Defining a case of severe NOE

A case of NOE may be classified as 'severe' 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 stylomastiod foramen, clivus, petrous apex.
    - MRI showing bone marrow oedema extending to central skull-base.
    - CT or MRI showing extensive soft tissue phlegmon below the skull base.
- Intracranial spread of the disease (dural thickening, extradural or subdural empyema, cerebral/cerebellar abscess)

Hodgson SH, *et al. BMJ Open* 2023; 13:e061349. doi: 10.1136/bmjopen-2022-061349

Comments:

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agree
Entirely agree
Agreed
I agree with these as severe local/anatomical features. I am not certain, but wanted to raise whether any systemic features should be considered (new onset delerium, renal impairment etc, without another cause). On balance, these are probably 'complex' rather than 'severe' disease, and therefore are reasonably left out?
happy with this
Something about unresponsive cases (culture -ve cases) would be helpful here
Agree
Agree
Happy with this
Agree
about right
Agreed
Agree with above definition.
Agree
What about to TMJ - seen several cases of this
Agreed
It isn't just erosion of bone marrow. I would just say bone and leave out the marrow. It's inflammation that is seen on the MRI and not necessarily oedema. Not sure I like the term phlegmon. It's a bit 18th century. Perhaps better to say extensive soft tissue involvement of the skull base. Other complications such as Gradenigo's would also be classified as severe. Similarly one occasionally sees abscess formation within the skull base.
as per the comment above - only a definite cases of NOE can have severe NOE
Instead of 'severe NOE' perhaps it should be call 'complicated NOE' people use the term 'Severe' to describe anything that is painful. A change in nomenclature will prevent clinicians using the term 'severe' as descriptor of symptoms, when in NOE (as is currently proposed) it is used as a descriptor clinical and radiological signs
agreed
Agree
yes
fair enough
Agree!
agree

III. CT scan is the first choice of imaging modality for a suspected case of NOE

Comments:

Showing all 26 responses Show less
happy with this but feel that MRI should be completed as it picks up the odd cases (recently had an inflammatory condition and have exclude malignancy). plus I also feel it is more useful for follow up.
Entirely agree
yes
yes
happy with this
Agree
Agree
Agree
No if I had a choice it would be post contrast MRI but this is not always possible due to availability (rare today) metal foreign bodies, implants and claustrophobia. CT/PET may then need to be considered
This was extensively discussed at the Oxford meeting but if we have agreed from the experienced radiologists that this is the case can we make it more specific ie. a FLAIR SEQUENCE WITH CONTRAST. For example
Agreed
Agree with CT as first choice of imaging because not all units have access to MRI.
Agree
Yes
Yes
Definitely not. It is very important to do both CT and MRI.
I'm becoming less convinced about this as I see more and more cases. CT is the most easily accessible imaging modality but MR is better, both for diagnosis abs as a baseline for monitoring.
CT is the first choice imaging modality while an MRI is also done at the same time to assess soft tissue invovement
Not controversial
agreed
Yes
I wouldn't be too didactic, CT and MR are both good tests for NOE, MR is more sensitive to soft tissue and marrow changes.
yes
Changes often more obvious on MRI once disease has spread medially - I would not specify modality
Agree
agree

IV. Defining a case of 'possible'[1] NOE

Possible[1] NOE is a severe 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 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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[1] See definition section

Hodgson SH, *et al. BMJ Open* 2023; 13:e061349. doi: 10.1136/bmjopen-2022-061349

Comments:

