# The DECODE Project: Delphi round 1

\*Required

1.	Email address *

Your email address is used to track your participation and allow you to review your responses. By entering your email you agree to the DECODE team using it only for the purposes of conducting this survey and communicating the results to you. You can withdraw your consent at anytime.

### DEveloping consensus Core Outcomes and Diagnostic criteria for acute otitis Externa

### Welcome

Thank you for participating as a stakeholder in the first round of a Delphi process to develop a diagnostic criteria and core outcome set (COS) for research into acute otitis externa.

Your answers to these survey questions are anonymous to everyone outside of the project steering committee, so please answer freely.

Participation in all three stages of the Delphi will mean you are recognised as a collaborator (identifiable on PubMed) in any subsequent presentations and publications resulting from this work.

You may have been provided with a Participant Information Sheet. A copy of this, should you wish to read it, may be found here: <a href="https://ENTintegrate.org/decode">https://ENTintegrate.org/decode</a>. Here you will find additional information in Frequently Asked Questions about how this Delphi process was developed, and also information on what will happen once you have completed this questionnaire.

#### Rationale

Research into otitis externa is heterogenous, with researchers using a wide variety of different diagnostic criteria and outcomes. This makes direct comparisons between previous studies difficult.

Our project aims to develop diagnostic criteria and a core outcome set for otitis externa to help standardise future research. We aim to survey key patient and professional stakeholders in an attempt to reach consensus.

### Survey methods

For the diagnosis, you will be asked which features you think are important to be included in a minimum diagnostic criteria.

For the Core Outcome Set, the Delphi process involves answering questions on three separate occasions to gather your opinions relating to the importance of different outcome measures for otitis externa:

- ROUND 1: You will be asked to rate all the possible outcomes and suggest any additional outcomes you think may be important.
- ROUND 2: You will be shown summaries of how YOU AND YOUR PEERS responded to items that did not reach consensus in round 1. You will be asked to rate these items again in light of this information.
- ROUND 3: You will be shown summaries of how EVERYONE responded to items that did not reach consensus in round 2. You will be asked to rate these items again in light of this information.

The identity of all panelists will remain confidential at all times.

#### Final consensus

After these 3 rounds, the outcomes reaching consensus (using criteria explained in the protocol) will either be included or excluded from the final Core Outcome Set. Outcomes not reaching a consensus will be reviewed by the DECODE steering committee and a final consensus will be reached as to whether the item should be included or not, based on the information from the Delphi process from each stakeholder group. The resulting Core Outcome Set will be submitted for publication in a peer reviewed journal.

### Thank you

Thank you once again for taking part. If you have any problems at any stage, please email info@entintegrate.org

INTEGRATE DECODE steering committee

Nurse

2.	Please select you stakeholder group *
	Mark only one oval.
	Audiologist

ENT registrar

ENT consultant - Otologist

ENT consultant - General / Non-otology

GP

Junior doctor (below ST3)

Microbiologist

Section 1: Diagnosis of acute otitis externa There are currently no accepted diagnostic criteria for acute otitis externa (AOE), which complicates patient selection for trials. For the purposes of these diagnostic criteria, localised infection in the external auditory canal (EAC)(e.g. furuncles) is excluded.

Firstly, We would like to work out when otitis externa changes from being 'acute' to being 'chronic'.

Otitis externa should be considered as 'chronic' after *
Mark only one oval.
2 weeks
3 weeks
4 weeks
5 weeks
6 weeks
7 weeks
8 weeks
9 weeks
10 weeks
11 weeks
12 weeks
Comments

### Signs and symptoms

Secondly, we'd like to establish the key features in the diagnosis of acute otitis externa. In a future round you will be able to state if these are essential criteria in all cases.

Please rate the importance of including the following features in the minimum DIAGNOSTIC criteria for acute otitis externa [13 items]

	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
6.	Unable to score/co	mmen	its								
7.	External auditory o	anal e	rythem	na							
	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
8.	Unable to score/co	mmen	ıts								
9.	External auditory o	anal a	ropulot	ions							
9.	External auditory of Mark only one oval.	ariai y	i ai iulat	.10115							
	mark only one oval.	1	2	3	4	5	6	7	8	0	
	Lowest importance	<u> </u>		<u> </u>	4	5	6		•	9	Highest importance
											. ngnest important

5.

Aural fullness

External auditory o	eanal o	odoma								
External auditory of Mark only one oval.	ariai O	ечетта	l							
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest impo
Generalised lethar	gy									
	1	2	3	4	5	6	7	8	9	
										Highest impo
Lowest importance										
Lowest importance										
Lowest importance  Unable to score/co	mmen	ıts								

Mark only one oval.											
	1	2	3	4	5	6	7	8	9		
Lowest importance										Highest impo	rtance
Unable to score/co	mmen	ts									
Itchiness											
Mark only one oval.											
	1	2	3	4	5	6	7	8	9		
Lowest importance										Highest impo	rtance
Unable to score/co	mmen	ts									
Jaw pain											
Jaw pain  Mark only one oval.											
	1	2	3	4	5	6	7	8	9		

Hearing impairment

crobiologic		cation o	f an org	ganism						
rk only one o										
		2	3	4	5	6	7	8	9	
west importa										Highest impo
dour related	to the ea	r								
rk only one o	val.									
	1	2	3	4	5	6	7	8	9	
west importa	ance									Highest impo
	lour related	lour related to the ea rk only one oval.	1 2	lour related to the ear rk only one oval.  1 2 3	lour related to the ear rk only one oval.  1 2 3 4	lour related to the ear rk only one oval.  1 2 3 4 5	lour related to the ear rk only one oval.  1 2 3 4 5 6	lour related to the ear rk only one oval.  1 2 3 4 5 6 7	lour related to the ear rk only one oval.  1 2 3 4 5 6 7 8	lour related to the ear  rk only one oval.  1 2 3 4 5 6 7 8 9

	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest impor	tance
26.	Unable to score/co	mmen	its									
27.	Otorrhoea (discha	rao fra	m tha	oar)								
27.		rge irc	iii tile	ear)								
	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest impor	tance
28.	Lowest importance  Unable to score/co	ommen	nts								Highest impor	tance
28.		ommen	nts								Highest impor	tance
28.		ommen	nts								Highest impor	tance
28.		ommen	nts								Highest impor	tance
28.		ommen	nts								Highest impor	tance
	Unable to score/co	ommen	nts								Highest impor	tance
	Unable to score/co	ommen	ets 2	3	4	5	6	7	8	9	Highest impor	tance

Otalgia (ear pain)

30.	Unable to sco	ore/comments
31.	Please state a	any other symptoms or signs that you think should be included in diagnostic titis externa
i		Currently there is no accepted set of outcome measures used in studies of patients with acute otitis externa (AOE). This can lead to difficulty in analysing and interpreting clinical
Sec	ction 2:	studies, which limits the effectiveness of our treatment of patients with AOE.
Cou	re tcome set	We'd like to establish which features of AOE should be included in a Core Outcome Set (COS) for use in all future studies of acute otitis externa (AOE).
	acute tis externa	The development of a Core Outcome Set (COS) first involves determining WHAT should be measured as an outcome, later establishing HOW this should be measured. The following questions hope to identify WHAT features should be measured.
n stı	udies lookina	at acute otitis externa studies, which of these OUTCOMES are important

to report? [42 items]

\*\*\*NOTE: This is different from the diagnosis section. This section asks: What OUTCOMES from the MANAGEMENT of acute otitis externa are important? ie what should studies tell us about if they're looking at different ways of managing acute otitis externa. Not how to diagnose acute otitis externa in the first place\*\*\*

[1-5] Studies should report...

	Mark only one oval.											
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	Lowest importance										Highest importa	ance
3.	Unable to score/co	ommer	nts									
,.	oriable to seer cree	orrinner	103									
ŀ.	on results of bac	terial c	or fung	al grov	vth on a	an ear	swab					
	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest importa	ance
	Unable to score/co	mmer	nts									
	if patients compl	leted tl	he cou	rse of	treatm	ent						
	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest importa	ance

...on improvement in the ability to concentrate

if patients wer	e compli	ant wit	h the t	reatme	ent					
Mark only one ova	I.									
	1	2	3	4	5	6	7	8	9	
Lowest importan	ce									Highest imp
Unable to score	/commer	nts								
if patients died	d during t	treatme	ent							
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	ce )									Highest imp
Lowest importan										
Lowest importan										
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Jnable to score/co	mmen	ts								
on improvements	s in rea	ctive c	over-he	ealing i	n the e	ar cana	al (calle	ed grar	nulation	ns)
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Lowest importance										Highest ii
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Unable to score/co	mmen	ts								
Unable to score/co	mmen	ts								

[6-10] Studies should report...

	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest import	ance
7.	Unable to score/co	mmer	nts									
8.	on improvement	s in ea	r canal	swellir	na (oec	dema)						
	Mark only one oval.				3 (***	,						
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest import	ance
).	Unable to score/co	mmer	nte									
<i>J</i> .	oriable to score/co	miner	11.3									
).	on improvement	s in ea	r pain (	(otalgia	n)							
	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest import	ance

...on improvements in ear canal redness (erythema)

	Unable to s	score/co	mmen	TS										
1-1	5] Studies s	hould re	eport											
2.	on the ea	ase of ap	plying	the tre	eatmer	nt								
	Mark only or	ne oval.												
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3. 4.		score/co	ommen		daily li	ving or	perfor	rming h	nouseh	old tas		Highe	st impor	rtan
	Unable to s	score/co	ommen		daily li			rming h	nouseh	old tas	isk 9	Highe	st impor	rtano

on any impact on	ability	√to car	e for tl	ne fam	ily					
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Lowest importance										Highest impo
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on any impact on	menta									
on any impact on  Mark only one oval.	menta									
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	Mark only one oval.										
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	Lowest importance										Highest importance
61.	Unable to score/co	mmen	its								
[16-2	20] Studies should r	eport.	••								
		•									
62.	on any impact or	n the al	oility to	o socia	lise						
	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
63.	Unable to score/co	mmen	its								

60.

...on any impact on sleep

Lowest importance	Mark only one ova	Ι.											
Lunable to score/comments on improvements in a feeling of fullness in the ear (aural fullness)  Mark only one oval.  1 2 3 4 5 6 7 8 9  Lowest importance		1		2	3	4	5	6	7	8	9		
on improvements in a feeling of fullness in the ear (aural fullness)  Mark only one oval.  1 2 3 4 5 6 7 8 9  Lowest importance	Lowest importan	ce _										Highest impor	rtance
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1 2 3 4 5 6 7 8 9  Lowest importance	on improveme	ents in a	a fe	eling (	of fulln	ess in t	the ear	· (aural	fullnes	ss)			
Lowest importance	Mark only one ova	Ι.											
. Unable to score/comments on improvements in a feeling of generalised weakness  Mark only one oval.  1 2 3 4 5 6 7 8 9		1		2	3	4	5	6	7	8	9		
on improvements in a feeling of generalised weakness  Mark only one oval.  1 2 3 4 5 6 7 8 9	Lowest importan	се										Highest impo	rtance
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Lowest importance Highest importan		1		2	3	4	5	6	7	8	9		
	Lowest importan	се										Highest impo	rtance

...on any impact on the ability to work

on improvement	s in hea	ərina ir	mpairm	nent						
Mark only one oval.		9								
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	eport	••	d rest							
5] Studies should r	eport	••	d rest							
5] Studies should r on any impact or	eport	••	d rest	4	5	6	7	8	9	

69.

Unable to score/comments

Highest impo
Highest impo
Highest impo
Highest impo
Highest impo

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Unable to score/co	ommen	nts								
on any local side  Mark only one oval.	effect	s of tre	eatmen	nts						
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest imp
Unable to score/co	ommen	nts								

...on improvements in the feeling of anxiety

	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
83.	Unable to score/co	mmor	nt c								
03.	Oriable to score/co	mmer	11.5								
84.	on the need for o	overnic	aht or i	n-hosn	nital car	re					
04.	Mark only one oval.	over ing	gi i C Oi ii	111000	rtai cai						
	wark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
85.	Unable to score/co	mmer	nts								
86.	on the need for p	oain re	lief								
	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance

...on the need for antibiotics

on the number/fr Mark only one oval.	equen	cy of v	isits to	ENT o	rthe G	·P				
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest impo
on the number o	f time:	s the tr	eatme	nt is ac	lminist	ered				
on the number o	of times	s the tr	reatme	nt is ac	dminist	ered				
	of time:	s the tr		ent is ac		ered 6	7	8	9	
							7	8	9	Highest impo
Mark only one oval.							7	8	9	Highest impo
Mark only one oval.	1	2					7	8	9	Highest impo

Mark only one oval.										
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest in
Jnable to score/co	ommen	ts								
									<i>'</i> .	
on improvement	s in an	y pain c	on pres	ssing ju	st in fr	ont of	the ear	· canal	(tragal	
	s in any	y pain c	on pres	ssing ju	st in fr	ont of	the ear	· canal	(tragal	
enderness)	s in any	y pain c	on pres	ssing ju	st in fr	ont of	the ear	canal	(tragal	

[31-35] Studies should report...

