

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Nuclear Medicine - 2001 Revision



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

The College of Physicians and Surgeons of Ontario

Vision Statement

The best quality care for the people of Ontario by the doctors of Ontario.

Mission Statement

The College of Physicians and Surgeons of Ontario merits the trust and respect of the public and the profession by:

1. Maintaining a rigorous and efficient regulatory process,
2. Focusing on the ongoing improvement of quality,
3. Being open and accountable,
4. Communicating clearly and effectively,
5. Promoting excellence in health care,
6. Working with others to achieve our vision.

We demand of ourselves the same exacting standards that we expect of the profession.

Goals

The vision of Council will be implemented by:

1. Advocating for quality health care in partnership with other stakeholders,
2. Integrating the roles of clinical education, evidence-based clinical practice and regulatory responsibilities to improve patient care at the individual and system level,
3. Evaluating and improving the effectiveness and efficiency of the current investigative and disciplinary processes and identifying potential alternatives,
4. Accelerating efforts to find creative ways to address physician resource needs without compromising registration standards,
5. Providing publicly accessible regulatory information about physicians
6. Engaging stakeholders in a public debate about the limits of medicine and focusing on what patients can expect from their physicians,
7. Establishing a comprehensive and effective communication plan to improve recognition of the CPSO by its stakeholders,
8. Establishing an effective and transparent governance model for the College.

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First Edition, August 1993:

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Second Edition, December 2001:

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Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessments in Independent Health Facilities. Regulation changes were introduced in 1999. These out-of-hospital facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine, pulmonary function, and sleep studies
- in treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health and Long-Term Care, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

Purpose of Clinical Practice Parameters

The Independent Health Facilities clinical practice parameters and facility standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of specialities. The primary purpose of this document is to assist physicians in developing their own quality management program and act as a guide for assessing the quality of patient care provided in the facilities.

Note: The parameters and standards are not intended to either replace a physician's clinical judgement or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.

In developing these clinical practice parameters, the objective is to create a range of appropriate options for given clinical situations, based on the available research data and the best professional consensus. The product, therefore, should not be thought of as being “cast in stone”, but rather subject to individual, clinically significant patient differences.

Role of the College of Physicians and Surgeons

At the beginning of this process, the College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

The Task Force members’ initial work, distributed in March 1991, was sent to the following organizations for their review and comments:

- all relevant specialty physicians in Ontario, national specialty societies and specialty sections of the Ontario Medical Association
- Ontario Chapter of the College of Family Physicians of Canada
- Canadian Medical Association
- American Medical Association
- Canadian Council on Health Facilities Accreditation
- College of Nurses of Ontario

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with “cookbook formulas.”
- parameters will need to be regularly updated based on appropriate research studies.

- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- monitoring service results in facilities. The College's information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America, requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Updating this Document

These parameters and standards, updated in the year 2001, are subject to periodic review, and amendments in the form of replacement pages may be issued from time to time. Such pages will be mailed automatically to all relevant independent health facilities.

The chapters included in this text represent the services most often considered by nuclear medicine physicians. Therefore three chapters that were included in the original edition, have now been removed: Brain Scintigraphy (J858/J658), Effective Renal Plasma Flow (ERPF) by blood sample method (J837/J637), and Glomerular Filtration Rate (GFR) by blood sample method (J838/J638). These procedures, and any other procedure in the OHIP fee schedule that is not included in this document, may still be performed.

It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

Chapter 1 Staffing a Facility

Overview

Nuclear medicine services are provided to patients by appropriately qualified medical, technical and clerical personnel taking into account the requirements of the Ontario Tripartite Nuclear Medicine Advisory Committee, Canadian Nuclear Safety Commission (CNSC) and the Independent Health Facilities Act.

Physician in Medical Charge of an in vivo nuclear medicine service

The facility has a designated physician in medical charge of the in vivo nuclear medicine service as required for licensing of the facility by the Canadian Nuclear Safety Commission.

Qualifications of Physician in Medical Charge of an in vivo nuclear medicine service

The physician in medical charge of an in vivo nuclear medicine service is a specialist certified in nuclear medicine by the Royal College of Physicians and Surgeons of Canada, or was previously approved by the Tripartite Committee on the basis of its requirements. (*Please see Appendix 1.*)

Note: The physician in medical charge of an in vivo nuclear medicine service may also function as the Radiation Safety Officer, and/or the Quality Advisor as required by the regulations under the Independent Health Facilities Act.

Responsibilities

Please see Ontario Tripartite Nuclear Medicine Advisory Committee, Information Sheet (Appendix 1).

Quality Advisor

The facility has a designated Quality Advisor, who is formally appointed and accepted in writing, as required by the regulations under the Independent Health Facilities Act.

Qualifications

The Quality Advisor holds a specialty qualification from the Royal College of Physicians and Surgeons of Canada in Nuclear Medicine.

Responsibilities

The Quality Advisor advises the facility owner/operator with respect to the quality of services provided and is responsible for advising the facility owner/operator on the professional aspects of the facility which includes, but is not limited to, the following:

- competence and the quality of patient care provided by other physicians
- quality of clinical and technical work performed by the technologists
- performance of procedures in accordance with a current procedure manual that reflects good medical and technical practice.
- ongoing education of the technologists
 - a record of the technologist's continuing medical education (CME) is available. The topics covered and the technologist's attendance is recorded.
- requirements for the presence of a physician during the performance of studies.
 - examples of these studies include pharmacological intervention such as dipyridamole stress tests, and studies that require physiological stress such as an exercise myocardial perfusion study.
- establishment and maintenance of a safe environment for both staff and patients.

Radiation Safety Officer

The facility has a designated radiation safety officer as required by the Canadian Nuclear Safety Commission. If the radiation safety officer is a professional other than the physician in medical charge of the facility, the physician in medical charge is available to the radiation safety officer to receive regular reports and for consultation on an emergency basis.

Other Medical Staff

In many instances, other physicians contribute to the patient services provided by the facility.

Qualifications

Physicians reporting procedures hold a specialty qualification from the Royal College of Physicians and Surgeons of Canada in Nuclear Medicine or have been previously grandfathered prior to 1996:

- Physicians who began practising nuclear medicine in an independent health facility after July 1, 1992 are required to show evidence of at least one full year of training in nuclear medicine in a Royal College accredited program.
- After July 1, 1996, physicians who begin practising nuclear medicine in an independent health facility are certified by the Royal College in this specialty.

Responsibilities

Physicians are responsible for:

- maintaining a level of competence for the range of studies being offered. This is accomplished by attending nuclear medicine review courses or conferences, reviewing current nuclear medicine literature, etc.
- contacting the Quality Advisor for advice regarding quality of care matters.
- should any complications or problems arise, either clinically or from the standpoint of radiation safety, informing the Quality Advisor.
- being present during the intervention studies, either pharmacological or physiological, during which the patient may require immediate medical attention.
 - These physicians are not required to be certified in nuclear medicine if their role is restricted to supervising stress studies or administering pharmaceuticals for enhancement of procedures.

