The Endocrine Society of Sri Lanka's

CLINICAL GUIDELINES

Thyroid Diseases

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Abbreviations

TSH	–	Thyroid Stimulating Hormone
FT4	–	Free thyroxine
FT3	–	Free tri-iodothyronine
FNC	–	Fine Needle Cytology
CPK	–	Creatinine Phosphophokinase
°C	–	Celsius
FBC	–	Full Blood Count
TRAb	–	TSH Receptor Antibody
TPOAb	–	Thyroid Peroxidase Antibody
RAI	–	Radio Active Iodine

Guidelines for management of hypothyroidism

Hypothyroidism is a commonly seen condition. Primary hypothyroidism results from under secretion of thyroid hormone and secondary hypothyroidism is caused by lack of TSH production from the pituitary. The most common cause for hypothyroidism in Sri Lanka is autoimmune thyroid disease (Hashimoto's thyroiditis).

Causes of primary hypothyroidism

- Autoimmune thyroiditis (Hashimoto's thyroiditis)
- Postpartum thyroiditis
- Drugs (e.g. amiodarone, lithium)
- Iatrogenic causes (e.g. radioactive iodine, thyroidectomy)
- Congenital hypothyroidism

Presentation and evaluation

Symptoms

- Tiredness, weakness, fatigue
- Sleepiness
- Cold intolerance
- Hoarseness of voice
- Hair loss
- Constipation
- Joint pains and muscle cramps
- Depression
- Menorrhagia
- Infertility
- Weight gain

Signs

- Goiter
- Bradycardia
- Oedema
- Hoarseness of voice
- Delayed relaxation of deep tendon reflexes
- Slow speech
- Cold dry skin

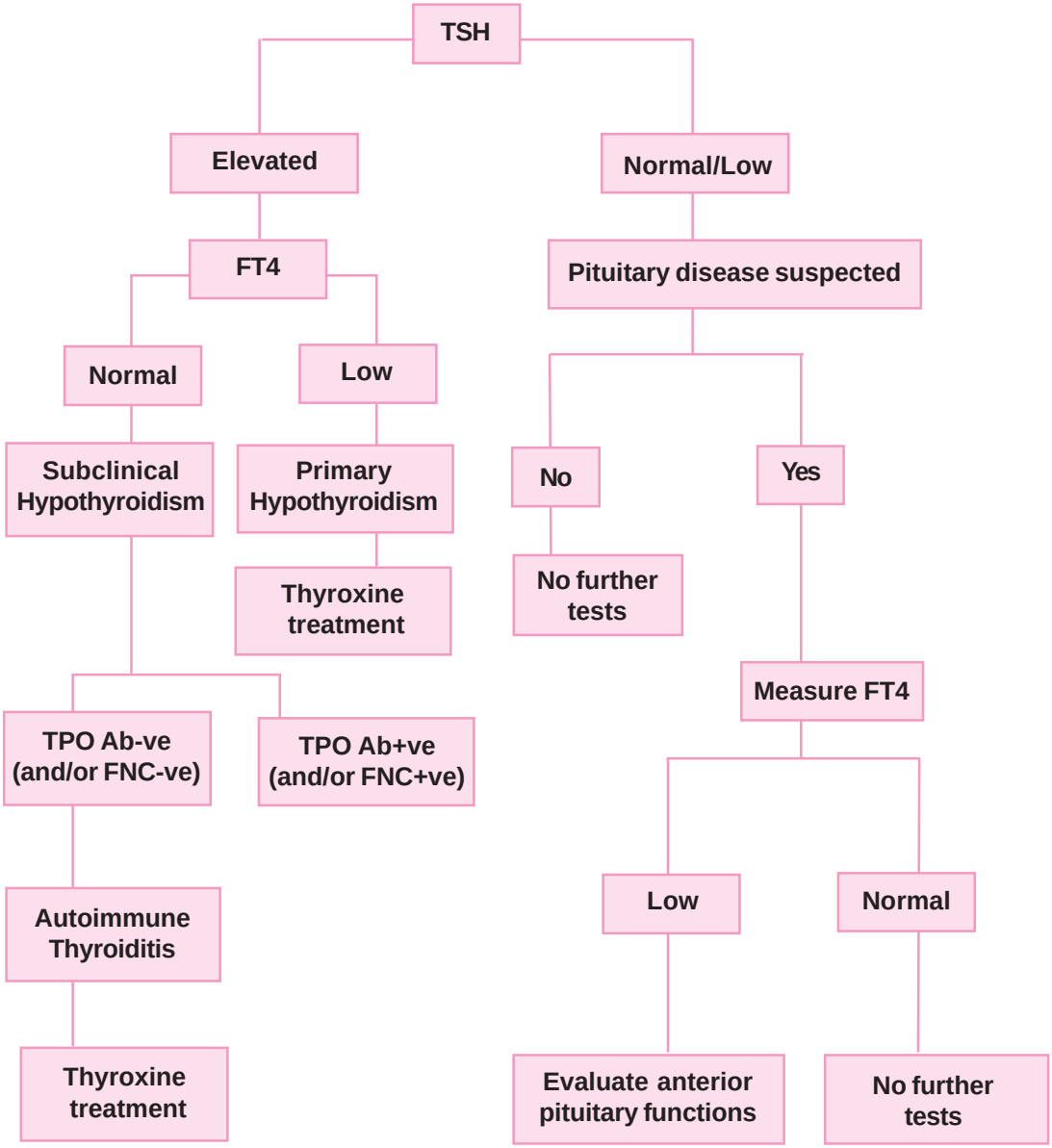
Indications for screening of hypothyroidism

