Thyroid cancer: assessment and management

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Bayer plc	4	22	We agree that recommendations from NICE technology appraisal guidance 535, Lenvatinib and sorafenib for treating differentiated thyroid cancer after 23 radioactive iodine (2018), should be cross-referred to in this clinical guideline.	Thank you for your comment.
British Association of Head and Neck Oncology Nurses	General	General	'Treatment for people with medullary thyroid cancer, anaplastic thyroid carcinoma, multiple endocrine neoplasia type 2, or thyroid lymphoma'. Poorly differentiated thyroid cancer, mixed disease patterns (e.g. papillary thyroid cancer with anaplastic components) and dual diagnoses (e.g. FTC and MTC concurrently) 5.2 CNS support Which isotope to use for radioisotope scans – I131 or I123 – and the concern of potential thyroid stunning with I131 scans (3.5 1.2, p6).	Thank you for your comments. We have reviewed the inclusion of treatment for people with cancers other than differentiated cancers. We have not prioritised these as management pathways are different and their inclusion would mean insufficient time was available for developing an adequately comprehensive and detailed guideline for differentiated thyroid cancer, the most prevalent type. The guideline will review information and support needs in Q5.1 (information and support needed by patients, carers and families). We recognise that this may currently be provided by nurse specialists and will make reference to this if the evidence allows this. Thank you for the information about radioisotopes. We will discuss the detail of radioisotopes with GC when developing the review protocol.

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British Dietetic Association	General	General	This appears to be a robust scoping document covering all elements of clinical treatment in thyroid cancer. There is emerging evidence about Prehabilitation/ ERAS prior to surgery improving outcomes including reducing length of stay, improving quality of life and having fewer treatment interruptions. Is this something that should be considered within this scoping paper?	Thank you for your comment. The issue of rehabilitation is not specific to thyroid cancer surgery so has not been prioritised for inclusion.
British Dietetic Association	2	8	? adding unconfirmed thyroid cancer	Thank you for your comment. We are unsure what this comment refers to. Whilst fine needle aspiration or biopsy can lead to ambiguous results in some, the majority of people are diagnosed.
British Dietetic Association	8	3	? adding malnutrition	Thank you for your comment. The list of outcomes is not exhaustive and the committee can add outcomes to individual questions as required. We consider that current inclusion of dysphagia will pick up issues related to swallowing and secondary nutrition issues.
British Nuclear Medicine Society	1	21	Treatment is by total or rarely partial (hemi)	Thank you for your comment. We have clarified the wording as you indicate.

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British Nuclear Medicine Society	3	20	Radioisotope scan options should probably be Iodine-123, 99mTechnetium **pertechnetate (99mTc04-)** and technetium MIBI scans. The radiation dose from thallium imaging is very high and no longer justified and has not been used in clinical practice for 20 years. Also it is more expensive than technetium MIBI	Thank you for your comment. We have added iodine 123 to the text. The purpose of the guideline is to evaluate all available data and provide recommendations based on evidence of safety, as well as clinical efficacy and cost-effectiveness. We can only legitimately recommend that something should not be used if we have evaluated it which is why thallium is included in scope.
British Nuclear Medicine Society	3	27	A real issue in 2020 is what to do with a suspected incidental thyroid cancer seen on FDG PET-CT done for another indication. This is a fairly common occurrence and should be addressed	Thank you for your comment. Patients with such findings would fit into the population covered by this guideline and so would be covered by the diagnostic pathway in this guideline.
British Nuclear Medicine Society	4	6-10	Radioiodine is given to ablate the remnant, as adjuvant treatment and treatment of known metastatic disease. Ablation of remnant should also be added as not mentioned or considered in the draft scope. Dynamic Risk Stratification should be added The current BTA guidelines use Dynamic risk stratification 9 months after RAI. For this US and Tg are used. However, it is not clear why only local imaging modality of the neck (US)	Thank you for your comment. We recognise that radioactive iodine has a number of purposes when used in the treatment of thyroid cancer. We are using the term 'residual' rather than 'remnant' in the scope. Question 4.2 covers dynamic risk stratification but does not specify specific modalities to allow

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			rather than WB imaging (WB iodine scan) is used for the assessment of recurrence/residual disease. Treatment is given by radioactive iodine and DRS should therefore be performed by 123 iodine scan, US and Tg (particularly in patients who had iodine positive disease after the first treatment - ablation).	the committee to inform the review questions with their expertise.
British Nuclear Medicine Society	4	11-15	Thyroglobulin (Tg) and anti Tg antibodies should be measured, including non-supressed measurements (on RTSH or off Thyroxine)	Thank you for your comment. We have added a question on testing for these to the scope.
British Nuclear Medicine Society	4	1-4	This needs to be risk stratified by initial size, histological grade, patient age and gender	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
British Nuclear Medicine Society	4	9, 10	Who should get radioiodine this needs to be risk stratified by iodine avidity, initial size, histological grade, patient age and gender and subsequent treatment by dynamic risk startifications using iodine scitigraphy and not just US In selecting patients for RAI therapy, demonstration of iodine avidity and cancer spread using RAI scintigraphy represents the core principle of radiotheragnostic approach that should guide personalised management instead of relying on less	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.

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			of a direct evidence for disease risk, such as the size of the primary.	
British Nuclear Medicine Society	6	12-20	When is it acceptable to do a core biopsy and when should a FNAC be performed	Thank you for your comment. We are asking a more fundamental question in this guideline – in **all** people with suspicious signs on US, which is the better follow-on diagnostic strategy – FNA or core biopsy? By having different population strata we may be able to discern the groups for whom FNAC or core biopsy are more appropriate.
British Nuclear Medicine Society	6	25-27	This needs to be risk stratified by initial size, histological grade, patient age and gender with a particular emphasis on stage 1 cancers	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
British Nuclear Medicine Society	6	31-33	Again this needs to be looked at by risk stratified by initial size, histological grade, patient age and gender	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
British Nuclear Medicine Society	6	23	Now there are a range of PET radiopharmaceuticals available this should be defined as FDG PET	Thank you for your comment. We will finalise the wording of the questions with the guideline committee.

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British Nuclear Medicine Society	7	7-9	This is vital and the risk of continuing hyperphysiological doses of thyroxine increasing risk of osteoporosis and secondary cancer needs to be weighed against recurrent cancer risk	Thank you. We will weigh up the benefits and harms during the systematic review.
British Nuclear Medicine Society	7	1	What is meant by the word 'dose'. Does this mean the activity given to the patient normally measured in Bq or the received dose as calculated by radiation dosimetry measured in Gy. It is vital this is clear	Thank you for this comment. When finalising the protocol for this review question we will ensure that the parameters of the dose are clear.
British Society for Paediatric Endocrinology and Diabetes	general	general	And actually, one thing to feedback is why is this only for >16s? We probably see one thyroid cancer every couple of years and always liaise with our adult colleagues and follow their treatment protocols. There are no NICE guidelines for children with thyroid cancer, so why not include them?	Thank you for your comment. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists**)** and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a different committee constituency than those for adult guideline and additional review questions which is not feasible within the timeline for the guideline.

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British Society for Paediatric Endocrinology and Diabetes	general	general	I suspect the evidence is rather thin for children < 16 years old. The guidance could still be used for younger children. I'd like the committee to review evidence on screening for thyroid cancer and investigations for persistent, asymptomatic and asymmetric goitres with normal thyroid function.	Thank you for your comment. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists) and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a different committee constituency than those for adult guideline and additional review questions which is not feasible within the timeline for the guideline. The guideline will assess the accuracy of ultrasound in assessment of thyroid nodules and will make recommendations where possible in this area. The NICE guideline on Thyroid disease: assessment and management has made recommendations on assessment of thyroid enlargement and when assessment should be repeated: https://www.nice.org.uk/guidance/ng145/chapter/Recommendations#diagnosing-managing-and-

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				monitoring-thyroid-enlargement-with-normal-thyroid-function
British Thyroid Foundation	3	7	The equality impact assessment confirms that there may be equality issues in respect of pregnancy and maternity which affect both men and women. This section could therefore include reference to fertility, pregnancy and maternity so that guideline users are clear that these groups of patients are covered.	Thank you for your comment. The current wording is for the scope only. The final guideline will make separate recommendations for people in these groups if that is necessary and ensure it is clear who is included.
British Thyroid Foundation	6	4	We often hear from patients who feel they have had worrying delays in their diagnosis because their GP hasn't recognised that their symptoms (lump, swallow problems etc.) are appropriate for referral. Since this guidance is also aimed at primary care doctors this section should include information that may help GPs assess when to refer a patient who presents with symptoms that warrant investigation.	Thank you for your comment. The recommendations on assessment of thyroid nodules will be relevant to primary care.
British Thyroid Foundation	7	22-24	The role of the clinical nurse specialist is crucial as a point of contact, reassurance and as a source of reliable information in between clinical appointments. We recommend that so far as possible patients are given appropriate verbal and written information at each stage of	Thank you for your comments and this information.

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			their diagnosis and treatment and follow up appointments. Patient organisations (whose information is endorsed by NHS recognised thyroid experts) can provide practical and peer support that is often not available from medical professionals. If they are not signposted to these organisations many patients will seek information from the internet which can be confusing, frightening and misleading. In particular patients need information to understand the risks of surgery and how to minimise them, how to prepare for RAI treatment and comprehensive advice about the low iodine diet. Since patients are likely to need lifelong levothyroxine treatment the implications of how this may impact on their lives should be discussed and appropriate information should be shared with them.	
National Cancer Research Institute	General	General	We feel it would be useful to include specific comment on the management of thyroid cancer presenting in pregnancy as this is a not uncommon scenario given the age group affected by thyroid cancer. Thyroid cancer management during pregnancy requires specific management for some issues including: postponing surgery even for U5/Thy5 lesions until after delivery with monitoring of the thyroid cancer, specific considerations relating to timing of administration of ablative 131-I in relation to breastfeeding, TSH targets during pregnancy etc. This needs to be addressed specifically or pregnancy needs to be excluded from the scope	Thank you for your comment. Women who are pregnant are not excluded from the scope and will be considered when we are making recommendations.

