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GENENDER-SPECIFIC SAFETY OUTCOME REPORTS FOR NEW MOLECULAR ENTITY DRUGS
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OBJECTIVES: To describe reporting rates of gender-specific safety outcomes for new molecular entity (NME) drugs approved from the US Food and Drug Administration (FDA) between 2009 and 2013. Data from the National Formulary (NDA) files for all NME drugs that were approved for systemic use in men and women were surveyed from the US FDA database. Specific reviews and key word searches were made for descriptions or tabulation of gender-specific inferential statistics on the drug safety section. The rates of inclusion of explicit descriptions or reports of statistical significance were calculated.

RESULTS: Of all 457 approved drugs during the study period, 118 NMEs were included for the evaluation. Of those, gender-specific risk estimates were available for 29 NMEs, 13% (95% CI 8.3% - 19.3%). Gender-specific risk estimates were included in 51% (60/118) of the NMEs. Of the 51 NMEs with gender-specific risk estimates, significant improvement in risk estimates from 29.17% (CI 18.50 - 39.83) to 61.76% (CI 49.08 – 74.45) at program completion was observed. All NMEs had a successful recommendation rate of 100% (29/29).

CONCLUSIONS: About one in four NDA reviews for NMEs was lacking sufficient descriptions on gender-specific safety outcomes and the format of the safety outcome reports by gender was inconsistent.

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IMPROVEMENTS IN SELF-REPORTED REAL-WORLD DECISION-MAKING ABILITY AFTER COMPLETION OF A COMPARATIVE EFFECTIVENESS RESEARCH CONTINUING EDUCATION CERTIFICATE
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OBJECTIVES: To describe the adoption and utilization of a CER Collaborative (AMCP, IPSOR, and NPC) developed task force reports and online CER Collaborative tools, to improve learner ability and confidence to assess CER studies for use in real-world decision-making.

METHODS: Twenty healthcare professionals registered for a 19-hour, ACSF-approved CER Certificate Program (CCP) which included five self-paced, online modules and case studies: prospective and retrospective observational studies, indirect treatment comparisons, models, and synthesizing information from studies with various designs. A final live workshop was conducted to develop learner skill through case presentation and peer critique. After CCP completion, learners assessed their ability to evaluate CER studies using a Likert scale (1=strongly disagree, 5=strongly agree).

RESULTS: In the first cohort of learners, 18 (90%) completed the program on schedule. Significant improvement in self-reported ability to evaluate CER study design on their relevance and credibility ranged from 29.17% (CI 18.50 - 39.83) to 61.76% (CI 49.08 – 74.45) at program completion. Learners indicated high confidence in their CER evidence assessment abilities (mean score 4.17, CI 3.93 - 4.46). CONCLUSIONS: As new or unfamiliar CER study designs and analyses become available, there will be an increasing need for clinicians and other decision-makers to understand how to assess the relevance and credibility of CER evidence using the developed CER Certificate Program, which was associated with improved healthcare decision-makers’ self-reported ability to evaluate CER and apply it for use in decision-making.

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PERCEPTIONS OF THE ROLES OF PATIENTS AND PAYERS IN PHARMACEUTICAL MARKET ACCESS
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OBJECTIVES: A review of the literature was conducted to determine whether there is an appropriate definition for market access. The original perception was that it relates to securing market authorization, as well as enabling prescribing of the product. A working definition for pharmaceutical market access was proposed as it relates to securing market authorization, as well as enabling prescribing of the product. A working definition for pharmaceutical market access was proposed as it relates to securing market authorization, as well as enabling prescribing of the product.

METHODS: A review of the literature was undertaken, followed by the development of a questionnaire aimed at eliciting the various determinants of pharmaceutical market access, both from the patient and payer perspectives. This survey was administered to professionals in three settings involving ISPOR European Congress, EMAUD educational course, and a pharmaceutical company, with forty eight, forty five, and seventeen respondents, respectively. The respondents were categorized as: patients, health care professionals, payers and other interested parties (e.g., patient advocates, policy makers, health technology assessment agencies, payers, and other HTA organizations). Trends in CER guidance were analyzed to provide insights on likely recommendations of new products as manufacturers navigate the market. METHODS: All analyses were performed using descriptive statistics. Confidence intervals were estimated for proportions of recommendations following full submission, resubmission or abbreviated submission were reviewed and sub divided into British National Formulary (BNF) category. RESULTS: From 2002-2014, there were 8 abbreviated submissions for orphan products, 68 full submissions and 25 full submissions. The positive recommendations rate (with or without restriction) from 2002-2013 was 53% (92); in 2014 this recommendation rate increased to 89% (n=9). Up to 2013, malignant disease and immunosuppressive treatments accounted for 40% of the technology appraisals, which overwrite earlier guidance, were not accounted for. In 2013, evidence for 7 orphan products was not submitted to the SMC within 13) but 100% were positive recommendations for orphan products than no-orphan products (67% versus 73%). Malignant disease and immunosuppressive treatments were the most common STAs but had the second lowest recommendation rate (53% n=71). Cardiovascular treatments were most consistently recommended (100%, n=19). CONCLUSIONS: A decreasing proportion of STAs include multiple technologies. There have been substantial variations in terms of recommendations for STAs and different approaches to orphan products, possibly due to the absence of appraisal recommendations or lack of evidence and evidence review groups which may contribute to the predictability of orphan products. Please provide the correct citation for this reference.