- Clinical suspicion of hypothyroidism
- Strong family history of hypothyroidism
- Newborns of mothers with thyroid diseases
- Past history of neck irradiation, RAI or thyroid surgery
- Patients on drugs such as lithium or amiodarone
- Children with Down syndrome
- Patients with other autoimmune diseases

Abnormal results in common lab tests that suggest hypothyroidism

- Hypercholesterolemia
- Hyponatremia
- Anaemia
- Elevated CPK
- Hyperprolactinemia

Evaluation of suspected Hypothyroidism



Treatment

- The mean replacement dosage of levothyroxine in an adult is 1.6 µg/kg per day and the dose requirement is lower in elderly.
- Therapy is usually initiated in patients under the age of 50 years with full replacement dose.

  Lower initial dose is indicated in those,
  - above 50 years
  - with cardiac disease

  Starting dose could be 25-50µg

  Evaluate clinically and with FT4 6-8 weekly till FT4 and TSH are normalized.
- Levothyroxine should be taken on an empty stomach upon waking in the morning, spaced out from meals, tea, coffee, by at least ½-1 hour duration.
- Recommended storage temperature for most brands of levothyroxine is less than 25° C.

In suspected central hypothyroidism, it is mandatory to evaluate the other anterior pituitary hormone secretion and to replace any cortisol deficiency prior to starting levothyroxine.

Causes of failure to normalize TSH during treatment

- Non compliance
- Factors affecting absorption
  - Taking levothyroxine close to a meal
  - Drug interfering in absorption
    (e.g. cholestyramine, ferrous sulfate, aluminium hydroxide antacids and calcium supplements)
  - Other causes of malabsorption
- Drugs accelerating metabolism
  (e.g. phenytoin, carbamazepine and rifampicin)
- Bioequivalence of different levothyroxine preparations may differ.

Follow Up

- Once the TSH concentration has been normalized, patient can be reviewed every 6 to 12 months.
- When the dosage or the type of thyroid preparation is changed, the TSH should be measured after 6 to 8 weeks.
- Patients should be monitored for symptoms and signs of overtreatment, which include tachycardia, palpitations, nervousness, tiredness, headache, increased excitability, sleeplessness, tremors, and possible angina.
- In thyroid carcinoma patients, aim of levothyroxine therapy is to achieve appropriate TSH suppression.

Hypothyroidism: Special situations

Hypothyroidism in Pregnancy

- Untreated hypothyroidism during pregnancy may increase the incidence of maternal and fetal complications including impairment of fetal cognitive development.
- Screening for thyroid dysfunction in pregnant women is recommended if they are symptomatic or have a family history of thyroid disease.
- Pregnant hypothyroid patients should be referred for specialized care.
- Women with overt or subclinical hypothyroidism should receive levothyroxine replacement to keep TSH within the trimester specific range.

