



PIPAC ESSENTIALS

How to Get Started with PIPAC

Richard L. Whelan, MD

System Chief, Colon & Rectal Surgery

Department of Surgery

Northwell Health Cancer Institute

©ISSPP 2019. This educational material is property of ISSPP and can be reused with mention of the source



Disclosures

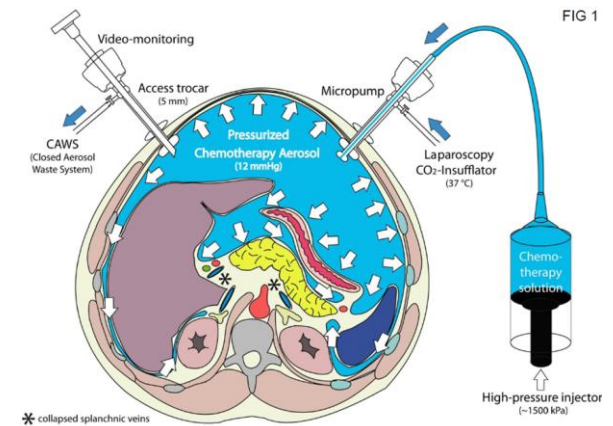
- I do not have relevant financial relationships.

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

The off-label or investigational use of Cisplatin, Doxorubicin, Oxaliplatin, Mitomycin C may be discussed.

Inform Yourself

- Learn about PIPAC
- Does it make sense for your hospital ?
- Read the literature
- Take the PIPAC didactic course
- Visit a PIPAC center and observe case(s) (required on site observation for certification)
- Attend ISSPP meeting ??



Building a PIPAC program (Summary)

- Educate all parties & build support
- Meet with all to be involved & stakeholders
- Appeal to administration
- Business plan /reimbursement issues
- Address safety issues
- Obtain high pressure injector & prepare OR
- Equipment list
- Identify volunteers for operative team
- Case simulation
- First case !!!

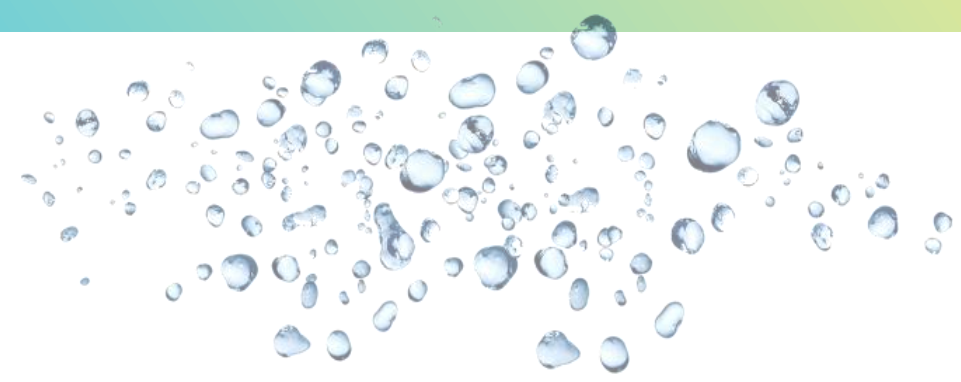


Build Support for PIPAC Program in your Hospital

- GYN Oncologic surgeons
 - Surgical oncologists
 - Colon and rectal surgeons
 - Tumor board
 - Medical oncology ??
 - Cancer Center / Institute
-
- Need a team of interested and committed people who will work together

