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ORIGINAL ARTICLE – PERITONEAL SURFACE MALIGNANCY

The Chicago Consensus on Peritoneal Surface Malignancies: Standards

Chicago Consensus Working Group

Chicago, IL

ABSTRACT The Chicago Consensus Working Group provides the following multidisciplinary recommendations for the care of patients with peritoneal surface malignancies. This article focuses on the standards of a peritoneal surface malignancy center, standards of billing and coding, standards of operative reports for cytoreductive surgery and hyperthermic intraperitoneal chemotherapy, standards of cytoreductive surgery training, and standards of intraoperative chemotherapy preparation. These guidelines are developed with input from leading experts including surgical oncologists, medical oncologists, pathologists, radiologists, palliative care physicians, and pharmacists. These guidelines recognize and address the emerging need for increased awareness in the appropriate management of peritoneal surface disease. They are not intended to replace the quest for higher levels of evidence.

This article provides multidisciplinary recommendations pertaining to the care of patients with peritoneal surface malignancies and constitutes 1 article in a series composed by the Chicago Consensus Working Group for the Management of Peritoneal Surface Malignancies.[1–10] Information regarding formation of the Chicago Consensus Group and explanation of the working group's consensus methodology is discussed.[1,2]

The collaborators for the Chicago Consensus Working Group are listed in the acknowledgments.

Correspondence to: K. Turaga, MD
Department of Surgery, University of Chicago, Chicago, IL
e-mail: kturaga@surgery.bsd.uchicago.edu

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STANDARDS OF A PERITONEAL SURFACE MALIGNANCY CENTER

A peritoneal surface malignancy center provides specialized care for patients with peritoneal surface diseases. To provide safe and effective care for patients with this complex set of diseases, it is essential for aspiring centers to create an environment that is conducive to providing patient-centered care.

A peritoneal surface malignancy center must have the expertise of dedicated physicians, nurses, and staff members and adequate facilities for delivering care while maintaining safety standards.[11]

Structure Standards

- The institution must have a defined surgical leader. The leader must have board eligibility or certification in general surgery, colorectal surgery, surgical oncology, or gynecologic oncology. The leader must also have significant demonstrated experience in cytoreductive surgical procedures (including visceral resections and peritonectomy procedures), chemotherapy delivery and safety in the operating room (OR), and management of hyperthermic fluid delivery. Experience will be demonstrated through the following:
  - Documented fellowship experience with cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) (see the Standards of CRS Training section).
  - Documentation of the requisite number of proctored/mentored cases in CRS/HIPEC.
  - Documentation of the number of CRS/HIPEC cases performed per year.
- A second board-eligible/certified surgeon must be available for operative and postoperative assistance/coverage.

- A multidisciplinary team must have a minimum of 1 named member from each of the following specialties: surgery, pathology, radiology, medical oncology (required), patient tracker/navigator, oncology-certified nurses, and psychosocial support staff (preferred).
- The institution must be a member of the American College of Surgeons Commission on Cancer or a National Cancer Institute—designated cancer center.
- The institution's pathology laboratory must be accredited by the College of American Pathologists.
- The institution's magnetic resonance imaging (MRI) facility must be accredited by the American College of Radiology.
- The institution must have continuously available intensive care unit (ICU) and blood bank support.
- A pharmacist with expertise in chemotherapy for drug preparation must be available.
- The institution must have 24-h availability of interventional radiology and complex endoscopy.[12]

Process Standards

- Tissue diagnosis confirmed prior to treatment (target rate $> 95\%$).
- Tumor markers (if relevant) obtained prior to surgery (target rate $> 95\%$).
- Cross-sectional imaging of the abdomen and pelvis obtained and reviewed less than 90 days prior to surgery (target rate 100%).
- Data from patients entered into institutional database (target rate 100%).
- Informed consent for surgery and chemotherapy obtained preoperatively (target rate 100%).
- Chemotherapy drugs labeled with (at a minimum) patient name, second patient identifier (such as medical record number), generic drug name, dose, volume of solution, and date/time of drug preparation (target rate 100%).[13]

Quality Standards

- Twelve or more CRS/HIPEC cases performed per surgeon per year.
  - For centers seeking to become designated peritoneal surface malignancy centers, this benchmark will be met during year 3.
- Operative report dictation less than 24 h after procedure (target rate 100%).
- Standardized synoptic pathology report issued within 2 weeks of surgery (target rate 90%).
- Monitoring of perfusate temperature during HIPEC (target rate 100%).
- Intraoperative core temperature monitoring (target rate 100%).
- Perfusion apparatus monitored throughout procedure (target rate 100%).
- Rate of complete cytoreduction (CC0/CC1) greater than 60% (required).
- Target 30-day mortality less than 5%.
- Target ostomy rate (permanent or temporary) at index operation or as a result of subsequent complication less than 25%.
- Hospital stay of less than 14 days (target rate $> 50\%$).
- ICU stay of less than 48 h (target rate $> 50\%$).
- Target transfusion rate less than 50%.
- Target readmission rate less than 33%.
- Target rate of major complications less than 40%.

