Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Pulmonary Function Studies -3rd Edition, April 2008

First Edition, October 1993
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The College of Physicians and Surgeons of Ontario

Our Strategic Plan

The Council of the College of Physicians and Surgeons of Ontario developed a strategic plan to establish College priorities for the next several years. The priorities articulated in the strategic plan serve as a guide to action and focus our energies toward attaining our new vision – **Quality Professionals, Healthy System, Public Trust.**

Our Mandate

Build and maintain an effective system of self-governance. The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves. It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek. Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes. We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we, as caring professionals, are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation

The public, through legislation, has empowered the profession to regulate itself through the College. Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system. To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

Contents Clinical Practice Parameters and Facility Standards: Pulmonary Function Studies

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. 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 (now the Canadian Council on Health Services 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.

Purpose of Pulmonary Function Laboratories

The purpose of a Pulmonary Function Laboratory (PFL) is to provide the referring physician with accurate measurements of the functioning of a patient's respiratory system in a manner that is safe for the patient and favourable to obtaining the optimum health of the patient.

These standards provide a framework for the structure and operation of a PFL to help realize these goals. This section presents standards relating to Quality Advisor and medical staff, the technologists, the record keeping function of the lab, and establishing a quality management program. The circumstances of medical practice vary widely across the Province of Ontario; this will influence the manner in which any PFL implements these standards.

Classes of Diagnostic Services

Diagnostic Services licensed under the Independent Health Facilities Act (IHFA) are those services for which the "technical fee" (cost of providing the service) has been removed from the Schedule of Benefits for Physicians' Services (SOB). These services are identified by a fee listed under the "h" column of the SOB. These "H" fees are translated into "F" (facility) fees for purposes of the IHFA.

Four classes of diagnostic services have been established by the Ministry of Health and Long-Term Care:

- Class A includes oximetry at rest, with exercise, and sleeping with or without added oxygen (J323, J332, J334).
- Class B includes lung volumes (J307, J311) single breath diffusing capacity (J310), airways resistance (J306), non-specific bronchial provocative testing (J333), and the measurement of maximum inspiratory and expiratory pressures (J340).
- Class C includes stage I exercise testing with or without added airflow measurements and performance of ECGs (J315, E450, E451).
- A final class of tests (other fee codes) requires individual approval for billing purposes (J309, J318, J319, J320, J322, J328, J330). These services are currently provided by a variety of physicians, in addition to those certified in Respiratory Disease.

Note:	*The facility licence granted by the Ministry of Health and Long-Term Care specifies the Classes of Diagnostic Services for which the facility may bill the Ontario Health Insurance Plan. The granting of a Class B licence does not include a licence for Class A tests unless Class A tests are specified on the licence.*

The term "Level" is used by Respiratory disease specialists and does not have any legislative basis under the Independent Health Facilities Act.

- Level I facilities perform tests in Class A only.
- Level II facilities perform tests in Class A and B.
- Level III facilities perform tests in Class A, B and C.

The Independent Health Facilities Act has legislated a relatively new concept: quality assurance in medical care. This concept is a gathering force in medicine throughout the western world, with conferences being held and increasing quantities of money being expanded into investigating the quality of medical care and its outcome. These parameters and standards are the initial phase of what will be an ongoing program of quality management in the practice of pulmonary function in independent health facilities.

Updating this Document

These parameters and standards, updated in the year 2008, 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. 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.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Pulmonary Function Studies

Volume 1

Facility Standards

Chapter 1 - Requisition and Reporting Forms

Overview

Requisition and Reporting forms are used to record the following information:

- basic demographic information
- clinical information
- tests required • other fee codes authorized.

Note:	*A sample Pulmonary Function Studies Requisition is provided in appendix I, and can be modified according to local requirements.*

Pulmonary Function Requisition

Basic demographic information is included on the Pulmonary Function Studies Requisition. Reserve an area at the upper right hand corner of the form for the Health Number imprint. The form is dated appropriately; the format is day, month, and year.

The information collected includes the patient's family name, first name and initial, address, postal code, and any cultural or religious beliefs which may affect medical care (e.g., Jehovah's Witness). Unless a latex-safe environment has been provided, questions regarding latex allergy should be asked of all patients. *See Appendix II Sample Latex Allergy Questionnaire*. Clinical information such as the presence of dyspnea, cough, or wheeze, is included in the requisition, as well as a list of the relevant medications that the patient is taking. Details of the patient's smoking history are also useful.

A working diagnosis and area for further comments is also present. The reason for testing is outlined on the requisition.

Tests required may include spirometry, or flow volume loop, even though they are not covered by the Independent Health Facilities Act. A post-bronchodilator test is performed when indicated.

These tests may act in a screening function and prevent redundant testing. For example, FEV_1 increases by 12% and 22cc's or more after a patient uses a bronchodilator may be suggestive of airway reactivity.

The list of tests offered by the Independent Health Facilities as authorized should then follow.

An explanation of the purpose of the test as part of the requisition is included.

Facility	Test Class	Test	OHIP Code
Level I facility	**Class A tests**	**oximetry**	**J323, J332, J334**
Level II facility	**Class A tests**		
	Class B tests	**lung volumes**	**J307, J311**
		single breath diffusing capacity	**J310**
		Airway resistance	**J306**
		non-specific bronchial provocative tests	**J333**
		MIPS & MEPS	**J340**
Level III facility	**Class A tests**		
	Class B tests		
	Class C tests	**stage I exercise testing**	**J315, E450,E451**
		exercise-induced asthma	**J330**

Other tests authorized to be performed in the facility are listed (for the complete list refer to the Preface).

A directive concerning full completion of the requisition and location of the pulmonary facility at the bottom of the requisition may be helpful.

The requisitioning physician's signature and OHIP identification number complete the form.

Report Form

The report form contains the same demographic information as the requisition and is dated appropriately, the format is day, month, year. The results can be expressed in a variety of ways (e.g., numerically or graphically), but should express readily the results of the test. Normal ranges for the results, appropriate to the tested individual, are included. The interpreter's signature completes the report.

Requisitions and report forms (preferably the originals) should be kept at the facility and should be available for inspection. Following a telephone requisition, the requisition must be signed by the requisitioning physician.

A written requisition from the referring physician is required by all facilities as stipulated in the Regulations under the Independent Health Facilities Act.

Chapter 2 - Staffing a Facility

Overview

Under the Independent Health Facilities Act (IHFA), every Independent Health Facility licensed to perform pulmonary function tests must employ a designated Quality Advisor.

Where an Independent Health Facility chooses to appoint a Medical Director, the Medical Director may also function as the Quality Advisor.

Staff must maintain patient confidentiality at all times.

Quality Advisor

The Quality Advisor is a physician licensed to practise in Ontario.

The Quality Advisor has the training and experience necessary to understand the physiological basis of the tests performed in the facility, to determine the relevance of these test results to the patient's clinical problem, and to advise the facility licensee on the conduct of all the professional aspects of the facility.

As evidence of the requisite training and experience the Quality Advisor:

- holds a specialty qualification from the Royal College of Physicians and Surgeons of Canada or its equivalent, in Respirology

or

- physician involved in conducting and interpreting exercise testing must be a Respirologist, and have a minimum exposure of 30 cases

or

- in lieu of the above, has a minimum of one year's experience in executing and interpreting pulmonary function testing, such tests to include those performed by the independent health facility of which the physician is Quality Advisor. In addition, the year's experience is gained under the supervision of a Quality Advisor holding the qualifications referred to in the above points.

Quality Advisor Responsibilities

The Quality Advisor is responsible to the facility licensee for the conduct of the professional aspects of the pulmonary function facility as defined in this document.

Whenever the Quality Advisor has reasonable grounds to believe the conduct of the facility is such as might jeopardize the safety of patients or the proper performance and interpretation of pulmonary function tests and where, in the judgement of the Quality Advisor, there is a constraint placed upon correcting the perceived deficiencies by actions taken or not taken by the facility licensee, then the Quality Advisor must report these concerns in writing to the Director, Independent Health Facilities. If the Quality Advisor considers it necessary, he or she may notify the Registrar, College of Physicians and Surgeons of Ontario.

The Quality Advisor is also responsible for advising the facility licensee on:

- the qualifications and work performed by other physicians employed in the facility.
- the qualifications and work performed by pulmonary function technologists employed in the facility, and where the nature and size of the facility warrants, the appointment of a chief technologist and office support staff.
- the accuracy and reliability of the equipment used in performing pulmonary function tests.
- whether the tests performed by the facility are done accurately and reliably.
- whether the tests performed by the facility are conducted safely, and whether procedures and equipment are available within the facility to manage any adverse reaction that may occur.
- the appropriate design, staffing, and equipping of the facility so as to ensure patient comfort and safety and the proper performance and reporting of pulmonary function tests.
- the proper design of pulmonary function test requisitions and reports.
- the maintenance of all necessary records.
- whether the pulmonary function test results are properly interpreted and promptly communicated to the referring physician.
- the establishment of a quality assurance program for the facility, including matters related to maintenance of a safe work environment.

Medical Staff

Medical staff includes other physicians employed by the facility who are licensed to practise in Ontario.

Medical Staff Qualifications

Such physicians:

- hold a specialty qualification from the Royal College of Physicians and Surgeons of Canada (or equivalent) in Respirology

or

- hold another specialty qualification from the Royal College of Physicians and Surgeons of Canada (or equivalent) and have a documented minimum of three months prior training and experience on the respiratory disease service of a university-affiliated teaching hospital, such training includes experience in the execution and interpretation of pulmonary function tests

or

- in lieu of the above, have a documented minimum of six months prior clinical experience in the execution and interpretation of pulmonary function testing. Documentation must be available in the Independent Health Facility.

Medical Staff Responsibilities

The medical staff is responsible for:

- the safe, accurate, and reliable performance of those tests which the physician will be interpreting.
- promptly communicating test results to the referring physician.
- assisting the Quality Advisor in performing other responsibilities that may be assigned to the physician and for which the physician has had appropriate training.
- preparing written reports for the Quality Advisor detailing any concerns the physician may have as to the safe and proper conduct of the facility.
    - a copy of any such report is provided to the facility licensee.

Technologist

Technical staff includes registered cardiopulmonary technologists (RCPT(P)), registered respiratory therapists (RRT), or other health care professionals as defined in this chapter.

Technologist Qualifications

These facility standards categorize pulmonary function facilities into Levels I, II, III as defined in the Preface.

Level I Facility

At a Level I facility the technologist staff include:

- a registered cardiopulmonary technologist (RCPT(P))

or

- a registered respiratory therapist (RRT)

or

- another health care professional whose formal training included studies in the anatomy and physiology of the cardiorespiratory system and whose subsequent experience included one month of training in the performance and quality control of spirometry and flow volume loop testing.

Note:	*All technologists in a Level I facility have current certification in Basic Cardiac Life Support.*

Levels II and III Facilities

At a Level II and III facility the technologist staff include:

- a registered cardiopulmonary technologist (RCPT)

or

- a registered respiratory therapist (RRT). To work in a facility not staffed by RCPT(P), the RRT must have one month formal training performing the pulmonary function tests which are conducted in the Independent Health Facility.
- another health care professional whose formal training included studies in anatomy and physiology of the cardiorespiratory system and whose subsequent experience and demonstrated competence in the performance of the pulmonary function tests conducted. Training is completed under the direct supervision of an RCPT(P) or an RRT.

Note:	*All technologists in a Level II or III facility must have current certification in Basic Cardiac Life Support.*

Chief Technologist Qualifications

The designation of a Chief Technologist is recommended in a facility with more than three technologists.

When a Chief Technologist is designated, he or she is a:

- registered cardiopulmonary technologist (RCPT(P)) with 4 years facility experience in a Level II or III facility.

or

- registered respiratory therapist (RRT) with 4 years of facility experience in a Level II or III facility.

Technologist Responsibilities

Technologists are current with the changing technical trends in the cardiopulmonary field by attending conferences, meetings or other forms of continuing education, and reading current relevant literature.

Technologists are responsible for the day-to-day operation of the facility, including:

- arranging patient appointments and staff work schedules.
- distributing to referring physicians and agencies the test requisitions and the completed test reports.
- maintaining proper policies and procedures.
- maintaining records of equipment calibration, maintenance, and repair procedures.
- maintaining copies of test observations and reports.
- maintaining administrative records.
- ensuring that safety policies and the equipment and facilities necessary for their implementation are in place and in working order.
- ensuring the safe and reliable performance of tests.
- observing infection control measures.
- maintaining all necessary facility supplies.

Technologists are also responsible for:

- performing testing procedures.
- implementing policies and procedures.
- assisting the Quality Advisor.

Chapter 3 - Facility Records

Overview

Facility records are retained and maintained by the facility.

Requisition Form

Written requisitions are completed for all pulmonary function tests performed in the facility.

- where an order for a test(s) has been dictated by telephone, the person to whom the order was dictated transcribes the test(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.

The requisition, prepared by the facility and provided to referring agencies, conforms to the requirements described in Chapter 1, Requisition and Reporting Forms.

Test Results

The facility retains the original results of all measurements made for each test for a period of time as specified by the IHFA Regulations. See Appendix III Independent Health Facilities Act - Ontario Regulation 57/ 92 -Amended to O.Reg. 14/95.

Test Report

A report is provided to the referring physician for each test performed in the facility.

The report includes the following information:

- personal data sufficient to identify the patient, the patient's age, height, and weight; the referring and reporting physicians, the name of facility performing the test, and the test date.
- the technologist's comments as to the reliability of the patient's performance during the test, where necessary.
- a summary of the original data obtained and calculations made during the test and, where feasible, of the graphical records.
- the reporting physician's interpretation of the original data as well as, where appropriate, comments as to the relevance of the results to the patient's presenting problem or suggestions as to patient management arising from the results.
- copies of all reports are retained with the requisition and original data for a period of time as specified by the IHFA Regulations

Policies and Procedures

To promote the performance of safe and reliable pulmonary function tests and to encourage uniform testing procedures between facilities, each pulmonary function facility maintains a permanent record of its policies and procedures. This record is further described in *Chapter 6, Equipment Standards* and includes:

- a description of the proper methodology for performing each test offered by the facility, including criteria to ensure that the results obtained are reliable
- the predicted normal values for each test offered by the facility, including the references from which these values were obtained
- procedures to be followed to maintain proper infection control are described in detail in the CPSO guidelines *Infection Control in the Physician's Office 2004* Edition booklet that is available for all physicians
- procedures to be followed for each test to ensure that the test is performed only on those patients for whom it can be performed safely
- general safety precautions to be followed in operating the facility and performing the tests to prevent adverse health effects from occurring in the facility
- specific first aid measures to be followed in the event of an adverse health effect, including a description of the arrangements made to transfer patients to an acute care facility when required
- a list of safety equipment and medications to be maintained by the facility
- routine maintenance procedures to be followed to ensure reliable and accurate testing equipment
- performing routine calibration and validation measures on test equipment regularly
- patient consent based on the scope of practice in the facility
    - a guide to the Health Care Consent Act states: "Patients must be able to obtain relevant information that reasonable persons in the same circumstances would want. This would include such information as the nature of the treatment, its benefits, the material risks and side effects, alternatives and the likely consequences of not having the treatment". (Members' Dialogue -A Guide to the Health Care Consent Act; pg 24; May 1996)
- latex anaphylaxis -please refer to Chapter 7 - Laboratory Safety and Infection Control
- Material Safety Data Sheets (MSDS), current within 3 years, for all chemicals are maintained in the facility
- a copy of the Workplace Hazardous Materials Information Systems (WHMIS) manual.

Operating and Administrative Records

Each facility maintains a log of activities performed by the facility which includes a record of each test performed together with fees submitted and received, as well as the original test data and reports referred to on page 13, Test Report.

Each facility maintains records of the following:

- all receipts and disbursements for the facility according to standard accounting principles.
- all maintenance, repair and calibration procedures performed (including biologic controls), results obtained, and, where appropriate, corrective action taken.
- all adverse health effects occurring during testing, action taken, and outcome.

Chapter 4 - Providing Quality Care

Overview

The facility institutes a Quality Management Program. It is recognized that quality management programs will vary depending on the facility size, scope of practice, and geographical considerations.