	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
97.	Unable to score/co	mmen	ts								
98.	on patient satisfa	action v	vith the	eir acce	ess to a	appropi	riate ca	are (for	diagn	osis &	treatment)
	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
99.	Unable to score/co	mmen	ts								
100.	on patient satis	faction	with th	ie leng	th of th	neir syr	nptom	S			
	Mark only one oval.			J		,					
		1	2	3	4	5	6	7	8	9	
	Lowest importance	e									Highest importanc

...on any impact on quality of life

101.	Unable to score	e/comme	nts									_
[36-4	0] Studies shoul	d report.	••									
102.	on patient sat services (ENT)	isfaction	with le	ngth o	f treatr	ment, ir	ncludin	g numl	oer of	visits to	o specialis	st
	Mark only one ova	al.										
		1	2	3	4	5	6	7	8	9		
	Lowest importar	nce									Highest in	nportance
103.	Unable to score	e/comme	nts									
104.	on patient sat		with th	ne requ	ired fre	equenc	cy of th	e treat	ments			_
		1	2	3	4	5	6	7	0	_		
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					1.6					
on patient satisfa Mark only one oval.	action	with th	e time	require	ea tor (	outpati	ent ap	pointm	ients	
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest in
Jnable to score/co	mmen	nts								
on any spread of	infect	ion bey	ond th	ne ear (	canal					
	infect	ion bey	ond th	ne ear d	canal					
	infect	ion bey	ond th		canal	6	7	8	9	
Mark only one oval.						6	7	8	9	Highest in
Mark only one oval.						6	7	8	9	Highest in
Mark only one oval.  Lowest importance	1	2				6	7	8	9	Highest in
Mark only one oval.  Lowest importance	1	2				6	7	8	9	Highest in
Mark only one oval.  Lowest importance	1	2				6	7	8	9	Highest in
on any spread of Mark only one oval.  Lowest importance  Jnable to score/co	1	2				6	7	8	9	Highest in

	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importanc
111.	Unable to score/co	mmen	ts								
[41-42	2] Studies should re	port									
112.	on any widesprea	ad (sys	temic)	side e	effects	of pain	relief				
	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importanc
113.	Unable to score/co	mmen	ts								

...on any time off work

	Mark only one oval.										
		1	2	3	4	5	6	7	8	9	
	Lowest importance										Highest importance
115.	Unable to score/co	mment	S								
And fi	nally										
116.	Please state any ot on the managemen					nk stuc	lies sho	ould inc	clude v	vhen re	eporting
*** TH That's it	ANK YOU ***										
externa.	ou for taking part. Your re This is round 1 of the pro es your answers for the n	cess. We	'll give you	u the fee	edback <sup>-</sup>						
Once yo	u're happy with your respo	onses, ple	ease hit su	ubmit to	record	them.					
Thank y	ou once again for taking p	part. If you	u have any	y proble	ms at aı	ny stage,	please e	mail <u>info</u>	<u>@entint</u>	<u>egrate.o</u> ı	cg
INTEGRA	ATE DECODE steering con	nmittee									

...on any widespread (systemic) side effects of treatments

Google Forms

# The DECODE Project: Delphi round 2

\*Required

1.	Email address *	

Your email address is used to track your participation and allow you to review your responses. By entering your email you agree to the DECODE team using it only for the purposes of conducting this survey and communicating the results to you. You can withdraw your consent at anytime.

### DEveloping consensus Core Outcomes and Diagnostic criteria for acute otitis Externa

### Welcome to round 2

Thank you for participating as a stakeholder in the second round of a Delphi process to develop a diagnostic criteria and core outcome set (COS) for research into acute otitis externa.

Your answers to these survey questions are anonymous to everyone outside of the project steering committee, so please answer freely.

Participation in all three stages of the Delphi will mean you are recognised as a collaborator (identifiable on PubMed) in any subsequent presentations and publications resulting from this work.

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Our project aims to develop diagnostic criteria and a core outcome set for otitis externa to help standardise future research. We aim to survey key patient and professional stakeholders in an attempt to reach consensus.

### Survey methods

For the diagnosis, you will be asked which features you think are important to be included in a minimum diagnostic criteria.

For the Core Outcome Set, the Delphi process involves answering questions on three separate occasions to gather your opinions relating to the importance of different outcome measures for otitis externa:

#### Completed:

- ROUND 1: You were asked to rate all the possible outcomes and suggest any additional outcomes you think may be important.

#### Now:

- ROUND 2: You will be shown summaries of how YOU AND YOUR PEERS responded to items that did not reach consensus in round 1. You will be asked to rate these items again in light of this information.

#### Later:

- ROUND 3: You will be shown summaries of how EVERYONE responded to items that did not reach consensus in round 2. You will be asked to rate these items again in light of this information.

The identity of all panelists will remain confidential at all times.

#### Final consensus

After these 3 rounds, the outcomes reaching consensus (using criteria explained in the protocol) will either be included or excluded from the final Core Outcome Set. Outcomes not reaching a consensus will be reviewed by the DECODE steering committee and a final consensus will be reached as to whether the item should be included or not, based on the information from the Delphi process from each stakeholder group. The resulting Core Outcome Set will be submitted for publication in a peer reviewed journal.

### Thank you

Thank you once again for taking part. If you have any problems at any stage, please email info@entintegrate.org

INTEGRATE DECODE steering committee

2.	Please select you stakeholder group *
	Mark only one oval.

•
Audiologist
ENT registrar
ENT consultant - Otologist
ENT consultant - General / Non-otology
GP
Junior doctor (below ST3)
Microbiologist
Nurse

### Changes to the survey

Thank you for all the comments you provided. These have all been reviewed by the steering committee. As a result of this feedback, the phrasing of some of the questions has been amended. We have also added new questions where it was felt the item was not previously covered. All your comments will be used to inform the final consensus process in instances where there remains disagreement after the 3 consultation rounds.

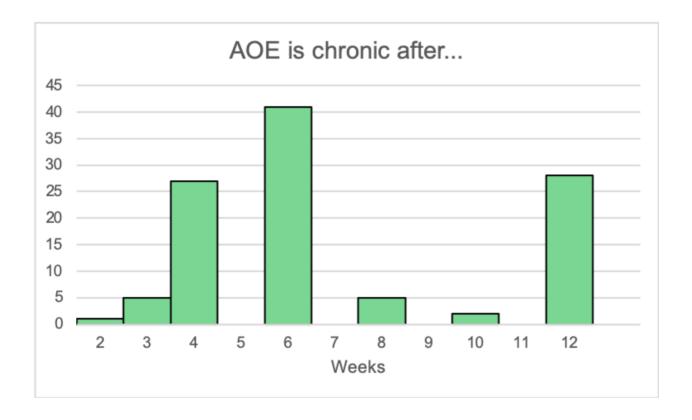
### SECTION 1: Diagnosis of acute otitis externa

There are currently no accepted diagnostic criteria for acute otitis externa (AOE), which complicates patient selection for trials.

For the purposes of these diagnostic criteria:

- Super localised infections of the external ear (e.g. furuncles) are excluded.
- Uncomplicated otitis externa is considered infection without spread beyond the soft tissues of the external ear.
- Necrotising otitis externa/skull base osteomyelitis is considered a different entity

#### Results from round 1:

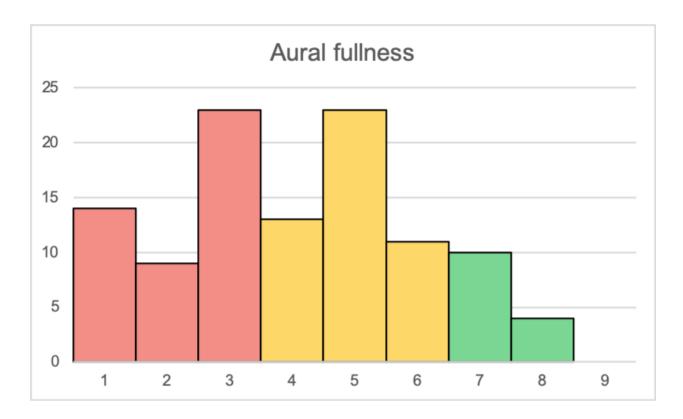


3.	From the onset of symptoms, treated or untreated acute otitis externa should be considered to have become 'chronic' after *
	Mark only one oval.
	2 weeks
	3 weeks
	4 weeks
	5 weeks
	6 weeks
	7 weeks
	8 weeks
	9 weeks
	10 weeks
	11 weeks
	12 weeks
4.	Comments
••	
	NS & SYMPTOMS
We'd	like to establish the KEY FEATURES in the diagnosis of acute otitis externa.
3 of	nsensus results from round 1 the 13 items from round 1 reached consensus amongst professionals to be included in the MINIMUM DIAGNOSTIC ERIA for AOE:
- Ext	ernal auditory canal oedema
- Ota	lgia (ear pain) rrhoea (discharge from the ear)
No it	ems were excluded in round 1.
Base	ed on your comments, 1 further item has been added.

- Squamous debris/keratin

Please rate the importance of including the following features in the MINIMUM DIAGNOSTIC CRITERIA for AOE: [10/13 items remaining, 1 new item]

### Results from round 1:



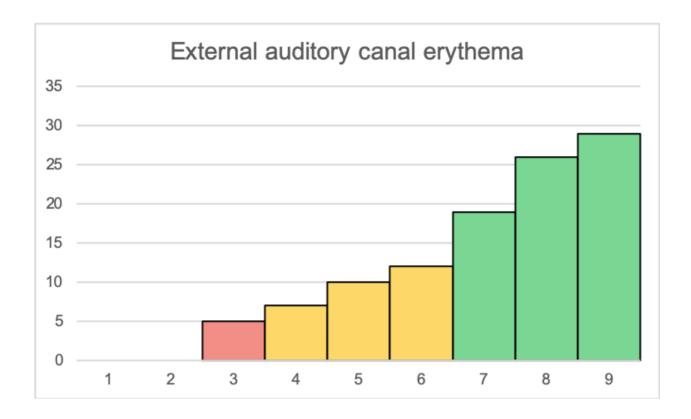
### 5. Aural fullness

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

6.	Unable to score/comments										

## Results from round 1:



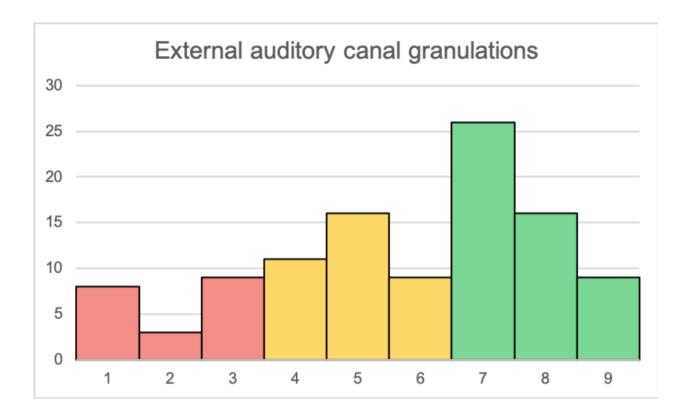
# 7. External auditory canal erythema

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

_			
Ω	Ilnahle	to score	<i>l</i> comments

## Results from round 1:

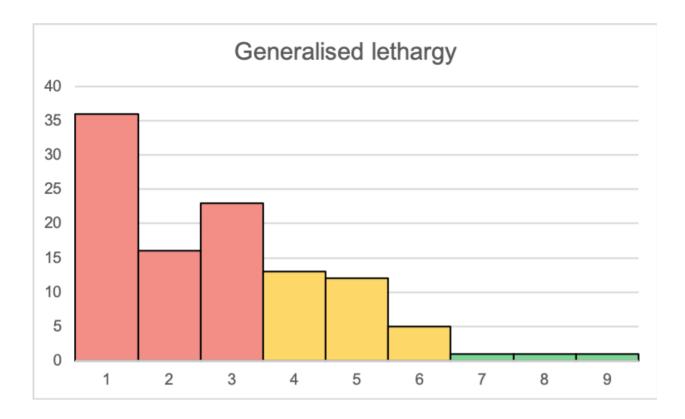


# 9. External auditory canal granulations

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

1	n	Hna	hla ta	score	comm	ante
		UHA	$\Box \Box \Box \Box$	SCOLE		

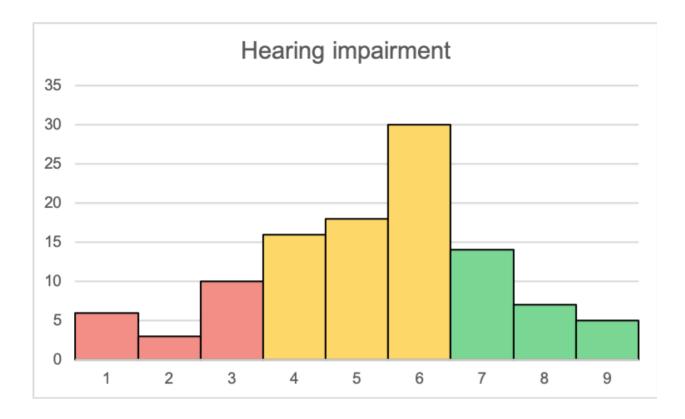


### 11. Generalised lethargy

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

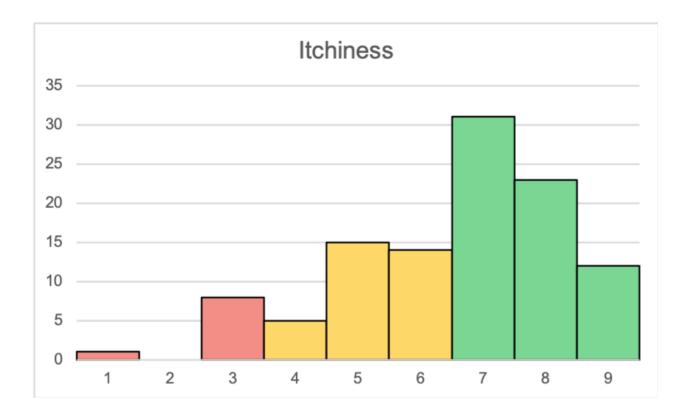
#### 12. Unable to score/comments



## 13. Hearing impairment

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

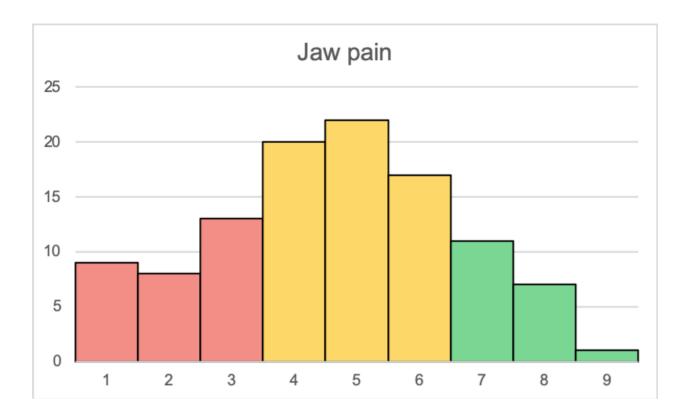
14	Unable to	ccorolco	mmonte
14	Unable to	score/co	mmenis