STANDARDS OF BILLING AND CODING

Currently, the practice of CRS (specifically, peritonectomy procedures) with or without intraperitoneal chemotherapy does not have clearly defined procedural terminology codes. Given this variability, which is influenced by locoregional hospital and payer differences (e.g., negotiated contracts with or without specific bundling practices), it is critical that providers optimize their documentation—in close collaboration with institutional coding experts—to ensure fiscal viability of CRS/HIPEC programs. This document aims to provide guidance regarding certain standards in the billing and coding of these procedures.

Physician Billing

Large-volume institutions have adopted 2 major strategies to account for work effort for CRS with or without intraperitoneal chemotherapy. These are (1) "bundled" work effort regardless of visceral resections performed and (2) additive individual procedures with or without discounting for additive procedures.

Accounting for the effort involved in administering intraperitoneal chemotherapy along with the preoperative counseling and postoperative care (although generally included as part of the "global" period) is less clear. Some institutions use administration of chemotherapy, hyperthermia, and insertion of tunneled catheter as combined codes for capturing work effort. Other institutions (on the basis of formal consulting agreements) have developed an imputed value for such relative value units.

The core principles of documentation include the following:

- Ensuring that pre-, intra-, and postoperative documentation **specifically** and **accurately** reflects severity of illness (SOI) and risk of mortality (ROM), which are translated into *International Classification of Diseases, Tenth Revision* diagnosis and procedure codes. Examples of documentation opportunities include the following:
  - Electrolyte disturbances.
  - Acute blood loss anemia.
  - Metastatic cancer sites.
  - Malnutrition (and severity of malnutrition).
  - Obesity/body mass index.
- Reinforcing the importance of thorough and accurate documentation with nonsurgical colleagues (case managers/social workers, nurses, dieticians, etc.) and other health care providers (advanced practice providers, residents, etc.).
- Clearly documenting visceral resections performed, especially if these are billed separately by procedure performed. Even if they are bundled, they should be documented clearly for optimal patient care.
- Specificity about the peritonectomy procedures performed, including size of tumor resection (billed as unlisted codes). Many institutions have created internal "dummy" codes with associated relative value units for each procedure (e.g., 58,957 for pelvic peritonectomy, 58,950 for hemidiaphragmatic/paracolic peritonectomy, or both).
- Omentectomy with description of the omental cake size. Many institutions, as guided by the National Correct Coding Initiative, have the omentectomy bundled into the cytoreduction unless it is the only procedure performed.
- Ureterolysis, if performed, and the level of complexity. Many institutions, however, have this irreversibly bundled into other procedures.
- Degree of complexity of the operation (duration, need for 2 surgeons, repeat surgery that may lead to the use of modifier 22).
- Specific details regarding the generation of hyperthermia, nature of chemoperfusate, and need for clinical vigilance during the chemoperfusion if performed.
- Details of abdominal wall resection and reconstruction, including separation of components if performed.
- Extent of any diaphragm resection, with repair.

Hospital Billing

It is strongly encouraged to work with the coding specialist and the billing department of the hospital for optimal billing for patients undergoing CRS with or without intraperitoneal chemotherapy. The following are recommended:

- Ensure documentation reflects the patient's true SOI and ROM.
- Identify modifiable risk factors that optimize degree of complexity of the risk-adjusted model [all patient refined diagnosis-related group (DRG)]:
  - Complication/comorbidity: a significant acute disease, significant acute manifestation of a chronic disease, advanced or end-stage chronic disease, or chronic disease associated with systemic physiological decompensation and debility that has consistently greater impact on hospital resources. Examples include acidosis, acute renal failure, postoperative ileus, urinary tract infection, stage 4 chronic kidney disease, and chronic systolic congestive heart failure.
  - Major complication/comorbidity: diagnosis codes that reflect the highest level of severity, leading to substantially increased hospital resource use such as intensive monitoring, expensive and technically complex services, and extensive care requiring a greater number of caregivers. Examples include acute diastolic heart failure, acute tubular necrosis, acute respiratory failure, sepsis, pneumonia, pulmonary embolism, and end-stage renal disease.
  - Relative weight: an assigned weight that is intended to reflect the relative resource consumption associated with each DRG. The higher the relative weight, the more resources it takes to care for that patient.
  - HIPEC/intraperitoneal (IP) chemotherapy procedure codes do not impact DRG assignment today. The CRS drives the DRG assignment. The HIPEC/IP chemotherapy procedure is considered medical, not surgical, for DRG assignment.
- Recognize that when patients undergo a 4-quadrant peritonectomy but have limited visceral resection such as an appendectomy, current software classifiers categorize these cases as appendectomies only.