Trimester	TSH
First	0.1-2.5 mIU/L
Second	0.2-3.0 mIU/L
Third	0.3-3.0 mIU/L

- Increase the dose of levothyroxine by about 30 percent as soon as pregnancy is confirmed, with further dose changes based upon serum TSH concentrations measured every four weeks until the TSH becomes normal for the trimester.
- The levothyroxine dose should be reduced to pre-pregnancy levels after delivery, with assessment of serum TSH four to six weeks later. Screening with TSH is recommended in neonates born to mothers with a thyroid disorder.

Hypothyroidism in elderly persons

- Because of high prevalence of hypothyroidism in this age group and as the symptoms may be subtle, including hoarseness of voice, deafness, confusion, dementia, ataxia, depression, dry skin, or hair loss, there should be a low threshold for screening.
- Thyroxine replacement therapy should be aimed to maintain TSH within normal range.

Congenital hypothyroidism in children

- Refer to a specialist center for treatment and follow up.
- Initial investigations include TSH, freeT4 and USS of the thyroid.
- Starting dose of levothyroxine in a neonate is 10-15 µg /kg once daily.
- Dose of levothyroxine should be titrated against the biochemical tests, age and weight of the child.
- On follow up TSH and free T4 should be measured more frequently in children.
  - 2-4 weekly after initial treatment, until free T4 normalizes
  - Every 1-2 monthly in the first 6 months
  - Every 3-4 monthly between 6 months and 3 years of age
  - Every 6-12 monthly from 3 years of age to end of growth
- When monitoring serum FT4 should be kept in the upper half of normal range and serum TSH should be kept within the reference range.
- Meticulous monitoring of growth parameters (length/ height, weight, and head circumference) and developmental assessment should be done on follow up.

Post partum hypothyroidism

- Presence of TPO antibodies during first trimester predict the development of postpartum thyroiditis. Repeat TSH 3 and 6 months postpartum.
- Risk of developing permanent hypothyroidism is high in patients who have history of postpartum thyroiditis. An annual TSH level should be performed in these women.
- Postpartum screening (TSH) is recommended for women with type 1diabetes mellitus at 3 and 6 months postpartum.
- Treatment with levothyroxine is indicated in all women with TSH >10 mIU/L and TSH 4-10 mIU/L who plan to have another pregnancy in the near future.
- Women with postpartum depression should be screened for hypothyroidism.

Subclinical hypothyroidism

- Subclinical hypothyroidism refers to mildly increased serum TSH levels (usually less than 10 mIU/L) in the setting of normal free T4.
- When TSH is between 5-10 mIU/L,TSH should be repeated after 3-6 months to confirm that it is a persistent problem.
- Usually it is asymptomatic.
- Treatment is justified when TSH is >10 mIU/L or in patients with TSH levels between 5 and 10 mIU/L in conjunction with goiter, positive anti-TPO antibodies, subfertility or when planning a pregnancy.

- An initial dosage of levothyroxine of 25 to 50 µg/day can be used and serum TSH should be measured in 6 to 8 weeks to adjust the dose.
- If a decision is made not to treat these patients, they should be evaluated at yearly intervals for evidence of progression.

Hypothyroid coma

Therapy of hypothyroid coma includes slow rise of core temperature, warm humidified oxygen by mask or ventilation, close monitoring of vital function, high dose of levothyroxine 300-500µg via nasogastric tube as starting dose followed by 50-100 µg daily till oral drugs can be taken. Hydrocortizone 50-100mg 6-8 hourly should be given for probable associated cortisol deficiency.

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Guidelines for management of hyperthyroidism

Hyperthyroidism includes diseases that are caused by excess synthesis and secretion of thyroid hormone by the thyroid gland. Excess thyroid hormone causes an increase in the metabolic rate and the hypermetabolic effect of it affects every system. Appropriate treatment of hyperthyroidism requires an accurate diagnosis. The prevalence of hyperthyroidism in women is 0.5-2%. All thyroid diseases occur more frequently in women than in men.

Causes of primary hyperthyroidism

- **"Hyperthyroidism"** – Thyrotoxicosis due to inappropriately high synthesis and secretion of thyroid hormone by the thyroid gland.
- **"Thyrotoxicosis"** – A clinical state that results from inappropriately high thyroid hormone action on tissues including exogenous thyroxine administration.

