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Special Report: Section 1

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

M. Marcaccio, B. Langer, B. Rumble, A. Hunter,
and the Expert Panel on HPB Surgical Oncology

A Special Project of the
Expert Panel on HPB Surgical Oncology, Cancer Care Ontario

Report Date: June 14, 2006

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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Special Report Series: Section 2

Hepatic, Pancreatic, and Biliary Tract (HPB) Surgical Oncology Standards: The Systematic Review

M. Marcaccio, B. Langer, B. Rumble, A. Hunter,
and the Expert Panel on HPB Surgical Oncology

A Special Project of the
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QUESTION

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

INTRODUCTION

Malignant diseases of the liver, pancreas, and biliary tract are complex problems that require multidisciplinary assessment and care in order to achieve optimum outcomes. At present, surgical resection remains the only realistic hope for long-term control of these tumours, yet outcomes for surgical resection are still far less than ideal. The surgical procedures themselves, along with the required preoperative investigation and perioperative care, are complex, resource intensive, and not without significant risk. While surgical treatment will benefit many, the combination of complexity and risk in the face of less than desirable tumour control requires that the highest possible standard of care be delivered in order to ensure that an appropriate ratio of benefit and risk can be obtained. Many patients with advanced disease will not benefit from aggressive surgical resection. Management of all patients, including those who are resectable and those who are not, requires a multidisciplinary team with the knowledge and tools to provide a full array of surgical intervention and systemic and radiation treatments. Additionally, supportive and palliative care is essential and will ultimately be needed by the majority of patients.

The Canadian Institute of Health Information (CIHI) data show that approximately 600 major liver, biliary tract, and pancreas resections were performed for cancer in Ontario in 2004/2005. The incidence of hepatic, pancreatic, and biliary malignancies is increasing at over 3% per year, as a function of our growing and aging population. The natural history of these cancers is dismal, with survival rates for pancreas cancer being less than 30% at one year and less than 5% at five years and for liver and biliary tract being less than 30% at five years. While there is demonstrable survival benefit from appropriate surgical and other treatment, the amount of benefit achievable is considerably less than in many other types of cancer. These results have aroused intense interest in finding new management strategies that will improve outcomes. There

is a need for HPB Centres that have a focused interest in these disorders and a commitment to innovation and clinical research, in order to both provide appropriate and up to date care and to develop the new therapies that will improve outcomes.

A comprehensive approach to the investigation of these patients is required in order to establish a correct diagnosis at the earliest possible time. Sophisticated technology and diagnostic expertise, especially in imaging and pathology, may not be widely available but is often required to sort out the more difficult cases. Accurate tumour staging forms an essential part of most treatment decisions and is critical in selecting appropriate patients for surgical resection.

The surgery itself requires judgment, experience, and technical skill to ensure proper preoperative planning, determine the appropriate extent of resection, exercise correct intraoperative decision making, and recognize and manage postoperative problems, including reoperative surgery when required. There is increasing evidence that larger volumes of surgery are associated with better outcomes for many kinds of surgical procedures, including liver and pancreatic resections. This relationship applies to both the individual surgeon and to the hospital. Although there may be many individual surgeon and hospital factors that underlie this effect, volume alone has been a consistent surrogate.

In 1999, a research project conducted under the auspices of the Institute of Clinical Evaluative Sciences was published in the *Canadian Medical Association Journal* (1). It reported wide variations in postoperative mortality among Ontario hospitals over a seven-year period, and noted the relationship between increased volume and better outcomes for complex resections involving the head of the pancreas. In response to this report, Cancer Care Ontario (CCO) convened an Expert Panel to discuss strategies to improve the care of these patients. A standards document (2) was developed that described the Panel's opinion with respect to the characteristics of surgeons and institutions involved in the care of these patients that would lead to optimum outcomes. The Panel also recommended a minimum volume threshold for hospitals of 10 major pancreatic resections and 25 total major liver, biliary, and pancreatic resections per year, and suggested that a benchmark mortality rate for major pancreatic resection of less than 5% was achievable. The guidelines were endorsed by the Board of CCO and widely disseminated, including direct delivery to all hospital Chief Executive Officers and Chiefs of Staff/Chiefs of Surgery.

In 2001, a CCO Surgical Oncology Program working group carried out a qualitative study of the effect of the guidelines on the delivery of complex pancreatic resection for cancer. The review revealed that many hospitals had made changes in their practices, including some that had discontinued these operations and others that had reorganized their care. A more recent review showed that there are significantly fewer hospitals performing pancreatic cancer surgery, the proportion of patients receiving these operations in hospitals doing more than 10 cases per year has increased, and the provincial mortality rate has fallen, compared to the period of study in the 1999 report, but is still higher than 5%. These statistics, however, also show that there are still a significant number of hospitals providing these complex resections but performing fewer than 10 pancreatic resections and 25 complex HPB resections per year.

As one of its initiatives in the area of quality improvement, CCO has initiated the development of standards to guide the evolution of our cancer care system. It was felt timely to review the previous pancreatic cancer surgery standards document and update and incorporate it into a standards document applicable to cancer of the liver, pancreas, and biliary tract, which recognizes the interrelated nature of these diseases. An Expert Panel was therefore convened by the Surgical Oncology Program (SOP) of CCO, in cooperation with the Program in Evidenced-Based Care (PEBC), and charged with the task of developing these standards, utilizing the successful document development process of the PEBC.

METHODS

This report, produced by the SOP and the PEBC, is a convenient and up-to-date source of the best available evidence on volume-related outcomes associated with hepatic, pancreatic, and biliary (HPB) surgery, developed through a systematic review of the available evidence, using the methods of the PEBC Practice Guidelines Development Cycle (3). Members of both the SOP and the PEBC disclosed any potential conflicts of interest. The SOP and the PEBC are both editorially independent of CCO and the Ontario Ministry of Health and Long-term Care (MoH&LTC).

Literature Search Strategy

The MEDLINE database (dB) was searched from 1966 to the second week of September 2005. The EMBASE dB was also searched from 1980 to week 39 2005. Appendix 2 details the MEDLINE search strategy; the EMBASE strategy was comparable but customized for the EMBASE terms. The search terms used covered the appropriate diseases, interventions, settings, and outcomes. Additional articles not located through the formal literature review were provided by some of the authors. A systematic review (4), not found in the formal search as the publication date was too recent to be captured by the review, was also obtained. Relevant articles and abstracts were selected by one reviewer, and data extraction was performed independently by two reviewers, with discrepancies resolved by consensus.

Inclusion Criteria

Articles were selected for inclusion in the systematic review of the evidence if they were fully published English language reports reporting volume-outcome measurements, for either surgeons or hospitals/institutions, in hepatic, pancreatic, or biliary cancer. Ideally, reports would provide both surgeon and hospital/institution volume-outcome measurements. The types of studies eligible for inclusion were randomized controlled trials (RCT), retrospective studies, and case-series reports (with at least 10 patients).

Outcomes of interest

The primary volume-outcome measurements that were of interest included short-term mortality/survival, adverse effects, hospital length of stay, and long-term survival (five-year optimal). Secondary outcomes of interest included costs (as reported in the jurisdiction where the trial was run), physician training, hospital/institutional requirements, and any diagnostic procedures used.

RESULTS

Literature Search Results

A total of 12 trial reports were obtained (1,5-15). None of the trial reports obtained were RCTs; all were retrospective in study design. The data on the relationship between volume categories and mortality, postoperative complications, length of stay, and cost are presented in Table 1 *(Mortality by surgeon-volume, pancreatic resections*), Table 2 (*Mortality by hospital-volume, pancreatic resections*), and Table 3 (*Mortality by hospital-volume, hepatic resections*). The three trials that provided volume-outcome data on surgeons for pancreatic resections (5-7) also provided volume-outcome data on hospitals. Additionally, another 11 trials provided volume-outcome data on hospitals for pancreatic resections only (1,5-14). A single trial reported volume-outcomes for hospitals for hepatic resections (15).