STANDARDS OF CRS AND HIPEC OPERATIVE REPORTS

Operative reports that are used for documenting peritoneal disease burden are encouraged to include the following components:

- Patient and surgeon details.

- Diagnosis: It is recommended to use standardized terminology indicating the histology of disease (such as *low-grade carcinoma peritonei from low-grade appendiceal mucinous neoplasm [LAMN]* rather than the generic term *pseudomyxoma peritonei*).
- Anesthetic procedures: Documentation of the use of regional anesthesia and significant anesthetic considerations, including fluids administered and blood loss, is recommended.
- Procedures performed: The use of laparoscopy, including the site for the ports, peritonectomy procedures, visceral resections, diversion procedures, and use of intraperitoneal chemotherapy with duration, temperature, and flow rate of perfusion should be documented. The performance of reconstructive procedures must also be clearly described. The completeness of cytoreduction must be documented by using either the completeness of cytoreduction score or the R score. Ablative procedures such as electroevaporative surgery, ultrasonic aspiration, or laser ablation must be described with areas of use. Such procedures by nature do not result in complete (CC0 or R0) cytoreduction and must be indicated as CC1 or CC2 (or R1 or R2a/b).
- Findings: A clear description of peritoneal disease burden and distribution must be provided and must include detailed assessment of the Morison pouch, right coronary ligaments, retrosplenic space, pelvic cul-de-sac, and seromesenteric junctions. Documentation using a well-described scoring system such as the peritoneal cancer index (PCI), simplified PCI, or Gilly score is recommended.

Template of Operative Report

Patient name:
Medical record number:
Date of birth:
Date of surgery:
Surgeon(s):
Assistant(s):

PREOPERATIVE DETAILS

1. Primary origin of carcinomatosis:
2. Synchronous or metachronous carcinomatosis:
3. Preoperative imaging:
4. Preoperative chemotherapy: Y/N.
5. Eastern Cooperative Oncology Group performance status:
6. American Society of Anesthesiologists class:

PREINCISION DETAILS

1. Anesthesia:
2. Preoperative deep vein thrombosis prophylaxis:
3. Preoperative antibiotics: Y/N, type:
4. Preoperative ureteral stents: Y/N.

EXPLORATION AND RESECTION

1. Laparoscopy before exploration: Y/N.
2. PCI index/distribution/lesions, size, range, locations:
3. Ascites present: Y/N, volume:
4. Peritonectomy sites:
5. Organs resected:
6. Number of anastomoses:
7. Loop or end stoma:
8. CCR or R score:

INTRAPERITONEAL CHEMOTHERAPY

1. Open or closed technique:
2. Type and dose of chemotherapy:
3. Inflow/outflow temperature probes:
4. Perfusate temperature at outflow:
5. Perfusate fluid volume and flow rate:
6. Perfusion time:

DISPOSITION

1. Extubated in OR/intubated:
2. Estimated blood loss:
3. Fluids administered:
4. Drains:
5. Disposition: ICU/floor.

NARRATIVE REPORT

Dictate your narrative operative report with any additional details.

STANDARDS OF CRS TRAINING

Purpose of CRS Training

The purpose of CRS training is to provide the structured educational and training experience necessary to achieve expertise in CRS. CRS training requires development of expertise as outlined in the framework of the Accreditation Council for Graduate Medical Education core competencies, including the following:

1. Patient care.
2. Medical knowledge.
3. Practice-based learning and improvement.
4. Interpersonal and communication skills.
5. Professionalism.
6. Systems-based practice.

Recommendations Regarding the Nature of CRS Training

The purpose of CRS training is to confirm that the recipient has received adequate education and training in the technical aspects of CRS, patient selection for CRS, and the postoperative management of patients after cytoreduction.

Clinical Experience Requirements

Active participation in the treatment of 20 patients with peritoneal surface malignancies is recommended. The following areas are covered:

Experience in both inpatient and outpatient management is *required*.

- Preoperative evaluation, assessment, and counseling of patients.
- Perioperative in-hospital care.
- Postoperative outpatient follow-up.

Participation in clinical management conferences is *required*.

