

Radioiodine in the management of benign thyroid disease

Clinical guidelines

Report of a Working Party 2007



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Preface

This report updates guidelines published in 1995 by the Royal College of Physicians (RCP) of London and has been written by a working group representing the several bodies involved in the administration of radioiodine for hyperthyroidism. Regular revision of guidelines is essential to ensure best practice, and the present working group has included developments in the past ten years in the legislation relating to radioiodine treatment, as well as advances in our understanding, such as the effect of radioiodine on thyroid eye disease. We have also extended the scope of the guidelines to incorporate information on the treatment of subclinical hyperthyroidism and non-toxic goitre. This in turn led to the change in the report's title, to encompass this range of benign thyroid disease, rather than hyperthyroidism alone.

The practice of guideline writing has also moved on, with the expectation that evidence is assessed and recommendations are made according to established criteria (see [Table 1](#)).

Unfortunately, much of the evidence supporting the way we give radioiodine is derived from custom and practice, and many of the fundamental principles we use are unlikely ever to be subject to controlled trial. This document is intended primarily to be a practical guide to the use of radioiodine for specialists who will be familiar with the previous guidance.

We have therefore chosen to keep the same format as the 1995 guidelines and to grade recommendations where we feel these can be estimated from the available evidence, without a wholesale revision and exhaustive review of the older literature. Where recommendations are made without a statement of the level, these can be taken as level [4]. Finally, we are grateful to the many individuals who have commented on drafts of this document, in particular to Michael Waller for his help with Appendix A, and to the staff of the RCP who have helped in the production of the final version.

March 2007

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Evidence and recommendations grading criteria

Table 1 Levels of evidence grading criteria

Levels of evidence	
Level	Type of evidence
1a	Evidence obtained from meta-analysis or randomised control trials
1b	Evidence from at least one randomised controlled trial
2a	Evidence obtained from at least one well-designed control study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
4	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities
Grading of recommendations	
Grade recommendations	
Evidence levels 1a, 1b	Requires at least one randomised controlled trial as part of the body of the literature of overall good quality and consistency addressing the specific recommendations
Evidence levels 2a, 2b, 3	Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation
Evidence level 4	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality

Glossary

Activity: the amount of radioactivity administered or prescribed, measured in MBq.

ALARP: as low as reasonably practicable

Antithyroid drugs (ATD): carbimazole, propylthiouracil

ARSAC: Administration of Radioactive Substances Advisory Committee

Comforter and carer: any individual who (other than as part of their occupation) knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing or has undergone any medical exposure.¹

Destructive thyroiditis: transient inflammation of the thyroid caused by viral infection, autoimmune damage or drugs (such as amiodarone), typically resulting in a phase of thyrotoxicosis followed by a phase of hypothyroidism.

EA: Environment Agency

EHS: Environment and Heritage Service (in Northern Ireland)

Euthyroid: the state of an individual with normal thyroid hormone levels.

Exemption limits: maximum activity of radioiodine that may be present in and disposed of from a specific area (such as a hospital) without the need for registration and authorisation under the Radioactive Substances Act.²

Graves' disease: hyperthyroidism due to thyroid stimulating antibodies directed against the TSH receptor. Associated with clinical evidence of thyroid eye disease in around 50% of patients.

Gy: gray; the international system unit of absorbed dose of radiation.

HSE: Health and Safety Executive

Hyperthyroidism: clinical state produced by excessive activity of the thyroid gland leading to thyrotoxicosis; common causes are Graves' disease and toxic nodular thyroid disease.

Hypothyroidism: clinical state produced by thyroid hormone insufficiency; common causes are autoimmunity and ietrogenic damage to the thyroid from radioiodine or surgery. Treatment is usually with levothyroxine tablets.

IRMER: Ionising Radiation (Medical Exposure) Regulations 2000

IRR99: Ionising Radiations Regulations 1999

MARS: Medicines (Administration of Radioactive Substances) Regulations 1978

MBq: megabecquerel; a measure of the amount of radioactivity ($1 \text{ MBq} = 1 \times 10^6$ disintegrations per second).

MDGN: Medical and Dental Guidance Notes 2002

mGy: milligray; a measure of the absorbed dose of radiation ($1 \text{ Gy} = 1 \text{ Joule/kg} = 100 \text{ rad}$)

MHRA: Medicines and Healthcare Products Regulatory Agency

MPE: medical physics expert

mSv: millisievert; a measure of effective dose to the body which is used for radiation protection purposes.