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National Cancer Research Institute	General	General	We feel that it would be appropriate to include or at least reference alternative guidance on the management of post-operative hypoparathyroidism, a potential complication of thyroid cancer surgery which causes significant long term morbidity. This should be included in the main outcomes (section 3.6 p7) alongside postoperative dysphagia which, in our experience, is a less significant problem. Vocal cord palsy should also be included in this section.	Thank you for your comments. We agree that post-operative hypoparathyroidism can cause long term morbidity. Hypoparathyroidism and post-operative changes in voice have now been added to the outcomes considered in each question. We do not plan to include management of hypoparathyroidism.
National Cancer Research Institute	General	General	We have some concerns about the composition of the proposed panel. In particular given the emerging importance of molecular pathology in this field we feel that including someone with expertise in this area will be essential. The panel currently appears to be heavily represented by surgeons, less so by oncologists/endocrinologists, groups that play a key role in the management of these patients in the UK.	Thank you for your comment. We will co-opt specialised expertise for specific meetings when it is needed such as for molecular pathology. The committee composition does include endocrinology and oncology. However early assessment, diagnosis and treatment is largely carried about by surgeons and this is an important part of the guideline scope.

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National Cancer Research Institute	2	15	It is confusing to include targeted therapies (tyrosine kinase inhibitors) as adjuvant therapy. A clear distinction should be made between postoperative adjuvant therapy which would include radioactive iodine and external beam radiotherapy and palliative treatments for advanced incurable disease which would include tyrosine kinase inhibitors.	Thank you for your comment. We have changed the wording to reflect this. Reference to TKIs has now been made separately in the context of targeted therapy for recurrent disease.
National Cancer Research Institute	3	8	We note that children have been specifically excluded from this guideline. This is of concern to us. Thyroid cancer is very rare in children, outcomes are generally good but management is complex and recognised to vary widely, as documented in a recent publication - K.A. Lee, M.T.A. Sharabiani,D. Tumino, J. Wadsley, V. Gill, G. Gerrard, R. Sindhu, M.N. Gaze, L. Moss. K Newbold 2019. Differentiated Thyroid Cancer in Children: A UK Multicentre Review and Review of the Literature. Clinical Oncology 31(6); 385-90. Paediatric patients in many centres are managed at the very least with the support of adult thyroid cancer teams due to the specific nature of the treatments (in particular radioactive iodine). We feel that this guideline presents an opportunity to standardise the management of these patients and to ensure that all children with thyroid cancer in the UK have the best chance of cure with the lowest chance of side effects from unnecessary treatment.	Thank you for your comment. We acknowledge your view regarding the exclusion of people 16 years and under. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists) and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a different committee constituency than those for adult guideline and additional review questions which is not feasible within the timeline for the guideline.

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National Cancer Research Institute	4	6	Treatment of residual, late metastatic or recurrent thyroid cancer should include surgery and tyrosine kinase inhbitors.	Thank you for your comment. This section (3.3) covers the areas this guideline will review. The use of tyrosine kinase inhibitors is covered by NICE technology appraisals. We will not review the evidence for these but they are included in the overall pathway.
National Cancer Research Institute	6	4	With regard to the use of ultrasound in the assessment of thyroid nodule, specific consideration should be given to the use of categorised reporting- eg the U classification.	Thank you for your comment and this suggestion. The question will assess diagnostic accuracy and we do expect the U classification to be part of the assessment and discussion by the guideline committee.
National Cancer Research Institute	6	8	Clarification is required as to what is meant by 'potentially malignant' nodules- does this refer to a U category on USS?	Thank you for your comment. We have changed the wording of here as the term "potentially malignant on ultrasound' was not helpful.
National Cancer Research Institute	6	16	A clear distinction needs to be made here between 'benign cytology' (Thy2) and 'non-diagnostic atypical features' (Thy3a) due to the significantly different risk of malignancy between these groups.	Thank you for your comment. The detail of the questions will be agreed by the guideline committee.

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National Cancer Research Institute	6	19	FNA is not able to 'suggest' follicular cancer, but merely suggests a follicular lesion or follicular neoplasia. This should be amended to the role of molecular testing to diagnose or rule out thyroid cancer in nodules with Thy3F cytology. It would also be appropriate to consider the value of molecular testing for other indeterminate categories, including Thy3a and Thy4.	Thank you for your comment. The detail of the questions will be agreed by the guideline committee.
National Cancer Research Institute	6	24	No mention is made in either section 2 (initial treatment) or section 3 (further treatment) of the importance of risk stratification in deciding on the most appropriate treatment for an individual patient. It is essential that this is considered and included since both the immediate and long-term management of differentiated thyroid cancer is based on risk stratification world-wide. It would also be useful to include guidance on the management of particularly high risk groups such as those with adverse histopathological features (eg tall cell papillary carcinoma, poorly differentiated carcinoma).	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
National Cancer Research Institute	6	25	This question fails to recognise that a proportion of patients (those with follicular cancers) will not have a diagnosis of thyroid cancer before their definitive treatment (lobectomy or total thyroidectomy) because it is not possible to make a diagnosis without examining the whole lesion histologically. Guidance could be given as to when lobectomy or total thyroidectomy are most appropriate and when additional investigations (eg core biopsy) might help in decision making.	Thank you for your comment.The question is currently worded to make clear that the intended population are those with differentiated cancers. We recognise that this includes people whose diagnosis may not be final. Earlier questions include potential additional investigations such as core biopsy.

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National Cancer Research Institute	6	25	It is unclear if the terms prophylactic and or therapeutic node dissection relate to central compartment or lateral neck dissection and if a distinction will be made	Thank you for your comment. The guideline committee will agree the final details of the question.
National Cancer Research Institute	6	28	Section 3 is confusing and muddled. It would be better to separate this into 1. Adjuvant therapy for patients who have had complete resection (this would include questions about optimal administration of radioiodine ablation therapy and appropriate use of external beam radiotherapy in the adjuvant setting) Therapy for residual, metastatic or recurrent thyroid cancer which would include further surgery, radioiodine therapy, external beam radiotherapy and targeted agents (tyrosine kinase inhibitors)	Thank you for your comment. We have amended the scope structure to reflect this.
National Cancer Research Institute	6	31	3.1: Is this for people who have had a total thyroidectomy only?	Thank you for your comment. This question is for any total thyroidectomy, hemi thyroidectomy or lobectomy that was followed by RAI. We will be stratifying for the different procedures.
National Cancer Research Institute	7	1	Reference is made to the optimal 'dose' of radioactive iodine. It is not clear whether this is referring to the activity of radioactive iodine administered or the absorbed dose to a target. It would also be useful to include comment on the value of dosimetry in radioiodine therapy to guide therapy, and whether there is any role for pretreatment imaging (eg with I123) to allow dosimetrically guided treatment. As per the comment above, separate guidance should be given	Thank you for this comment. When finalising the protocol for this review question we will ensure that the parameters of the dose are clear.

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			regarding use of radioactive iodine ablation in the adjuvant setting and use of radioiodine therapy in advanced disease.	
National Cancer Research Institute	7	6	Section 4 is very difficult to follow since no consideration is given to clear distinction between different treatment groups i.e. those who have had lobectomy, total thyroidectomy without radioiodine and total thyroidectomy with radioiodine. See also our comment above on risk stratification	Thank you for your comments. Stratification will be introduced into each systematic review protocol taking into account all these issues.
National Cancer Research Institute	7	7	4.1: reference is made to radioiodine treatment: does this mean ablation or therapy – the term used for radioiodine administration in those with recurrent, residual or metastatic disease	Thank you for your comment. We intend it to cover both situations.
National Cancer Research Institute	7	7	4.1: it is better to talk about TSH targets. Levothyroxine is not just used for TSH suppression but replacement treatment with levothyroxine is required and specific TSH targets are recommended by all national and international guidelines	Thank you for this comment. We are particularly interested in TSH suppression in this question. NICE already has guidance on thyroxine when used for replacement.
National Cancer Research Institute	7	10	4.2: No mention is made of whether thyroglobulin is stimulated or not.	Thank you for your comment. We will stratify for stimulated, non-stimulated and highly sensitive assays.
National Cancer Research Institute	7	14	4.3: does this section relate to all patients, i.e.those who have had a hemithyroidectomy, total thyroidectomy or total thyroidectomy + radioiodine ablation?	Thank you for your question. This section refers to all patients but appropriate stratification will be introduced into the question protocol as appropriate.

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National Cancer Research Institute	7	19	4.4: this question does not specify the type of follow-up: the use of thyroglobulin measurement, frequency of imaging, different TSH targets depending on risk stratification. It appears that the clinical and cost-effectiveness of these will only be assessed at 1-2 years post initial treatment whereas these are important issues to be addressed in the longer term management of patients	Thank you for your comment. We anticipate that review questions 4.2 and 4.3 will allow the committee to make recommendations in the areas you suggest.
National Cancer Research Institute	8	3	Osteoporosis is listed as a potential outcome, presumably secondary to TSH suppression. It would be appropriate to include cardiovascular adverse effects as these are also a significant problem.	Thank you for this comment – we have now added cardiovascular disease as a new outcome.
Parathyroid UK	1	1.12	We have seen younger and older patients with thyroid cancer (ie 8 – late 70's)	Thank you for your comment. We have changed the wording to reflect this.
Parathyroid UK	1	1.18	The rise in thyroid cancer has led to a significant rise in post-surgical hypoparathyroidism	Thank you for your comment. We have added hypoparathyroidism to the list of outcomes on page 8 to ensure this is included.
Parathyroid UK	1	1.24	And possibly without parathyroid glands either due to 10% risk of permanent post- surgical hypoparathyroidism.	Thank you for your comment. Adverse effects of surgery will be an outcome in the relevant reviews questions. We have added hypoparathyroidism to the list of outcomes on page 8.

