# Challenges in Generating Evidence for Obesity Therapies

Laura Eaton, RN, BSN, CCRN-R

# Current ways to generate evidence for obesity therapies

- Randomized controlled trials
- Post-approval studies
- Investigator initiated studies
- Bariatric surgery registries

# Challenges with RCT for Obesity Therapies

- Patient Compliance
- Potential for subject self un-blinding in sham controlled studies
- Lack of standardized behavioral modification programs among sites
- Lack of standardized outcome measures (e.g., %TBWL versus %BMI loss) between studies and sponsors
- No head to head device trials (not all devices are created equally)
- Difficult to collect health economic data needed to support coverage and coding
- Typically small sample sizes
- Long-term follow-up (beyond 5 years) difficult
- Costly

# Challenges with Post-Approval Studies

- After FDA approves a device, clinicians typically use marketed devices in a broader patient population and for longer periods than are entailed in premarket studies
- Post-approval study designs typically mimic pivotal study design and are not representative of a “real world” setting
  - Does not enable collection of data on off-label uses
- Similar issues as RCT (e.g., patient retention, long-term follow-up, etc.)
- Highly burdensome and repetitive

# Challenges with Current Registries

- Only Bariatric Surgery Centers of Excellence participating in obesity intervention registries (BOLD, MBSA-QIP)
- Limited collection of data for endoscopic procedures
- Passive reporting of adverse events
- Device utilization is not representative of actual usage in U.S.
- Device manufacturers have limited, to no, access to data or reports

# Opportunities for Future Registries

- Track the experience of a broader patient population and practice setting for a longer period
  - Indefinite follow-up period over the full product lifecycle
  - Quickly identify poorly performing devices
- Support coding and reimbursement by linking registries with electronic health information
- Collectively gather data from all disciplines who are using obesity intervention devices and therapies
- Streamline data collection through efficiencies that reduce time and cost of reporting
- Provide unique device-specific data

# Conclusions

- Evidence generation for post-approval studies is highly burdensome and doesn't provide real-world evidence
  - Time and cost of PAS distracts from device innovation
- Bariatric Surgery and Gastroenterology societies have become better at registries
  - We can leverage this experience to provide evidence at a lower overall cost than PAS
- Auditing & monitoring of study data and study progress will need to be considered
  - FDA, manufacturers, patient advocates, and clinical societies need to come together to be successful

# Questions?