Ophthalmopathy: also known as thyroid eye disease; clinically evident as lid retraction, periorbital oedema, proptosis and/or diplopia in around 50% of patients with Graves' disease.

QA: quality assurance

RPA: radiation protection adviser

SEPA: Scottish Environment Protection Agency

T3: tri-iodothyronine

T4: thyroxine

Thyroid crisis (or storm): severe exacerbation of thyrotoxicosis often resulting in death if inadequately treated.

Thyroid eye disease: see ophthalmopathy.

Thyrotoxicosis: a state produced by elevated thyroid hormone levels in the blood; may be due to hyperthyroidism, excessive ingestion of thyroid hormone or destructive thyroiditis.

Toxic (nodular) goitre: hyperthyroidism produced by a nodular enlargement of the thyroid with autonomous function of one or more nodules.

TSH: thyroid stimulating hormone

¹³¹I: radioiodine

I Overview of radioiodine therapy

Indications

1.1 Radioiodine (^{131}I) has been used in therapy for hyperthyroidism for more than 60 years. Radioiodine is indicated in cases of hyperthyroidism due to Graves' disease or toxic goitre (solitary toxic adenomas or multi-nodular goitre) and is effective in curing hyperthyroidism in virtually all patients who are given single or multiple doses.^{3,4} [2a] There is an emerging role for ^{131}I in the treatment of subclinical hyperthyroidism, at least in the USA.⁵ [2b] Radioiodine is also indicated for treatment of euthyroid goitre in selected cases.⁶ [2a] Radioiodine is not an appropriate treatment for thyrotoxicosis secondary to thyroiditis or for thyrotoxicosis associated with iodine excess. A European Association of Nuclear Medicine survey for 2002 indicated that approximately 6,000 doses were administered in the UK that year.

1.2 In Graves' disease, radioiodine may be administered as first-line treatment, or may be given if treatment with an antithyroid drug (ATD) has failed to result in long-term remission. This may be due to difficulty with patient management, unacceptable or serious side effects, resistance to drug therapy (a very rare occurrence) or, most commonly, the relapsing nature of the underlying disorder. Radioiodine is also indicated if hyperthyroidism is not controlled or recurs after thyroid surgery.

1.3 For persistent hyperthyroidism due to toxic nodular goitre, radioiodine represents the treatment of choice since ATDs are not curative in this condition.^{3,4} [2b] In euthyroid subjects with diffuse or nodular goitre, surgery has been the treatment of choice to reduce goitre size and relieve compressive symptoms. Recently, it has been shown that radioiodine is effective in reducing goitre size by 50% at one year,⁶ accompanied by a significant reduction in associated symptoms and signs.⁷ [2a]

Factors determining whether radioiodine treatment is appropriate

1.4 Factors that influence the decision to proceed to radioiodine therapy in hyperthyroid subjects include patient age, gender, diagnosis, severity of hyperthyroidism, the presence of other medical conditions, access to radioiodine, and patient and doctor preference. In euthyroid subjects with goitre, similar factors are relevant to the decision-making process, especially pertinent being goitre size, availability of surgery and likelihood of surgical complications. All patients considering radioiodine treatment should be counselled regarding treatment options by an accredited specialist in the treatment of thyroid disease.⁸ [4]

1.5 Most hyperthyroid patients aged less than 40 years have Graves' disease. In this group it is common practice in the UK to administer a course of ATD treatment, although many clinicians prescribe radioiodine as a first choice because of the relatively low rates of long-term remission associated with ATD alone.⁹ [2b] Failure to control hyperthyroidism with carbimazole or propylthiouracil, due to difficulties in management or, more commonly, recurrence of hyperthyroidism after withdrawal of an ATD, are indications for radioiodine therapy in view of

the long-term morbidity and potential mortality associated with poorly controlled thyrotoxicosis.^{10,11} [2a] Serious side effects such as agranulocytosis and hepatic dysfunction are contraindications to further ATD treatment; such patients should proceed to radioiodine therapy as soon as possible. Relapse of hyperthyroidism after withdrawal of an ATD is an indication for surgery or radioiodine in Graves' disease since further courses of drug therapy rarely result in long-term remission once relapse has occurred. If there are features suggestive of a malignancy, surgery is indicated.