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Parathyroid UK	1	1.25	The long-term implications of post surgical hypopara include lifelong treatment with active vitamin D analogues, vitamin D, calcium and magnesium supplements (and replacement parathyroid hormone when available.)	Thank you for your comment. Adverse effects of surgery such as these will be an outcome in the relevant review questions. We have added hypoparathyroidism to the list of outcomes on page 8.
Parathyroid UK	2	1.10	Choice of surgery also depends on risk to parathyroids eg in central neck dissection	Thank you for your comment. Adverse effects of surgery such as these (hypoparathyroidism) will be an outcome in the relevant review questions comparing treatments.
Parathyroid UK	2	1.15	RAI can also damage parathyroid glands	Thank you for your comment. Adverse effects of RAI such as these will be an outcome in the relevant review questions (hypoparathyroidism).
Parathyroid UK	2	1.3	A need for re-operation increases risk of damage to parathyroid glands	Thank you for your comment. Hypoparathyroidism has been added as an outcome.
Parathyroid UK	3	3.3.17	Pre -surgery: informed consent -risks of surgery especially to parathyroid glands MUST be discussed with patient and further patient information given at this point. Hypoparathyroidism pre-surgery preventative treatment	Thank you for your comment. We have a review question aimed at evaluating the information

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			should include correction of vit D deficiency. Any modifiable risks should be considered.	required by patients, their families and their carers.
Parathyroid UK	4	1	Consider whether central neck dissection really necessary as this increases risk of hypoparathyroidism.	Thank you for your comment. Question 2.1 will look at the benefits and harms of the different forms of surgery, which will allow recommendations that consider these issues.
Parathyroid UK	4	9	Consider RAI risk to parathyroid glands	Thank you for your comment. The adverse effects of therapies will be included in all review questions, and will be considered when making recommendations. Hypoparathyroidism has now been added to the list of outcomes on pages 7-8.
Parathyroid UK	4	11	There MUST be immediate postop short term monitoring for early detection of post op hypo/hypercalcaemia symptoms, and treatment if necessary. Patients must be given advice on what to look out for, who to contact in an emergency and when to return for follow up (ie sooner than usual). Immediately post op is a very critical time – all healthcare	Thank you for this comment. The guideline will cover information and support for patients at different stages of assessment and treatment.

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			professionals should be aware of the Society for Endocrinology acute emergency treatment guidelines and symptoms of hypocalcaemia.	
Parathyroid UK	4	11	Long term monitoring and treatment of permanent hypoparathyroidism. Consider frequency and duration of monitoring, who should monitor and how (bloods, urine and imaging). Maintenance of calcium, phosphate, magnesium and vit D homeostasis is challenging and needs close supervision and frequent monitoring by blood test. This is a life threatening, lifelong condition that needs careful management and referral to an expert calcium specialist. Refer to ESE hypoparathyroidism guidelines.	Thank you for this comment. The risks and outcomes from surgery including hypoparathyroidism are included in the guideline. The long term management of hypoparathyroidism and other complications will not be covered due to different expertise and evidence that would be required to inform this.
Parathyroid UK	4	16	AND post surgical hypoparathyroidism as well! Extremely important that patients receive patient information leaflets and are signposted to the Parathyroid UK patient support group.	Thank you for your comment. We have included a question on the information required by patients, their families and their carers.
Parathyroid UK	5	2	Any surgical advice in these guidelines also needs to refer to risks of post surgical hypoparathyroidism re pre op advice, follow up , monitoring and advice/consent to patients.	Thank you for your comment. We will consider adverse effects in the intervention review questions and we are also conducting a review evaluating the information required by patients, their carers and their families.

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Parathyroid UK	6	24	How, during initial treatment of hemi or total thyroidectomy, are identification and preservation of the parathyroid glands going to be considered to reduce the risk (and cost) of inadvertent removal and consequent lifelong treatment of life threatening hypoparathyroidism and the dramatic reduction in quality of life this leads to? This should always be considered at any point where the necessity/severity of an operation is in doubt.	Thank you for your comment. We have added 'hypoparathyroidism' as an outcome to ensure this potential adverse event is considered. The detail of surgical technique is outside the scope of a NICE guideline
Parathyroid UK	7	2	Consider possible detrimental effect of RAI on parathyroid glands	Thank you. Hypoparathyroidism has been added as an outcome and so this will be considered in all review questions where appropriate.
Parathyroid UK	7	23	The possibility and true incidence rate of post surgical hypoparathyroidism need to be fully discussed PRIOR to an operation. The patient, their family and carers need to be well informed of all the risks, what symptoms to look out for, who to contact, what to do in an emergency. This is a challenging and life threatening condition and patients will need lifelong treatment and ongoing and emergencysupport. They need to have patient information leaflets on how to manage their condition and be signposted to the parathyroid UK telephone helpline, website and support group.	Thank you for your comment and suggestions for what should be included in the recommendations.
Parathyroid UK	7	25	Permanent post surgical hypoparathyroidism is a serious and lifelong main outcome. The incidence of post-surgical hypoparathyroidism is unknown in the UK but probably affects at least 14,000 people in the UK. It can happen in about 30% of operations to the neck although most of these	Thank you for this comment – we have now added hypoparathyroidism' as a new outcome.

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			cases will be temporary, lasting up to 6 months. However, in around 10% of cases, hypoparathyroidsm will be permanent. This is a significant risk which cannot be ignored.	
Royal College of General Practitioners	3	17	Can the committee consider adding clinical examination to the assessment adding the need for a primary care 2 week wait referral for suspected thyroid cancer with any unexplained thyroid lump as per NICE NG12 to ensure the full pathway from initial presentation to diagnosis is covered in one guideline	Thank you for your comment. The current scope includes the accuracy of ultrasound which will inform the recommendations on urgency of referral. We are aware of potential overlap with NG12 and NG145 (Thyroid disease).
Royal College of General Practitioners	3	17	Can the committee define which, if any situations would be appropriate for a primary care clinician to organise thyroid ultrasound scanning in the assessment of thyroid abnormalities	Thank you for your comment. The current scope includes the accuracy of ultrasound which will inform the recommendations on urgency of referral and therefore when/if ultrasound scan should be organised in primary care. We are aware of potential overlap with NG12 and NG145 (Thyroid disease).
Royal College of General Practitioners	4	11	Can the committee include the expected frequency of TSH measurement in follow up of thyroid cancer patient to be undertaken in primary care, as these patients will be under the care of their GP for the rest of their life, often without on-going intensive secondary care follow up	Thank you for your comment. The guideline does include a question of frequency and method of follow up which will inform this area.

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Royal College of Nursing	General	General	Thank you for the opportunity to contribute to this guideline. The RCN does not have any comments to add on this occasion	Thank you for your comment.
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond the above consultation. We would like to endorse the responses submitted by the Association of British Clinical Diabetologists (ABCD), the BNMS, and the NCRI Thyroid Cancer Subgroup. We would also wish to make the following comments from the perspective of Nuclear Medicine. We are grateful to Dr Stefan Voo, Dr John Buscombe and Dr Sabina Dizdarevic for coordinating the below.	Thank you.
Royal College of Physicians	1	21, 22	Radioactive iodine treatment is commonly recommended/performed after total thyroidectomy and only rarely after partial (hemi-) thyroidectomy.	Thank you for your comment. We have replaced 'often' with 'sometimes' to reflect this.
Royal College of Physicians	3	20	Radioistope scan options should probably be ^{123}Iodine, ^{99m}Technetium pertechnetate ($^{99m}Tc^{04-}$) and ^{99m}Technetium SESTAMIBI scans. The radiation dose from thallium imaging is very high and no longer justified and has not been used in clinical practice for 20 years. Also it is more expensive than all ^{99m}Technetium-labeled tracers and scans.	Thank you for your comment. . We have added iodine 123 to the text. The purpose of the guideline is to evaluate all evidence and provide recommendations based on safety, as well as clinical efficacy and cost-effectiveness. We can only legitimately recommend that something should not be used if we have evaluated it which is why thallium is included in scope. .

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Royal College of Physicians	3	27	A real issue in 2020 is what to do with a suspected incidental thyroid cancer seen on FDG PET-CT done for another indication. This is a fairly common occurrence and should be addressed.	Thank you for your comment. Patients with such findings would fit into the population covered by this guideline and so would be covered by the diagnostic pathway in this guideline. .
Royal College of Physicians	4	1-5	The initial treatment of thyroid cancer should be risk stratified by initial size, histological grade, patient age and gender.	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
Royal College of Physicians	4	6-9	Who should get radioactive iodine needs to be risk stratified by iodine avidity, initial size, histological grade, patient age and gender and subsequent treatment by dynamic risk stratifications using iodine scintigraphy and not just ultrasound (US). Please note that demonstration of iodine avidity and cancer spread using radioactive iodine scintigraphy represents the core principle of radiotheragnostic approach that should guide personalised management instead of relying on less of a direct evidence for disease risk, such as the size of the primary.	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
Royal College of Physicians	4	13	Thyroglobulin (Tg) and anti Tg antibodies should be measured for Follow-up and monitoring purposes, including	Thank you for your comment. The scope has been amended to clarify this.

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			also non-suppressed measurements (on recombinant TSH or off Thyroxine)	
Royal College of Physicians	6	12-21	When is it acceptable to do a core biopsy and when should a FNAC be performed?	Thank you for your comment. We are asking a more fundamental question in this guideline – in **all** people with suspicious signs on US, which is the better follow-on diagnostic strategy – FNA or core biopsy? By stratifying for different population groups defined by particular characteristics (decided on the basis of biological plausibility pre-hoc to reduce bias) we may be able to discern the groups for whom FNAC or core biopsy are more appropriate.
Royal College of Physicians	6	25-27	This needs to be risk stratified by initial size, histological grade, patient age and gender with a particular emphasis on stage 1 cancers.	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
Royal College of Physicians	6	31-33	This needs to be looked at by risk stratified by initial size, histological grade, patient age and gender.	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.