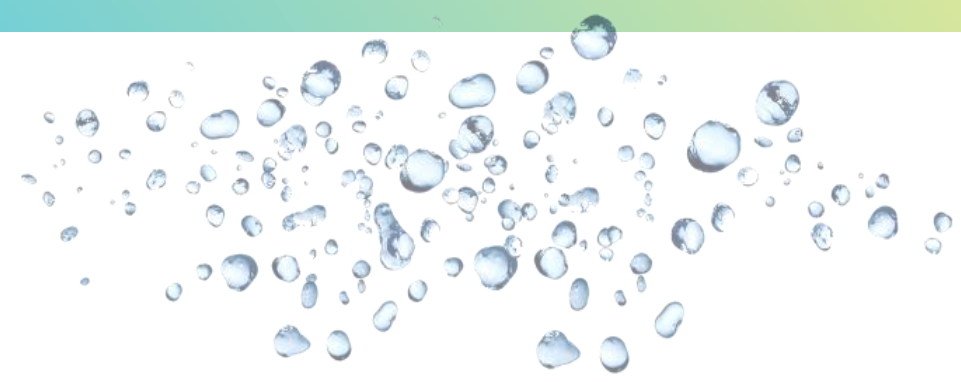


Possible pushback and antagonism



- Select specialists committed to CRS HIPEC
- Medical oncology
 - No level 1 evidence
 - Systemic chemo is best option if CRS/HIPEC ruled out
- Biosafety department: safety concerns
- Administration: cost of program, lack of CPT code presently

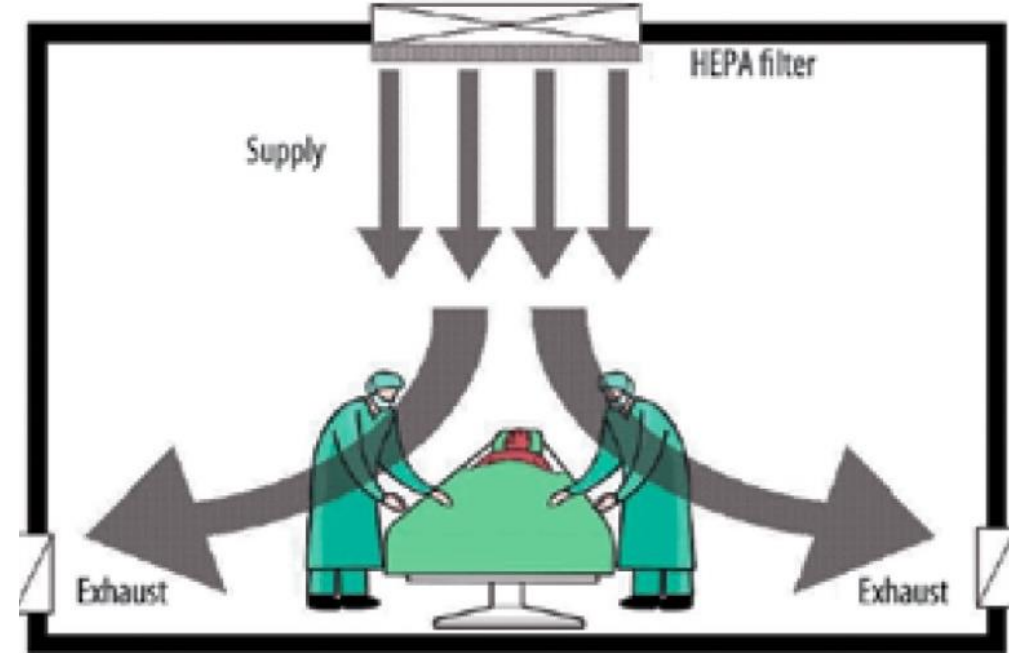
Must tackle the safety issue head on



- Field day for the biosafety people
- Aerosol chemotherapy sounds scary and dangerous
- Will the staff be exposed to chemo?
 - OR staff
 - PACU staff
- Is it safe to enter the room during and after the treatment?