### 15. Itchiness

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

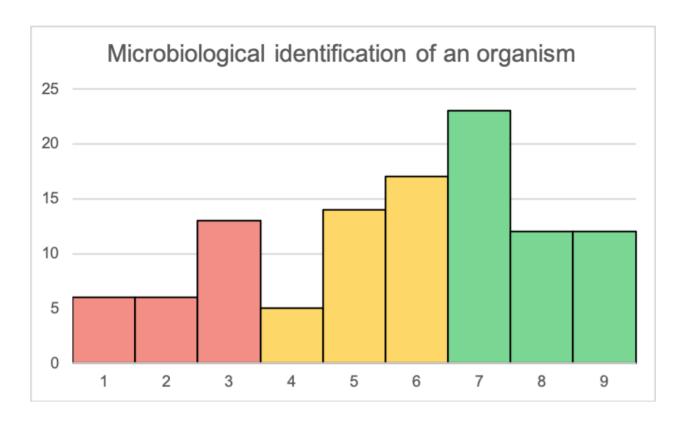
16	Linable to	cooro	comments
In	I INANIA TO	SCORE	COMMENTS



## 17. Jaw pain

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

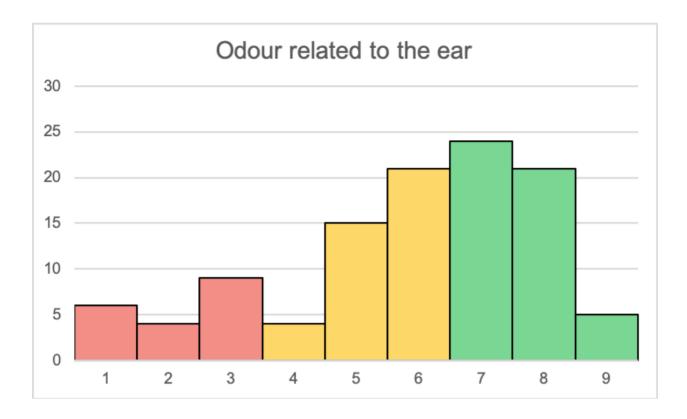
1	Ω	Unable t	o ccoro	<i>l</i> comments
	^			



## 19. Microbiological identification of an organism

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

00	I I a a la La Ara	1-	
20	Unable to	score/co	omments

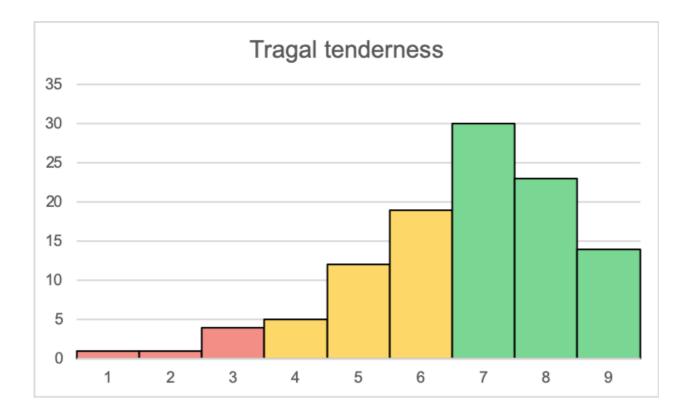


#### 21. Odour related to the ear

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

#### 22. Unable to score/comments



## 23. Tragal tenderness

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

**NEW ITEM:** 

#### 25. Squamous debris/keratin

Mark only one oval.

		ı	2	3	4	5	0	/	8	9	
Ī	Lowest importance										Highest importance
l	Jnable to score/co	mmen	its								

Section 2: Core outcome set for acute otitis externa Currently there is no accepted set of outcome measures used in studies of patients with acute otitis externa (AOE). This can lead to difficulty in analysing and interpreting clinical studies, which limits the effectiveness of our treatment of patients with AOE.

We'd like to establish which features of AOE should be included in a Core Outcome Set (COS) for use in all future studies of acute otitis externa (AOE).

The development of a Core Outcome Set (COS) first involves determining WHAT should be measured as an outcome, later establishing HOW this should be measured. The following questions hope to identify WHAT features should be measured.

#### Consensus results from round 1

17 of the 42 items reached consensus amongst professionals to be included in the CORE OUTCOME SET for AOE.

- ...if patients completed the course of treatment
- ...if patients were compliant with the treatment
- ...on improvements in discharge from the ear (otorrhoea)
- ...on improvements in reactive over-healing in the ear canal (called granulations)
- ...on improvements in ear canal redness (erythema)
- ...on improvements in ear canal swelling (oedema)
- ...on improvements in ear pain (otalgia)
- ...on improvements in hearing impairment
- ...on improvements in itchiness
- ...on any local side effects of treatments
- ...on the need for antibiotics
- ...on the need for overnight or in-hospital care
- ...on the need for pain relief
- ...on the number/frequency of visits to ENT or the GP
- ...on the number of times the treatment is administered
- ...on any spread of infection beyond the ear canal
- ...on any widespread (systemic) side effects of treatments

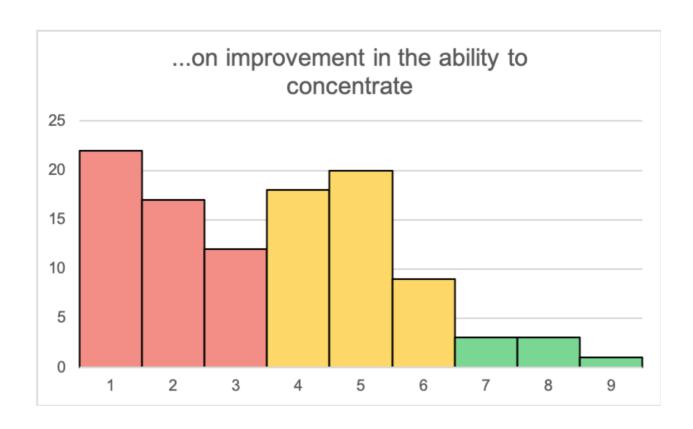
No items were excluded in round 1.

Based on your feedback, 1 item has been added:

...the time to resolution of symptoms

\*\*\*These outcomes have NOT reached consensus. Please use the feedback from round 1 to FOCUS on which OUTCOMES you would like to EXCLUDE (or INCLUDE) in an ESSENTIAL outcome set, for trials in acute otitis externa\*\*\*

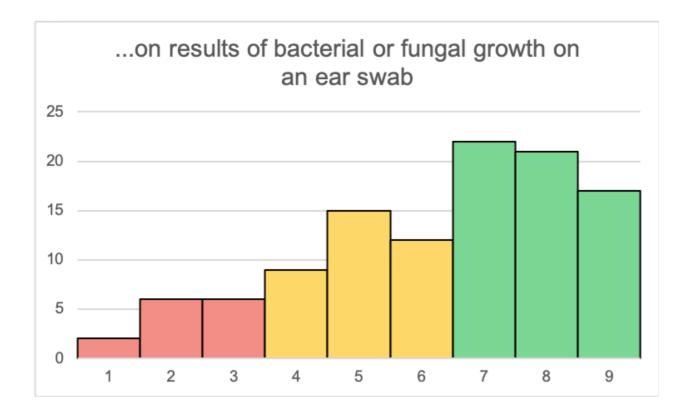
[1-5] Studies should report...



#### 27. ...on improvement in the ability to concentrate

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

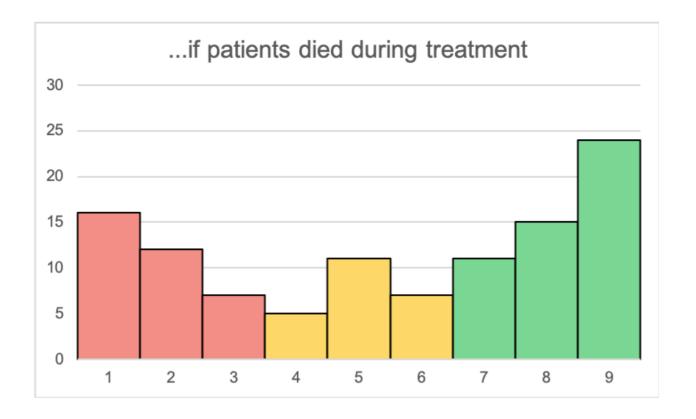
28.	Unable to score/comments



## 29. ...on results of bacterial or fungal growth on an ear swab

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

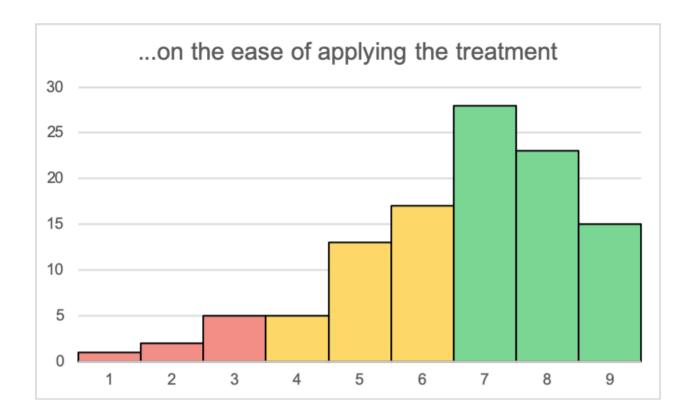
30.	Ilnahla	to score	comments.
อบ.	unable	to score/	comments



## 31. ...if patients died during treatment

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

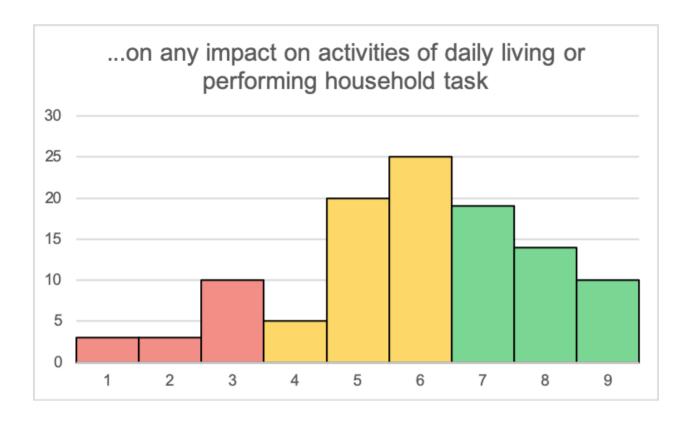
32.	Unable	to score	comments
02.	OHODIC		COLLICITION



## 33. ...on the ease of applying the treatment

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

34.	П	Inah	ما	to	SCOR	~/c	com	ments
JT.	$\mathbf{u}$	ııav		w	3601	-1		HIGHES



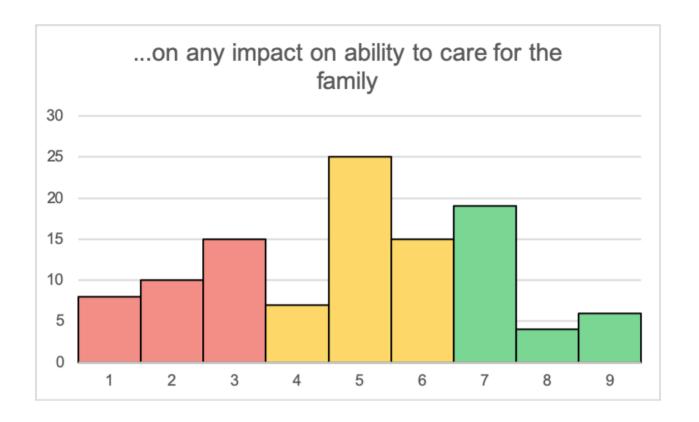
35. ...on any impact on activities of daily living or performing household task

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

36. Unable to score/comments

[6-10] Studies should report...