Presentation and evaluation

Symptoms

- Weight loss despite increased appetite
- Anxiety
- Increased perspiration
- Heat intolerance
- Tremor
- Hyperactivity
- Palpitations
- Oligomenorrhea

Signs

- Restlessness
- Tachycardia
- Systolic hypertension
- Warm, moist, smooth skin
- Lid lag
- Fine tremor
- Muscle weakness

Elderly may have no symptoms at all

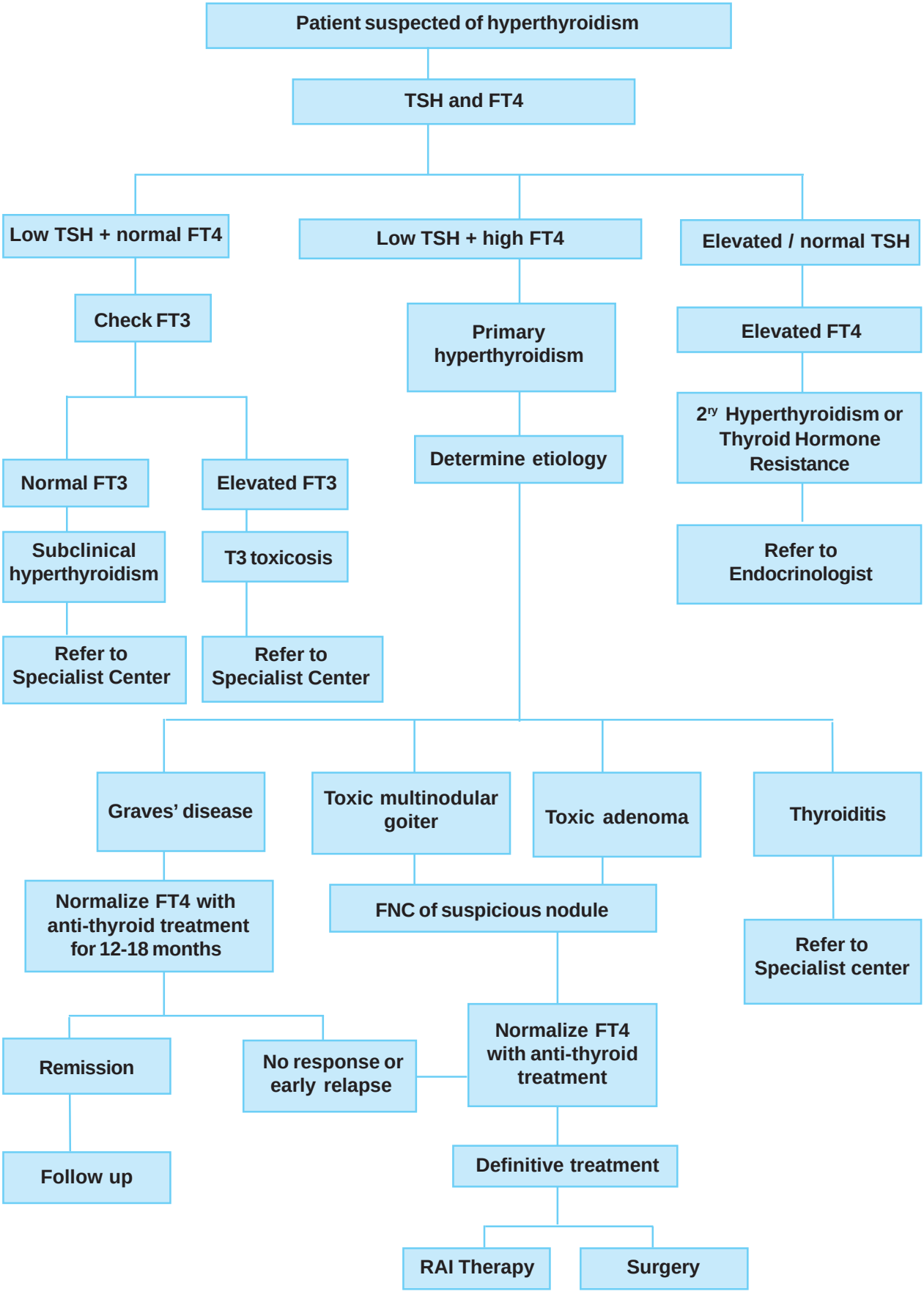
Indications for screening of hyperthyroidism