1.6 Although ATDs and surgery are generally regarded as the treatments of choice in childhood Graves' disease, radioiodine is effective in this age group. A recent retrospective study of 116 subjects treated with radioiodine at under 20 years old revealed cure of hyperthyroidism without any increased incidence of thyroid cancer, leukaemia or congenital abnormalities in offspring.¹² [3]

1.7 Pregnancy and breast feeding represent absolute contraindications to radioiodine treatment. In patients of reproductive age, their plans for pregnancy, including assisted conception, must be taken into consideration in planning the timing of therapy. It may also be necessary to postpone radioiodine treatment (and continue with medical treatment), even in relapsed disease, until breast feeding has ended and the age of the child is sufficient to allow compliance with radiation protection regulations. Further information on pregnancy and breast feeding is given in [section 2.17](#).

Causes and severity of hyperthyroidism

Graves' disease

1.8 Although radioiodine therapy is effective in patients with Graves' disease, those with large goitre, patients with more severe biochemical disease and possibly men and younger patients are less likely to respond to a single dose of radioiodine.¹³ [2a] The effect of such treatment on thyroid eye disease (ophthalmopathy) is still uncertain (see also [sections 2.28–2.30](#)). A large retrospective study revealed no difference in the development or worsening of thyroid eye disease in patients treated with an ATD, thyroid surgery or radioiodine.¹⁴ In contrast, a prospective study comparing the risk of development or worsening of eye disease after treatment with radioiodine, surgery or an ATD suggested a greater risk with radioiodine.¹⁵ Others have shown the development or worsening of thyroid eye disease to be more frequent in those treated with radioiodine than with an ATD, although worsening of eye disease can be prevented by administration of steroids for a few weeks after treatment.¹⁶ [1b] Early administration of thyroxine for hypothyroidism following radioiodine is also important to reduce the occurrence or worsening of thyroid eye disease.¹⁷ [1b]

Toxic nodular goitre

1.9 Radioiodine is the treatment of choice for toxic nodular goitre.^{3,4} Goitre size is a determinant of clinical outcome in patients treated with radioiodine, but a reduction in goitre size can be expected in most patients. In patients with very large goitre and upper airways obstruction there is a theoretical risk of worsening airways obstruction following radioiodine treatment, although in practice this complication is rarely seen. In the longer term, radioiodine represents a successful means of reducing goitre size.

- ▶ There is no evidence of any fetal or maternal risk in pregnancy or its outcome in women who receive radioiodine provided the above guidelines are followed. A person living in the same house as a pregnant woman may receive radioiodine provided there is no close or prolonged contact with the pregnant woman.

Breast feeding

- ▶ Breast feeding must be discontinued permanently through a pregnancy when radioiodine is given as iodine is concentrated in milk, but is safe in subsequent pregnancies.

Other

- ▶ Situations where it is clear that the safety of other persons in relation to exposure to radiation cannot be guaranteed.

2.18 Additional care should be taken in patients who are incontinent of urine; they should be catheterised before radioiodine administration to allow safe disposal of urine containing radioiodine, and MPE advice should be sought. [Sections 2.28–2.30](#) set out precautions in those with thyroid eye disease.

2.19 Even in cases of known iodine sensitivity, radioiodine administration is very unlikely to precipitate a hypersensitivity reaction. The elemental iodine content of radioiodine preparations is 0.05–0.18 µg. This is very significantly lower than average daily iodine intake (>150 µg/day) in the UK.

Duties of the clinician assessing the patient

2.20 At the initial consultation, the clinician should record the following:

- ▶ clinical data relevant to the prescription of radioiodine or to the outcome of treatment, particularly regarding:
 - aetiology: diagnostic biochemistry, clinical features and ultrasound usually differentiate Graves' disease from nodular thyrotoxicosis. Perchnetate or ¹²³I thyroid imaging is useful to identify patients with acute thyroiditis, factitious hyperthyroidism and unsuspected non-functioning nodules, as well as to exclude recent exogenous iodine administration (for instance, amiodarone or intravenous contrast media), which would impair radioiodine uptake by the thyroid
 - drug history: ATDs; beta adrenergic blocking agents
 - history of significant heart disease
 - heart rate and rhythm
 - thyroid size
 - goitre type
 - signs of thyroid eye disease
 - recent thyroid function tests.
- ▶ personal or social factors that would determine the need for special radiation protection advice, or plans for conception that would preclude radioiodine.