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Royal College of Physicians	6	23	Now there are a range of PET radiopharmaceuticals available. This should be defined here clearly as FDG PET (^{18}F-labeled fluorodeoxyglucose PET).	Thank you for your comment. We will finalise the wording of the questions with the guideline committee.
Royal College of Physicians	7	14-21	Dynamic Risk Stratification should be added. The current British Thyroid Association Guidelines use Dynamic Risk Stratification 9 months after radioactive iodine. For this US and Tg are used. However, it is already well-accepted that, besides local imaging modality of the neck (US), whole body iodine imaging should be used for the assessment of recurrence/residual disease. Treatment is given by radioactive iodine and Dynamic Risk Stratification should therefore be performed by ^{123}Iodine scan, US and Tg (particularly in patients who had iodine positive disease after the first treatment - ablation).	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
Royal College of Physicians	7	1-3 4, 5	Radioactive iodine treatment is indeed given for patients after thyroidectomy for differentiated thyroid cancer. However, radioactive iodine is given also to ablate residual disease after thyroidectomy, as adjuvant treatment, and also as potentially curative treatment of known metastatic or recurrent disease. This should be considered also in the draft scope, besides the external beam radiotherapy.	Thank you for this comment. We will be including these different populations when examining the evidence.
Royal College of Physicians	7	7-9	The risk of continuing hyperphysiological doses of thyroxine, including an increasing risk of osteoporosis and secondary cancer, needs to be weighed against recurrent cancer risk.	Thank you for this comment. We will weigh up the benefits and harms during the systematic review.

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Royal College of Physicians	7	1	Please clarify what is meant here by the word 'dose'. Does this mean the activity given to the patient normally measured in Bq (Becquerel) or the received radiation dose as calculated by radiation dosimetry measured in Gy (Gray).It is vital this is clear!	Thank you for this comment. When finalising the protocol for this review question we will ensure that the parameters of the dose are clear.
Royal College of Physicians and Surgeons of Glasgow	General	General	The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the United Kingdom. While NICE has a remit for England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments. The College welcomes this draft Scope on Thyroid Cancer: Assessment and management. Although an uncommon cancer, if it is assessed and manged correctly, it carries a good prognosis. The College considers this review timely and appropriate. It considers that the scope covers all relevant areas and factors.	Thank you.
Royal Free London	1	11	Autopsy studies would suggest that thyroid cancer is not uncommon and may exist in as much as 70% of the population at the time of death. Indeed ultrasound detected thyroid nodules exist in 50% of the population and the thyroid cancer risk is 5-10% in an given nodule.	Thank you for your comment. We have acknowledged these points in the document.

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Royal Free London	3	14	Is there scope to explore how these recommendations sit within the 28/62 day NHS England Cancer framework of diagnosis and treatment? It is the case that repeat fine needle aspiration cytology sample is required before a surgical plan can be established and UK Endocrine Pathology Society recommends waiting 6-8 weeks between successive samples which cannot be performed within 28 day framework. Consideration may be needed to be given for a novel timed pathway framework for thyroid nodules and suspect cancer.	Thank you for your comment and for highlighting potential issues with investigations and planning with NHSE cancer framework. This document is not a list of recommendations, but a description of the scope of the proposed guideline. Recommendations will be made by the guideline committee based on evidence derived from systematic reviews within each area. Development of recommendations does take into account issues related to implementation of the recommendations.
Royal Free London	3	21	Blood tests that inform clinical decision making may include thyroid peroxidase antibody levels pre-op and the use of early post-operative thyroglobulin measure to determine the need for ablation dose radio-iodine in the low risk patient.	Thank you for your comment. We have added a question on the indications for blood tests (Q 1.2) as part of early assessment. The use of thyroglobulin post operatively is included in question 4.1.

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Royal Free London	6	10	Regarding active surveillance of thyroid nodules a key consideration will be where this takes place and the skill set of the clinician undertaking this evaluation. It has been recognised anecdotally that the use of non-hospital based ultrasound services is increasing the upstaging of nodule risk in any given population of patients scanned. Additionally due to the large clinical iceberg of thyroid nodules in the community (approx. 50% of adults) it may not be possible for hospital based follow-up to be possible. Consideration may need to be given on primary care led follow-up with clear re-referral triggers back to secondary care.	Thank you for your comment. We recognise that variations in the way active surveillance is provided will vary between studies and this will be taken into account in the analysis and also in committee discussion.
Royal Free London	7	9	Consideration should be given to evaluating the benefits of the various degrees of TSH suppression against the hazards of osteoporosis and atrial fibrillation.	Thank you for your comment. The hazard of osteoporosis will be covered by the use of the osteoporosis outcome in the reviews. We have also added cardiovascular adverse events as an outcome.
Royal Free London	8	2	A key post-op measure must be post-operative dysphonia. This is typically the result of injury to the recurrent laryngeal nerve and or the superior laryngeal nerve and is a mandatory outcome measure in surgery. It really must be included as an end point in itself.	Thank you for this comment – we have now added post-operative voice change as a new outcome.
Royal Free London	8	3	An additional consideration should be atrial fibrillation or more generically the cardio-vascular sequelae of long term TSH suppression	Thank you for this comment – we have now added cardiovascular disease as a new outcome.

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society for Endocrinology	General	General	We feel it would be useful to include specific comment on the management of thyroid cancer presenting in pregnancy as this is a not uncommon scenario given the age group affected by thyroid cancer. Thyroid cancer management during pregnancy requires specific management for some issues including: postponing surgery even for U5/Thy5 lesions until after delivery with monitoring of the thyroid cancer, specific considerations relating to timing of administration of ablative 131-I in relation to breastfeeding, TSH targets during pregnancy etc. This needs to be addressed specifically or pregnancy needs to be excluded from the scope	Thank you for your comment. Women who are pregnant are not excluded from the guideline and we will consider the requirement to make recommendations for women who are pregnant as the guideline is developed.
Society for Endocrinology	General	General	We feel that it would be appropriate to include or at least reference alternative guidance on the management of post-operative hypoparathyroidism, a potential complication of thyroid cancer surgery which causes significant long term morbidity. This should be included in the main outcomes (section 3.6 p7) alongside postoperative dysphagia which, in our experience, is a less significant problem. Vocal cord palsy should also be included in this section.	Thank you for your comment. We have added hypothyroidism and post-operative voice change to the outcomes on pages 7-8.
Society for Endocrinology	General	General	We have some concerns about the composition of the proposed panel. In particular given the emerging importance of molecular pathology in this field we feel that including someone with expertise in this area will be essential. The panel currently appears to be heavily represented by surgeons, with only 1 endocrinologist and 1 oncologist. In	Thank you for your comment. We will co-opt specialised expertise for specific meetings when it is needed such as for molecular pathology. The committee composition does include endocrinology and oncology. However early

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			many areas differentiated thyroid cancer is managed by endocrinologists and specialist nurses after initial surgical treatment.	assessment, diagnosis and treatment is largely carried about by surgeons and this is an important part of the guideline scope.
Society for Endocrinology	General	General	Many low risk thyroid cancers (after excluding incidental microcarcinomas) are now being treated with lobectomy alone. Follow up with thyroglobulin is difficult due to residual thyroid tissue. Despite these being low risk cancers duration of follow up and the best modality by which to do this (?annual USS) is not clear and it would be useful to have guidance.	Thank you for your comment. We will risk stratify all questions so that people with low risk thyroid cancers are covered. We have altered the wording of Question 4.3 to clarify this.
Society for Endocrinology	General	General	There is no comment on monitoring of patients who either maintain or develop thyroglobulin antibodies, and reference should be given to management of these individuals stratified for those who have had ablative therapy or not.	Thank you. We have a question (4.3) about follow up and have added 'method' of follow up as this will be influenced by factors such as presence of thyroglobulin antibodies.
Society for Endocrinology	General	General	We feel it would be useful to include specific comment on the management of thyroid cancer presenting in pregnancy as this is a not uncommon scenario given the age group affected by thyroid cancer. Thyroid cancer management during pregnancy requires specific management for some issues including: postponing surgery even for U5/Thy5 lesions until after delivery with monitoring of the thyroid cancer, specific considerations relating to timing of administration of ablative 131-I in relation to breastfeeding, TSH targets during pregnancy etc. This needs to be addressed specifically or pregnancy needs to be excluded from the scope	Thank you for your comment. Women who are pregnant are not excluded from the guideline and we will consider the requirement to make specific recommendations for women who are pregnant as the guideline is developed.

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Society for Endocrinology	General	General	We have some concerns about the composition of the proposed panel. In particular given the emerging importance of molecular pathology in this field we feel that including someone with expertise in this area will be essential. The panel currently appears to be heavily represented by surgeons, with only 1 endocrinologist and 1 oncologist. In many areas differentiated thyroid cancer is managed by endocrinologists and specialist nurses after initial surgical treatment.	Thank you for your comment. We will co-opt specialised expertise for specific meetings when it is needed such as for molecular pathology. As you indicate the committee composition does include endocrinology and oncology and specialist nurse. However early assessment, diagnosis and treatment is largely carried about by surgeons and this is an important part of the guideline scope.
Society for Endocrinology	1	21	No mention is made of TSH suppression as part of the management of differentiated thyroid cancer	Thank you for your comment. This issue is covered in Q3.4 on p7.
Society for Endocrinology	1	21	No mention is made of TSH suppression as part of the management of differentiated thyroid cancer	Thank you for your comment. This issue is covered in Q3.4 on p7.

