Canadian Agency for Drugs and Technologies in Health is funding initiatives such as the Canadian Platform To Increase Usage of Real-world Evidence (CAPTURE) project in which physicians collaborate on gathering RWD to inform and improve standard health care practices. Finally, some US hospitals are leveraging the RWD they generate to optimize clinical and economic outcomes for their populations. Additionally, US payers are funding comparative effectiveness studies in crowded markets with costly assets and generic competition. CONCLUSIONS: There is a need to monitor HTA agencies’ use of RWD to optimize access of the right treatments to the right patients. There is also a need to approach evidence generation in a systematic manner to differentiate assets beyond approval and initial F&R as well as to generate evidence only for those gaps that will impact health care decisions.

PHP112 EVIDENCE-BASED PRACTICE RECOMMENDATIONS: HEALTH QUALITY ONTARIO’S APPROACH
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OBJECTIVES: As part of the Ontario Government’s health system funding reform initiative, the Evidence Development and Standards division at Health Quality Ontario (HQO) was tasked with developing episodes of care consisting of evidence-based, best practice recommendations. The HQO clinical handbooks span both medical and surgical conditions, in acute care and community-based settings, and include between 25 and 100 recommendations each. The objective is to describe HQO’s methodology for developing evidence-based recommended best practices for episodes of care. OBJECTIVES: To develop the rapid timelines of the government mandated funding reforms.
METHODS: Over a 1-year period, the times taken for deriving evidence-based recommended practices was systematically and iteratively developed by HQO clinical epidemiologists in collaboration with methodologists, clinical experts and stakeholders to develop recommendations. The resulting approach for applying evidence-based best practice recommendations included consideration of various evidence sources and consensus from expert panels which were formed for each of the clinical topics. Preference was given to existing Ontario Health Technology Assessment Committee (OHTAC) recommendations as these are developed under a decision-making framework that considers the clinical benefit offered by a health intervention, in addition to value for money, societal and ethical considerations; and economic and organizational feasibility. RESULTS: The approach for applying evidence-based best practice recommendations did not exist, international guidelines were reviewed and selected based on their relevance and assessment of the rigor of the underlying evidence using the AGREE II instrument. Uncertainty or conflict between the guidelines, or by the expert panel members, was addressed with a multiple stakeholder process. The approach was given to existing Ontario Health Technology Assessment Committee (OHTAC) recommendations to the right patients. There is also a need to approach evidence generation in a systematic manner to differentiate assets beyond approval and initial F&R as well as to generate evidence only for those gaps that will impact health care decisions.

HEALTH CARE USE & POLICY STUDIES – Patient Registries & Post-Marketing Studies

PHP113 PERCEIVED BENEFITS AND BARRIERS OF MANUFACTURER POST-MARKETING OUTCOMES STUDY COLLABORATIONS
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OBJECTIVES: To assess the currently perceived benefits and barriers of post-marketing, payer-manufacturer collaborations by US pharmaceutical manufacturers. METHODS: Regional and national US payers and pharmaceutical manufacturers with experience in collaborative post-marketing outcomes study endeavors were invited to participate in an hour-long telephone survey. The survey consisted of questions regarding their perceptions on the benefits and barriers of potential post-marketing outcomes study collaborations, as well as attributes of potential collaborators, studies, products or diseases that would be most highly valued. Descriptive statistics were used to characterize the survey responses. RESULTS: A total of 12 payers and 4 pharmaceutical manufacturer representatives participated in the survey. Payers most often mentioned that the greatest benefit to partnering with manufacturers was the value manufacturers bring in terms of expertise and resources (58%). Benefits manufacturers identified included demonstrating consistency in outcomes data relative to randomized clinical trial data and effectiveness in real-world populations. The two most commonly cited barriers by payers regarding participation in these post-marketing outcomes research collaborations included misaligned incentives (58%) and resource intensiveness (58%). The manufacturers felt that payers were generally wary of these types of collaborations due to possible perceptions of influence, and noted that payers are usually only willing to engage and focus on high-budget impact projects and collaborations. Payers’ most important consideration when selecting a pharmaceutical partner for outcomes studies was the willingness of the manufacturer to contribute financially (42%) and analysis (40%) independent of the development objectives and expectations is critical for a successful partnership. CONCLUSIONS: As competition in the pharmaceutical marketplace increases and recent US health care reform moves forward, payer-manufacturer post-marketing outcomes research collaborations will be increasingly critical as a demonstration of value to all stakeholders.

