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Involving Children and Parents in Core Outcome Set Development:

Experience from the MOMENT study

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On behalf of the MOMENT investigative team

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NHS Foundation Trust

mOMEnt

Management of Otitis Media with Effusion
in childreN with ClefT Palate

Investigative Team:

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Mohiuddin S, Payne K, Fenwick E, O’Brien K, Bruce IA
A model-based cost-effectiveness analysis of grommets-led care pathway for children with cleft palate affected by otitis media with effusion
The European Journal of Health Economics (Accepted Ms. No. EJHE-D-13-00212R1)

Harman NL, Bruce IA, Callery P, Tierney S, Owaise Sharif M, O’Brien K, Williamson PR
MOMENT: Management of Otitis Media with Effusion in Cleft Palate. - Protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey.
Trials 2013; 14 (1):70 (Epub) (PMID 23497540)

I Bruce, N Harman, P Williamson, S Tierney, P Callery, S Mohuiddin, K Payne, E Fenwick, J Kirkham , K O'Brien
The management of Otitis Media with Effusion (OME) in children with Cleft Palate: A feasibility study and economic evaluation. (mOMEnt)
NIHR HTA report. In press

MOMENT was funded by the
NIHR HTA programme

NHS
National Institute for
Health Research

INVOLVE

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Why involve members of the public in research?

No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost efficient as well.

Professor Dame Sally Davies, Chief Medical Officer.

(Foreword in Staley, K.(2009) Exploring Impact: public involvement in NHS, public health and social care research. INVOLVE, Eastleigh)

www.invo.org.uk

Why involve members of the public in research?

Ensure your research effort is patient focused

Maximise the opportunity to effect change in patient care

Benefit from the perspective of people directly effected by the condition

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Cleft Lip & Palate Association

Rosanna Preston
CEO
Cleft Lip and Palate Association (CLAPA)

Jo Hossell
Parent of patient with Cleft Palate

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Patient organisation interview (Introduction to CLAPA)

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Patient organisation interview (Introduction to CLAPA): What can we learn?

- Benefit from access to pre-existing regional structures to ‘reach out’ to patients and parents throughout your country

- Cooperate with appropriate focus / special interest groups within patient organisations

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What made you want to get involved?

What made you want to get involved?

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What made you want to get involved?: What can we learn?

- To ensure the ‘patient’s voice is heard’
- Ensure study benefited from input of those with ‘lived experience’ of the condition
- Ensure outcomes of most importance to patients are considered
- Opportunity to facilitate direct involvement of patient group membership

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Engaging with parents about a COS study

Engaging with parents about a COS study

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Engaging with parents about a COS study: What can we learn?

- Use existing and trusted channels of communication
- Patients are busy too!
- Work with patients at the planning stage to make involvement as easy as possible
- PPI is not an ‘add-on’
- Ensure sufficient resources are available to support patient involvement
- Explain to patients why they should contribute to the COS

What did you think were the key challenges to involving patients / carers / parents in the study?

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What did you think were the key challenges to involving patients / carers / parents in the study?: What can we learn?

- Practical aspects of arranging ‘face to face’ meetings and the potential benefits of designing ‘on-line’ studies
- Ensure comprehensive involvement from all sections of a patient group and society, including ‘hard to reach’ groups
- Avoid selection bias by promoting involvement to the entire membership of an organisation
- Support patients to become involved by providing relevant education regarding research methodology and COS

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What might discourage patients from getting involved?

What might discourage patients from getting involved?: What can we learn?

- Researchers need to explain why the opinions of patents are important
- Patient opinion is valuable whatever it is and even when it is different from other stakeholder opinion

How did you tell your members about the COS study?

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How did you tell your members about the COS study?: What can we learn?

- Work with the patient organisation and utilise existing communication channels and strategies
- Present the study to relevant councils/subgroups and ask for advice about how best to engage with its members
- Try to create outreach opportunities at existing conferences

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What did you think about the questionnaire used for the Delphi exercise?

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What did you think about the questionnaire used for the Delphi exercise?: What can we learn?