Goals of a Quality Management Program

The goals of a Quality Management program are to:

- inform the referring physician population as to the most appropriate use of pulmonary function testing.
- ensure the safe and reliable performance of testing.
- provide prompt and properly interpreted reports to the referring physician that will contribute to a favourable health outcome for the patient.
- improve the quality of service provided by the facility staff through such mechanisms as educational programs, attending conferences and meetings or other forms of continuing education, and reading current relevant literature.
- achieve these goals with the most efficient and appropriate use of resources.

The facility establishes a Quality Advisory Committee and appoints a Quality Advisor as required by regulations under the Independent Health Facilities Act.

A successful quality management program depends on regularly maintaining and reviewing the facility records required of each facility.

Quality Management Activities

Quality management activities include, but are not limited to, the following:

- establishing a mechanism for periodically reviewing selected original data for all types of tests performed by the facility to establish that the tests are performed properly and the tests are reliable.
- regularly reviewing calibration and validation data on testing equipment, noting any deviations from accepted norms and recording corrective action taken.

- reporting, to a member of the physician staff, all adverse health effects occurring during testing, the action taken, the outcome achieved, and recording the recommendations made for future prevention.
- establishing a mechanism for reviewing the pattern of tests that the facility is requested to perform. This is to determine whether the tests ordered are appropriate to the presenting clinical problem and whether the most effective use of the facility is being made in assessing these various clinical problems. Information and insights obtained from these reviews are used to further educate the facility staff and the referring physicians as to the most effective and efficient use of the facility.
- periodically reviewing the reports issued by the facility to ensure that:
    - test results are issued within two weeks
    - physicians interpret the tests accurately.
- periodically surveying patients to determine their satisfaction with the services provided by the facility and to seek their suggestions for improvements.
- periodically surveying referring physicians to determine their satisfaction with the service provided by the facility, their opinion as to whether the facility results have favourably influenced patient health outcomes, and to seek their suggestions for improvements.

Chapter 5 - Facility Standards

Overview

Facility standards are provided for the health and safety of both the facility staff and all patients. These include reference values, equipment (including gases and ventilation, electrical safety), infection control, and emergency procedures.

Facility Standards

Significant differences in test results often occur between and even within facilities due to the use of different techniques, measurements, calculations, predicted equations, and quality control. To reduce this variability, standards are published and/or generally accepted guidelines are established for all routine pulmonary function tests.

In this document, standards are presented for:

- oxygen saturation by oximetry
- carbon monoxide diffusing capacity
- functional residual capacity and airways resistance by body plethysmography
- functional residual capacity by closed circuit helium dilution and nitrogen washout
- non-specific bronchial provocative test
- exercise-induced asthma assessment
- stage 1 exercise test
- maximum inspiratory pressures and maximum expiratory pressures
- arterial blood gases.

References are provided for more detail on instrumentation, techniques, measurements, calculations, and quality control.

Note:	*Facility and technical standards must be included in the policy and procedures manual of the independent health facility. Standards and policies are updated at least annually and approved by the medical and technical directors of the pulmonary function facility.*

Reference Values

Appropriate predicted or normal values are necessary if meaningful interpretations of pulmonary function studies are to be made. There are many predicted values in the literature from which to choose. When selecting the best reference values for the facility, a number of factors are considered.

Predicted values with a large pool of both male and female subjects that vary in age (from 20-80 or so) and height are preferable. The population of subjects should be heterogeneous across towns and cities, socioeconomic status, religion, and occupation. The equipment and techniques for test procedures and calculations are similar to those used in the facility.

To determine if the reference values selected are suitable, test 10-20 non-smoking healthy male and female subjects of varying ages and heights and apply the predicted values to the data. If the results are within the accepted ranges of normal for each test, then the reference values were properly chosen.

Reference values should be consistent over time.

The decision to correct for racial or ethnic background of the patient rests with the Quality Advisor and may be based on the proportion of such patients studied in the facility. On the other hand, the decision may be not to incorporate these corrections into the normative predictive equations but consider the effects in the interpretation. Further discussion on this subject is available in the statement by the American Thoracic Society (ATS) ("Lung function testing: Selection of Reference Values and Interpretive Strategies"; ARRD 1991, 144:1202-1218) and in the ATS manual.

Biologic Control

A biologic control is a healthy, non-smoking individual who has no known lung disease; these individuals must be available for repeated testing and typically work in the facility. Testing of these individuals on a regular basis is recommended to ensure reproducible results over time, particularly in "black box" systems that cannot easily be calibrated.

Chapter 6 - Equipment Standards

Overview

The operating efficiency of any facility depends not only on the expertise of the staff but also on the reliability of the equipment which is used for testing.

Equipment selection is integral to acquiring accurate test results. This applies to all diagnostic equipment whether it is used for clinical, diagnostic, or epidemiologic purposes.

Instrumentation recommendations are followed to provide accurate data and information that is comparable from facility to facility and from one time period to another.

Equipment accuracy is determined by regular calibration checks. The results obtained must conform to recognized standards. The frequency of calibration is mandated by documents of the ATS (American Thoracic Society) and ERS (European Respiratory Society) standards for spirometry, lung diffusion and lung volumes. Physicians and staff must be fully familiar with the most current recommendations of the ATS/ERS regarding pulmonary function standards.

Each facility must establish a Quality Control Program to monitor that the equipment used produces measurements within acceptable limits of accuracy and precision of a test procedure.

Compliance with the minimal recommendations for spirometry, lung diffusion and lung volumes as published in 2005 by the joint publications of the ATS/ERS Task Force is mandatory.

The following summarizes the standard equipment recommended by the ATS/ERS in its publications on spirometry, lung diffusion and lung volumes.

Spirometer

The accuracy of a spirometer system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system, from volume or flow transducer to recorder, display, or processor. An error at any step in the process affects the accuracy of the results obtained. The spirometer must be capable of accumulating volume for at least 15 seconds and measuring volumes of at least 8L (BTPS) for measurements of FVC and FEV_1. The spirometer must be capable of accumulating volume for at least 30 seconds for measurements of VC and IC.

Volume Accuracy

The accuracy of a spirometer measuring volume should be at least ± 3% of reading or ± 0.05 L, whichever is greater, with flows between 0 and 14 L/s.

Time Calibration

The time scale of a mechanical recorder must be checked with a stopwatch. The indicated time must be accurate to within ± 2%.

Flow Resistance

The total resistance to airflow must be < 1.5 cm H_2O/L at 14.0 L/s

Flow Accuracy

In the range of flows to be measured (-14 to +14 L/s) the measured flows must be within ± 5% of reading or ± 0.02 L/s, whichever is greater.

Whenever a flow signal is integrated to measure volume, the volume accuracy requirements are ±3.0% of reading or ±0.05 L, whichever is greater, with flows between -14 to + 14L/s.

Quality Control

The equipment calibration and quality control must include the following:

- Records of acceptable operation of new equipment or equipment after repairs or other alterations
- Records of calibration and quality control logs
- Records of updates or changes in computer software, hardware and pulmonary function equipment operating system

Part of the quality control activities is data collection and analysis. All calibration and quality control data should be properly analyzed and plotted. The technologist must be familiar with the terms and definitions used in the quality control program. The following "Terms and Definitions" are obtained from Chapter 5, "Quality Control", page 1-2 of the Pulmonary Function Laboratory Management Manual, 2nd Edition by ATS, 2005

Terms and Definitions

Accuracy

How well the measurement reflects the true or correct value.

Precision

Measurement variability (repeatability); it is completely independent of accuracy or truth.

Random errors

Errors that occur without prediction or regularity, tend to decrease precision and often result from inherent variation in the instrumentation.

Systemic error

Errors within the test system or methodology (e.g., instrument calibration or malfunction) that tend to produce bias.

Biologic Standard

Healthy non-smoking individual used in quality control

Standard deviation (SD)

A measurement of variability or tendency of values to vary from the arithmetic mean. It is the square root of the variance.

Coefficient of variation

A mathematical expression of variability calculated by dividing the SD by the mean.

The following devices are required in calibration and quality control activities:

Calibrated Syringe

The accuracy of the calibrated syringe must be within ± 15 ml for a 3-L syringe or ± 0.5% of the full scale. The calibrated syringe should be checked/revalidated at an interval (e.g., annually) recommended by the manufacturer. A leak check for the calibrating syringe should be performed monthly.

A computerized syringe (i.e., computerized forced vital capacity simulator) can be used for calibration and quality control of volume and flow parameters (FVC, FEV_1, $FEF_{25-75\%}$, $FEF_{25\%/50\%/75\%}$) measured by spirometers. Also, the computerized syringe checks the time scale accuracy indirectly. This calibration/quality control tool is ideal for assessing the accuracy of computerized spirometry systems (both hardware and software)."

Ambient Environmental Devices (Thermometer, Hydrometer and Barometer)

Internal temperature, humidity (if applicable) and barometric pressure devices that form part of the pulmonary function system must be verified with an external traceable thermometer, hydrometer and barometer before equipment calibration or quality control.

In recent years, most spirometers in new pulmonary function systems are flow based because of their compact size. The volume based spirometer is less popular because of its inherent size. There are distinctive quality control procedures between volume-type and flow-type spirometers.

For Volume-type Spirometer:

The volume accuracy must be checked at least daily with a single discharge of a 3-L calibrated syringe. The measured volume should meet the accuracy requirement of ± 3.5%. (includes ± 0.5% accuracy limit for 3-L syringe).

Leaks should be checked daily by applying a constant positive pressure of ≥ 3.0 cm H_2O with the tubing outlet of the spirometer occluded. A loss of > 30 ml after one

minute indicates the presence of leakage. Corrective action must be taken before patient testing.

Linearity of the spirometer from zero to maximum volume should be checked at least quarterly by introducing 1-L increments from zero to maximum volume with a calibrated syringe. The linearity check is acceptable when the measured values meet the volume accuracy requirements of ± 3.5%.

For Flow-Type Spirometer:

The volume accuracy must be checked at least daily using a 3-L calibrated syringe to simulate inspiratory and expiratory flows at least three times to give a range of flows varying between ± 0.5 and ± 12 L/s with injection times of between 0.5 second and 6 seconds. The volume at each flow should meet the accuracy requirement of ± 3.5%.

Linearity of the flow sensor should be checked weekly using a 3-L calibrated syringe with three relatively constant flows, one at low flow (0-2 L/s), one at mid-flow (4-6 L/s) and one at high-flow (8-12 L/s). The linearity check is acceptable when the measured values meet the accuracy requirement of ± 3.5% and difference between the highest volume and lowest volume is < 0.105L.

The Facility must keep organized, easy to read binders for the following:

- Records of acceptable operation (verification and validation) of new equipment and servicing of equipment after repairs or other alterations
- Records of calibration and quality control logs
- Records of calibration of calibrators
- Records of preventive maintenance on daily, weekly or yearly basis as per manufacture recommendations
- Records of updates or changes in computer software, hardware and pulmonary function equipment operating system

All records should be kept for at least 2 years.

Gas Analyzers

Helium (He)/Methane (CH_4)/Neon (Ne) and carbon monoxide (CO) analyzers of a diffusion system.

As only the ratios of CO and He/CH_4/Ne are important, it is not necessary to accurately measure either CO or He/CH_4/Ne concentrations if the analyzers are linear. Though infrared devices for measuring CO concentrations are inherently non-linear, many of the instruments currently being marketed have circuitry to linearize them.

Computerized systems take the raw alinear output from the gas analyzer and apply a linearizing algorithm. It is assumed by the manufacturer that since the gas analyzer output will maintain its' non-linear characteristics and the analog-to-digital input card and the computer algorithm will never change, then the gas analyzers never need to be individually calibrated. The best check for valid test results is performing biologic calibrations on a number of individuals monthly.

Accuracy and Linearity

The meter or its linearized output is linear within ± 0.5% of the full scale range.

For systems that do not have a linearizing algorithm known concentrations of gravimetrically analyzed gases are used to establish linearity in the helium analyzer which is linear by design.

The CO analyzer is calibrated using a dilution technique whereby a 0.3% gravimetric gas is diluted using a super syringe. The subsequent dilution of the helium is used to calibrate the expected (or true) dilution of the carbon monoxide.

All values plotted are within ± 0.5% of the true concentration, (e.g., the acceptable accuracy range for 10% He is between 9.95 – 10.05%).

Gases and Ventilation

In facilities where oxygen, compressed air and a vacuum source are not provided in wall outlets, these must be available in the facility for regular use. Compressed gas cylinders must be properly labelled and secured to a wall or placed in a stationary cart whether or not they are in use.

In rooms where pharmacological challenge testing is done, adequate ventilation is available and filters are used on the expiratory circuit of the mouthpiece apparatus.

In addition, the Workplace Hazardous Materials Information System (WHMIS) is developed to reduce exposure to harmful substances and to minimize the effects associated with these exposures. WHMIS covers compressed gases as well as reactive and corrosive materials, oxidizing agents (e.g., O2), flammable or combustible materials, and poisonous and infectious substances. For more information, contact the Occupational Health and Safety Department at the Ministry of Labour.

Electrical Safety

All equipment used at the facility must be CSA approved.

Staff should learn how to correctly operate and care for the electrical equipment used in the facility. Cords, plugs, and outlets are routinely checked for damage. All receptacles are of the three-prong type. If any piece of electrical equipment appears to operate in an abnormal manner (strange noises or hums, sparks, fuzzy tracings, etc.) it must be removed and repaired by a qualified person. If possible, do not touch an electrical device with one hand and a patient with the other hand.

Chapter 7 - Laboratory Safety and Infection Control

Overview

Nosocomial infections are a potential risk during pulmonary function testing. A clean mouthpiece and noseclip is used for each patient. Disposable bacterial filters are to be used unless the circuitry is changed after each patient.

Most infectious diseases are transmitted by direct contact with contaminated equipment or an airborne route. An infection control program to reduce the risk of transmission to an acceptable level – realizing that zero risk is not attainable – includes:

- reprocessing used equipment
- routine practices
- droplet precautions (for febrile and severe respiratory illness)
- airborne transmission precautions (for tuberculosis)

Cleaning, Disinfection and Sterilization of Equipment

Cleaning

Cleaning is the first important step in reprocessing equipment. Effective cleaning will maximize the efficacy of any subsequent disinfection or sterilization process. An item that is not properly cleaned can not be disinfected or sterilized with assurance.

Effective cleaning can physically remove a large number of microorganisms. Soil or other foreign material can shield and protect microorganisms or even interact to neutralize the action of the disinfectant or sterilant. Furthermore, after gluteraldehyde treatment, which acts as a fixative, any organic material left on the item is extremely difficult to remove.

The cleaning of used and contaminated equipment consists of the following:

- Sorting and soaking
- Removal of organic material
- Rinsing
- Drying

Disinfection and Sterilization

There are many materials and methods for disinfecting and sterilizing equipment. Manufacturers' recommendations should always be followed. Pulmonary function equipment is classified as semi-critical items and requires high-level disinfection. For

detailed information regarding cleaning, disinfection and sterilization of medical instruments please refer to the CPSO's "Infection Control in the Physician's Office" 2004 edition, p.34 to 44 (http://www.cpso.on.ca/Publications/infectioncontrolv2.pdf).

If equipment is contaminated with blood or sputum it must be sterilized immediately after it is used. Some chemicals will sterilize faster if they are heated. To eliminate toxic chemical residues, equipment is thoroughly rinsed and air dried before reusing.

Equipment that cannot be subjected to heat or chemicals must be sterilized using ethylene oxide (gas sterilization). The equipment must be thoroughly cleaned and packaged before it is sterilized. Equipment sterilized by this method must be aerated for approximately 48 hours (or less if heat is applied) before use.

Infection Control Program

Infection control consists of evidence-based practices and precautions used to prevent the transmission of pathogens causing infection, and includes the knowledge and skills required to implement appropriate interventions. Infection control practices are intended to protect patients, health care workers, and the public from exposure to infectious diseases. The infection control program is designed to reduce the risk of transmission to an acceptable level – realizing that zero risk is not attainable – by taking the appropriate isolation precautions.