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Society for Endocrinology	1	22	This should state radioactive iodine ablation. This is different from radioactive iodine treatment	Thank you for your comment. We have used this terminology because radioactive iodine is given both as ablation and as an adjuvant treatment and the same single dose may do both.
Society for Endocrinology	1	22	This should state radioactive iodine ablation. This is different from radioactive iodine treatment	Thank you for your comment. We have used this terminology because radioactive iodine is given both as ablation and as an adjuvant treatment and the same single dose may do both.
Society for Endocrinology	1	26	It is confusing that there is a sudden jump from discussion about thyroid cancer management and then about nodules and their size.	Thank you for your comment. We have moved the paragraph to an earlier section.
Society for Endocrinology	1	26	It is confusing that there is a sudden jump from discussion about thyroid cancer management and then about nodules and their size.	Thank you for your comment. We have moved the paragraph to an earlier section.
Society for Endocrinology	2	9	It should be made clear this is a 'core biopsy'	Thank you for your comment. We have added the phrase 'needle core' prior to 'biopsy'.

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Society for Endocrinology	2	15	It is confusing to include targeted therapies (tyrosine kinase inhibitors) as adjuvant therapy. A clear distinction should be made between postoperative adjuvant therapy which would include radioactive iodine and external beam radiotherapy and palliative treatments for advanced incurable disease which would include tyrosine kinase inhibitors.	Thank you for your comment. We have changed the wording to reflect this. Reference to TKIs has now been made separately in the context of targeted therapy for recurrent disease.
Society for Endocrinology	2	15	It is confusing to include targeted therapies (tyrosine kinase inhibitors) as adjuvant therapy. A clear distinction should be made between postoperative adjuvant therapy which would include radioactive iodine and external beam radiotherapy and palliative treatments for advanced incurable disease which would include tyrosine kinase inhibitors.	Thank you for your comment. We have changed the wording to reflect this. Reference to TKIs has now been made separately in the context of targeted therapy for recurrent disease.
Society for Endocrinology	3	8	Children have been excluded from the scope and that is of concern. We appreciate that thyroid cancer is rare in children, outcomes are generally good but management is complex. Paediatric patients in many centres are managed at the very least with the support of adult thyroid cancer teams due to the specific nature of the treatments (in particular radioactive iodine). We feel that this guideline presents an opportunity to standardise the management of these patients and to ensure that all children with thyroid cancer in the UK have the best chance of cure with the lowest chance of side effects from unnecessary treatment.	Thank you for your comment. We acknowledge your view regarding the exclusion of people 16 years and under. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists) and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a different committee constituency than those for adult guideline and

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				additional review questions which is not feasible within the timeline for the guideline.
Society for Endocrinology	3	8	Children have been excluded from the scope and that is of concern. We appreciate that thyroid cancer is rare in children, outcomes are generally good but management is complex. Paediatric patients in many centres are managed at the very least with the support of adult thyroid cancer teams due to the specific nature of the treatments (in particular radioactive iodine). We feel that this guideline presents an opportunity to standardise the management of these patients and to ensure that all children with thyroid cancer in the UK have the best chance of cure with the lowest chance of side effects from unnecessary treatment.	Thank you for your comment. We acknowledge your view regarding the exclusion of people 16 years and under. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists) and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a different committee constituency than those for adult guideline and additional review questions which is not feasible within the timeline for the guideline.
Society for Endocrinology	3	21	There is mention of blood tests here but these are not mentioned again in the more detailed scope	Thank you for your comment. We have added a question on the indications for blood tests (Q 1.2)

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society for Endocrinology	3	21	There is mention of blood tests here but these are not mentioned again in the more detailed scope	Thank you for your comment. We have added a question on the indications for blood tests (Q 1.2)
Society for Endocrinology	3	27	The use of isotope bone scan should additionally be considered here given metastatic spread is frequently to bone	Thank you for your comment. Bone scans have now been added to this section of the scope and to Q1.8.
Society for Endocrinology	4	6	Treatment of thyroid cancer metastasis may also include metastasectomy from bone and lung, particularly if single metastasis, and should also be considered in this section.	Thank you for your comment. We acknowledge that metastasectomy of single metastasis may occur but consider that this is a specialist topic outside the general care of people with differentiated thyroid cancer.
Society for Endocrinology	4	11	This section needs to differentiate between the time before risk stratification at 9-12months and that after this time point. With the advent of highly sensitive assays (i.e. Beckmann assay) use of these in contrast to stimulated thyroglobulin should be considered.	Thank you. We agree that the approach differs at different time points and this will be included in detailed review protocols developed during the guideline. We have added highly sensitive assays to the questions.

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Society for Endocrinology	6	8	Clarification is required as to what is meant by 'potentially malignant' nodules- does this refer to a particular category of ultrasound scoring system?	Thank you for your comment. We have changed the wording of here as the term "potentially malignant on ultrasound' was not helpful.
Society for Endocrinology	6	8	Clarification is required as to what is meant by 'potentially malignant' nodules- does this refer to a particular category of ultrasound scoring system?	Thank you for your comment. We have changed the wording of here as the term "potentially malignant on ultrasound' was not helpful. In the context of Q1.4 and 1.5 we are referring to ultrasound size/classification of thyroid nodule that could be used as a threshold to decide on active surveillance/discharge rather than biopsy. This question will compare such thresholds in terms of the best subsequent strategy (active surveillance/discharge or biopsy).
Society for Endocrinology	6	16	A clear distinction needs to be made here between 'benign cytology' (Thy2) and 'non-diagnostic atypical features' (Thy3a) due to the significantly different risk of malignancy between these groups.	Thank you for your comment. The detail of the questions will be agreed by the guideline committee.
Society for Endocrinology	6	16	A clear distinction needs to be made here between 'benign cytology' (Thy2) and 'non-diagnostic atypical features' (Thy3a) due to the significantly different risk of malignancy between these groups.	Thank you for your comment. The detail of the questions will be agreed by the guideline committee.

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society for Endocrinology	6	19	FNA and thyroid US are not able to 'suggest' follicular cancer, but merely suggests a follicular lesion of follicular neoplasia. This should be amended to the role of molecular testing to diagnose or rule out thyoid cancer in nodules with Thy3F cytology. It would also be appropriate to consider the value of molecular testing for other indeterminate categories, including Thy3a and Thy4.	Thank you for your comment. We have changed the wording of the questions to allow the committee to consider the populations groups that should be included.
Society for Endocrinology	6	19	FNA and thyroid US are not able to 'suggest' follicular cancer, but merely suggests a follicular lesion of follicular neoplasia. This should be amended to the role of molecular testing to diagnose or rule out thyroid cancer in nodules with Thy3F cytology. It would also be appropriate to consider the value of molecular testing for other indeterminate categories, including Thy3a and Thy4.	Thank you for your comment. We have changed the wording of the questions to allow the committee to consider the populations groups that should be included.
Society for Endocrinology	6	22	The use of an isotope bone scan should also be considered in staging disease.	Thank you – we have now added this to the scope.
Society for Endocrinology	6	24	No mention is made in either section 2 (initial treatment) or section 3 (further treatment) of the importance of risk stratification in deciding on the most appropriate treatment for an individual patient. It is essential that this is considered and included since both the immediate and long-term management of differentiated thyroid cancer is based on risk stratification world-wide. It would also be useful to include guidance on the management of particularly high risk groups such as those with adverse histopathological features (eg tall cell papillary carcinoma, poorly differentiated carcinoma).	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.

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Society for Endocrinology	6	24	No mention is made in either section 2 (initial treatment) or section 3 (further treatment) of the importance of risk stratification in deciding on the most appropriate treatment for an individual patient. It is essential that this is considered and included since both the immediate and long-term management of differentiated thyroid cancer is based on risk stratification world-wide. It would also be useful to include guidance on the management of particularly high risk groups such as those with adverse histopathological features (eg tall cell papillary carcinoma, poorly differentiated carcinoma).	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
Society for Endocrinology	6	25	This question fails to recognise that a proportion of patients (those with follicular cancers) will not have a diagnosis of thyroid cancer before their definitive treatment (lobectomy or total thyroidectomy) because it is not possible to make a diagnosis without examining the whole lesion histologically. Guidance could be given as to when lobectomy or total thyroidectomy are most appropriate and when additional investigations (eg core biopsy) might help in decision making.	Thank you for your comment. The question is currently worded to make clear that the intended population are those with differentiated cancers. We recognise that this includes people whose diagnosis may not be final. Earlier questions include potential additional investigations such as core biopsy.
Society for Endocrinology	6	25	It is unclear if the terms prophylactic and or therapeutic node dissection relate to central compartment or lateral neck dissection and if a distinction will be made	Thank you for your comment. Both locations of nodes will be included and it is likely that analyses will be stratified for these if agreed by the committee.

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Society for Endocrinology	6	25	This question fails to recognise that a proportion of patients (those with follicular cancers) will not have a diagnosis of thyroid cancer before their definitive treatment (lobectomy or total thyroidectomy) because it is not possible to make a diagnosis without examining the whole lesion histologically. Guidance could be given as to when lobectomy or total thyroidectomy are most appropriate and when additional investigations (eg core biopsy) might help in decision making.	Thank you for your comment. The question is currently worded to make clear that the intended population are those with differentiated cancers. We recognise that this includes people whose diagnosis may not be final. Earlier questions include potential additional investigations such as core biopsy.
Society for Endocrinology	6	25	It is unclear if the terms prophylactic and or therapeutic node dissection relate to central compartment or lateral neck dissection and if a distinction will be made	Thank you for your comment. Both locations of nodes will be included and it is likely that analyses will be stratified for these if agreed by the committee.
Society for Endocrinology	6	28	Section 3 is confusing and muddled. It would be better to separate this into 2. Adjuvant therapy for patients who have had complete resection (this would include questions about optimal administration of radioiodine ablation therapy and appropriate use of external beam radiotherapy in the adjuvant setting) Therapy for residual, metastatic or recurrent thyroid cancer which would include further surgery, radioiodine therapy, external beam radiotherapy and targeted agents (tyrosine kinase inhibitors)	Thank you for your comment. We have amended the scope structure to reflect this.