- Patients need to be able to easily understand the language used

- Ask for advice from patients about the language and methodology used

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The list of outcomes used for Health Professionals was reviewed and re-worded using a lay description that was tested for readability using the NIACE SMOG calculator

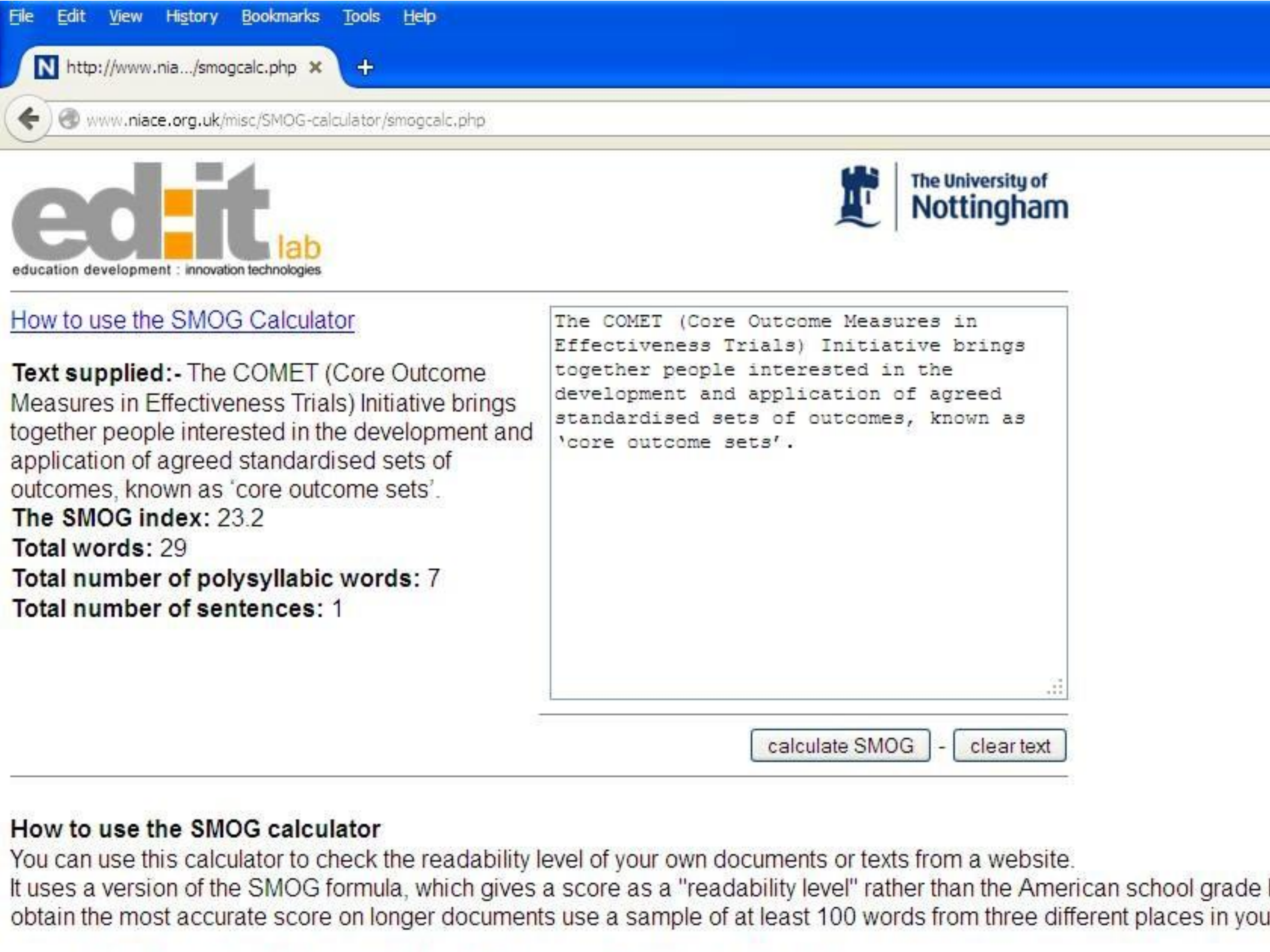
Also checked for understanding by the CLAPA children and young person’s council and the local CLAPA ‘Happy Faces’ group

Some outcomes which related to specific clinical observations were combined so that parents and children scored a total of 36 outcomes representing the 45 outcomes identified from the SR

Parents asked to score each of the outcomes listed using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) scale of 1-9

In the online survey the scale was presented in the format 1-9 with 1-3 labelled as “Not that important”, 4-6 labelled as “Important” and 7- 9 labelled as ‘”really important”

Also provided with an option to add anything else that they considered relevant in a free text box



How to use the SMOG Calculator

Text supplied:- The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets'.