- Multidisciplinary tumor boards.
- Morbidity and mortality conference.

Participation in advanced care planning is *suggested*.

- Discussion of advanced directives and living will.
- Management and palliation of advanced malignancies.

Experience with intra-abdominal imaging interpretation is *suggested*.

- Familiarity with intra-abdominal computed tomography (CT) and MRI, with specific attention to the peritoneum and mesentery.

Technical Components of the Surgery

- Expertise in visceral resections, including splenectomy, colon and rectal resections, and gastric, small bowel, pancreas, and liver resections, is *required*.
- Expertise in peritonectomy procedures is *required*.
- Expertise in ablative techniques such as electroevaporative surgery, argon laser ablation, and ultrasonic aspiration is *required*.
- Expertise in hysterectomy and bilateral salpingo-oophorectomy and bladder resections is *preferred*.

Educational Activities

- Continuing education.
  - Participation in national educational conferences (e.g., Society of Surgical Oncology Advanced Cancer Therapies meeting, etc.).
  - Participation in multicenter clinical discussions (e.g., University of Pittsburgh Medical Center regional perfusion videoconference).

Procedure Requirements

Surgeon's role: to achieve independent expertise in CRS, it is recommended that the surgeon be the primary surgeon for at least 70% of the cases (Table 1).

STANDARDS FOR THE PREPARATION OF INTRAOPERATIVE CHEMOTHERAPY

Best-practice chemotherapy standards exist for the safe prescribing, preparation, and administration of chemotherapy. Published standards by the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society address parenteral and oral routes of chemotherapy, whether administered in an ambulatory or an inpatient setting.[1] The OR poses a unique environment, with relative unfamiliarity of the delivery of cytotoxic agents among most nursing and pharmacy OR staff members. These guidelines are meant to reduce the risk of errors from the administration of chemotherapy and can be applied to HIPEC.

Institutions performing HIPEC should have a written policy that outlines who can order, prepare, and administer HIPEC. This policy should describe the credentials of these individuals and how competency is demonstrated on a periodic basis. The policy should be written, reviewed, and approved by surgeons, oncologists, nurses, and pharmacists involved with HIPEC. It is important to recognize that existing chemotherapy policies may need to be amended if current policy restricts the ordering of chemotherapy to a specialty.

We recommend HIPEC be ordered through computerized provider order entry by using a standard electronic chemotherapy order set. Order set(s) should be literature based and validated by surgeons performing HIPEC. Prescribing chemotherapy outside established order sets

TABLE 1 Recommended case numbers for individuals undergoing cytoreductive surgery training

Type of procedure	Recommended case number
Overall cytoreductive surgery cases	20
Diaphragmatic peritonectomy	5
Pelvic peritonectomy	5
Intraperitoneal chemotherapy	5

should be discouraged. Commonly prescribed chemotherapy agents used in HIPEC and relevant clinical pearls are presented in Table 2.

Communication between the team delivering intraoperative chemotherapy and the chemotherapy pharmacy team is critical. Issues with drug procurement or national shortage should be reported to the operative team per usual pharmacy procedures. It is essential to adequately communicate the timing, concentration, and volume of the intraoperative chemotherapy. This information is required to establish a sufficient quantity of chemotherapy to keep in stock to support the HIPEC program.

The HIPEC program should indicate to pharmacy staff the hours when chemotherapy may be ordered and the expected turnaround time for drug delivery. Ideally, chemotherapy should be ordered in advance to allow pharmacy staff adequate time to properly check dosing

TABLE 2 Properties of chemotherapy agents commonly used in intraperitoneal delivery[14,15]

Chemotherapy agent	Malignancy type	IV volume/ concentration	Stability	Preparation instructions	Monitoring/laboratory parameters
Cisplatin	Peritoneal mesothelioma (single agent or with doxorubicin) Gastric cancer (with mitomycin) Ovarian cancer (with paclitaxel)	50–100 mL to achieve final concentration of 0.05–2 mg/mL	48 h RT	Dilute in NS, D51/2NS, D5NS Not stable in D5W Do not use aluminum-containing IV sets	CMP, CBC Addition of sodium thiosulfate is used for renal protection
Carboplatin	Ovarian cancer Peritoneal mesothelioma	50–100 mL to achieve final concentration of 0.5–4 mg/mL	8 h RT	Dilute in D5W or NS	CMP, CBC
Mitomycin C	Peritoneal mesothelioma Gastric cancer Colon cancer Appendiceal cancer Mucinous ovarian tumors	50–100 mL	7 days RT, 14 days RF	Dilute in NS Not stable in D5W Protect from light	CMP, CBC
Oxaliplatin	Appendix cancer Colon cancer	50–100 mL	6 h RT, 24 h RF	Dilute in D5W Not stable in NS	CMP, CBC
Doxorubicin	Peritoneal mesothelioma (with cisplatin) Ovarian cancer (with paclitaxel or mitomycin) Desmoplastic round cell tumors	50–100 mL	48 h RT	Dilute in NS or D5W	CMP, CBC
Paclitaxel	Ovarian cancer (with cisplatin)	50–100 mL to achieve a concentration of 0.3–1.2 mg/mL	27 h RT	Dilute in NS or D5W Dispense in non-PVC-containing IV bags and tubing	CMP, CBC Premedication with steroid and antihistamine is not required for HIPEC

