Cancer of the upper aerodigestive tract (update)

Consultation on draft guideline - Stakeholder comments table

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British HIV Association (BHIVA)	General	General	General	Prior to treatment all patients should have an HIV test	Thank you for your comment. HIV testing was not within the scope of this update, and therefore evidence on this was not reviewed, and it was not possible for the committee to make recommendations on this topic. HIV testing is covered by another NICE guideline (NG60): HIV testing: increasing uptake among people who may have undiagnosed HIV
British HIV Association (BHIVA)	General	General	General	Careful attention must be paid to potential drug interactions between antiretrovirals and chemotherapy.	Thank you for your comment. Drug interactions with chemotherapy were not within the scope of this update, and therefore evidence on this was not reviewed, and it was not possible for the committee to make recommendations on this topic. It would be expected that clinicians check drug interactions between antiretrovirals and other medicines as part of the care provided for people with HIV.
British Association of Oral and Maxillofacial Surgeons	Short	7	1.3.5	1. The recommendation that all patients with early oral cancer should undergo surgical staging of the neck does not withstand scrutiny in our view. It is predicated upon an assumption that all patients are at an appreciable risk of occult metastases. A not infrequent occurrence is the finding of a focus (or foci) of early invasive SCC within an extensive area of dysplastic change (<1mm in depth and similar	Thank you for your comments. The recommendations you discuss were not within the scope of this update of the guideline, and therefore no evidence on these topics was reviewed, nor was it possible to make any changes to these recommendations. However, the

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				diameter. The risk of further primary SCC outweighs the risk of occult metastases and surgery to the neck is likely to alter patterns of lymphatic drainage and complicate management of subsequent primary cancers. This is reflected in the NICE sensitivity analysis where watch and wait was the strategy having the greatest cost-utility when the risk of occult metastasis was <15%. The U.S. NCCN Guidelines advocate observation with a DOI <2mm. Our limited data support the latter approach. Of 113 patients undergoing SLNBx 31 have been pN+ve of which only 1 had a DOI of <2mm. The denominator value is 29 (the number of patients undergoing SLNBx with a DOI <2mm) giving a risk of occult metastasis of 3 to 4% in this group. In equal measure, a number of patients with early oral cancer present with significant frailty and/or advanced co-morbidity rendering them unable to withstand radical radiotherapy; fit only for a limited surgical intervention. The identification of occult metastases in this group exposes the individual to increased risk for no proven benefit. The wording of the recommendation should reflect these realities of clinical practice in our view. 2. Only those patients who are pN0 derive benefit from SLNB. Those who are pN+ve would have been better served by undergoing an elective lymphadenectomy at the outset. The decision to employ SLNB therefore should be in those where it is more likely that they do not harbor occult	information you have cited has been passed to the NICE guideline surveillance team for consideration when future updates of the guideline are being considered.

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				metastatic disease. The precise threshold for this is not clear in our view and, as Professor McGurk points out, patient preference should play a significant role here. How big a role is yet another example of the tension that exists between individual autonomy and utilitarian ethical considerations in a 3rd party payer healthcare system. The NICE cost-utility analysis sets this level at a threshold that includes the majority of patients. It is our view that the 8th edition UICC TNM staging rules is helpful in this respect. Of eight patients with a depth of invasion greater than 10 mm six had occult metastases present and we think would have been better served by an initial lymphadenectomy. For those patients with a T1 tumour on 8th edition rules just under 20% had occult metastases and represents an appropriate level of risk in our view. 3. I do not think that some of the assumptions upon which the NICE cost-utility analysis was made stand up to scrutiny. SLNB as it applies to oral cancer is not directly comparable to that used in breast ca. where lymphoscintigraphy is seldom employed. All patients undergoing SLNB for oral cancer undergo imaging and most will have SPECT-CT. Some departments advocate dynamic lymphoscintigraphy as well as planar imaging involving further scan time. Our protocol has been to advocate further lymphadenectomy in sn+ve patients only where further pathological findings would influence the choice of adjuvant therapy. Even this conservative approach more than half of the sn+ve patients will have further neck surgery extending the overall duration	

