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CLINICAL PRACTICE

U.S. PIPAC Registry

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Disclosures

- I do not have any relevant financial relationships with any ineligible companies.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

Objectives and Goals

- Create a single repository of data captured from PIPAC patients in the United States
- Comprehensive database
- Monitor treatment paradigms, quality, benchmarking, and identify research opportunities
- Collaborative resource for all contributing centers

Objectives and Goals

- Organized system to collect uniform data
- Inclusive, not exclusive
- Pervasiveness of PIPAC is inevitable and trials are costly
  - Risk of exclusion of patient data if not “on trial”

Enhance and expand national collaboration, development, and scientific approach to treating primary and secondary malignant peritoneal diseases

ISSPP Database

- Established in 2016; Contemporary database launched in 2020
- Established to gain insight regarding treatment and response evaluation
- REDCap
- Located in Odense, Denmark

ISSPP Database

- 4 Modules
  - Patient
  - Treatment
  - Complications
  - Follow-up (including response evaluation)
- Lacks neoadjuvant treatment details

ISSPP Database – Report from December 2023

- 12 centers
- 809 patients; 2456 PIPAC procedures
- 4 centers included 93% of patients
- Significant missing data in some variables - ~10% for date of death

Mortensen. Pleura and Peritoneum, 2023

U.S. Registry - Aims

- Patient-centered
  - Clinician and patient derived data
  - Patient-reported outcomes
- Improved clinical practice
  - Mechanism for benchmarking
- Quality, Efficiency, Cost-effectiveness
  - Quality and efficiency of data collection
  - Data governance and sharing

U.S. Registry - Aims

- Transparency and Access
  - Provide routine feedback to participants
- Data linkage, longitudinal follow-up
  - Follow-up for comprehensive review of outcome

U.S. Registry - Considerations

- Easy online access – REDCap
- Central registry must house deidentified data
  - Identified data can be stored at each individual site
- Requires local IRB approval, data sharing agreements and contracting
- Requires patient informed consent for data sharing
- Eventual funding source will be needed to ensure data completeness and integrity
- Development of some governance authority, but allow for transparent sharing of data

U.S. Registry – Opportunities for Standardization

- Development of standardized templates and operative notes
  - Document disease elements that are important
  - Allow for future ease of data entry
- Pathologic reporting
- Follow-up and surveillance

U.S. Registry – General Components

- Patient Demographics
- Presentation/Workup
  - Histology, mutations, metastatic burden
- Patient history
- PIPAC Details
  - Detailed PCI information, ascites, pathology, device used
- Follow-up
  - Morbidity, cancer specific follow-up

Next Steps

- Still in development
- Need your feedback and participation
- Develop clinically relevant questions and variables, allow for easy access, efficient entry with minimal time burden
- Email Merchea.Amit@mayo.edu for copy of data dictionary to review and provide feedback