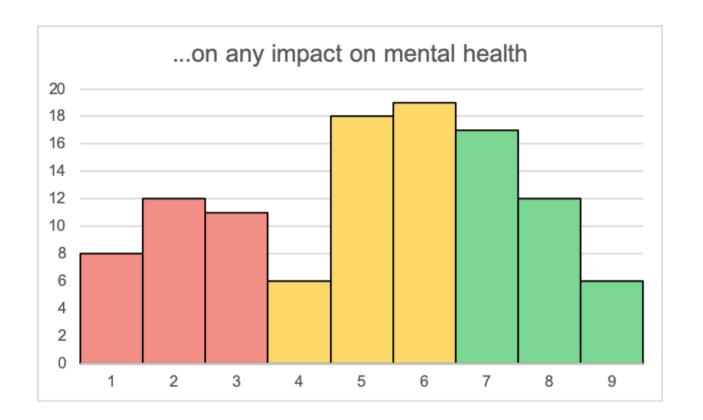


37. ...on any impact on ability to care for the family (for adults)

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

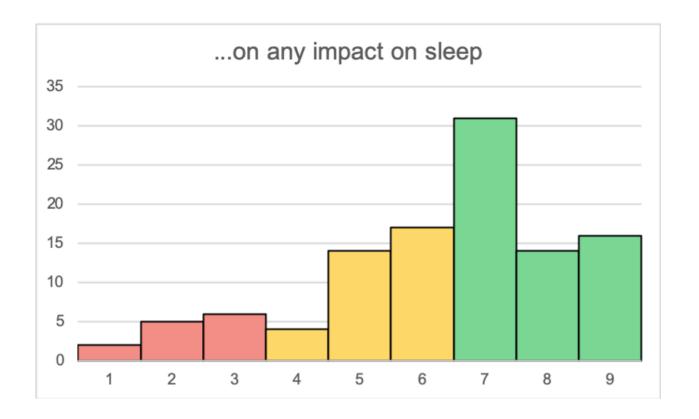
38. Unable to score/comments



## 39. ...on any impact on mental health

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

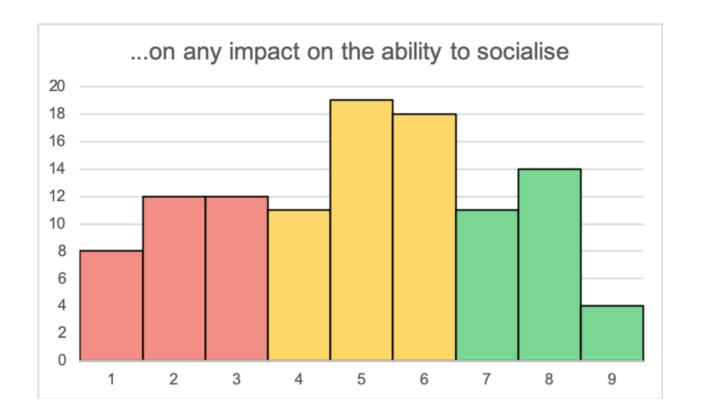
40.	Unable to score/comments	



## 41. ...on any impact on sleep

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

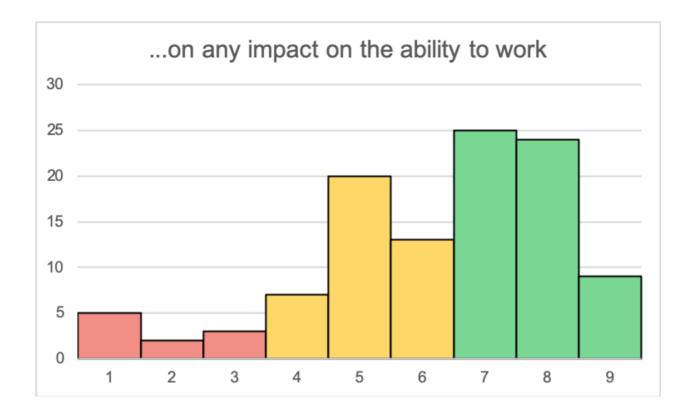
42.	Unable to	score	comments
44.	OHADIE LO	20016	COHINEINS



## 43. ...on any impact on the ability to socialise

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

44.	Unable to	o score/	comments
<b>TT.</b>	OHADIC K	J 3001 <i>01</i>	COHINEINS



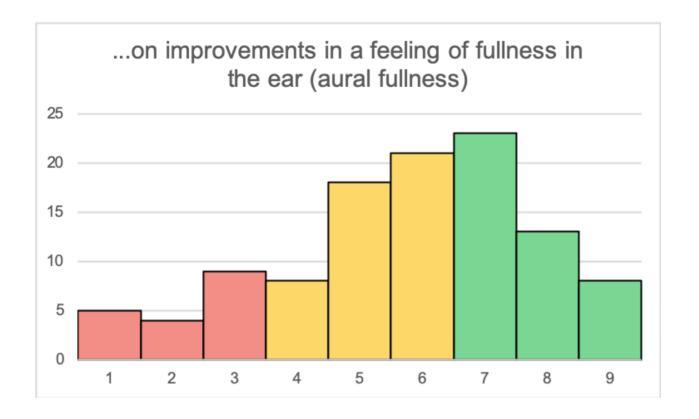
### 45. ...on any impact on the ability to work

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

46. Unable to score/comments

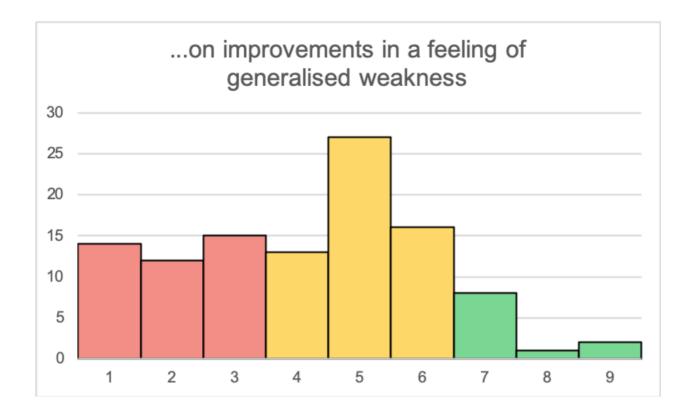
[11-15] Studies should report...



### 47. ...on improvements in a feeling of fullness in the ear (aural fullness)

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

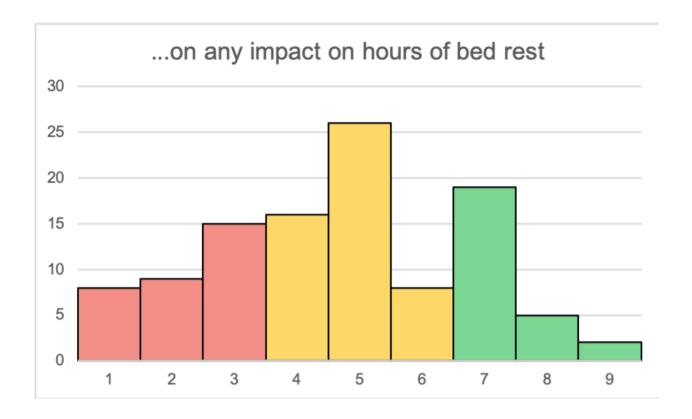
48.	Unable t	to score	comments
TO.	OHUDIC	$\omega$ 30010/	CONTINUENCE



## 49. ...on improvements in a feeling of generalised weakness

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

50	) [		กล	h	حا	to	SCO	re/	con	nments	2
υL	,	J	110	IJ	1	w	うしい	1 57	COL		



## 51. ...on any impact on hours of bed rest

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

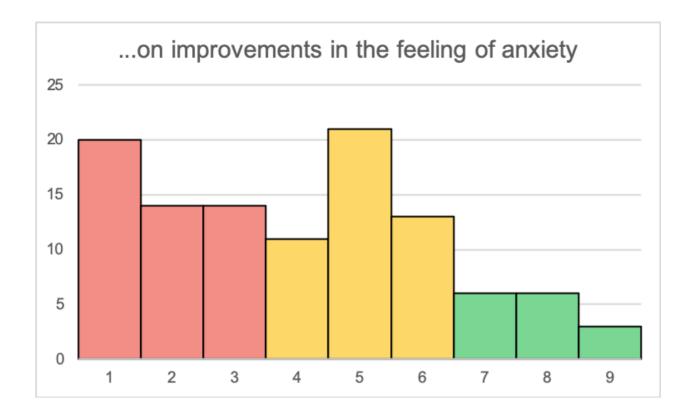
52.	Unable	to score	comments.
JZ.	OHADIC	しし うしいしてん	COHHICILIS



## 53. ...on improvements in pain in the jaw

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

54.	Unable	to score	comments /
<b>υ</b> Τ.	OHIGDIC	10 300101	CONTINUENCE



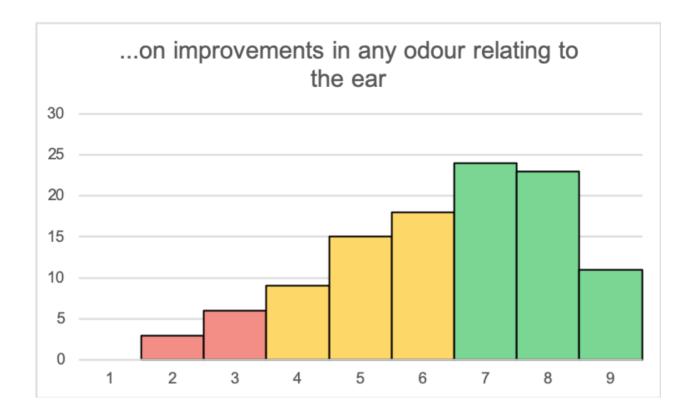
## 55. ...on improvements in the feeling of anxiety

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

56.	Unable to score/commen	ıts
00.		

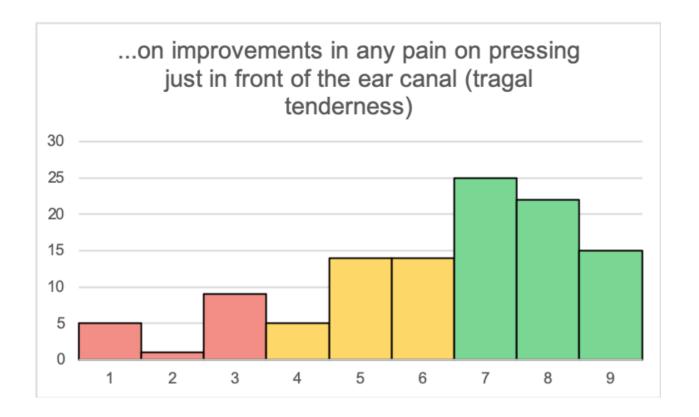
[16-20] Studies should report...



## 57. ...on improvements in any odour relating to the ear

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

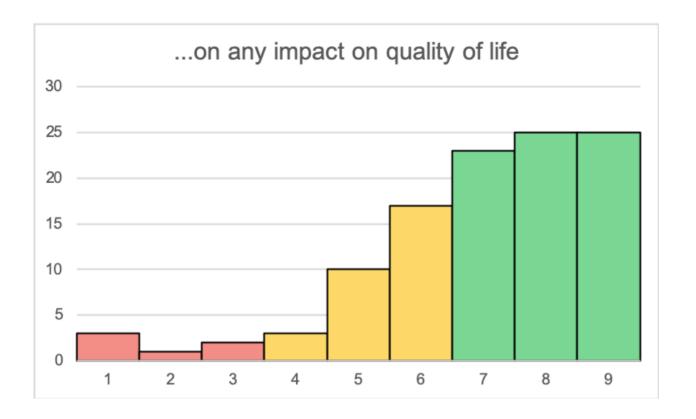
58.	Unable to score/comments	
JO.	2119016 10 20016/001111161113	



59. ...on improvements in any pain on pressing just in front of the ear canal (tragal tenderness)

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

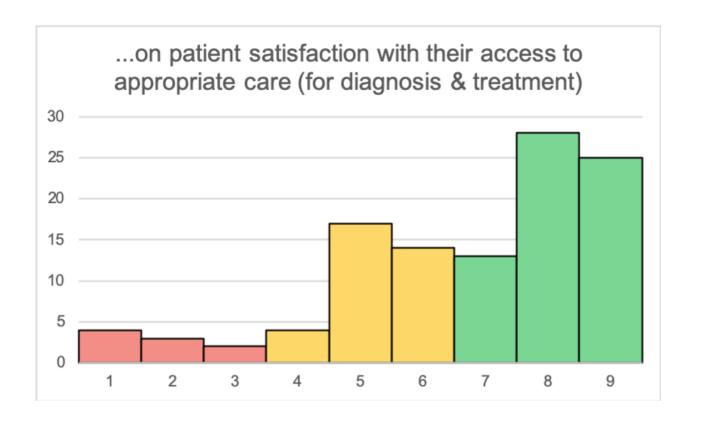
60.	Unable to score/comments



## 61. ...on any impact on quality of life

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

62.	Unable to	o score	comments
UZ.	OHUDIC U	$\sigma$	COILLICITIS

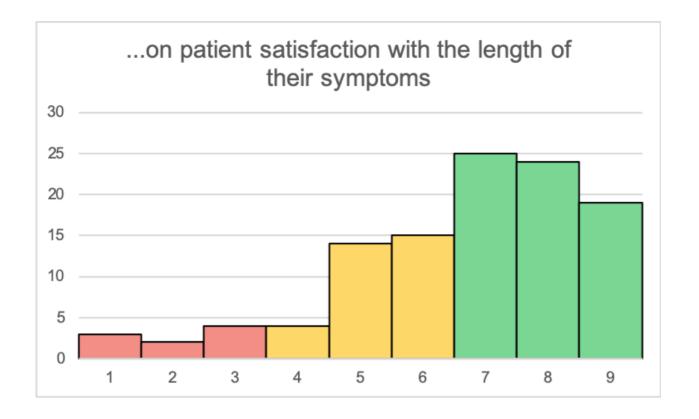


63. ...on patient satisfaction with their access to appropriate care (for diagnosis & treatment)

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

64. Unable to score/comments



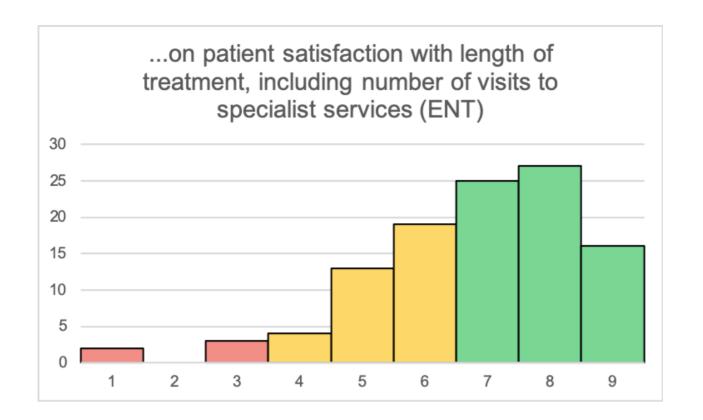
65. ...on patient satisfaction with the length of their symptoms

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

66. Unable to score/comments

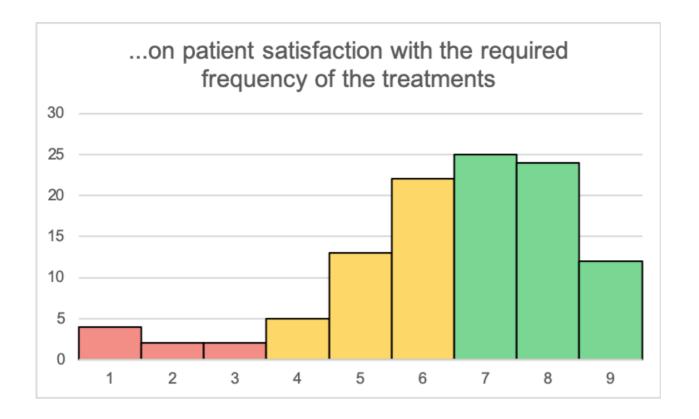
[21-25] Studies should report...



