NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal

Prophylactic removal of impacted third molars (review of TA1) [ID898]

Consultee and commentator comment form

Please use this form for submitting your comments on the draft scope and provisional matrix of consultees and commentators. It is important that you complete and return this form even if you have no comments.

Enter the name of your organisation here:

British Association of Oral Surgeons, Faculty of Dental Surgery RCSEng and Faculty of General Dental Practice (UK)

Comments on the draft scope

The remit is the brief for an appraisal. The draft scope, developed from the draft remit outlines the question that the appraisal would answer (Appendix A).

Please submit your comments on the draft scope using the table below. **Please take note of any questions that have been highlighted in the draft scope itself** (usually found at the end of the document).

If you have been asked to comment on documents for more than one appraisal, please use a separate comment form for each topic, even if the issues are similar.

If you do not have any comments to make on the draft scope, please state this in the box below.

Comment 1: the remit

Section	*Notes*	Your comments
Appropriateness	*It is important that appropriate topics are referred to NICE to ensure that NICE guidance is relevant, timely and addresses priority issues, which will help improve the health of the population. Would it be appropriate to refer this topic to NICE for appraisal?*	**Yes**, It is appropriate for NICE reappraisal.
Wording	*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.*	**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.

Section	*Notes*	Your comments
		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 It is our view that this definition does not entirely reflect what is outlined in the technology section of the draft guidance which states that *'the reasons for prophylactically removing **asymptomatic or pathology-free** impacted third molars could be to reduce the risk of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.
Timing Issues	*What is the relative urgency of this appraisal to the NHS?*	**Currently many patients are currently suffering harm due delayed surgery** unnecessary antibiotic prescription, wrong site surgery and permanent nerve injury due to poor practice.
Any additional comments on the remit 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 2: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	The background information is brief but focuses entirely on prophylactic surgery. Currently prophylactic surgery is indicated if

Section	*Notes*	Your comments
		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.
The technology/ intervention	*Is the description of the technology or technologies accurate?*	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.
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	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.
Comparators	*Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?*	Intervention versus no intervention. Conventional surgery versus coronectomy. Variations of adjunctive medical interventions (steroids, analgesia, antibiotics). Surgical follow up and home-check versus none.
Outcomes	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	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. High level acute post-surgical pain. Persistent pain (may be due to nerve injury or

Section	*Notes*	Your comments
		TMD). Wrong site surgery.
Economic analysis	*Comments on aspects such as the appropriate time horizon.*	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.
Equality	*NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the remit and scope may need changing in order to meet these aims. In particular, 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)] is/are/will be licensed;* • *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;* • *could have any adverse impact on people with a particular disability or disabilities.* *Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.*	Nothing to add. Risk assessment and high risk surgery are limited to specialist practice (oral surgery). 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).
Other considerations	*Suggestions for additional issues to be covered by the appraisal are welcome.*	The essence of all NICE reviews is to maximise patient safety in relation to health interventions. The suggested review concentrates only on

Section	*Notes*	Your comments
		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 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.
Innovation	*Do you consider the technology 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)?* *Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* *Please identify the nature of the data which you*	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

Section	*Notes*	Your comments
	understand to be available to enable the Appraisal Committee to take account of these benefits.	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.
Questions for consultation	*Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).*	See below.

Any additional comments on the draft scope

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*
- *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

Section	*Notes*	Your comments

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 distoangular) M3Ms as all can potentially require therapeutic, interventional or prophylactic removal.

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

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)

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*

Section	*Notes*	Your comments

- *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 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 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*

Section	*Notes*	Your comments
• *BSA* • *HES* • *Published data on complications*		

Comment 3: provisional matrix of consultees and commentators

The provisional matrix of consultees and commentators (Appendix B) is a list of organisations that we have identified as being appropriate to participate in this appraisal. If you have any comments on this list, please submit them in the box below.

As NICE is committed to promoting equality and eliminating unlawful discrimination we are keen to know if we have missed any important organisations from the lists contained within the matrix and which organisations we should include who have a particular focus on relevant equality issues.

If you do not have any comments to make on the provisional matrix of consultees and commentators, please cross this box: ☐

Comments on the provisional matrix of consultees and commentators
SSPSEG (patient Safety surgical group NHS England should be included) *Patient groups from Trigeminal Nerve injury.org.uk*

Comment 4: regulatory issues (for manufacturers to complete) <u>Not applicable</u>

Section	*Notes*	Your comments
Remit	*Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.*	
Current or proposed marketing authorisation	*What are the current indications for the technology?*	
	What are the planned indications for the technology?	
	FOR EACH PLANNED INDICATION:	
	Which regulatory process are you following	
	? What is the target date (mm/yyyy) for regulatory submission?	

Section	*Notes*	Your comments
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable)	
	What is the anticipated date for regulatory approval?	
	What is the anticipated date for UK launch?	
	Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.	
Economic model software	*NICE accepts executable economic models using standard software, that is, Excel , DATA, R or WinBUGs. Please indicate which software will be used. If you plan to submit a model in a non-standard package, NICE, in association with the AG, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the AG with temporary licences for the non – standard software for the duration of the appraisal. NICE reserves the right to reject economic models in non-standard software*	

Please return this form via NICE Docs/Appraisals by 5pm on 17 December 2015