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Evidence-Based Series Special Report 17-2 Version 2

A Quality Initiative of the
Program in Evidence-based Care (PEBC), Cancer Care Ontario (CCO)

Hepatic, Pancreatic, and Biliary Tract (HPB) Surgical Oncology Standards

The Expert Panel on HPB Surgical Oncology

A Special Project of the Surgical Oncology Program, Cancer Care Ontario and
The Program in Evidence-Based Care, Cancer Care Ontario
Developed by the Expert Panel on HPB Surgical Oncology

An assessment conducted in January 2023 placed Guideline 17-2 Version 2 IN REVIEW. This means that it is undergoing a review for currency and relevance. It is still appropriate for this document to be available while this updating process unfolds. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

EBS 17-2 is comprised of 4 sections. You can access the summary and full report here: https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/546

Section 1: Standards (ENDORSED)
Section 2: Systematic Review
Section 3: Standards Development and External Review - Methods and Results
Section 4: Document Review Summary and Tool

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Evidence-Based Series #17-2 Version 2: Section 2

Hepatic, Pancreatic, and Biliary Tract (HPB) Surgical Oncology Standards

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A Special Project of the Surgical Oncology Program, Cancer Care Ontario and
The Program in Evidence-Based Care, Cancer Care Ontario
Developed by the Expert Panel on HPB Surgical Oncology

Report Date: June 14, 2006

These guideline recommendations have been ENDORSED, which means that the recommendations are still current and relevant for decision making. Please see Section 4: Document Review Summary and Tool for a summary of updated evidence published between 2006 and 2015 and for details on how this Clinical Practice Guideline was ENDORSED.

QUESTION

What is the optimum organization for the delivery of cancer-related hepatic, pancreatic, and biliary tract surgery in Ontario?

SCOPE OF STANDARDS

The following standards, developed by the Expert Panel on HPB Surgical Oncology, apply to hepatic, pancreatic, and biliary tract cancer surgery and include the full spectrum of multidisciplinary assessment and treatment:

- Management of primary and secondary liver cancer by hepatic resection or locally destructive techniques (ablation by any modality, hepatic artery embolization with or without chemotherapy, etc.).
- Management of cancer of the pancreas and peri-ampullary region by pancreatic resection.
- Management of tumours of the biliary tract (including gallbladder) by surgical resection.

The standards cover the full range of resources and expertise needed for the care of these patients and recognize that a multidisciplinary team approach is necessary for optimum

management. Specific criteria relating to the characteristics of surgeons and institutions involved in HPB surgery are described.

SURGEON CRITERIA

General Characteristics

General characteristics for surgeons undertaking the management of patients with HPB cancer are as follows:

- Knowledgeable regarding the biology of HPB cancer, its natural history, appropriate investigation, and the whole range of treatment options.
- Skilled in modern techniques of surgery of the liver, pancreas, and biliary tract, including capability for managing vascular complications and vascular reconstruction.
- Experienced in the management of patients with hepatobiliary and pancreatic diseases, especially the management of early and late postoperative complications.
- Committed to providing excellence in care to patients with HPB diseases and to advancing knowledge in the field in order to improve patient outcomes.
- Committed to participating as a member of a multidisciplinary oncology team.
- Committed to participating in Cancer Care Ontario quality initiatives.

Training

Although there is not a formally recognized subspecialty in HPB surgery, the complex nature of this subspecialty area has lead to the development of training programs designed to provide the kind of expertise and experience necessary to appropriately manage patients with HPB diseases. Thus, appropriate training would include certification by the Royal College of Physicians and Surgeons of Canada in General Surgery (or its equivalent) plus the completion of a period of advanced training in HPB surgery designed to attain a high level of proficiency in the management of the complex surgical problems found in this patient population. The training program should specifically focus on the management of malignant disease and result in the trainee acquiring competence to manage not only routine cases but also those requiring more complex resection and reconstruction. Thus, surgeons practicing HPB surgery should have completed one of the following:

- A specific formal Fellowship in HPB surgery, or
- A Fellowship in liver transplant that includes a major focus in non-transplant HPB cases, or
- A Surgical Oncology Fellowship with a major emphasis on HPB surgery

Surgeons that trained prior to the existence of HPB or Surgical Oncology Fellowships may have received such training in less formal ways, such as extended post-residency training in a busy HPB service or mentoring and progressive experience in the early years of their staff appointment in a hospital where a busy HPB service was present. The increasing complexity of HPB surgery and the development of excellent quality formal fellowship training supports the use of the new standard for surgeons now entering the system.

All surgeons should maintain their expertise and knowledge through continuing professional development programs and a commitment to a career focussed on HPB surgery.

HOSPITAL CRITERIA

General Characteristics

A tertiary care HPB surgical centre should be capable of managing the full range of surgical care for patients with diseases of the liver, pancreas, and biliary tract, from the most complex to the most common, in a single hospital. A minimum of two HPB surgeons should be on staff in order to provide intraoperative assistance and continuous preoperative and postoperative care, while allowing for appropriate personal and professional leave. The hospital should have an

affiliation with a Regional Cancer Program, and the HPB Program should include teaching, research, quality improvement, and program advancement elements.

