National Institute for Health and Care Excellence

Multiple Technology Appraisal (MTA)

Prophylactic removal of impacted third molars [ID898]

Response to consultee and commentator comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultees	Comments [sic]	Action
Appropriateness	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Yes, It is appropriate for NICE reappraisal.	Comment noted.
	Cochrane Oral Health Group	Yes, I think it is appropriate to refer this topic to NICE for appraisal.	Comment noted.

Section	Consultees	Comments [sic]	Action
Wording	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	The essence of all NICE reviews is to maximise patient safety in relation to health interventions. The suggested review concentrates only on prophylactic removal of third molars in relation to risk prevention of second molar caries. We would recommend that the reappraisal should include not just risk assessment on non-surgery, but also the risk assessment of interventions. The scope as drafted sets out the proposed remit as 'to appraise the clinical and cost effectiveness of the **prophylactic removal of impacted mandibular third molars**'. It is our view that this definition does not entirely reflect what is outlined in the technology section of the draft guidance which states that *'the reasons for prophylactically removing **asymptomatic or pathology-free** impacted third molars could be to reduce the risk of infection, untreatable decay, cysts, tumours and destruction of adjacent teeth/bone.'* The suggestions on possible revisions to the remit in the scoping document do not, in our view, represent suitable alternatives and we would suggest extending the current remit along the following lines: *to appraise the clinical and cost effectiveness of the prophylactic removal of impacted third molars in patients with or without pathology, and to provide a framework for risk assessment of the value of interventions.* Prevention of complications including nerve injury, prevention of unnecessary antibiotic prescription, and prevention of wrong site surgery should be strongly considered as well.	Comment noted. The purpose of an appraisal is to appraise the health benefits and the costs of those technologies notified by the Secretary of State for Health and to make recommendations to the NHS. This topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area.

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	Cochrane Oral Health Group	I suggest a change to the wording. I think the remit should focus on the prophylactic removal of pathology-free and/or trouble-free wisdom teeth as there is a universal understanding that third molars with symptoms or pathoses require extraction or surgically removal.	Comment noted. The population has been amended to include pathology-free or trouble-free impacted third molars.
Timing Issues	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	**Currently many patients are currently suffering harm due delayed surgery** unnecessary antibiotic prescription, wrong site surgery and permanent nerve injury due to poor practice.	Comment noted. A partial review of TA1 has been scheduled into the work programme.
	Cochrane Oral Health Group	I believe that the Institute's guideline on the extraction of wisdom teeth require a prompt update as this topic is of relevance to the oral health of the UK's population (and other countries/communities without formal guidance but which follow the UK's practice) and it addresses a priority concern within the field of third molar surgery.	Comment noted. A partial review of TA1 has been scheduled into the work programme.

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Additional comments on the draft remit	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	The proposal is too narrow and we recommend revisions to the scope as outlined above. Needs to be broadened to include best evidence practice for: Risk assessment; surgical practice, adjunctive medical care and follow up	Comment noted. This topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area.
	Cochrane Oral Health Group	An impacted wisdom tooth is termed 'asymptomatic' when the patient does not experience symptoms, but it has been recognised that trouble-free teeth are often not disease- or pathology-free.	Comment noted. The population has been amended to include pathology-free or trouble-free impacted third molars

Comment 2: the draft scope

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Background information	British Association of Oral Surgeons,	The background information is brief but focuses entirely on prophylactic surgery.	Comment noted. This section of the scope is only intended to be a brief description of the

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	Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Currently prophylactic surgery is indicated if the M3M lies within a surgical field of a fracture, removal if surrounded by pathology requiring an intervention, or orthognathic surgery. There is no mention of patients requiring prophylactic surgery for prevention of disease for patient prescribed radiation therapy (risk osteoradionecrosis) or bone modulating drugs e.g. bisphosphonates, Rankl inhibitors and others (prevention of osteoradionecrosis) Due to the focus of the proposed review assessing prophylactic surgery only there is no background about risk assessment to prevent complications including; nerve injury, wrong site surgery prolonged pain etc.	background to the condition and treatment options. If relevant, consultees can submit such information to be considered as part of the evidence base, alongside the Assessment Group's report. Comment noted. This topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area.
	Cochrane Oral Health Group	Not all pathoses associated with third molar retention have been clearly illustrated. Such as tooth decay in the adjacent molars which may be untreatable and require extraction, multiple episodes of pericoronitis, periodontal disease (probing depth >4mm) affecting the third and/or adjacent second molar and crowding of lower anterior incisors/dimensional changes in the dental arch.	Comment noted. Comment noted. This topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area. If relevant, consultees can submit such information to be considered