Synthesizing the Evidence

As none of the trials obtained were RCTs, no pooling was possible. Instead, mean cases per hospital per year or mean cases per surgeon per year were calculated and used as the unit of comparison both between trials and between volume categories within trials.

Table 1. Surgeon-Volume measures [3 studies].

Study	Study type	Disease site	Type of intervention	Volume categories (per surgeon per year)	Total No. of surgeons over study period N (%)	Total No. of patients over study period N (%)	Mortality N (%)	Compli-cations (%)	Length of stay d	Cost ($)	Notes
Edge et al, 1993 [USA] (5) Jan 1, 1989 to Dec 31, 1990 [2 years]	Retro-spective audit of discharge coding data	Pan-creas, ampulla of Vater	Pancreaticoduodenectomy, N=168; Total pancreatectomy, N=11; Distal pancreatectomy, N=30; Islet tumour resection, N=14	0-0.9	51 (56)	51 (23)	2 (3.9)	14 (27) (major)	17	No compl. $15,424 Minor $21,607 Major $44,899 all per two year	Surgeons performing 0.5-1.5 resections had significantly more minor and major complications than those performing ≥2 (p=0.011)
				1-1.9	22 (24)	50 (22)	5 (10.0)	12 (24) (major)	14.5		
			Total # surgeons: 91 Total # patients: 223	≥2 Mean = 3.4	18 (20)	122 (55)	6 (4.9)	20 (16) (major) p=0.0163 for 0.5-1.5 cases vs. ≥2 cases	15		
Lieberman et al, 1995 [USA] (6) 1984 to 1991 [8 years]	Retro-spective audit of discharge abstracts from the NY State Depart-ment of Health	Pan-creas, biliary tree, ampulla of Vater	Resections for: Pancreatic ductal adenocarcinomas, 55%; Tumours affecting the Ampulla of Vater, 16%; Distal bile duct adenocarcinoma, 8%; Duodenal adenocarcinoma, 8%; Islet cell tumours, 3%	<1.13	687	1321 (67)	172 (13) [a]	NR	34 (a)	NR	Standardized mortality rates reported; Surgeon's experience not significantly related to perioperative deaths when hospital volume is controlled
				1.13-5.13	57	355 (18)	34 (9.7) [b]		26 (b)		
			Total # surgeons: 748 Total # patients: 1972	>5.13 Mean = 9.3	4	296 (15)	18 (6) [c] X^2 p<0.001 for a vs. b, c		27 (c) X^2 p<0.05 for a vs. b, c		
Nordback et al, 2002 [Finland] (7) Study period: 1990 to 1994 [5 years]	Retro-spective study on National Hospital Discharge database	Pancreas (resec-tion of the head of the pan-creas)	Resections for: Multiple indications, 292 pts of 374 pts total required resection for malignancy Standard resection of the head of the pancreas, including partial gastric resection, N=270/350, 77% Pylorus-preserving resection of the head of the pancreas, N= 76/350, 22% Duodenum-preserving resection (Berger's resection), N=4/350, 1%	0-1.1	74 (75.5%)	NR	Low (<1) 18/125 (14%)	Low (<1) 53/125 (42%)	Low (<1) 24 (range 9-70)	NR	Pancreatic resections performed in high-volume hospitals by high-volume surgeons was associated with decreased postop morbidity, mortality, and hospital stay, and the authors recommend that pancreatic head surgery be limited to only a few hospitals and only a few surgeons.
				1.2-2	20 (20%)	NR	Medium (1-3) 16/164 (10%)	Medium (1-3) 68/164 (41.4%)	Medium (1-3) 23 (range 7-100)		
			Total # surgeons: 98 Total # patients: 350	2.2-3	1 (1%)	NR	High (>3) 2/61 (3%)	High (>3) 15/61 (24.6%)	High (>3) 18 (range 8-63)		
				3.2-4	2 (2%)	NR					
				4.2-6	1 (1%)	NR					

Abbreviations: compl., complications; d, day; NR, not reported; vs., versus; yr, year; N, number; NA, not applicable.

Table 2. Hospital-Volume measures (pancreatic) [11 studies].

Study	Study type	Disease site	Type of intervention	Volume categories (per hospital per year)	Total No. of hospitals over study period N (%)	Total No. of patients over study period N (%)	Mortality N (%)	Compli-cations	Length of stay d	Cost ($)	Notes
Edge et al, 1993 [USA] (5) Jan 1, 1989 to Dec 31, 1990 [2 years]	Retro-spective audit of discharge coding data	Pan-creas, ampulla of Vater	Pancreaticoduodenectomy, N=168; Total pancreatectomy, N=11; Distal pancreatectomy, N=30; Islet tumour resection, N=14 Total # hospitals: 26 Total # patients: 223	0-0.9	10 (38)	27 (12)	2 (7.4)	7 (25.9) (major)	15	No compl. $15,424 Minor $21,607 Major $44,899 all per two year	Morbidity and mortality did not correlate with caseload
				1-1.9	9 (35)	78 (35)	5 (6.4)	15 (19.2) (major)	16		
				≥2 Mean = 8.4	7 (27)	118 (53)	6 (5.1)	24 (20.3) (major)	15		
Lieberman et al, 1995 [USA] (6) 1984 to 1991 [8 years]	Retro-spective audit of discharge abstracts from the NY State Depart-ment of Health	Pan-creas, biliary tree, ampulla of Vater	Resections for: Pancreatic ductal adenocarcinomas, 55%; Tumours affecting the Ampulla of Vater, 16%; Distal bile duct adenocarcinoma, 8%; Duodenal adenocarcinoma, 8%; Islet cell tumours, 3% Total # hospitals: 184 Total # patients: 1972	<1.25	124 (67)	473 (24)	11 (18.9) [a]	NR	35 (a)	NR	Standardized mortality rates reported; Increased hospital volume associated with decreased mortality and length of stay
				1.25-6.25	57 (31)	1065 (54)	16 (11.8) [b]		32 (b)		
				6.38-10	1 (<1)	59 (3)	1 (12.9) [c]		22 (c)		
				≥10.13 Mean = 23.4	2 (1)	375 (19)	3 (5.5) [d]		27 (d)		
							X^2 test p<0.001 for a vs. b, d and a, b vs. d		X^2 test p<0.05 for a, b vs. c, d		
Glasgow et al, 1996 [USA] (8) 1990 to 1994 [5 years]	Retro-spective audit of discharge abstracts	Pancreas , biliary tree, ampulla of Vater, duo-denum, islet cells	Pancreaticoduodenectomy, 83.5%; Proximal subtotal pancreatectomy, 9.3%; Total pancreatectomy, 7.2% Total # hospitals: 298 Total # patients: 1705	<1	210 (70)	510 (30)	72 (14.1)	NR	22.7	$87,857	Men (p=0.006) and older patients (p<0.0001) had significantly higher operative mortality; High volume centres had reduced resource-demand scale scores
				1.2-2	53 (18)	395 (23)	41 (10.4)		22.7	$76,593	
				2.2-4	20 (7)	258 (15)	23 (8.9)		22.9	$78,003	
				4.2-6	9 (3)	228 (13)	13 (5.7)		20.2	$70,959	
				6.2-10	4 (1)	171 (10)	14 (8.2)		23.9	$111,497	
				>10 Mean = 14.3	2 (1)	143 (8)	5 (3.5)		20.5	$71,588	
							p<0.0001		p=ns	p=ns	
Imperato et al, 1996 [USA] (9) 1991 to 1994	Retrospec tive audit of claims reports from Medicare database	Pancreas	Pancreaticoduodenectomy, 100% Total # hospitals: 117 Total # patients: 579	Regional hospital	2 (2)	138 (24)	3 (2.2)	NR	22.4	NR	A single provider was responsible for all cases in the 5.25-6.25 group; In-hospital mortality and length of stay significantly less at the high-volume regional
				Other hospital	115 (98)	441 (76)	54 (12)		32.9		
							p=0.0002		p<0.001		
				0-1.25	89 (76)	2.2 (mean/ hospital)	12.7 (14.3)		NR		