67. ...on patient satisfaction with length of treatment, including number of visits to specialist services (ENT)

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

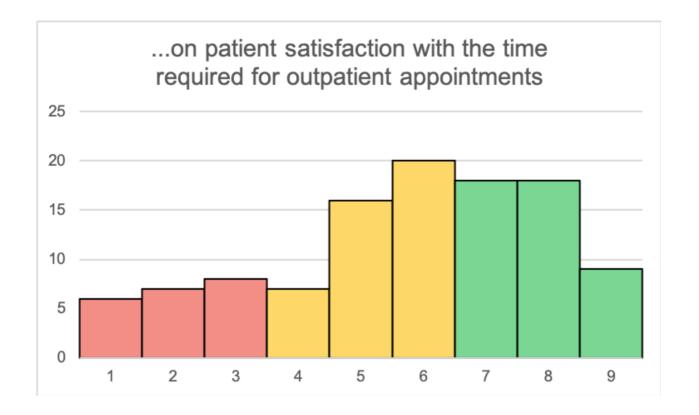
68.	Unable to score/comments



69. ...on patient satisfaction with the required frequency of the treatments

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

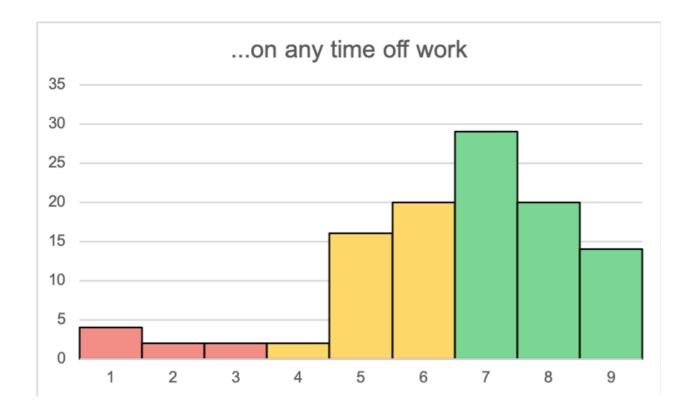
70.	Unable to score/comments	



### 71. ...on patient satisfaction with the time required for outpatient appointments

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

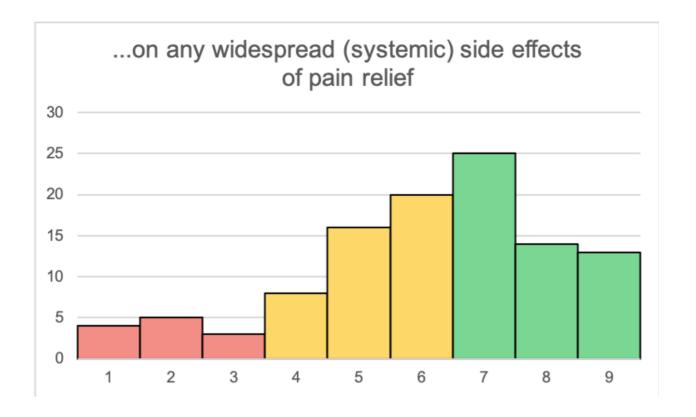
72	П	กล	hl	0	to	SCO	re/	col	mm	nents	
1 /	$\mathbf{U}$	ı ıa	M		L()	300	I (-/	$\mathbf{C}$		ICI ILO	



## 73. ...on any time off work

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

74.	Unable	to score/	comments
<i>,</i> T.	OHIGOIC	10 300101	CONTINUENCE



75. ...on any widespread (systemic) side effects of pain relief

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

**NEW ITEMS:** 

[1-4] Studies should report...

		1	2	3	4	5	6	7	8	9	112-1
	Lowest importance										Highest impor
	Unable to score/co	ommen	ts								
	LANIK VOLL ***										
	HANK YOU ***										
i	t!  you for taking part. Your  a. This is round 2 of the p  ces your answers for the  ou're happy with your res	rocess. next rou	We'll give ınd, to re	you the ach a co	feedbac nsensus.	k from ev					
i	t! you for taking part. Your a. This is round 2 of the p ces your answers for the	process. next rou sponses,	We'll give ind, to re please h	e you the ach a co	feedbac nsensus. to recor	k from ev	eryone's	respons	es to thi	s round,	then ask if this

77.

...the time to resolution of symptoms

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Google Forms

# The DECODE Project: Delphi round 3

\*Required

1.	Email address *

Your email address is used to track your participation and allow you to review your responses. By entering your email you agree to the DECODE team using it only for the purposes of conducting this survey and communicating the results to you. You can withdraw your consent at anytime.

#### DEveloping consensus Core Outcomes and Diagnostic criteria for acute otitis Externa

#### Welcome to round 3

Thank you for participating as a stakeholder in the second round of a Delphi process to develop a diagnostic criteria and core outcome set (COS) for research into acute otitis externa.

Your answers to these survey questions are anonymous to everyone outside of the project steering committee, so please answer freely.

Participation in all three stages of the Delphi will mean you are recognised as a collaborator (identifiable on PubMed) in any subsequent presentations and publications resulting from this work.

You may have been provided with a Participant Information Sheet. A copy of this, should you wish to read it, may be found here: <a href="https://ENTintegrate.org/decode">https://ENTintegrate.org/decode</a>. Here you will find additional information in Frequently Asked Questions about how this Delphi process was developed, and also information on what will happen once you have completed this questionnaire.

#### Rationale

Research into otitis externa is heterogenous, with researchers using a wide variety of different diagnostic criteria and outcomes. This makes direct comparisons between previous studies difficult.

Our project aims to develop diagnostic criteria and a core outcome set for otitis externa to help standardise future research. We aim to survey key patient and professional stakeholders in an attempt to reach consensus.

#### Survey methods

For the diagnosis, you will be asked which features you think are important to be included in a minimum diagnostic criteria.

For the Core Outcome Set, the Delphi process involves answering questions on three separate occasions to gather your opinions relating to the importance of different outcome measures for otitis externa:

#### Completed:

- ROUND 1: You were asked to rate all the possible outcomes and suggest any additional outcomes you think may be important.
- ROUND 2: You were shown summaries of how YOU AND YOUR PEERS responded to items that did not reach consensus in round 1. You were asked to rate these items again, in light of this information.

#### Now:

- ROUND 3: You will be shown summaries of how PATIENTS AND PROFESSIONALS responded to items that did not yet reach consensus. You are asked to rate these items again in light of this information.

#### Final consensus

After these 3 rounds, the outcomes reaching consensus (using criteria explained in the protocol) will either be included or excluded from the final Core Outcome Set. Outcomes not reaching a consensus will be reviewed by the DECODE steering committee and a final consensus will be reached as to whether the item should be included or not, based on the information from the Delphi process from each stakeholder group. The resulting Core Outcome Set will be submitted for publication in a peer reviewed journal.

Th	ar	٦k	VC	u
	aı	IN	VC	u

Thank you once again for taking part. If you have any problems at any stage, please email info@entintegrate.org

INTEGRATE DECODE steering committee

2.	Please select you stakeholder group *
	Mark only one oval.
	Audiologist
	ENT registrar
	ENT consultant - Otologist
	ENT consultant - General / Non-otology
	○ GP
	Junior doctor (below ST3)
	Microbiologist
	Nurse

#### Changes to the survey

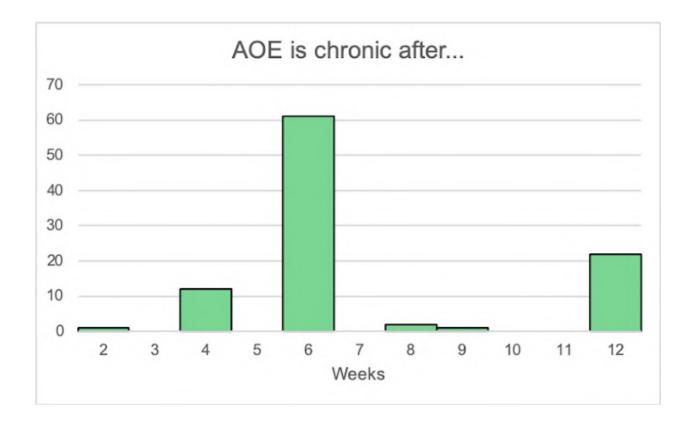
Thank you again for all the comments you have provided. These have all been reviewed by the steering committee. As a result of this feedback, the phrasing of some of the questions has been amended. All your comments will be used to inform the final consensus process in instances where there remains disagreement after the 3 consultation rounds.

#### SECTION 1: Diagnosis of acute otitis externa

There are currently no accepted diagnostic criteria for acute otitis externa (AOE), which complicates patient selection for trials.

For the purposes of these diagnostic criteria:

- Super localised infections of the external ear (e.g. furuncles) are excluded.
- Uncomplicated otitis externa is considered infection without spread beyond the soft tissues of the external ear.
- Necrotising otitis externa/skull base osteomyelitis is considered a different entity



3. From the onset of symptoms, treated or untreated acute otitis externa should be considered to have become 'chronic' after... \*

Mark only one oval.

( ) 2 week
------------

3 weeks

4 weeks

5 weeks

6 weeks

7 weeks

8 weeks

9 weeks

10 weeks

11 weeks

12 weeks

1.	Comments

### **SIGNS & SYMPTOMS**

We'd like to establish the KEY FEATURES in the diagnosis of acute otitis externa.

### Consensus results after round 2

7 of 14 items have now reached consensus for the DIAGNOSTIC CRITERIA for AOE:

6 items have been included:

- External auditory canal erythema
- Itchiness
- Tragal tenderness
- External auditory canal oedema
- Otalgia (ear pain)
- Otorrhoea (discharge from the ear)

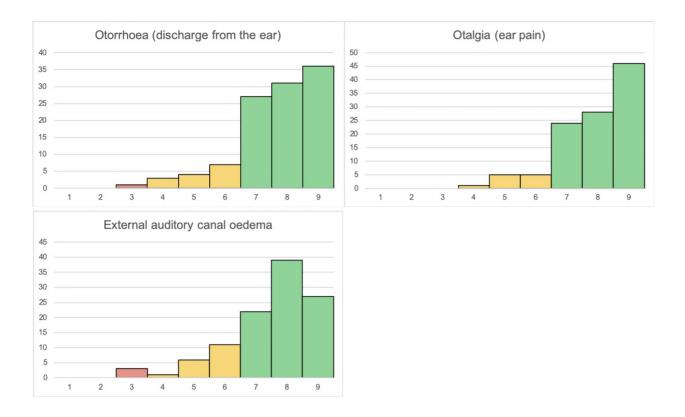
1 item has been excluded:

- Generalised lethargy

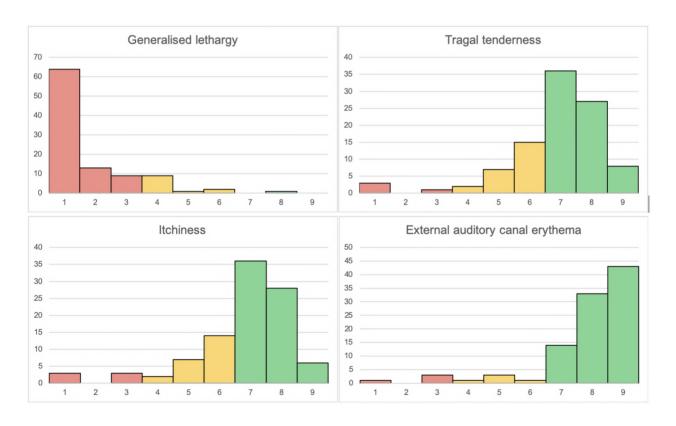
7 items are yet to reach consensus:

- Aural Fullness
- External auditory canal granulations
- Hearing impairment
- Jaw pain
- Microbiological identification of an organism
- Odour related to the ear
- Squamous debris/keratin

## Items reaching consensus in round 1:



## Items reaching consensus in round 2:



Please rate the importance of the following signs and symptoms of AOE, INCLUSION or EXCLUSION from a DIAGNOSTIC CRITERIA: [7 items remaining]

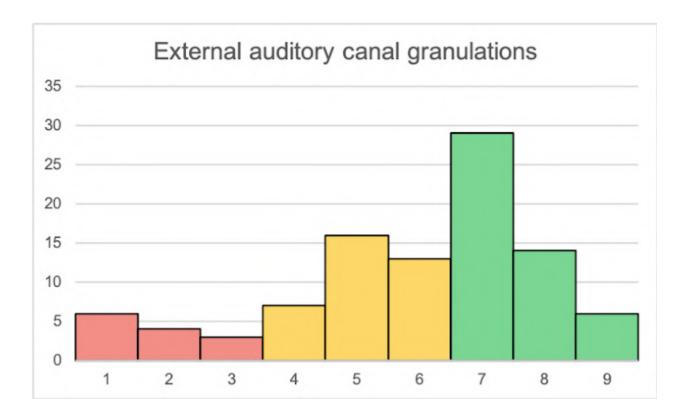


## 5. Your answer for round 3: Aural fullness

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

6. Ui	nable	to	score/	comments/
-------	-------	----	--------	-----------



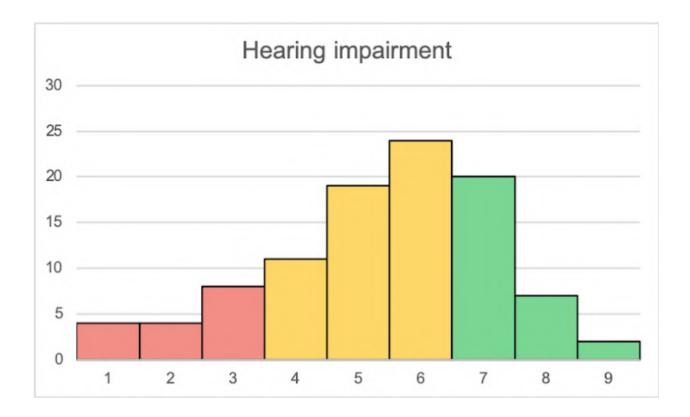
## 7. Your answer for round 3: External auditory canal granulations

Mark only one oval.