The SMOG index: 23.2

Total words: 29

Total number of polysyllabic words: 7

Total number of sentences: 1

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Effectiveness Trials) Initiative brings
together people interested in the
development and application of agreed
standardised sets of outcomes, known as
'core outcome sets'.
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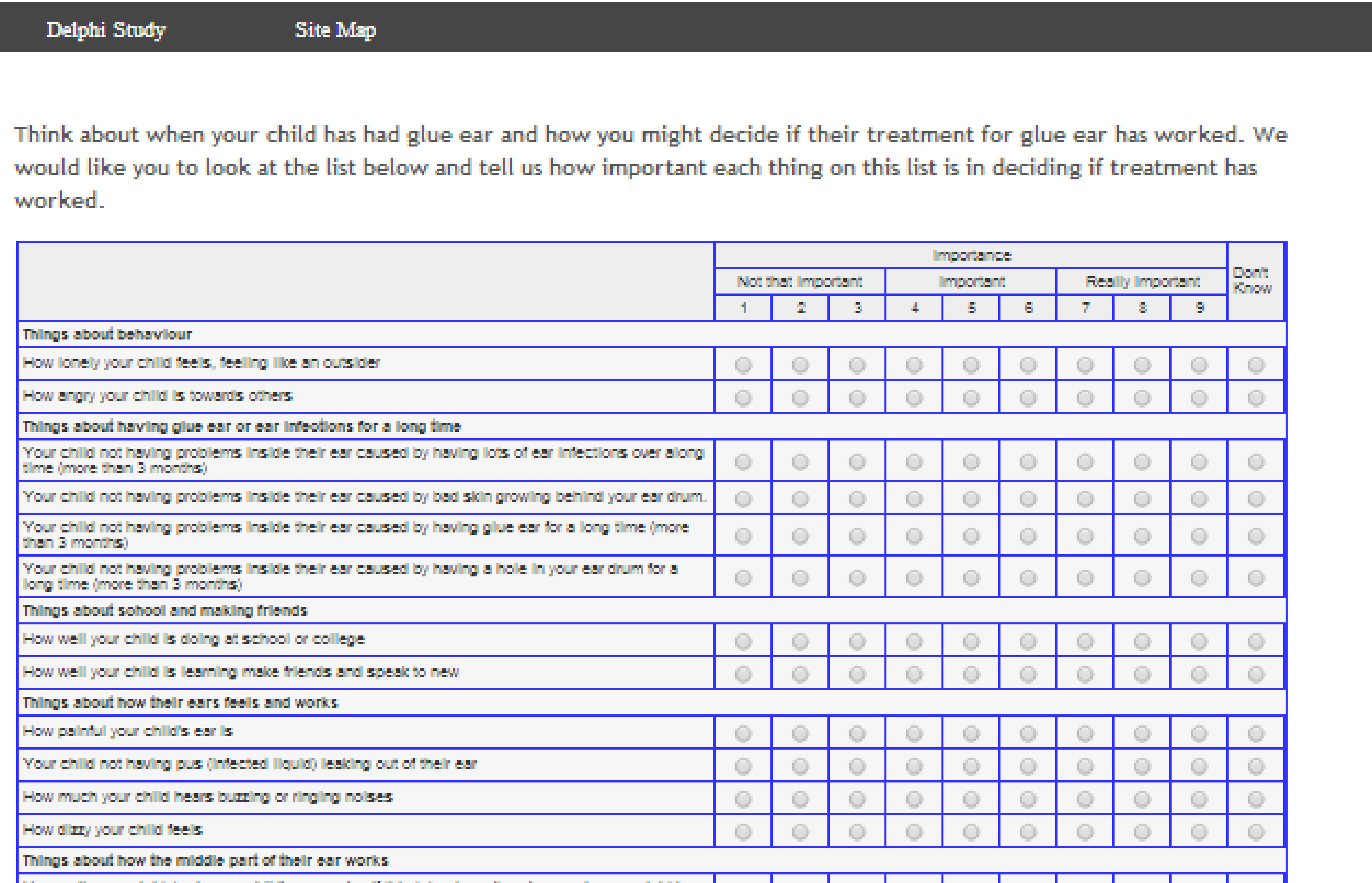
How to use the SMOG calculator

You can use this calculator to check the readability level of your own documents or texts from a website.