[4 years]							(RR= 6.87)				hospitals when compared with the low-volume hospitals
				1.5-2.5	19 (16)	7.2 (mean/ hospital)	2.2 (11.7) (RR= 5.08)				
				2.75-3.75	4 (3)	12.0 (mean/ hospital)	<1 (6.3) (RR= 3.08)				
				4-5	2 (2)	19.5 (mean/ hospital)	<1 (5) (RR= 2.09)				
				5.25-6.25	1 (1)	21.0 (mean/ hospital)	<1 (19) (RR= 9.46)				
				>6.25 Mean = 17.2	2 (2)	69.0 (mean/ hospital)	<1 (2.17) (RR= 1.0)				
Gordon et al, 1998 [USA] (10) Jan 1984 to Dec 1995 [12 years]	Retrospective audit of hospital discharge data	Pan-creas	Open Pancreaticoduodenectomy for cancer treatment (Whipple procedure): 100% Total # hospitals: 43 Total # patients: 795	<20 surgeries/yr for 6 of 12 yrs on study	42 (98)	458 (58)	65 (14.2)	NR	NR	NR	Only one hospital met inclusion criteria for high-volume; One pancreaticoduo-denectomy required for inclusion in study; Concluded that regionalization of surgery could lower overall in-hospital mortality rate
				≥20 Mean = 28	1 (2)	337 (42)	6.1 (1.8)				
Sosa et al, 1998 [USA] (11) 1990 to 1995 [6 years]	Retrospective cross-sectional	Pan-creas	<u>Pancreatic resections:</u> Pancreaticoduodenectomy – 36.3% Total pancreatectomy – 3.8% <u>Palliative bypass:</u> Gastrojunostomy Biliary-enteric bypasses such as cholecysto-, choledocho-, and hepaticojejunostomy (all three, 21%), double-bypass (22.8%), stent (16%). Total # hospitals: 48 Total # patients: 1236 (1306 resections)	<5	40 (83)	438 (43)	Resec-tions: 99.3 (18.8)	NR	Resec-tions: 23.6	Resec-tions: US 33,249	Patients appear to benefit from referral to a high-volume provider
							Bypass-es: 80.8 (15.3)		Bypass-es: 19.6	Bypass-es: US 17,483	
							Stents: 51.7 (9.8)		Stents: 11.4	Stents: US 9,564	
							p<0.05		p<0.05	p<0.05	
				5-19	7 (14.6)	270 (21.8)	Resec-tions: 18.6 (6.9)		Resec-tions: 21.1	Resec-tions: US 26,053	
							Bypass-es: 28.4 (10.5)		Bypass-es: 17.2	Bypass-es: US 15,654	

							Stents: 29.4 (10.9)		Stents: 8.6	Stents: US 9,760	
							p<0.05		p<0.05	p<0.05 (med vs. low)	
				≥20 Mean = 88	1 (2)	528 (42.7)	Resec-tions: 4 (0.9)		Resec-tions: 18.2	Resec-tions: US 22,379	
							Bypass-es: 18.4 (4.2)		Bypass-es: 15.1	Bypass-es: US 17,377	
							Stents: 7 (1.6)		Stents: 7.6	Stents: US 8,373	
							p=ns		p<0.05	p=ns	
Simunovic et al, 1999 [Canada] (1) 1988-89 to 1994-95 [6 years]	Retro-spective chart audit	Pancreas	Total pancreatectomy Radical Pancreaticoduodenectomy Total # hospitals: 68 Total # patients: 842	<3.7	56 (82)	354 (42)	5.7 (11.3)	NR	30.5	NR	Outcomes reported without readmissions; Odds of dying from pancreatic resection were 5.1 and 4.5 times greater (p<0.01) and average length of stay for patients 7.7 d and 9.2 longer (p<0.01) in low-volume vs. high-volume and medium-volume vs. high-volume centres respectively
				3.7-7	10 (15)	282 (33)	5 (12.4)		33.5		
				>7 Mean = 17.2	2 (3)	206 (24)	<1 (3.4)		25.3		
							p<0.01		p<0.05		
Gouma et al, 2000 [Nether-lands] (12) Jan 1994 to Dec 1998 [part B] [5 years]	Retrospec tive audit of National Medical Registry	Pancreas	Open pancreaticoduodenectomy; cancer and non cancer treatment Total # hospitals: NR Total # patients: 1124	<1	NR	463 (41)	15 (16)	NR	NR	NR	Average number of resections per year increased from 17 to 50 over the study period; Compared with low-volume hospitals, both relative risk and absolute risk were significantly lower in high-volume hospitals
				1-1.8		205 (18)	5 (13)				
				2-4.8		235 (21)	4 (8)				
				≥5		223 (20)	<1 (1)				
							p<0.05, (<5) vs. (10-24) and (<5) vs. (≥25)				
Birkmeyer et al, 2002 [USA] (13) 1994 to 1999 [6 years]	Retrospec tive audit of Medicare database	Pancreas	Pancreatic resection Total # hospitals: 1868 Total # patients: 10530	<1	1027 (55)	1563 (15)	275 (17.6)	NR	NR	NR	Veterans Affairs Outcome Group study; Included patients between 65-99 years of age covered by fee-for-service
				1-2	560 (30)	2757 (26)	425 (15.4)				
				3-5	168 (9)	1885 (18)	219 (11.6)				

				6-16	93 (5)	2166 (21)	163 (7.5)				
				>16 Mean = 18.9	19 (1)	2159 (21)	82 (3.8)				
Nordback et al, 2002 [Finland] (7) Study period: 1990 to 1994 [5 years]	Retro-spective study on National Hospital discharge database	Pancreas (resec-tion of the head of the pan-creas)	Resections for: Multiple indications, 292 pts of 374 pts total required resection for malignancy Standard resection of the head of the pancreas, including partial gastric resection, N=270/350, 77% Pylorus-preserving resection of the head of the pancreas, N= 76/350, 22% Duodenum-preserving resection (Berger's resection), N=4/350, 1% Total # hospitals: 33 Total # patients: 350	0-5	13 (39%)	NR	Low (<1) 26/201 (13%)	Low (<1) 82/201 (40.7%)	Low (<1) 23 (range 8-100)	NR	Pancreatic resections performed in high-volume hospitals by high-volume surgeons was associated with decreased postop morbidity, mortality, and hospital stay, and the authors recommend that pancreatic head surgery be limited to only a few hospitals and only a few surgeons.
				6-10	11 (33%)						
				11-15	4 (12%)		Medium (1-3) 8/93 (7%)	Medium (1-3) 38/91 (40.8%)	Medium (1-3) 23 (range 7-81)		
				16-20	1 (3%)						
				21-30	1 (3%)		High (>3) 2/56 (4%)	High (>3) 16/50 (28.6%)	High (>3) 18 (range 8-58)		
				31-40	2 (6%)						
				41-50	0						
				>50	1 (3%)						
Ho et al, 2003 [USA] (14) Study period: 1988 to 1998 [11 years]	Retro-spective hospital discharge claims for California and Florida	Pancreas	Pancreaticoduodenectomy (Whipple procedure) Total # hospitals: 500 Total # patients: 6652	1	NR	1197 (18)	159 (13.3)	NR	NR	NR	Higher-volume hospitals reported lower mortality rates, and high-volume was a more reliable predictor of decreased mortality than increased experience was.
				2-3	NR	1996 (30)	236 (11.8)				
				4-9	NR	1929 (29)	170 (8.8)				
				>10	NR	1530 (23)	63 (4.1)				

Abbreviations: d, day; NR, not reported; ns, not significant; OR, odds ratio; RR, relative risk; vs., versus; yr, year

Table 3. Hospital-Volume measures (liver) [1 study].