- Patients with clinical features of thyrotoxicosis
- Patients with a goiter
- Patients with unexplained tachyarrhythmia
- Patients on amiodarone

Biochemical screening for hyperthyroidism

- Low clinical probability - TSH
- High clinical probability - TSH and FT4

Evaluation of suspected hyperthyroidism



Causes of hyperthyroidism

Cause	Goiter/ ultrasound scan	Specific clinical features	Radioiodine uptake scan	Other tests
Graves'	Diffuse non tender Bruit + ↑ vascularity on US	Graves' orbitopathy Pretibial myxedema	Diffuse increased uptake	TRAB+
Toxic MNG	Nodules +		Patchy increased uptake	
Toxic adenoma	Single nodule		Single hot nodule	
Subacute thyroiditis	Tender diffuse goiter		Reduced uptake	High ESR
Hashi-toxicosis	Diffuse goiter		Reduced uptake	TPO Ab +

Treatment of hyperthyroidism

Symptomatic treatment

- **Indications**
  - Symptomatic thyrotoxicosis
  - Patients with resting heart rates in excess of 90 bpm
  - Coexistent cardiovascular disease.
- **First line treatment**
  - Beta blockers propranolol 10-40mg tid, atenolol 25-100mg bid
  - If Beta blockers are contraindicated (bronchial asthma, COPD) use diltiazem 30-60 mg tid or verapamil 40-120 tid
  - Stop Beta blockers once the patient is euthyroid

Specific treatment

- Antithyroid medication – preferred first line treatment for Grave's disease and until definitive treatment for toxic multinodular goiter and toxic adenoma.
- Radioactive iodine therapy (RAI)
- Thyroidectomy

Antithyroid medication

- **First line treatment**

  Carbimazole/ methimazole: (Dose titration regime) Start with higher doses (30-45 mg/daily or divided) and titrate downwards to a lower dose (5-10 mg/day). Block and replace regime is generally not recommended.

- **Monitoring treatment**

  Evaluate with FT4 every 4 weekly initially until FT4 normalizes and then both FT4 and TSH 8-12 weekly.

- **Duration of treatment**

  12-18 months. Following remission, thyroid function should be monitored 3 monthly for 1 year and then annually.

- **Relapse or failure to achieve remission following antithyroid medication**

  Refer to a specialist center.

- **Side effects and precautions**

  - Baseline FBC and liver profile.
  - Routine monitoring during treatment is not recommended.
  - Patient education to seek medical advice urgently in the presence of side effects (pruritic rash, jaundice, pharyngitis, fever) with urgent FBC and liver functions is mandatory.
  - Approach to side effects

    Minor cutaneous reaction: concurrent antihistamine therapy without stopping the drug.

    Persistent minor side effects or serious allergic reaction : stop the offending drug and refer to a specialist center.

Indications for propylthiouracil

- First trimester of pregnancy
- Thyroid storm
- Minor persistent reactions to carbimazole in patients who refuse RAI or surgery
- All patients who require propylthiouracil should be referred to a specialist center.
  (carbimazole 5 mg = propylthiouracil 50 mg)

Radioactive iodine (RAI) therapy

The decision to administer RAI should be made in a specialist center.

- **Pre treatment preparation**
  - Prior to RAI euthyroidism should be achieved.
  - Medical therapy of comorbid conditions should be optimized.
  - Pregnancy should be excluded in females of childbearing age.
  - Antithyroid drugs should be discontinued 1 week prior to RAI therapy (please refer local radiation center advice).
  - Pre-treatment counseling on radiation safety and fertility including contraception for at least 6 months should be given.

- **Follow-up after RAI therapy**
  - Patients need assessment of FT4 within 1-2 months.
  - In severe hyperthyroidism patients may require recommencement of antithyroid medication and more frequent monitoring.
  - Patients need life long monitoring for the development of permanent hypothyroidism.
  - If hyperthyroidism persists after 6 months following RAI, refer to a specialist Endocrine center.

Surgery

The decision to perform surgery should be made in a specialist center.