Routine Practices

Routine practices describe the system of practices recommended by Health Canada (Standard Precautions is the counterpart term used by the US Centers for Disease Control and Prevention) which incorporates the bloodborne pathogen precautions or Universal Precautions (UP) and non-bloodborne pathogen precautions or Body Substance Precautions (BSP). Routine practices are designed to reduce the risk of transmission of pathogens from blood, all body fluids, secretions, excretions, and drainage of wounds from all patients (are considered potentially infectious) regardless of infection status.

Routine practices, or its equivalent, should be used during all patient care, and includes:

- Hand washing or cleansing with an alcohol based sanitizer before and after any direct contact with a patient.
- The use of additional barrier precautions to prevent health care worker contact with a patient's blood, body fluids, non intact skin or mucous membranes.
- The wearing of surgical masks and eye protection or face shields where appropriate to protect the mucous membranes of the eyes, nose and mouth during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.
- Gloves are to be worn when there is a risk of body fluid contact with hands; gloves should be used as an additional measure, not as a substitute for hand washing.

- Gowns are to be worn during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions that could contaminate uniform or clothing.

Droplet Precautions

Droplet precautions describe the type of precaution designed to reduce the risk of droplet transmission of infectious diseases. Droplet transmission involves contact of the mucous membrane of the eyes, nose, and mouth of a susceptible person (host) with large particle droplets containing pathogenic microorganisms generated from a person who exhibits a clinical disease or who is a known or suspected carrier of the pathogenic microorganism (source). The source person generates these droplets from coughing, sneezing, talking, or performing pulmonary function tests. Transmission via large particle droplets requires close contact between the source person and susceptible host because these droplets (larger than 5 um in size) do not remain suspended in the air and generally travel through the air short distances of 1 meter (3 feet) or less. In addition to routine precautions, droplet precautions should be used for a patient with known or suspected to have a droplet transmitted infection.

Droplet precautions consists of:

- Placing the source person in a single room if possible, or separated from other people by at least 1 meter and minimizing the time spent in the waiting room.
- Wearing a water resistant surgical or procedural mask and eye protection or face shield.

Airborne Precautions

Airborne precautions describe the type of precaution designed to reduce the risk of airborne transmission of infectious diseases. Airborne transmission occurs by dissemination of airborne droplet nuclei (smaller than μ5 m in size) evaporated from larger droplets or dust particles containing microorganisms that remain suspended in the air for long periods of time. Microorganisms carried in this manner can be widely dispersed by air currents and inhaled by susceptible hosts over a longer distance (in the same room or different rooms) from the source person. There is evidence of airborne transmission of source patients with tuberculosis.

Airborne precautions consist of:

- Patients suspected of having active pulmonary TB should not have pulmonary function tests until this diagnosis is excluded.
- Placing and confining the patient with known or suspected infectious tuberculosis in an examining room keeping the door closed at all times. This room should have negative pressure relative to the surrounding areas with exhaust vented outside or filtered through high-efficiency filters if recirculated to other areas in the facility.

- Wearing special high-efficiency masks with adequate facial seal (N95 respirator) when entering room of patient with known or suspected infectious pulmonary tuberculosis.

Because pulmonary function laboratories may be asked to evaluate individuals with symptoms consistent with active pulmonary tuberculosis (TB), transmission to other patients and health care workers remains a potential risk. TB remains an important potential occupational hazard in health care facilities that serve populations at high risk (including Aboriginal Canadians, the inner city poor, or emigrants from countries in Asia, Eastern Europe, Africa and Latin America where TB is still common).

Recent U.S. reports have documented outbreaks of multi-drug resistant TB in health care facilities, and also the failure of these facilities to implement appropriate TB control measures. In these outbreaks, 18 to 35 percent of exposed workers had documented conversions on tuberculin testing; health care workers infected with HIV are particularly susceptible. A consistent contributing factor to nosocomial outbreaks is a delay in diagnosis, due to lack of physician awareness, atypical clinical presentations or inadequate diagnostic facilities. BCG does not confer complete protection; TB can still occur in vaccinated health care workers.

It is very difficult to estimate precisely the infectiousness of an index case, but infectiousness is higher if the patient has extensive disease on chest radiographs, positive sputum smears for acid-fast bacilli, or is not receiving effective therapy. A patient with frequent cough or who undergoes cough-inducing procedures is also thought to be more infectious.

All health care workers are under an ethical and legal duty to both protect the health of their patients and to maintain confidentiality. Staff with symptoms compatible with tuberculosis should seek advice from Occupational Health or from their own doctor so that they do not expose patients to infection.

Recent Canadian guidelines do not specifically address TB precautions in pulmonary function laboratories. By inference, however, recommendations might include:

- All staff should be aware of the infection control guidelines for patients with known or suspected tuberculosis.
- Patients suspected of having active pulmonary TB should not have pulmonary function tests until this diagnosis is excluded.
- When a patient with active tuberculosis is tested before the diagnosis is known, identification of the contacts in the Lab at the time of testing, and immediate notification of the Public Health Department are required.
- Lab personnel should undergo two-step tuberculin testing before employment and have regular tuberculin skin tests thereafter.
- In pulmonary function labs that serve populations at high risk, appropriate ventilation strategies should be employed. The relative cost-effectiveness of adequate ventilation, ultraviolet light and personal masks/ respirators remain controversial. Front-line personnel should consider the use of high-efficiency particulate air filter (HEPA) masks.

Latex Anaphylaxis

Natural rubber latex is a common component of many medical supplies. Although most often associated with disposable gloves, other items which contain latex include airways, intravenous tubing, syringes and stethoscopes. The reporting of allergic reactions to latex has dramatically increased in the past 10 years. Frequent users of latex products may develop allergies to latex proteins, with resulting allergic reactions varying from mild to life-threatening.

Providing a Latex-Safe Environment

A latex-safe environment should be the goal of every health care facility. Latex has been used in the manufacture of pulmonary function circuits, and especially in disposable mouthpieces, nose clips and tubing. While reported reactions in exposed patients are rare, it would appear prudent to use latex-free products wherever possible. Emergency carts with latex-free medical products should be available.

Patients/Staff At Risk for Latex Anaphylaxis

Latex-free equipment and supplies must be used. Individuals at high-risk for latex allergy include healthcare workers, atopic patients, and those who have undergone multiple invasive procedures. Unless a latex-safe environment has been provided, questions regarding latex allergy should be asked of all patients. Patients suspected of having latex allergy should be referred for consultation and confirmatory testing prior to further exposures. Please see Appendix II for A Sample Latex Allergy Questionnaire.

For the benefit of both patients and staff, the use of latex gloves should be avoided. Routine practices dictate that all staff in direct contact with patients wear gloves. Contact dermatitis (allergic or irritant) is a common consequence of using latex gloves, and this may be involved in the development of true allergies to latex. Immediate reactions might include:

- rhinitis
- conjunctivitis
- urticaria
- angioedema
- asthma
- anaphylaxis

Allergenic latex proteins are also absorbed on glove powder, and may become airborne and inhaled when gloves are removed. All staff are encouraged to review up-to-date Guidelines for the Management of Latex Allergies. Web-site address http://acaai.org/public/physicians/latex.htm

Chapter 8 - Emergency Procedures

Overview

Emergency policies and procedures are documented in the facility manual and must include medical emergencies and fire safety.

Medical Emergencies

Each facility performing exercise testing and bronchoprovocative testing is equipped with a:

- sphygmomanometer
- stethoscope
- wheelchair
- oxygen source with mask
- connective tubing
- resuscitation tray with resuscitation equipment
- airway management equipment
- appropriate drugs

Note:	*The contents of the resuscitation tray are checked monthly for expiry dates on all drugs and sterile equipment*

Fire Safety

It is each staff person's responsibility to be aware of the facility's policies and procedures with respect to fire safety and fire prevention. Common sense is stressed so that emergency exits are not blocked and fire barrier doors are not propped open. A fire manual is available and reviewed twice a year. It includes the responsibilities for fire prevention, the classes of fires and extinguishers, steps on discovery of a fire, plans for reporting fires, fire evacuation plans, and maps. Fire numbers are posted on all telephones. Appropriate fire extinguishers are easily accessible and are checked each month and replaced if outdated or used.

When a fire is discovered:

- remove patients from immediate danger
- enclose area, close doors and windows upon leaving
- turn lights on

- turn off gas cylinders
- activate alarm
- call fire department, give location, your name, and type of fire
- try to extinguish the fire only if it is feasible

An evacuation plan is prepared and is practised periodically

For specific fire safety prevention and evacuation procedures, contact your local fire department.

Chapter 9 - Oxygen Saturation by Oximetry

Overview

Oxygen saturation by pulse oximetry (SpO_2) is a non-invasive estimate of hemoglobin oxygen saturation using the absorption of different wave lengths of light from oxygenated and deoxygenated hemoglobin. Pulse oximetry is performed at rest, exercise, and different levels of supplemental oxygen to assess for desaturation.

Instrumentation

Pulse oximeter with a probe for attachment to a peripheral site (e.g., finger, ear, forehead).

Technique

The patient should have refrained from smoking or from inhaling second hand smoke for one hour. Apply the probe to a clean site. Nail polish and/or artificial acrylic nails must be removed prior to testing, (alternatively an ear or forehead transflectance probe may be used). Excessive light, excessive motion, low perfusion or electrical interference at the probe site may cause erroneous readings. Do not use an inflated blood pressure cuff on the same limb as the oximeter probe. If oxygen saturation was measured also during exercise, observe the patient for 3 to 5 minutes post exercise for cardiac or neurological signs or symptoms.

Measurements

Oxygen saturation and heart rate can be obtained from the digital display. The plethysmographic waveform and signal strength indicator must be used to assess validity of the data. A comparison of pulse oximeter heart rate reading to one from palpation and an ECG, if available, can be used to check adequate perfusion at the probe site.

Quality Control

Calibration is performed according to the manufacturer's recommendations. With conventional pulse oximetry, the instruments are generally accurate to as low as 83% saturation when patients are being tested under steady state conditions. When using the older standard oximeters, check the manufacturers' recommendations for accuracy ranges. Skin thickness and skin pigmentation can affect the results obtained from oximetry.

For the saturation to accurately reflect steady state conditions, the patient must be continuously breathing a given F_IO_2 for a minimum of 5 minutes and possibly as long as 20 minutes depending on the degree of airflow limitation prior to the measurement being recorded.

Biologic controls should be monitored and documented monthly. The SpO_2 should be validated, if possible, by comparison with the measured oxygen saturation determined from an in vitro (hemolyzed) arterial blood sample (SaO_2) using a spectrophotometric oximeter (i.e., co-oximeter).

Chapter 10 - Carbon Monoxide Diffusing Capacity

Overview

Carbon monoxide diffusing capacity ($D_L$co) is a non-invasive measurement of the transfer of carbon monoxide (CO) from the alveoli to the pulmonary capillaries per minute for each mm Hg pressure gradient for CO. The single-breath determination of $D_L$co is the most widely used and standardized method. $D_L$co measurements are used in the diagnosis and management of obstructive, restrictive, and pulmonary vascular diseases.

Instrumentation

The equipment for $D_L$co testing is as follows:

- a spirometer with kymograph or pneumotachometer linear over an 8 L volume range and with a ±3.0% volume accuracy (±3.5% accounting for testing syringe accuracy of ±0.5%)
- a single sample (ss) or continuous real-time (crt) gas analyzer system linear from zero to full span within ±0.5% such as an infrared absorption gas analyzer (ss/crt for CO) methane (CH_4)), thermal conductivity analyzer (ss for CO, helium (He), and neon (Ne)), fuel cell (ss for CO), multigas LED (Light Emitting Diode) analyzer (crt for CO and CH_4)
- a bag-in-box system (consisting of a valve system with separate bags for inspired dry test gas and exhaled alveolar sample) with circuit resistance < 1.5 cm H_2O at a flow of 6 L/s or a demand valve (and a compressed gas source) with sensitivity < 10 cm H_2O for 6 L/s flow
- a compressed gas cylinder of test gas mixture consisting of 0.3% CO, the appropriate inert tracer gas (10% He, 10% Ne, or 0.3% CH_4), 21% oxygen (O_2), and balance nitrogen (N_2)
- a carbon dioxide (CO_2) absorber (e.g., Soda Lime) and a water (H_2O) absorber (e.g., Drierite) or H_2O vapour permeable tubing (e.g., PERMAPURE) if CO_2 and H_2O interfere with gas analyzer performance
- a timing device accurate to ± 1% over 10 s (100 ms)
- an automatic data acquisition and computation system (i.e., computer)
- a CO-oximeter to measure hemoglobin (Hb) and carboxyhemoglobin (COHb) is highly recommended

Technique

The patient should be sitting quietly for 5 minutes before starting the test and remain seated throughout the test. For patients on continuous O_2 therapy, the ordering physician or Medical Director/Quality Advisor should be consulted before it is removed. If clinically acceptable, the supplemental O_2 should be discontinued for 10 minutes prior to testing.

The patient is connected to the DLco system and breathes quietly. After at least 3 stable breaths, the patient exhales slowly to residual volume (RV) for a duration that is limited to 6 s. When at or near RV, the patient inhales rapidly (in less than 4 s) to total lung capacity (TLC) so that the inspired volume (V_I) is >85% of the largest vital capacity (VC). The patient breath holds for approximately 10 s (± 2 s), relaxing against a closed valve. During the breath-hold time (BHT), ensure that no expiratory effort against a closed airway (Valsalva manoeuvre) and no inspiratory effort against a closed airway (Mueller manoeuvre) is made. The Valsalva manoeuvre generates excessive positive intrathoracic pressure and the Mueller manoeuvre generates excessive negative intrathoracic pressure that may decrease and increase the DLco, respectively. After the BHT, the patient exhales at a moderate speed (< 4 s) in order to wash out the deadspace of 0.75 to 1.0 L or 0.5 L for VC < 2.0 L and collect an alveolar gas sample of 0.5 to 1.0 L (collection time < 3 s).

Two acceptable tests that are within 10% of the highest value or within 3 mL CO/min/mm Hg are obtained and averaged. No more than 5 tests should be performed as this can decrease the measure DLco by ~ 3-3.5%. The DLco should be adjusted to give a value standardized to a Hb of 146 g/L for adult and adolescent males and 134 g/L for adult female and children < 15 years old. Testing manoeuvres should be separated by a 4 minute interval to allow for the adequate elimination of test gas from the lungs. For patients with obstructive airway disease, this testing interval should be at least 10 minutes.

Measurements

The volume-time tracing of each acceptable DLco manoeuvre should be recorded.

The DLco test should yield the following:

- a V_I of > 85% of the largest VC
- the BHT determined using the Jones and Mead method
- actual or ratios of initial (i.e., test gas) and final (i.e., alveolar) CO and tracer gas concentrations
- the alveolar volume (V_A) by single breath dilution of the tracer gas
- unadjusted DLco from the average of two acceptable tests
- adjusted DLco for Hb and COHb (recommended)
- DLco/V_A ratio representing the DLco per unit lung volume (involved in diffusion)
- DLco should also be adjusted if COHb is greater than 2%

Calculations

DL_{CO} SB (ml/min/mmHg, STPD) = $[V_A(STPD) * 60 / (P_B - 47) * t] * \ln (FA_{CO,0} / FA_{CO,t})$

where:
V_A = alveolar volume, mL (STPD)
60 = conversion factor for seconds to minutes
P_B = barometric pressure, mm Hg.
t = breath-hold time, seconds
$FA_{CO,0}$ = fractional concentration of CO in the alveolar gas at beginning of breath-hold
$FA_{CO,t}$ = fractional concentration of CO in the alveolar gas at end of breath-hold

$V_A = (V_I - VD_{inst} - VD_{anat}) * (FI_{Tr} / FE_{Tr}) *$ (ATPD to STPD Factor)

where:
V_I = inspired volume, mL (ATPD)
VD_{ins} = instrument dead space volume, mL
VD_{anat} = anatomic dead space volume, mL
FI_{Tr} = fractional concentration of inspired tracer gas
FE_{Tr} = fractional concentration of expired tracer gas

(ATPD to STPD Factor) = $(P_B * 273) / (760 * (273 + T))$

where:
T = temperature in °C

Quality Control

The spirometer should be calibrated each day using a validated 3 L syringe; the volume accuracy limit should be ±3.5%. Thus, after injecting 3 L into a spirometer, the recovered volume should be 3 ± 0.105 L. For pneumotachometers, varying flow rates are injected using a 3 L syringe to check for the same recovered volume accuracy range.