Unable to score/comments

8.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

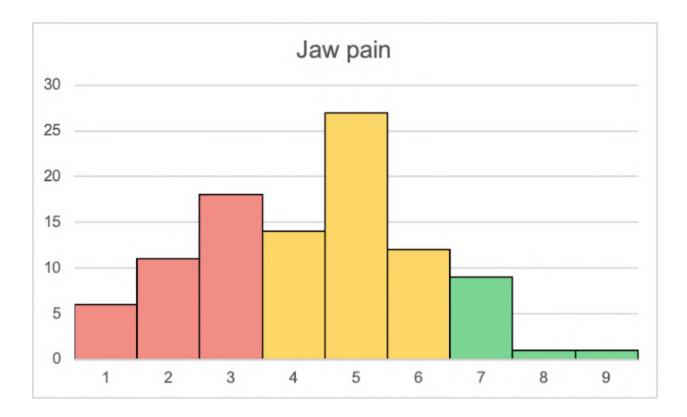


# 9. Your answer for round 3: Hearing impairment

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

1	Λ	Hnablo	to cooro	<i>l</i> comments
	11	Linanie	TO SCORE	COMMENIS

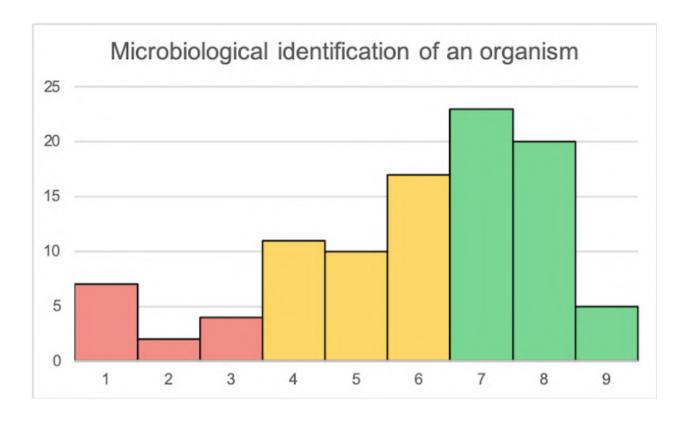


# 11. Your answer for round 3: Jaw pain

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

### 12. Unable to score/comments



# 13. Your answer for round 3: Microbiological identification of an organism

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

14.	Unable to score/comments
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Results from round 2:

	Mark only one oval.											
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest impor	tanc
16.	Unable to score/co	mmer	nts									
Resu	ılts from round 2:											
17.	Your answer for ro	und 3·	Squar	nous d	ebris/k	eratin						
	Mark only one oval.		990.0									
		1	2	3	4	5	6	7	8	9		
	Lowest importance										Highest impor	tanc
18.	Unable to score/co	mmer	nts									

15.

Your answer for round 3: Odour related to the ear

Section 2:
Core
outcome set
for acute
otitis externa

Currently there is no accepted set of outcome measures used in studies of patients with acute otitis externa (AOE). This can lead to difficulty in analysing and interpreting clinical studies, which limits the effectiveness of our treatment of patients with AOE.

We'd like to establish which features of AOE should be included in a Core Outcome Set (COS) for use in all future studies of acute otitis externa (AOE).

The development of a Core Outcome Set (COS) first involves determining WHAT should be measured as an outcome, later establishing HOW this should be measured. The following questions hope to identify WHAT features should be measured.

#### Consensus results from round 2

In round 2, a further 11 of the 43 items reached consensus amongst professionals.

26 of the 43 items have now unambiguously reached consensus between patients and professionals, to be included in the CORE OUTCOME SET for AOE.

#### INCLUDED outcomes:

- ...on the number/frequency of visits to ENT or the GP
- ...on the need for pain relief
- ...on the need for overnight or in-hospital care
- ...on the need for antibiotics
- ...on the ease of applying the treatment
- ...on results of bacterial or fungal growth on an ear swab
- ...on patient satisfaction with their access to appropriate care (for diagnosis & treatment)
- ...on patient satisfaction with the required frequency of the treatments
- ...on patient satisfaction with the length of their symptoms
- ...on patient satisfaction with length of treatment, including number of visits to specialist services (ENT)
- ...on improvements in itchiness
- ...on improvements in hearing impairment
- ...on improvements in ear pain (otalgia)
- ...on improvements in ear canal swelling (oedema)
- ...on improvements in ear canal redness (erythema)
- ...on improvements in discharge from the ear (otorrhoea)
- ...on improvements in any pain on pressing just in front of the ear canal (tragal tenderness)
- ...on any widespread (systemic) side effects of treatments
- ...on any time off work
- ...on any spread of infection beyond the ear canal
- ...on any local side effects of treatments
- ...on any impact on quality of life
- ...if patients were compliant with the treatment
- ...if patients completed the course of treatment
- ...on the number of times the treatment is administered
- ...the time to resolution of symptoms

#### EXCLUDED outcome:

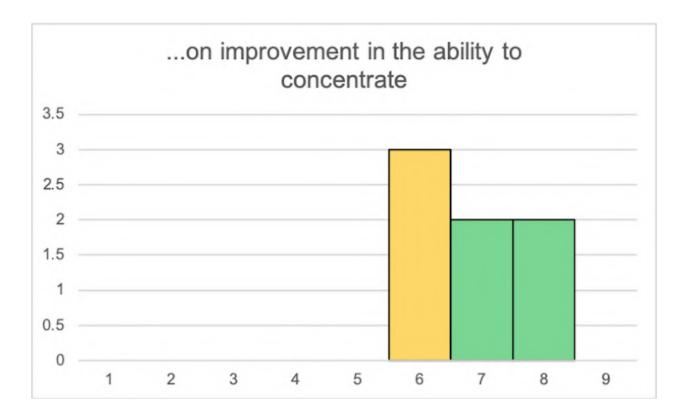
- No outcomes have been unambiguously excluded

#### Round 3

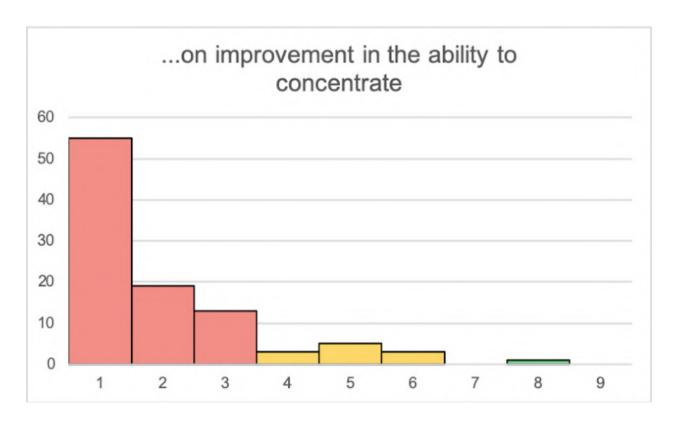
17 COS items remain undecided amongst professionals and patients for round 3.

You will now be shown 2 graphs, one of patient responses and of professional responses.

\*\*\*Please rate these OUTCOMES as to whether they could be INCLUDED or EXCLUDED in an ESSENTIAL outcome set for trials in acute otitis externa\*\*\* [17 outcomes]



Professionals' responses from round 1: [excluded by professionals]



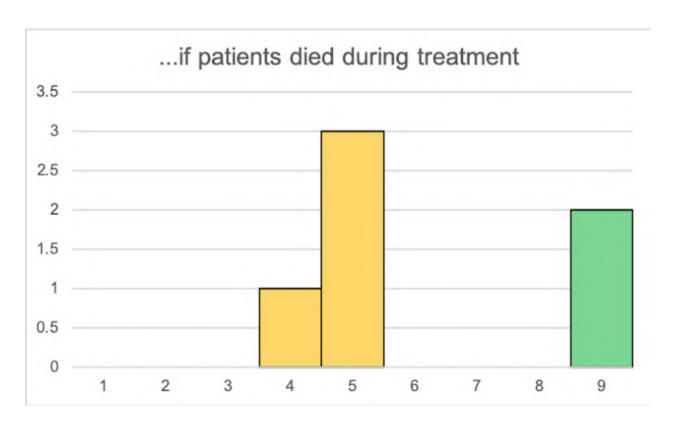
19. Your answer for round 3: Studies should report ...on improvement in the ability to concentrate

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

20. Unable to score/comments

Patients' responses from round 2: [no consensus]

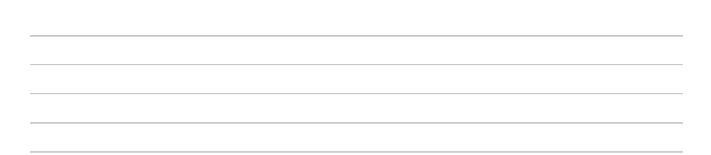


21. Your answer for round 3: Studies should report ...if patients died during treatment

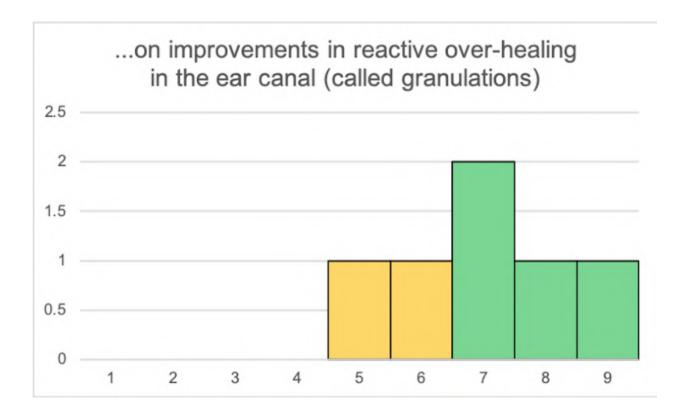
Mark only one oval.



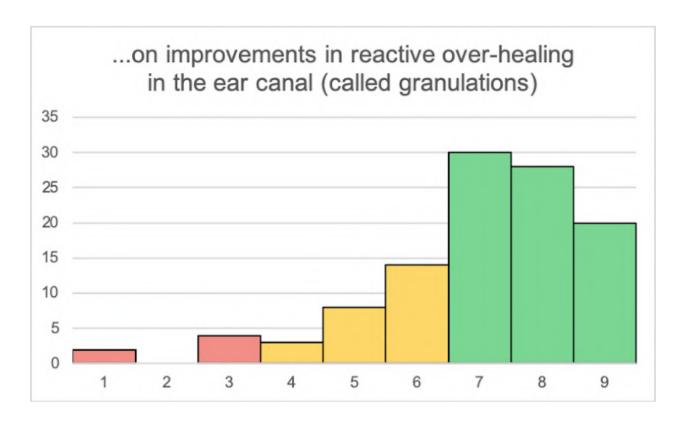
22. Unable to score/comments



Patients' responses from round 2: [no consensus]



Professionals' responses from round 1: [included by professionals]

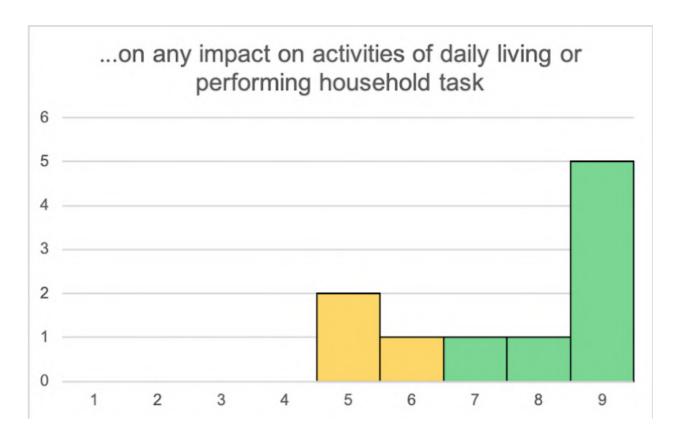


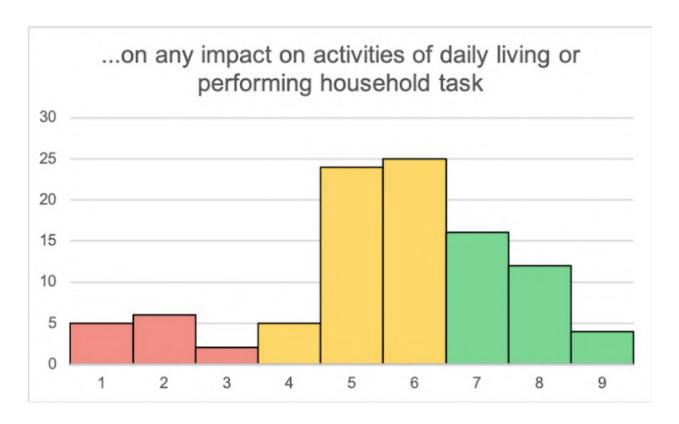
23. Your answer for round 3: Studies should report ...on improvements in reactive overhealing in the ear canal (called granulations)

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

24.	Unable to score/comments												





25. Your answer for round 3: Studies should report ...on any impact on activities of daily living or performing household task

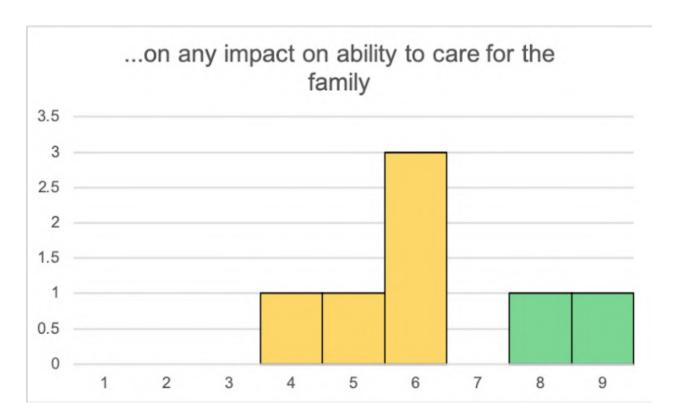
Mark only one oval.