Technologists

Technologists fulfill all of the requirements for a certificate of registration provided by the College of Medical Radiation Technologists.

Technologists attend and document their attendance at relevant continuing medical education programs.

Technologists Performing BMD Studies

Technologists are registered by the College of Medical Radiation Technologists of Ontario. Technologists other than MRT(N), must show evidence of successful completion of a recognized technologist's course in the performance of Bone Mineral Densitometry studies, such as from the International, or Canadian Society of Clinical Densitometry.

Chapter 2 Facilities, Equipment and Supplies

Overview

There is adequate space, facilities, equipment and supplies to perform the nuclear medicine procedures in a safe and efficient manner, ensuring the effective care and privacy of patients.

Facilities, Equipment and Supplies

In a facility where stress tests are performed, there is appropriate medical supervision and other skilled staff. An emergency cart and resuscitation equipment is immediately available. All staff are trained in emergency procedures which are appropriate to the role they would assume in an emergency.

Appropriate safety precautions are maintained against electrical, mechanical, and chemical and radiation hazards, as well as against fire and explosion, so that personnel and patients are not endangered.

All equipment is of a contemporary standard which is properly maintained and calibrated. Written records of the instrumentation quality control program are available.

The facility must have a selection of current nuclear medicine textbooks, on general and specific topics, in clinical applications and basic sciences. In addition, there should be a selection of various nuclear medicine journals available for reference.

Chapter 3 Developing Policies and Procedures

Overview

There are current written policies and procedures to provide the staff with clear direction on the scope and limitations of their functions and responsibility for patient care.

Developing Policies and Procedures

The procedure manual is available within the department for consultation, and is reviewed at least annually, revised as necessary, and dated to indicate the time of the last review or revision.

Procedures in the manual include, but are not limited to:

- specific protocols for the techniques performed at the facility, including appropriate patient preparation, radiopharmaceutical dose, and specific patient instructions following the procedure.
- policies regarding requisition of tests from referring physicians and reporting mechanisms.
- special considerations with regard to emergency requests.
- methods to handle patients requiring emergency medical attention.
- radiation safety policies and radiopharmaceuticals quality control procedures including:
 - emergency procedures for minor and major spills
 - acquisition, storage, security, preparation, administration, and disposal of radiopharmaceuticals
 - optimum dosage of radiopharmaceutical for patients of different ages
 - methods for reducing organ doses in various procedures
 - precautions to be followed in women of reproductive age
 - protocols to be followed in case radiopharmaceuticals are misadministered e.g., incorrect radiopharmaceutical or overdosage.
- policies and procedures for establishing and maintaining a program to evaluate the technical performance of the instruments used for imaging, radiation monitoring and film processing. This includes procedures for testing instruments according to manufacturers' guidelines and any applicable regulations.

Chapter 4 Requesting and Reporting Mechanisms

Overview

The relationship between the referring physician and the physician practising nuclear medicine is consultative.

Although the ultimate responsibility for the appropriateness of requested procedures is that of the referring physician, the physician practising nuclear medicine communicates to the referring physician his or her concerns about the potential risk to the patient, the complexity of the procedure, or the cost of the procedure.

Requesting and Reporting Mechanisms

Written requisitions are completed for all nuclear medicine procedures.

Note: When an order for a procedure is dictated by telephone, the person to whom the order was dictated transcribes the procedure(s) ordered, the working diagnosis, the name of the requisitioning physician, the date and time of the order, and signs the record of the order.

An appropriate request specifies:

- the service requested
- a concise statement of the reason for the examination
- any additional relevant history, physical findings

or

- other information useful for interpreting or modifying the test procedure.

With reason, the physician practising nuclear medicine may alter the study requested, if in his/her judgement the appropriate test was not requested. Similarly, if the physician practising nuclear medicine believes that it is in the patient's best interest not to perform a procedure, it is at the discretion of this physician to cancel the request, and inform the referring physician as to reasons for cancelling or substituting the test.

Reports reach the referring physician as quickly and as efficiently as possible. Independent health facilities are likely to differ widely in their reporting methods. A mechanism is in place to identify urgent requests and to communicate critical examination results on a timely basis.

Copies of all reports and written requests are considered part of the patient record. These documents are maintained in a systematic manner and retained for a period stipulated by the regulations under the Independent Health Facilities Act, 1989. *See Appendix II, Independent Health Facilities Act- Ontario Regulation 57/92 - Amended to O.Reg. 14/95.*

A mechanism is in place which enables the reporting physician to solicit follow-up information for the medical outcome component of the quality management program.

Chapter 5 Providing Quality Care

Overview

A quality management program is a planned, systematic, and comprehensive strategy which permits internal and external review of the measures taken to provide the highest possible quality of medical care and patient safety.

To comply with the Independent Health Facilities Act, Section 6.1(d), the facility establishes and maintains a system to monitor the results of the services provided. The quality management program is designed to assure high standards and to promote optimal patient health care in Ontario.

The facility establishes a quality management program appropriate for its volume and the type of service provided. It is recognized that facilities will vary depending on their size, scope of practice and geographical considerations.

The facility's quality management program and associated documentation are subject to assessment by the College of Physicians and Surgeons of Ontario. The legislation requires that the findings of quality assessments be reported to the Director of Independent Health Facilities of the Ministry of Health and Long-Term Care.

Radiation Safety

The facility adheres to the requirements of the Canadian Nuclear Safety Commission (CNSC).

All procedures adhere to the ALARA concept in order to protect the patient, the facility staff, the public and the environment.

The ALARA concept is that radiation exposure should be kept “as low as is reasonably achievable”, taking into account the state of the technology and economics of improvement in relation to the benefits to the public health and safety, and other societal and socioeconomical considerations.

Radiation safety policies, as outlined in chapter 3 *Developing Policies and Procedures*, are implemented.

Radiopharmaceuticals

Radiopharmaceuticals policies outlined in the chapter on Developing Policies and Procedures are implemented.

The quality management program meets the regulatory requirements of the Canadian Nuclear Safety Commission and the Health Protection Branch of Health Canada.

Data which result from the application of the radiopharmaceutical quality control protocols and dispensing records are retained and logged on the appropriate forms. The forms are easily understood and quickly accessible to facilitate recognizing problems as they occur. These conform to the *Guidelines for Radiopharmaceutical Quality Assurance in Nuclear Medicine* published by the Health Protection Branch of Health Canada.

Instrumentation

Instrumentation policies, as outlined in chapter 3 *Developing Policies and Procedures*, are implemented.

Equipment Testing

When equipment is installed, it must undergo acceptance testing. Performance parameters are recorded for future comparisons. When equipment performance diverges from the expected results, maintenance is carried out.

Gamma Cameras

Routine gamma camera quality control procedures must be performed, and results logged for future reference. These include, but are not limited to:

- flood field uniformity
- isotope energy peaking, or pulse height analysis
- SPECT centre of rotation
- Gamma camera safety systems.