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agree
Entirely agree
This is a good definition
yes - is there a need to specify how immunodeficiency is defined? important to make sure this term is regarded broadly enough to include diabetes. Does being very old and frail with co-morbid problems count as being 'immunodeficient'? (for the purposes of this definition, I would say yes).
happy with this
failure to respond is divisive as might be used as easy get out clause. Nominally this includes all diabetics with otitis which is quite a big patient group and a definition like this may open the floodgates for referrals.
agree
This very similar to the Friedmann and Cohen obligatory and possible criteria of definite NOE. I think if the and was changed to or for the last 4 criteria (immunodeficiency, night pain, raised markers and failure to adequate treatment) would be more non-specific. As it stands its very specific
Agree
This is a very clinical definition which for possible is appropriate. Are we able to define the population better. Does this ever present like this is under 18 year olds or even in young adults. I feel it may not
seems ok
An alternative term could be 'severe OE'
Agree with above definition.
Agree
Agree
So essentially "possible" becomes anyone without imaging and "true" becomes only those ones who get a biopsy? I am not sure this quite works, for us the true would be the top criteria but without mandating it is CT, occasionally might jsut have had MR and often no biopsy.
Seems reasonable. Do we need a category of 'Probable NOE'?
A lot of the criteria for possible NOE are not in the definition of true NOE. That doesn't seem logical (see comments above re: immunosupression and intractable, non-responding pain)
is the failure to respond part of the any features? I think it should be definitely in the definition as this moves it from severe OE to possible NOE
Possible is the same as definite according to previous Delphi rounds.
NICE definition of Acute Otits externa is below 3 weeks. Any failure to respond after 3 weeks of treatment should be investigated for NOE
not controversial
agreed
ok
What about not responding to appropriate and or repeated courses of oral abx
fair enough
"Immunodeficiency including diabetes mellitus"
agree

V. Defining a NOE case of non-response to therapy

A case of NOE is defined as non-reponsive to therapy if:

There is no improvement in otalgia or otorrhoea or inflammation or granulation tissue in the EAC after 14 days of optimum analgesia, anti-infective therapy, aural care and optimisation of immune state

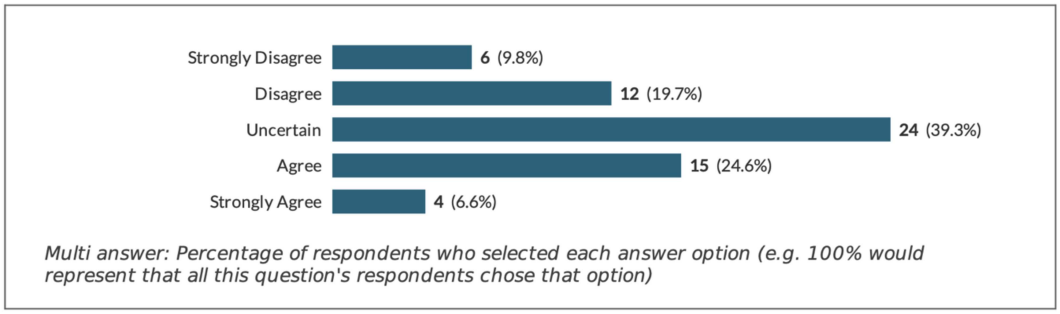
Comments:

Showing all 24 responses Show less
agree
Entirely agree
OK
Does 'anti-infective therapy' need to be further defined? eg does topical therapy count? oral amox for 2 weeks meets the case definition stated above, but most of us wouldn't be surprised if not much response in a classic NOE case. Should the definition say something more specific, e.g. 'appropriate systemic (oral or IV)' anti-infective therapy?
agreed
I would suggest a longer time period of 4 weeks.
Agree
Fine
Agree
I think this is fair
consider in absence of immunosuppression /diabetes - if the purpose of this definition is to alter antibiotic therapy without culture results
Agreed
Agree with above definition.
Agree
Should we state what anti infective treatment ie systemic? Cipro flocs in orally or taxocin
yes
It would need at least a month of appropriate treatment before a case of NOE is classed as non-responsive to therapy. Once NOE is diagnosed the minimum period of therapy we use is 6 weeks.
perhaps define 'improvement'. (using a visual analalogue scale?)You may not expect a resolution in pain. ottorrhoea or granulation in this period
agreed
yes
Effective and optimised antimicrobial therapy?
should it be specified whether the anti-infective therapy is systemic?
Agree.
agree