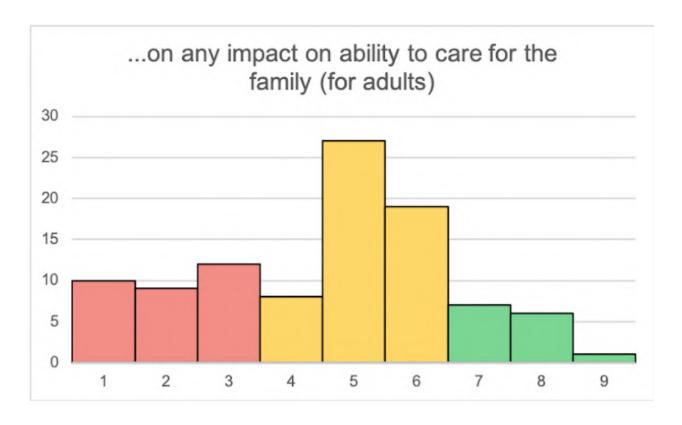
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

26. Unable to score/comments



Patients' responses from round 2: [no consensus]





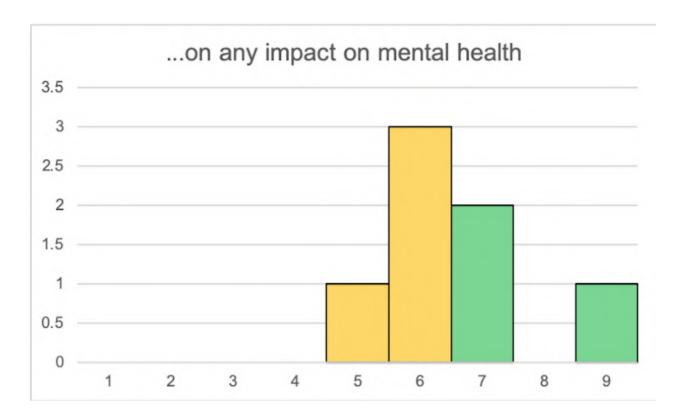
27. Your answer for round 3: Studies should report ...on any impact on ability to care for the family (for adults)

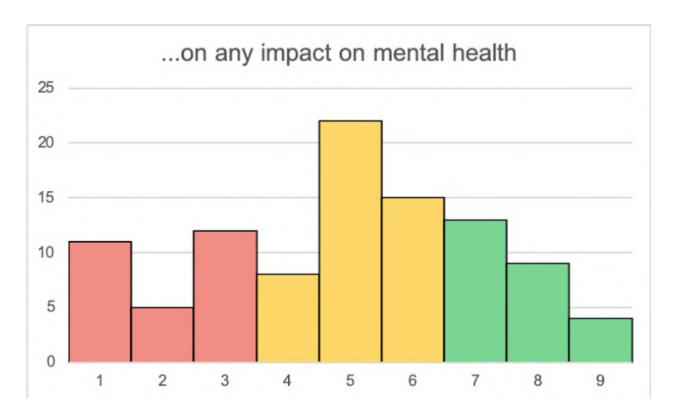
Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

28.	Unable to score/comments

[6-10] Studies should report...





29. Your answer for round 3: Studies should report ...on any impact on mental health

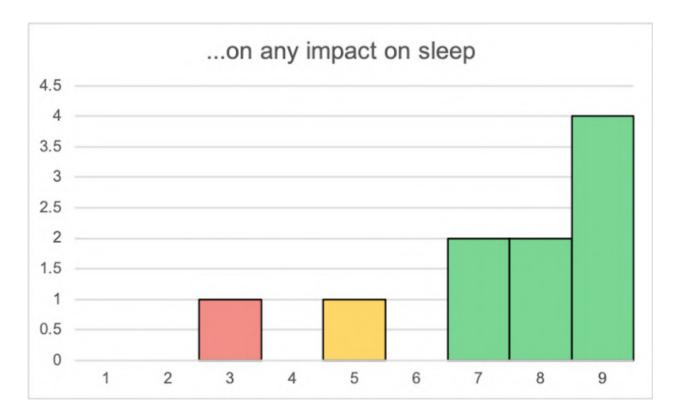
Mark only one oval.

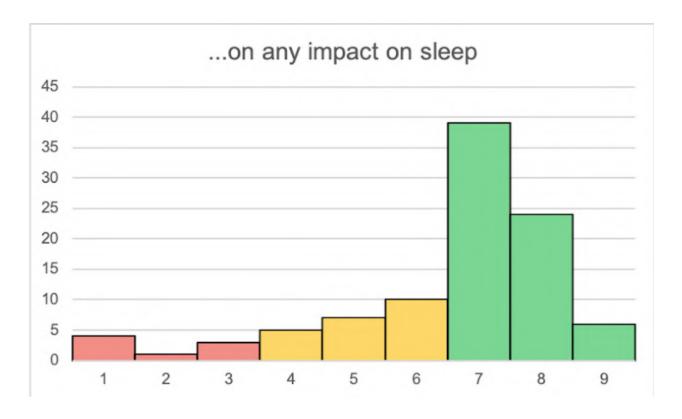
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

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30.	Ullat	יוב נכ	) SCOLE	:/COII	ments



Patients' responses from round 1: [included by patients]



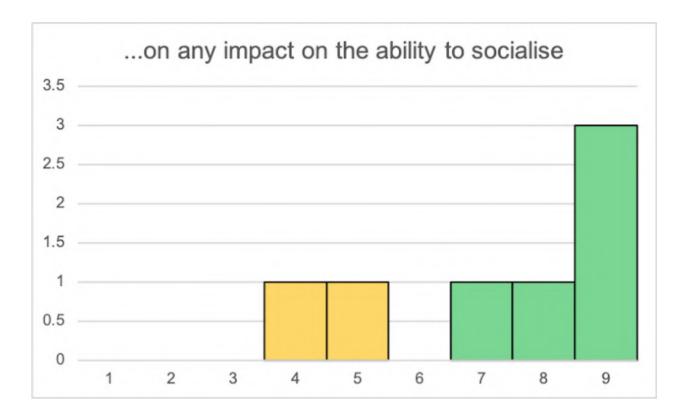


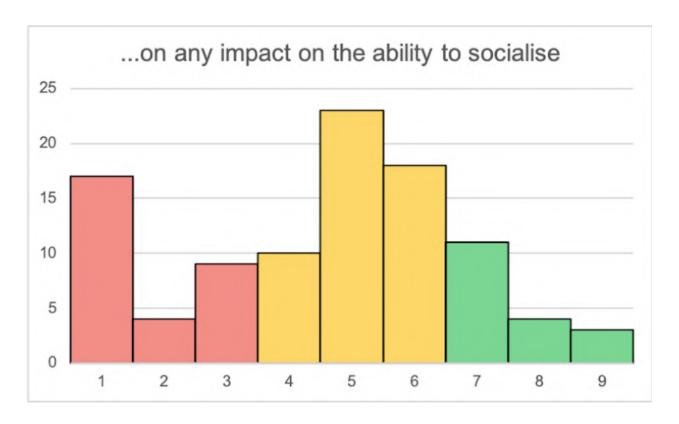
# 31. Your answer for round 3: Studies should report ...on any impact on sleep

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

32.	Unable to score/comments									



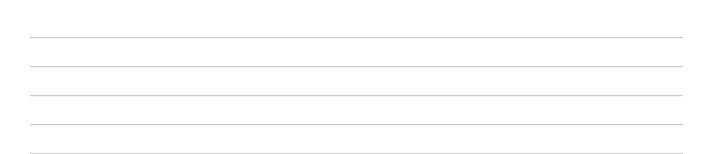


33. Your answer for round 3: Studies should report ...on any impact on the ability to socialise

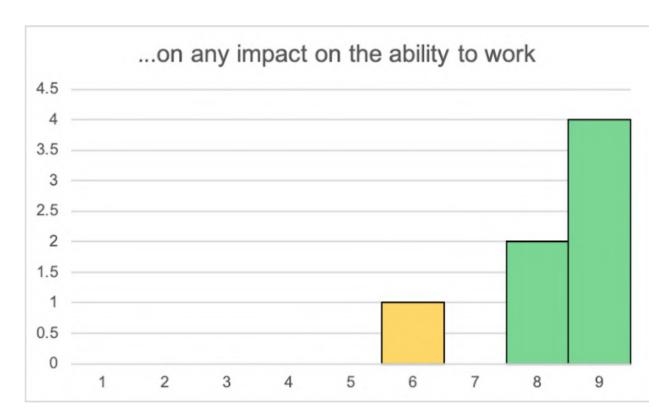
Mark only one oval.

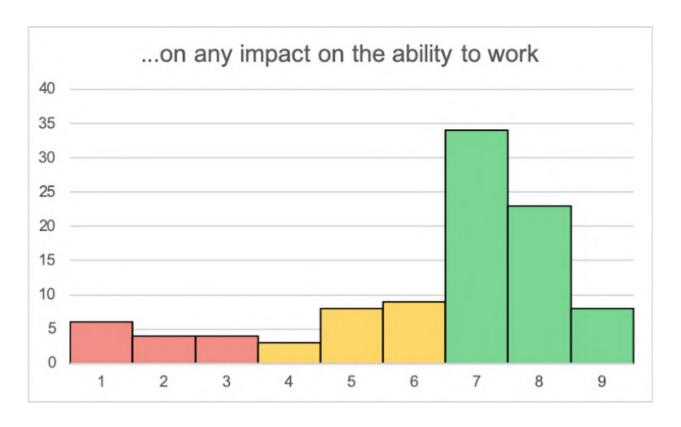
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

34. Unable to score/comments



Patients' responses from round 2: [included by patients]



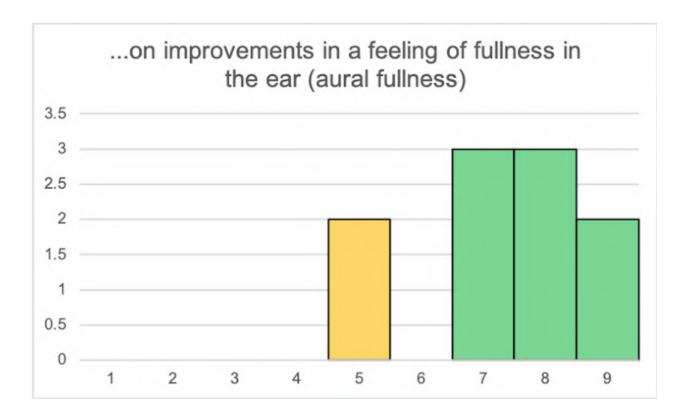


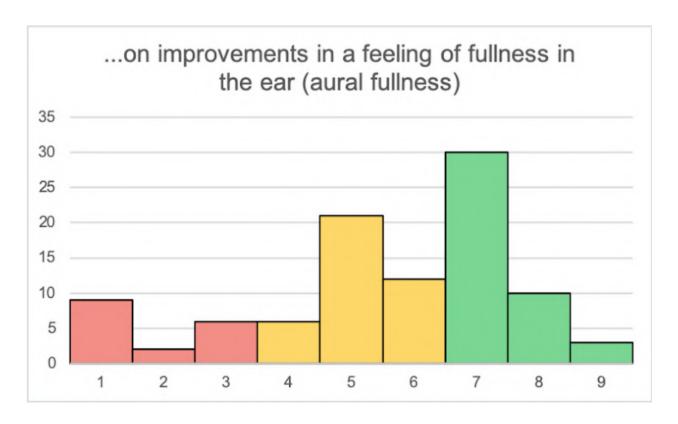
35. Your answer for round 3: Studies should report ...on any impact on the ability to work

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

Unable to score/comments									
	Unable to score/comments								





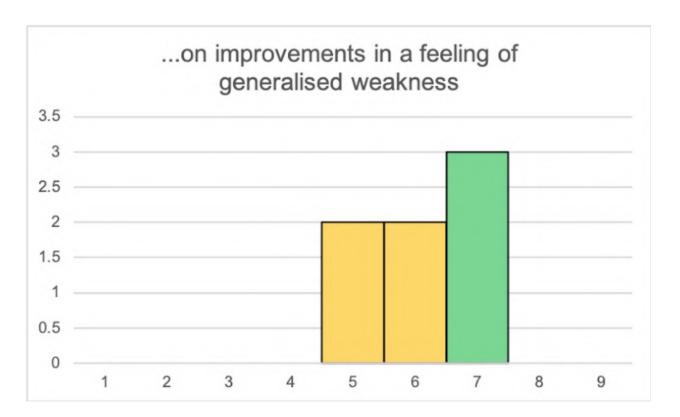
37. Your answer for round 3: Studies should report ...on improvements in a feeling of fullness in the ear (aural fullness)