For continuous real-time gas analysis, a two point calibration of the infrared analyzer using zero and test gas concentration to within ±0.5% of test gas is required before each test. Hence, the analysis of 0.3% CO, should be within ±0.0015% of the true value.

For gas chromatography analysis, separation of the test gas concentration into its component gases and detection by a thermal conductivity analyzer to give a single chromatograph tracing with a Ne and CO peak (i.e., a "one point" determination) is required before each test.

For infrared CO analyzers with electronic linearization and He analyzers, a linear response (i.e., when the analyzer is adjusted to zero and full scale using the test gas concentration) is established before each test. Linearity check using a minimum of

three serial gas dilutions or primary standards (maximum error of no more than ±0.0015%) is required every three months.

The timing device should be checked for accuracy within ±1% over 10 s (100 ms) every three months.

Chapter 11 - Functional Residual Capacity by Closed Circuit Helium Dilution and Open Circuit Nitrogen Washout

Overview

Functional residual capacity (FRC) may be measured by gas dilution techniques. The two commonly used gas dilution methods both require the use of a physiologically inert gas that is relatively insoluble in blood and tissues. FRC measurement by helium dilution requires a closed circuit and involves the wash in and equilibration with a trace concentration of helium. Whereas FRC by nitrogen washout is an open system, the resident gas (nitrogen) is replaced by breathing 100% oxygen usually via a demand valve

Note:	*These methods may underestimate thoracic gas volume in patients with moderate to severe airways obstruction.*

Instrumentation

Pulmonary Function System with volume displacement/flow sensing spirometer, helium (He) analyzer (katharometer), or emission-type N_2 analyzer. Other systems derive the alveolar N_2 concentration from deduction of expired O_2 and CO_2 from oxygen and carbon dioxide analyzers respectively.

Compressed-gas cylinder (s) of test gas (s) used by the laboratory (e.g., 100% O_2, or 100% He, 21% O_2 with balance N_2).

Mouthpiece, tubing, nose clip, CO_2 and O_2 absorbers, and other miscellaneous equipment or supplies needed (e.g., facial tissue and chart paper).

Technique

Helium Dilution

The patient is turned into the spirometer at the end-tidal point after a stable end tidal expiratory level (usually takes 5-8 breaths) is established. Instruct the patient to breathe normally until equilibrium of the helium occurs (approximately five minutes). Occasional slow inspiratory capacity manoeuvres may be done to speed the equilibration process. Oxygen is added to the system to replace what the patient consumes, either by the bolus method or the volume-stabilized method. Equilibration has occurred when the He changes < 0.02% in 30 seconds. The patient is instructed to perform a slow vital capacity (SVC) manoeuvre either at the beginning or at the

end of the trial so other lung volumes can be calculated. The patient is turned out of the system at the end-tidal point.

Nitrogen Washout

The patient is connected to the mouthpiece. When a stable tidal volume and respiratory rate are maintained, the patient is turned into the system such that 100% oxygen is inhaled from a demand valve or a reservoir. The end of the test is reached when $N_2 \leq 1.5\%$. The patient is instructed to perform a slow vital capacity manoeuvre either at the beginning or at the end of the trial so that other lung volumes can be calculated. The end expiratory nitrogen concentration is recorded as the alveolar nitrogen, although it likely underestimates the true alveolar nitrogen when there is significant airflow limitation.

Measurements

Helium Dilution

Helium readings are recorded every 15 seconds until equilibration occurs. Equilibration is defined as no change greater than 0.02% helium in 30 seconds. IC (Inspiratory capacity), VC (Vital Capacity), and ERV (Expiratory Reserve Volume) are measured from the volume recording. Perform at least two technically satisfactory results. The mean values of the IC and FRC should be reported while the highest VC should be reported. The acceptable results should agree within 10%, rounded to two decimal places. A minimum of 5 minutes should elapse between reported trials.

Nitrogen Washout

The patient must be breathing room air at least 15 minutes prior to the measurement. In most instances this will assume that alveolar nitrogen (N_2) is near 80%. Testing is continued until nitrogen concentration falls below 1.5% for at least three successive breaths. The volume is collected in the spirometer and its nitrogen concentration is measured. Perform at least two technically satisfactory measurements. Allow at least 15 minutes between each one. In patients with severe obstructive disease, the time between trials should be at least 1 hour. The mean values of the IC and FRC should be reported while the highest VC should be reported. The acceptable results should agree within 10%, rounded to two decimal places.

Calculations

Helium Dilution

$Vds = (C_2 * Vol\ added) / (C_1 - C_2)$

$FRC\ (L) = [((C_1 - C_2) * (Vds + Vol\ added)) / C_2 \pm switch\ error \pm O_2\ Diff - 125\ ml] * BTPS\ Factor$

where:

Vds =	Apparatus Dead Space
C_1 =	initial helium concentration
C_2 =	final helium concentration
O_2 diff =	oxygen difference

Nitrogen Washout

The dead-space from the spirometer needs to be estimated and subtracted in the calculations.

$FRC\ (L) = [((V_E + VD1) * (FE - F1) - (VD2) * (FN) - VTIS) / (FA1 - FA2)] * BTPS\ Factor$

where:

V_E =	volume expired into spirometer (L)
VD1 =	spirometer deadspace volume
VD2 =	spirometer + tubing deadspace volume
FE =	[N2] in spirometer at end of washout.
F1 =	[N2] in the oxygen source
FN =	[N2] in spirometer at beginning of washout
VTIS=	volume correction for tissue N2
FA1 =	initial alveolar [N2] (assumed to be .81)
FA2 =	Final alveolar [N2] concentration

A value of 30mls/minute is the estimated volume correction for nitrogen elimination from blood and tissues.

The FRC calculation must be corrected for the switch-in error if necessary.

Quality Control

Helium Dilution

The spirometer is physically calibrated every three months over the full range of the instrument and should be accurate over a 8L range to ±3.5% of the volume added. A daily 3L volume calibration (verification) and leak check is performed.

A two point (zero to full scale) calibration of the helium analyzer is performed daily.

Biologic controls must be monitored and documented on a monthly basis.

Nitrogen Washout

The spirometer is calibrated as above. The accuracy and linearity of the N_2 analyzer is checked before each patient by performing a 2-point calibration using zero and 80% nitrogen. A 3-point linear check is required initially and every 6 months thereafter (0%, 40%, 80% nitrogen). If N_2 is derived from deductions of CO_2 and O_2, the respective analyzers must be checked according to the manufacturer.

The pneumotach must be calibrated using room air for the inhaled check and O_2 for the exhaled check.

Biologic controls must be monitored and documented on a monthly basis.

Chapter 12 - Functional Residual Capacity and Airway Resistance by Body Plethysmography

Overview

Functional residual capacity (FRC) can be determined by body plethysmography (FRCpleth) by measuring the thoracic gas volume (V_{TG}) at the end of a tidal breath. Airway resistance may be obtained by additional plethysmographic measurements.

Body Plethysmography

Plethysmography measures all compressible gas in the thorax. It is not affected by poorly or non-ventilated areas of the lung. The most common type of plethysmograph for clinical use is the constant-volume, variable-pressure box, though other types can be used.

Instrumentation

A body plethysmograph with a pneumotach for measuring flows <2 L/second and two variable reluctance pressure transducers, one accurate to ± 2 cm H_2O for measuring box pressure and one accurate between ± 20 to 50 cm H_2O for measuring mouth pressure.

A computer or rapid recording instrument for displaying $\dot{V}$/Pbox and Pm/Pbox is also required.

Technique

The patient, seated comfortably in the plethysmograph, breathes quietly through the mouthpiece apparatus with fingertips placed on both cheeks to control measurement error. When the end expiratory volume is stable, the airway is occluded and the patient is instructed to pant gently against the closed shutter at a frequency of 0.5 to 1.0 Hz, but not greater than 1.5 Hz. Panting frequencies outside of this range may cause errors. A slow vital capacity (SVC) manoeuvre should also be included and should precede the panting manoeuvre. SVC must also be performed prior to FVC manoeuvre.

Measurements

Obtain at least three acceptable trials (consisting of 3-5 technically satisfactory panting and IC manoeuvres) that agree within 5% of the mean and report the mean value. The highest two vital capacity measurements should be within 0.15 litres and

within 5% of FVC for non obstructive patients. The highest vital capacity obtained should be reported. The reported value should be rounded to two decimal places.

Calculations

V_{TG} (L) = (((Pboxcal / Pmouthcal) / Tan1) * (PB – 47 mmHg) * 1.36 * (1 – (BodyWt / 1.05 / BoxVol)) / 1000 ml/L

where:

Pboxcal	=	calibration factor for box pressure (e.g.: 1" = 15 ml)
Pmouthcal	=	calibration factor for mouth pressure (e.g.: 1" = 5 cm H2O)
Tan1	=	Pmouth/Pbox
PB	=	ambient barometric pressure in mmHg
1.36	=	conversion factor from mmHg to cmH2O
BodyWt	=	Body weight in Kg
1.05	=	assumed density of human body
BoxVol	=	Box volume in Liters (e.g: 800 L)

Quality Control

Equipment calibration should be performed at least once daily before testing patients and every four hours during use. The box pressure transducer is calibrated using a 30-50 mL sine-wave pump. The mouth pressure transducer is calibrated using a water manometer and a calibration pump capable of generating 0 – 1.5 L/s for flow. An electronic signal to represent each of box pressure, mouth pressure, and flow can be used to represent the physical calibration. It is performed before each patient is tested. Volume-measuring-device calibration (verification) with a 3.0 L calibrating syringe should be performed daily.

The box leak check and physical equipment calibration is performed monthly. Biologic controls must be monitored and documented on a monthly basis.

Airways Resistance

The body plethysmograph can also be used to measure airway resistance (R_{AW}). The instrumentation and quality control are the same as described in the FRC plethysmography manoeuvre.

Technique for Measuring Airways Resistance

The patient, seated comfortably in the plethysmograph, performs uniform shallow (50-100 mL) panting technique at a frequency of 1.5 – 2 Hz with the shutter assembly open. The shutter is then closed and the patient continues to pant at the same frequency.

Measurements

When the shutter is open, $\dot{V}$/Pbox measurements are taken. When the shutter is closed, Pm/Pbox measurements are taken. R_{AW} is calculated from the ratio of open-and-closed-shutter tangents for each manoeuvre. Reported R_{AW} should be averaged from three to five separate, acceptable manoeuvres are those that agree within 10% of the mean value.

Calculations

Observed Raw (cmH2O/L/sec) = (Tan1 / Tan2) * (Pmouthcal/$\dot{V}$cal)

where:

Tan1	= Pmouth/Pbox
Tan2	= $\dot{V}$/Pbox
Pmouthcal	= calibration factor for mouth pressure (e.g.: 1" = 5 cmH2O)
$\dot{V}$cal	= calibration factor for flow (e.g.: 1" = 1.25 L/sec)

Chapter 13 - Non-Specific Bronchial Provocative Test

Overview

Non-specific bronchial provocative test involves inhaling a non-specific pharmacologic agent to induce diffuse airway narrowing. The two most common pharmacologic agents used are methacholine and histamine. The commonly used industrial methacholine is not approved by any North American regulatory bodies. Therefore, if a facility decides to use industrial methacholine, patients should be made aware of this information. Alternatively, Provocholine®, which is approved in the United States, may be used as the agent for bronchial provocation.

- Provocholine® is from Methapharm Inc., 19 Isabel Drive, RR 4, Brantford, Ontario N3T 5L7. 1-800-287-7686. www.methapharm.com.

The following medications should not be taken within the listed time frames prior to initiation of the challenge test:

Medication withholding recommendations for methacholine challenge test

Short-acting inhaled bronchodilators (eg. albuterol, salbutamol)	8 hours
Medium-acting bronchodilators such as ipratropium	24 hours
Long-acting inhaled bronchodilators, such as salmeterol, formoterol	48 hours
Anticholinergics	24 hours
Cromolyn sodium	8 hours
Nedocromil	48 hours
Liquid theophylline	12 hours
Intermediate-acting theophylline	24 hours
Long-acting theophylline	48 hours
Leukotriene modifiers	24 hours
Antihistamine	Not usually withheld for methacholine challenges
Foods	
Coffee, tea, cola drinks, chocolate	Day of study

Beta-adrenergic blocking agents: The Provocholine® package insert states methacholine inhalation challenge should not be performed in patients receiving any beta-adrenergic blocking agent because in such patients responses to methacholine chloride can be exaggerated or prolonged, and may not respond as readily to accepted modalities of treatment. Withholding of beta-adrenergic blocking agents or performing the challenge in patients taking such agents should be performed with caution and only upon specific orders from the ordering physician.

Note:	*The authors do not recommend routinely withholding oral or inhaled corticosteroids, but their anti-inflammatory effect may decrease bronchial responsiveness . Inhaled corticosteriods may need to be withheld depending on the question being asked. (ATS Guidelines for Methacholine Challenge Testing, Am J Respir Crit Care Med 2000; 16:309-29).*

The Medical Director of the laboratory, another physician, or another person appropriately trained to treat acute bronchospasm, including appropriate use of resuscitation equipment, must be physically present to respond quickly to an emergency. Patients should not be left unattended during the procedure once the administration of methacholine/Provocholine® has begun.

Instrumentation

A calibrated nebulizer for reproducible and standard aerosolization of the agent. For the tidal breathing method, nebulizers must deliver an aerosol with a particle mass median diameter (MMD) between 1.0 and 3.6 µm at an output of within 0.13 mL per minute.

Nebulizers for the five-breath dosimeter method should deliver 9µL +/-10% of solution per 0.6 seconds actuation during inhalation. A high quality nebulizer that generates aerosols with a particle size between 1.0 to 3µm should be used.

A spirometry system that meets current American Thoracic Society standards.

The testing room must have adequate ventilation (ie., at least two complete air exchanges/hour). Exhalation filters should be used on the nebulizer to minimize the chance that the technician will be exposed to the methacholine/Provocholine® aerosol.

A body plethysmograph may be used if airways resistance instead of FEV_1 is the indicative response parameter.

Histamine or methacholine/Provocholine® diluted to the appropriate dose ranges.

Methacholine/Provocholine® should be diluted using a sterile sodium chloride (NaCl) solution (0.9%) with or without a preservative. For further information on the preparation of methacholine/Provocholine® from powder refer to the ATS Pulmonary Function Lab manual Chapter 12, p. 3-5. Expiry (after reconstitution) is 3 months refrigerated (4 degrees Celsius) for methacholine and 2 weeks refrigerated (4 degrees

Celsius) for Provocholine®.

A consent form describing the procedure should be carefully read and signed by the patient or parent/legal guardian of the patient prior to the challenge. The consent form should not provide information that will suggest a specific outcome. If a facility is using methacholine, the consent form must state that it is not an approved substance. Resuscitation equipment with the corresponding drug interventions is mandatory.

Note:	*If benzyl alcohol is used as a preservative, then concentrations > 0.9% may cause small cracks to form in the plastic material of the Wright nebulizers.*

Technique

There are two widely accepted methods for performing inhalation challenges.

The first method involves two minutes of tidal breathing from the nebulizer where the response parameter (usually FEV_1) is followed from 30 seconds after each dose and repeated at 90 seconds and at 3 minutes if FEV_1 is still dropping. The test is terminated when the maximum dose is reached or a positive response is obtained. This is usually defined as a drop in FEV_1 of 20%. If sGaw or sRaw is measured, report the concentration that causes a 40% fall in sGaw or a 40% rise in sRaw.

In the second method, the subject inhales five deep breaths of the methacholine or histamine from a nebulizer, holding near TLC for a few seconds then expiring normally. If no change occurs in the monitoring parameters (usually FEV_1) after three minutes, the next dose is given.

