

Society of Nuclear Medicine Procedure Guideline for Therapy of Thyroid Disease with Iodine-131 (Sodium Iodide)

Version 2.0

Authors: Edward B. Silberstein, MD (University of Cincinnati Hospital, Cincinnati, OH); Abass Alavi, MD (Hospital of the University of Pennsylvania, Philadelphia, PA); Helena R. Balon, MD (William Beaumont Hospital, Royal Oak, MI); David V. Becker, MD (New York Hospital–Cornell Medical Center, New York, NY); David R. Brill, MD (Chambersburg Hospital, Chambersburg, PA); Susan E. M. Clarke, MD (Guy’s Hospital, London, U.K.); Chaitanya Divgi, MD (Memorial Sloan Kettering Cancer Center, New York, NY); Stanley J. Goldsmith, MD (New York–Presbyterian/Weill Cornell Medical Center, New York, NY); Robert J. Lull, MD (San Francisco General Hospital, San Francisco, CA); Donald A. Meier, MD (William Beaumont Hospital, Royal Oak, MI); Henry D. Royal, MD (Mallinckrodt Institute of Radiology, St. Louis, MO); Jeffry A. Siegel, PhD (Nuclear Physics Enterprises, Wellington, FL); Alan D. Waxman, MD (Cedars-Sinai Medical Center, Los Angeles, CA).

I. Purpose

The purpose of this guideline is to assist nuclear medicine practitioners in evaluating patients for therapy with ^{131}I (sodium iodide) for benign or malignant conditions of the thyroid gland, performing this treatment, understanding and evaluating the sequelae of therapy, and reporting the results of therapy.

II. Background Information and Definitions

Oral administration of ^{131}I has been a commonly accepted procedure for treatment of benign and malignant conditions of the thyroid since the 1940s. Physicians responsible for treating such patients should have an understanding of the clinical pathophysiology and natural history of the disease processes, should be familiar with alternative forms of therapy, and should be able to collaborate closely with other physicians involved in the management of the patient’s condition. The treating physician should either see patients in consultation with the physician assuming overall management of the patient’s condition or be prepared to assume that role. In the United States, the treating physician should be board certified in Nuclear Medicine, Radiology, or Radiation Oncology or be able to document equivalent training, competency, and experience in the safe use and administration of therapeutic amounts of ^{131}I . In Europe, the treating physician should be board certified in Nuclear Medicine or Radiation Oncology.

Licensure to possess ^{131}I and regulations regarding the release of patients treated with radioiodine vary from jurisdiction to jurisdiction. Physicians engaged in therapy with ^{131}I must be knowledgeable

about, and in compliance with, all applicable laws and regulations. The facility in which treatment is performed must have appropriate personnel, radiation safety equipment, and procedures available for waste handling and disposal, monitoring personnel for accidental contamination, and controlling spread of ^{131}I .

Definitions

- A. $^{131}\text{Iodine}$ is a β -emitting radionuclide with a physical half-life of 8.1 d; a principal γ -ray of 364 KeV; and a principal β -particle with a maximum energy of 0.61 MeV, an average energy of 0.192 MeV, and a range in tissue of 0.8 mm.
- B. *Therapy* means the oral administration of ^{131}I as sodium iodide.
- C. *Benign conditions* include Graves’ disease (toxic diffuse goiter), toxic or nontoxic nodular goiter, and autonomously functioning toxic or nontoxic nodules.
- D. *Malignant conditions* include thyroid cancer that is sufficiently differentiated to be able to synthesize thyroglobulin and, in most cases, accumulate radioiodine.

III. Examples of Clinical and Research Applications

A. Benign Conditions

- 1. Hyperthyroidism
 ^{131}I may be indicated for the treatment of Graves’ disease, toxic multinodular goiter, or toxic autonomously functioning thyroid nodule(s).
- 2. Nontoxic multinodular goiter

¹³¹I therapy has been used successfully to diminish the size of nontoxic multinodular goiter.