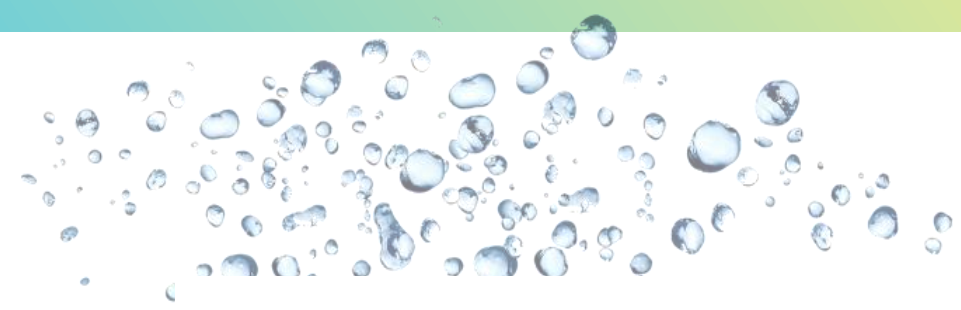
Must educate all concerned about PIPAC

- Short presentations to the various stakeholders
- Perhaps a separate presentation centered on safety issues for Biosafety and OR staff
- Provide the stats on safety and the real risks (quite small)
 - Amount of chemo far less than HIPEC
 - Potential leakage sites are small & secure (unlike HIPEC)
 - Vast majority of the chemo stays in the body (no recirculation)
 - If aerosol injected into room
- Allay the fears
 - Staff will leave room for drug infusion
 - Positive pressure OR air circulation systems fully filter air in 18-22 minutes
 - PIPAC dedicated cartridge gas masks will be available for key staff if leak should occur

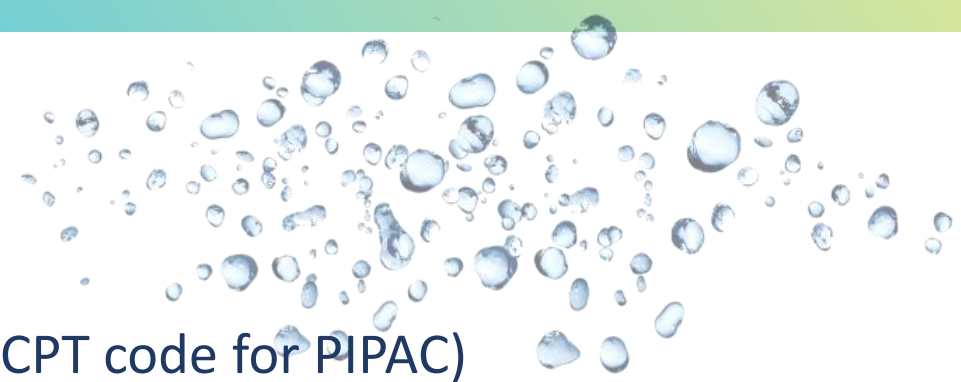


Administration concerns

- Efficacy
- Safety
- Costs:
 - Startup
 - Per case costs
- Reimbursement expectations
- Projected case volume
- Potential benefits
- Need to prepare a budget and simple business plan

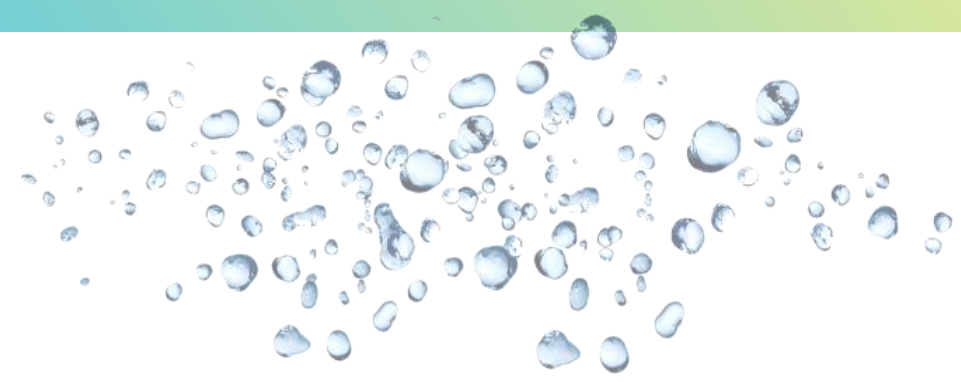


Reimbursement



- The capnopen and PIPAC are not FDA approved (there is no CPT code for PIPAC)
- Cannot bill for aerosol infusion of chemotherapy
- Can usually bill for SOC procedures such as:
 - Laparoscopy and peritoneal biopsy
 - The cost of the chemotherapy (depending on the agent)
 - Interval radiologic imaging & marker studies
- At Northwell, reimbursement was obtained for 6/9 procedures (2/3 patients)
- Out of state patients/insurance are a challenge
- Need simple business plan