The following 10 doubling concentrations of methacholine/Provocholine® are prepared in sterile vials according to the Complete ATS-Recommended Dilution Schedule:

Diluent (saline)

0.03 mg/ml

0.06 mg/ml

0.125 mg/ml

0.25 mg/ml

0.5 mg/ml

1 mg/ml

2 mg/ml

4 mg/ml

8 mg/ml

16 mg/ml

Using the Shortened ATS-Recommended Dilution Schedule, the following 5

concentrations of methacholine/Provocholine® are prepared in sterile vials:

Diluent (Saline)

0.0625 mg/ml

0.25 mg/ml

1 mg/ml

4 mg/ml

16 mg/ml

The post-diluent FEV_1 (or sGaw or sRaw) is the reference point or baseline.

Shortening the test procedure

1. The number of doses administered can be reduced to save time. This can be accomplished by starting at a higher dose, or increasing the difference in concentrations between doses. The 1999 Methacholine Challenge Test Guideline recommends using a four-fold increase in concentrations for the 5-breath dosimeter technique if time is to be saved. However, the ATS Guideline warns against increasing the difference between concentrations when the patient is a child, is known to have moderate or severe asthma, has airflow obstruction on baseline spirometry, or if the FEV1 fell by more than 10% after the previous methacholine dose. In these situations, the two-fold increase in concentrations should be used.
2. According to the ATS manual, Hargreave and colleagues have suggested a guideline based on drug therapy and ventilatory function to shorten the procedure in adults.
    - If the patient's FEV_1 >80% of predicted and does not fall by more than 10% after inhalation of the diluent and the patient takes no pulmonary medications, the starting dose can be as high as 1 to 2 mg/mL.
    - If the FEV_1 falls less than 5% after a dose of methacholine then the next concentration may be omitted.
    - If the patient takes bronchodilators, the starting dose can be approximately 0.25 mg/mL.
    - If the patient takes corticosteroids for asthma, the starting dose can be 0.125 mg/mL.
    - In all other instances and for children, the starting dose should be 0.03 mg/mL.

Once the test is terminated, the patient is then given a bronchodilator, if required, and monitored to ensure no further airway narrowing occurs.

Measurements

FEV_1 measured at 30 and 90 seconds or sRaw (or sGaw) is measured with each dose for the duration of the test.

At each dose, the highest FEV_1 is reported from the acceptable manoeuvres.

Calculations

A single number PC_{20} may be used to summarize the results for clinical purposes.

PC_{20} is calculated or interpolated from the graph of delta FEV_1 versus methacholine/Provocholine® or histamine concentration. If the FEV_1 does not fall by 20% after the highest methacholine concentration, the PC_{20} is reported as being >16 mg/ml. If the FEV_1 falls by >20% after inhalation of the diluent, a PC_{20} is not reported.

$$PC_{20} = \text{antilog}\,[\log C_1 + [(20 - R_1) * (\log C_2 - \log C_1)] / (R_2 - R_1)]$$

where:
C_1 = second to last methacholine concentration
C_2 = final concentration of methacholine
R_1 = percent fall in FEV_1 after C_1
R_2 = percent fall in FEV_1 after C_2

Quality Control

A new nebulizer's output should be determined by full calibration prior to use. The corresponding flow rate necessary to deliver the appropriate output must be recorded and used consistently. Subsequent checks of nebulizer output every 6 months need only test the output at that flow rate. If output varies by more than 10% during verification a full calibration must be performed.

For initial verification, the challenge procedure must separate patients with normal airways from patients with hyper-responsive airways. This is done by performing the challenge on at least 3 non-asthmatic individuals, who should have no response, and 3 individuals known to have asthma.

Spirometers must be calibrated according to recommendations in Chapter 6.

Methacholine/Provocholine® and histamine must be refrigerated at 4 degrees celsius. Methacholine and histamine may be stored for 3 months. Provocholine® may be stored for 2 weeks. Methacholine/Provocholine® and histamine must be warmed to

room temperature prior to use. Any unused solution remaining in the nebulizer must be discarded.

Chapter 14 - Exercise Challenge Testing for Asthma

Overview

Exercise-induced asthma assessment is an exercise challenge test designed to induce bronchoconstriction by exercising the patient to a standard percentage of their maximum heart rate or maximum ventilation and sustaining that target workload for a period of time. Non-invasive parameters such as heart rate, blood pressure, and oxygen saturation are measured and recorded. The major factors that determine the severity of exercise-induced bronchoconstriction (EIB) are the pulmonary ventilation reached and sustained during exercise and the water content and temperature of the inspired air.

The Medical Director of the laboratory, another physician, or another person appropriately trained to treat acute bronchospasm, including appropriate use of resuscitation equipment, must be physically present to respond quickly to an emergency. Patients should not be left unattended during the procedure once the exercise has begun.

Instrumentation

Instrumentation includes a:

- treadmill or cycle ergometer
- 12 lead printed-copy capacity ECG
- blood pressure cuff and sphygmomanometer
- calibrated spirometer
- metered dose inhaled bronchodilators
- pulse oximeter
- hydrometer
- thermometer
- equipment for measuring ventilation (optional)

Note:	*Resuscitation equipment is mandatory.*

Technique

Check that the patient has refrained from medications as outlined in *Chapter 13 Non-Specific Bronchial Provocative Testing*. The patient should abstain from eating a heavy meal, smoking cigarettes, and consuming alcohol and drinks containing caffeine 3 hours prior to test and should have refrained from heavy exercise for at least 4 hours. Informed consent should be obtained and witnessed by personnel who can accurately describe the test and potential risks. Perform a baseline spirometry. The FEV_1 must be greater than 1.5 L or 70% of predicted in order to proceed.

Obtain baseline ECG and blood pressure. Leave cuff on the arm in case it is needed. Calculate the predicted maximum heart rate. The target heart rate is 80-90% of this. Ventilation should reach 40-60% of the predicted maximum voluntary ventilation.

Approach the target workload while the patient inspires dry air less than 25 degrees C. The treadmill grade is set at approximately 6%.

An acceptable workload can be achieved in two ways. Either by the patient achieving 80-90% maximum predicted heart rate, which is the most common approach, or maximal ventilation can also be monitored, however this requires monitoring expired gas during exercise. Exercise intensities can be chosen to target 40-60% (80% in elite athletes) of the calculated maximum voluntary ventilation (MVV).

The target minute ventilation and heart rate must be reached quickly. General consensus is that the overall exercise time be 6 to 10 minutes. Two methods of achieving the desired exercise level are:

1. Rapid increase in the work rate over the first 1 to 2 minutes to the pre-determined work rate, then continue for 6 to 8 minutes.
2. In adults it is recommended for safety reasons that the high-work plateau be approached in three steps to allow for careful observations of the cardiopulmonary response: 2 minutes warm-up at a low intensity, 2 minutes at a moderate work rate, 5 to 8 minutes at the target work rate.

Following exercise, there should be a brief cool-down phase at a reduced work rate for 1 to 2 minutes.

Target settings are only the "best guess" and are adjusted to suit the patient's fitness level. Apply nose clips during exercise to ensure mouth breathing.

Measurements

A 12 lead ECG must be applied. At least 3 leads must be monitored throughout exercise and at least 3 minutes post exercise. Spirometry is measured pre-exercise and at 5, 10, 15, 20, and 30 minutes post-exercise. If the FEV_1 falls by less than 20%, complete all measurements and give the patient a bronchodilator only if FEV_1 has not returned to within 10% of baseline value. If the FEV_1 fall is greater than 20%, give the patient a bronchodilator immediately and continue monitoring FEV_1 until it returns to within 10% of baseline value. Subjective symptoms (e.g., Borg scale) pre,

during and post-exercise should be obtained and quantified post exercise. Record room temperature and the speed, grade, and duration of exercise.

Calculations

Estimated MVV = FEV_1 (L) * 35
Maximum heart rate = 210 – (0.65 * Age)

% drop in FEV_1 from PreExercise Baseline =
[(PreExercise Baseline FEV_1 – PostExercise FEV_1)/PreExercise Baseline FEV_1] * 100

The criterion for a positive test remains controversial. While some authors consider a drop of 10% in FEV_1 as an abnormal result, others consider a drop of 15% as more diagnostic for exercise-induced bronchoconstriction.

Quality Control

Treadmill or bicycle need not be calibrated as actual workload and grade are not relevant as long as the target heart rate is achieved and maintained. The spirometer should be calibrated according to Chapter 6. The respiratory circuit is checked weekly for leaks.

Vigorous exercise must be avoided for at least four hours before testing as prior exercise has been found to exert a protective effect on the airways.

When treatment efficacy is being monitored, some medications may be continued as directed by the requisitioning physician. These medications must be noted on the report.

Chapter 15 - Stage I Exercise Test

Overview

Stage I Exercise Test is a progressive, graded power test on a cycle ergometer or treadmill. The patient exercises until a symptomatic or safety limitation is reached. Non-invasive parameters such as workload, ventilation, heart rate, oxygen uptake, carbon dioxide output, oxygen saturation, and blood pressure are measured and recorded.

The physician must be in attendance during the Stage 1 Exercise Test. (For a more detailed description the reader is directed to the ATS document, Chapter 19 "Cardiopulmonary Exercise Test").

Instrumentation

Instrumentation used includes a:

- Calibrated cycle ergometer or treadmill
- Two or three lead EKG for continuous monitoring, with 12 lead capacity
- Mixing chamber or Douglas bags to collect expired ventilation
- Blood pressure cuff and sphygmomanometer
- Respiratory valves, tubing, noseclip, and mouthpiece
- Flow sensing device (e.g., turbine, pneumotach, pitot tube, mass flow sensor) for measuring ventilation.
- Pulse Oximeter for measuring oxygen saturation
- Computerized system for continuous data acquisition, display and printing of results

If a stage 2 test is performed optional equipment includes O_2 and CO_2 analyzers for measuring expired oxygen and carbon dioxide concentrations.

Note:	*Resuscitation equipment is mandatory.*

Techniques

A basic standard protocol for stage I exercise testing is widely accepted and is briefly described. ECG electrodes, blood pressure cuff, mouthpiece, and respiratory valve assembly are attached to the patient. Resting measurements are taken. The workload is increased by equal increments every minute. During the last 15 seconds of each

minute, all parameters being measured are recorded. The test is continued until the patient is symptom-limited or until the attending physician stops the test.

Note:	*The Borg scale is the preferred method of rating symptom limitation which rates breathing and leg fatigue from 0 (no symptoms) to 10 (maximal symptoms).*

Measurements

Continuous heart rate, blood pressure, ventilation, expired gas concentration, workload, and oxygen saturation are measured each minute for the duration of the exercise test.

Calculations

Calculations

$\dot{V}_I F_I N_2 = \dot{V}_E F_E N_2$

$\dot{V}_E$ (L/min) BTPS $= \dot{V}_I * (F_I N_2 / F_E N_2) *$ BTPS factor

$\dot{V}_I$ (L/min) BTPS $= \dot{V}_E * (F_E N_2 / F_I N_2) *$ BTPS factor

$F_E N_2 = 1 - F_E O_2 - F_E CO_2$

$\dot{V}O_2$ (L/min) $= \dot{V}_I$ (STPD) * $F_I O_2 - \dot{V}_E$ (STPD) * $F_E O_2$

$\dot{V}CO_2$ (L/min) $= \dot{V}_I$ (STPD) * $F_I CO_2 - \dot{V}_E$ (STPD) * $F_E CO_2$

$R = \dot{V}_{CO2} / \dot{V}_{O2}$

Quality Control

Many of the current exercise systems integrate devices measuring ventilation, expired gases, saturation, ECG with either the exercise bicycle or treadmill with a computerized system. As such the test procedures and calibration methodology are usually governed by proprietary algorithms. Nevertheless, minimal calibration requirements apply. Am J Resp Crit Care Med Vol 167, p222 (2003):

Equipment	Range	Accuracy*	Reproducibility	Frequency Response	Test Signal
		(%)	(%)	(*ms*)	
O2 analyzer	0–100%	1%	1%	< 130	Minimal two-point calibration
CO2 analyzer	0–10%	1%	1%	<130	Minimal two-point calibration
Flow meter	0–14 L/s	3%	3 %	< 40	3-L syringe
Cyc. Ergom.	0–400 W	2% or 3W above 25W			Dynamic torque meter
Treadmill	0–10 mph	0.2 mph			Timed revolution of marker on belt
	0–20% grade	0.5%			Measurement with carpenter's ruler

* Linearity within the indicated percentage of full scale for each apparatus.

The system must be calibrated daily or prior to testing and includes calibration of the air flow or volume transducer, two point calibration of each gas analyzer with two precision-analyzed gas mixtures (i.e., 5% CO_2 & 12% O_2; 0% CO_2 & 21% O_2). In systems utilizing breath-by-breath gas exchange measurements the delay time between solenoid activation and detection of change in gas analyzer output should also be measured daily. Less frequent calibrations include blood pressure transducers, exercise bicycle or treadmill.

With mechanical bicycles several workloads are tested using known weights for accuracy yearly. Pedaling frequency is monitored carefully.

Electronic bicycles are calibrated yearly with a physical balance such as a torque calibrator.

The belt velocity and treadmill grade are tested yearly. For more specific calibration techniques, follow the manufacturer's recommendations.

Note:	*In older non-integrated systems individual measurement components require specific calibrations.*

CO_2 analyzers tend to be alinear so at least a five point calibration between 0 -7% is necessary. Alternatively, a calibration curve can be built using a dilution technique. CO_2 analyzers are accurate to ± 0.03% of the reading. O_2 analyzers are inherently linear and only require a three point calibration using 0% O_2, 15% O_2, and 100% O_2 with an accuracy of ±0.03%.

The flow sensing device is appropriately calibrated (see Chapter 6). The respiratory circuit is checked weekly for leaks.

Reproducibility may be assessed with biological controls using one or two healthy laboratory personnel. Although the ATS document recommends at least monthly tests, this may not be practical and instead quarterly biological testing is recommended. Care must be taken to conduct this test on the same time of the day, as there may be significant diurnal variation and to use an identical protocol.

Chapter 16 - Maximal Inspiratory Pressures and Maximal Expiratory Pressures

Overview

The Maximal Inspiratory Pressure test (MIP) is designed to determine the maximum pressure the inspiratory muscles can generate. It is normally measured at residual volume (RV). Whereas, the Maximal Expiratory Pressure test (MEP) is designed to determine the maximum pressure the expiratory muscles can generate; it is normally measured at total lung capacity (TLC).

Instrumentation

The equipment can be as simple as a portable strain gauge or electronic handheld pressure manometer. Most new pulmonary function systems incorporate these tests with simple lung volume level indication to TLC or RV.

A typical portable handheld unit consists of a three-way valve with a 2.5 cm internal diameter. One outlet is open to room air, the other outlet is sealed with a rubber stopper and contains a small hole of 1.0- 2.0 mm inside diameter as a "controlled leak" and 15 mm in length. The purpose of a small hole during the measurement of MIP is to prevent glottic closure as well as facial muscles from generating artificial higher pressure.

A rubber mouthpiece and nose clip.

Techniques and Measurements

Patients should sustain maximum pressure for at least one second. Although either peak or sustained pressure can be measured, the Task Force is biased to the measurement of sustained pressures as predictive values are based on sustained pressure measurements.

Place a tight-fitting rubber mouthpiece onto the mouthpiece adapter.

Explain the procedure to the patient; ensure that there is no contraindication for the test.

Instruct the patient to keep a tight lip seal and to give maximum effort.

Maximal Inspiratory Pressure

Ensure that the patient is in the upright sitting position and the "controlled leak" is properly in place.

Place the mouthpiece properly in the patient's mouth and apply a nose clip.

Instruct the patient to breathe out all the way slowly, and remind the patient to keep the lips tight around the mouthpiece.

When the patient is at residual volume, close shutter and instruct the patient to immediately breathe in as hard as possible for at least 1 second.

A minimum of 3 and a maximum of 8 measurements must be obtained.

If the final effort is the highest value, instruct the patient to perform one more measurement.