B. Thyroid Cancer

1. ¹³¹I therapy has been used for postoperative ablation of thyroid remnants after thyroidectomy.
2. ¹³¹I therapy has been used to treat residual thyroid cancer and metastatic disease after partial or complete thyroidectomy.
 - a. Treatment of differentiated thyroid cancer with radioiodine should be considered in the post surgical management of such patients with any of the following: tumor size >1.5 cm; tumor size <1.5 cm if there is unfavorable histology (tall cell, sclerosing or other variants); lymph node metastases; multifocal disease, which could represent intrathyroidal metastases; lymphatic or vascular invasion; capsular invasion or penetration including peri-thyroidal soft tissue involvement; metastases to lung, bone, liver, etc. Brain sites must be approached with caution as intracerebral bleeding and cerebral edema may occur. In general, the greater the invasive quality of the cancer, the higher the dosage consideration should be.
 - b. Perioperative staging should evaluate:
 - i. lymph nodes in the neck; ultrasound is cheaper and more widely employed (for staging and biopsy) than MRI but there do not appear to be differences in sensitivity;
 - ii. lung metastases, for which computed tomography (without contrast) is far more sensitive than chest x-ray;
 - iii. bone metastases, especially in the presence of musculoskeletal symptoms, employing the bone scan and/or bone x-rays (each appear to be about 60–70% sensitive). PET imaging with F-18-FDG or F-18 sodium fluoride for this purpose may prove valuable.

- b. The treating physician must explain the procedure, treatment, complications, side effects, therapeutic alternatives, and expected outcome to the patient. Written information should be provided to the patient.
 - c. The treating physician must obtain written informed consent before therapy.
2. For therapy of hyperthyroidism and nontoxic multinodular goiter
 - a. The results from recent measurements of thyroid hormone levels (free T4, free T3) and thyroid-stimulating hormone (TSH) should be available and reviewed. The avidity of the thyroid gland for iodide must be established. This can be accomplished quantitatively using a recent radioiodine uptake (RAIU) or qualitatively using a thyroid scan. These procedures will differentiate silent thyroiditis and thyrotoxicosis factitia from other forms of hyperthyroidism.
 - b. Pretreatment of selected patients with antithyroid drugs (ATD) to deplete thyroid hormone stores may be helpful. ¹³¹I therapy can cause radiation thyroiditis with release of stored thyroid hormone into the circulation, resulting in occasional transient worsening of hyperthyroidism and, rarely, precipitation of thyroid storm. This is more likely to occur in patients with large, iodine-avid multinodular glands who are given larger amounts of ¹³¹I. Accordingly, elderly patients and patients with significant preexisting heart disease, severe systemic illness, or debility may benefit from pretreatment with ATD. The ATD should be discontinued for at least 3 d before the radioiodine therapy is given. The ATD can be resumed 2–3 d after treatment with ¹³¹I. Some experts recommend administering a higher dosage of ¹³¹I in patients who have been pretreated with ATD. A randomized study found no effect of pretreatment of Graves' disease with/without methimazole on outcome. Similarly antithyroid drugs had no effect in outcome of Graves' disease in another study, but here the outcome of radioiodine therapy for toxic nodular goiter was adversely affected. Treatment with β -blockers can be helpful for symptomatic control. β -blockers need not be discontinued before treatment with ¹³¹I.
 - c. The consent form should include the following items specific to the therapy of hyperthyroidism:

IV. Procedure

A. Patient Preparation

1. For all patients
 - a. All patients must discontinue use of iodide-containing preparations, thyroid hormones, unless rhTSH is used, and other medications that could potentially affect the ability of thyroid tissue to accumulate iodide for a sufficient time before contemplated therapy (Table 1).

Table 1
Drug Interactions

Type of medication	Recommended time of withdrawal
Antithyroid medication (e.g., propylthiouracil, methimazole, carbimazole) and multivitamins	3 d for antithyroid drugs 7 d for multivitamins*
Natural or synthetic thyroid hormone (e.g., thyroxine, triiodothyronine)	10–14 d for triiodothyronine 3–4 wk for thyroxine
Kelp, agar, carageen, Lugol's solution, potassium iodide solution ("SSKI")	2–3 wk, depending on iodide content*
Topical iodine (e.g., surgical skin preparation)	2–3 wk*
Radiographic contrast agents	
Intravenous (water soluble)	3–4 wk, assuming normal renal function
Lipophilic agents (rarely used)	>1 mo
Amiodarone	3–6 mo or longer

*These time intervals relate to hyperthyroid patients. For hypothyroid thyroid cancer patients, a 6-wk time interval is recommended.