Patient information and consent

2.21 At the initial consultation patients should be advised of what the treatment consists of and its effectiveness, with particular regard to:

- ▶ the slow onset of action of radioiodine
- ▶ the possibility of persistent or recurrent hyperthyroidism and what may be done about it
- ▶ the possibility of hypothyroidism and its symptoms, implications and treatment
- ▶ the need for regular follow-up to detect hypothyroidism.

2.22 Before treatment, patients should be advised of recommendations with regard to radiation protection and informed of the implications of radioiodine treatment in relation to work, travel and contact with the family (Appendices A and B).

- ▶ The patient may need to take time off work for a period related to the activity of radioiodine received and the nature of their work.
- ▶ The patient should avoid prolonged close contact with children and with pregnant women for a period of time related to the activity of radioiodine received.
- ▶ There may be restrictions on travel related to the activity of radioiodine received.

Premenopausal women should be advised to avoid pregnancy within six months of radioiodine administration (see [section 2.17](#)).

2.23 An information sheet should be given to patients following the initial consultation (the information it should include is detailed in Appendix B). This will summarise information contained in [sections 2.21–2.22](#) and contain a contact telephone number in case of problems. Close communication with the GP is essential and is covered in detail in [sections 3–4](#).

2.24 Before radioiodine administration, patients should sign a consent to treatment form using the current NHS template ([Appendix C](#)), indicating that they understand the advice concerning radiation protection, the outcome with regard to risks of hypothyroidism and (where appropriate) that they are neither pregnant nor breast feeding.

2.25 Following radioiodine administration, patients should be given an information card clearly stating the date on which the radioiodine was taken, the total activity, and the duration for which special precautions are necessary (the information it should include is detailed in Appendix D). The card should be carried by the patient during the time special precautions are necessary. A telephone contact number should also be given on the card. Patients should be informed that some screening procedures at ports and airports may detect residual radioactivity several months after radioiodine administration, and the card should be carried on all commercial flights for six months after treatment.

Subclinical hyperthyroidism

2.26 There is little evidence to indicate the activity of radioiodine that should be administered in treating this condition. If a patient has subclinical hyperthyroidism associated with a clinically

4 Monitoring and follow-up after the first year

Rationale

4.1 Regular review of thyroid function tests in patients who have undergone radioiodine treatment for hyperthyroidism is essential to assess the efficacy of the treatment and for timely detection of changes in thyroid status. Initial follow-up is usually conducted by the consultant who has clinical care of the patient, with subsequent monitoring in general practice (see [section 3](#)). The main consequence of radioiodine therapy is the development of hypothyroidism, but a small number of patients (around 10–20%) will require a second or rarely a third or even fourth dose of radioiodine because of continuing hyperthyroidism. The prevalence of hypothyroidism following treatment has been estimated to be 90% over a typical patient's lifetime. Therefore all patients should have thyroid function tests followed up indefinitely.

4.2 It is recommended that a fail-safe monitoring system be adopted to support regular patient monitoring with standardised follow-up. This may best be facilitated using a computer-based system. The extremes of unnecessary follow-up and of patients 'dropping through the net' will thus be minimised. Such a system will also provide information in an auditable format for the assessment and maintenance of the quality of patient care. The responsibility for life-long follow-up should not rest solely with the GP; patients have an important role to play, and specialists have a legitimate interest in long-term follow-up. Shared care is a management strategy that facilitates joint responsibility between general practitioners, consultants and patients in cost-effective follow-up.

Communication between specialist, general practitioner and patient

4.3 In keeping with best practice and Department of Health guidelines, copies of clinic letters should be routinely copied to the patient. After leaving the clinic, patients may well think of additional questions they would like to have asked, or find that concerns subsequently arise. Patients should be provided with details of someone they can contact following the consultation if they have any further questions or concerns. Since patients may turn to their GPs for advice, the GP should be sent a copy of the information sheet (Appendix B) given to the patient (including any standardised information regarding restrictions to which the patient will be subjected), in addition to the clinic letter outlining the proposed treatment.

4.4 Following the administration of radioiodine, a letter indicating the date of treatment and the activity given should be sent to the general practitioner and copied to the patient. This letter should include an indication of when the patient is to be reviewed at the hospital clinic and the duration of hospital visits (usually one year). Patients must be made aware of the need for regular review of their condition.