It uses a version of the SMOG formula, which gives a score as a "readability level" rather than the American school grade

obtain the most accurate score on longer documents use a sample of at least 100 words from three different places in you

Guyatt GH, Oxman AD, Kunz R, Atkins D, Brozek J, Vist G, Alderson P, Glasziou P, Falck-Ytter Y, Schünemann HJ: **GRADE guidelines: 2. Framing the question and deciding on important outcomes.** *J Clin Epidemiol* 2011, **64**:395–400



Think about when your child has had glue ear and how you might decide if their treatment for glue ear has worked. We would like you to look at the list below and tell us how important each thing on this list is in deciding if treatment has worked.

	Importance									Don't Know
	Not that important			Important			Really important			
	1	2	3	4	5	6	7	8	9	
Things about behaviour										
How lonely your child feels, feeling like an outsider	○	○	○	○	○	○	○	○	○	○
How angry your child is towards others	○	○	○	○	○	○	○	○	○	○
Things about having glue ear or ear infections for a long time										
Your child not having problems inside their ear caused by having lots of ear infections over along time (more than 3 months)	○	○	○	○	○	○	○	○	○	○
Your child not having problems inside their ear caused by bad skin growing behind your ear drum.	○	○	○	○	○	○	○	○	○	○
Your child not having problems inside their ear caused by having glue ear for a long time (more than 3 months)	○	○	○	○	○	○	○	○	○	○
Your child not having problems inside their ear caused by having a hole in your ear drum for a long time (more than 3 months)	○	○	○	○	○	○	○	○	○	○
Things about school and making friends										
How well your child is doing at school or college	○	○	○	○	○	○	○	○	○	○
How well your child is learning make friends and speak to new	○	○	○	○	○	○	○	○	○	○
Things about how their ears feels and works										
How painful your child's ear is	○	○	○	○	○	○	○	○	○	○
Your child not having pus (infected liquid) leaking out of their ear	○	○	○	○	○	○	○	○	○	○
How much your child hears buzzing or ringing noises	○	○	○	○	○	○	○	○	○	○
How dizzy your child feels	○	○	○	○	○	○	○	○	○	○
Things about how the middle part of their ear works										

Children aged 7-16 years were shown the same list of outcomes as parents

Scoring system adapted to use a traffic light system where the scores 1-3 were represented by a red box labelled as “not that important”, scores 4-6 as an amber box labelled as “important” and scores 7-9 as a green box labelled “really important”