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			as part of the evidence base, alongside the Assessment Group's report.
The technology/ intervention	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Yes. But again there are omissions. To minimise the risk of nerve injury pre-op assessment and altered surgical approach (coronectomy) may be necessary and should be considered	Comment noted. This topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area.
	Cochrane Oral Health Group	Prophylactic removal of third molars	Comment noted.
Population	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	No. All patients presenting with M3Ms must be included. All ages and all types of angulation (not just mesioangular). There may be good indications to remove vertical, distoangular and horizontally impacted teeth in various age groups.	Comment noted. The population in the scope is not restricted by age or type of angulation. It covers all people with pathology-free or trouble-free impacted mandibular third molars.
	Cochrane Oral Health Group	Consideration may be given to the following subgroups: Patients with trouble-free and pathology-free meso-angular or horizontally impacted mandibular third molars with low risk to IAN injury.	Comment noted. The scope has been amended to include the following subgroup: People with mesioangular or horizontally impacted third

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			molars. Other subgroups may be considered during the appraisal process, if relevant.
Comparators	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Intervention versus no intervention. Conventional surgery versus coronectomy. Variations of adjunctive medical interventions (steroids, analgesia, antibiotics). Surgical follow up and home-check versus none.	Comment noted. Prophylactic removal of third molars will be compared with standard of care without prophylactic removal of third molars. Consultees have the opportunity to submit evidence of what constitutes standard of care in their submissions.
	Cochrane Oral Health Group	Retention Consideration my be given to the following subgroups: Mesio-angular or horizontally impacted mandibular third molars.	Comment noted. Prophylactic removal of third molars will be compared with standard of care without prophylactic removal of third molars. Consultees have the opportunity to submit evidence of what constitutes standard of care in their submissions. The scope has been amended to include the following subgroup: People with mesioangular or horizontally impacted third molars
Outcomes	British Association of Oral Surgeons,	Dry socket (both single and multiple events). Nerve injury (lingual and inferior alveolar).	Comment noted. These outcomes would be covered by those listed in the scope,

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	Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Osteomyelitis (or persistent infection requiring re treatment). Repeated surgery for failed extraction or complications of coronectomy. High level acute post-surgical pain. Persistent pain (may be due to nerve injury or TMD). Wrong site surgery.	that is, pathology associated with retention of third molars; post-operative complications following extraction; adverse effects of treatment and health-related quality of life.
	Cochrane Oral Health Group	Consideration may be given to: Patient satisfaction Quality of life	Comment noted. Consideration of indirect benefits of treatment (such as patient satisfaction) do not form part of the NICE reference case. However, information about wider societal benefits can be included in any evidence submission for consideration by the Committee
Economic analysis	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	The effect NICE 1 (2000) have taken 10-15 years to establish proof of adverse outcomes. Perhaps a similar horizon is needed for amended guidelines.	Comment noted. The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect all important differences in costs or outcomes between the technologies being compared.
	Cochrane Oral Health Group	QALY Days of work	Comment noted. For the cost-effectiveness analyses health effects should be expressed in

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		Direct cost associated with retention/removal of wisdom teeth and treating any associated symptoms of complications.	QALYs (see section 5.3.1 of the NICE Guide to the methods of technology appraisal). When non-reference-case analyses include these broader costs, explicit methods of valuation are required. In all cases, these costs should be reported separately from NHS and personal social services costs, and not included in the ICER. (see section 5.5.11 of the NICE Guide to the methods of technology appraisal). Consideration of indirect benefits of treatment (such as work productivity) do not form part of the NICE reference case. However, information about wider societal benefits and costs of treatment can be included in any evidence submission for consideration by the Committee.
Equality and Diversity	British Association of Oral Surgeons, Faculty of	*"please tell us if the remit and scope:* • *could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)]*	Comment noted.