The test is said to be reproducible when the highest two values are within 10%.

Depending on the patient, allow the patient to rest for 30 to 60 seconds between tests.

Maximal Expiratory Pressure

Ensure that the patient is in the upright sitting position (the "controlled leak" needs not to be removed as it will not change the lung volumes significantly).

Place the mouthpiece properly in the patient's mouth and apply a nose clip.

Instruct the patient to apply hands to cheeks.

Instruct the patient to breathe in all the way slowly, and remind the patient to keep the lips tight around the mouthpiece.

As soon as the patient cannot breathe in anymore (at TLC level), instruct the patient to immediately push out as hard as possible for at least 1 second.

A minimum of 3 and a maximum of 8 measurements must be obtained. If the final effort is the highest value, instruct the patient to perform one more measurement.

The test is said to be reproducible when the highest two values are within 10%.

Depending on the patient, allow the patient to rest for 30 to 60 seconds between tests.

Indications for test termination

- Syncope
- Angina
- Dizziness/headache/muscle cramping not relieved by rest
- Mental confusion
- Patient requests to stop

Calculations

If a recorder is used, measure the centimeter deflection of the pressure reading and convert to a pressure reading (usually 1 cm deflection = 10 cm H_2O). Measure and record all values sustained for at least 1 second. Report the highest most reproducible, sustained MIP and MEP that meet the acceptability criteria. Results are reported in cm H_2O and compared to predicted values that are based on the same lung volumes as the observed values. If a strain gauge or manometer is used, the only measurement that can be recorded is peak pressure.

Quality Control

Check the calibration of the measurement system with water/mercury manometer or traceable electronic digital pressure monitor each day of use. Ensure that the measurement system reads "zero" at ambient pressure. Using a specialized syringe, apply 100 cm H_2O from the manometer for both negative and positive pressures. The measured reading should be within 5% of the expected value. Adjust the measured reading appropriately to the system or a recorder if required.

Pressure transducers must be calibrated quarterly over the range of use ±200 cm H_2O.

To accurately interpret the results, poor patient cooperation must be distinguished from actual muscle weakness.

Chapter 17 - Arterial Blood Sampling, Blood Gas Analysis and Hemoximetry

Overview

Arterial blood is usually drawn anaerobically from the radial artery via a single percutaneous needle puncture. Alternatively, an arterialized capillary blood sample can be collected from a finger or ear lobe prick. Either method provides a specimen for blood gas analysis and hemoximetry.

The analysis of arterial blood provides information on the oxygenation, ventilatory, and acid-base status in evaluating respiratory function; arterialized venous blood provides an estimate of arterial values. The values directly measured from the arterial or arterialized blood are the carbon dioxide tension (PCO_2), oxygen tension (PO_2) and the hydrogen ion concentration (pH). Other derived or calculated values that are clinically useful are the plasma bicarbonate (HCO_3^-), base excess/deficit, and oxygen saturation (calculated SO_2). The usual values measured in hemoximetry (i.e., Co-oximetry) are the concentration of total hemoglobin (tHb), oxyhemoglobin (O_2Hb), carboxyhemoglobin (COHb), methemoglobin (MetHb), and oxygen saturation of tHb (measured SO_2)

Instrumentation

The instrumentation for arterial blood sampling, blood gas analysis and hemoximetry are as follows:

- An automated blood gas analyzer system consisting of:
    - a pH electrode (Sanz electrode) and reference electrode for measuring the pH
    - a PCO_2 electrode (Severinghaus electrode) for measuring the $PaCO_2$
    - a PO_2 electrode (Clarke electrode) for measuring the PaO_2
    - a fixed multiple wavelength spectrophotometer (co-oximeter) for measuring tHB, O_2Hb, COHb
    - calibrating gas mixtures and solutions for pH, PCO_2, and PaO_2
    - reagents (rinse, salt-bridge, cleaning solutions) and accessories (electrode membranes, thermal paper, pump tubing)
- three levels (i.e., normal, acidosis, alkalosis) of commercially prepared (aqueous buffer or fluorocarbon-based) quality control material
- personal protective equipment (gloves, outerwear, eyewear)

- preheparinized syringes with a 22 to 25 gauge needles or capillary tubes, engineered sharps (i.e., lancets), antiseptic solution, sterile gauze pads, puncture resistant sharps container
- instrument's operator manual

Techniques

Perform a modified Allen test to assess the adequacy of collateral circulation through the ulnar artery. The modified Allen test must be positive (i.e., good ulnar blood flow) to proceed with the radial puncture. Wipe the puncture site with alcohol and place the patient's hand into a relaxed supine position. Support the patient's hand with a rolled towel while hyper-extending the patient's wrist to approximately 45^{o} from horizontal. Palpate the radial artery to locate a maximal pulse point (MPP) by pressing your index and middle finger on the artery. Slowly advance the needle with the bevel facing upward to pierce the skin at approximately a 45^{o} angle toward the MPP until the blood begins to fill the heparinized syringe. If the artery is missed, slowly withdraw the needle to almost the skin surface then redirect the needle. Withdraw it after an adequate amount of blood (about 1 mL) is obtained and immediately compress the puncture site using a sterile gauge for approximately five minutes (longer time is necessary for patients with bleeding disorders or on anticoagulant therapy). Cap the needle using a one-handed technique and prepare the blood specimen (e.g., expel any air bubbles from the sample) for immediate analysis.

In the case of a negative Allen test and for younger patients, blood can be taken from the finger or ear lobe. Warm up the selected puncture site and wipe it with alcohol. Prick the site with a lancet and allow the free forming blood droplet to fill a capillary tube. After collection, apply firm pressure to the puncture site with a sterile gauge and prepare the sample for immediate analysis.

If the blood is not immediately analyzed it should be stored in ice.

Follow the manufacturer's instructions for injecting or aspirating the specimen into the blood gas analyzer.

Calculations

All measured and calculated values are reported from the blood gas analyzer printout. Refer to the instrument's reference manual for all the equations used.

Quality Control

Most blood gas analyzers automatically calibrate the electrodes and spectrophotometer to determine the status (zero point), sensitivity (comparison between actual and theoretical electrode readings), and drift (stability between calibrations). Follow the manufacturer's recommended time schedule for calibration. In general, a one-point calibration is performed every 30 minutes or before each

patient sample. A two-point calibration is performed at least every eight hours and after any corrective maintenance to the electrode.

pH electrode

A one-point calibration is performed using calibrating solution with normal pH (e.g., 7.40) to determine the status of the electrode. A two-point calibration is performed every 8 hours using two pH buffer solutions (e.g., 7.40 and 6.80) to determine the sensitivity of the electrode. The drift is obtained during the one- and two-point calibrations to determine the electrode performance.

PCO_2 electrode

A one-point calibration is performed using a precision CO_2 gas mixture (e.g., 5.00 %) to determine the status of the electrode. A two-point calibration is performed using two precise mixtures of CO_2 gas concentrations (e.g., 5.00 % and 10.00 %) to determine the sensitivity of the electrode. The drift is obtained during the one- and two-point calibrations to determine the electrode performance.

PO_2 electrode

A zero point value is performed using 0 % O_2 (i.e., 100% pure CO_2). A one-point calibration is performed using one O_2 gas concentration (e.g., 20.00 %) to determine the sensitivity and the drift is calculated.

Co-oximeter

The spectrophotometer is calibrated over all the fixed wavelengths using a water sample (i.e., calibrating solution) to determine the zero point status and drift. A tHb calibration is recommended every three months using a tHb calibrating solution to obtain a calibration factor.

At least two levels of quality control (QC) material must be analyzed every eight hours during which the instrument is used for patient sample analysis. The acceptable QC data range (mean ± 2 standard deviation from the mean) provided by the manufacturer may be used. The laboratory may also establish their own acceptable ranges by running 20 samples for each level of QC materials with specific lot numbers to be used. In order to avoid defining ranges for a new lot number, ensure there is an adequate supply of the levels of selected lot numbers for the ensuing period of QC testing (e.g., one year).

Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Pulmonary Function Studies

Volume 2

Clinical Practice Parameters

Chapter 18 - Clinical Practice Parameters

Overview

Pulmonary function testing is performed most commonly to:

- assist in a differential diagnosis
- estimate prognosis
- follow the course of a disease or its response to therapy
- estimate the risk of procedures or therapy
- detect untoward reactions to drugs
- assess functional impairment and/or disability.

Clinical Practice Parameters

Chapters 19 to 27 outline clinical guidelines for performing pulmonary function tests.

Note:	*Tests are listed by individual OHIP billing codes.*

Prerequisites

The listed **prerequisites** detail conditions that must be fulfilled or information that must be available prior to testing.

Indications

The listed **indications** are those that are of proven utility or those that are deemed useful by majority consensus. Other indications may exist, however, the present literature does not support the widespread use of these tests in other circumstances.

Contraindications

The listed **contraindications** are either proven hazards or are considered to put the patient at risk by majority consensus. Other contraindications may exist in any particular patient. The Quality Advisor and his or her staff accept responsibility for the safety of these and all other patients undergoing evaluation.

Reporting Guidelines

The listed reporting guidelines include observations or variables that are normally addressed and recorded in a report to the requisitioning physician.

Chapter 19 - Oxygen Saturation by Oximetry

Overview

Determining oxygen saturation by pulse oximetry (SpO_2) allows for the non invasive estimation and monitoring of blood oxygenation. The SpO_2 is usually obtained from the finger or ear at rest, exercise, or different levels of supplemental oxygen. Many of the studies on pulse oximetry employed healthy volunteers (for derivation of calibration curves) and relatively few investigations were done in ambulatory patients with cardiopulmonary disease.

Note:	*Routine use of oximetry is not considered an appropriate standard of care.*

Prerequisites

There are no prerequisites for this test.

Indications

Indications for this test include the need to:

- estimate oxygen saturation with or without supplemental oxygen therapy if there is a clinical suspicion of desaturation, in association with exertional dyspnea, lung disease or a reduced diffusing capacity
- document changes in oxygen saturation with exercise, (usually in patient with SaO_2 >90% at rest)
- monitor changes in oxygen saturation during sleep
- document improvement in oxygen desaturation following change in therapy or in level of oxygen supplementation

Contraindications

Exercise oximetry should not be performed in patients with uncontrolled systemic hypertension, recent systemic or pulmonary embolism, or unstable angina pectoris and other cardiac disease or a myocardial infarction within the last four weeks if facilities for electrocardiographic monitoring and patient resuscitation are unavailable.

If saturation is continually monitored, a change in values of ± 3-4% is clinically significant. Oximetry is performed in the sitting position; if different, it should be documented.

If SaO_2 is measured at different levels of F_IO_2 , then up to 20 minutes equilibration time may be required between determinations.

Limitations/Validation of Procedure (see ATS Manual Ed 2, Chapter 17, p8-9)

Situations or outside interference may affect pulse-oximeter readings, limit precision or limit the performance of a pulse-oximeter instrument.

- Motion artifact can interfere with pulse oximeter measurements. Some pulse oximeters are better than others at rejecting motion artifact.
- COHb falsely elevates SpO_2 values; high MetHb values cause falsely low values on pulse oximeters when the O_2 saturation is >85%, and falsely high values when O_2 saturation is <85%.
- Intravascular dyes, including methylene blue, indigo carmine, and indocyanine green, have been reported to lower SpO_2 measurements. Exposure of measuring probe to ambient light during measurement.
- Low perfusion states, from vasoconstriction or hypothermia.
- Nail polish or acrylic nail coverings can alter oximetry readings when a finger probe is used; black, blue, and green nail polish significantly lower readings. It is recommended that any nail polish be routinely removed before finger probes are used for pulse oximetry.
- Inability to detect saturations below 83% with the same degree of accuracy and precision as at higher saturations.
- Inability to quantify the degree of hyperoxemia present
- Hyper-bilirubinemia has been shown NOT to affect the accuracy of SpO_2 readings.
- Skin pigmentation

To validate pulse-oximeter readings, direct measurement of SaO_2 may be made on a CO-oximeter. The correlation of SpO_2 to SaO_2 should be done simultaneously with initial testing of the patient, then periodically re-evaluated if the patient's clinical status has changed.

- When a disparity exists (>3%) between the SpO_2 and SaO_2 readings, the situation requires evaluation. The clinical presentation of the patient, function of CO-oximeter, and pulse-oximeter monitor probe site should be evaluated. Causes for the discrepancy should be explored before results are reported. Improved correlation may be found by using alternative probe sites on the patient or by substituting other available probes or oximeters. Due to "physical conditions,"

some patients do not have reliable pulse-oximeter readings. If troubleshooting steps do not resolve disparities, the pulse-oximetry readings should not be reported. A statement describing the corrective actions attempted should be placed in the medical record and ABG analysis suggested for continued patient evaluation.

- Compared to CO-oximetry, the accuracy of pulse oximetry is about ± 5% for O_2 saturations above 85% and less accurate at lower O_2 saturations.

A normal SpO_2 in the presence of an elevated inspired O_2 concentration provides little or no information on the adequacy of patient ventilation. Pulse oximetry alone should not be relied upon as the sole monitor for patient status in situations such as bronchoscopy, intubation, or cardiac arrest.

Chapter 20 - Carbon Monoxide Diffusing Capacity (DLCO)

Overview

Determining the patient's carbon monoxide diffusing capacity (D_LCO) by single-breath technique allows for an estimation of the rate of diffusion of the respiratory gases across the alveolar-capillary membrane. The $D_L$co is affected by both the resistance to diffusion presented by the lung itself and by the rate of carbon monoxide (CO) uptake by hemoglobin in the pulmonary capillaries. Therefore, the $D_L$co may be abnormal in parenchymal lung disease with ventilation-perfusion imbalance, as well as with intrinsic pulmonary vascular disease. There is a wide variance among the published reference equations for determining normal values for $D_L$co as well as interfacility differences in testing equipment and technique.

Prerequisites

The patient should refrain from smoking on the day of the test. The patient should not eat a large meal or exercise vigorously before the test. Supplemental oxygen should be discontinued for at least 10 minutes before testing upon approval from the ordering physician or the Medical Director/Quality Advisor.

Indications

Indications for this test include the need to:

- establish the presence of parenchymal lung disease in patients with an obstructive ventilatory impairment (e.g., differentiating asthma from underlying emphysema)
- establish the presence of parenchymal lung disease in patients with a restrictive ventilatory impairment (e.g., differentiates intrinsic lung disease from an extrapulmonary process)
- establish the presence of parenchymal lung disease in patients with otherwise normal pulmonary function studies (e.g., asbestosis, fibrosing alveolitis, drug-induced or radiation pneumonitis, pneumocystis pneumonia)
- help assess disease severity in patients with parenchymal or pulmonary vascular disease and to estimate functional impairment and/or disability
- help monitor progression of parenchymal lung disease or assess its response to therapy
- help monitor patients with pulmonary hemorrhage syndromes

Contraindications

There are no contraindications for this test. Relative contraindications may include mental confusion, poor muscular coordination, or an inability to adequately seal lips on the instrument's mouthpiece.

Reporting Guidelines

- The average of at least two acceptable $D_L$co tests should be reported with the predicted and percent-predicted $D_L$co. Any adjustments for Hb and COHb concentration should be reported.
- The $D_L$co calculation is based on the alveolar volume (V_A), which represents the lung volume in which the tracer gas and CO distributes and then the CO transfers across the alveolar-capillary membrane. Hence, the $D_L$co measurement must be interpreted in relation to only its V_A and not a separately determined V_A or total lung capacity (TLC) from more accurate techniques.
- Comparison of patient measurement to predicted normal values, using 95% confidence limits to identify abnormal results.
- Lower limits of normal for $D_L$co must be interpreted with caution since measurements as low as 75% of the predicted normal value is within the 95% confidence interval in many studies.
- The $D_L$co should be interpreted with caution in patients with FEV_1 below 1 L or in those who have smoked within two hours prior to testing.