Follow-up after Surgery

- Stop Carbimazole at the time of surgery.
- Beta-adrenergic blockade should be slowly discontinued following surgery.
- Serum calcium should be measured and hypocalcaemia should be managed accordingly.
- The need to start thyroxine post operatively is decided by the surgical team and dose adjustment can be done with subsequent evaluation of thyroid functions.

Grave's Ophthalmopathy (GO)

- Features suggestive of active GO include retro-orbital pain, painful eye movements, redness and swelling of eye lids, redness of conjunctiva and reduced visual acuity.
- In active GO radioactive iodine is contraindicated.

  Patients with active GO must be referred to an Ophthalmologist and Endocrinologist.

Thyroid storm

General management

- Thermal regulation (aggressive cooling and acetaminophen therapy)
- Volume resuscitation
- Treatment of arrhythmias using standard anti-arrhythmic drugs
- Treatment of precipitating cause (e.g. antibiotic for bacterial infection)

Specific management

- Propylthiouracil 200 mg 6 hourly (to block thyroid hormone synthesis and T4 to T3 conversion)
- Potassium iodide therapy (Lugol solution: 5 -7 drops tid), should be started 6 hours after starting propylthiouracil (to inhibit thyroid hormone release)
- Beta blockers (propranolol 40 mg every 4-6 hourly) or calcium channel blockers if beta blockers are contraindicated
- Intravenous hydrocortisone 100mg 6 hourly (to inhibit T4 to T3 conversion).

Hyperthyroidism in Special Situations

Grave's disease in children and adolescents

- First-line treatment: Carbimazole/ methimazole.
- Use minimum possible dose to keep the patient euthyroid.
- If the child has not gone into remission in 2-3 years while on antithyroid medication, referral to an Endocrinologist / Paediatric Endocrinologist is indicated.
- Beta blocker therapy is indicated if the patient is having tachycardia (above age specific heart rate).

Hyperthyroidism in pregnancy

All pregnant patients with thyrotoxicosis should be referred to an Endocrinologist.

Diagnosis of hyperthyroidism in pregnancy

- Use TSH and FT4
- If trimester-specific reference ranges for TSH are not available in the local laboratory, the following reference ranges are recommended

Trimester	TSH
First	0.1-2.5 mIU/L
Second	0.2-3.0 mIU/L
Third	0.3-3.0 mIU/L

Monitoring and Maintenance

- TSH and FT4: 2-4 weekly
- Target: FT4 in the upper non pregnant reference range.
- There is no evidence that treatment of subclinical hyperthyroidism improves pregnancy outcome, and treatment could potentially adversely affect fetal outcome.
- All newborns of mothers with Grave's disease should be evaluated for thyroid dysfunction and treated if necessary.

Transient hCG-mediated TSH suppression in early pregnancy (transient hyperthyroidism in pregnancy) should not be treated with antithyroid drug therapy.

Management of Subclinical Hyperthyroidism (SH)

- Definition: Low TSH with normal FT4 and FT3 in the absence of overt clinical features of thyrotoxicosis.
- When subclinical hyperthyroidism is suspected biochemically, exclude other causes such as concurrent corticosteroid therapy, central hypothyroidism, and nonthyroidal illness.
- Once detected, TSH should be repeated after 3 - 6 months to confirm that it is a persistent problem.
- Refer to a specialist center to decide on test mode of treatment.

Subclinical hyperthyroidism: when to treat

Factor	TSH(<0.1 mIU/L)	TSH (0.1-0.5 mIU/L)
Age >65	Treat	Consider treating
Age <65 with comorbidities		
Heart disease	Treat	Consider treating
Hyperthyroid symptoms	Treat	Consider treating
Osteoporosis	Treat	No treatment
Age <65, asymptomatic	Consider treating	No treatment

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Guidelines for management of thyroid nodules

Nodular thyroid disease is a common clinical problem. A thyroid nodule is a discrete lesion within the thyroid gland that is clinically or radiologically distinct from the surrounding thyroid parenchyma. Thyroid nodules need to be evaluated to delineate their aetiology and plan subsequent management accordingly. One main aim of this evaluation is to identify malignant nodules but it is important to keep in mind that all thyroid nodules are not malignant. Thyroid incidentalomas are non-palpable nodules detected on ultrasound scan or other anatomic imaging studies; these have the same risk of malignancy as palpable nodules with the same size.

