

transparency in both process (committee membership, conduct of meetings) and outcomes (publication of how individual decisions were made). Several opportunities exist to improve transparency, including release of relevant documentation to the public domain. Consistency could potentially be enhanced by the introduction of MCDA-like approaches or the introduction of other more explicit decision rules. However, such initiatives are limited by the resource-intensity of implementation and potential lack of acceptability to decision-makers. **RECOMMENDATIONS:** Six key recommendations are presented. These largely consider the establishment of procedures and resources for the appropriate documentation and release of information to the public, and the leveraging of local expertise to focus on refinement of the drug reimbursement decision-making process, particularly regarding existing and potential decision rules.

PCP27

EVIDENCE-BASED VALUATION: A NOVEL FRAMEWORK FOR DRUG PRICING

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OBJECTIVES: Value demonstration in healthcare remains a challenge. We examined traditional approaches to pricing and the evolution of value-based pricing (VBP), to inform development of a new framework for evidence-based valuation (EBV). EBV incorporates clinical, economic and humanistic factors, as well as stakeholder perception of key product attributes, to estimate a comprehensive value-based price range for medicines. **METHODS:** EBV provides a healthcare-specific structured framework for estimating an intervention's price based on its value to various stakeholders. The EBV framework quantifies four key variables – comparator cost, differentiation, quality of evidence and market forces – to derive a valuation reflecting utility gained healthcare stakeholders. In practice, utilization of EBV includes: identifying key clinical and non-clinical value attributes; assessing evidence requirements; and leveraging elements of HEOR, multicriteria decision analysis, and primary research to quantify value of key attributes. We tested this model in 7 oncology products across different indications: three drugs indicated for renal cell carcinoma, three drugs for prostate cancer, and one drug for melanoma. HTAs, published trial results, and publications archived in PubMed between 2005 and 2017 were analyzed to identify key value attributes. The following five attributes were considered: overall survival (OS); progression free survival (PFS); population size; trial comparator; and adverse events. **RESULTS:** An aggregate value was generated for each product using the selected attributes based upon the published trial results and after assigning scores based on qualitative criteria. Initial value scores had a moderately positive correlation with WAC ($r=0.67$). While it is not expected that EBV should be perfectly correlated with WAC, limitations may include lack of inclusion of discounts from WAC, small qualitative sample size and limited set of product attributes included in the exercise. **CONCLUSIONS:** The method described offers a means to appraise pharmaceuticals in an environment increasingly focused on evidence-based medicine and value-based healthcare.

PCP28

AN ALGORITHMIC APPROACH TO OPTIMAL STUDY DESIGN FOR OUTCOMES RESEARCH

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OBJECTIVES: Research design is complicated by a multitude of factors, including the differing evidentiary needs of health system stakeholders, the differing measures that meet their needs, and the differing methodologic approaches that can be used to collect clinical, economic and real-world data. Health economists have developed algorithms for use in selecting the most appropriate modeling approach, but no such solution exists for selecting the most appropriate real-world research design. The objective of this study was to develop and test an algorithm that addresses this gap. **METHODS:** The algorithm consists of a series of structured yes/no questions, as follows: (1) Is the study focused on an intervention? (2) If so, is the intervention on the market? (3) Is the study intended to be comparative? (4) If so, is treatment assigned by study protocol? (5) Are data needed for the study available from existing sources? (6) If so, are those existing sources accessible in computerized form (i.e., in administrative claims or electronic medical records)? And (7) is the study setting real world? As research designs vary dramatically in terms of time and cost requirements, the algorithm steers the researcher to the most cost-effective option first in those instances in which multiple approaches are viable. **RESULTS:** Responding to each of these yes/no questions within the structure of the algorithm successfully guides the researcher to one of six different research designs: (1) retrospective database analysis; (2) manual chart review; (3) prospective non-interventional study / registry; (4) traditional randomized controlled trial; (5) pragmatic clinical trial; or (6) economic modeling. **CONCLUSIONS:** Algorithms have proven invaluable to guide health economists on optimal selection of modeling approach. This research shows that an algorithmic approach also can facilitate selection of optimal real-world research design based on structured responses to a series of questions regarding the study focus and objectives.