PHP114 ARE PROMOTIONAL STRATEGIES OF LIFESTYLE DRUGS DIFFERENT FROM NON-LIFESTYLE DRUGS? A CONTENT ANALYSIS OF DTC PRINT MEDIA
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OBJECTIVES: The objective of this study was to compare the promotional strategies of drugs (LSD) that target lifestyle drugs (NSLD) by content analyzing DTC print advertisements. METHODS: 142 print advertisements were analyzed to see how LSD and NSLD ads differed with respect to rational appeals, emotional appeals and readability Mann-Whitney U test was performed to compare the ads’ likelihood with respect to the type of promotional claims. Descriptive statistics were computed to summarize data pertaining to different ad features. The dataset was composed of 64 LSD advertisements and 78 NSLD advertisements. The reliability of the study was measured by Cohen’s Kappa for two raters and was found to be adequate for all the variables used in the instrument. RESULTS: Significant differences were observed between LSD and NSLD ads with respect to both emotional appeals (p= 0.009) and rational appeals (p=0.000) based on Mann-Whitney U test. LSD ads focused more on emotional appeals while NSLD ads were heavy on rational content. A logistic regression analysis revealed likelihood estimates for ad claims appearing in the two groups. Feasibility calculated by Gunning-Fog Index for LSD’s was 8.84 and for NSLD’s was 11.56. Flensch-Kinscard grade level for LSD and NSLD was found to be 7.65 and 10.73, respectively, indicating increased complexity of language in NSLD ads, which was mostly reflecting of the greater use of technical scientific language. LSD ads differed with respect to type of content, presentation, structure and complexity as well as promotional strategies adopted. Rational appeals were more predictive of NSLD at type while emotional appeals were predominant in LSD ads.

PHP115 OPPORTUNITIES FOR THE FUTURE OF UNITED STATES MEDICAL DEVICE SURVEILLANCE: AN ANALYSIS OF THE JOINT REPLACEMENT REGISTRY (JRR) LANDSCAPE IN THE UNITED STATES
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OBJECTIVES: Annually, over 1 million people in the U.S. undergo hip or knee replacement registries. Registries provide one mechanism to understand the benefits and risks of medical device technologies. OBJECTIVES: To evaluate feasibility of creating one coordinated, national JRR for post-market surveillance. METHODS: Avalere identified the largest international Consortium of Orthopaedic Registries participants’ list, PubMed searches, abstract reviews, and web searches. Using publicly available sources, characteristics of each registry were recorded in a table. Avalere assessed this data to better understand the feasibility of harmonizing these registry efforts. RESULTS: In total, 25 JRRs were identified: 3 national, 4 state, and 18 local. Established between 1967 and 2011, the registries spanned 14 states with objectives including post-market surveillance, outcomes of operations, research, provider feedback, and value-based purchasing. Of the 20 registries with enrollment information, 15 enrolled 1-10 hospitals, 4 enrolled 11-50 hospitals, and 1 enrolled more than 200 hospitals. One registry collected only Level I data; 2 collect Levels I-I-I, 9 collect Levels I-I-III, and 2 collect Levels I-I-V; 11 registries did not have data level collection information. Registry funding sources were self-funded (n=7), publicly funded (n=1), private payer (n=1), and a combination (n=2). CONCLUSIONS: U.S. registries typically are established to serve the needs of one or two operating organization, which influences factors such as the registry’s mission, recruitment efforts, and data level collected. While the number of JRRs reflects stakeholders’ recognition of their value, the disparate (and sometimes competing) national efforts may pose challenges to the creation of a national JRR that can coordinate existing registries, ensure high quality data collection, and facilitate early surveillance to support federal regulatory needs.

HEALTH CARE USE & POLICY STUDIES – Prescribing Behavior & Treatment Guidelines

PHP116 USE OF GLASSWAL ANTIMICROBIAL AUDIT TOOL (GAAT) TO ASSESS ANTIMICROBIAL USE IN THE ICUS OF AN INDIAN PUBLIC TEACHING HOSPITAL
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OBJECTIVES: Continuous, indiscriminate and excessive use of antimicrobial agents very detrimental to emergence of antimicrobial-resistant organisms. Antimicrobial resistance substantially raises health care costs and influences patient outcomes (morbidity & mortality). There is a dearth of data available on appropriateness of parenteral antimicrobial therapy in the ICUs, especially in Indian settings. This study involves applying the GAAT criteria to assess the antimicrobial use. METHODS: This prospective observational study was carried out in the intensive care units of a public teaching hospital over a period of 12 weeks. All the relevant data was recorded in a pre-specified form and was based on standardized ECMI criteria. Adherence to the first 7 days of ICU stay and the changes made in the treatment regimen were carefully evaluated. Parenteral antimicrobial therapy was assessed for appropriateness using GAAT. Theavaneous antimicrobial therapy was assessed and the percentage of two or more of the GAAT criteria were met. RESULTS: 85 ICU patients’ records were screened during the study period. Out of total 85 patients, 44 patients were male while remaining 41 were females. Of these, 74 patient records were found to have complete data for studying GAAT criteria. The parenteral therapy was found to be appropriate in 61 patients (82%), as per GAAT criteria. CONCLUSIONS: Parenteral antimicrobial therapy, as per GAAT, in this study was appropriate in 82% of the patients. This is a preliminary study, future large scale studies should be carried out over a longer period of time to draw any logical conclusion.