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	Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	*is/are/will be licensed"* Nothing to add. • *"could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology"* Risk assessment and high risk surgery are limited to specialist practice (oral surgery). • *could have any adverse impact on people with a particular disability or disabilities.* Cannot think of any impact on this group (difficulty accessing cone beam scanners to assess the relationship of the third molar roots and the IDC when evaluating the need for coronectomy).	Comment noted. This is only an equalities issue if the remit and scope could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population. The Committee will ensure that any recommendations do not discriminate against any groups protected under the Equality Act. Comment noted.
	Cochrane Oral Health Group	-	
Other considerations	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental	The essence of all NICE reviews is to maximise patient safety in relation to health interventions. The suggested review concentrates only on prophylactic removal of third molars I relation to risk prevention of second molar caries. We would recommend that the re appraisal should be much broader and	Comment noted. The purpose of an appraisal is to appraise the health benefits and the costs of those technologies notified by the Secretary of State for Health and to make recommendations to the NHS. This topic is a partial review of

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	Practice (UK)	include not just risk assessment on non-surgery but also the risk assessment of interventions (both medical and surgical) and prevention of complications including nerve injury, along with prevention of unnecessary antibiotic prescription and prevention of wrong site surgery. Currently prophylactic surgery is indicated if the M3M lies within a surgical field of a fracture, removal if surrounded by pathology requiring surgical intervention or an orthognathic surgical field. There is no mention of patients requiring prophylactic surgery for prevention of disease for patient prescribed radiation therapy (risk osteoradionecrosis) or bone modulating drugs e.g. bisphosphonates, Rankl inhibitors and others (prevention of osteoradionecrosis). Due to the focus of the proposed review assessing prophylactic surgery only there is no background about risk assessment to prevent complications including; nerve injury, wrong site surgery prolonged pain etc.	technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area. Consultees have the opportunity to submit evidence for any relevant subgroups in their submissions, where appropriate.
	Cochrane Oral Health Group	*Suggestions for additional issues to be covered by the appraisal are welcome:* • The increasing incidence of distal surface caries pre and post NICE guidance in different populations. • The increasing number of third molar extractions in the past 7 years. • Other international wisdom tooth guidance and approaches. (Germany, US and Scandinavia) • Evidence based decision making in health care and it's three main components; research evidence, clinical expertise and consideration of the individual patient's values, situation and preference.	Comment noted.

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Innovation	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Yes. This would be a step change in the management of patients with M3Ms. Many patients would benefit from earlier removal of low risk M3Ms to prevent M2M disease and subsequent potential loss. Surgical complications are significantly reduced in patients under 25 years of age. Updating the NICE guidance using evidence base would lower the patient age at surgery and help to minimise all surgical complications. Clear guidance on adjunctive medical care will improve antibiotic stewardship and reduce patient risk. NICE guidance may also contribute to patient safety with recommendations to prevent complications including wrong site surgery and improve reporting or patient safety incidents to thereon continue patient safety.	Comment noted. Potential innovation can be highlighted in any evidence submissions. The guidance can only assess the clinical and cost-effectiveness of, and make recommendations on, the intervention under appraisal, that is, the prophylactic removal of third molars.
	Cochrane Oral Health Group	No comments	No action required.
Questions for consultation	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of	See below.	Comment noted.

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	General Dental Practice (UK)		
	Cochrane Oral Health Group	No comments.	No action required.
Additional comments on the draft scope.	British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)	Is the remit 'to appraise the clinical and cost effectiveness of the prophylactic removal of impacted mandibular third molars' appropriate? *Yes but all aspects of care must be evaluated including medical and surgical therapeutic care, resultant dental rehabilitation, impact on other health care sectors (A&E, GMP. Pharmacists).* Based on the studies considered during the review process, is it more appropriate for the remit of this review to focus only on the prophylactic removal of disease-free (healthy) impacted mandibular third molars; that is, a partial update of TA1 (specifically recommendations 1.1 and 1.2 of the original guidance)? *There are current in accuracies in the NICE TA1 guidance with omission of medical indications for M3M extraction including radiation and Bisphosphonates* *The possible terminology of timing of M3M extractions may include;* • *Therapeutic*	Comment noted. This topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area. Comment noted. This can be considered in the Assessment Report and evidence submissions.