4.5 We recommend that initial follow-up of patients who have received radioiodine therapy is conducted by the medical team under the supervision of the consultant who has clinical care of the patient. This should normally include an arrangement to identify and recall non-attendees. The cooperation of the GP in helping to trace non-attendees should be obtained. The role of

Appendix B

Information for patients having radioiodine treatment for hyperthyroidism

What is hyperthyroidism?

Your thyroid gland is in your neck, in front of your windpipe. It produces a hormone called thyroxine which acts as your 'body clock', keeping your body working properly. Thyroxine has a direct effect on your heart rate, bowel activity, skin and organs. Hyperthyroidism (also known as Graves' disease, thyrotoxicosis and overactive thyroid) develops when your thyroid gland produces too much thyroxine, making your body clock run too fast.

What is radioiodine treatment?

Radioiodine treatment uses radioactive iodine to cure hyperthyroidism. The radioactivity destroys the overactive thyroid tissue and slows down the production of thyroxine. The thyroid gland uses most of the iodine, so only a small amount of radioactivity is needed.

What about my tablets?

If you have been given tablets to control your hyperthyroidism, you will need to stop taking them before your radioiodine treatment starts. The letter giving you your appointment for radioiodine treatment will tell you when to stop taking your tablets. You can only have radioiodine treatment after you have stopped taking your tablets, so please follow the instructions carefully.

Also, if you are taking any tablets which contain iodine or kelp (a seaweed which contains iodine), such as vitamin or mineral supplements, you will need to stop taking them at least a week before being treated with radioiodine. (If you have thyroid problems it is best not to take any tablets or vitamin supplements which contain iodine or kelp.)

How is the radioiodine given?

The radioiodine is given either as a drink or as a capsule. The drink tastes just like water and only contains a small amount of radioiodine. The capsule looks like those used for many other medicines and you swallow it whole with a drink of water.

How long does the radioiodine take to work?

It can take between a few weeks and several months for the treatment to work. Most people with hyperthyroidism (80–90% of people) are cured by a single dose of radioiodine. If the treatment has not worked within six months, it can be repeated.

Is radioiodine treatment dangerous?

No, its safety record is excellent. Radioiodine treatment has been given to millions of people since it was introduced in the early 1940s.

Where else in the body does radioiodine go?

Most of the radioiodine goes to the thyroid gland within a few hours. The rest will pass out of your body in your urine during the first few days after treatment. How long this will take depends on how much you are given.

Can I have the treatment if I am pregnant or breast feeding?

No. Radioiodine can harm unborn babies and babies that are being breast fed. You will not be given radioiodine treatment if you are pregnant or wish to continue breast feeding. You should avoid getting pregnant for six months after your treatment.

Are there any risks in having children afterwards?

No effects on the unborn babies of women who have been treated with radioiodine more than six months before they got pregnant, or on the health of those children, have been shown in over sixty years of experience in using radioiodine treatment. The treatment does not affect a woman's fertility.

Can I father children after radioiodine treatment?

Men should be careful not to father children for four months after radioiodine treatment. The treatment does not affect a man's fertility.

Will there be any danger to my family or friends?

After your radioiodine treatment, your body will contain some radioactivity, which will decrease every day. If you follow the advice you are given, other people may receive only an insignificant radiation dose from you. You will be able to continue shopping, cooking and doing other day-to-day household activities as normal. However, you will need to take some simple precautions for some time after your treatment to stop your family, friends and other people coming into contact with too much of the radiation.

How long you will need to do these things will depend on the amount of radioiodine you have been given. Your specialist will give you advice on the precautions at least a week before your treatment.

If you are given a large dose of radioiodine, you may have to stay in hospital for a few days after the treatment to reduce the risk of other people coming into contact with radiation.

You can travel home by public transport as long as you do not spend more than one hour sitting next to the same person on the bus, train or tube. You can drive yourself home. If someone else is driving you home, you should sit on the back seat, as far away from them as possible.

Hygiene

- ▶ Most of the radioiodine leaves your body in your urine and sweat during the first few days after your treatment. Drinking plenty of fluids and going to the toilet a lot will speed this up process.
- ▶ Men should urinate (wee) sitting down on the toilet to avoid getting radioiodine on the edge of the toilet.
- ▶ After going to the toilet you should flush it twice.
- ▶ Always wash your hands well after going to the toilet.
- ▶ Make sure that no one else uses your towels and face cloths.
- ▶ Wash all your crockery and cutlery thoroughly.