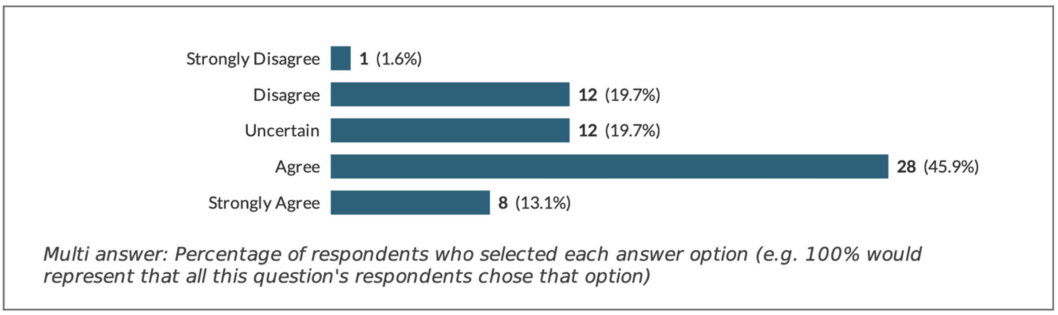
The following definitions have not yet reached consensus

I. Defining a case of relapsed NOE

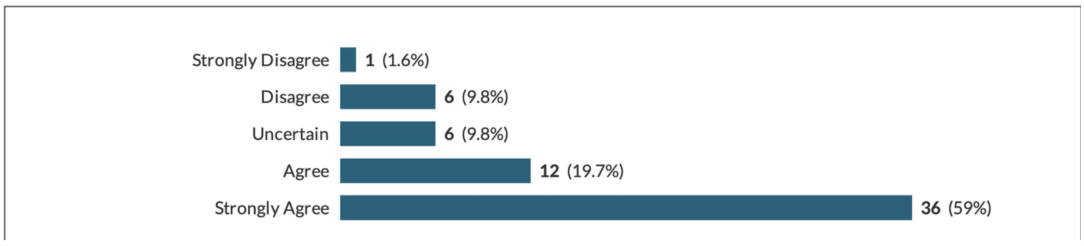
A case of NOE is considered to be treated and cured if a patient has no pain nor otorrhoea for a minimum period of *1 month* after completing antibiotic therapy



A case of NOE is considered to be treated and cured if a patient has no pain nor otorrhoea for a minimum period of *2 months* after completing antibiotic therapy



A case of NOE is considered to be treated and cured if a patient has no pain nor otorrhoea for a minimum period of *3 months* after completing antibiotic therapy



Comments:

