The US Food and Drug Administration allows a previously unapproved device to be used clinically to collect safety and effectiveness data under their Investigational Device Exemption (IDE) category. The process usually falls under 3 different trial categories: noninferiority, equivalency, and superiority. To confidently inform our patients, understanding the basic concepts of these trials is paramount. The purpose of this manuscript was to provide a comprehensive review of these topics using recently published IDE trials and economic analyses of cervical total disc replacement as illustrative examples.

CASE STUDY MOBI-C ARTIFICIAL CERVICAL DISC:

In 2006, an IDE was initiated to study the safety and effectiveness of total disc replacement controlled against the standard of care, anterior cervical discectomy, and fusion. Under the IDE, randomized controlled trials comparing both 1 and 2 level cervical disease were completed. The sponsor designed the initial trial as noninferiority; however, using adaptive methodology, superiority could be claimed in the 2-level investigation. REVIEWING HEALTHCARE ECONOMICS:

Healthcare economics are critical in medical decision making and reimbursement practices. Once both cost- and quality-adjusted life-year (QALY) are known for each patient, the incremental cost-effectiveness ratio is calculated. Willingness-to-pay is controversial, but a commonly cited guideline considers interventions costing below 20 000 $/QALY strongly cost effective and more than 100 000 $/QALY as not cost effective.

While large Food and Drug Administration IDE studies are often besieged by complex statistical considerations and calculations, it is fundamentally important that clinicians understand at least the terminology and basic concepts on a practical level [1)].

1)
Ament JD, Mollan S, Greenan K, Binyamin T, Kim KD. Understanding United States Investigational Device Exemption Studies-Clinical Relevance and Importance for Healthcare Economics. Neurosurgery. 2017 Jun 1;80(6):840-846. doi: 10.1093/neuros/nyx048. PubMed PMID: 28368529.