Other precautions

Your specialist will advise you about the following activities at least a week before your treatment is given. How long these precautions will apply for will depend on the amount of radioiodine you receive. Different precautions may apply for different lengths of time, but some may be for up to two to four weeks.

For the time advised:

- ▶ Limit your contact with children, especially children under 3 years of age. If you have your own children or have a job where you have contact with children, it is important to talk to the specialist about this as soon as possible.
- ▶ Stay more than an arm's length away from other people.
- ▶ Sleep alone.
- ▶ Take a few days off work if your job brings you into close contact with other people.

- ▶ Avoid going to places like cinemas, theatres, pubs and restaurants, where you may be in close contact with other people.
- ▶ Avoid travelling on public transport, apart from your journey home from hospital.

Carry the card

Your specialist will give you a card with the details of your treatment. You should carry this with you until you no longer have to follow any of these instructions. You should also carry the card with you if you are travelling through ports or on international flights for six months after treatment. Some security devices at airports are so sensitive that they may detect that you have had radioiodine treatment even after this length of time.

Will I need to see a doctor after the radioiodine treatment?

Yes, you will need to see either the doctor you saw at the clinic or your family doctor. You will have to have regular blood tests to monitor how the treatment is affecting your thyroid gland.

Are there any short-term side effects?

Most people notice no side effects from the treatment. A few people develop symptoms of an overactive thyroid (such as palpitations and sweating), usually five to ten days after the treatment. For this reason, your doctor may tell you to take a tablet called a beta-blocker for a few weeks after the treatment, and they may tell you to start taking your antithyroid tablets again.

Your thyroid gland may become underactive at a time ranging from a few months after treatment to many years later, causing 'hypothyroidism'. In a small number of people, this happens quite soon after radioiodine treatment. The blood tests will show whether this has happened.

If your thyroid gland does become underactive, your doctor will give you thyroxine tablets to replace the thyroxine that your thyroid gland is no longer producing. The tablets are very safe and contain a man-made version of the natural thyroxine that your body is unable to produce enough of. It may take a little time to find the right dose of thyroxine for you. You will not have to pay prescription charges for thyroxine tablets.

Thyroid eye disease (which can develop in Graves' disease) may get worse after the treatment. The doctor will discuss this with you before you have the treatment and may suggest that you take a steroid called prednisolone for a month or two after the treatment.

More information

You can get more information about radioiodine treatment and thyroid disease from:

The British Thyroid Foundation
PO Box 97
Clifford
Wetherby
West Yorkshire
LS23 6XD

Phone or fax: 01423 709707 or 01423 709448

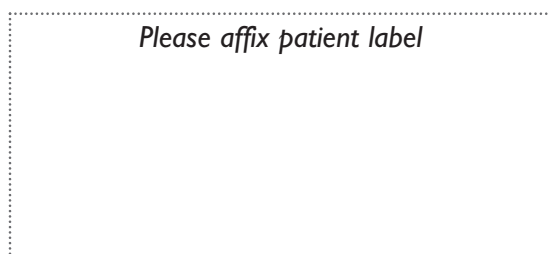
Website: www.btf-thyoid.org

If you have any questions or you need more advice, please call the following number.

Phone:.....

Appendix C

Sample consent form to be used for patients for whom radioiodine therapy has been prescribed



INSERT HOSPITAL DETAILS

Patient/parental agreement to investigation or treatment

¹³¹I Radioiodine treatment for hyperthyroidism or non-toxic goitre

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy).

The intended benefits: I have explained the procedure to the patient/parent. In particular, I have explained that this treatment is being proposed to treat the thyroid gland which has become overactive and/or enlarged.

Serious or frequently occurring risks: Several radioiodine treatments may be required. There may be a short period of thyroid overactivity following the radioiodine treatment. The thyroid gland may stop working completely after this treatment and regular blood tests will be required to check the functioning of the gland. Thyroxine treatment may become necessary. In patients with thyroid eye disease, the possible risks of radioiodine treatment have been discussed. I have satisfied myself that the patient, if female, is not pregnant and that she is aware that pregnancy must be avoided for six months. Male patients should not father children for four months.