Causes of thyroid nodules

Benign

- Colloid nodule
- Hyperplastic nodule
- Non-toxic-toxic multinodular goitre
- Autoimmune/other forms of thyroiditis

Malignant

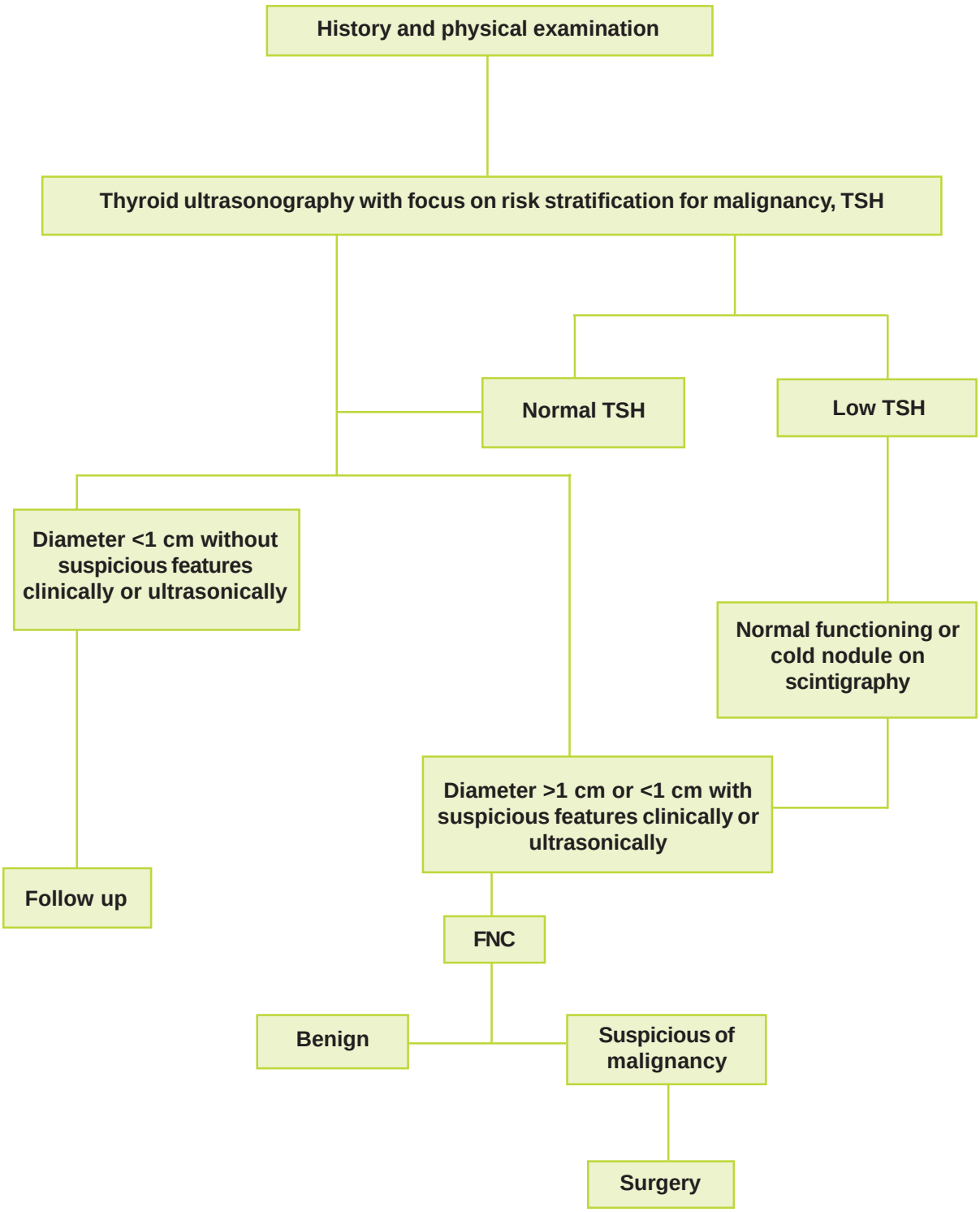
- Thyroid carcinoma - papillary, follicular, medullary, anaplastic
- Lymphoma
- Other / metastasis

Indicators of a high risk thyroid nodule

While the below-mentioned features are classical features, it must be remembered that many patients do not come with these typical features