IV intravenous, *RT* room temperature, *NS* normal saline, *D51/2NS* dextrose 5% and 0.45% normal saline, *D5NS* dextrose 5% and normal saline, *D5W* dextrose 5%, *CMP* complete metabolic panel, *CBC* complete blood count, *RF* refrigerated, *PVC* polyvinyl chloride, *HIPEC* hyperthermic intraperitoneal chemotherapy.

calculations, laboratory parameters, and supportive care and to allow for dedicated time to ensure safe and accurate drug preparation and verification.

Prior to chemotherapy administration, documentation confirming the name and dose of chemotherapy that will be used in HIPEC must be available in the electronic health record. Patient consent should be obtained and a signed copy should be accessible to both pharmacy and nursing staff. Best-practice consent should include the names of the chemotherapy agents to be administered and a list of expected adverse effects at a minimum.

The order set should include the generic name of the chemotherapy, the dose per square meter or flat dose, the base bag volume, base fluid, and date of administration. The order should indicate the dosing frequency. Furthermore, the order should indicate the route of administration of chemotherapy, especially when being used as bidirectional chemotherapy (intravenous and intraperitoneal).

The pharmacy label should include at minimum the patient name, medical record number, generic name of chemotherapy, dose in appropriate units, volume and type of base fluid, frequency, route of administration, and time medication is due. An auxiliary label signifying to staff that the drug product is classified as chemotherapy is also recommended. Supportive care typically ordered with systemic chemotherapy should be considered; however, note that the emetogenic and myelosuppressive effects of HIPEC are generally less. HIPEC orders should be verified via a dual check system by 2 licensed pharmacists and nurses trained and competent in chemotherapy preparation and administration.

Because of the large volume of fluid exchanged during surgery, the base bag volume for chemotherapy should be kept to a minimum. We suggest 50 to 100 mL total. Chemotherapy bags should be delivered at room temperature with tubing commensurate with needs established by the perfusion team.

Chemotherapy is considered an antineoplastic hazardous drug per the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) guidelines. Therefore, pharmacy staff should prepare HIPEC in a biologic class II safety cabinet with established primary and secondary controls to prevent exposure. Safeguards used to prepare HIPEC do not differ from those used to prepare parenteral chemotherapy. Personal protective equipment should be worn in the OR setting by the surgeons and nursing staff. Drugs should be dispensed using a closed system transfer device meant to further diminish occupational exposure. Given the hazardous nature of chemotherapy, HIPEC-containing material should be disposed of in a hazardous waste container. This practice should be maintained in the postoperative period until most of the drug has been excreted (48 h). Double gloving with latex gloves (or chemotherapy-safe nonlatex gloves) is recommended for the OR team. Personal protective equipment including eye protection and chemotherapy-safe gloves is essential for staff members who are not scrubbed in. Trace waste, such as that found in an empty chemotherapy bag and tubing, is disposed of in a chemotherapy-designated bin. Large-volume waste from the chemotherapy volume exchange should be disposed of in a black hazardous material container. Detailed spillage policies, along with an emergency procedure in case of a large-volume spill and exposure to the team, should be readily available and accessible to the staff.

The CDC NIOSH guidelines state that most chemotherapy is hazardous to both men and women actively trying to conceive, women who are pregnant or may become pregnant, and women who are breastfeeding, because the drug may be present in breast milk.[14] Therefore, these agents may present an inherent reproductive risk to health workers from occupational exposure. While the consistent and proper use of personal protective equipment minimizes the risk of occupational exposure during administration of HIPEC, the risk is not eliminated. Reproductive risk can include fetal loss, teratogenicity, and/or fertility impairment. The ASCO recently published the 2019 ASCO standards on the safe handling of hazardous drugs. To minimize the risk of occupational exposure to hazardous drugs, standard 5 of this document recommends that health care settings consider potential alternative duty options for workers who are actively trying to conceive, are pregnant, or are breastfeeding.[15]

Despite the inherent risks, with proper application of the procedures described herein a safe, efficient, and effective HIPEC program can be implemented.