Study	Study type	Disease site	Type of intervention	Volume categories (per yr)	Total No. of surgeons over study period (%)	Total No. of patients over study period (%)	Mortality N (%)	Compli-cations	Length of stay d	Cost ($)	Notes
Choti et al, 1998 [USA] (15) Jan 1990 to June 1996 [7 years]	Retro-spective hospital discharge data from 52 acute-care hospitals (non-federal)	Liver	Partial hepatectomy Hepatic lobectomy Total # hospitals: 52 Total # patients: 606	Low-volume: ≤15/year High-volume: >15/year Mean = 37.7	35 (97) 1 (3)	342 (56) 264 (44)	4 (7.9) 3.9 (1.5) p<0.01		Low-volume: 13.2 High-volume: 12.7 p=ns	Minor: $17,923 Major: $22,485 p=ns	RR for mortality was 5.2 times higher at low-volume centres compared with high-volume centres (p<0.01). Average costs were higher at low-volume centres for major resections ($21,090 versus $30,000; p<0.05)

The Impact of Surgeon-Volume on Outcomes [Pancreatic]

Three trials were obtained that described the relationship between surgeon volume and patient outcomes (5-7). All three of these trials only included patients undergoing pancreatic resections. The types of procedures used and the reasons for the resection are given in Table 1, along with all reported outcomes. The number of patients included in these trials ranged from a low of 223 (5) to a high of 1,972 (6). All of the trials (5-7) reported mortality rates stratified by surgeon volumes, and in two of the trials (6,7), a trend of lower mortality was observed related to higher surgeon volumes. This trend was not observed in one trial (5), possibly resulting from the volume categories not being wide enough to detect subtle differences, as this trial had a very narrow range with an upper limit of ≥two per year, while the other two trials had upper limits of ≥5.13 per year (6) and 4.2-six per year (7).

Two of these trials (5,7) also provided data on postoperative complications stratified by surgeon volume. A similar trend was observed for postoperative complications, with higher surgeon volume categories being associated with a low incidence of complications.

All of the trials obtained (5-7) provided data on hospital length of stay stratified by surgeon volumes. A similar trend was observed for hospital length of stay, with higher surgeon volume categories being associated with a shorter hospital stay.

The observed trends in these trials provide some evidence that surgeons who perform a greater volume of pancreatic resections per year are also able to provide their patients with benefits in survival, postoperative complication rates, and shorter lengths of stay.

The Impact of Hospital-Volume on Outcomes [Pancreatic]

Eleven trials were obtained that described the relationship between hospital-volumes and patient outcomes in pancreatic resections (1,5-14). Types of procedures used and the reasons for the resection are given in Table 2 along with all outcomes. The number of patients included in these trials ranged from a low of 223 (5) to a high of 10530 (13).

All eleven trials described the relationship between volume categories and mortality. In five studies, overall reductions in mortality were reported from the low to the highest volume category and also between the volume categories within each study itself (5,7,12-14). Another five studies, while reporting variances in the trend towards lower mortality between volume categories within each trial itself, did show overall trends towards lower mortality from the lowest to the highest volume category (1,6,8-10). The trial by Sosa et al (11) showed a trend toward lower mortality between >5 and 5-16 procedures volume categories for resections (<5 volume category, 18.8% versus 5-16 volume category, 6.9%) Five of the eleven studies reported that the observed mortality reductions were statistically significant from low-volume to high-volume centres, either for all volume categories or from the lowest to the highest volume category (1,6,8,11,12).

The data strongly suggests that hospitals with high volumes of pancreatic resections have lower operative mortality rates than those with low volumes. The five studies in which hospitals in high-volume categories achieved postoperative mortality rates below 5% (1,8,9,11,13) had analysis thresholds of 6.25, 10, 16, 17, and 20, respectively. The mean hospital volume/year in those hospitals were 17.2, 14.3, 18.9, 17.2, and 88. It is not possible to calculate an exact threshold that represents a minimum volume to result in a mortality rate of less than 5%, but it is likely that it lies somewhere between 15 and 25 cases per year.

Only three trials reported outcomes on postoperative complications stratified by hospital-volumes (5,7,13). In these trials, the relationship between higher hospital volumes and postoperative complications was not as clear as the relationship between hospital volumes and mortality, as none of the three trials shows a clear association between higher volumes and better outcomes. However, in all three cases, the highest hospital-volume categories reported fewer postoperative complications than the lowest hospital-volume categories.

Nine of the trials reported comparable outcomes on the relationship between hospital volumes and in-hospital length of stay (1,5-9,11,14,15). In these trials, the relationship between higher hospital volumes and in-hospital length of stay was not as clear as the relationship between hospital volumes and

mortality. Four trials (7,9,14,15) reported a clear trend with higher hospital volumes being associated with a shorter in-hospital length of stay, and four trials (1,5,6,8) did not.

The Impact of Hospital-Volume on Outcomes [Hepatic]

One trial was obtained that examined the relationship between hospital volumes and mortality in hepatic resections (15). In this study, a statistically significant reduction in mortality was detected for institutions that performed more than 15 hepatic resections per year compared with institutions that performed fewer than 15 hepatic resections per year ($p<0.01$). No difference was detected for comparisons of length of stay between high- and low-volume centres.

Systematic Reviews

In the one systematic review obtained (4), the relationship between hospital volume and mortality following pancreatic resection was explored. A total of 12 retrospective trials involving a total of 19,688 patients were obtained and included in that systematic review, all of which are included in this report (1,5-14). As the trials were too heterogeneous to allow pooling of data, a qualitative analysis was performed. Analysis using two arbitrarily defined cut-off points for clinical importance (a low value of five per year and a high value of 24 per year), found that centres that performed fewer than five pancreatic resections per year reported hospital mortality rates ranging from 13.8% to 16.5%, and in contrast to this, centres that performed 24 or more pancreatic resections per year reported hospital mortality rates ranging from 0% to 3.5%. The authors of that review state that this qualitative analysis provides convincing evidence for an inverse relationship between hospital mortality and hospital volume and are advocating for the centralization of services to provide pancreatic resections.

Environmental Scan Strategy

A Web search of provincial, national, and international surgery associations, including those dedicated to HPB surgery, was conducted between September and November 2005. As well, unpublished sources were sought by contacting surgical opinion leaders in each region and through direct contact with known leaders in the field of HPB surgery. Sources 1 and 2 from the practice organization document list below were forwarded from Expert Panel members.

Environmental Scan Results

Six practice organization documents were located through the search strategy:

1. British Association for the Study of the Liver. National Plan for Liver Services UK. 2004 (18).
2. Cancer Care Ontario Pancreatic Task Force. Criteria for Delivery of Pancreatic Cancer Surgery. 1999 (2).
3. New York State Committee on Quality Improvement in Living Liver Donation. A report to: New York State Transplant Council and New York State Department of Health 2002 (19).
4. Department of Health; National Cancer Guidance Steering Group. Guidance on Commissioning Cancer Services: Improving Outcomes in Upper Gastro-Intestinal Cancers: The Manual. 2001 (20).
5. Guidelines for Resection of Colorectal Cancer Liver Metastases. 2005 (21).
6. The Leapfrog Group. Evidence-Based Hospital Referral Fact Sheet. 2004 Apr 7 version (22).

All of the practice organization documents were developed through expert consensus and were generally similar in that they recognized the need for the regionalization of these complex services in order to concentrate experience in dedicated institutions with dedicated health professionals. Those from the United Kingdom, where there is a more regional approach to healthcare planning, were the most comprehensive.

The recommendations addressed aspects of care that were felt to be important in determining quality and outcomes in this complex area of surgical practice. The necessary components include the formal surgeon and institutional focus on HPB cancer surgery; a comprehensive array of physical and human resources with the training and experience to provide for the most complex patient care situations; a formal organizational structure with administrative leadership and accountability; a

commitment to clinical care, education, and innovation; and an adequate volume of procedures (based on either a defined number of index procedures or the size of population served). A summary of key elements from the HPB practice documents are shown in Table 4.