- i. More than one ¹³¹I treatment may be necessary.
- ii. The risk of eventual hypothyroidism is high, especially after treatment of Graves' disease, and lifelong daily ingestion of a thyroid hormone tablet would then be necessary.
- iii. Long-term follow-up will be necessary.
- iv. Ophthalmopathy may worsen or develop after ¹³¹I therapy for Graves' disease.
- d. Recombinant rhTSH, as an off-label use, has been employed in patients with non-toxic multinodular goiter to maximize thyroid gland uptake and minimize the radiation dose to the rest of the body.
3. For therapy of thyroid cancer
 - a. Thyroid hormone medications must be withheld for a time sufficient to permit an adequate rise in TSH (>30 uU/mL). This is at least 10–14 d for triiodothyronine (T3) and 3–4 wk for thyroxine (T4). TSH may not rise to this level if a large volume of functioning tissue remains. If rhTSH is employed to assess residual thyroid tissue post-thyroidectomy for patients on thyroid hormone replacement, the serum thyroglobulin (Tg) should be obtained as a baseline while the patient's serum thyrotropin (TSH) is suppressed and repeated after rhTSH stimulation. This is done on all patients who are being evaluated using the rhTSH I-131 scan approach for determining residual disease status. A 4 mCi (148 MBq) I-131 dosage has been shown to be more effective than lower activities. A thyroglobulin rise of 2 ng/mL is suggestive of residual disease even in the presence of a negative scan. Recombinant human TSH (rhTSH) is not currently approved in the United States or Europe for use in ¹³¹I therapy, although there is FDA approval for use in diagnostic testing. The off-label use of rhTSH for ablation has been successfully employed to ablate thyroid remnants post-thyroidectomy.
 - b. For patients receiving an ablative dose or treatment dose of radioiodine following a partial or complete thyroidectomy for thyroid cancer, the results from a recent measurement of TSH and the operative and histology reports should be available and reviewed. A stimulated serum thyroglobulin should be obtained in the hypothyroid state or after rhTSH injections. A complete blood count and other laboratory tests, such as a serum calcium (to exclude hypoparathyroidism postthyroidectomy), and serum creatinine, may be helpful.

- c. Most experts recommend a low-iodide diet for 10–14 d before administration of therapy to improve radioiodine uptake even with rhTSH. This is not a low salt diet but a low iodine diet and non-iodized salt is widely available. Table 2 lists major food groups and other common sources of iodine. Red dye number 3, erythrosine B, a tetraiodofluorescein salt, is found in many processed red- or pink-colored foods and medications. Institutions should develop guidance sheets to assist patients in dealing with the low iodine diet including non-iodized salt. The use of a diuretic such as hydrochlorthiazide is another possible technique for reducing the body iodine content, but the side effects of hypokalemia and hypotension from this approach must be monitored closely. Thyroid hormone contains iodine, and some clinicians have suggested stopping thyroid hormones for 5–7 d before administration of I-131 therapy if rhTSH is employed.
- d. The presence of iodine-accumulating thyroid tissue is documented by uptake measurement and imaging (see “Procedure Guideline for Extended Scintigraphy of Differentiated Thyroid Cancer”). A small minority of patients will either need no I-131 ablative therapy (no remnant left) or have too much residual tissue to give I-131 safely. A preablation scan may sometimes also reveal metastases in neck, lung, bone, and brain, causing a reevaluation of the use of I-131, or at least a change in I-131 dosage. There are experts in the field who believe this happens too infrequently to justify the time and cost required for preablation scanning.