STANDARDS OF IMAGING

High-quality cross-sectional imaging is essential in the appropriate management of patients with peritoneal surface malignancies. Preferred modalities of peritoneal imaging include multislice CT and contrast-enhanced MRI. Although ultrasound is used for dynamic imaging of ascites, it is not currently used as a primary modality for the diagnosis or surveillance of peritoneal disease. Expertise in interpretation of images with a specific focus on clinically relevant features (mesenteric foreshortening, involvement of the portal triad, inferior vena cava bursa, diaphragmatic involvement, multifocal bowel obstruction, involvement of the seminal vesicles, ureteral obstruction, etc.) is recommended. Specific documentation of burden of disease to facilitate the calculation of an imaging PCI is recommended.

Patients with high-grade disease should receive systemic staging performed with standard accepted modalities. Patients with mucinous tumors are overrepresented among those who develop peritoneal metastases, and FGD^{18}-PET scans may be less sensitive in this population. Preferred staging of the peritoneum includes multidetector contrast-enhanced CT scans or contrast-enhanced MRI. Peritoneal-specific protocols are heterogeneous but favor distension of the intestines with large-volume oral contrast material, use of rectal contrast material in patients with concern for pelvic disease, use of intravenous contrast material with delayed sequences, and use of diffusion-weighted imaging with b values of 500 to 1000 s/mm.[2] Appropriate distension of the intestine can help reveal periserosal tumors. In patients with chronic renal failure who are receiving dialysis, CT of the abdomen and pelvis with intravenous iodinated contrast material and oral contrast material can be used. In patients with chronic renal failure (glomerular filtration rate < 30 mL/min) who are not receiving dialysis, intravenous gadolinium-based contrast agents can be administered in select cases using gadoterate meglumine (preferably) or hepatocellular agents such as gadoxetate disodium or gadobenate dimeglumine.

