Embedding Clinical Trials in the AHSQC

Michael J. Rosen MD, FACS
Director, DDSI Research
Paradigm Shift in Clinical Research
Objectives

• Why perform a registry based trial?
• How do we technically design a Randomized Controlled Trial embedded in the AHSQC?
• What does it take for you to get involved?
• What will the next RCT be, group discussion?
What is a Registry-Based Clinical Trial?

• Designed to test the effectiveness of an intervention in routine clinical practice

• But Use Registries to:
  - collect the data
  - randomize subjects
  - assess the outcomes of interest
What is the benefit of a Registry-Based Trial?
Challenges of Traditional RCT’s

- Logistics
- Expensive
- Difficult to Enroll
- Difficult to Follow-up
- Limited Generalizability of findings
Why a Registry-Based Trial?

- **Facilitated Logistics**
  - No Extra Platforms
  - Data Collected During Routine Practice

- **Low Cost**
  - Data Collection in the Registry
  - Less need for dedicated research staff

- **All is SOC**
  - Better ability to enroll
  - Better ability to complete follow-up

- **Enhanced Generalizability**
  - Hypothesis is tested in the real world
  - Different settings/populations
This is Research, No Longer QI

- Surgeon Obtain Written Consent
- Recorded in paper and EMR
- Baseline PRO’s
- Baseline Pain Scores
Randomization

- At time of randomization
- Surgeon calls Hot-line
- Assigned intervention is communicated and recorded
# Data Collection through AHSQC

### Patient Details

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### Is this patient enrolled in an AHSQC Registry-Based Clinical Trial?

- [ ] Yes
- [x] No

Select AHSQC Clinical Trial:

- [ ] [GTR-000124-31] Trilevel

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Keywords: Data Collection, AHSQC, Patient List Search, Details.
Ongoing Embedded RCTs
Community Based Trials

Is this patient enrolled in an AHSQC Registry-Based Clinical Trial? * 🔄
- Yes
- No

Select AHSQC Clinical Trial *
- NCT03541941 - Exparel vs Bupivacaine Hydrochloride vs. Placebo for Postoperative Analgesia after Open Retromuscular Hernia Repair
- NCT03082391 - Heavy Weight Versus Medium Weight Mesh in Ventral Hernia Repair (Cleveland Clinic)
- NCT03276871 - Telescopic Dissection vs. Balloon Dissection in Laparoscopic TEP inguinal hernia repair (Cleveland Clinic)
- NCT03283982 - Laparoscopic vs. Robotic Ventral Hernia Repair with IPOM (Cleveland Clinic)
Follow-up visits

• Based on standard of care
  • 30 days, 1 year
  • Surgeon Enters Follow-up Info
  • Patient fill AHSQC PRO’s while in the waiting room
Data Outside of AHSQC

- Redcap
- Adds
  - Cost
  - Complexity
A few take home points...

1. It is feasible to run a RCT with low cost and facilitated logistics? Yes!

2. Can you participate in AHSQC-based trials if you want to? Yes!

But,

3. This is Research! Written Consent, IRB policies, Human and Patient Data Safeguards
What does it take for you to participate?

- Active participation in the AHSQC
- Plan for PRO completion in routine practice
  - Nurse hands out to all preop and post op
  - Fellows input data
- Plan for who signs consents
- Plan for who updates regulatory binder
Heavy Weight versus Medium Weight Mesh for Clean Retromuscular VHR

- Total Patients: 352
- Current Enrollment: 326
- Trial Ongoing: 18 Months
- Participating Centers: CCF, Greenville, MCW, Vanderbilt
18 Months
Telescopc versus Balloon Dissection for TEP Inguinal Hernia Repairs

- Total Patients: 40
- Current Enrollment: 38
- Trial Ongoing: 12 Months
- Participating Centers:
  - CCF Main Campus, Fairview, Hillcrest, Twinsburg ASC
Where are we now ...

Enrollments Status

Goal

1
10
26
40

1-Oct 1-Nov 1-Dec 1-Jan 1-Feb 1-Mar 1-Apr 1-May 1-Jun 1-Jul 1-Aug
Laparoscopic versus Robotic IPOM

- Total Patients: 70
- Current Enrollment: 26
- Trial Ongoing: 12 Months
- Participating Centers: CCF Main Campus
RCT of Exparel/Bupivicaine/Placebo for Open Retromuscular VHR

- Total Patients: 162
- Current Enrollment: 14
- Trial Ongoing: 2 Months
- Participating Centers:
  - CCF
So What’s Next?

• Thoughts??????
Potential Options

• Are preoperative antibiotics necessary prior to clean open ventral hernia repair with mesh?

• Repeat RCT of mesh versus no mesh for small to medium sized defects in open VHR with 4:1 Closure (Luijendijk RW, NEJM, 2000)
Other Ideas

- Sac imbrication during robotic inguinal repairs
- Mesh fixation yes or no for retromuscular repairs
- Foley for lap inguinal repairs yes or no
Discussion