In the absence of antithyroglobulin antibodies, an elevated or rising serum thyroglobulin may also be a useful indicator of residual or recurrent thyroid cancer and may be an indication for radioiodine therapy even in the absence of discernible activity following a diagnostic dose of ¹³¹I. An elevated serum thyroglobulin does not guarantee iodine avidity of the tumor. If the thyroglobulin is elevated but no discernible activity is seen on the diagnostic I-123 or I-131 scan, there may still be visualization of thyroid tissue on a post therapy scan, and, in fact, the serum thyroglobulin may fall. However, with continuous TSH suppression the serum thyroglobulin may fall without I-131 therapy, and there has never been a study demon-

strating that recurrence rates and prognosis are altered by such a course of empiric I-131 therapy. There are risks from administering radioiodine to the patient which must be weighed against uncertain benefits in this situation, although such empiric I-131 therapy often causes a decrease in thyroglobulin levels, presumably reflecting a cytotoxic effect. Both F-18 FDG PET scan (probably more sensitive after TSH stimulation) and thyroid ultrasound may be helpful in identifying thyroid cancer metastases when the I-131 scan is negative but the stimulated serum thyroglobulin is elevated. Older data indicate that when F-18 FDG is unavailable, Tc-99m-sestamibi and Tl-201 scintigraphy may detect thyroid cancer with reasonable sensitivity.

- e. A written informed consent form must be obtained and should include the following items specific for the therapy of thyroid cancer:
 - i. The purpose of the treatment is to destroy normal and cancerous thyroid tissue. Other normal tissues may also be affected.
 - ii. More than one ¹³¹I treatment may be necessary.
 - iii. Early side effects may include mucositis, nausea, occasional vomiting, pain and tenderness in the salivary glands, loss of saliva or taste, unusual, often metallic-like alterations in taste, neck pain and swelling if a sizeable thyroid remnant remains after surgery, and decreased white blood cell count that may result in increased susceptibility for infection. Generally, these side effects are temporary.
 - iv. Late side effects may include temporary infertility (in men this can be permanent as dosages progressively ex-

Table 2
Dietary Sources of Iodine

Iodized salt
Milk/dairy products
Eggs
Seafood
Seaweed and kelp products
Commercial bread made with iodide conditioners
Chocolate
Iodide-containing multivitamins
FDC red dye #3

ceed 7.4–11.1 GBq [200–300 mCi]); rarely, permanent damage to the salivary glands resulting in loss of saliva or sialolithiasis, excessive dental caries, and reduced taste; dry eyes; epiphora from scarring of the lacrimal ducts, and possibly the very rare development of other malignancies, including those of the stomach, bladder, colon, and salivary glands, and leukemia. If there is a causative role for radioiodine in reported neoplasms post therapy, and this is still an unsettled issue, these usually occur after more than one dosage, but no threshold has been established.

- v. These late side effects are rarely seen and should not deter a patient from taking ¹³¹I for treatment of thyroid cancer.

B. Information Pertinent to Performing the Procedure

1. For all patients
 - a. The treating physician must obtain the patient's thyroid-related medical history and perform a directed physical examination. The cumulative administered activity of ¹³¹I should be reviewed and recorded in the patient's record.
 - b. The treating physician must confirm that appropriate laboratory testing has been performed and must review the results of these tests.
 - c. Female patients who have the potential to be pregnant should routinely be tested for pregnancy within 72 hours or less before administration of the ¹³¹I treatment. Occasionally, when historical information clearly indicates pregnancy is impossible, a pregnancy test may be omitted at the discretion of the treating physician.
 - d. All potentially breastfeeding/lactating women should be asked if they are lactating. If so, they should be asked to stop breastfeeding, and therapy must be delayed until lactation ceases in order to minimize the radiation dose to the breast. Lactation (and the ability of the breast to concentrate large amounts of iodine) completely ceases 4–6 wk post partum (with no breastfeeding) or 4–6 wk after breastfeeding stops. The patient may not resume breastfeeding for that child. Nursing may resume with the birth of another child.
 - e. The treating physician should confirm that the patient is continent of urine or that arrangements are made to prevent contamination caused by incontinence.
 - f. The patient's identity must be confirmed in accordance with institutional policy before administration of ¹³¹I.
 - g. Confused patients may not be able to tolerate admission and isolation in a hospital.
2. For hyperthyroid patients
 - a. Dose selection. A variety of methods have been used to select the amount of administered activity. One method is to use the estimated thyroid gland size and the results of a 24-h RAIU test to calculate the amount of ¹³¹I to administer in order to achieve a desired concentration of ¹³¹I in the thyroid gland. Delivered activity of 2.96–7.4 MBq (80–200 μCi) per gram of thyroid tissue is generally appropriate. The thyroid radiation dose depends on the RAIU, as well as the biological half-life of the radioiodine in the thyroid gland. The biological half-life can vary widely.
 - b. Thyroid dosages toward the upper end of the range (i.e., 7.4 MBq/gm [200 μCi/gm]) are especially suitable for patients with nodular goiters, very large toxic diffuse goiters, and repeat therapies. In much of Europe, empiric rather than calculated dosage strategies are often used.
3. For thyroid cancer patients
 - a. Dose selection. A variety of approaches have been used to select the amount of administered activity. General guidelines are listed below:
 - i. For postoperative ablation of thyroid bed remnants, activity in the range of 2.75–5.5 GBq (75–150 mCi) is typically administered, depending on the RAIU and amount of residual functioning tissue present.
 - ii. For treatment of presumed thyroid cancer in the neck or mediastinal lymph nodes, activity in the range of 5.55–7.4 GBq (150–200 mCi) is typically administered.
 - iii. For treatment of distant metastases, activity of >7.4 GBq (200 mCi) is often given. The radiation dose to the bone marrow is typically the limiting factor. Most experts recommend that the estimated radiation dose to the bone marrow be less than 200 cGy [200 rads]). Detailed dosimetry may be indicated in patients who are treated with large amounts of radioactive iodine to determine how much ¹³¹I can be safely administered. Retention of radioiodine in the body at 48 h should be <4.44 GBq (120 mCi), or <2.96 GBq (80