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		• *Interceptive* • *Interventional* • *Prophylactic* *All should be included in the review* *Along with risk assessment (preoperative) and holistic aspect of patient care (post operative).* Is there any new evidence to suggest that recommendation 1.3 in the original guidance for third molars with evidence of pathology needs updating? *Yes it needs updating. Currently prophylactic surgery is indicated if the M3M lies within a surgical field of a fracture, removal if surrounded by pathology requiring surgical intervention or an orthognathic surgical field.* *There is no mention of patients requiring prophylactic surgery for prevention of disease for patient prescribed radiation therapy (risk osteoradionecrosis) or bone modulating drugs e.g. bisphosphonates, Rankl inhibitors and others (prevention of osteoradionecrosis)* Should the review focus only on people with mesioangular third molars? That is, should the population in the scope be 'People with impacted mesioangular mandibular third molars'? *The review must include all impactions (Horizontal, mesioangular and*	Comment noted. Comment noted. The scope is only intended to give a brief description of the background to the condition and treatment options. Consultees can submit relevant evidence as part of their evidence submissions. The submissions will be considered by the Committee alongside the Assessment Group's report. Comment noted. This topic is a partial review of technology

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		distoangular) M3Ms as all can potentially require therapeutic, interventional or prophylactic removal.	appraisal 1 (TA1), that is, of the prophylactic removal of third molars. It is not a clinical guideline of the entire therapeutic area.
		Have all relevant comparators for the prophylactic removal of third molars been included in the scope? *No , many are excluded* *Intervention versus no intervention* *Conventional surgery versus coronectomy* *Variations of Adjunctive medical interventions (steroids, analgesia, Antibiotics)* *Surgical follow up and home-check versus none* *Management of complications* *Reporting of patient safety incidents*	Comment noted. Prophylactic removal of third molars will be compared with standard of care without prophylactic removal of third molars. Consultees have the opportunity to submit evidence of what constitutes standard of care in their submissions.
		What is considered to be established clinical practice in the NHS for people requiring prophylactic removal of third molars? How should standard care be defined? *Currently prophylactic surgery is indicated if the M3M lies within a surgical field of a fracture of future surgery required for pathology or orthognathic surgery.* *There is no mention of patients requiring prophylactic surgery for prevention of disease for patient prescribed Radiation therapy (risk osteoradionecrosis) or Bone modulating drugs e.g. bisphosphonates, Rankl inhibitors and others (prevention of osteoradionecrosis)*	Comment noted. Consultees can submit relevant evidence as part of their evidence submissions. The submissions will be considered by the Committee alongside the Assessment Group's report. A clear rationale as to why these subgroups are relevant should be included, and relevant

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		A further subset of patients requiring interventional or interceptive surgery would be a. *those with impacted (any angulation), partially erupted M3Ms that are low risk* b. *periodontal disease of M2M and widespread poorly controlled perio disease* c. *Younger patients where M3Ms are impacted with partial root development likely to involve Inferior dental canal later) with no prospect of M3M eruption into a functional position* Are the outcomes listed appropriate? Are there any other outcomes that should be included? *We would suggest;* • *Dry socket (both single and multiple events)* • *Nerve injury (lingual and inferior alveolar)* • *Osteomyelitis (or persistent infection requiring re treatment)* • *Repeated surgery for failed extraction or complications of coronectomy* • *Jaw fracture* • *High level acute postsurgical pain* • *Persistent pain (may be due to nerve injury or TMD)* • *Wrong site surgery* Are there any other subgroups of people in whom prophylactic removal of third molars is expected to be more clinically effective and cost effective or other groups that should be examined separately? *Patients requiring prophylactic surgery for prevention of disease for patient prescribed radiation therapy (risk osteoradionecrosis) or bone modulating drugs e.g. bisphosphonates, Rankl inhibitors and others (prevention of*	evidence presented. Please see section 5.10 of the Guide to the methods of technology appraisal for details regarding analysis of data for patient subgroups. It should be noted that this topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area. Comment noted. These outcomes would be covered by those listed in the scope, that is, pathology associated with retention of third molars; post-operative complications following extraction; adverse effects of treatment and health-related quality of life.