Anesthesia



- If its so safe why do we have to leave the room ?
- You want us to monitor the patient from the scrub room or hall?
- What if we need to go back in the room (gas mask)
- Need to educate them and, if requested, get a slave monitor for scrub room or hall
- Audio monitor is an option
- Have them talk to anesthesiologist from COH, Mayo, or NW

Build a volunteer team

- Scrub techs
- Circulating RN's
- Anesthesiologists

- For PIPAC program it is best to have the involvement of:
 - Medical oncologist
 - Pathologist
 - Pharmacist



High Pressure Injector: Biggest startup expense

- May share with vascular surgery or radiology, however, that creates logistical hurdles and requires moving machine around hospital (in radiology most units are ceiling mounted)
- Ideally, a dedicated machine is bought for PIPAC cases
- Machine configuration for PIPAC is different
 - Injector should be mobile
 - Control panel and computer is on separate wheeled cart from the injector pedestal
 - Need long cord connecting the “in room” injector and the hallway control panel
- Be aware that PIPAC is an “off label” use of the HP Injector
- Bayer Medrad Stellant is most commonly used machine
- Cost is about \$30,000
- Department funds? Philanthropy ?
- Split costs between GYN, Surg Onc, Colorectal, Cancer Center



Cables between HP Injector & Control Panel

- Need way out of the OR to the scrub room or hall
- Options:
 - Under the OR door
 - Via hole in the wall (HILTI Sleeve)
- Cover cables to prevent tripping

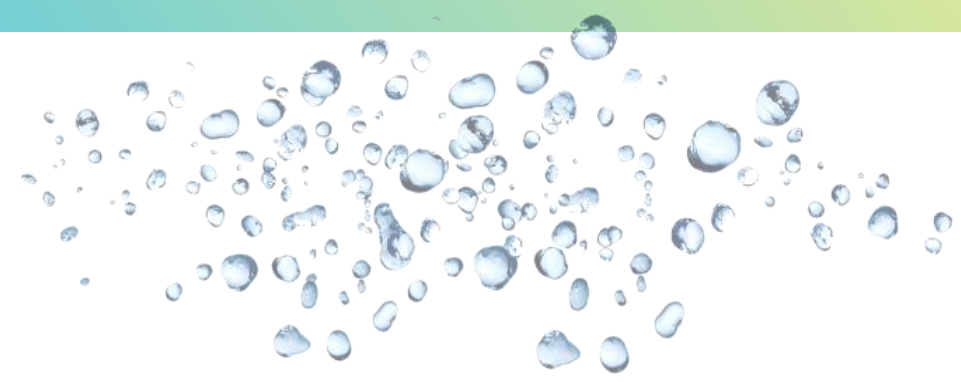


Disposable equipment for procedure

- Balloon ports (12 mm and 5 mm)
- Injector syringes (200 ml, can get 1 or pack of 2)
- Laparoscopic camera bag (holds tubing from HP injector to patient)
- CO2 filter (between CO2 insufflator & port)
- Exsufflation filters (from port to suction cannister)
- Suction traps for ascites collection
- Chemo floor protection
- Chemo disposal container