ACKNOWLEDGMENT Collaborators: **Alejandro Plana, BA**, Department of Surgery, University of Chicago, Chicago, IL; **Francisco J. Izquierdo, MD**, Department of Surgery, Clínica Santa María, Providencia, Chile; **Darryl Schuitevoerder, MBBS**, Department of Surgery, University of Chicago, Chicago, IL; **Daniel E. Abbott, MD**, Department of Surgery, University of Wisconsin, Madison, WI; **Sherif Abdel-Misih, MD**, Surgery, Stony Brook University, Stony Brook, NY; **Steven A. Ahrendt, MD**, Department of Surgery, University of Colorado, Aurora, CO; **Mazin Al-kasspooles, MD**, Division of Surgical Oncology, Department of Surgery, University of Kansas Medical Center, Kansas City, KS; **Farin Amersi, MD**, Cedars-Sinai Medical Center; **Amanda K. Arrington, MD**, Surgery, University of Arizona, Tucson, AZ; **Brian Badgwell, MD, MS**, Surgical Oncology, MD Anderson Cancer Center, Houston, TX; **Robert M. Barone, MD, MS**, UCSD School Medicine Division of Surgical Oncology, Surgery, Sharp HealthCare, La Jolla, CA; **Joel M. Baumgartner, MD, MAS**, Surgery, University of California, San Diego, La Jolla, CA; **Richard N. Berri, MD**, Surgical Oncology, Ascension St. John Hospital, Grosse Pointe Woods, MI; **Lana Bijelic, MD**, Surgical Oncology, Inova Schar Cancer Institute, Fairfax, VA; **Wilbur B. Bowne, MD**, Surgery, Drexel University College of Medicine, Philadelphia, PA; **Dan G. Blazer III, MD**, Surgery, Duke University, Durham, NC; **Charles Komen Brown, MD, PhD**, Surgery, AMITA Health, La Grange, IL/Emphasis>, Medicine, University of Chicago, Chicago, IL; **Carlos H.F. Chan, MD, PhD**, Department of Surgery, University of Iowa Hospitals and Clinics, Iowa City, IA; **Clifford S. Cho, MD**, Department of Surgery, University of Michigan Medical School, Ann Arbor, MI; **M. Haroon A. Choudry, MD**, Surgery, Surgical Oncology, University of Pittsburgh, Pittsburgh, PA; **Callisia N. Clarke, MD, MS**, Surgery, Medical College of Wisconsin, Milwaukee, WI; **James C. Cusack Jr., MD**, Department of Surgery, Massachusetts General Hospital, Boston, MA; **Abraham H. Dachman, MD**, Radiology, UChicago Medicine, Chicago, IL; **Jeremiah L. Deneve, DO**, Surgery, University of Tennessee Health Science Center, Memphis, TN; **Sean P. Dineen, MD**, GI Oncology, Moffitt Cancer Center, Tampa, FL; **Oliver S. Eng, MD**, Surgery, University of Chicago, Chicago, IL; **Leopoldo J. Fernandez, MD**, Surgical Oncology, Virginia Commonwealth University Massey Cancer Center, Hunter Holmes McGuire, VAMC, Richmond, VA; **James Fleshman, MD**, Department of Surgery, Baylor University Medical Center, Dallas, TX; **T. Clark Gamblin, MD, MS, MBA**, Department of Surgery, Medical College of Wisconsin, Milwaukee, WI; **Alexandra Gangi, MD**, Surgical Oncology, Department of Surgery, Cedars-Sinai Medical Center, Los Angeles, CA; **Georgios V. Georgakis, MD, PhD**, Division of Surgical Oncology, Department of Surgery, Stony Brook University, Stony Brook, NY; **Erin W. Gilbert, MD**, Department of Surgery, Oregon Health & Science University, Portland, OR; **Martin D. Goodman, MD**, Surgical Oncology, Tufts Medical Center, Boston, MA; **Anand Govindarajan, MD, MSc**, Division of General Surgery, Sinai Health System, University of Toronto, Toronto, ON, Canada; **Travis E. Grotz, MD**, Department of Surgery, Mayo Clinic, Rochester, MN; **Vadim Gushchin, MD**, Surgical Oncology, Institute for Cancer Care at Mercy, Baltimore, MD; **Nader Hanna, MD**, Surgery, University of Maryland School of Medicine, Baltimore, MD; **Carla Harmath, MD**, Radiology, University of Chicago, Chicago, IL; **John Hart, MD**, Department of Pathology, University of Chicago, Chicago, IL; **Andrea Hayes-Jordan, MD**, Division of Pediatric Surgery, Department of Surgery, University of North Carolina School of Medicine, Chapel Hill, NC; **Aliya N. Husain, MD**, Pathology, University of Chicago, Chicago, IL; **Kamran Idrees, MD, MSCI, MMHC**, Department of Surgery, Vanderbilt University Medical Center, Nashville, TN; **Chukwuemeka Ihemelandu, MD**, Surgical Oncology, MedStar Georgetown University Medical Center, Washington, DC; **Haejin In, MD, MBA, MPH**, Surgery, Montefiore Medical Center, Bronx, NY; **Fabian M. Johnston, MD, MHS**, Surgery, Johns Hopkins University, Baltimore, MD; **David Jiang, MD**, Department of Surgery, University of Chicago, Chicago, IL; **John M. Kane III, MD**, Surgical Oncology, Roswell Park Comprehensive Cancer Center, Buffalo, NY; **Giorgos Karakousis, MD**, Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA; **Kaitlyn J. Kelly, MD**, Surgery, University of California San Diego, La Jolla, CA; **Timothy J. Kennedy, MD, MBA**, GI Surgical Oncology, Rutgers Cancer Institute of New Jersey, New Brunswick, NJ; **Xavier M. Keutgen, MD**, Endocrine Surgery Research Program, Division of Surgical Oncology, University of Chicago, Surgery, Chicago, IL; **Hedy Lee Kindler, MD**, Section of Hematology/Oncology, University of Chicago, Chicago, IL; **Michael D. Kluger, MD, MPH**, Division of GI & Endocrine Surgery, Columbia University College of Physicians and Surgeons, New York, NY; **Byrne Lee, MD**, Division of Surgical Oncology, City of Hope, Duarte, CA; **Lloyd A. Mack, MD, MSc**, Departments of Surgery and Oncology, University of Calgary, Calgary, AB, Canada; **Ugwuji N. Maduekwe, MD, MMSc**, Division of Surgical Oncology and Endocrine Surgery, Department of Surgery, The University of North Carolina at Chapel Hill, Chapel Hill, NC; **Grace Z. Mak, MD**, Section of Pediatric Surgery, Department of Surgery, The University of Chicago, Chicago, IL; **Joshua M.V. Mammen, MD, PhD**, Department of Surgery, University of Kansas, Kansas City, KS; **Melvy Sarah Mathew, MD**, Department of Radiology, University of Chicago, Chicago, IL; **Marcovalerio Melis, MD**, Surgery, NYU School of Medicine, New York, NY; **Nelya Melnitchouk, MD, MSc**, Department of Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, MA; **Ryan P. Merkow, MD, MS**, Department of Surgery, Feinberg School of Medicine, Northwestern University; **Dejan Micic, MD**, Department of Gastroenterology, University of Chicago, Chicago, IL; **Harveshp Mogal, MD, MS**, Surgery, Medical College of Wisconsin, Milwaukee, WI; **Mecker G. Möller, MD**, Division of Surgical Oncology, Department of Surgery, University of Miami Miller School of Medicine, Miami, FL; **Garrett M. Nash, MD, MPH**, Surgery, Memorial Sloan Kettering, New York, NY; **Aytekin Oto, MD, MBA**, Radiology, University of Chicago,