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Society for Endocrinology	6	28	Section 3 is confusing and muddled. It would be better to separate this into 3. Adjuvant therapy for patients who have had complete resection (this would include questions about optimal administration of radioiodine ablation therapy and appropriate use of external beam radiotherapy in the adjuvant setting) Therapy for residual, metastatic or recurrent thyroid cancer which would include further surgery, radioiodine therapy, external beam radiotherapy and targeted agents (tyrosine kinase inhibitors)	Thank you for your comment. We have amended the scope structure to reflect this.
Society for Endocrinology	6	31	3.1: Is this for people who have had a total thyroidectomy only?	Thank you for your comment. This question is for any total thyroidectomy, hemi thyroidectomy or lobectomy that was followed by RAI. We will be stratifying for the different procedures.
Society for Endocrinology	6	31	3.1: Is this for people who have had a total thyroidectomy only?	Thank you for your comment. This question is for any total thyroidectomy, hemi thyroidectomy or lobectomy that was followed by RAI. We will be stratifying for the different procedures.
Society for Endocrinology	7	1	Reference is made to the optimal 'dose' of radioactive iodine. It is not clear whether this is referring to the activity of radioactive iodine administered or the absorbed dose to a target. It would also be useful to include comment on the value of dosimetry in radioiodine therapy to guide therapy, and whether there is any role for pretreatment imaging (eg with I123) to allow dosimetrically guided treatment. As per	Thank you for this comment. When finalising the protocol for this review question we will ensure that the parameters of the dose are clear.

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			the comment above, separate guidance should be given regarding use of radioactive iodine ablation in the adjuvant setting and use of radioiodine therapy in advanced disease.	
Society for Endocrinology	7	1	Reference is made to the optimal 'dose' of radioactive iodine. It is not clear whether this is referring to the activity of radioactive iodine administered or the absorbed dose to a target. It would also be useful to include comment on the value of dosimetry in radioiodine therapy to guide therapy, and whether there is any role for pre-treatment imaging (eg with I123) to allow dosimetrically guided treatment. As per the comment above, separate guidance should be given regarding use of radioactive iodine ablation in the adjuvant setting and use of radioiodine therapy in advanced disease.	Thank you for this comment. When finalising the protocol for this review question we will ensure that the parameters of the dose are clear.
Society for Endocrinology	7	6	Section 4 is very difficult to follow since no consideration is given to clear distinction between different treatment groups i.e. those who have had lobectomy, total thyroidectomy without radioiodine and total thyroidectomy with radioiodine. See also our comment above on risk stratification	Thank you for your comments. Stratification will be introduced into each systematic review protocol taking into account all these issues.
Society for Endocrinology	7	6	Section 4 is very difficult to follow. There needs to be differentiation between initial management prior to risk stratification, and management thereafter. No consideration is given to clear distinction between different treatment groups i.e. those who have had lobectomy, total thyroidectomy without radioiodine and total	Thank you for your comments. Stratification will be introduced into each systematic review protocol taking into account all these issues.

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			thyroidectomy with radioiodine. See also our comment above on risk stratification.	
Society for Endocrinology	7	7	4.1: reference is made to radioiodine treatment: does this mean ablation or therapy – the term used for radioiodine administration in those with recurrent, residual or metastatic disease	Thank you for your comment. We intend it to cover both situations.
Society for Endocrinology	7	7	4.1: it is better to talk about TSH targets. Levothyroxine is not just used for TSH suppression but replacement treatment with levothyroxine is required and specific TSH targets are recommended by all national and international guidelines	Thank you for this comment. We are particularly interested in TSH suppression in this question. NICE already has guidance on thyroxine when used for replacement.
Society for Endocrinology	7	7	4.1: reference is made to radioiodine treatment: does this mean ablation or therapy – the term used for radioiodine administration in those with recurrent, residual or metastatic disease	Thank you for your comment. We intend it to cover both situations.
Society for Endocrinology	7	7	4.1: it is better to talk about TSH targets. Levothyroxine is not just used for TSH suppression but replacement treatment with levothyroxine is required and specific TSH targets are recommended by all national and international guidelines	Thank you for this comment. We are particularly interested in TSH suppression in this question. NICE already has guidance on thyroxine when used for replacement.
Society for Endocrinology	7	10	4.2: No mention is made of whether thyroglobulin is stimulated or not.	Thank you for your comment. We will stratify for stimulated, non-stimulated and highly sensitive assays.
Society for Endocrinology	7	10	4.2: No mention is made of whether thyroglobulin is stimulated or not. Neck ultrasound is probably the first and	Thank you for your comment. We will stratify for stimulated, non-stimulated and highly sensitive

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			most frequently used imaging modality in monitoring of residual or recurrent disease.	assays. Our understanding is that ultrasound is not first line but is it is used for looking for disease if thyroglobulin positive
Society for Endocrinology	7	14	4.3: does this section relate to all patients, i.e. those who have had a hemithyroidectomy, total thyroidectomy or total thyroidectomy + radioiodine ablation?	Thank you for your question. This section refers to all patients but appropriate stratification will be introduced into the question protocol as appropriate.
Society for Endocrinology	7	14	4.3: does this section relate to all patients, i.e. those who have had a hemithyroidectomy, total thyroidectomy or total thyroidectomy + radioiodine ablation?	Thank you for your question. This section refers to all patients but appropriate stratification will be introduced into the question protocol as appropriate.
Society for Endocrinology	7	19	4.4: this question does not specify the type of follow-up: the use of thyroglobulin measurement, frequency of imaging, different TSH targets depending on risk stratification. It appears that the clinical and cost-effectiveness of these will only be assessed at 1-2 years post initial treatment whereas these are important issues to be addressed in the longer term management of patients	Thank you for your comment. We anticipate that review questions 4.2 and 4.3 will allow the committee to make recommendations in the areas you suggest.
Society for Endocrinology	7	19	4.4: this question does not specify the type of follow-up: the use of thyroglobulin measurement, frequency of imaging, different TSH targets depending on risk stratification. It appears that the clinical and cost-effectiveness of these will only be assessed at 1-2 years post initial treatment whereas	Thank you for your comment. We anticipate that review questions 4.2 and 4.3 will allow the committee to make recommendations in the areas you suggest.

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			these are important issues to be addressed in the longer term management of patients	
The Society and College of Radiographers			The Society and College of Radiographers has no comments at this stage on the draft scope but will review the full report once shared with stakeholders.	Thank you for your comment.
The Thyroid Trust	3	5 and 8	The draft scope currently excludes children and young people. We feel this group should be included so that it is in line with the NICE thyroid diseases guideline (just published), and because there is to our knowledge no separate guideline to direct people to for the diagnosis and treatment of thyroid cancer in children and young people.	Thank you for your comment. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists**)** and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a different committee constituency than those for adult guideline and additional review questions which is not feasible within the timeline for the guideline.
The Thyroid Trust	4	1	In the section 'Initial treatment of thyroid cancer' we propose adding 'active surveillance' (or 'watchful waiting') to the list of options for the initial treatment of thyroid cancer as this is increasingly being offered to patients with small tumours. See for example the study by Sakai T et al (Thyroid, 2019) which found that patients with 1-2 cm papillary thyroid	Thank you for your comment. We will include active surveillance of diagnosed cancers and have added this to section 1 (why this guideline is needed), section 3.3 (activities, services or aspects of care) and section 3.5 (key issues and draft questions).

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			cancers had similar progression rates to patients with <1 cm cancers during active surveillance and that delayed surgery was not associated with any harm in these patients.	
The Thyroid Trust	4	11	In the section 'Follow-Up and Monitoring' we suggest including 'Management of side effects of surgery and radioactive iodine treatment' (such as hypoparathyroidism, voice issues, and salivary gland problems).	Thank you for your comments. We agree that post-operative side effects can cause long term morbidity. Hypoparathyroidism and post-operative changes in voice have now been added to the outcomes considered in each question. This will allow us to highlight these complications. It is not feasible to include management of each complication within the scope of the guideline.
The Thyroid Trust	4	11	In the section 'Follow-up and Monitoring' we propose adding **'Prognosis'.**	Thank you for this point. We agree that being able to predict later outcomes is important for planning of treatment and monitoring. Under the 'Follow up and monitoring' heading we already include prediction of risk and recurrence and will be including short and longterm outcomes when examining interventions. We do not consider that an additional section or question on prognosis will help inform management.

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Thyroid Trust	4	23	We note that treatment with tyrosine kinase inhibitors (TKIs) will not be included here but that the document will cross-refer to the NICE guidance on lenvatinib and sorafenib which was published in August 2018. We understand the rationale for this but are concerned this may fail to take full account of more recent studies published since this guidance was issued on treating patients with these agents in tandem and/or of newer agents, for example selumetinib. We would advocate a summary section on TKIs within this document which then cross-refers to the relevant NICE documents.	Thank you for your comment. This section (3.3) covers the areas this guideline will review. The use of tyrosine kinase inhibitors is covered by NICE technology appraisals. We will not review the evidence for these but they are included in the overall pathway. A pathway will be published on the NICE website alongside the guideline which will draw together all relevant NICE guidance.
The Thyroid Trust	6	24	We propose adding as section 2.2; 'For people with small, low-risk papillary thyroid cancers (microcarcinomas and tumours <1cm), what is the clinical and cost-effectiveness of closely monitoring the thyroid cancer over time, instead of treating it with immediate surgery – i.e., active surveillance. See also point 2 above.	Thank you for your comment. We will include active surveillance of diagnosed cancers and have added this to section 1 (why this guideline is needed), section 3.3 (activities, services or aspects of care) and section 3.5 (key issues and draft questions).
The Thyroid Trust	6	24	We propose adding as section 2.3 'For people who undergo thyroid surgery, what is the risk of temporary or permanent side-effects such as, hypocalcaemia (low blood calcium), hypoparathyroidism, and voice damage?'	Thanks for this comment. These side effects have now been added to the list of outcomes to be considered in the review questions, so this question will be answered as part of question 2.1