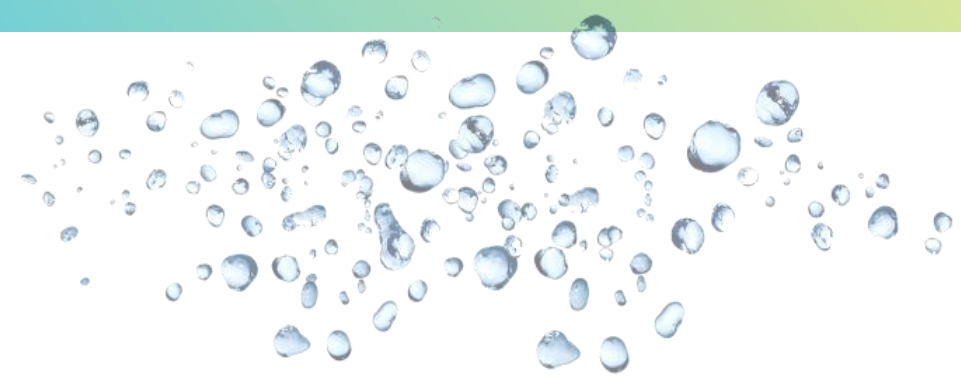


Pharmacy



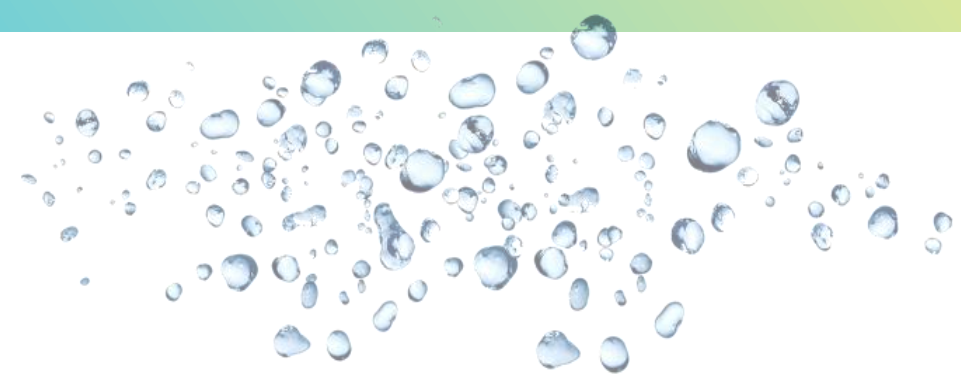
- Need presentation and discussion
- Need to articulate a PIPAC protocol
 - Need to be notified about upcoming cases
 - Since procedure are same day admits
- Need research pharmacy to formulate the drug(s)
- They can also hold the aerosolizing devices (capnopen)

Pathology



- Need their buy in as well
- Four peritoneal biopsies are generally sent / procedure
- Ascites for cytology will be sent as well
- Present PRGS scoring system for peritoneal biopsies
- Standard pathology also requested
- Multiple laparoscopies/PIPAC will be done

Step 2: Regulatory Steps



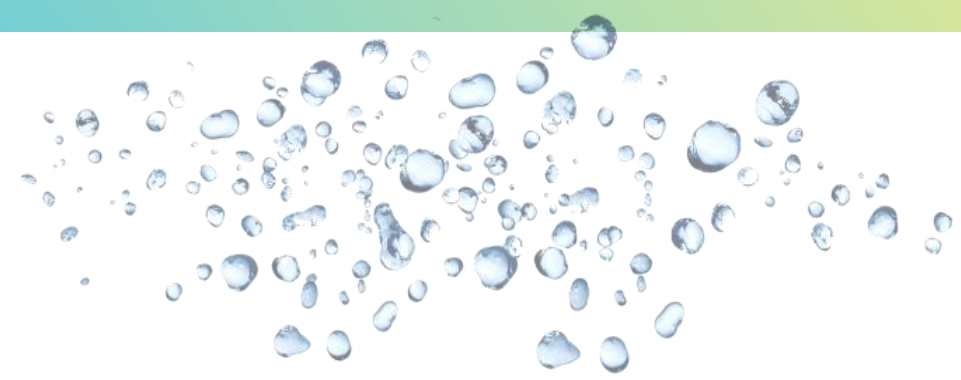
- Contact the IRB for advice
- Write and submit a study protocol or join an ongoing study
- Meet hospital system/ University regulations regarding new procedures