Chicago, IL; **Colette R. Pameijer, MD**, Department of Surgery, Penn State College of Medicine, Hershey, PA; **Sandeep Parsad, PharmD, MBA**, Department of Pharmacy, University of Chicago, Chicago, IL; **Pritesh Patel, MD**, Department of Radiology, University of Chicago, Chicago, IL; **Blase N. Polite, MD, MPP**, Department of Medicine, University of Chicago, Chicago, IL; **Sam G. Pappas, MD**, Surgery, Rush University Medical Center, Chicago, IL; **Patricio M. Polanco, MD**, Division of Surgical Oncology, Department of Surgery, University of Texas Southwestern Medical Center, Dallas, TX; **Sanjay S. Reddy, MD**, Department of Surgery, Fox Chase Cancer Center, Philadelphia, PA; **Richard Royal, MD**, Surgical Oncology, MD Anderson Cancer Center, Houston, TX; **George Salti, MD**, Surgical Oncology, Edward-Elmhurst Health and University of Illinois at Chicago, Chicago, IL; **Armando Sardi, MD**, Surgical Oncology, Mercy Medical Center, Baltimore, MD; **Namrata Setia, MD**, Department of Pathology, University of Chicago, Chicago, IL; **Maheswari Senthil, MD**, Surgical Oncology, Loma Linda University Health, Loma Linda, CA; **Scott K. Sherman, MD**, Surgery, University of Chicago, Chicago, IL; **Lucas Sideris, MD, FRCSC**, Surgery, University of Montreal, Montreal, QC, Canada; **Joseph Skitzki, MD**, Department of Surgical Oncology, Roswell Park Comprehensive Cancer Center, Buffalo, NY; **Brandy Strickland Snyder, CPP**, Department of Pharmacy, Wake Forest University, Winston-Salem, NC; **Sandy Tun, MD**, Section of Geriatrics and Palliative Medicine, Department of Medicine, University of Chicago Medicine, Chicago, IL; **Jula Veerapong, MD**, Surgical Oncology, University of California San Diego, La Jolla, CA; **Konstantinos I. Votanopoulos, MD, PhD**, Surgery, Wake Forest, Winston-Salem, NC; **Michael G. White, MD, MSc**, Department of Surgery, The University of Chicago, Chicago, IL; **Joshua H. Winer, MD**, Division of Surgical Oncology, Emory University, Atlanta, GA; **Shu-Yuan Xiao, MD**, University of Chicago, Chicago, IL, and Department of Pathology, Wuhan University Zhongnan Hospital, Wuhan, China; **Rhonda K. Yantiss, MD**, Weill Cornell Medicine, Pathology and Laboratory Medicine, New York, NY; **Nita Ahuja, MD, MBA**, Surgery, Yale University, New Haven, CT; **Andrew M. Lowy, MD**, Department of Surgery, UC San Diego Health, La Jolla, CA; **H. Richard Alexander Jr., MD**, Division of Surgical Oncology, Rutgers Cancer Institute of New Jersey, New Brunswick, NJ; **Jesus Esquivel, MD**, Surgical Oncology, Frederick Memorial Hospital, Frederick, MD; **Jason M. Foster, MD**, Division of Surgical Oncology, Surgery, University of Nebraska/Nebraska Medicine, Omaha, NE; **Daniel M. Labow, MD**, Department of Surgery, Icahn School of Medicine at Mount Sinai, New York, NY; **Laura A. Lambert, MD**, General Surgery, Huntsman Cancer Institute/University of Utah, Salt Lake City, UT; **Edward A. Levine, MD**, Surgical Oncology, Wake Forest University, Winston-Salem, NC; **Charles Staley, MD**, Department of Surgery, Emory University School of Medicine, Atlanta, GA; **Paul H. Sugarbaker, MD**, MedStar Washington Hospital Center, Washington, DC; **David L. Bartlett, MD**, Surgery, University of Pittsburgh, Pittsburgh, PA; **Kiran K. Turaga, MD, MPH**, Department of Surgery, University of Chicago, Chicago, IL.

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