

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 P&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

Brener SS, Nikitovic M, Chambers A, Ghazipura M, Schaik AK, Lambrinos AI, Levin L  
Health Quality Ontario, Toronto, ON, Canada

**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 within the rapid timelines of the government mandated funding reform. **METHODS:** Over a 1-year period, the method for deriving evidence-based recommended practices was systematically and iteratively developed by HQO clinical epidemiologists in collaboration with methodologists, clinical experts and stakeholders. **RESULTS:** The resulting approach for applying evidence to 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 using 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. Where OHTAC recommendations did not exist, international guidelines were reviewed and selected based on their contextual relevance and assessment of their rigor of development using the AGREE II instrument. Uncertainty or conflict between the guidelines, or by the expert panel members, was addressed with systematic evaluations of the literature through rapid reviews and evidence-based analyses. **CONCLUSIONS:** While continually evolving to balance thoroughness and timeliness of evidence, HQO has developed a method of deriving episode of care recommended best practices set on an evidentiary base within a time-constrained government mandate.

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

##### PHP113

##### PERCEIVED BENEFITS AND BARRIERS OF PAYER-MANUFACTURER POST-MARKETING OUTCOMES STUDY COLLABORATIONS

Olvey EL<sup>1</sup>, Svoboda K<sup>2</sup>, Coraggio R<sup>2</sup>, White NP<sup>1</sup>, Yi D<sup>2</sup>, del Rosario C<sup>2</sup>, Malik S<sup>2</sup>  
<sup>1</sup>NucleusX Market Access, Altanta, GA, USA, <sup>2</sup>Perceptient LLC, Somerville, NJ, USA

**OBJECTIVES:** To assess the currently perceived benefits and barriers of post-marketing payer-manufacturer outcomes study collaborations by US payers and 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 four 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 are 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 compromise and align on objectives (42%). Manufacturers agreed that alignment on 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

Shanbhag P<sup>1</sup>, Kapratwar A<sup>1</sup>, Nayak R<sup>2</sup>

<sup>1</sup>St. Johns University, Fresh Meadows, NY, USA, <sup>2</sup>St. John's University, Jamaica, NY, USA

**OBJECTIVES:** The objective of this study was to compare the promotional strategies of life style drugs (LSD) with non-lifestyle drugs (NLSD) by content analyzing print advertisements. **METHODS:** 142 print advertisements were analyzed to see how LSD and NLSD ad messages differed with respect to rational appeals, emotional appeals and readability. Mann-Whitney U test was performed to compare the two groups of drug advertisements 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 NLSD advertisements. Inter-rater reliability 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 NLSD ads with respect to both emotional appeals (p= 0.000) and rational appeals (p=0.000) based on Mann-Whitney U test. LSD ads focused more on emotional appeals while NLSD ads were heavy on rational content. A logistic regression analysis revealed likelihood estimates for ad claims appearing in the two groups. Readability calculated by Gunning-Fog Index for LSD's was 8.84 and for NLSD's was 11.56. Flesch-Kincaid grade level for LSD and NLSD was found to be 7.65 and 10.73, respectively, indicating increased complexity of language in NLSD ads, which was mostly reflecting of the greater use of technical scientific language. **CONCLUSIONS:** The two groups of ads clearly differed with respect to type of content, presentation, structure and complexity as well as promotional strategies adopted. Rational appeals were more predictive of NLSD ad 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

Pratt KI, Song KM, Mitchell K

Avalere Health LLC, Washington, DC, USA

**OBJECTIVES:** Annually, over 1 million people in the U.S. undergo hip or knee replacements. Registries provide one mechanism to understand the benefits and risks of joint replacement in specific populations or care settings. Although countries such as Australia and Sweden have successfully established centralized JRRs, the U.S. has not. Avalere analyzed the diverse landscape of U.S. JRRs to determine the feasibility of creating one coordinated, national JRR for post-market surveillance. **METHODS:** Avalere identified JRRs in the U.S. through the 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, outcome improvement, 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-II; 9 collect Levels I-III; and 2 collect Levels I-IV; 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 their 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) nature of 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 GLASGOW ANTIMICROBIAL AUDIT TOOL (GAAT) TO ASSESS ANTIMICROBIAL USE IN THE ICUS OF AN INDIAN PUBLIC TEACHING HOSPITAL

Gudapati BNS<sup>1</sup>, Tiwari P<sup>2</sup>, Gombar S<sup>3</sup>, D'cruz S<sup>4</sup>, Sachdev A<sup>4</sup>

<sup>1</sup>National Institute of Pharmaceutical Education and Research, Mohali, India, <sup>2</sup>National Institute of Pharmaceutical Education and Research (NIPER), S.A.S Nagar, India, <sup>3</sup>Government Medical College & Hospital, Chandigarh, India, <sup>4</sup>Government Medical College and Hospital, Chandigarh, India

**OBJECTIVES:** Continuous, indiscriminate and excessive use of antimicrobial agents leads 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-designed standardized performa and analyzed. The patients were followed for 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. Intravenous antimicrobial therapy was considered appropriate if 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 antimicrobial 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.