These should be performed as recommended by the manufacturer, or at a frequency necessary to maintain required specifications.

Well Counter, Dose Calibrator, and Survey Meters

The well counter, dose calibrator, and survey meters are:

- compared against known reference sources at regular intervals to monitor stability and accuracy.
- checked daily against background contamination.

Film Processor

The film processor receives regular service and chemicals are renewed.

Additional Components of Quality Management

Additional components of quality management include a review of:

- goals and objectives
- policies and procedures
- incidents, adverse drug reactions, complications
- clinical data e.g. assessing accuracy of interpretation, appropriateness of examinations.
- recommendations from other assessing bodies such as the Canadian Nuclear Safety Commission and the Health Protection Branch, Health Canada.
- staff performance appraisals
- mechanisms for evaluating diagnostic efficacy
- patient and referring physician satisfaction mechanisms.

All staff of the facility receive the results of such reviews.

All staff of the facility participate in planning strategies to overcome any deficiencies and to continuously improve the services provided to patients.

Chapter 6 Clinical Practice Parameters Overview

Overview

The following chapters summarize the most common nuclear medicine procedures currently in clinical use. It reflects the opinion of the Nuclear Medicine Task Force of The College of Physicians and Surgeons of Ontario on the appropriate indications and use of these procedures.

While pregnancy and breastfeeding are relative contraindications to the use of radiopharmaceuticals, the nuclear medicine physician needs to be consulted prior to administration. The balance between the risks and the benefits of performing the test(s) will be considered.

Performing Appropriate Tests

The physician practising nuclear medicine ensures that the appropriate tests are performed for the appropriate indications. Where various modalities and tests are used to diagnose similar conditions, the physician practising nuclear medicine satisfies him/herself that there is no redundancy and that the additional test is of clinical significance.

Note: Taking into account the patient's best interests and being aware of the current status of available resources, the Task Force discourages the use of “screening” tests or “routine” studies that do not have a clinical indication.

Chapter 7

First Transit without Blood Pool Images

OHIP Code: J804/J604

Overview

After the intravenous injection of radionuclide bolus, dynamic imaging of the first transit (blood flow) is recorded. Immediate or blood pool images are not performed when the information to be gained does not contribute to the diagnostic process.

Clinical Indications

The test may be performed in conjunction with radiocolloid liver-spleen scanning, hepatobiliary scanning, Meckel's diverticulum scanning, 99m Tc brain perfusion, thyroid scanning, salivary gland scanning and other scans where additional diagnostic information may be relevant.

The clinical indications of radionuclide angiography are very wide and varied (see OHIP Code J867/J667). From a technical standpoint, this test can be incorporated with many scanning procedures. However, it is important that the physician practising nuclear medicine consider the expected diagnostic value or clinical significance of the information to be gained prior to adding radionuclide angiography to other scanning procedures.

Reporting Guidelines

The results of the test are reported in conjunction with the organ functional images.

References

Please refer to OHIP Code J867/J667 for clinical indications.

Chapter 8 First Transit with Blood Pool Images

OHIP Code: J867/J667

Overview

Dynamic imaging is performed following the intravenous administration of a radionuclide bolus. After recording the first transit (blood flow), a static (blood pool) image of the same region of interest is obtained, usually immediately or soon after completing the flow study.

Prerequisites

Radionuclide blood flow studies may be requested by the referring physician for their inherent diagnostic value in specific clinical situations. More often, however, they are performed as the initial component of other nuclear imaging procedures is made mostly with the discretion of the practising nuclear medicine physician. In such situations, the decision to perform or not to perform the flow study must be made before administering radionuclide to the patient.

In general, to make this decision, the physician practising nuclear medicine takes into account whether by knowing the vascularity of the examined part, he/she is better able to interpret the test by pinpointing the diagnosis or by narrowing the differential diagnosis under consideration. In this regard, a normal or an abnormal result can add valuable information. The immediate or blood pool images are performed in conjunction with the flow study when the information to be gained is expected to contribute to the diagnostic process.

Clinical Indications

The clinical indications are very wide and varied. Detailed lists of indications are beyond the scope of this document.

However, before adding the blood flow study or blood pool images to any test, the physician practising nuclear medicine needs to consider the diagnostic yield or clinical significance of the information to be gained, as well as the implication of a false negative or a false positive result.

Reporting Guidelines

The test results are reported in conjunction with the organ functional image.

Chapter 9 Myocardial Perfusion Scintigraphy

OHIP Codes:

- J807/J607-resting, immediate post stress
- J808/J608-delayed
- J866/J666-application of SPECT (1 per exam)
- J809/J609-application of SPECT (2 per exam)

Overview

Myocardial perfusion scintigraphy is a non-invasive procedure used to detect and evaluate coronary artery disease. Diffusible radiolabelled compounds such as ²⁰¹Thallium, and ^{99m}Tc labelled products distribute in myocardial tissue proportional to regional blood flow. Consequently, those regions with relatively higher blood flow at the time of injection appear more intense on scintiscan compared to regions with a relatively lower blood flow.

The current standard of practice usually requires SPECT for optimal localization and increased sensitivity and specificity of diagnoses. If the facility does not have the capability of SPECT, nuclear cardiology should not be performed.

Note: Guidelines for various stress procedures are not addressed by these Clinical Practice Parameters. If exercise or pharmacological stress tests are performed, this should be done under the supervision of a physician, and with appropriate resuscitation equipment immediately available.

Clinical Indications

Clinical indications for performing myocardial perfusion scintigraphy include the need to:

- evaluate coronary artery disease.
- assess coronary revascularization, i.e. post-CABG, post-PTCA, post-anticoagulation.
- detect myocardial infarction.

- perform post-myocardial infarction risk stratification.
- evaluate cardiac status prior to cardiac or non-cardiac surgery.

Reporting Guidelines

Myocardial perfusion studies are interpreted in light of the stress test and other clinical information. The following information is reported:

- a description of the results of the test.
- a clinical impression.
- recommendations for further procedures, if indicated.

Chapter 10 Myocardial Wall Motion Studies with Ejection Fraction

OHIP Codes:

- J813/J613- myocardial wall motion studies with ejection fraction
- J814/J614- repeat same day to a maximum of three repeats

Overview

This may be performed with ^{99m}Tc labelled red blood cells, or by gated SPECT myocardial perfusion images, at rest or during exercise. Consequent analysis allows the assessment of cardiac chamber volumes, myocardial contractility and global or segmented ventricular function.

Gated blood pool studies may be performed as an independent test. Gated SPECT is generally performed in conjunction with myocardial perfusion scans.

Clinical Indications

Clinical indications for performing myocardial wall motion studies include the need to assess:

- cardiac function and morphology in congenital heart disease.
- coronary artery disease (ischaemia or infarction).
- intrinsic myocardial disease.
- cardiac valvular disease.
- response to therapy (drug, angioplasty, bypass).
- complications of chemotherapy.