Chapter 21 - Functional Residual Capacity (FRC)

Overview

Determining the functional residual capacity (FRC) by either closed circuit gas (helium dilution or nitrogen washout) or plethysmographic techniques allows for the calculation of static lung volumes. The gas dilution techniques measure the gas in the lungs communicating with the mouth. Plethysmography, which measures all compressible gas in the thorax is more accurate and is preferred. Considerable differences in the predicted values for absolute lung volumes exist among the available studies. Each facility should select the reference standards which are most appropriate to their patient population.

Prerequisites

Spirometry is properly performed and the results are known prior to determining the FRC.

Indications

Indications for this test include the need to:

- establish/confirm a restrictive ventilatory defect
- establish/confirm hyperinflation and gas trapping
- help monitor progression of lung disease or assess its response to therapy
- to differentiate types of lung disease processes characterized by airflow limitation that have similar spirometry
- make preoperative assessments when surgical procedure is known to affect lung function

Contraindications

Discontinuation of supplemental oxygen or interruption of IV medications may be contraindicated in some patients. Check with physician prior to testing.

Relative contraindications for performing static lung volumes include all those considered for spirometry. The relative contraindications for forced expired manoeuvres are the following:

- If a patient has a pneumothorax and testing is required the QA/Lab Director decides whether the pneumothorax is small and clinically stable in order to

proceed with measurements. If measurements are done, results should take into account the pneumothorax

- Recent myocardial infarction, or unstable cardiac status, ophthalmic surgery, abdominal surgery
- Significant ongoing hemoptysis
- Presence or suspected presence of active tuberculosis or other communicable respiratory disease (febrile and severe respiratory illness)

Reporting Guidelines

The report includes:

- results of baseline spirometry.
- comparison of patient measurement to predicted normal values, using 95% confidence limits to identify abnormal results.
- in the case of abnormal results, type of ventilatory abnormality expected.
- FRC measurement method used to derive the value (i.e., FRC_{N2}, $FRC_{He,}$ FRC_{pleth}).

Chapter 22 - Nonspecific Bronchial Provocative Test

Overview

A nonspecific bronchial provocative test (or bronchoprovocation study) is a technique that allows one to determine the presence or absence of bronchial hyperreactivity manifesting as diffuse airway narrowing. Most often a pharmacologic agent, such as methacholine/Provocholine® or histamine, is used for this purpose. Bronchoprovocation studies are most appropriate in the presence of a normal or near-normal baseline FEV_1, (or sRaw, sGaw).

Bronchoprovocation studies are difficult to interpret and may be dangerous in patients with significant persistent airflow obstruction; pre-and post-bronchodilator testing or a therapeutic trial may be more appropriate.

Prerequisites

Acceptable and reproducible spirometry (or sRaw, sGaw), must be performed and the results known prior to testing. Bronchoprovocation studies are most useful when the pre-test probability of asthma is intermediate (30-70%). Other conditions that can affect bronchial hyper-responsiveness should be considered (see below):

FACTORS THAT INCREASE BRONCHIAL RESPONSIVENESS

Factor	Duration of Effect
Exposure to environmental antigens	1 – 3 weeks
Occupational sensitivities	Months
Respiratory infection	3 – 6 weeks
Air pollutants	1 week
Cigarette smoke	Uncertain*
Chemical irritants	Days to months

*****Studies of the acute effects of smoking on airway hyper-reactivity and methacholine challenge testing are not consistent. There is some evidence of a brief acute effect that can be avoided by asking subjects to refrain from smoking for a few hours before testing.

Patients should be advised to avoid certain medications prior to bronchoprovocation testing *(please see overview section Chapter 13 -Non-Specific Bronchial Provocative Test)*

Indications

Indications for this test include the need to:

- rule out the diagnosis of asthma as an etiology for unexplained cough, dyspnea, wheeze or chest tightness in the currently symptomatic patient
- diagnose asthma as the cause of cough, dyspnea, wheeze or chest tightness, when used in conjunction with a subsequent trial of specific therapy
- objectively confirm a suspected diagnosis of asthma in patients with atypical presentations, or lack of response to conventional therapy
- confirm bronchial hyper-responsiveness in patients suspected of having occupational asthma

Note:	*Some patients may only react to specific chemical or biologic triggers.*

Contraindications

The following conditions are considered contraindications to pharmacologic bronchoprovocative studies.

CONTRAINDICATIONS FOR METHACHOLINE/PROVOCHOLINE® CHALLENGE TESTING

Absolute:
Severe airflow limitation (FEV_1 < 50% predicted or < 1.0 L)
Heart attack or stroke in last 3 months
Uncontrolled hypertension, systolic BP > 200, or diastolic BP > 100
Known arterial aneurysm

Relative:
Moderate airflow limitation (FEV_1 < 60% predicted or < 1.5 L)
Inability to perform acceptable-quality spirometry
Pregnancy
Nursing mothers
Current use of cholinesterase inhibitor medication (for myasthenia gravis)
Current use of beta-adrenergic blocking agent

Reporting Guidelines

Results should be reported as a percent decrease in FEV_1, sGaw or increase in sRaw from baseline.

Data should be presented for each step in the protocol, including the postbronchodilator test, where appropriate. A single number, PC_{20} (or PC_{40}sRaw, PC_{40}sGaw) may be used to summarize the results for clinical purposes. If the

bronchoprovocation study is positive, some quantification of hyperreactivity should be provided (see table below)

CATEGORIZATION OF BRONCHIAL HYPER RESPONSIVENESS

PC_{20} (mg/ml)	**Interpretation***
>16	**Normal bronchial hyper responsiveness**
4.0-16	**Borderline BHR**
1.0-4.0	**Mild BHR (positive test)**
<1.0	**Moderate to severe BHR**

Note: *Another categorization is also available – see reference under Bibliography/Chapter 22/ Histamine and methacholine inhalation test: tidal breathing method: laboratory procedure and standardization.*

*Before applying this interpretation scheme, the following must be considered:

- baseline airway obstruction is absent
- spirometry quality is good
- there is substantial post challenge FEV_1 recovery

- If the FEV_1 does not fall by at least 20% after the highest concentration (e.g., 16 mg/mL) then the PC_{20} should be reported as ">16 mg/mL". If the FEV_1 falls by more than 20% after inhalation of the diluent, a PC_{20} is not reported. Instead state "there was a significant decrease in lung function after inhalation of the diluent and methacholine/Provocholine® was not given."

Chapter 23 - Exercise Challenge Testing for Asthma

Overview

Exercise induces airway narrowing in the majority of patients with asthma. The major factors that determine the severity of exercise-induced bronchoconstriction (EIB) are the pulmonary ventilation reached and sustained during exercise and the water content and temperature of the inspired air. Exercise is used as a challenge test to make a diagnosis of EIB in asthmatic patients with a history of breathlessness during or after exertion. Such a diagnosis cannot always be made by a methacholine bronchoprovocation study and EIB cannot be excluded by a negative response to methacholine. Exercise testing may also be used to determine the effectiveness of medications prescribed to prevent EIB.

Prerequisites

Acceptable and reproducible spirometry is performed and the results known prior to exercise challenge. A resting electrocardiogram is performed and the results known to the supervising physician. Pulmonary medications should be withheld according to the guidelines in Chapter 13. In addition, short acting antihistamines should be withheld for 48 hours prior to testing, and long acting antihistamines for three days. Vigorous exercise should be avoided for at least 4 hours before testing, as prior exercise may exert a protective effect against EIB.

Indications

Indications for this test include the need to:

- diagnose asthma as the cause of cough, dyspnea, wheeze or chest tightness, that occurs during or soon after exercise
- objectively confirm a suspected diagnosis of asthma in patients with atypical presentations, or lack of response to conventional therapy

Contraindications

CONTRAINDICATIONS FOR PERFORMING EXERCISE CHALLENGE TESTING. (ATS, Chapter 13)

Absolute Contraindications:

- Severe airflow limitation (FEV_1) <50% predicted, or <1.0 L in adults)
- Heart attack or stroke in last 3 months

- Changes in the resting ECG that suggest an acute or recent myocardial event
- Unstable cardiac ischemia or malignant arrhythmias
- Severe aortic stenosis or suspected or known aortic aneurysm
- Uncontrolled hypertension, systolic blood pressure (BP) >200 mmHg, diastolic BP >100 mmHg

Relative Contraindications:

- Moderate airflow limitation (FEV_1<60% predicted, or 1.5 L in adults)
- Inability to perform acceptable-quality spirometry
- Known electrolyte abnormalities
- Uncontrolled diabetes
- Orthopedic or other limitations to exercise
- Current or recent respiratory tract infection

INDICATIONS FOR STOPPING AN EXERCISE TEST:

Cardiac signs and symptoms

- Progressive angina (3 on a 1 - 4 scale)
- Ventricular tachycardia
- >2 to 4 mm horizontal or down-sloping ST depression
- A significant drop (>20 mm Hg) in blood pressure or failure of the blood pressure to rise over several minutes of exercise
- Onset of second or third degree heart block
- Exercise-induced left bundle branch block
- Sustained supraventricular tachycardia

Other symptoms

- Lightheadedness, confusion, nausea, ataxia, pallor, etc.
- Patient complains of severe chest tightness or wheezing
- Volitional termination by the patient (i.e. cannot continue)

Monitoring

Failure of the ECG or blood-pressure monitoring system

Reporting Guidelines

The FEV_1 is the primary outcome variable; a decrease below 90% of the baseline FEV_1 (i.e., a 10% decrease) is a generally accepted abnormal response (some authors suggest a decrease of 15% is more diagnostic of EIB).

Spirometry should be performed in the seated position both before and serially after exercise. In most cases, the nadir (low point) in FEV_1 occurs within 5 - 10 minutes of cessation of exercise, but it is occasionally not reached until 30 minutes. An appropriate post-exercise testing schedule is 5, 10, 15, 20 and 30 minutes after cessation of exercise. If the FEV_1 has returned from its nadir to the baseline level or greater, spirometry testing may be terminated 20 minutes post-exercise. Without confirming the FEV_1 has reached its nadir, it is not possible to assess the severity of EIB.

Other variables that need to be recorded are:

- Type of exercise device
- Sustained work rate and ventilation
- Total exercise time
- Maximum HR and length of time at target HR
- Interpretation of the ECG
- O_2 saturation via pulse oximetry, if measured

Chapter 24 - Stage 1 Exercise Testing

Overview

Symptomatic limitation of exercise tolerance depends on the function of the whole organism, including the subjective response to stress. Respiratory exercise testing attempts to quantify the impairment in respiratory exercise and identify the limiting mechanisms (pulmonary, cardiac) that accompanies many pulmonary disorders.

Prerequisites

When exercise testing is done to detect or evaluate pulmonary disease, spirometry was properly performed and the results known prior to testing. A resting electrocardiogram was performed and the results known to the supervising physician except for young, otherwise healthy, individuals.

Indications

Indications for this test include the need to:

- objectively assess symptoms (especially dyspnea) that limit exercise performance
- detect early disease of the cardiopulmonary system (e.g., interstitial lung disease) that may limit exercise performance
- identify the contribution of multiple factors (cardiac reserve, pulmonary reserve, neuromuscular function, etc.) to poor exercise performance
- detect exercise-related oxygen desaturation
- assess and quantify impairment and/or occupational disability
- assist in predicting post-operative pulmonary function prior to lung resection

Contraindications and Safety

The contraindications for performing the exercise test includes those below. This list, however, should not replace good clinical judgement.

Absolute contraindications

- Recent complicated myocardial infarction
- Changes in the resting ECG that suggest an acute or recent myocardial event
- Unstable angina
- Uncontrolled cardiac arrhythmias

- Severe aortic stenosis and known or suspected dissecting aortic aneurysm
- Active or suspected acute pericarditis or myocarditis
- Acute congestive heart failure
- Acute febrile illness
- Acute asthma
- Recent systemic or pulmonary embolus
- Significant emotional distress (psychosis)

Relative/Contraindications

- Systemic hypertension. Resting systolic >200 mmHg, diastolic >120 mmHg
- Resting tachycardia (>120 beats per minute)
- Frequent ventricular or atrial ectopy
- Moderate aortic stenosis
- Other moderate or severe valvular heart disease
- Known electrolyte abnormalities (e.g., hypokalemia and hypomagnesemia)
- Uncontrolled diabetes
- Orthopedic limitations to exercise
- Neuromuscular, musculoskeletal or rheumatoid diseases that are exacerbated by exercise
- Advanced or complicated pregnancy
- Cardiomyopathy

Monitored exercise testing is considered relatively safe with a reported complication rate of 0.5 to 1.0 in 10,000 tests.

Criteria for immediately stopping the exercise test:

In the vast majority of exercise tests, patients should be verbally encouraged before and during the test, to give a maximal effort with the goal of achieving physiologic limitation. Exceeding a preset heart rate criterion is not a useful criterion for stopping exercise. The most accepted criteria for exercise termination before symptom limitation are:

- Chest pain suggestive of ischemia
- Ischemic ECG changes
- Complex ectopy
- Second or third degree heart block

- Fall in systolic blood pressure >20 mmHg from the highest value during exercise
- Hypertension (>250 mmHg systolic; >120 mmHg diastolic)
- Severe desaturation: $SpO_2 \leq 80\%$ when accompanied by symptoms and signs of severe hypoxemia
- Sudden pallor
- Loss of coordination
- Mental confusion
- Dizziness or faintness
- Signs of respiratory failure

In situations in which the exercise is terminated because of the above criteria, the patient should be observed until the patient is stable and physiologic variables have returned to baseline conditions.

Reporting Guidelines

The report includes:

- description of the exercise study protocol completed **or** when, and reason why the test was stopped prematurely
- symptoms reported by the patient (Borg Scale score)
- some mention of the presence or absence of clinically significant changes in blood pressure or heart rate or rhythm
- an evaluation of exercise performance and the ventilatory response to exercise (e.g., ventilation, tidal volume, maximal oxygen intake, oxygen saturation, etc.)
- precise identification of the factor(s) that limits exercise performance

Chapter 25 - Maximal Inspiratory and Expiratory Pressures

Overview

Maximal Inspiratory and Expiratory Pressures (MIP/MEP) measure the strength of the respiratory muscles. The MIP measures the strength of diaphragm whereas the MEP measures the strength of intercostal and abdominal muscles. It is a common practice that MEP is measured at total lung capacity (TLC) and MIP is measured at residual volume (RV). These tests are very effort-dependent and the patient must be well motivated in order to obtain the interpretable results. These tests are normally used to identify muscle weakness or inefficiency as a cause of dyspnea or hypoventilation and should not be routinely performed otherwise.

Prerequisites

Spirometry was properly performed and there is no contraindication.

Indications

Indications for this test include the need to:

- identify respiratory muscle weakness as a cause for unexplained dyspnea, hypoventilation or non-parenchymal lung restriction with reduced peak flow or vital capacity
- assess and quantify the respiratory muscle weakness for patients with known neuromuscular diseases (e.g. Guillan-Barré syndrome, myasthenia gravis, polymyositis and amyotrophic lateral sclerosis) or chest deformities (e.g. scoliosis)

Contraindications

MIP/MEP manoeuvres should be performed with caution in the following circumstances:

- recent myocardial infarction (within 4 weeks) or myocarditis
- unstable angina/chest wall pain
- uncontrolled systemic hypertension
- recent pneumothorax
- lung biopsy within previous week

- significant ongoing hemoptysis
- recent eye, abdominal, or spinal surgery

Reporting Guidelines

The report includes:

- results of baseline spirometry
- comments on patient's condition
- technical comments on patient effort
- comparison of patient measurement to predicted normal values
- comments on the significance and relevance of the results to the patient's pathophysiology

Chapter 26 - Airways Resistance (R_{AW})

Overview

Airways Resistance (R_{AW}) refers to the flow resistance in the airways between the mouth and alveoli. The measurement of airways resistance may be useful in differentiating central from peripheral airway obstruction since R_{AW} is particularly sensitive to obstruction in the central airways. In assessing the response to brochodilators, R_{AW} may be more sensitive than spirometry or flow volume curves.

At present, there is no proven clinical role for the routine determination of Airways Resistance (R_{AW}). Patients with obstructive lung disease are more appropriately followed with simple spirometry.

Indications

Indications for this test include the need to:

Further evaluate airflow limitation beyond spirometry.