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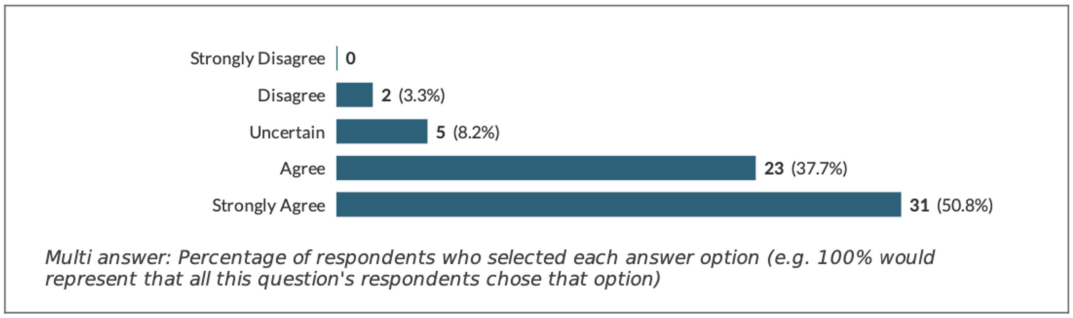
have seen cases of relapse follwoing a period of up to 6 months where they were reportedly asymptomatic. I think higher chance of this occuring in elderly immunocompromised individuals
None
It is difficult to give a time frame as all cases are different.
I routinely get follow up scans to check changes/inflammation not worsening
I am not involved in the treatment of patients with NOE
Treatment failure is defined after 14 days of therapy - 1 month is probably too soon, whereas 3 months would give more confidence that relapse is unlikley. Is it worth defining early and late relapse (e.g. <1 month and > 3 months) as the cause of relapse may be different - early may indicate inadequate duration of treatment whereas late relapse may indicate the evolution of resistance or persisting nidus?
Defining cure on basis of pain/otorrhoea resolution alone is concerning as most of us will have seen late relapses. Imaging would be an additional factor.
If CRP changes were evident during the active infection, this can be another useful marker or resolution (ie remains low).
3 months
Do we have any good data on mean time to relapse.
The highest incidence of recurrence is in the first 4 weeks but there is a steady tail off thereafter. 1 month is too short to claim a cure
I guess this depends on at what stage you complete antibiotics. I usually treat for an additional 2-3 months once the EAC skin is normal.
Relying on pain as a marker for cure can be dangerous as with recurrence of pain, patients can develop cranial neuropathy
Deep seated bacterial infections can take time to represent such as in dis it is and pji this may be indolent and take time to present
For me, 6 weeks would be the cutting point to consider it treated and cured.
would a repeat imaging have any role for the above if compared with baseline scans
I think the term cured requires a longer period of time of being symptom free and so I have chosen 3 months. It also takes time for MRI findings to show improvement.
Most relapses occur within a few weeks to a month of stopping antibiotic. Most recurrences of infection occur within 3 months and can often be predicted by the underling comorbidities and/or anatomical defects of the patient concerned.
Depends how long the course of antibiotics is. If it is at least 6 weeks then I opt for 2 months. If shorter then 3 months
For me, the minimum cut off would be 6 weeks.
Like that it is clinical"cure" not radiological but time post treatment is trickier- i think 2 months feels long enough to wait but not 3 months...
Normalised inflammatory markers and lack of progression on the MRI are also critical indicators of cure
I would rely on MRI imaging too
Again I'd say appropriate and dose optimised antimicrobial therapy. I'd change all antibiotic to antimicrobial
Difficult, I haven't seen many relapsed cases to have a feel, I recall two who I think relapsed fairly quickly.

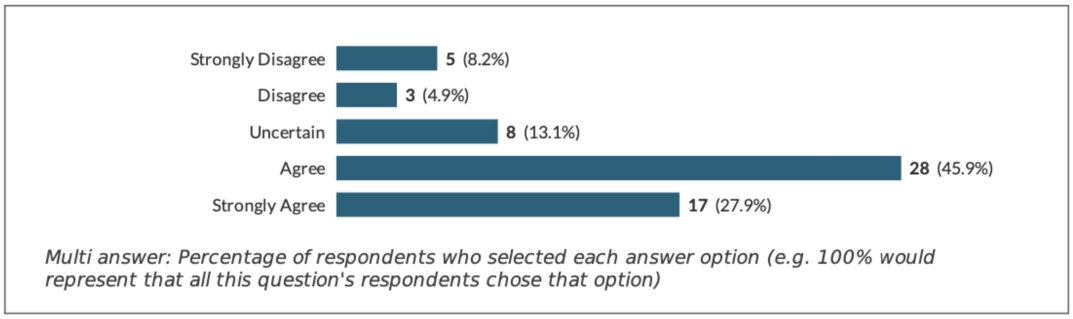
II. Imaging in NOE

If the original CT scan does not show any bony changes, then if clinical suspicion is high MRI scan is indicated