- mCi) if diffuse lung metastases are present, to reduce the risk of radiation pneumonitis and myelosuppression.
- Oral administration of lithium carbonate prolongs the intrathyroidal biological half-life of administered ¹³¹I and occasionally may be useful in patients who have a rapid turnover of radioactive iodine. Serum lithium levels should be monitored to avoid toxicity. A short effective ¹³¹I half-life can be a source of failure of ¹³¹I therapy in metastatic lesions.
 - Side effects may occur and are generally dose related. These are listed above in the consent form out-line found in Section IV.A.3.e. Hydration of the patient, with instructions urging frequent urination for several days to a week and efforts to increase salivary flow, may reduce radiation exposure to the bladder and salivary glands. Antiemetics may be helpful. The patient should have at least 1 bowel movement a day to reduce colon exposure. Laxatives may be necessary.
 - Patients should have whole body scintigraphy approximately 3–14 d after treatment for staging purposes.
 - A patient is required by the NRC to remain in the hospital if any individual member of the public is likely to exceed a radiation dose of 5 mSv (500 mrem) from that patient. Licensees may authorize patient release from the treating facility according to the relevant NRC Guideline, when the survey meter reading is less than 48.5 mrem/h (or the equivalent unit mR/h) at one meter or when the oral I-131 dosage is 221 mCi or less.
 - Since the overall recurrence rate for thyroid cancer approaches 20%, and up to 10% of recurrences occur after twenty years, long term follow-up of the patient is recommended, both to maintain suppressed serum TSH levels (kept below normal but at or above about 0.1 uU/mL to reduce the risk of osteoporosis and atrial fibrillation) and to detect new sites of thyroid cancer.

C. Precautions

- The precautions indicated in IV.A.3.e. must be respected.
- The treating physician must instruct the patient on how to reduce unnecessary radiation exposure to family members and members of the public. Written instructions should be provided both to reduce patient dose and that to the population and may be required in some jurisdictions. With simple precautions, the ra-

diation dose to family members is low (<1 mSv) even when patients are not admitted to a hospital.

- Following treatment, patients should not become pregnant until their medical condition has been optimized. Opinions vary widely as to how long to defer pregnancy. Some centers recommend 6 mos after ¹³¹I therapy for patients with hyperthyroidism and 12 mos for patients with thyroid cancer. The 12-mo interval allows for follow-up imaging to evaluate the effectiveness of the cancer treatment.
- If the patient is to be treated as an inpatient, nursing personnel must be instructed on radiation safety. Selected nursing personnel may be provided appropriate radiation monitors (film badge, direct-reading dosimeters, etc.). Any significant medical conditions should be noted and contingency plans made in case radiation precautions must be breached for a medical emergency. Concern about radiation exposure should not interfere with the prompt, appropriate medical treatment of the patient should an acute medical problem develop.
- Radiation surveys of the thyroid gland should be performed periodically on personnel administering ¹³¹I.
- Patients must be provided with a written document stating they have been given a radioactive substance for documentation of the source of radiation in case it is detected by monitoring devices during travel.
- A serum TSH should be obtained 6–8 wk after therapy to be certain that adequate TSH suppression has been achieved. Some experts find an 8–10-wk interval is more appropriate, but a definitive study on this issue is not yet available.