- Family history of thyroid cancer or thyroid cancer syndrome (e.g multiple endocrine neoplasia)
- Rapid nodule growth
- A very firm/hard nodule
- Clinical signs of fixity to surrounding structures
- Vocal cord paralysis/hoarseness of voice
- Regional lymph node enlargement or the presence of another lesion (e.g a lung mass on respiratory examination) that suggests a distant metastases.
- Male gender
- Extremes of age (<20 or >70 years) Nodule >4 cm in size
- The presence of pressure symptoms

Evaluation of a thyroid nodule



All thyroid nodules >1 cm in size, including both palpable and non-palpable nodules need to be evaluated. Nodules that are below 1 cm need to be evaluated based on individual risk.

The tests required are:

TSH level

Ultrasonography

Fine needle cytology (FNC)

The ultrasonographic patterns that suggest malignancy

- Irregular shape
- Hypoechogenecity
- Heterogenous internal echoes
- Microcalcifications
- Absence of a halo
- An anteroposterior to transverse diameter ratio (A/T) greater than 1
- Infiltration into regional structures and suspicious regional lymph nodes.
- Purely central vascular pattern

Ultrasound guided fine needle cytology is preferred in

- The presence of two or more thyroid nodules >1 cm.
  (those with a suspicious sonographic appearance should be aspirated preferentially)
- Suspicious nodules, taking multiple aspirates
  If none of the nodules has a suspicious sonographic appearance. (aspirate the largest nodules only and observe the others with serial US examinations)

FNC findings

FNC finding	NCI/Bethesda category	BTA/RCP Thy1-Thy 5 category
Insufficient cytology or nondiagnostic smears	I	Thy 1 and Thy 1c (cystic lesions)
Benign - includes nodular goiter, colloid nodule, hyperplastic/adenomatoid nodule, Hashimoto's thyroiditis, granulomatous thyroiditis	II	Thy 2 and Thy 2c (cystic lesions)
Atypia of undertemined significance or follicular lesions of undetermined significance (atypical follicular lesions, cellular follicular lesion, neoplasm cannot be ruled out)	III	Thy 3a (atypia)
Follicular neoplasm or suspicious of follicular neoplasm and include hurthle neoplasm	IV	Thy 3f (follicular)
Suspicious of malignancy	V	Thy 4
Malignant (papillary, medullary, anaplastic, lymphoma, metastatic)	VI	Thy 5

Management after fine-needle cytology

- If diagnostic or suspicious for Papillary carcinoma of thyroid, surgery is recommended .
- If a follicular neoplasm is suspected the options are surgery, thyroid scintigraphy or observation with repeat FNC later. The choice would depend on the size of the lesion and other risk factors.
- If the nodule is benign on cytology, further immediate diagnostic studies or treatment are not routinely required.
- Recurrent benign cystic thyroid nodules should be considered for surgical removal based on compressive symptoms and cosmetic concerns.

The role of medical therapy of patients with benign thyroid nodules

- Routine suppression therapy of benign thyroid nodules is not recommended.
- Patients with growing nodules that are benign after repeat biopsy should be considered for continued monitoring or intervention with surgery.

Long-term follow up of patients with thyroid nodules

- All benign thyroid nodules should be followed up with regular clinical evaluation and serial ultrasound examinations 6-18 months after the initial FNC. If nodule size is stable (i.e., no more than a 50% change in volume or <20% increase in at least two nodule dimensions in solid nodules or in the solid portion of mixed cystic-solid nodules), the interval before the next follow-up clinical examination or ultrasound may be longer,

  e.g every 3-5 years.

- If there is evidence for nodule growth either by palpation or by ultrasonography, FNC should be repeated, preferably with ultrasound guidance.

Management of thyroid nodules in pregnancy

- Pregnancy is associated with growth of pre-existing thyroid nodules and the growth of new nodules. The evaluation is the same as for a nonpregnant patient, but a radionuclide scan is contraindicated.

- Refer for expert opinion.

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Foot Note

In case of unusual thyroid function test pattern deviating from the clinical context of the patient exclude nonthyroidal illness and concurrent administration of interfering medication.

Having excluded above refer to a specialist endocrine centre for further evaluation including assessment for hormone assay interference.