Table 4. Recommendations from HPB practice organization documents.

SURGEON CRITERIA
National Plan for Liver Services UK (2004) ▪ Sufficient complement of HPB consultant surgeons able to provide continuous 24 hour coverage throughout the year, who are supported by specialist registrars ▪ Each hepatology centre should be able to provide training in HPB surgery. This is essential to maintain the flow of qualified clinicians in this subspecialty
CCO – Criteria for the Delivery of Pancreatic Cancer Surgery (1999) ▪ Completion of training in general surgery plus a period of advanced training in HPB and pancreatic surgery ▪ Competency to manage routine cases and complex resections and reconstructions of biliary tract, intestine, pancreas and vascular structures ▪ Ideally, there should be more than one surgeon
NY State Committee on Quality Improvement in Living Liver Donation (2002) ▪ All surgeons should be board certified in general surgery and have demonstrated experience in liver transplant surgery ▪ Two surgeons should have demonstrated experience in live donor hepactomy (15 procedures) or major hepatobiliary resectional surgery (20 procedures) or surgical fellowship at an American Society of Transplant Surgeons approved liver transplant fellowship program with demonstrated experience (15 procedures)
Guidelines for Resection of Colorectal Cancer Liver Metastases (University of Edinburgh, 2005) ▪ At least two specialist surgeons trained in, and maintaining a special interest in liver resection surgery, and who can demonstrate a high level of skill and training in this area.
HOSPITAL CRITERIA
National Plan for Liver Services UK (2004) <u>Volume</u>: ▪ Each centre should serve a population of 2-4 million <u>Physical Resources:</u> ▪ Appropriately equipped facilities (including CUSA dissector, harmonic scalpel, intra-operative ultrasonography, argon beam coagulator, laparoscopic equipment, ablation treatment equipment, etc) ▪ Sufficient ICU beds to accommodate at least 95% of hepatology/HPB emergencies ▪ High quality diagnostic facilities (US, CT, MRI, PET) 7 days a week ▪ Diagnostic and therapeutic endoscopy and ERCP 24 hours a day ▪ Coverage in hepatology, hepatobiliary surgery and intensive care medicine to provide service 365 days a year <u>Human Resources</u>: ▪ Nurse specialists to coordinate the care of patients and to facilitate communication and provide psychological, spiritual, social and palliative care ▪ Medical support from consultation hepatologists or gastroenterologists with HPB interest able to provide continuous 24 hour coverage ▪ Interventional radiologist, ideally available 365 days a year ▪ Specialized liver pathologist onsite ▪ Intensivist/anaesthetist with interest in hepatology or HPB should be available ▪ Oncology team - Palliative care professionals, Pharmacist with interest in liver disease, Data Manager <u>Organization</u> ▪ Group (10-15) of managed clinical network providing liver services across UK. ▪ Managed networks responsible for: o Targeting resources where most needed o Agreeing to common protocols and service patterns o Monitoring clinical outcomes of treatment pathways • Patient pathways to be determined by National and International guidelines • Meetings weekly with HPB surgery, hepatology, pathology, oncology, radiology and specialist nurses. <u>Innovation</u>: ▪ Networks should have clinical trials facility and an active research programme ▪ MCNs (Multicare Networks) should actively participate in clinical research that aims to improve the management of liver and HPB surgery patients. ▪ Participation in multi-centre trials…should be a priority.
CCO – Criteria for the Delivery of Pancreatic Cancer Surgery (1999) <u>Volume</u>: ▪ Surgical volumes in the range of 25 cases per year (including 10 major pancreatic resections) should be minimum targets,

with 50 cases per year an optimum volume for HPB service

Physical Resources:

- Fully equipped; Available 24/7; Capability for intraoperative ultrasound and fluoroscopy; With ventilator capacity; Ultrasound, Colour Doppler, CT, MRI (may be offsite), Angiography, PTC, All available 24/7; Dialysis, PTN
- Infectious disease

Human Resources:

- Ideally more than 1 surgeon involved
- A sufficient complement of HPB consultant surgeons able to provide continuous 24 hour cover throughout the year. The consultants should be supported by specialist registrars.
- Radiologists skilled in angiography, embolization, transhepatic stenting, abscess drainage
- Anesthesiologist with capability to manage long and complex operations
- Dedicated trained critical care physicians
- Endoscopists: Physicians with capability to perform endoscopic diagnosis (ERCP) and treatment (papillotomy, endoscopic stenting)
- Nursing care, experienced in management of complex abdominal surgical problems, particularly HPB and pancreatic diseases, abdominal sepsis and fistulas
- Medical and radiation oncologists to consult for pre and post operative interdisciplinary decision making
- Supportive care, including pain management, psychosocial support and palliative care

Organization

- Team approach, including surgical and non-surgical specialists
- Regular review of patient management (educational round, morbidity and mortality review, formal ongoing outcome measurement and quality assurance)
- Information system in place to support quality assurance and to facilitate interface with Cancer Care Ontario, education, consultation and management programs

Innovation

To advance knowledge in the field to improve patient outcomes

NY State Committee on Quality Improvement in Living Liver Donation (2002)

Human Resources:

- Two liver transplant attending surgeons, one present for entire procedure and both present for critical portions
- A third should be present in recipient operating room
- Two separate anesthesia attending physicians and teams for donor and recipient operations
- 24/7 coverage of transplant service by general surgery residents at year 2 level or higher, transplant fellows or physician extenders (nurse practitioners or physician assistants)
- Nursing staff, with ongoing education and training in live donor transplantation nursing care.
- Radiologist with experience in evaluation of liver transplant patients
- Interventional radiologists

NHS Executive: Improving outcomes in upper gastro-intestinal cancers (2001)

Volume:

- Cancer centres should draw patients from catchment areas of with populations of 2-4 million
- Minimum acceptable population size is 1 million for sparsely populated areas
- Team could expect at least 200 new patients requiring specialist treatment per year

Physical Resources:

- Provision of adequate and appropriate facilities for surgery and post-operative care
- Availability of EUS, spiral CT facilities, MRCP and ERCP at Cancer Centres

Human Resources:

- All members should be specialists in management of pancreatic cancer
- A designated lead clinician (physician or surgeon) who will take overall responsibility for assessment and treatment of patients
- Team Members include: Specialist HPB surgeons, Gastroenterologist, Anesthetist/intensivist, Radiotherapy specialist (clinical oncologist), Chemotherapy specialist with expertise in treatment of upper GI cancers, Radiologist with GI sub-specialty interest and expertise in interventions, Histopathologist, Cytopathologist, Dietitian, Clinical nurse specialist, Palliative care specialist, One or more members should be trained in endoscopic ultrasonography, Gastroenterologist with interest in upper GI cancers, Clinical nurse specialist with knowledge of upper GI cancer, Endoscopist with expertise in stenting, Interventional radiologist

Organization:

- Cancer Network in which roles of hospitals which offer upper GI services are specified
- Systems to link and coordinate activities of the hospitals within the Network
- Adequate systems and support for rapid communication between teams within the Network
- Evidence-based assessment, treatment and referral guidelines agreed by specialist teams throughout the network
- Systems for Network-wide audit of procedures and outcomes
- Evidence of regular team meetings at Cancer Units and Centres

Guidelines for Resection of Colorectal Cancer Liver Metastases (University of Edinburgh, 2005)

Volume:

- Liver resection should be based in a cancer centre serving a population of at least two million

Human Resources: ▪ At least two specialist surgeons trained in, and maintaining a special interest in liver resection surgery, and who can demonstrate a high level of skill and training in this area. Organization ▪ Consideration of patients for resection of liver metastases should be carried out in a single high volume centre ▪ Patients under consideration of treatment for hepatic metastases should be discussed at a multidisciplinary meeting ▪ The team should also include an oncologist, diagnostic and interventional radiologist with an expertise in hepatobiliary disease, histopathologist, and clinical nurse specialist.
The Leapfrog Group: Evidence-Based Hospital Referral Fact Sheet (2004) Volume: ▪ Evidence-based hospital referral Safety Standard indicates that the volume of surgery procedures for pancreatic resection is > 11/year

Abbreviations: NHS, National Health Service; NY, New York; UK, United Kingdom

DISCUSSION

The Expert Panel on HPB Surgical Oncology used the evidence that was available from the published literature, standards from other jurisdictions, data on provincial activity, and their own expert opinion to reach consensus on standards for HPB cancer surgery in Ontario. They also took into account issues of population distribution in Ontario, current regional service organization, distribution of HPB surgery volumes and the educational and research mandates of the various stakeholders.

