1 2	NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
3	Guideline scope
4	Thyroid disease: assessment and
5	management
6 7	The Department of Health in England has asked NICE to develop a clinical guideline on thyroid disease.
8 9	The guideline will be developed using the methods and processes outlined in Developing NICE guidelines: the manual .
10 11	This guideline will also be used to develop the NICE quality standard for thyroid disease.
12	1 Why the guideline is needed
13	Key facts and figures
14	Thyroid disease comprises thyroid enlargement and thyroid hormonal
15	dysfunction. Thyroid enlargement may be benign, resulting in nodules or
16	goitre, or malignant in people with thyroid cancer. Conditions causing
17	abnormal thyroid function can be broadly divided into those that result in
18	thyroid gland underactivity (hypothyroidism) or overactivity (thyrotoxicosis).
19	Thyroid enlargement is common. Clinically detectable goitres or thyroid
20	nodules are present in 15% of the UK population, and the lifetime risk of
21	developing a thyroid nodule is estimated at 5–10%. In many cases, thyroid
22	glands harboring malignancy are clinically indistinguishable from those that do
23	not. Most people with a non-malignant enlarged thyroid gland and normal
24	thyroid function need no treatment.
25	Hypothyroidism is a condition of thyroid hormone deficiency and is usually
26	caused by autoimmune Hashimoto's thyroiditis. Hypothyroidism is prevalent in
27	2% of the UK population and in more than 5% of people aged over 60, with

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28	women being 5-10 times more commonly affected than men. Long-term
29	consequences of hypothyroidism include cardiovascular disease and an

- increase in cardiovascular risk factors, including hypercholesterolaemia.
- 31 Thyrotoxicosis is a disorder of excess circulating thyroid hormones caused by
- increased production and secretion (hyperthyroidism) or by release of stored
- thyroid hormones (thyroiditis). In the UK, autoimmune hyperthyroidism
- 34 (Graves' disease) is the most common form in 60–80% of cases and
- 35 Thyrotoxicosis is a common endocrine disorder with a prevalence of 2% in UK
- women and 0.2% in men. Graves' disease is caused by a genetic
- 37 predisposition to the development of stimulating thyroid auto-antibodies and
- occurs mostly in women aged 30–60 years. Thyrotoxicosis affects 1-2 per
- 39 10,000 children who may be severely affected, with poor educational
- 40 performance often being an early feature. Long-term consequences of
- 41 hyperthyroidism include increased cardiovascular morbidity and mortality and
- 42 bone-related complications including osteoporosis.
- 43 Subclinical thyroid dysfunction is a biochemical diagnosis of abnormal levels
- of serum thyroid stimulating hormone with normal circulating thyroid hormone
- 45 levels (thyroxine [T4] and tri-iodothyronine [T3]). It is often detected
- incidentally, although some people may have symptoms of hypothyroidism or
- 47 hyperthyroidism. The prevalence of subclinical thyrotoxicosis is 0.5–10% and
- 48 that of subclinical hypothyroidism is 4–20%, these wide ranges reflecting
- 49 differences in the studied populations Data on long-term consequences of
- sublinical thyroid dysfunction have been largely derived from populations aged
- more than 65 years. They include increased cardiovascular morbidity and
- 52 mortality, increased risk of osteoporosis and potential links to dementia.

Current practice

53

- 54 There is variation in how thyroid disease is investigated and managed in
- 55 primary and secondary care settings. There are currently no standardised
- 56 diagnostic or referral criteria in the UK to guide decision-making in primary
- care for people with structural thyroid abnormalities or enlargement. In
- secondary care there is significant variation in the types of diagnostic tests
- and imaging used, as well as in surgical and non-surgical management and

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- strategies for people with hypothyroidism is currently lacking. In addition,
- 62 guidance on optimal treatment and follow-up strategies is needed for
- 63 managing thyrotoxicosis, which is usually done in a shared care setting
- between primary and secondary care. Opinions regarding the need to treat
- subclinical thyroid dysfunction, especially in older people, are widely varied
- 66 globally.
- This guideline will aim to improve the diagnosis, management and follow-up of
- 68 people with non-malignant thyroid enlargement associated with normal thyroid
- 69 function.