Hospitals that do not have tertiary HPB services will provide care for patients with common HPB conditions. They should have an established relationship with a tertiary care HPB Centre to facilitate consultation and the referral of common and uncommon cases through a regional care network such as the Local Health Integrated Networks (LHINs), so that all patients may have access to high-quality care in the appropriate setting. These hospitals and their professional staff would also play an important role in the initial diagnostic investigation and surgical follow-up of patients with complex problems. Participation in such a regional care network should lead to both better access to and quality of care.

The capability to provide optimal HPB care requires that an institution ensure the availability of the appropriate physical, fiscal, and human resources needed for the complete spectrum of patient care, from early diagnosis to long-term management and supportive care. A hospital should have a definable system of care for HPB patients that is integrated with the other components of the broader cancer care system.

Specific System Requirements

- Formal acknowledgement by the hospital that it is a Centre for HPB Surgery and therefore has a distinct HPB Surgery Program with definable leadership structure and accountability.
- A commitment to provide HPB surgery in a timely manner, including the support of and commitment to the targets set by the provincial wait-time strategy.
- A system of patient care that ensures multidisciplinary management, including Multidisciplinary Cancer Conferences (i.e., tumour boards) involving the appropriate health care professionals to ensure that patients receive the most appropriate treatment. This is essential for the achievement of optimal patient outcomes.
- A system for the regular review of the program, including clinical and educational rounds, morbidity and mortality review, and quality assurance, including a system for regular tracking of patient outcomes. This includes participation in all quality improvement programs of Cancer Care Ontario.
- Participation in regional cancer programs and the planning processes of the LHINs.
- Infrastructure support for participation in local and national clinical research studies.

Physical Resources

- Appropriately equipped operating rooms available 24 hours a day, seven days a week. This includes the capability for intraoperative imaging (fluoroscopy and ultrasound) and appropriate adjunctive therapy (e.g., radiofrequency ablation).
- Full range of diagnostic imaging ability, including ultrasound (all modalities, including Doppler), computerized tomography (CT) scan, magnetic resonance imaging (MRI), angiography, and interventional radiology, with the appropriate staff skilled in HPB interventions.
- Diagnostic and therapeutic Interventional Endoscopy available 24 hours per day, seven days per week.
- An appropriately equipped intensive care unit (ICU) capable of providing the appropriate range of ventilation modalities, dialysis, and the physical facilities for management of complex infectious problems.
- A fully developed nutrition service, including total parenteral nutrition (TPN).

Human Resources

HPB services are optimally delivered in a multidisciplinary team setting and require a full range of skilled health care professionals for optimum outcomes. These include:

- Qualified HPB surgeons (see Surgeon Criteria and Training).
- Radiologists with appropriate expertise across the full range of angiography, biliary tree imaging, abscess management, and ablative techniques.
- Dedicated, certified critical care physicians.
- An endoscopy service with advanced skills in biliary therapeutic endoscopy.
- Nursing personnel experienced in the management of complex abdominal surgical problems, particularly HPB diseases, abdominal sepsis, and fistulae.
- Medical and radiation oncology services available for consultation and interdisciplinary decision making.
- Supportive care, including pain management, psychosocial support, and palliative care.
- Allied health professionals, including nutritional care, occupational, and physical therapists.
- A pathologist with a special interest in HPB diseases and a commitment to developing the appropriate expertise.
- Administrative support, including a system of data management to meet the needs of the HPB Service.
- Availability of an appropriate spectrum of physician subspecialties to provide the required support to HPB patients, especially infectious disease practitioners.
- Anaesthesiologists with expertise in managing long complex operations in which patients may potentially become unstable and in patients with impaired liver function.

Volume of HPB Surgery

The hospital with an HPB Service should have an adequate volume of index cases to maintain the skills of the multidisciplinary team, function as a tertiary referral centre, justify the resource investment required, and assure that optimum outcomes are achieved.

An HPB Centre should carry out a minimum of 50 index HPB cases per year (index cases include formal anatomic resection of one or more liver segments, all Whipple and total pancreatic resections, and all resections with reconstruction of the biliary tract). The volume should include at least 20 pancreatic resections.

OUTCOME MEASURES, BENCHMARKS, AND QUALITY ASSURANCE

The following outcomes are considered reasonable and achievable at HPB Centres across Ontario:

- A mortality rate (30-day plus in hospital) of less than 5% for major pancreatic resection
- A mortality rate (30-day plus in hospital) of less than 3% for anatomical liver resection.

DEVELOPMENT OF THE STANDARDS DOCUMENT

Evidence on HPB cancer surgery was gathered through a systematic search of the literature and a scan of documents from organizations concerned with quality practice in HPB surgery. Evidence was reviewed by members of the Expert Panel on HPB Surgical Oncology (see Appendix 1, Section 3) investigating the delivery of cancer-related HPB surgery in Ontario. The Panel included HPB surgeons, general surgeons, a medical oncologist, a radiation oncologist, a hospital chief executive officer, a Cancer Care Ontario regional vice president, a pathologist, a radiologist, and methodologists. The members came from across the province and provided appropriate regional representation.

The Expert Panel developed the standards, using a combination of evidence-based analysis, recommendations from other jurisdictions, and their own expert opinion based on experience. The Panel analyzed data on the current distribution of HPB cancer surgery across Ontario to inform the process, and in particular to assist in developing the volume standards. The standards proposed represent a consensus of the Expert Panel, and are intended to accommodate the long-range needs of the province, including the ability to manage the

projected increase in demand for HPB cancer surgical care over the next decade due to the growing and aging population.

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