Reporting Guidelines

The following information is reported:

- ejection fraction and other cardiac parameters available i.e. diastolic functions, ventricular volumes, etc.
- description of morphology of heart chambers and major vascular structures.
- description of wall motion, response to exercise.

- clinical impression.
- suggestions for further relevant investigation.

Chapter 11 Thyroid Uptake and Repeat

OHIP Code:

- J817/J617- Thyroid Uptake
- J870/J670- Repeat

Overview

Initially the extrathyroidal iodine pool is labelled with orally or IV administered ^{131}I or ^{123}I . An estimate of thyroid gland activity is generated by determining the fraction of administered radionuclide retained in the thyroid gland following a specific interval of time (i.e., 10 minutes, 1, 2, 4, or 24 hours etc.).

Thyroid uptake may also be approximated in a similar fashion following the intravenous administration of $^{99\text{m}}\text{Tc}$ Pertechnetate.

Prerequisites

Inquiry should be made to determine if the patient is taking any medications that may interfere with the test and this information should be taken into account.

Clinical Indications

Clinical indications for performing a thyroid uptake include the need to assess:

- thyroid function in hyperthyroidism.
- thyroid function in hypothyroidism.
- function following medical therapy including ablation or suppression.
- thyroid function in response to diagnostic intervention (e.g., T_3 suppression test).

Reporting Guidelines

There may be a slight regional variation depending on the iodine content of the referral population's diet. The facility's normal range is included in the report.

Thyroid uptake is also interpreted in the context of numerous potential influencing factors including systemic illness, medications, and an altered iodine pool.

Chapter 12 Thyroid Scintigraphy with Tc 99m, I-131, or I-123

OHIP Codes:

- J871/ J671 - with I-123
- J818/J618 - Technetium 99m or I-131

Overview

When I-131, I-123 or ^{99m}Tc Pertechnetate is administered, the images generated provide a map of the distribution of function within the thyroid gland or in non-thyroidal locations.

Prerequisites

Inquiry should be made to determine if the patient is taking any medications that may interfere with the test and this information should be taken into account.

Clinical Indications

Clinical indications for performing thyroid scintigraphy include the need to assess the:

- distribution of function within the thyroid gland.
- function of a specific thyroid lesion.
- function of ectopic or malpositioned thyroid tissue.
- function of malignant thyroid tissue in a thyroidal or non-thyroidal location.
- response of the thyroid gland or contained lesion to therapy or diagnostic intervention.

Reporting Guidelines

The accuracy of thyroid scintigraphy is augmented by correlating the findings with palpation or ultrasound scan findings.

A nodule which concentrates ^{99m}Tc may still have malignant potential. A follow-up study with radio-iodine may be recommended by the Nuclear Physician.

Chapter 13 Biliary Scintigraphy

OHIP Codes: J831/J631

Overview

Radionuclide hepatobiliary imaging has proved to be extremely useful in diagnosing a wide variety of disorders of the liver and biliary tract. The lack of morbidity and mortality of the procedure has resulted in rapid and widespread clinical acceptance.

The ^{99m}Tc iminodiacetic acid analogues are handled in the liver by the same carrier mediated anionic clearance mechanism as bilirubin. The images generated reflect the distribution of bilirubin and consequently the state of hepatobiliary function. The test has a very high sensitivity and specificity rapidly allowing the physician to arrive at an accurate diagnosis.

In certain instances pharmacological intervention (i.e., IV cholecystokinin) can simulate physiological functions such as eating. Such provocative testing further increases the clinical utility of the test.

Prerequisites

Patient should fast for approximately four hours, but not for more than 24 hours, as this may result in normal gall bladders not filling.

Clinical Indications

Clinical indications for performing hepatobiliary scintigraphy include the need to:

- evaluate the patency of the biliary tract in patients who are suspected of having intrahepatic, cystic, or common bile duct obstruction or biliary atresia.
- assess the function of the hepatobiliary system following pharmacological intervention when chronic cholecystitis, calculus, cholecystitis or biliary dyskinesia are a clinical concern.
- perform a post-cholecystectomy evaluation of the biliary tract to assess for duct patency, bile leak, or cystic duct remnant.
- evaluate the biliary enteric anastomoses.

- evaluate other surgical anastomoses involving the gastro-intestinal tract such as Billroth I, Billroth II, and Whipple resection.
- evaluate duodenogastric reflux.
- evaluate liver transplant patients.
- detect bile leaks.

Reporting Guidelines

The following information is reported:

- in the case of pharmacological intervention, the name, dosage, and route used to administer the drug. The presence or absence of adverse effects.
- test results are described.
- clinical impressions.

Chapter 14 Liver and Spleen Scintigraphy

OHIP Code: J832/J632

Overview

The liver and spleen are both principle organs of the reticuloendothelial system. RES function can be assessed by recording the distribution of intravenously administered microcolloids labelled with a radionuclide. ^{99m}Tc Sulfur Colloid is the most common agent used, but other similar compounds are commercially available. For detecting haemangioma, liver imaging with ^{99m}Tc labelled red cells is advised. Imaging may be planar or SPECT.

Clinical Indications

Clinical indications for performing a liver and spleen scintigraphy include the need to:

- assess functional imaging of liver and spleen to evaluate structural lesions detected by anatomic imaging technologies like ultrasound, CT, MR.
- assess hepatosplenic involvement in diffuse hepatic disease processes including those of a neoplastic, inflammatory, or metabolic nature.
- assess hepatosplenic involvement in the presence of vascular disease including venous thrombosis, arterial infarct, and portosystemic shunting.
- detect haemangiomas with labelled RBC's.

Reporting Guidelines

Radionuclide liver scans are complimentary to other imaging modalities, and in some situations, comparing the nuclear with other imaging techniques is advised.

In evaluating sepsis, a gallium scan (J852/J652 or J853/J653) may be recommended.

Chapter 15 Dynamic Renal Imaging

OHIP Code: J834/J634

Overview

This study consists of sequentially imaging the kidneys, ureters and bladder following an intravenous injection of a radiopharmaceutical which is excreted through the urinary tract.

This fee code is billed if there is no computer quantification of perfusion or function performed, otherwise J835/J635 is appropriate.

In conjunction with dynamic renal imaging, codes J804/J604 (first transit without blood pool images), and/or J836/J636 (static renal scintigraphy) may be billed.

Clinical Indications

This test is used as a means of evaluating renal morphology, function and drainage. Common clinical indications include hypertension, urinary obstruction, renal infarction, infection, neoplasm, renal failure, urinary leaks or trauma, and evaluating renal transplants.

Reporting Guidelines

A report should include an evaluation of any unilateral, bilateral or focal disease, or any extra-renal abnormalities. Where appropriate, correlation with renal ultrasound, or radiographic studies is made.