D. Radiopharmaceutical

- See Sections IV.B.2 and IV.B.3 for guidance on selection of the amount of administered activity for the treatment of hyperthyroidism and thyroid cancer, respectively. Therapeutic ¹³¹I can be administered in liquid or capsule form, and the prescribed amount must be verified in a dose calibrator before administration. If a liquid form is used, strategies for minimizing volatilization during dosage preparation and administration should be used, for example, venting the dose into a filtering system, such as a fume hood, and administering the dose to the patient shortly thereafter.
- Radiation Dosimetry in Adults. See Tables 3 and 4.

E. Reporting

The report to the referring physician should include the justification for therapy, should indicate

Table 3
Radiation Absorbed Dose from I-131 (NaI)

Organ	mGy/MBq	rad/mCi
Assuming no thyroid uptake (athyrotic)*		
Bladder wall	0.610	2.3
Lower colon wall	0.043	0.16
Kidneys	0.065	0.24
Ovaries	0.042	0.16
Testes	0.037	0.14
Stomach	0.034	0.13
Assuming 55% thyroid uptake and 20-g gland (hyperthyroid) [†]		
Thyroid	790	2,923
Bladder wall	0.290	1.1
Breast	0.091	0.34
Upper colon wall	0.058	0.21
Ovaries	0.041	0.15
Testes	0.026	0.10

*From ICRP 53, Page 275.

[†]From ICRP 53, page 278.

that informed consent (including possible side effects) was obtained, and that the patient was informed of home radiation safety precautions.

V. Issues Requiring Further Clarification

- The use of ¹³¹I whole-body imaging in patients following total thyroidectomy before initial ¹³¹I therapy for thyroid cancer.
- Whether “stunning” of the thyroid remnant has clinical significance.
- The role of alternative imaging agents, such as ¹²³I, to avoid possible stunning.

Table 4
Radiation Dose to Red Marrow for 74–7,400 MBq (2–200 mCi) ¹³¹I*

Thyroid uptake (%)	Adult mGy/MBq (rad/mCi)	Child (10 y) mGy/MBq (rad/mCi)
0	0.035 (0.13)	0.065 (0.25)
5	0.038 (0.14)	0.070 (0.26)
35	0.086 (0.32)	0.160 (0.59)
45	0.100 (0.37)	0.190 (0.70)
55	0.120 (0.45)	0.220 (0.81)

*Dose may vary depending on the whole-body effective half-life of ¹³¹I. From ICRP 53, pp. 275–278.

- The necessity of treating small (<1.5 cm) papillary cancers with ¹³¹I if there is favorable histology and no evidence of lymph node or distant metastatic involvement.
- The role of recombinant human TSH in therapy in yielding results equivalent to giving I-131 therapy with endogenous TSH elevation.
- The frequency and duration of long-term follow-up after I-131 therapy for thyroid cancer in a variety of clinical situations.
- Predicting the duration of time for the TSH to exceed 30 uU/mL in individual patients after thyroid hormone withdrawal before I-131 therapy.

VI. Concise Bibliography

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VII. Disclaimer

The Society of Nuclear Medicine (SNM) has written and approved these guidelines as an educational tool designed to promote the cost-effective use of high-quality nuclear medicine procedures or in the conduct of research and to assist practitioners in providing appropriate care for patients. The guidelines should not be deemed inclusive of all proper procedures nor exclusive of other procedures reasonably directed to obtaining the same results. They are neither inflexible rules nor requirements of practice and are not intended nor should they be used to establish a legal standard of care. For these reasons, SNM cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment about the propriety of any specific procedure or course of action must be made by the physician when considering the circumstances presented. Thus, an approach that differs from the guidelines is not necessarily below the standard of care. A conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in his or her reasonable judgment, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines.

All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.