The body of evidence on the optimum organization for delivery of HPB cancer surgery in the published and unpublished literature is quite limited. Most studies are focused on the volume-outcome relationship. As indicators of performance in an individual institution, the studies have significant limitations, including the inherent risk of referral bias and potentially confounding co-interactions. The published studies are also limited by a lack of standardization in their reporting of outcomes and in the methodology used to define high- and low-volume centres. They also tended to focus on single procedures or types of procedures rather than the full range of HPB cancer surgery. The Panel considered trying to plot a volume-outcomes curve from raw data in the studies but this proved to not be feasible.

Notwithstanding these limitations, the Panel noted that all the studies did show a definite trend for improved outcome with increasing volume, both for surgeons and hospitals. There was consensus for the concept that these patients present very complex oncological problems and require an integrated approach by a dedicated team with access to advanced levels of expertise, system resources, and integrated care, in order to achieve the best possible outcomes. The Panel felt quite strongly that carrying out isolated surgical procedures in the absence of a comprehensive system of care is not likely to result in appropriate outcomes. There was consensus that, in keeping with the current trend within Ontario, the centralization of complex surgical procedures should continue and that the development of integrated regional networks of care will allow appropriate participation in HPB cancer care by the remaining institutions. This will assist in the goal of providing appropriate care as close to home as possible, whenever possible.

The Expert Panel on HPB Surgical Oncology discussed the issue of volume standards and, while acknowledging the previously discussed problems in the available literature, did reach consensus on this issue. The Panel agreed that the specific structural or process factors that influence the volume-outcome relationship were not discernable from the current literature. They felt that the predominant focus at this time should be on the institution as a whole and, therefore, felt it most appropriate to define an overall volume for an institution rather than define an individual surgeon volume. The Panel also felt it appropriate to consider the major hepatopancreaticobiliary surgical procedures, for both benign and malignant disease, as part of the institutional volume. This opinion is based on the similarities in the surgical management of these patients and the fact that the volume-outcome data is often based on all procedures rather than only cancer procedures. The procedures are resection of the pancreatic head (or total pancreatectomy) with duodenum, anatomic resection of the liver, and resection and reconstruction of the biliary tract. The Panel also felt that, in developing the volume standard of the number of index surgical procedures per institution, there should be some consideration also of the size of the population served, the optimum utilization of specialized hospital resources, and the need to maintain expertise and skills in the entire interdisciplinary team. This recognizes the realities of population distribution and

current health care organization in the province of Ontario, and the Panel felt that the number of index cases would serve as an adequate surrogate for the volumes of the other components of comprehensive cancer care.

After due deliberation, the Expert Panel reached consensus that a minimum institutional volume of 50 index HPB surgery cases per year is required to maintain the skills of the multidisciplinary team, provide the regional consultation and referral service, and achieve appropriate outcomes in Ontario. The Panel also concluded that the evidence demonstrated better outcomes with increasing volume at all volume levels. The Panel recognized that applying a criterion based on this finding would result in a relatively small number of institutions providing complex HPB cancer surgery and that the development of regional networks of care will be critical to providing optimum integrated care across the province. It is also recognized that some regions do not currently have the case volume to support the recommended targets. Additionally, some major University Centres, where participation in complex HPB surgery is important to the broader institutional educational mandate, will also face challenges in meeting the volume targets. However, the Panel believes that the combination of further regional consolidation and the increasing volume of care required by a growing and aging population will provide solutions to these difficult issues and that it will be possible to provide both excellent care and meet regional and institutional needs with the standards described.

CONCLUSIONS

Based on its study of the available evidence and the consensus process, the Expert Panel on HPB Surgical Oncology have identified several characteristics that institutions and surgeons providing care for patients with cancer of the liver, pancreas, and biliary tract should have in order to achieve the best possible outcomes for this patient population.

Surgeon Criteria

General characteristics for surgeons undertaking the management of patients with HPB cancer include knowledge of the biological behaviour and natural history of and range of treatment options for these patients. The surgeons are to be skilled in modern techniques of HPB surgery, and knowledgeable about the management of the early and late postoperative complications. They are committed to providing excellence in care, and to advancing knowledge in the field. They support and participate actively as a member of a multidisciplinary team and are committed to advancing knowledge to improve the care of these patients. They are also committed to participation in quality assurance initiatives.

Surgeons carrying out complex operations will have advanced training in HPB surgery and provide consultation services, leadership, and professional development support to other surgical providers who also have an important role in the care of patients with hepatopancreaticobiliary disorders including cancer.

Hospital Criteria

Institutions providing complex surgical procedures for HPB cancer require a comprehensive range of fiscal and human resources in order to meet the needs of this patient population. Organizationally, institutional commitment to multidisciplinary care that includes regular case conferencing, quality assurance activities (including regular outcomes review), and an information management system to provide the necessary data is a key requirement. Such institutions must be committed to working in a system of regional care, including a linkage with a regional cancer centre, and have a commitment to evidence-based practice, including the use of appropriately developed guidelines.

They will have the human resources required to provide the full range of necessary care on a continuous basis. This includes a minimum of two surgeons with specific training in HPB surgery and access to all necessary medical specialists, specifically including focused expertise in diagnostic and interventional radiology, HPB pathology, anaesthesiology, medical oncology, and radiation oncology.

They will have the physical resources necessary, including fully equipped and available operating rooms that have intraoperative imaging and adjunct modalities such as radiofrequency ablation, technologies for liver parenchymal division, and technologies for minimally invasive surgery. They will

have appropriate facilities for postoperative care (ward and ICU) that are able to deal with the common postoperative problems, including renal failure. Imaging services for both diagnostic and interventional purposes need to be available on a continuous basis and to include a full array of technologies.

An HPB Surgical Centre needs to have a critical mass of patients in order to achieve appropriate outcomes. The recommendation is that they carry out at least 50 major HPB cases annually, including at least 20 pancreatic resections.

Overall, the Expert Panel on HPB Surgical Oncology believes that the benefits associated with the implementation of these standards would result in improvements in patient outcomes, including lower operative mortality rates, the reduced frequency of serious complications, better disease-free and overall survival, and improved quality of life for HPB cancer patients. The Expert Panel feels that these standards will provide useful guidelines to those responsible for the organization of health care, including governments, Cancer Care regional vice presidents, regional planning authorities (LHINs), hospital CEOs, surgeons, and other health care professionals, in the planning of integrated regional and provincial cancer services.

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program in evidence-based care
a cancer care ontario program

programme de soins fondé sur des preuves
un programme de action cancer ontario

Special Report: Section 3

Hepatic, Pancreatic, and Biliary Tract (HPB) Surgical Oncology Standards: Standards Development and External Review—Methods and Results

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and the Expert Panel on HPB Surgical Oncology

A Special Project of the
Expert Panel on HPB Surgical Oncology, Cancer Care Ontario

Report Date: June 14, 2006

THE SURGICAL ONCOLOGY PROGRAM AND THE PROGRAM IN EVIDENCE-BASED CARE COLLABORATION

The Surgical Oncology Program (SOP) and the Program in Evidence-Based Care (PEBC) are initiatives of Cancer Care Ontario (CCO). The mandate of the SOP is to improve the delivery of cancer surgery in Ontario through initiatives designed to increase access to care, improve the quality of care, support the recruitment and retention of cancer surgeons, support knowledge transfer and evidence-based practice, and foster research and innovation. The mandate of the PEBC is to improve the lives of Ontarians affected by cancer, through the development, dissemination, implementation, and the evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care. The SOP and the PEBC have worked collaboratively on a number of occasions to develop evidence-based materials relevant to the surgical community in Ontario, which includes the creation of HPB surgical oncology standards.