I have also discussed what the procedure is likely to involve (including the specific written requirement to avoid contact with children and pregnant women and to take time off work), the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved. I have informed the patient/parent that they can withdraw their consent for treatment at any time.

Radioiodine activity to be administered
 MBq ¹³¹I (±10%)

The following leaflet/tape has been provided:

'Thyrotoxicosis and its management' and 'Radioiodine treatment instructions'

Signed Date
 Name (PRINT)..... Job title

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe s/he/they can understand.

Signed Date
 Name (PRINT).....

Statement of patient or person with parental responsibility for patient

- ▶ I agree to the procedure described above.
- ▶ I understand that you cannot give me a guarantee that a particular person will perform the procedure. However, the person will have appropriate experience.
- ▶ I confirm that I am/the patient is not pregnant or breast feeding.

Signed Date
 Name (PRINT)..... Relationship to patient.....

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient/parent has signed the form in advance)

- ▶ I have discussed relevant written radiation protection advice.
- ▶ I have confirmed that the patient/parent has no further questions and wishes the procedure to go ahead.

Signed Date
 Name (PRINT)..... Job title

Copy accepted by patient: yes / no (please circle)

Appendix D

Sample patient information card

Radionuclide instruction card

Patient name

Patient address

Registration number

Consultant name

Radionuclide ¹³¹I MBq

Administered on

Signed

Hospital address

Please observe the following instructions

Avoid prolonged close contact (a distance of less than 1 metre) with children and pregnant women for the following number of days:

.....

Sleep apart from your partner for the following number of days:

.....

Do not return to work for the following number of days:

.....

Avoid close contact (less than 1 metre) with any other person for more than three hours for the following number of days:

.....

Please carry this card with you at all times for 4 weeks after your treatment and for 6 months when travelling through ports and airports, and if travelling abroad.

Appendix E

Elements of a system to support long-term follow-up of patients treated with radioiodine

Structured systems (computerised or manual) are important to ensure long-term follow-up of patients treated with radioiodine, specifically to prompt regular biochemical testing to detect the onset of hypothyroidism and to ensure that any subsequent treatment with thyroxine is correctly adjusted to achieve biochemical targets.^{65–67}

Ensuring long-term follow-up is an important and intrinsic component of the care provided by the thyroid specialist. Such follow-up is facilitated by the presence of a computerised system linked to details of radioiodine treatments, and should ideally be compatible with both hospital and primary care IT systems. Long-term follow-up may be undertaken in primary care, in agreement with the specialist, GP and patient, and is again facilitated by the presence of a computerised system.

Characteristics of follow-up systems

- ▶ All patients treated with radioiodine should be identified. Mechanisms should be in place to capture all patients, such as through links to radioiodine prescribing records.
- ▶ All relevant data should be collected, and should comprise:
 - patient demographic details and identifiers (hospital/NHS numbers)
 - details of thyroid specialist and GP
 - date(s) and dose(s) of radioiodine treatments
 - dates and results of serial thyroid function tests
 - date of initiation of thyroxine therapy.
- ▶ Additional data may be recorded, especially to facilitate long-term audit of outcomes and research. These data may include:
 - aetiology of hyperthyroidism
 - presence and severity of thyroid eye disease
 - and details of ATD therapy.
- ▶ Data collection should fit easily into a normal clinical routine. Data may be managed in such a way as to facilitate updating of general hospital and/or primary care records and/or to generate routine correspondence.
- ▶ The system should provide useful information. Data should be used:
 - to inform day-to-day care
 - for quality assurance of patient care

- for long-term patient follow-up
- for the review of treatment practices and outcomes.
- ▶ The system must ensure regular recall of patients for biochemical testing (typically at annual intervals):
 - systems must be in place to identify defaulters from follow-up and to prompt further recall
 - systems should be sufficiently flexible to allow recording of biochemical data from several laboratory sources
 - systems should ideally highlight abnormal results in order to facilitate clinical intervention when appropriate.
- ▶ Procedures must be in place to ensure complete and accurate data collection and overall implementation of effective follow-up.

Indicators of data quality

Regular data validation should include the following indicators of quality:

- ▶ completeness – are data available for all radioiodine treated patients?
- ▶ consistency – are findings recorded consistently throughout the patient record?
- ▶ accuracy – is there variation between observers?
- ▶ face validity – would an alternative method for collecting data give similar results?
- ▶ relevance – do the data as recorded allow prediction of those at risk?

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