70 2 Who the guideline is for

- People using services, their families and carers, and the public will be able to
- use the guideline to find out more about what NICE recommends, and help
- 73 them make decisions.
- 74 This guideline is for:
- Healthcare professionals
- People with non-malignant thyroid enlargement
- People with suspected or confirmed thyroid disease

78

- 79 NICE guidelines cover health and care in England. Decisions on how they
- apply in other UK countries are made by ministers in the Welsh Government,
- 81 Scottish Government, and Northern Ireland Executive.

82 Equality considerations

- 83 NICE has carried out <u>an equality impact assessment</u> during scoping. The
- 84 assessment:
- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

87 **3 What the guideline will cover**

88 3.1 Who is the focus?

- 89 Groups that will be covered
- Children, young people and adults with thyroid disease.
- No specific subgroups of people have been identified as needing specific
- 92 consideration.
- 93 Groups that will not be covered
- 94 Neonates.
- Pregnant women (guidance is currently being developed by the Royal
- 96 College of Obstetricians & Gynaecologists).
- **97 3.2 Settings**
- 98 Settings that will be covered
- 99 The guideline will cover all settings in which NHS-funded healthcare is
- 100 received.
- 101 3.3 Activities, services or aspects of care
- 102 Key areas that will be covered
- We will look at evidence in the areas below when developing the guideline,
- but it may not be possible to make recommendations in all the areas.
- Note that guideline recommendations for medicines will normally fall within
- licensed indications; exceptionally, and only if clearly supported by evidence,
- use outside a licensed indication may be recommended. The guideline will
- assume that prescribers will use a medicine's summary of product
- 109 characteristics to inform decisions made with individual patients.
- 110 1 Investigation of thyroid dysfunction or thyroid enlargement
- 111 Indications for thyroid function tests
- 112 Indications for other tests or imaging

113	2	Management of non-malignant thyroid enlargement with normal thyroid
114		function
115		 Referral for surgery
116		Non-surgical treatment
117		 Monitoring non-malignant thyroid enlargement
118	3	Management of primary hypothyroidism
119		 Treatment options: T4; T3; combination of both
120		 Monitoring hypothyroidism
121	4	Management of thyrotoxicosis
122		 Treatment options: antithyroid drugs; radioiodine; surgery
123		 Monitoring thyrotoxicosis
124	5	Management of subclinical thyroid dysfunction
125		 Treating subclinical hypothyroidism
126		 Treating subclinical thyrotoxicosis
127		 Monitoring subclinical thyroid dysfunction
128	6	Information for people with thyroid disease, their families and carers
129	Are	eas that will not be covered
130	1	Management of thyroid eye disease
131	2	Thyroid cancer (except preliminary investigation)
132	3	Screening for congenital hypothyroidism
133	4	Acute thyroid dysfunction (thyroid storm and myxoedema coma)
134	5	Thyroid disease in pregnant women
135	6	Management of thyroid diseases with iodine and selenium
136		supplementation
137	7	Drug-induced thyroid dysfunction
138	8	Management of thyroid diseases with dietary and lifestyle interventions
139	Rel	ated NICE guidance
140	• (Osteoporosis: assessing the risk of fragility fracture (2012, last updated
141	2	2017) NICE clinical guideline CG146
142	• <u>\</u>	Ultrasound-guided percutaneous radiofrequency ablation for benign thyroid
143	<u>r</u>	nodules (2016) NICE interventional procedure guidance 562.

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144	•	Coeliac disease: recognition, assessment and management (2015) NIC	Έ
145		guideline NG20.	

- Type 1 diabetes in adults: diagnosis and management (2015) NICE
 quideline NG17.
- Minimally invasive video-assisted thyroidectomy (2014) Interventional procedure guidance 499.
- Intraoperative nerve monitoring during thyroid surgery (2008) Interventional procedure guidance 255.

152 NICE guidance about the experience of people using NHS services

- NICE has produced the following guidance on the experience of people using
- the NHS. This guideline will not include additional recommendations on these
- topics unless there are specific issues related to thyroid disease:
- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76

159 **3.4 Economic aspects**

- We will take economic aspects into account when making recommendations.
- We will develop an economic plan that states for each review question (or key
- area in the scope) whether economic considerations are relevant, and if so
- whether this is an area that should be prioritised for economic modelling and
- analysis. We will review the economic evidence and carry out economic
- analyses, using an NHS and personal social services (PSS) perspective, as
- appropriate.