The PEBC is best known for producing high-quality evidence-based practice guideline reports, using the methods of the Practice Guidelines Development Cycle (1,2). A typical PEBC report consists of the comprehensive systematic review of the clinical evidence on a specific cancer-related topic, the interpretation of and consensus agreement on that evidence, the resulting clinical recommendations, and the results of an external review by Ontario clinicians for whom the topic is relevant. The PEBC has a formal standardized process to ensure the timeliness of each clinical practice guideline report, conducting routine periodic reviews and evaluations of the scientific literature and, where appropriate, integrating that literature with the original practice guideline report information.

As part of its quality improvement mandate, the SOP convenes expert panels for the selection of quality indicators and the development of clinical guidelines and organizational standards. The panels are comprised of surgeons, other clinicians, health care administrators, other health care professionals, and methodologists and are established on an as-needed basis

for specific quality initiatives, such as the development of the HPB surgical oncology standards. In this instance, the SOP coordinated the development of the Expert Panel on HPB Surgical Oncology, and the PEBC contributed methodological expertise. The PEBC process and report format has been adapted for this HPB standards document.

The Evidence-Based Series

This Evidence-Based Series is comprised of the following three sections:

- *Section 1: Standards* This section contains the standards derived by the Expert Panel on HPB Surgical Oncology through systematic review, an environmental scan, interpretation of the clinical and scientific literature, and consensus process, as well as through a formalized external review by Ontario practitioners and administrators.
- *Section 2: Systematic Review* This section presents the comprehensive systematic review of the clinical and scientific research, the environmental scan, and the Panel discussion on the topic and the conclusions drawn by the Expert Panel on HPB Surgical Oncology
- *Section 3: Methodology of the Standards Development and External Review Process* This section summarizes the standards development process and the results of the formal external review by Ontario practitioners and administrators of the draft version of the HPB surgical oncology standards and systematic review.

DEVELOPMENT OF THE EVIDENCED-BASED SERIES

Developing the Draft Systematic Review and Standards

This Evidence-Based Series was developed by the Expert Panel on HPB Surgical Oncology. The series is a convenient and up-to-date source of the best available evidence on hepatic, pancreatic, and biliary tract surgical oncology standards, developed through systematic review, evidence synthesis, and input from practitioners and health care administrators in Ontario. Section 2 contains the systematic review of the evidence on outcomes related to the optimum delivery of cancer-related HPB surgery. The draft recommendations derived from the interpretation of that evidence by members of the Expert Panel are detailed in Section 1. Sections 1 and 2, along with Section 3, were circulated to Ontario practitioners and administrators for their feedback. Section 3 presents the feedback process results and any changes made to the draft document. This series represents the third collaboration between Cancer Care Ontario's SOP and PEBC.

Expert Panel Consensus Process

The recommendations were based on available information regarding surgeon and other team member training and experience, resource requirements, centre organization, and the relationship of volumes to outcomes. Information from the environmental scan plus the experience of panel members led to a consensus on all issues but the volume thresholds. The literature search showed a consistent relationship between centre volume and postoperative mortality for radical pancreatic resection but not as consistent a relationship for liver resection. Members of the Expert Panel agreed with this interpretation of the evidence, and the main discussion within the Expert Panel focused on what would be a reasonable minimum volume to set as the provincial standard, given the limitations of the data reviewed. Members of the Expert Panel reached consensus on the volume numbers as stated.

External Review by Ontario Clinicians

Following the review and discussion of Sections 1 and 2 of this evidence-based series, the Expert panel on HPB Surgical Oncology circulated the clinical practice guideline and systematic review to clinicians, hospital administrators, and other stakeholders within the Province of

Ontario for review and feedback. Box 1 summarizes the draft standards and supporting evidence developed by the panel.

BOX 1:
DRAFT RECOMMENDATIONS
(approved for external review March 20, 2006)

SURGEON CRITERIA

General Characteristics

The 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 the 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 (CCO) 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 reach a high level of proficiency in the management of the complex surgical problems found in this patient population. The training program should focus specifically 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 either:

- A specific formal Fellowship in HPB surgery, or
- A Surgical Oncology Fellowship with a major emphasis on HPB surgery

Surgeons who trained prior to the existence of HPB or Surgical Oncology Fellowships may have had 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 with a busy HPB service. The increasing complexity of HPB surgery and the development of excellent-quality, formal fellowship training support the use of the new standards 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 focus 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 referral of common and uncommon cases through a regional network of care such as 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 to provide for the complete spectrum of patient care from early diagnosis to long-term management and supportive care. Hospitals 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 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 of regular review of the program, including clinical and educational rounds, morbidity and mortality review, and quality assurance, including a system for the regular tracking of patient outcomes. This includes participation in all quality improvement programs of Cancer Care Ontario.
- Participation in Regional and Provincial Integrated Networks of Care as outlined in the CCO Provincial Cancer Plan (2004), through 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 (i.e., radiofrequency ablation).

- A full range of diagnostic imaging ability including ultrasound (all modalities including Doppler), CT scan, MRI, angiography, and interventional radiology with appropriate skills 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 angiographic, 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 and occupational and physical therapists.
- 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 as required in a tertiary referral centre, to justify the resource investment required, and to 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 resections of the head of the pancreas, 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.

Methods

Feedback was obtained through a mailed survey of 264 clinicians and other relevant stakeholders (see Table 1 for a description of the population surveyed). The survey sample was comprised of 239 clinicians and 25 administrators or other stakeholders. The survey consisted of items evaluating the methods, results, and interpretive summary used to inform the draft standards and whether the draft standards should be approved as a standards document. Written comments were invited. The survey was mailed out on March 20, 2006. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The Expert Panel on HPB Surgical Oncology reviewed the results of the survey.

Results

Ninety-one responses were received out of the 264 surveys sent (34.5% response rate; average response rate for PEBC/SOP collaborative reports = 42.4% (n=4)). Responses include returned completed surveys as well as phone, fax, and email responses. Of the practitioners who responded, 55 indicated that the report was relevant to their clinical practice, and they completed the survey. See Table 1 for a breakdown of survey results obtained by respondent category. Key results of the practitioner feedback survey are summarized in Table 2.

Table 1. Description of survey sample population

Category	Sent	Received
Medical oncologists	17	4
Radiation oncologists	13	6
Surgeons	145	53
Pathologists	1	-
Gastroenterologists	1	1
Medical imaging specialists	4	2
LHIN CEOs	7	-
Hospital Chief of Staff	12	3
Hospital Chief of Surgery	16	6
Cancer Surgery Investment personnel	8	3

Head, Surgical Oncology	7	4
Hospital CEO	19	7
Medical School Representative	3	1
Regional Vice-President	6	1
Other (various)	5	-
TOTALS	**264**	**91**

Note: LHIN, Local Health Integration Networks; CEO, Chief Executive Officer.

Table 2. Responses to eighteen items on the external review survey.