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		osteoradionecrosis). *A further subset of patients requiring interventional or interceptive surgery would be* *a. those with impacted (any angulation), partially erupted M3Ms that are low risk* *b. periodontal disease of M2M and widespread poorly controlled perio disease* *Younger patients where M3Ms are impacted with partial root development likely to involve Inferior dental canal later) with no prospect of M3M eruption into a functional position.* Do you consider the prophylactic removal of third molars to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)? *Yes we believe that this would be a step change in the management of patients with M3Ms.* *Many patients would benefit from earlier removal of low risk M3Ms to prevent M2M disease and subsequent loss.* *Surgical complications are significantly reduced in patients under 25 years of age. Updating the NICE guidance using evidence base would lower the patient age at surgery and help to minimise all surgical complications.* *Clear guidance on adjunctive medical care will improve antibiotic stewardship*	Comment noted. Consultees can submit relevant evidence as part of their evidence submissions. The submissions will be considered by the Committee alongside the Assessment Group's report. A clear rationale as to why these subgroups are relevant should be included, and relevant evidence presented. Please see section 5.10 of the Guide to the methods of technology appraisal for details regarding analysis of data for patient subgroups. It should be noted that this topic is a partial review of technology appraisal 1 (TA1), that is, of the prophylactic removal of impacted mandibular third molars. It is not a clinical guideline of the entire therapeutic area. Comment noted. Potential innovation can be highlighted

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		and reduce patient risk. *NICE guidance may also contribute to patient safety with recommendations to prevent complications including wrong site surgery and improve reporting or patient safety incidents to thereon continue patient safety.* Do you consider that the prophylactic removal of third molars can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? *This will depend upon the scope and horizon of the analysis.* Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits. • *NRLS* • *StEIS* • *BSA* • *HES* • *Published data on complications*	in any evidence submissions. Comment noted. Potential innovation can be highlighted in any evidence submissions.
	Cochrane Oral Health Group	In order to prevent harm or supervised neglect the standard routing programme of dental care needs to be different for seemingly pathology-free impacted third molars.	Comment noted.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Department of Health

Response to consultee and commentator comments on the provisional matrix of consultees and commentators (pre-referral)

Version of matrix of consultees and commentators reviewed: Provisional matrix of consultees and commentators sent for consultation					
Summary of comments, action taken, and justification of action:					
	Proposal:	Proposal made by:		Action taken: Removed/Added/Not included/Noted	Justification:
1.	Add NHS Education Scotland (NES)	Cochrane Oral Health Group		Added	This organisation has an area of interest closely related to this appraisal topic and meets the selection criteria to participate in this appraisal. NHS Education Scotland has therefore been added to the matrix of consultees and commentators under 'general – commentators'.

2.	Add National Dental Advisory Committee (NDAC)	Cochrane Oral Health Group		Added	This organisation has an area of interest closely related to this appraisal topic and meets the selection criteria to participate in this appraisal. National Dental Advisory Committee has therefore been added to the matrix of consultees and commentators under 'general – commentators'.
3.	Add Scottish Dental Clinical Effectiveness Programme (SDCEP)	Cochrane Oral Health Group		Not Added	This organisation is part of NHS Education Scotland which is already listed on the matrix under 'commentators'. The Scottish Dental Clinical Effectiveness Programme has therefore not been included on the matrix of consultees and commentators.

4.	Include SSPSEG (Surgical Services Patient Safety Group, NHS England)	British Association of Oral Surgeons, Faculty of Dental Surgery (Royal College of Surgeons) and Faculty of General Dental Practice (UK)		Not included	This organisation is a sub-group of NHS England which is already listed on the matrix under 'consultees – other'. SSPSEG has therefore not been included on the matrix of consultees and commentators.
5.	Include patient groups from Trigeminal Nerve Injury Foundation	British Association of Oral Surgeons, Faculty of Dental Surgery (Royal College of Surgeons) and Faculty of General Dental Practice (UK)		Added	This organisation has an area of interest closely related to this appraisal topic and meets the selection criteria to participate in this appraisal. Trigeminal Nerve Injury Foundation has therefore been added to the matrix of consultees and commentators under 'professional groups'.