Chapter 16 Computer Assessed Renal Function (includes first transit)

OHIP Codes: J835/J635

Overview

This test assesses renal blood flow and function. The radionuclide is given as an intravenous bolus and data is dynamically collected by computer for about 30 minutes.

Data analysis yields qualitative and quantitative information for each individual kidney.

In some patients, delayed static renal imaging may be required, usually at 1-3 hours after radionuclide is administered.

Radionuclides Used

A GFR or renal cortical imaging agent labelled with ^{99m}Tc or labelled hippuran is used.

Note: I-131 hippuran is not suitable for imaging renal blood flow (first transit), but can be used for the functional (renogram) component of the test. If I-131 hippuran is used, the patient usually undergoes a separate renal blood flow study using a ^{99m}Tc labelled renal agent.

Prerequisites

Unless there is a fluid restriction, the patient is usually well hydrated orally before the test.

With the use of radio-iodo-hippuran (particularly in the case of I-131), some, but not all physicians elect to give a single dose of Lugol's iodine orally (or an alternative agent) to the patient to block thyroidal uptake of free radio-iodide.

Clinical Indications

The test assesses the renal blood flow and function in many situations, including pre-renal, renal, and post-renal causes. The test is often required to evaluate individual renal function. For example: congenital renal abnormalities, vascular problems, renal parenchymal disease from multiple causes, space occupying lesions, obstructive uropathy, renal trauma, renal transplant, etc.

Reporting Guidelines

The following information is requested:

- the radionuclide agent(s) used.
- describe and interpret the data. If available, correlate data with other information or imaging tests.
- if warranted, recommend other tests.

Chapter 17 Repeat Computer Assessed Renal Function after Pharmacological Intervention

OHIP Codes: J880/J680

Overview

An assessment of the renal blood flow and function using computer assisted quantification may be repeated on the same day as J835/J635 with pharmacological intervention using:

- furosemide in patients with possible obstructive uropathy.
- ACE inhibitors (captopril is the most common drug used) in patients with possible renal artery stenosis.

Prerequisites

Intervention with furosemide

Diuresis will establish if obstructive uropathy is present or not in patients with hydronephrosis or hydroureter. Furosemide is a potent diuretic. When administered intravenously it is given and supervised by a physician who is familiar with its possible side effects and the necessary precautions for its use.

Intervention with ACE inhibitors

Intervention is aimed at assessing the effect of the ACE inhibitor on the kidney to improve the sensitivity and specificity of the renal study for the diagnosis of renovascular hypertension.

Before the test, obtain a detailed history of the drugs the patient is taking or was recently receiving. Some medications may have to be discontinued before the test but this must be cleared with the consent of the referring physician when appropriate.

A supervising physician approves the administration of the ACE inhibitor for the specific patient. This is because ACE inhibitors may cause side effects or interact with other drugs. Active treatment may be required if complications arise after its use.

A baseline blood pressure measurement is obtained before administering the ACE inhibitor. The blood pressure is measured repeatedly during the first hour after it is administered and at the end of the procedure.

Clinical Indications

Intervening with furosemide to establish whether obstruction is present or not in patients with dilatation of the renal pelvis or ureter.

Intervening with ACE inhibitors: in patients with possible renovascular hypertension.

Contraindications and Precautions

The patient is well hydrated and haemodynamically stable prior to administering of furosemide or captopril.

Drug Allergy

Please see above prerequisites concerning the use of the interventional drugs. See also the prerequisites and contraindications under chapter 16 Computer Assessed Renal Function (includes first transit), OHIP codes J835/J635.

Reporting Guidelines

The test findings are reported quantitatively, including comparing the results with the pre-intervention data. If any side effects occur as a result of using such drugs, these are reported along with any treatment given.

Chapter 18 Static Renal Scintigraphy

OHIP Codes: J836/J636

Overview

This test is performed to evaluate renal morphology and may be performed as a separate study or in conjunction with dynamic renal imaging (J834/J634). If it is performed as part of dynamic imaging, it is usually performed after 1-2 hours delay, at which time the collecting systems and pelvis have fully drained. Additional views of the kidney (obliques or magnified images) may be required.

Usually, static renal imaging of the parenchyma uses those radiopharmaceuticals which preferentially bind to the tubules such as 99m Tc-DMSA or 99m Tc-glucoheptonate.

If required, Single Photon Emission Computed Tomography (SPECT) imaging (J866/J666) may be billed in conjunction with this procedure.

Clinical Indications

Clinical indications for this test include the need to assess renal size, shape, location, and function, particularly in evaluating congenital abnormalities, space occupying lesions (tumour vs hypertrophy), renal parenchymal scarring in inflammatory disease, trauma, etc.

Reporting Guidelines

Where appropriate, a correlation is made with renal ultrasound or other radiographic assessments of the kidneys.

Chapter 19 Bone Scintigraphy

OHIP Codes:

- J850/J650- general survey
- J851/J651- single site

Overview

Images of the skeleton are obtained after administering intravenous radiopharmaceuticals which localize in the mineral compartment of the skeleton and reflect the distribution of bone metabolism. As bone scans show physiological processes and radiographs demonstrate anatomical detail, these techniques are complimentary.

When a study is restricted to a single site (skull, hands, feet, etc.), OHIP code J851/J651 is used. If more than one site is imaged, or the whole body is scanned, J850/J650 is appropriate. In conjunction with these codes, first transit with blood pool images (J867/J667), or SPECT (J866/J666) may be added.

Clinical Indications

Clinical indications for performing a bone scan include the need to:

- detect skeletal metastatic disease. This may be performed in the initial staging, periodic follow-up, or evaluation of therapy.
- detect skeletal lesions in symptomatic patients where radiographs are normal. This could include traumatic, inflammatory, arthritic, or other causes of occult bone pain.
- evaluate the metabolic activity of abnormalities seen on radiographs (i.e. incidental sclerotic densities, old vs new fracture, activity of Paget's disease etc.).
- evaluate viability of bone when there are circulatory disturbances (i.e. avascular necrosis, bone grafts, or post-trauma).
- detect traumatic, inflammatory, or arthritic conditions, to evaluate their metabolic activity, and response to treatment, or complications of the disease or its treatment.
- detect complications or to follow the healing response following surgical procedures to the skeletal system.

- detect soft tissue lesions such as heterotopic ossification, myositis, metastatic calcification, and other conditions which may show uptake of the radiopharmaceutical.

In various other disease processes affecting the musculoskeletal system or joints, where determining increased, or decreased metabolic activity will compliment clinical, laboratory or other diagnostic imaging techniques in the evaluation of the disease, or its treatment.

Reporting Guidelines

Radionuclide bone scans compliment other imaging modalities, and in some situations, comparing nuclear and other imaging techniques is advisable.

In evaluating the sepsis, a gallium scan (J852/J652, or J853/J653) may be recommended.