Item	Number (%)		
	Strongly agree or agree	**Neither agree nor disagree**	**Strongly disagree or disagree**
There is a need for a standards document on this topic	87	11	2
The evidence (literature search and environmental scan) is relevant and complete (e.g., no key information sources or studies missed, nor any included that should not have been)	84	9	7
I agree with the methodology used to summarize the evidence	85	7	7
The draft standards are in agreement with my understanding of the evidence	82	7	11
The draft standards in this report are clear	93	6	2
I agree with the draft standards as stated	75	13	13
The draft standards are suitable for the Ontario context.	67	15	18
The draft standards are too rigid to apply in the Ontario context	40	9	51
When applied, the draft standards will produce more benefits for patients than harms	82	11	7
The draft standards report presents a series of options that can be implemented	59	24	17
To apply the draft standards will require reorganization of services/care in my practice setting	50	13	37
The standards will be associated with more appropriate utilization of health care resources	60	29	11
The draft standards in this report are achievable	76	9	15
The draft report presents standards that are likely to be supported by a majority of my colleagues	69	15	15
The draft standards reflect a more desirable system for improving the quality of patient care than current practice	78	17	6
I would feel comfortable if patients received the care recommended in these draft standards	86	9	5
These draft standards should be formally approved	74	11	15
	Not at all likely or unlikely	**Unsure**	**Very likely or likely**
If these draft standards were to be approved how likely would you be to apply the recommendations to the clinical care or organizational and/or administrative decisions for which you are professionally responsible?	77	9	13

Eighty-seven percent of all respondents agreed that there exists a need for guidance on this clinical topic, 84% agreed that the evidence reviewed was relevant and complete, 85% agreed that the methods used in formulating the standards was correct, and 82% of all

respondents were in complete agreement with the draft standards. Seventy-four percent of all respondents supported the draft report being approved as a standards document and stated that they would use the recommended standards in their own practice. The observed discordance between the result for the final question and the preceding 18 questions may be explained by the change in response structure where the previous 18 questions used a consistent scoring method but the final question deviated from this, which may explain the low approval score for the final question. The change in response structure for the final question was intentional to monitor the attentiveness of the respondents. The incongruent result suggests there may be some level of inattentiveness on part of the respondents.

Summary of Written Comments and Expert Panel Responses

Twenty-five of the 55 total respondents (45.5%) provided written comments. The main points contained in the written comments are displayed in the following chart along with the Expert Panel discussion and responses.

Comment 1: SURGEON NUMBERS: Several respondents forwarded concerns regarding the recommendation that a minimum of two HPB surgeons should be on staff in order to provide intra-operative assistance and continuous preoperative and postoperative care, while allowing for appropriate personal and professional leave.
Response: The overall emphasis of the standards reflects the concept of a designated unit, based on at least 2 surgeons for coverage, and continuity of care. Even in smaller tertiary centres, it should be possible to have two surgeons, who have the training described, commit to the level of participation in HPB care required by the standard. *Overall:* Agreed no changes to the HPB Standards document are warranted.
Comment 2: CASE VOLUME: Several respondents raised concern with respect to the validity of the volume target. A question was raised about including a specific target for liver resection.
Response: While, in some of the studies, there may be occasional high-volume centres with a high mortality rate, they are relatively few and do not diminish the consistent and clear evidence of improved outcomes with higher volumes. The Expert Panel reaffirms that using the mean cases per hospital per year or the mean cases per surgeon per year as the unit of comparison, as was performed in this document, is a valid method, given the limitations of the data obtained. Distal pancreatectomies are not considered to be index cases, and the 50-case minimum refers to procedures listed in the Standards document. There is evidence to support the minimum number of pancreatic resections, but there is very little volume data available for liver resections. The total of 50 HPB cases per year is the number expected to be generated in a population of 1 million and includes 20 pancreatic resections. *Overall:* Agreed under Volume of HPB Surgery replace “all resections of the head of the pancreas with “all Whipple and total pancreatic resections”.
Comment 3: IMPACT OF VOLUME TARGET: Several respondents raised concerns that the standards in general, and volume targets in particular, would lead to some institutions and surgeons no longer being able to perform the index procedures.

Response:
In order to meet the volume standards, HPB index cases will be done in a relatively small number of centres. The number reflects the caseload expected to be generated by a referral population of one million and is appropriate for the Ontario situation. Regions will have to support their referral centres, in order to help them achieve the target. For the most part, this has already occurred in Ontario.

Overall: Agreed no changes to the HPB Standards document are warranted.

Comment 4:
FUNDING: The question of funding being withheld from institutions performing these procedures at low volumes was raised.

Response:
Funding of procedures is a hospital-based decision, and outside the mandate of the PEBC and the Expert Panel.

Overall: Agreed no changes to the HPB Standards document are warranted.

Comment 5:
TEACHING REQUIREMENT: Concern was expressed that the teaching requirement would exclude non-university hospitals

Response:
The teaching requirement is not specifically for undergraduate or postgraduate training in medicine; it reflects the need for education of the team and the broader health care community in the appropriate management of these problems. This is necessary for appropriate quality in both teaching and non-teaching centres.

Overall: Agreed no changes to the HPB Standards document are warranted.

Comment 6:
INFRASTRUCTURE REQUIREMENTS: Clarification was requested with respect to the location and availability of some of the support resources

Response:
The required support services do not necessarily have to be continuously on site, rather they need to be continuously available when required. The wording in the Standards reflects this.

Overall: Agreed no changes to the HPB Standards document are warranted.

Comment 7:
TRAINING REQUIREMENTS: Questions were raised with respect to whether transplant training would meet the standard. It was also suggested that more specificity be included with respect to the term “major focus on HPB surgery.”

Response:
These standards have been modified to reflect that HPB training can be achieved in both transplant and non-transplant programs, as well as surgical oncology fellowships. It is difficult to be more specific in defining the components of training as there are no agreed-upon standards for these training programs at this time.

Overall: Agreed add a second bullet under Training Requirements “A Fellowship in liver transplant which includes a major focus in non-transplant HPB cases, or…”

Report Approval Panel

The PEBC Report Approval Panel (RAP) reviewed the draft Standards document in an advisory capacity in March 2006. The RAP consists of two members, including an oncologist, with expertise in clinical and methodology issues. Following review, the RAP motioned to fully endorse this document. No comments, requests for clarifications, or revisions were submitted for Expert Panel consideration.

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Appendix 1: Expert Panel on HPB Surgical Oncology members.

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Appendix 2: Literature search (MEDLINE).

exp Liver Neoplasms/su [Surgery]
exp HEPATECTOMY/ 5265
exp Liver Neoplasms/su [Surgery] 5249
hepatic surgery.mp. 180
exp LIVER/su [Surgery] 1430
1 or 2 or 3 or 4 or 5 9268
exp PANCREAS/su [Surgery] 857
exp Pancreatic Neoplasms/su [Surgery] 3132
pancreas surgery.mp. 25
exp PANCREATECTOMY/ 1864
7 or 8 or 9 or 10 4724
exp Biliary Tract Diseases/su [Surgery] 7065
biliary surgery.mp. 195
exp CHOLECYSTECTOMY/ 5855
exp Biliary Tract Surgical Procedures/ 7771
12 or 13 or 14 or 15 11471
6 or 11 or 16 23954
surgery/st 448
surgery/ma 252
surgery/sn 185
surgical procedures, operative/ 6597
surgery department, hospital/ 1062
general surgeon$.tw. 749
general surgery$.ti. 360
exp Colorectal Surgery/ 420
"colon and rectal surgery (specialty)"/ 420
18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 9558
exp Disease-Free Survival/ 14682
exp SURVIVAL/ 1134
exp Survival Rate/ 46033
exp Patient Readmission/ 2044
exp Postoperative Complications/ 101643
"outcome assessment (health care)"/ 18519
exp "outcome and process assessment (health care)"/ 232760
28 or 29 or 30 or 31 or 32 or 33 or 34 354262
exp Patient Admission/ 6118
exp Health Manpower/ 1315
hospital volume$.tw. 233
exp Hospital Mortality/ 6570
surgeon volume$.tw. 95
surgical volume$.tw. 97
exp HOSPITALS/
36 or 37 or 38 or 39 or 40 or 41 or 42
17 and 27 and 35 and 43