by the year 2020, primarily because of external demands and internal investments.

**PHP17** SURGICAL INNOVATION: DO WE NEED A MORE BALANCED FRAMEWORK FOR EVIDENCE?

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**OBJECTIVES:** Health technology assessment bodies are increasingly reviewing the clinical and economic evidence on various surgical procedures. Such reviews typically use a hierarchy of evidence, with randomized controlled trials (RCTs) designated Level I evidence and case-control and case-series studies designated Levels III and IV. The objective of this study was to explore the evidence available to determine the value of a well-established surgical procedure.

**METHODS:** A structured search of PubMed was conducted on rotator cuff surgery using Medical Subject Heading search terms. Internet searches identified evidence-based guidelines for this condition. **RESULTS:** Two RCTs evaluating the efficacy of arthroscopic repair of rotator cuff tears concluded that arthroscopic repair was superior to the alternatives studied. Ten systematic reviews examining studies of surgical technique modifications for rotator cuff surgery were identified. All 10 reviews reported that, despite limitations, there was enough evidence to identify surgical techniques that resulted in improved clinical outcomes. Most of the systematic reviews found Level III or Level IV evidence recommending one type of surgery over another. In 2010, the American Academy of Orthopaedic Surgeons (AAOS) published evidence-based guidelines to improve treatment for 25 different rotator cuff problems; 74 studies were deemed of sufficient quality for use in the guidelines. However, more than half of the guidelines’ recommendations (n=15) were inconclusive owing to the levels of evidence available for review. **CONCLUSIONS:** The pharmacological framework for evidence hierarchy often may not be appropriate for surgical procedures and devices. There is a challenge to running clinical trials in surgical setting, making them impractical and unaffordable. Especially with well-established procedures, evidence review will require a balanced approach using the best available evidence and clinical expertise.

**PHP18** THE EVOLUTION OF OUTCOMES GUARANTEES, DO THEY ALIGN WITH THE PRINCIPLES OF THE AFFORDABLE CARE ACT (ACA)?

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**OBJECTIVES:** The Affordable Care Act (ACA) has been upheld by the United States Supreme Court. Four principles of the ACA are driving changes in the US health care system, those principles are improving outcomes, quality, safety and containing costs. This study looks at several product outcome guarantees to see if they support the cited ACA principles to benefit the health care system.

**METHODS:** A review and analysis of published payer coverage policies and contracts entered into by product manufacturers with several US payers. **RESULTS:** Three publically available examples were analyzed and described here. A literature search was conducted on outcomes guarantees and contract risk transfers. The objective is to examine the complexities to determining outcomes guarantees with well-established surgical procedures. A structured search of PubMed was conducted on rotator cuff surgery using Medical Subject Heading search terms. Internet searches identified evidence-based guidelines for this condition. The objective is to explore the evidence available to determine the value of a well-established surgical procedure. **CONCLUSIONS:** The pharmacological framework for evidence hierarchy often may not be appropriate for surgical procedures and devices. There is a challenge to running clinical trials in surgical setting, making them impractical and unaffordable. Especially with well-established procedures, evidence review will require a balanced approach using the best available evidence and clinical expertise.

**PHP22** PAYMENT PERSPECTIVES ON THE FUTURE USE OF CER TO INFORM COVERAGE AND REIMBURSEMENT DECISIONS FOR NEW DRUGS

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**OBJECTIVES:** Our aim was to gather perspectives from a diverse group of payers on how they are changing their field of evidence (CER) and relative effectiveness (RE) to impact evidentiary standards for pricing and coverage decisions by 2020. **METHODS:** We conducted semi-structured interviews with 40 officials representing 20 payers, primarily those in the US and Europe. An online survey was used to assess current use of CER/RE evidence and potential trends that might influence its use for decision making by 2020. **RESULTS:** The interviews enabled to elicit discourses of CER and RE being around 4 hypothetical cases resembling therapeutics expected to be more common and poised to create policy challenges by 2020. Topics included acceptance of designs (e.g., pragmatic trials) and analytic methods associated with CER/RE (e.g., indirect comparisons). A systematic current review was used to extract relevant information. **RESULTS:** While there was marked diversity in responses, there were some common themes. Respondents anticipate growing reliance on policy levers such as conditional reimbursement and prior authorization to control diffusion. Randomization will remain an essential component to assess comparative effectiveness. Respondents anticipate more aggressively using techniques like cluster randomization to conduct studies in their populations and more important insights into situations when certain CER evidence may be acceptable (e.g., observational data when differences between drugs are largely convenience). Payers would like to see but remain skeptical about harmonized approaches such as adaptive licensing to stage CER, in development in the US. **CONCLUSIONS:** Industry perceptions of CER will change payer's evidentiary requirements in the future are consistent with our findings. This arises both from a growing investment in analyses of their own data to anticipate and respond to potential trends that might influence their use for decision making by 2020. The objective of this study was to explore the evidence available to determine the value of a well-established surgical procedure.

**CONCLUSIONS:** The pharmacological framework for evidence hierarchy often may not be appropriate for surgical procedures and devices. There is a challenge to running clinical trials in surgical setting, making them impractical and unaffordable. Especially with well-established procedures, evidence review will require a balanced approach using the best available evidence and clinical expertise.

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