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				of treatment and exposing patients to further risk of surgical complications as well as increased costs. Further lymphadenectomy procedures have not been shown to improve survival in melanoma of breast ca. and are less commonly advocated in the latter. When the current SLNB service for early oral cancer in Glasgow, building on work carried out by the Canniesburn unit since the 1990's, was initiated in 2009-2010 our ambition was to use the same protocol for pathological assessment as had been used for research purposes in Glasgow, and in the SENT trial. However, as a service provision the pathology department was unable to resource that protocol estimating that it would require a medical laboratory scientific officer an entire day to prepare the slides for examination by a histopathologist when a metastasis was not apparent early in the assessment process. Having undertaken a survey of the literature at the time the pathologists determined that there was no worldwide consensus around that protocol. They have provided us with the same pathological assessment as applied to sentinel lymph nodes assessed das part of the management of breast carcinoma. The false negative rate associated is 8%- comparable to case series that have employed the research protocol for pathological assessment. It is likely that the best practice document for the uptake of SLNB in early oral cancer for the UK will recommend the SENT protocol. It is not clear whether this is deliverable across the NHS and is considerably more costly	

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				than that associated with SLNB for breast ca. and melanoma. 4. Professor Mark McGurk and Dr Clare Schilling have convened an international consensus conference on the use of SLNB in early oral cancer over the next couple of weeks. An extension to the consultation period by a month would be useful until the deliberations of that meeting take place. 5. Professor Mark McGurk, Dr Clare Schilling, and Professor Richard Shaw have proposed a randomized controlled trial assessing the value of SLNB in patients in early oral cancer. The procedure is at a stage in development when an RCT is required and their efforts should be supported. That effort might be given impetus if the NICE Guideline recognized the absence of level 1 evidence assessing the value of SLNB in early oral cancer and made a research recommendation accordingly. Further to Mr McMahons summary I think it is also worth noting that there is an assumption in the current guideline that SLNB is 'better for patients' than an elective neck dissection. The evidence on functional outcomes and HRQoL of cervical SLNB vs elective neck dissection is sparse, under powered and contradictory. There is a paucity of evidence to support or refute a clinically significant difference in these outcomes between the two techniques.	

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				This is complicated further by the fact that those staged SLNB positive may be disadvantaged by a SLNB approach. Given this, as well as the resource issues and other points mentioned above, ideally there should be some evidence of benefit to patients (at least to those staged SLNB negative) if a SLNB approach is to be recommended. Again, the situation in head and neck is different than in breast, where axillary dissections can be associated with significant morbidity (lymphoedema etc). We know that the HRQoL outcomes after selective neck dissection are generally very good (but not perfect). OSCC patients may not have the same ability to benefit from SLNB as those with cancer in other sites. I am currently an ST In Liverpool and am studying an MD on this topic with Prof Shaw, Mr A Schache and Mr S Rogers and will be looking at patients from Liverpool, Glasgow and London to investigate this issue. The research protocol will be presented at the SLNB consensus meeting next week. I think it important that NICE recognise the limited evidence of patient benefit when making its decision.	
British Association of Oral and Maxillofacial Surgeons	Short	13	1.9.4	My other concern on this NICE guidance draft is on ORN, which it recommends neither HBO or medical therapy unless in a clinical trial setting. I am sure it will put us in a very difficult position, when most drug and therapeutic committees in primary and secondary care are declining to fund pentoxifylline and vitamin E.	Thank you for your comments. The recommendations you discuss were not within the scope of this update of the guideline, and therefore no evidence on these topics was reviewed, nor was it possible to make any changes to these

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				I understand that Professor Shaw and others are planning a national trial and I feel that it is premature for NICE to publish a statement of this kind at this stage.	recommendations. However, the information you have cited has been passed to the NICE guideline surveillance team for consideration when future updates of the guideline are being considered.

**None of the stakeholders who commented on this clinical guideline have declared any links to the tobacco industry.*

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