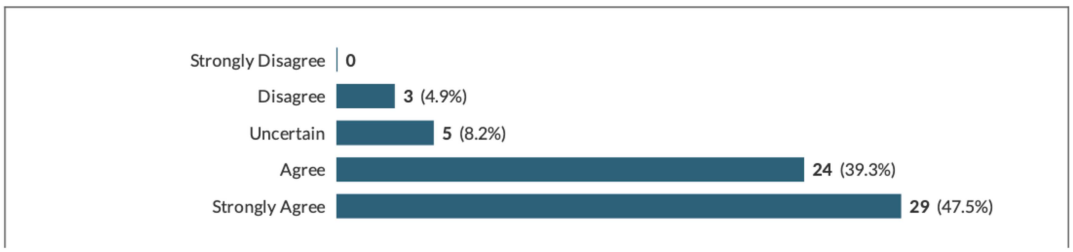
Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option)

If there is suspicion of relapse of NOE a repeat CT scan is indicated



Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option)

If there is suspicion of relapse of NOE and the repeat CT scan does not show any bony changes, then MRI scan is indicated



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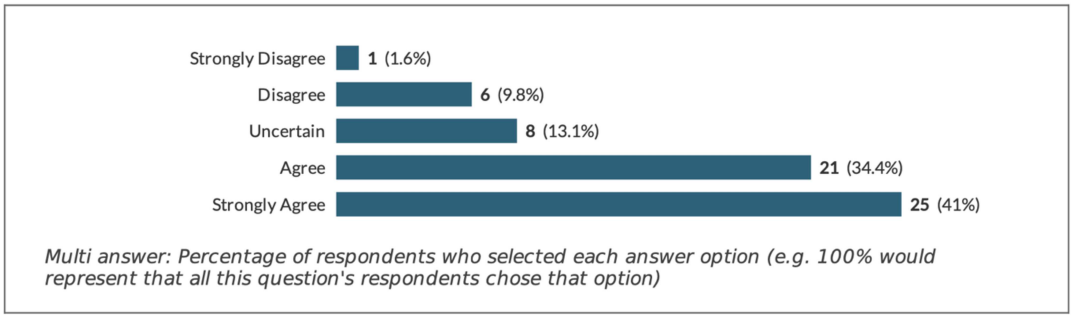
personally I feel that MRI's are better are looking at changes over time including relapse as it is often the soft tissue invovlement extent that changes. Only severe case tend to get further bone destruction.
I am unclear about the utility of MRI for diagnosing relapse as the bony oedema may persist for weeks/months (?) and a repeat MRI scan may only be helpful if the patients have interval MRI imaging and at the end of therapy. This would have a resource implication, and potentially drive further treatment as the MRI changes are likely to lag behind CT and clinical parameters
Unlikely to be no bony changes in a true relapse case as that was part of the criteria for original NOE diagnosis.
CT changes typically occur several weeks after the osteitis. Can therefore be late signs. CT is rarely performed AFTER resolution of NOE, therefore we have no baseline scan for comparison. Comparing to the initial diagnostic CT does not tell us when these changes occur. Gallium scan is a more time sensitive imaging modality.
MR is sufficient if there was a previous CT (from first diagnosis)
often more time efficient to repeat both CT and MRI as only one may not give the answer
bony changes can remain so for beyond a year therefore CT may be difficult to interpret. More work needs to be done with PET/CT for the above
they all should have basline MRI scans and in case of suspicion of relapse, MRI should be performed rather than CT and compared to the original MRI. MRI is much more sensitive to detect changes compared to CT
I think a pet ct would be better as further bony change is likely to be seen even when healing if the relapse is close to the initial event. A ct one year later would be acceptable but not two months after disease
I do not feel a second CT is required. MRI is better at tracking flare-ups.
The imaging modalities CT and MRI identify different tissue involvement. CT will pick up bone erosion. MRI will pick up soft tissue involvement. Bacterial infection and fungal infection also behave differently with fungal infection being more frequently associated with extension of infection into the skull base i.e. skull base osteomyelitis.
If the original CT scan does not show bony changes, I would only consider MRI if the clinical suspicion was dubious and was considering other differentials. If there was a high clinical suspicion such as CN VII palsy and granulation/otorrhea in a diabetic then I'd treat as NOE without MRI.
after discussion with consultant radiologist. You could have a scenario where the CT settings were not perfect for the purpose of the scan
CT is a poor means of monitoring NOE. Contrast enhanced T1 MRI is the gold standard
Relapse is a clinical diagnosis, there will not have been time for radiological changes to subside to make a diagnosis on imaging.
I would tend to use MRI 1st line looking for relapses
We do an MRI scan as routine on all proven or suspicious cases of NOE.
CT should be the first port of call for suspected recurrent NOE, even if the original CT was normal. Advantages due to speed, availability and difficulty of optimising and interpreting subtle cases on MRI, especially in non-specialist centres.
We use MRI for monitoring reponse to treatment/relapse
MR and Ct are complementary - MR changes are long-lived and may not reassure despite clinical improvement, CT may be less sensitive! MDM discussion would be great if it can be funded/supported
I think this neglects the very useful role on Nuclear medicine imaging (Gallium/technetium scan

