Health Technology Assessment (HTA) and Real World Evidence (RWE)

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Disclosure

I have the following relevant financial relationships to disclose:
• Employed by Johnson & Johnson Inc.
Emerging global concepts in HTAs for Medical Devices

- Need for HTAs to be fit for purpose, recognizing differences between devices and drugs
  - Regulatory pathways differ by evidence requirements
  - Significant challenges for RCTs to be conducted in surgical procedures
  - Lack of evidence protection for devices
  - Strong effect of surgeon and hospital on outcomes
  - Rapid life cycles and lack of standard comparator group
- RWE provides a new source of evidence beyond RCTs and requires time and usage for evaluation
  - Science and capabilities emerging across industry and healthcare
RWE Capability a Significant Investment to Ensure High Quality and Robust Data

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Source: Deloitte Analysis
Medical Devices: Application of RWE

- HTA evaluations after launch allow for the evaluation of evidence after period of adoption
  - Registries, Observational Studies, Large Database Analyses

- Hospital procurement process and Value Assessment Committees evaluate “Total Value” including service model, inventory management, sterilization, professional education in addition to technology evidence AND may consider coverage with evidence or alternative contracting models to capture proof of value

- Industry can play a pivotal role with emerging investment capabilities in RWE to provide up to date analyses leveraging large databases and reports from registries to hospitals, payers, and surgeons
UK – Total Hip Replacement

- **Objective**: To appraise the clinical and cost effectiveness of total hip replacement and surface replacement

- **Clinical evidence**: a combination of “traditional” methods (a systematic review of RCTs, published and registry studies) and RWE (individual patient data from the National Joint Registry)

- **Collaborative process**
  - Leveraged insights on the joint registry and availability of patient level data (NJR)
  - Training on the complex combination of products
  - Insights on patient registry data
  - Provided real world time and motion data
  - Identified a broad range of surgeons, patient societies, and surgical societies for NICE to reach out to for insights
  - Surgeon roundtable insights to fill gaps

- **Insights**
  - Inclusive process: organizations invited to participate as consultees and commentators

Source: https://www.nice.org.uk/guidance/ta304
Canada – Drug Eluting Stents

• In 2002, uncertainty on who would benefit the most from this new technology and no long-term follow up studies

• In 2003, Ontario approved $12M for DES within a field evaluation to independently assess effectiveness and cost-effectiveness allowing immediate diffusion through coverage with evidence development

• Almost 20,000 patients were included in this field evaluation

• In 2007, OHTAC issued it’s recommendation on DES utilization based on their field evaluation:
  • DES should be offered to patients who have 1) diabetes and 2) long lesions and/or narrow lesions
  • Continue with the data collection

• Insights:
  • Re-assessment helped to target appropriate patients and diminish uncertainty: not a yes/no answer

US-Bariatric Surgery

- 2000: Benefits of bariatric surgery not well understood beyond weight loss and perceived as a “life style/cosmetic” procedure

- 2008: Large US claims data allowed for longer term evaluations and impact on significant comorbidities including diabetes

- Multiple RWE studies to validate and duplicate value of bariatric surgery

- 2017: Medicare National Coverage Policy, Majority of private payers provide coverage also cover

Insights

- Example where broader benefits only established with time
- Increased understanding of obesity as a disease
- Only RWE could explore these benefits in a timely and efficient way
Opportunities

- Thinking of re-assessment not as an “on/off” decision but as a way to assess optimal clinical practice

- Leveraging HTA to evaluate and refine good clinical practice

- Given that HTA resources are scarce, there should be a clear clinical/policy question that needs to be addressed (and the methodology needs to be fit for purpose)

- Collaborate for better access to data

- Establish collaborative, transparent reassessment processes that may enable risk sharing and/or the optimal deployment of a technology