Chapter 20 Gallium Scintigraphy

OHIP Codes:

- J852/J652 - general survey
- J853/J653 - single survey

Overview

After intravenous administration of gallium, imaging is carried out from four hours post-injection and up to 10 days post-injection. Planar or SPECT studies may be undertaken. Depending on the clinical circumstances, a bowel preparation may be undertaken.

Clinical Indications

Clinical indications for performing gallium scintigraphy include the need to investigate and evaluate inflammatory and related processes which include:

- pyrexia of unknown origin.
- pulmonary inflammatory diseases including:
 - infectious
 - granulomatous disease
 - drug and radiation induced injury.
- abdominal and pelvic inflammations including:
 - localized and diffuse infections
 - retroperitoneal fibrosis
 - renal parenchymal and peri-renal infections.
- inflammatory disease of the skeleton including:
 - osteomyelitis
 - joint space infection
 - discitis
 - assessment of post-operative complications of prostheses.
- cardiac and mediastinal structures.

Tumour detection, staging, and assessment. Most commonly:

- Burkitt's lymphoma, Hodgkin's, and non-Hodgkin's lymphoma
- malignant melanoma
- hepatocellular carcinoma
- lung carcinoma
- haematologic malignancies
- sarcomas
- seminomas.

Reporting Guidelines

The following information is reported:

- dosage and route of radiocompound administration.
- times at which imaging was carried out and any bowel preparation undertaken. Whether SPECT or planar images were obtained.
- test results are described.
- correlation with other imaging modalities, if available.
- an opinion to include further recommendations if appropriate.

Chapter 21 Bone Mineral Content by Dual Photon Absorptiometry (Bone Densitometry)

OHIP Codes:

- X152/X153 - Low risk patient
- X149/X155 - High risk patient

Note: For the purpose of this service “high risk patient” means a patient at risk for accelerated bone loss due to either states of high bone turnover such as primary hyperthyroidism and glucocorticoid induced osteopenia, or due to such other conditions as have been determined by the Scientific Advisory Board of the Osteoporosis Society of Canada which prevail at the time the service is rendered. “Low risk patient” means any patient who is not a high risk patient (Extract from OHIP Schedule of Benefits)

Overview

It is established that, where there is a progressive loss of bone throughout the skeleton associated with aging and other metabolic bone disorders, the risk of fractures is increased due to decrease in bone strength. This condition is commonly referred to as osteoporosis, but in fact bone mineral density (BMD) measures osteopenia, of which osteoporosis is only one cause.

Bone Densitometry

Decreased bone mineral density produces an important public health problem that will worsen in the future as the population ages. Bone mass is measured safely, accurately, and precisely by dual energy x-ray absorptiometry.

There are current therapies available for preserving or increasing bone mass in those people who are thought to be at a significant fracture risk.

It is important to realize that bone mass measurement is **not** intended to be a diagnostic test for fracture. Rather, it measures a risk factor and as such, is performed primarily on those individuals who by age, sex, longterm glucocorticoid therapy, or associated medical illnesses are known to be susceptible to bone mineral loss.

An appropriate location for the test should be available, respecting patient privacy. The studies must be performed on a contemporary dual photon x-ray densitometer. Daily Quality Control must be performed, and the results stored for reference.

Prerequisites

A comprehensive questionnaire to elicit clinical information and other factors that might compromise this test, such as radiological contrast agents, radioactive materials, and any previous surgery.

Clinical Indications

The following represents a list of potential indications. These indications are subject to change as the equipment becomes more precise and longitudinal data on the results of therapeutic programs become available. A bone densitometry is indicated in:

- estrogen deficient women to diagnose significantly low bone mass and to make decisions about hormone replacement therapy.
 - estrogen deficiency following menopause, oophorectomy, or prolonged amenorrhea from any cause is associated with bone loss.
- individuals with vertebral abnormalities or roentgenographic osteopenia, to diagnose spinal osteoporosis and to make decisions about further diagnostic evaluation and therapy. There is evidence that many of the individuals with vertebral abnormalities do not have significant osteoporosis and therefore would not benefit from therapy which is costly and has risks.
- individuals receiving long-term glucocorticoid therapy, to diagnose low bone mass and to adjust therapy.
- individuals with primary asymptomatic hyperparathyroidism, to diagnose low bone mass in order to identify those at risk of severe skeletal disease who may be candidates for surgical intervention.
- individuals with evidence of osteomalacia such as low serum calcium, low serum phosphorus, and/or elevated alkaline phosphatase.
- individuals with one or more risk factors:
 - hypogonadism
 - ethanol abuse
 - osteoporosis on radiograph
 - fracture with minor trauma or atraumatic fracture.
- patients with prolonged immobilization (more than 2 months) and especially if the disability is likely to be prolonged and/or permanent.

- individuals with renal disease with a creatinine clearance of less than 50 ml/min. or renal tubular disorders.
- patients with rheumatoid arthritis or ankylosing spondylitis that has been active/symptomatic over a period of five years.
- individuals who use anticonvulsant therapy over a prolonged period (5 years or more).
- individuals who have been on thyroid replacement for a prolonged period (10 years or more).

Bone densitometry is also indicated to evaluate and monitor the treatment program.

The frequency of repeat studies for “high risk” and “low risk” patients is according to the Schedule of Benefits.

Reporting Guidelines

The interpretation of BMD studies must reflect age, sex, weight, ethnic origin, and risk factors as well as comparing the young normal data base.

The absolute measurement of bone mass in gm/cm^2 , the percentage value and/or standard deviation (T or Z scores) compared to the young normal control group and to the age-matched group is incorporated into a narrative paragraph that is meaningful to the referring physician. When possible, the report should suggest to the referring physician the advisability of pursuing further investigation, instituting a therapeutic regimen and/or the necessity of a repeat assessment at an appropriate time interval.

Chapter 22 Brain Scintigraphy with Single - Photon Emission Computed Tomography

OHIP CODES:

- J858/J658- Brain Scintigraphy
- J866/J666- Application of Tomography (SPECT)

Overview

Regional cerebral blood flow imaging reflects the extraction of radioactive tracers from the blood by brain tissue, and is relative to blood flow. Lipophilic agents such as Tc labelled ECD or HMPAO are injected intravenously, and SPECT imaging provides information on brain perfusion and metabolism which is complementary to CT or MRI anatomic imaging.

Clinical Indications

Clinical indications for performing this test include:

- cerebrovascular disease (stroke, transient ischaemic attack (TIA), vasculitis)
- epilepsy
- dementia
- neuropsychiatric disorders
- extrapyramidal disorders
- brain tumours
- HIV brain related disorders
- herpes simplex encephalitis
- subarachnoid haemorrhage
- brain death
- head injury
- migraine headaches.

Reporting Guidelines

The physician has experience in interpreting tomographic images, as well as a good knowledge of the technical aspects of tomographic acquisition and reconstruction so that artifacts will be recognized.

When possible, the functional imaging study is correlated with the other anatomic studies to optimize the interpretation.