III. MDT

Cases of definite and possible NOE should be discussed in a MDT forum ideally involving ENT, infection and radiology



Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option)

Any further comments?

Showing all 32 responses Show less
I think this is the ideal to aim for but it is difficult with such small numbers and fluctuations in numbers across the year.
May not need to be a formal MDT meeting but rather one that involves all disciplines by email or virtually
In an ideal world (well resourced) then strongly agree. Is this a UK approach, or intended to be applicable in other settings? for a global audience, this would not be possible and perhaps should be an aspiration rather than essential.
Only complex / recurring cases
There are resource issues to address but this would be a desirable practice.
Difficult to convene as cases are relatively sporadic even in large centres. A monthly/bimonthly meeting might be worthwhile (case numbers wise) but is too infrequent to inform management plan of case seen the next day.
These teams should agree protocols and work together, but a formal MDT is not required. We do not have ID on site in our unit.
So much resources. difficult to justify efficiency.
Ideally but unclear if resources to support this. Is there a role for a national MDT for difficult cases as for TB and fungal infections?
MDT working while ideal should not be mandated as it is impractical for a low volume condition and in the majority of simple cases not required.
This is a complex pathology therefore it needs an MDT approach particularly as there is the emergence of microbial resistance and multiple problems with therapy - rash, deranged LFT, neutropaenia as well as the ongoing debate about imaging to diagnose and monitor treatment response
In an ideal world - but this does not happen here
MDt may also be needed for potential ambulatory management of these cohort of patients using continue infusion devices for administering antibiotics

The MDT approach brings early care from relevant specialties to the patient thus improving outcome.
If this is feasible depending on the size of the unit and availability of specialists.
I agree in theory that this would be ideal. Practically, with relatively low numbers annually (albeit anecdotally rising), I'm not sure there would be enough cases to justify a formal MDT. I would STRONGLY agree with a national cross-specialty protocol, however.
I have a number of patients who are treated with a good pathway however if there are issues then I discuss at teleconference with skull base surgeons
You may not have a microbiologist attending, but still useful to discuss
I don't think microbiology have to be in the MDT but should certainly be involved in the decision making. Radiology and ENT are mandatory. Some centres may also mange these patients through infectious diseases
Concept is good but will need to think about how this is funded
Definite and possible NOE are the same thing according to previous Delphi rounds! Not all centres have access to an MDT.
Not necessarily a formal meeting though.
If there is a standard pathway for management, only the unresponsive ones need to be discussed.
A discussion should occur but is there a requirement for all cases of NOE to be discussed in a formal MDT???
If support/funding available though.
may not be possible in all cases
MDT can happen virtually or via e mail discussions
I'd suggest they also need to include infection pharmacy / antimicrobial pharmacy particularly around the dose optimisation angle
likely to involve discussion on a case by case basis rather than a regular MDT
MDT is advisable for any uncommon and potentially serious condition in principle.
Utilise each specialty, but a formal MDT is not essential. I would be concerned if the outcome said it can only be managed by MDT
we have done this by joining up a series of two way conversations in the past. virtual platforms it will facilitate mdts within and between centres