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3.5 Key issues and draft questions

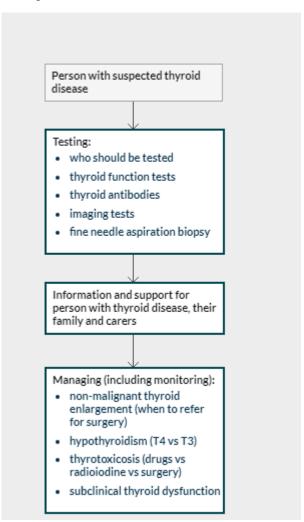
- 168 While writing this scope, we have identified the following key issues, and key
- 169 questions related to them:
- 170 1 Investigating thyroid dysfunction or thyroid enlargement
- 171 1.1 Who should be investigated for thyroid disease?
- 1.2 Which thyroid function tests should be requested?
- 1.3 When should thyroid antibodies be tested?

174		1.4 Which imaging tests should be requested?
175		1.5 Which people with structural thyroid abnormalities should have a
176		fine-needle aspiration biopsy and should this be under ultrasound
177		guidance?
178	2	Managing non-malignant thyroid enlargement with normal thyroid
179		function
180		2.1 Which people with non-malignant thyroid enlargement should be
181		referred for surgery?
182		2.2 What is the clinical and cost effectiveness of non-surgical treatments
183		for non-malignant thyroid enlargement?
184		2.3 How should non-malignant thyroid enlargement be monitored?
185	3	Managing primary hypothyroidism
186		3.1 What is the clinical and cost effectiveness of using levothyroxine [L-
187		T4], liothyronine [L-T3], combination of L-T4 and L-T3 and thyroid
188		extracts to treat primary hypothyroidism?
189		3.2 How should hypothyroidism be monitored?
190	4	Managing thyrotoxicosis
191		4.1 What is the clinical and cost effectiveness of using radioactive iodine
192		vs antithyroid drugs vs surgery to treat thyrotoxicosis secondary to
193		Graves' disease?
194		4.2 What is the clinical and cost effectiveness of using radioactive iodine
195		vs surgery to treat thyrotoxicosis secondary to toxic nodular goitre?
196		4.3 When anti-thyroid drugs are used, what is the most clinical and cost
197		effective way of using these drugs to treat thyrotoxicosis (for example
198		choice of drugs, different treatment regimens)?
199		4.4 When radioactive iodine is used, what is the most clinical and cost
200		effective way of using this treatment to treat thyrotoxicosis (for example
201		different dosing strategies)?
202		4.5 When surgery is indicated, what is the most clinical and cost
203		effective way of using surgery to treat thyrotoxicosis (for example total vs
204		subtotal thyroidectomy)?
205		4.6 How should thyrotoxicosis be monitored?
206	5	Managing subclinical thyroid dysfunction

207		5.1 What is the clinical and cost effectiveness of treating subclinical
208		hypothyroidism?
209		5.2 What is the clinical and cost effectiveness of treating subclinical
210		thyrotoxicosis?
211		5.3 How should subclinical thyroid dysfunction be monitored?
212	6	Information for people with thyroid disease, their families and carers
213		6.1 What information should people with thyroid disease, their family and
214		carers receive?
215	The	key questions may be used to develop more detailed review questions,
216	whic	ch guide the systematic review of the literature.
217	3.6	Main outcomes
218	The	main outcomes that will be considered when searching for and assessing
219	the e	evidence are:
220	1	Quality of life.
221	2	Mortality.
222	3	Resource use.
223	4	Adverse effects of treatment.
224	4	NICE quality standards and NICE Pathways
225	4.1	NICE quality standards
226	NIC	E quality standards that may use this guideline as an evidence
227	sou	rce when they are being developed
228	• T	hyroid disease. Publication date to be confirmed.
229	4.2	NICE Pathways
230	NIC	E Pathways bring together everything we have said on a topic in an
231		ractive flowchart. When this guideline is published, the recommendations
232		be included in the NICE Pathway on thyroid disease (in development).

- 233 An outline based on this scope is included below. It will be adapted and more
- detail added as the recommendations are written during guideline
- 235 development.

Thyroid disease overview



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5 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 16 October to 13 November 2017.

The guideline is expected to be published in November 2019.

You can follow progress of the guideline at

https://www.nice.org.uk/guidance/indevelopment/gid-ng10074.

Our website has information about how NICE guidelines are developed.

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