Chapter 23 Perfusion and Ventilation Scintigraphy

OHIP CODES:

- J860/J660- Perfusion and ventilation scintigraphy - same day
- J887/J687- Ventilation lung scintigraphy
- J859/J659- Perfusion lung scintigraphy

Overview

A radionuclide ventilation scan demonstrates the patency of airways and the distribution of aerated lung tissue. The patient inhales radio tracers in gaseous, aerosol, or particulate form. Multiple images in various projections are obtained with a gamma camera.

A radionuclide perfusion lung scan demonstrates the distribution of the pulmonary blood flow following the intravenous injection of radioactive labelled particles which temporarily embolize the pulmonary capillary bed. Multiple images in various projections are obtained using a gamma camera.

Commonly, these two procedures are performed consecutively, on the same day. In some situations a computer analysis of the ventilation/perfusion ratios, aerosol, or gas washout, may be of clinical value.

Clinical Indications

Clinical indications for performing ventilation and perfusion lung scans include the need to:

- diagnose suspected pulmonary embolism.
- evaluate shortness of breath, obstructive lung disease, abnormal blood gases or chest pain.
- assess chronic obstructive pulmonary disease (COPD) or lung cancer, including pre-operative assessment with quantification.
- evaluate congenital heart or lung disease.
- quantify aerosol washout studies for inflammatory lung disease.

Contraindications

Severe pulmonary hypertension and severe right to left shunts are relative contraindications for perfusion lung scans.

Reporting Guidelines

A lung scan to diagnose pulmonary embolism is treated as an emergency request. A positive lung scan could indicate a high probability for a pulmonary embolism. This condition requires the nuclear medicine physician to communicate with the referring physician.

When the lung scan is abnormal it is good clinical practice to correlate this information with the chest x-ray results.

Note: If the chest x-ray is not available for comparison with an abnormal lung scan, the reporting physician must ensure that the referring physician is alerted to make the appropriate correlation.

Chapter 24 Single Photon Emission Computed Tomography (SPECT)

OHIP Codes:

- J866/J666- one time per examination
- J809/J609- for use with stress and rest myocardial perfusion only.
Maximum 2 times per study

Overview

SPECT is the acquisition, reconstruction, and interpretation of cross-sectional nuclear medicine images. This is an “add-on” procedure, which is billed in conjunction with the fee code for the routine planar study.

Prerequisites

This technique requires the use of a gamma camera with one or more detector heads which rotate around the patient, in an arc, or full circle during acquisition. The data acquired is processed using specialized reconstruction software to generate tomographic slices. A good knowledge of the technical aspects of tomographic acquisition and reconstruction is needed, so that artifacts will be recognized.

Tomographic cameras require additional quality control procedures, such as centres of rotation, special floods, and phantoms.

Clinical Indications

It is generally accepted that tomography improves image diagnosis by permitting more accurate anatomic localization, and improved lesion detection. By eliminating activity from the foreground and background which might obscure abnormalities, tomographic data is used as the basis for sophisticated graphic displays, such as Bullseye or 3-D reconstruction.

Brain perfusion imaging requires tomographic imaging for most applications, to localize the distribution of perfusion to the grey matter and to recognize deeper structures such as basal ganglia. It is also useful in conventional blood-brain barrier brain scans to enhance the detection of small lesions and to separate calvarial from cerebral pathology.

Tomographic myocardial perfusion imaging (thallium, technetium-labelled MIBI etc.) have improved sensitivity and specificity compared with planar imaging. Difficulties in interpreting planar images such as breast attenuation, overlap of the right ventricle, and depth variation of the walls are reduced using tomography. SPECT improves the detection and localization of myocardial infarction using technetium-labelled pyrophosphate.

Detecting deep-seated liver lesions is improved with tomography as this technique permits visualization into the central portions of the liver and may demonstrate anatomic structures not readily seen on planar imaging. Haemangioma detection, with labelled RBC's, is improved with much smaller haemangiomas being detected using SPECT.

In bone scanning, SPECT improves the detection of subtle lesions and is used effectively in evaluating complications following spine surgery and in avascular necrosis of the hip, lesions about the knees, and base of the skull.

SPECT improves the detection of involved lymph nodes when gallium scanning is used in the staging of lymphoma and improves the detection of lesions in the liver and abdomen.

Contraindications

The images are highly dependent on the performance of the gamma camera and selection of the reconstruction filters. Strict gamma camera quality control protocols must be observed and the technologist is familiar with the appropriate selection of reconstruction parameters. An inexperienced physician might not recognize poor quality images or artifacts.

SPECT is generally not useful in structures with flat dimensions (hands, long bones, or thyroid).

Reporting Guidelines

The test results are reported in conjunction with the organ functional images.

Appendix I Ontario Tripartite Nuclear Medicine Advisory Committee Criteria for Physicians in Medical Charge of an In Vivo Nuclear Medicine Facility (original text)

Overview

The physician in medical charge of an in vivo nuclear medicine service in Ontario shall have such formal qualifications and training as shall allow the Tripartite Nuclear Medicine Advisory Committee to recommend licensing of the facility to the Atomic Energy Control Board [currently the Canadian Nuclear Safety Commission]. *The Committee recognizes the standard on Royal College Certification in nuclear medicine for medical directors as established in CMA General Council resolution #87-70, but appreciates the need for a period of transition.* As at January 1990, physicians with the following qualifications are acceptable to the Tripartite Committee, a licensed Ontario physician:

Category 1

- certified by the Royal College of Physicians and Surgeons of Canada as a specialist in nuclear medicine.

Category 2

- A licensed Ontario physician who is not certified in nuclear medicine, but who has practiced comprehensive nuclear medicine substantially full-time for five years prior to January 1, 1986, or who was the designated physician on an AECB [currently the CNSC] licence issued prior to January 1, 1986.
 - *Note:* As of January 1, 1991, this option will cease to exist for applicants who are not already designated as medical directors on an existing in vivo nuclear medicine licence.

Category 3

- In the absence of a physician in categories 1 and 2, as an interim measure for a hospital facility, the Advisory Committee may accept a licensed Ontario physician certified by the Royal College of Physicians and Surgeons of Canada as a specialist in an area other than nuclear medicine but having a minimum of one year of full-time nuclear medicine training in a University-affiliated program. This one year of training should be within the five years immediately preceding the 1st of January of the year in which an application for licensing from the involved facility is first received.

The Advisory Committee will review the appropriateness of this designated physician on each AECB [now the CNSC] licence renewal.

A physician designated under Category 3 cannot transfer this authority to another facility.

- *Note:* As of January 1, 1991 this category will not longer apply to new applicants.

In summary, as of January 1, 1991, physicians acceptable to take medical charge of a nuclear medicine facility will be:

- a licensed Ontario physician certified by the Royal College of Physicians and Surgeons of Canada as a specialist in nuclear medicine,

or

- a licensed Ontario physician uncertified in nuclear medicine who was a supervising physician approved by the Ontario Tripartite Nuclear Medicine Advisory Committee as of December 31, 1990.
- a supervising physician approved under Category 3 prior to December 31, 1990. This physician, however, cannot transfer this supervisory authority to another facility.