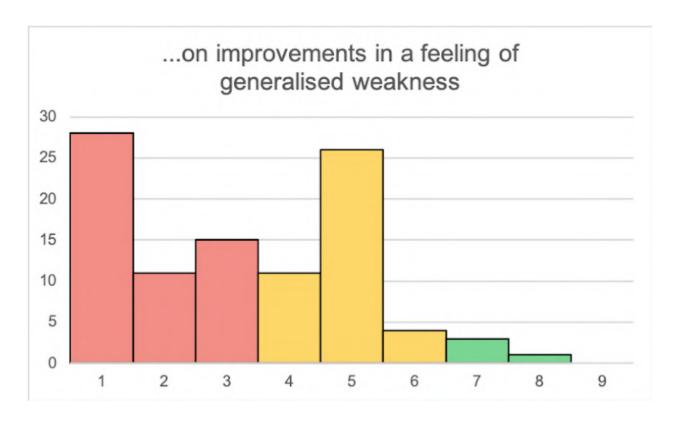
Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

38. Unable to score/comments

Patients' responses from round 2: [no consensus]





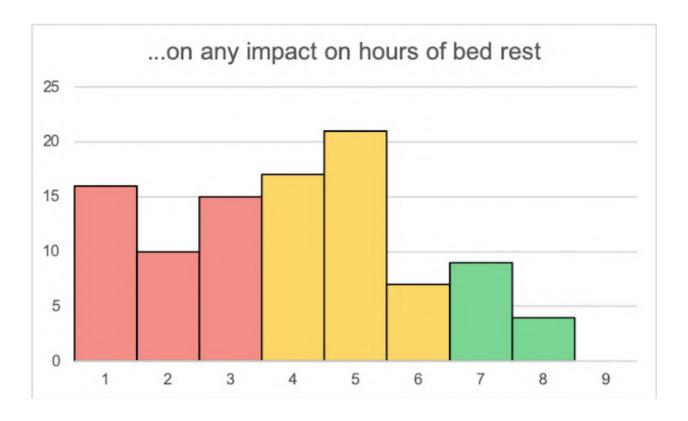
39. Your answer for round 3: Studies should report ...on improvements in a feeling of generalised weakness

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

40.	Unable to score/comments									

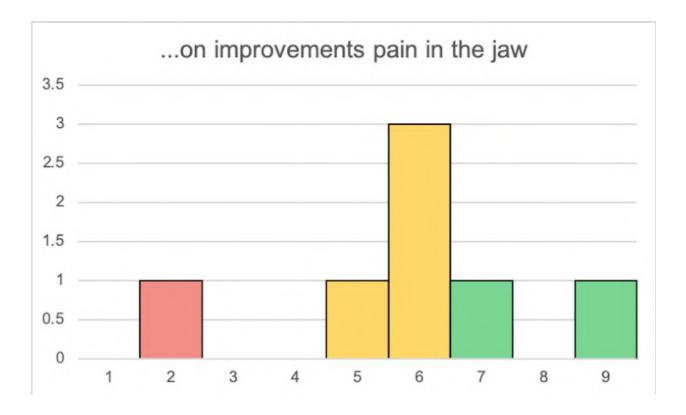
Patients' responses from round 2: [no consensus]

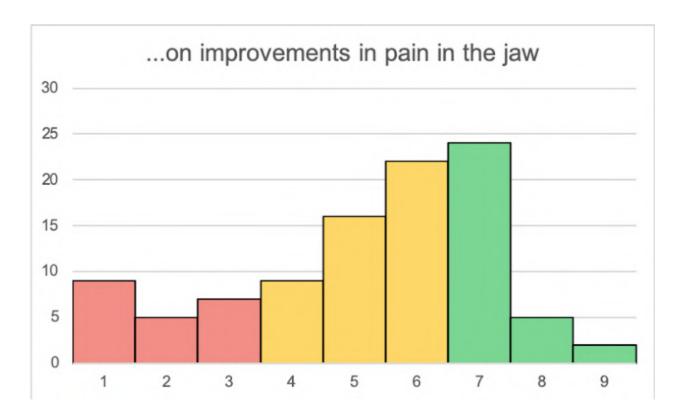


41. Your answer for round 3: Studies should report ...on any impact on hours of bed rest

Mark only one oval.

42.	Unable to score/comments									
		_								



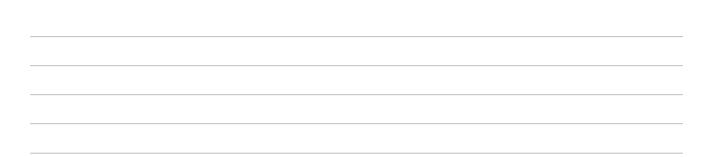


43. Your answer for round 3: Studies should report ...on improvements in pain in the jaw

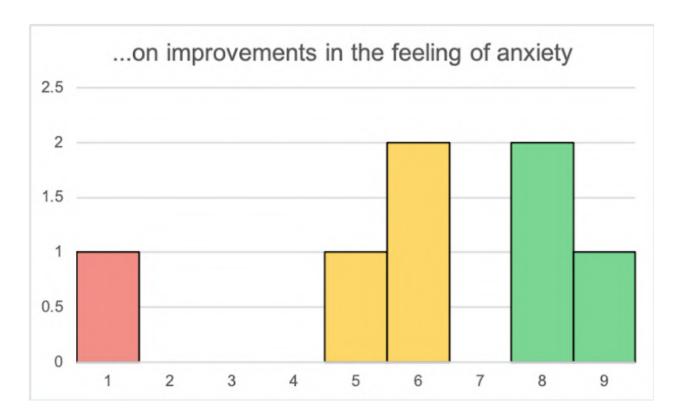
Mark only one oval.

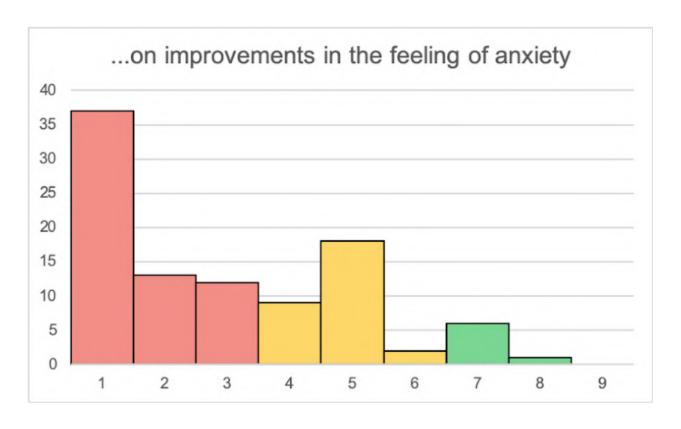
	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

44. Unable to score/comments



Patients' responses from round 2: [no consensus]



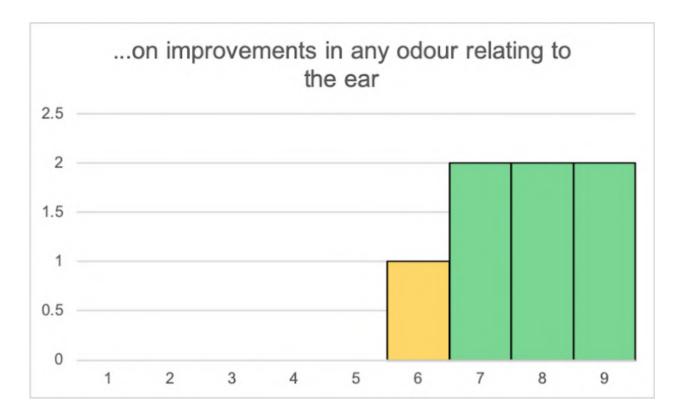


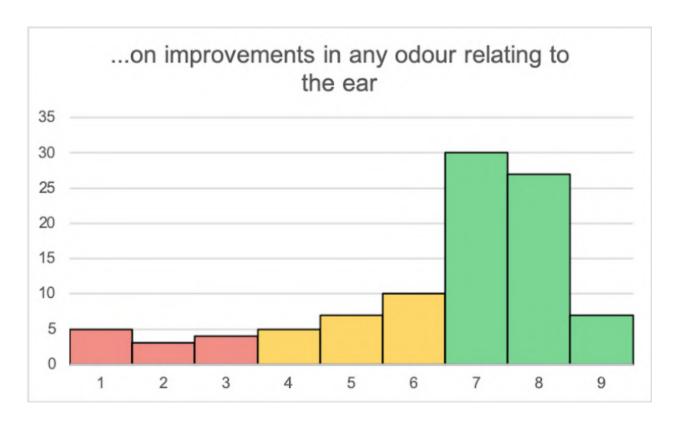
45. Your answer for round 3: Studies should report ...on improvements in the feeling of anxiety

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

46.	Unable to score/comments	





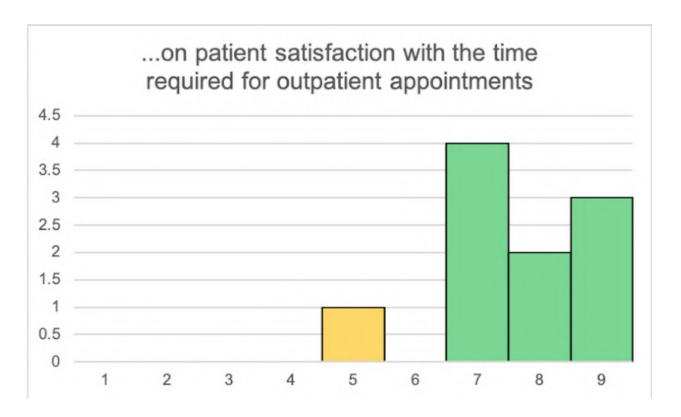
47. Your answer for round 3: Studies should report ...on improvements in any odour relating to the ear

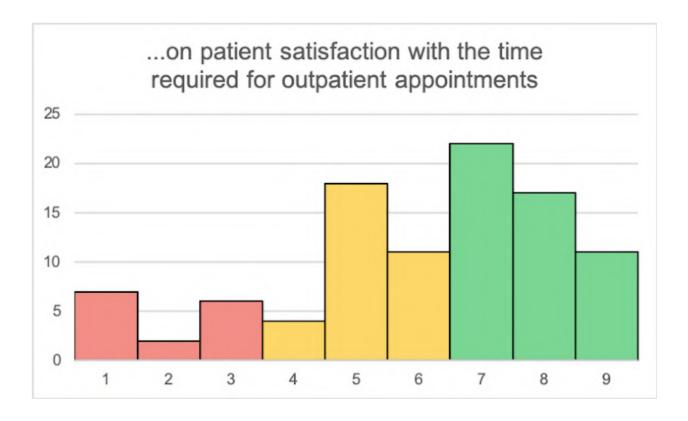
Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

48. Unable to score/comments

Patients' responses from round 1: [included by patients]



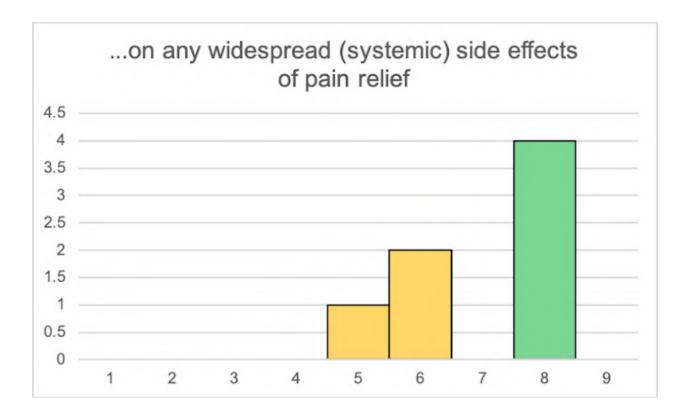


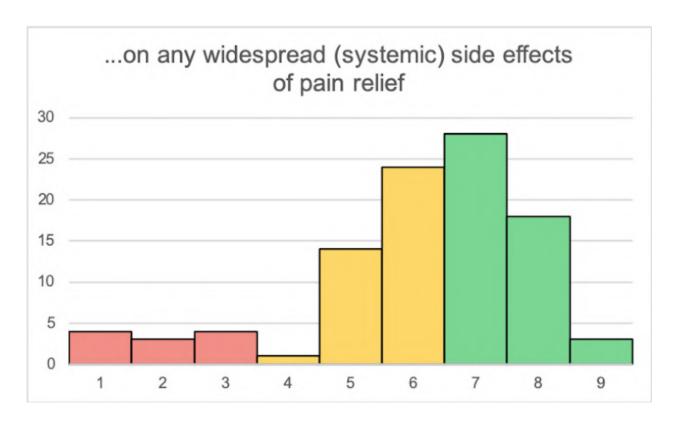
49. Your answer for round 3: Studies should report ...on patient satisfaction with the time required for outpatient appointments

Mark only one oval.

	1	2	3	4	5	6	7	8	9	
Lowest importance										Highest importance

50.	Unable to score/comments





		1	2	3	4	5	6	7	8	9	
Lowest	importance										Highest impor
Unable	to score/co	mmen	ts								
HANK Y	OU ***										
it!											
	king part. Your ound 3 of the p								outcome	set for	acute otitis
you're happ	y with your res	ponses,	please hi	t submit	t to recor	d them.					
	anain fantaliin.				hlama a a t				of a O a matic		
you once	again for taking			any pro	biems at	any stag	je, piease	e emaii <u>ir</u>	<u>iro@entii</u>	<u>itegrate.</u>	<u>.org</u>
	ODE steering c	ommittee	9								

Your answer for round 3: Studies should report ...on any widespread (systemic) side

51.

effects of pain relief

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