Before 1st patient do simulated case in the operating room

- Plastic bin with lid will serve as patient
 - Trocars placed through the lid
 - Saline with methylene blue is the “chemo”
- Room set up & equipment availability
- Set up HP injector
- Anesthesia remote monitoring check
- Run the checklist
- Load the syringe & make connection to “patient”
- Leave room
- Initiate the infusion
- Simulation will inform & educate everyone

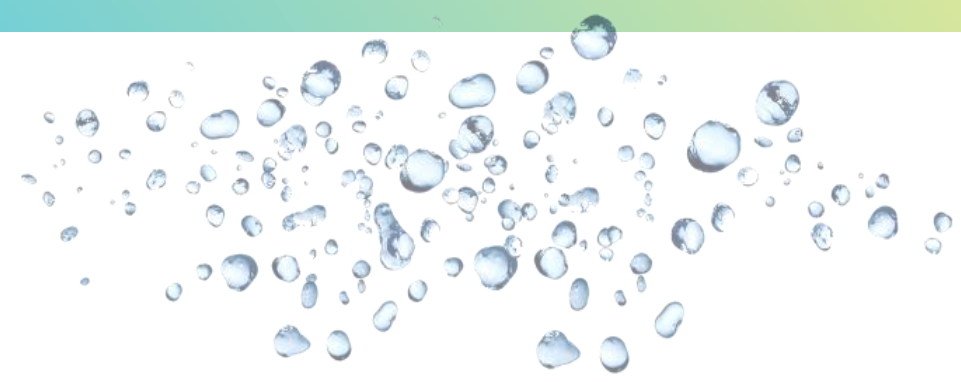


Step 4: First PIPAC Procedure



- **Open an off-label program**
- **Identify the first patients**
 - Good condition !
 - Be careful !
 - No previous surgery advisable
- **Ask an experienced PIPAC physician to be with you for the first procedure**
- **Check-up on everything**
- **Perform the first PIPAC**

Step 5: Data Management



- Ask for the access code for the PIPAC registry
- Input your cases
- Create your own Excel list
- Follow your patients closely

Step 6: External Communication

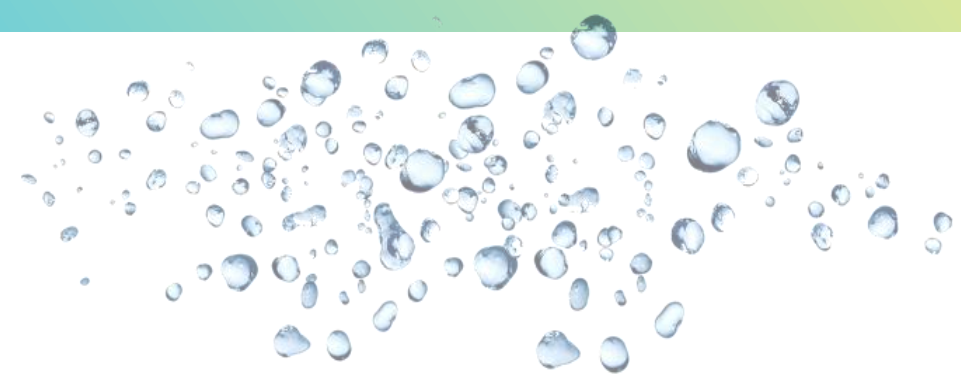


- **Keep a low profile**
 - Do not yet inform the mass media
 - Be prepared if you do so

- **Be careful with publications on off-label cohorts**

- **Be careful with your website**
 - Focus on peritoneal metastases
 - No advertising for off-label therapy

Step 7: Later on



- **Do not push the indications**
 - no desperate patients
 - no extraperitoneal metastases
 - exception: pleural effusion in ovarian cancer
- **Publish your results**
 - Requirement of Helsinki declaration

Building a PIPAC program (Summary)

- Educate & build support
- Identify interested parties & stakeholders
- Address safety issues
- Make business plan & address reimbursement issues
- Gain backing of administration
- Obtain high pressure injector & prepare OR
- Equipment list
- Identify & educate operative team
- Case simulation → First case