Children and Young People Council

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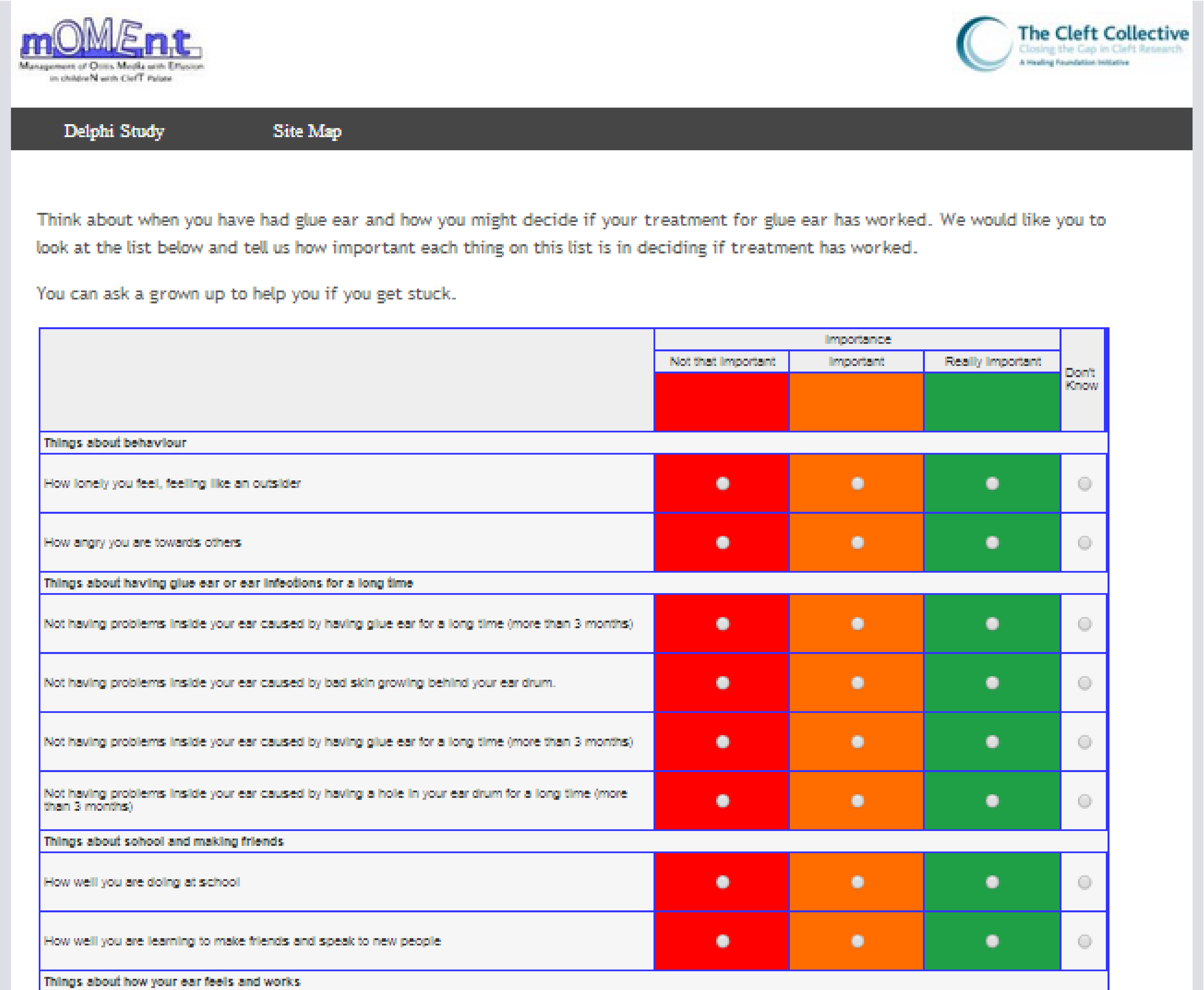

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Think about when you have had glue ear and how you might decide if your treatment for glue ear has worked. We would like you to look at the list below and tell us how important each thing on this list is in deciding if treatment has worked.

You can ask a grown up to help you if you get stuck.

	Importance			Don't Know
	Not that important	Important	Really important	
	🟥	🟧	🟩	
Things about behaviour				
How lonely you feel, feeling like an outsider	○	○	○	○
How angry you are towards others	○	○	○	○
Things about having glue ear or ear infections for a long time				
Not having problems inside your ear caused by having glue ear for a long time (more than 3 months)	○	○	○	○
Not having problems inside your ear caused by bad skin growing behind your ear drum.	○	○	○	○
Not having problems inside your ear caused by having glue ear for a long time (more than 3 months)	○	○	○	○
Not having problems inside your ear caused by having a hole in your ear drum for a long time (more than 3 months)	○	○	○	○
Things about school and making friends				
How well you are doing at school	○	○	○	○
How well you are learning to make friends and speak to new people	○	○	○	○
Things about how your ear feels and works				

What did you think about the Consensus meeting?

What did you think about the Consensus meeting?: What can we learn?

- Emphasise the importance of patient involvement at the start
- Ensure that all views are given equal value
- Prior to the meeting, provide detailed proprietary material to support involvement and refresh understanding

What advice would you give researchers developing similar COS?

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What advice would you give researchers developing similar COS?

- Emphasise to patients the importance of their involvement
- Explain the real benefits to the study of patient involvement
- Make the language accessible to patients
- Involve patients in the early planning and design phases

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What advice would you give about working with a patient organisation to develop a COS?

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What advice would you give about working with a patient organisation to develop a COS?: What can we learn?

- Seek advice about how best to engage with individuals within the patient organisation
- Gain support from entire organisation and relevant subgroups/special interest groups
- ‘Sell the benefit’
- Describe the experience of taking part, along with opinions of the impact of existing COS

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Involving Children and Parents in Core Outcome Set Development:

Experience from the MOMENT study

- Involve people with ‘lived experience’
- Emphasise the importance and value of patient involvement
- Seek patient involvement early in the process
- Use existing communication channels and communication networks where available
- Ensure the language used is accessible
- Ensure patient involvement is properly resourced
- Provide the necessary patient education to support involvement and understanding of COS

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