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The Thyroid Trust	6	29	We propose including as section 3.3: 'For people with small, well-differentiated thyroid cancer that does not seem to have spread, what is the clinical and cost-effectiveness of monitoring them instead of treating them immediately with radioactive iodine?'	Thank you for your comment. We do intend to include no radiotherapy and consider this is already covered in question 3.1.
The Thyroid Trust	7	6	In the section on 'Follow-Up and Monitoring' we propose mentioning the incidence of post-operative hypocalcaemia and hypoparathyroidism (POSH) and how to monitor and manage this.	Thank you for your comments. We agree that post-operative side effects can cause long term morbidity. Hypoparathyroidism and post-operative changes in voice have now been added to the outcomes considered in each question. This will allow us to highlight these complications. It is not feasible to include management of each complication within the scope of the guideline.
The Thyroid Trust	7	6	In the section on 'Follow-Up and Monitoring' we propose adding a question about the incidence of post-operative voice issues and how this can be managed.	Thank you for your comments. We agree that post-operative side effects can cause long term morbidity. Hypoparathyroidism and post-operative changes in voice have now been added to the outcomes considered in each question. This will allow us to highlight these complications. It is not feasible to

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				include management of each complication within the scope of the guideline.
The Thyroid Trust	7	6	In the section on 'Follow-Up and Monitoring' we propose adding a question on what is the optimal way to manage patients who do not thrive on levothyroxine alone, and the possible role of liothyronine (T3)	Thank you for your comment. Long term thyroid replacement is covered by NICE guideline NG145 Thyroid disease: assessment and management.
The Thyroid Trust	7	25	In the section on 'Main Outcomes' we propose adding incidence of post-operative hypocalcaemia, hypoparathyroidism, and voice issues	Thank you for your comment. Hypoparathyroidism and post-operative changes in voice have now been added to the outcomes considered in each question.
The Thyroid Trust	7	25	In the section on 'Main Outcomes' we propose adding salivary gland issues arising after radioactive iodine treatment.	Thank you for your comment. The outcomes listed as postoperative complications are given as examples. The guideline committee will determine the final list of outcomes that will be considered.
The Thyroid Trust	8	3	In the section on 'Main Outcomes' we suggest also including heart arrhythmias alongside osteoporosis as a possible consequence of TSH suppression.	Thank you for your comment. This will be included as part of cardiovascular disease outcomes.
Thyroid Cancer Forum-UK	1	12	Thyroid cancer affects all ages so should not state 20s to 60s	Thank you for your comment. We have changed wording to reflect this.

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Thyroid Cancer Forum-UK	2	2	Recurrent disease is mentioned but there is a significant cohort of patients who will have residual disease as evidenced by abnormal biochemistry (thyroglobulin, thyroglobulin antibody) and or imaging	Thank you for your comment. Residual as well as recurrent disease is included in the scope.
Thyroid Cancer Forum-UK	2	7	Patients often present with cervical nodal disease as the first event as well as presenting with thyroid nodule	Thank you for your comment. We agree, and methods of assessment and staging as well as node dissection are included in the scope.
Thyroid Cancer Forum-UK	2	15	Important to specify that targeted therapy is not used in the adjuvant setting	Thank you for your comment. We have changed the wording to reflect this. Reference to TKIs has now been made separately in the context of targeted therapy for recurrent disease.
Thyroid Cancer Forum-UK	4	5	Prophylactic nodal surgery should specifically refer to level 6/central compartment (it does not include lateral neck nodes)	Thank you for your comment. We feel that both locations are important and should be covered. When designing the question protocol we may be able to stratify for these locations in the reviews if felt appropriate by the committee.
Thyroid Cancer Forum-UK	4	6	Differentiated thyroid cancer dedifferentiate to poorly differentiated or anaplastic thyroid cancer and behave more aggressively. Access to molecular profiling with next generation sequencing has a role to play in prognostication and selection of targeted therapy. Due to disease rarity,	Thank you for your comment. We are aware that this is a developing area and will include molecular testing where possible. However we do not plan to cover management of these

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			clinical trials in this clinical arena are very limited and difficult to run. In light of this an acceptance that NGS testing could provide a subset of patients with potentially helpful systemic therapy options would be very valuable. NHS Wales and NHS England will have NGS available via the national gene directories in 2020 and patients with actionable targets could benefit significantly from targeted therapies. Some of these are not however appraised and approved specifically for use in the thyroid cancer setting and this is detrimental to patient outcomes.	cancers and targeted therapies will therefore be outside the scope of the guideline.
Thyroid Cancer Forum-UK	4	10	Need to include targeted therapy/TKI, denosumab/bisphsphonates	Thank you for this comment. This section (3.3) covers the areas this guideline will review. The use of tyrosine kinase inhibitors and denosumab are covered by NICE technology appraisals. We will not review the evidence for these but they are included in the overall pathway.
Thyroid Cancer Forum-UK	6	4	Incorporating the U1-5 USS scoring system universally means that all clinical teams are assessing nodules in the same manner and results can be more easily interpreted and audited	Thank you for your comment.
Thyroid Cancer Forum-UK	6	19	FNAC cannot technically suggest follicular thyroid cancer, it would be better to state follicular lesion	Thank you for this clarification.

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Thyroid Cancer Forum-UK	6	24	Important to utilise risk stratification when deciding on initial treatment. Both patient characteristics and tumour/staging information influences the treatment recommendation	Thank you for your comment. When formulating the review question protocols we will devise appropriate stratification strategies to allow any differential efficacy between risk strata to be apparent.
Thyroid Cancer Forum-UK	6	27	Important to mention prophylactic vs. therapeutic nodal surgery refers only to level 6/central nodal surgery	Thank you for this information. Further detail will be specified in the review question.
Thyroid Cancer Forum-UK	6	28	Further treatment needs to be broken down in to more distinct groups: adjuvant treatment post surgery vs residual/recurrent disease vs. metastatic disease	Thank you for your comment. We have amended the scope structure to reflect this.
Thyroid Cancer Forum-UK	7	1	Need to distinguish whether this refers to administered activity of radioiodine or absorbed dose. Unlike external beam radiotherapy where individualised dose plans are standard practice there is no current provision for individualised treatment for radioiodine so patients receive an empiric administered activity of radioiodine. The introduction of individualised dosimetry would help address this issue and would be in keeping with EU Directive stating all patients should have individualised treatment.	Thank you for this comment. When finalising the protocol for this review question we will ensure that the parameters of the dose are clear.
Thyroid Cancer Forum-UK	7	1	Need to distinguish between adjuvant and therapeutic radioiodine use post surgery	Thank you for your comment. We will stratify the systematic review question to take account of different populations.
Thyroid Cancer Forum-UK	7	6	Follow up and monitoring differs according to the dynamic risk stratification category for each patient	Thank you for your comments. Stratification will be introduced into each systematic review protocol taking into account all these issues.

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Thyroid Cancer Forum-UK	7	12	Need to state if basal or stimulated thyroglobulin	Thank you for your comment. We will stratify for stimulated, non-stimulated and highly sensitive assays and have no altered the question to clarify this.
Thyroid Cancer Forum-UK	7	19	Follow up frequency and duration varies according to patient risk group so need to separate the analysis for each group to make it meaningful	Thank you for your comment. We will aim to stratify the analyses for different patient risk groups
Thyroid Cancer Forum-UK	8	8	Add cardiovascular morbidity	Thank you for this comment – we have now added cardiovascular disease as a new outcome.
UK Endocrine Pathology Society	Page 3	5	**There is a strong case for including paediatric thyroid cancer within the guideline**. Thyroid cancer occurs at all ages not just 20s-60s.If paediatric thyroid cancer is not included in this document it will not be dealt with adequately elsewhere by other relevant guidance and there will be gap in professional guidance and service provision in England, Wales, and Northern Ireland. Hence our view would be that this guideline should cover both paediatric and adult thyroid cancer.	Thank you for your comment. We acknowledge your view regarding a gap in guidance. We recognise that the recommendations made for those over 16 may be relevant to treatment of cancer in younger people. However the care for children is different, and is carried out by different teams (children need specialised treatment jointly with paediatric surgeons and oncologists) and the type of cancers seen in younger people may also be different. The formal inclusion of these areas would require a

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				different committee constituency than those for adult guideline and additional review questions which is not feasible within the timeline for the guideline.
UK Endocrine Pathology Society	Page 3	5	**Suspected and confirmed thyroid cancer**.There needs to be a definition of "suspected thyroid cancer". Approximately 5-7% of the adult population have subclinical thyroid cancer, thyroid micro-carcinoma, as identified by rates of coincidental papillary micro-carcinoma in patients undergoing thyroidectomy for clinically benign goitres or in autopsy studies. The definition of '*suspected thyroid cancer'* should be those patients who have thyroid lumps or nodules, which are clinically suspected of being potentially cancerous, or who have investigations which raise the possibility of thyroid cancer **over and above a background risk level of around 5 to 7%,** (e.g. a cytology showing Thy 3a or Thy3f, Thy4, or Thy5), or an ultrasound scan of the thyroid which shows changes which are not entirely normal, (i.e. not U2 but U3, U4 or U5), or other risk factors (e.g. family history or genetics or previous radioiodine or previous radiation to the neck for example).	Thank you for your comment. We have mentioned 'suspected' thyroid cancer at this point to emphasise that at the diagnostic stage of the care pathway the guideline is relevant to those who have clinical signs of possible thyroid cancer but who have not yet been diagnosed. We have therefore used the term in a looser sense than you have defined it, to mean anyone for whom the investigating clinician may have enough suspicion to initiate investigations.
UK Endocrine Pathology Society	Page 3	23	If the guideline is intended to cover fine-needle aspiration cytology **it is essential that a pathologist with wide experience of thyroid fine-needle aspiration cytology is a member of the guideline committee**	Thank you for your comment. We plan to recruit an experienced cytopathologist to the guideline committee.