PCP29

DELPHI METHOD: A QUALITATIVE APPROACH FOR QUANTITATIVE RESULTS

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BACKGROUND: Delphi method involves gathering expert opinion through a series of progressive and iterative questionnaires to reach consensus. In low-resource setting, researchers may not be able to conduct surveys representative of target population in order to obtain precise estimates of health outcomes. Delphi method has increasingly been used to obtain quantitative data, such as estimating country-specific prevalence and disease-specific costs, probabilities or resource utilization for health economic models. Although results from this method have an equal potential to affect the study quality and validity, it has received proportionally less attention in terms of description in the methodology section. Given the variance in

the use of Delphi method, reporting guidelines could help improve reporting of this research, and thereby allow readers to be aware of the accuracy of data and conclusions. **APPROACH:** We proposed a set of reporting guidelines to communicate quantitative findings derived from this method. These include (1) explaining how the Delphi method is used, (2) stating variables which have to be estimated by the expert panel, (3) providing definition of the variables, (4) specifying references of base values which experts referred to, (5) describing expert panel selection with eligibility criteria and including conflicts of interest, (6) outlining participation and attrition rates for each round, (7) detailing statistical analyses and interpretation in arriving at final agreed values, (8) reporting both quantitative results and textual comments for each round of analysis and (9) appending revised questionnaires. **CONCLUSION:** We anticipate the implementation of this will promote transparent and accurate reporting of research using Delphi method for obtaining quantitative data.

PCP30

PERSPECTIVES OF QUALITY RISK MANAGEMENT APPLICATION IN ECONOMICAL EVALUATIONS ALONGSIDE CLINICAL TRIALS

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Integration of economical analysis into clinical trials becomes a widespread practice over the past two decades because it provides a number of advantages and feasibility for cost-effectiveness studies. At the same time, weaknesses related to trial-based "artificial" nature of such studies represent challenges for proper conduction of economical evaluations. Thus development of effective practical approaches focused on assurance reliability of economic data generated alongside a clinical trial is of great interest. Application of risk-based management in "piggyback" evaluations is a perspective way helping to couple with issues that hamper collection of sound health-economic data in each particular trial. It is rational to forecast risks that compromise data validity at the stage of trial planning and elaborate a plan of its mitigating using risk-proportionate approach. Identification of risks should include analysis of risk factors causing issues in a particular trial-based economical evaluation by following areas: trial design, subjects' enrollment and randomization, data collection and analysis. It is reasonable to monitor economic data quality and completeness using key risk indicators enabling to control identified risks influence in real time. In this way, quality assurance measures are implemented in a proportionate manner according to risks value. Sponsors and researches involved in clinical trials with economical evaluations should pay special attention to elaboration of quality risk management plan including risk identification, assessment and control. It is important to implement key points of this plan during all stages of economic data collection. Applying key risk indicators during study monitoring, study sponsors will successfully integrate health-economic data into clinical trial data management system ensuring its robustness and validity in a rational manner. Thus, application of quality risk management is an effective strategy for overriding challenges of cost-effectiveness analysis alongside clinical trial strengthening its position as an important tool of generating evidence-based clinical and economic data.

PCP31

WEB-BASED COMPUTERIZED ADAPTIVE TESTING VIA AN OPEN-SOURCE PLATFORM

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OBJECTIVES: OpenCAT is an open-source computerized adaptive testing (CAT) web delivery platform built with reusability, accessibility, and adaptability in mind. CAT survey question sequences are dynamic and tailored to individual participants, presenting as few questions as possible while collecting all the necessary information. The aim of building this platform is to help patients assess their recovery progress, to allow clinicians and researchers to administer adaptive questionnaires and collect results for further analysis, and to let IT personnel easily deploy the system in a variety of environments—including when HIPAA requirements apply. **DESIGN:** It is designed with accessibility in mind, and offers full Section 508 and WCAG 2.0 Level AA compliance to enable use within federally-funded research programs or when contracted by a federal agency. Furthermore, the user interface is optimized for use with both a touchscreen and a mouse, and adapts to any screen size (from smartphones to desktop computers). **ARCHITECTURE:** For developers, it is written with modularity in mind. The platform allows for an easy replacement of item banks, incorporation of different adaptive testing algorithms, and delivery of different data visualizations, all without touching the core of the application. By making the platform open source and providing a RESTful API, while simultaneously enabling proprietary algorithms and item banks to remain private, we encourage widespread community adoption and reusability across different audiences and patient populations. OpenCAT can also be deployed as a Docker image, which makes the application portable, scalable, and platform-agnostic. **CONCLUSIONS:** OpenCAT has been utilized within the scope of two projects so far. We continue to incorporate feedback from researchers, organizations, and users, expanding the feature set. Planned future work includes a stand-alone version for deployment in settings without internet access.

PCP32

MEASURING TREATMENT SATISFACTION WITH MEDICATION FROM PATIENTS' PERSPECTIVE: CONCEPTUAL MODELS AND A REVIEW OF MEASURES

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PURPOSE: Review the nature of patient satisfaction with care and treatment satisfaction, summarize a conceptual model for treatment satisfaction with medication (TSM), assess and refine TSM conceptual model based on qualitative analysis; and compare current measures of treatment satisfaction with medication. **DESCRIPTION:** Patient satisfaction with care is considered to be: a health out-