Information Sheet

The licensee, that is the institution, holds ultimate responsibility for radiation safety in the licensed facility. Nothing in the following should be construed as altering this. The physician in medical charge of an in vivo nuclear medicine service assumes the following responsibilities for the service:

- selecting, establishing, supervising and regularly revising all investigations and procedures offered by the service.
- preparing and maintaining an up-to-date procedure manual for each investigation and procedure offered by the service.
- establishing and maintaining an appropriate safe environment and appropriate medical supervision for patients undergoing procedures in the nuclear medicine department.
- establishing and maintaining a continuing mechanism for competent, experienced and clinically relevant reporting of investigations. This is of particular importance when the physician in charge is not based full time at the location of the facility in question.
- if nominated as the Radiation Safety Officer for the service, he or she will carry out the appropriate duties. Otherwise, the physician must meet regularly with and receive reports from the Radiation Safety Officer to be

assured that radiation safety is maintained. The physician must be available for consultation with the Radiation Safety Officer should an urgent problem arise.

- establishing and supervising quality control practices and medical audit activities.
- participating in the appointment, supervision, training and discipline of the technological and professional staff of the laboratory to the extent necessary to be assured that all clinical procedures are carried out as safely, effectively and efficiently as possible.

The physician shall be on the premises of the laboratory for a period of time commensurate with the above responsibilities and the work load of the laboratory.

The proposed medical supervision will be assessed by the Tripartite Committee prior to making its recommendation to the AECB.

The physician shall be a member of the medical staff of any hospital in which the service is located. **Preferably**, the physician should have a contract with the facility in respect of his or her responsibilities for the Nuclear Medicine service.

Appendix II Independent Health Facilities Act - Ontario Regulation 57/92 -Amended to O. Reg. 14/95

General

Quality Advisor and Advisory Committee

- 1 (1) Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.

(3) The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

(4) It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.

(5) In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.

(6) A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O Reg 57/92, s.1.
- 2 (1) Every licensee shall appoint an advisory committee to advise the quality advisor.

(2) The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.

(3) The quality advisor shall be the chair of the advisory committee.

(4) Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O Reg. 57/92, s.2.

3 (1) Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall inform the Director in writing forthwith.

(3) Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3.

Standards

4 (1) Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.

(2) Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.

(3) If the quality advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.

5 Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.

6 (1) Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a laboratory for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.

(2) The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

- 7 (1) Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee's qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.
- (2) Every licensee shall retain an employee's employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.
- 8 (1) Every licensee of an independent health facility shall maintain a record of qualifications and work history for:
- (A) each person the licensee contracts with to manage the facility; and
 - (B) each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.
- (2) The record shall include a record of any registration with or licensing by the governing body of a health profession.
- (3) Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.
- 9 (1) Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.
- (2) A declaration of professional standing must include the following information:
1. The physician's name
 2. The physician's registration number with the College of Physicians and Surgeons of Ontario
 3. The physician's number registered with the Health Insurance Division of the Ministry of Health.
 4. The class of the physician's licence issued under Part III of the *Health Disciplines Act* and any terms and conditions attached to it.
 5. The physician's specialty.
- (3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).

(4) Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.

(5) Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O. Reg. 57/92, s.9.

Patient Records

10 (1) Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.

(2) A patient's health record must include:

- (a) the patient's name and home address
- (b) the patient's date of birth
- (c) the patient's health number
- (d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (f) a history of the patient
- (g) a written record of any orders for examinations, tests, consultations or treatments
- (h) particulars of any examination of the patient
- (i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports
- (j) any reports of treatment including any physicians' operative reports
- (k) any orders for and reports of any discharge of the patient from supervised care
- (l) any consents; and
- (m) any diagnoses of the patient.

(3) A patient's health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received only such services.

(4) Every licensee shall ensure that every part of a patient's record has a reference on it identifying the patient or the record.

(5) If information in a patient's record is kept in the form of a chart, each entry in the chart must be dated and it must be initialed by the person authorizing the entry. O. Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O. Reg. 57/92, s.11.

12 (1) No licensee shall allow any person to examine a patient's health record or give any person any information, copy or thing from a patient's health record except as required by any Act or regulation made under an Act or as required or allowed by this section. O. Reg. 57/92, s.12(1).

(2) Every licensee shall provide copies from a patient's health record to any of the following persons on request:

1. The patient.

2. A personal representative who is authorized by the patient to obtain copies from the record.

3. If the patient is dead, the patient's legal representative

4. If the patient is incapable of giving an authorization described in paragraph 2,

- (i) a lawfully authorized substitute decision maker
- (ii) a person to whom the patient is married
- (iii) a person of the opposite or same sex, with whom the patient is living in a conjugal relationship outside marriage if the patient and the person:
 - A. Have cohabited for at least one year
 - B. Are together the parents of a child, or
 - C. Have together entered into a cohabitation agreement under section 53 of the *Family Law Act*
- (iv) the patient's child if the child is sixteen years old or older
- (v) the patient's parent. O. Reg. 57/92, s. 12(2); O. Reg. 14/95, s.1

(3)A licensee may provide copies from a patient's health record to any person authorized by a person to whom the licensee is required to provide copies under subsection(2).

(4)A licensee may, for the purpose of providing health care, or assisting in the provision of health care, to a patient, allow a health professional to examine the patient's health record or give a health professional any information, copy or thing from the health record.

(5)A licensee may provide to the person described in subsection (6) information or copies from a patient health record if anything which could identify the patient is removed from the information or copies.

(6)Subsection (5) applies to:

1. Any person if the information or copies are to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.
2. The Ontario Cancer Treatment and Research Foundation.

(7)A licensee may charge a reasonable fee for any information, copies or thing provided under this section. O. Reg. 57/92, s.12(3-7).

Books and Accounts

12.1(1)This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled “Schedule of Facility Fees”.

(2)Every licensee shall keep the following records in relation to the independent health facility:

1. Current financial records showing:

(i) the amounts paid by the Minister to the licensee under section 24 of the Act.

(ii) the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee’s licence, and

(iii) the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.

2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee’s licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.

3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.

4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

(3)Every licensee shall ensure that the records required under section (2):

(a) are kept in the independent health facility; and

(b) are kept in a bound or looseleaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4) Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5) Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act*. O. Reg. 283/94, s.1, *part*.

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/94, s.1, *part*.

Notices

13 Every licensee of an independent health facility,

(a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and

(b) who ceases operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14 Every licensee of an independent health facility shall give the Director:

(a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and

(b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/92, s.14.

Miscellaneous

15 It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.

16(1) The fee for a licence is \$100.

(2) The fee for the transfer of a licence is \$100.

(3) The fee for the renewal of a licence is \$100. O. Reg. 57/92, s.16.

17 The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

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