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UK Endocrine Pathology Society	Page 3	24	If the guideline intends to cover needle core biopsy it is **essential that a pathologist with experience of thyroid needle core biopsy is a member of the guideline committee**	Thank you for your comment and suggestion. Applicants for committee positions are assessed again criteria including their experience of procedures under review. Specific additional expertise can also be found via a co-opted member or an expert witness.
UK Endocrine Pathology Society	Page 3	25	**If the guideline intends to cover molecular testing if the diagnosis is uncertain**, **this would require a molecular pathologist to be a member of the guideline committee, or someone with wide expertise in molecular testing of the thyroid using FNA cytology. This expertise is not readily available in the UK as molecular testing for thyroid FNA cytology has not been implemented in the UK**. The guideline committee will probably therefore have to rely on an external consultant or adviser e.g. Prof Bryan McIver in Miami or Prof Yuri Nikiforov in Pittsburgh in North America would useful suggestion(s) as an external adviser(s) on molecular diagnosis with a level of expertise not readily available in the UK.	Thank you for this information and your suggestions. We can co-opt specialised expertise for specific meetings or seek expert witnesses as required.
UK Endocrine Pathology Society	Page 4	5	What about level VI lymph node dissection versus prophylactic ipsilateral lymph node dissection?	Thank you for your comment. This is covered by question 2.1

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UK Endocrine Pathology Society	Page 4	5	**Please define what 'disease positive' lymph nodes means**, is this clinical, imaging by ultrasound or CT or MRI, or proven by FNA, or evidence of recurrence or residual disease post therapy, i.e. structural disease recurrence based on either clinical impression, imaging, or raised serum thyroglobulin or other tumour markers e.g. BRAF V600E ctDNA?	Thank you for your comment. We will review the appropriate definition with the guideline committee when agreeing the protocol for review question.
UK Endocrine Pathology Society	Page 4	11	This draft refers to follow-up and monitoring. All modern guidelines including those from both the British Thyroid Association and American Thyroid Association **recommend dynamic risk stratification for follow-up based on combination of tumour type, tumour TNM stage, and biomarkers** to risk lesions from low, intermediate, and high risk. The guidance therefore needs to incorporate a risk management approach which accords with the best evidence available to date as per best clinical practice.	Thank you for your comment. The recommendations on follow up and monitoring made in this guideline will be based upon the committee's interpretation of the evidence reviews, including dynamic risk stratification.
UK Endocrine Pathology Society	Page 4	19	The proposed draft scope does not include anaplastic thyroid carcinoma. There is some overlap between poorly differentiated carcinoma and anaplastic thyroid carcinoma in both tumour behaviour and molecular profile. **It should be made clear that this guidance <u>does</u> include poorly differentiated thyroid carcinoma**	Thank you for your comment. We will discuss this with the committee when we set the review questions.
UK Endocrine Pathology Society	Page 6	1.6-1.7	Between 1.6 and 1.7 – there is nothing about the surgical management after Thy3f, Thy4 and Thy5. **We suggest additional items to:**	Thank you for your comment. We have changed the wording of questions to allow the guideline committee to clarify the populations to include in these questions.

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			- assess diagnostic hemi-thyroidectomy vs. active surveillance for Thy3f. **- possibly the same, plus repeat FNA or even core biopsy for Thy4.** **- then for Thy5, this should assess hemithyroidectomy vs. total thyroidectomy, possibly even active surveillance in some cases (small lesions).** The guideline should also assess the economics of active surveillance, eg for Thy5 lesions that are small & stable - this is now one treatment option in The ATA Thyroid Cancer Guidance and is widely practised in Japan and Asia.	
UK Endocrine Pathology Society	Page 6	1.4	It is proposed to assess the diagnostic accuracy of fine needle aspiration cytology with rapid on site assessment, fine-needle aspiration cytology without rapid on site assessment and core biopsy. These methods have never been subjected to a comparative randomised controlled trial (RCT). All the published evidence therefore is retrospective, or from non-randomised prospective studies and the case-control studies that compare rapid on-site evaluation with no rapid on-site evaluation are poorly powered with small numbers of cases, and none are from the UK, and so these are not particularly helpful or reliable. The evidence from literature seems to be that rapid on-site assessment will improve rates of non-diagnostic Thy1 aspirates if the rates of Thy1 aspirates are high, but this has never been shown	Thank you for this comment. Question 1.5 (the questions have been re-ordered in scope post consultation) is worded such that randomised evidence would not be used. We will be looking at the diagnostic accuracy of each method relative to an appropriate gold standard such as histopathological findings. Thank you for your suggestion of evidence that may be available from expert witnesses. We will consider this during guideline development.

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			prospectively in a RCT and it is also possible to achieve relatively good rates of Thy1 ultrasound guided aspirates i.e. 10% or below without use of rapid on-site assessment if the medical radiologists or radiology practitioners concerned are well trained and skilled in fine-needle aspiration with good training and feedback. **There is a case for inviting a radiology practitioner with expertise in thyroid ultrasound to present to the committee data on results achieved including those for non-diagnostic Thy1 aspirates by radiology practitioners in centres where this is practised.** **Rapid on-site assessment is recommended in recent relevant professional guidance e.g. in the recent Royal College of Pathologists Tissue Pathway for Diagnostic Cytology** https://www.rcpath.org/uploads/assets/b328ab3d-f574-40f1-8717c32ccfc4f7d8/G086-Tissue-pathways-for-diagnostic-cytopathology.pdf **There should be assessment of the effectiveness of cytology reporting categories (eg Thy1, Thy1c, Thy2, Thy3a, Thy3f, Thy4 & Thy5)** Regarding core biopsies, these are used far less frequently that FNA and usually only in selected circumstances (eg after Thy1 FNA or in suspected lymphoma or anaplastic	

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			carcinoma). Therefore, there is little in the literature as stated above. As in our point 4 above, suitable expertise in thyroid core biopsies is required on the committee.	
UK Endocrine Pathology Society	Page 6	1.5	**What is meant by '*non-diagnostic atypical features'***? Presumably this refers to aspirates that are Thy3a, Thy3f and Thy 4. These are usually termed "indeterminate". The phrase "non-diagnostic atypical features" is not ideal because in cytopathology the word "non-diagnostic" is often used interchangeably with "inadequate". This would be better separated into one item for "benign cytology" (ie Thy2) and a separate one for appropriately defined abnormal cytology falling short of diagnostic of malignancy. (ie Thy3a, Thy3f or Thy4). For surgically operated nodules this risk of malignancy data and hence the risk of carcinoma is now available in a recently published meta-analysis for the RCPath Thy system https://acsjournals.onlinelibrary.wiley.com/doi/abs/10.1002/cncy.22201	Thank you for your comment. We have removed the term atypical as this was unhelpful. We agree there are two likely groups- those with benign cytology and those where cytology falls short of diagnosis.
UK Endocrine Pathology Society	Page 6	1.6	**Follicular carcinoma cannot be diagnosed on thyroid fine-needle aspiration or needle core biopsy of the thyroid.** Approximately 85% of new thyroid cancers are papillary thyroid carcinomas which **can** be diagnosed often	Thank you for your comment. We have changed the wording of questions to allow the guideline committee to clarify the populations to include in these questions.

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			on thyroid FNA **BUT** follicular thyroid carcinomas are typically reported as either Thy3a, Thy3f or occasionally Thy4 or Thy2. This item is also a sudden leap to molecular testing. There are preceding items to assess the value of repeat FNA, active surveillance or discharge for Thy2 and Thy3a, then a leap to assessing the value of molecular testing for Thy3f. **We suggest also assessment of the value of molecular testing for Thy3a and Thy4 as well as Thy3f (which are equivalent to the Bethesda Thyroid Cytology Categories III, IV and V respectively), as 'rule in' tests and 'rule out tests for thyroid surgery.** This approach of 'rule in' and 'rule-out' malignancy testing is already widely used in multiple publications in the peer-reviewed published literature and in international guidelines e.g. in Ferris et al. The American Thyroid Association Statement on Surgical Application of Molecular Profiling for Thyroid Nodules: Current Impact on Perioperative Decision Making https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4519104/ and multiple other publications The wording is unclear and imprecise and should be changed to - ***For people with fine needle aspiration***	

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			samples where the possibility of a follicular neoplasm of the thyroid is suspected what is the effectiveness of molecular testing? (the effectiveness would have to be validated of course by histological assessment) – hence nodule excision and not by cytology or core biopsy alone	
UK Endocrine Pathology Society	Page 6	1.7	Could add word "pre-operatively" at end of this item.	Thank you for this comment. The section heading has been changed to make clear that these questions are related to initial staging.
UK Endocrine Pathology Society	Page 6	2.1	There is no recognition here of how the diagnosis of differentiated thyroid cancer has been reached. It could be on FNA or histology for PTC but only on histology for FTC.	Thank you for your comment. We are assuming that the population group in this question have been accurately diagnosed.
UK Endocrine Pathology Society	Page 6	1.1 and 1.3	If the guidance is proposed to include the accuracy of diagnostic ultrasound for thyroid nodule malignancies or nodules with malignant potential **then this committee should include a consultant diagnostic radiologist with an interest in, and a high level of expertise in thyroid ultrasound** **There should be mention of assessing the effectiveness of <u>categorised reporting</u> (eg U score) for ultrasound.** **1.3 and 1.4 – what is meant by "potentially malignant on ultrasound"** – U3-U5? U4-U5? And this should be consistent	Thank you for your comment. Membership of the committee will be based on appropriate experience and expertise, alongside other considerations. We have altered the wording to remove the phase "Potentially malignant on ultrasound". In the context of Q1.3 and 1.4 we are referring to ultrasound size/classification of thyroid nodule that could be used as a threshold to decide on active surveillance/discharge rather than biopsy. This question will compare such thresholds in

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			with the definition used for "suspected thyroid cancer" (our point 2 above).	terms of the best subsequent strategy (active surveillance/discharge or biopsy).
UK Endocrine Pathology Society	Page 9	flowchart	This states "fine needle aspiration and core biopsy" – both would not usually be used so this should be rephrased.	Thank you for your comment. The scope has been amended accordingly