Determine the response to bronchodilator.

Determine bronchial hyperactivity in response to methacholine or histamine.

Monitor the response to treatment.

Relative contraindications

Mental confusion, muscular incoordination, body casts, or other conditions that prevent the patient from entering the plethysmograph or adequately performing the required manoeuvres (i.e., panting against a closed shutter).

Claustrophobia that may be aggravated by entering the plethysmograph.

Presence of devices or other conditions, such as continuous intravenous infusions with pumps or other equipment that will not fit into the plethysmograph, that should not be disconnected, or that might interfere with pressure changes (e.g. chest tubes).

Continuous O_2 therapy that should not be temporarily disconnected.

If a patient has a pneumothorax and testing is required the QA/Lab Director decides whether the pneumothorax is small and clinically stable in order to proceed with measurements. If measurements are done, results should take into account the pneumothorax.

Reporting Guidelines

The reported Raw and related indices

- Should be calculated from the ratio of open- and closed-shutter tangents for each manoeuvre.
- Should be averaged from three to five separate, acceptable manoeuvres (which may require as many as eight to ten trials).
- Should have the open shutter tangent (Flow/Box Pressure) measured between flows of +0.5 to -0.5 L/s. For loops that display hysteresis, the inspiratory limbs may be used and the report should contain a comment noting this.
- Comparison of patient measurements to predicted normal values, using 95% confidence limits to identify normal results.

Report of test results should contain a technologist's statement about test quality, patients' understanding of testing process, and, if appropriate, which criteria were not achieved.

Chapter 27 - Arterial Blood Sampling, Blood Gas Analysis and Hemoximetry

Overview

A sample of arterial blood is obtained from the radial artery or arterialized venous blood from the finger or ear lobe. The specimen is analyzed using a blood gas analyzer for the direct measurement of the arterial or arterialized partial pressures of carbon dioxide and oxygen (PCO_2 and PO_2), hydrogen ion activity (pH), bicarbonate (HCO_3), base excess/deficit, oxygen saturation (SO_2), total hemoglobin (tHb), oxyhemoglobin (O_2Hb) and carboxyhemoglobin (COHb).

Prerequisites

Before arterial blood sampling, verify or document the following:

- patient comfort
- supplemental oxygen concentration
- patient body position
- site of specimen collection

Indications

Indications for arterial blood sampling, blood gas analysis and hemoximetry include:

- Evaluation of the adequacy of a patient's ventilation ($PaCO_2$), acid-base (pH and $PaCO_2$) and oxygenation (PaO_2 and O_2Hb) status
- Evaluation of the oxygen-carrying capacity of blood (PO_2, O_2Hb, tHb and dyshemoglobin saturations) and right-left shunt (Qsp/Qt)
- Diagnostic evaluation of the patient's need for supplemental oxygen due to resting hypoxemia, exercise desaturation, and respiratory failure.
- Quantification of the patient's response to therapeutic intervention or modalities (e.g., adequacy of supplemental oxygen prescription, follow respiratory failure)
- Monitoring the severity and progression of a documented disease process (e.g., hypercapnia in end stage COPD, used in the A-a gradient as an objective indicator of diffuse pulmonary infiltrates)
- Detection of acute or chronic exposure to carbon monoxide (CO) or other toxic chemical or therapeutic materials that interfere with the O_2/Hb reactions or other test procedures (e.g., $D_L$co)

- Assessment using direct measurements of PaO_2, $PaCO_2$, pH, SaO_2, and lactate during a cardiopulmonary exercise test (Stage 3 & 4 Exercise Test)

Contraindications

Contraindications for arterial blood sampling include:

- A negative modified Allen test for the radial puncture site
- Performance of a puncture through a lesion or distal to a surgical shunt
- Coagulapathy or medium to high dose anticoagulation therapy (relative contraindication)

Reporting Guidelines

The report includes:

- measured values for arterial blood gas analysis and hemoximetry
- normal reference ranges for each value
- puncture site of the sample (e.g., radial artery, finger, or ear lobe)
- fractional concentration of inspired oxygen of the sample (e.g., room air or supplemental oxygen liter flow rate)

Appendix I - Recommended Guidelines for Preventing Allergic Reactions to Natural Rubber Latex

Background

The latex allergy is an enormous public health problem faced by health care workers and patients. Healthcare workers have become the fastest group to experience latex sensitivity and more often its adverse affects.

Latex is a common component in health care products and consumer products. In 1989 there were 400 reported anaphylactic reactions and 15 deaths due to latex contact.

The implementation of universal precautions in 1987, to prevent HIV and other blood borne pathogens infections resulted in an increased demand for gloves. Manufacturing processes may have temporarily changed to meet this dramatically increased demand for gloves, resulting in latex products with higher allergic and irritant properties being produced and used. Repeated exposure to latex products can cause hypersensitivity reactions locally and systemically. Reducing exposure to latex products will definitely decrease sensitization and symptoms. There is no treatment for latex allergy except complete avoidance of latex.

Goals in Management

The two major goals in the management of latex reactions are successful identification and treatment of all dermatitis, to prevent future sensitization and identification of latex allergy to prevent serious life treating sequelae whenever possible.

Types of Reactions to Latex

Irritant contact dermatitis

- most common type of reaction
- not an allergic reaction involving the immune system but rather a skin irritation caused by the chemicals added to the latex during the manufacturing of the glove powder itself, repeated irritation from sweating under the gloves or from gloves rubbing against the hands, characterized by dry, flaky skin and papules, redness, fissures an thickening of skin

Allergic contact dermatitis: Type IV

- Delayed type hypersensitivity

- A cell-mediated allergic reaction to the chemicals used during the processing of latex. The more common sensitizers/allergens are thiurams and carbamates (accelertors)
- Results from prolonged contact with these chemicals in gloves
- Symptoms usually appear 6 to 48 hours after exposure
- Characterized by localized redness, clustered vesicles, swelling, itching, cracking eczema and fingertip fissures

Immediate allergic reaction: Type I

- An immediate immunoglobulin E mediated allergic response to the latex protein themselves
- Reaction usually occurs 5 to 30 minutes after exposure
- The response is introduced by direct contact with latex on non-intact skin resulting in sensitization before manifesting as a generalized reaction
- Once sensitivity has been initiated, any contact with latex may cause a recurrence of the reaction
- The protein allergens have been found in water-soluble extracts from latex rubber film. It may also be absorbed by glove powder, which may become airborne
- The severity of the immediate reaction will depend in the route of exposure; cutaneous, mucosal, inhalation and parenteral , the amount of latex allergen and the degree of individual sensitivity
- Mild reactions involve skin redness-hives-itchiness
- More severe reactions may imply edema, itching, conjunctivitis around the eyes, rhinitis, nasal itching, sneezing, shortness of breath, asthma, airway obstruction due to bronchospasm, anaphylactic shock

Risk Factors for Latex Sensitivity and Allergy

- Persons with spina bifida
- Patients and congenital urogenital defects, history of indwelling urinary catheters or repeated catheterizations
- Patients who have undergone recurrent surgical procedures
- Workers with ongoing latex exposure – health care workers, housekeepers, food handlers, tire manufacture workers, workers in industry who use gloves regularly
- Atopic individuals – persons with multiple allergic conditions, eczema, asthma, rhinitis

- Individuals allergic to certain food, banana, avocado, chestnut, apricot, kiwi, papaya, passion fruit, pineapple, peach, nectarine, plum, cherry, melon, fig, grape, potato, tomato and celery may cause a cross reactivity with latex protein
- No treatments are available to cure latex allergy. The best treatment is to avoid exposure. The treatment for individual allergic to latex is to ensure a safe environment. Medications are available to alleviate the allergy symptoms

Recommendations

Patients

- All patients are assessed for adverse reactions or contraindicated substance during their admission assessment. We should provide a latex safe environment for patients allergic and sensitive to latex.
- History for presence of allergies such as hay fever, childhood or adult eczema, asthma and food allergies
- Multiple surgeries
- Undiagnosed reactions or complications during surgery anesthesia or dental work – angioedema, shortness of breath, rash
- History of latex exposure: type of latex device, nature and duration of exposure
- History of latex allergy such as cutaneous symptoms (dermatitis-eczema-urticaria) respiratory symptoms, (rhinitis, wheezing, coughing, sneezing, shortness of breath)
- Any respiratory symptoms experienced when in contact with products containing rubber
- Other systems such as itchy hands, conjunctivitis, localized angioedema, possible systemic anaphylactic symptoms with the use of household latex cleaning gloves, balloons, condoms and diaphragms

If a patient has any of the above categories the following measure should be taken:

- Patients with severe documented allergy to latex should be assessed for the need of a private room
- A cart containing all latex free supplies that are necessary for patient care from admission to discharge. This cart will follow patient to other departments
- Wear non-latex examination and sterile gloves. Vinyl gloves should be changed every 15 minutes to protect the health care worker from borne pathogens
- Identify chart, patient, bed, medication profile, kardex, physicians order sheet with latex allergy stickers
- Post latex allergy sign on patient's door

- Wear a cover gown if the possibility that our uniform contains residues of powder from latex gloves
- Tape over IV tubing ports and do not use
- Do not inject via T-connectors, buritrol or IV bag, inject and administer medication only through plastic stopcock
- Remove stoppers from vial then draw up medication. Needle puncturing a rubber stopper can shear off particles of latex, and cause a systemic reaction
- Glass syringe or latex free syringe must be used, if plastic syringe are used, the solution must be injected immediately after being drawn up
- If pulse oximetry is used, cover finger with tegaderm then apply probe. The inside surface of most pulse oximeters is covered with latex
- Avoid skin contact with the bulb and tubing o fht blood pressure cuff by placing cloth under the rubber to shield the skin
- Stethoscope tubing can be covered with a stockinette
- If catheterization is necessary, use silastic foley catheter
- Utilize single dose ampoules for parenteral medication
- Patients that are highly reactive may require medications at the bedside. Epinephrine should be available if an anaphylactic shock occurs
- If the patient develops an allergic reaction, remove suspected allergen and provide immediate care
- All staff interacting with this patient must follow proper hand washing procedures before caring for these patients in order to minimize the exposure to and transfer of latex protein

Health Care Workers

Health care workers should protect themselves from latex exposure and allergy in the workplace:

- Use non-latex gloves for activities that do not involve contact with blood or body fluid
- For activities where contact with infectious materials is expected and latex gloves are used, choose a reduced protein, powder free glove
- Workers with hand dermatitis should never wear oil hand cream or lotion with latex gloves. Oil breaks down latex, damages the glove barrier and releases additional allergen. Detergents and other chemicals also degrade latex gloves
- After removing gloves, wash hands with soap and dry thoroughly, never re-use glove

- If you experience any symptoms possibly related to latex allergy, report it to Health and Safety Department, avoid contact with latex gloves until you see your allergist
- Attend latex allergy education session

If allergic to latex:

- Avoid contact with latex gloves, latex containing products and objects such as computer keyboards, telephones, that have been contaminated with latex gloves or glove powder
- Avoid areas where you might inhale the powder from latex gloves worn by other workers
- Wear medical alert bracelet
- Attend latex allergy education session
- Carry an emergency epinephrine auto-injector
- Avoid cross-reacting food such as: kiwi, avocado, chestnut
- Follow your physician's instructions for dealing with allergic reaction to latex

Institution

To eliminate or reduce the risk for latex sensitization of asymptomatic staff and minimize the risk of latex exposure to staff already sensitized:

- Eliminate unnecessary use of latex gloves by providing workers with non-latex gloves when there is minimal potential for contact with blood or bodily fluid
- When selecting a latex glove for barrier protection from infectious materials, choose a reduced protein, powder free glove. Glove should be approved by the Canadian General Standard Board
- Provide education to employees about latex allergies, hand care and the importance of early care for dermatitis or other allergy symptoms. Identify and instruct worker in work practices to prevent exposure
- Implement a latex allergy assessment protocol including a screening history questionnaire and protocol of evaluation and treatment of latex reaction symptoms
- Conduct a worksite evaluation, identify areas contaminated with latex dust and make sure cleaning is done more frequently. Ensure that filtration and ventilation systems provide adequately re-circulated air in area with high levels of latex aerosols
- Alternative latex free devices must be available
- Identification of medical product containing latex
- Incorporate latex allergy education as part of the annual safety and infection control program, orientation program and also conduct in services

Once a diagnosis of latex allergy is confirmed, the employee should accommodate the affected workers. Extremely sensitive individuals may have to be re-assigned to areas where no latex gloves are used.

Appendix II - Sample Latex Allergy Questionnaire

Overview

A sample latex allergy questionnaire is provided on the following pages.

Sample Latex Allergy Questionnaire

I. Risk Factor Assessment

Please circle Y or N to answer the following questions:

Exposure History

Are you a health care worker?	Y	N
Do you wear latex gloves regularly or are you otherwise exposed to latex regularly?	Y	N
Do you have a history of eczema or other rashes on your hands?	Y	N
Do you have a medical history of frequent surgeries or invasive medical procedures?	Y	N
Did these take place when you were an infant?	Y	N
Do you have a history of "hay fever" or other common allergies?	Y	N
Do your fellow workers wear latex gloves regularly?	Y	N
Do you take beta-blocker medication?	Y	N

Circle any foods below that cause hives, itching of the lips or throat, or more severe symptoms when you eat or handle them:

Avocado	Kiwi	Apricot	Figs	Apple
Papaya	Banana	Passion fruit	Pear	Pineapple
Melon	Tomato	Celery	Peach	Chestnut
Potatoes	Carrot	Cherry	Nectarine	Hazelnut
Plum	Grape	Strawberry		

II. Contact Dermatitis Assessment

For patients who wear latex gloves frequently

Do you have rash, itching, cracking, chapping, scaling, or weeping of the skin from latex glove use?	Y	N
Have these symptoms recently changes or worsened?	Y	N
Have you used different brands of latex gloves?	Y	N
If so, have your symptoms persisted?	Y	N
Have you used non-latex gloves?	Y	N
If so, have you had the same or similar symptoms as with latex gloves?	Y	N
Do these symptoms persist when you stop wearing all gloves?	Y	N

III. Contact Urticaria (Hives) Assessment

For patients who wear latex gloves frequently

When you wear or are around others wearing latex gloves do you get hives, red itchy swollen hands within 30 minutes or, “water blisters” on your hands within a day?	Y	N

IV. Aerosol Reaction Assessment

When you wear or are around others wearing latex gloves, have you noted any of the following:

Itchy, red eyes, fits of sneezing, runny or stuffy nose, itching of the nose or palate?	Y	N
Shortness of breath, wheezing, chest tightness or difficulty breathing?	Y	N
Other acute reactions, including generalized or severe swelling or shock?	Y	N

V. History of Reactions Suggestive of Latex Allergy

Do you have a history of anaphylaxis or of intra-operative shock?	Y	N
Have you had itching, swelling or other symptoms following dental, rectal or pelvic exams?	Y	N
Do condoms, diaphragms or latex sexual aids cause itching or swelling?	Y	N
Do rubber handles, rubber bands or elastic bands or clothing cause any discomfort	Y	N

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

Note:	*Ontario Regulation 57/92 has previously been amended. Those amendments are listed in the Table of Regulations - Legislative History Overview which can be found at www.e-laws.gov.on.ca. Facilities are encouraged to check the Government Website for updates.*

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 licencee 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 patients 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 on such service.

(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.

(4)On the transfer of a licence under section 11 of the Act, the transferor of the licence shall transfer to the transferee of the licence, in a manner that will protect the privacy of the records, the records maintained under section 10 of this Regulation, and the transferee of the licence shall retain those records in accordance with this section.

Section 12 of the Regulation is revoked and the following substituted:

12 (1)No licensee shall allow any person to have access to any information concerning a patient that is not subject to the Personal Health Information Protection Act, 2004 except in accordance with subsection (3).

(2)The reference to "information concerning a patient" in subsection (1) includes information or copies from a health record, even if anything that could identify the patient is removed.

(3)A licensee may provide information described in subsection (1) to the following persons if anything that could identify the patient is removed from the information:

1. Any person, if the information is 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. Cancer Care Ontario. O Reg. 346/04, s.2.

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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