unique challenges for achieving reimbursement and market access. In the current study, we identified key issues influencing imaging diagnostics reimbursement and market access through a review of global health technology assessments (HTAs). **METHODS:** We identified and reviewed global imaging diagnostics HTAs for criteria scrutinized and concerns registered by the issuing agencies. Technologies reviewed in HTAs included computed tomography (CT), ultrasound, positron emission tomography (PET), single photon emission CT (SPECT), magnetic resonance imaging (MRI), laser scanning, thermography and standard camera-based methods. Diagnostic applications were relevant to oncology, gastroenterology, cardiovascular, degenerative, injury/infection, and neurological disease indications. **RESULTS:** For imaging diagnostic applications, HTA agencies scrutinized a variety of criteria fitting categories of evidence relevant to all diagnostic testing. These categories included Clinical Validity/Utility, Economic Value/Cost, Testing Logistics, and Safety/Ethical Considerations. Scrutinized criteria that were unique to imaging diagnostic applications mainly pertained to the Testing Logistics and Safety/Ethical Considerations categories of evidence, such as impact of adding new diagnostic applications on patient wait times for existing imaging procedures (especially for applications using platforms with already burdened queues), safety of imaging diagnostics-associated radiopharmaceuticals and contrast agents, and radiation dose/potential health impact of exposure. **CONCLUSIONS:** Imaging diagnostics hold the potential to improve health outcomes and reduce health care costs through earlier disease detection and avoidance of more invasive methods. To increase the likelihood of favorable reimbursement and market access for novel imaging diagnostic applications, evidence to support HTA review should be considered and planned for early in product development.

PHP30

GETTING TO BETTER VALUE FROM MEDICAL DEVICES: REIMBURSEMENT AND PRICING POLICIES IN EUROPE AND THE UNITED STATES

Sorenson C[1], Drummond M[2], Burns LR[3]
[1]*London School of Economics and European Health Technology Institute for Socio-Economic Research, London, UK,* [2]*University of York, Heslington, UK,* [3]*University of Pennsylvania, Philadelphia, PA, USA*

OBJECTIVES: There is growing concern about the unsustainable rise in health care costs and whether such spending levels are commensurate with better quality of care and improved health outcomes. Consequently, policy makers are aiming to attain greater value from new technologies. This study sought to examine existing reimbursement and pricing policies for medical devices in Europe and the US, identify key challenges in defining and assessing their value, and explore various policy options to obtain greater value from these technologies. **METHODS:** The study examined the respective reimbursement and pricing systems for medical devices based on a critical review of available, relevant scientific and grey literature. In addition, the websites of national payers (e.g., CMS) and HTA bodies (e.g., NICE) were reviewed for key policy documents. **RESULTS:** Current reimbursement and pricing systems for medical devices in both Europe and the US raise a number of issues: 1) the majority of countries apply the same assessment and reimbursement and pricing frameworks to all technologies; 2) most funding decisions in the US are made at the local level, where policies and evidence standards can vary across states/payers; 3) where evidence of value is used in decision making, notably in Europe, it is generally better linked to coverage determinations, as opposed to identifying appropriate reimbursement prices; and 4) a number of methodological challenges exist for measuring the value of devices, including generating evidence of effectiveness via RCTs, accounting for the 'learning curve' of clinicians as well as the complex impact of medical devices on health systems, and capturing some of the benefits afforded by medical devices (e.g., increased patient convenience). **CONCLUSIONS:** New policies focused on improving the clinical and economic base on devices, developing new approaches to assess their value, and strengthening the link between reimbursement and evidence of value are needed.

PHP31

HARMONIZATION OF HEALTH TECHNOLOGY ASSESSEMENT AND REGULATORY PROCESSES AND EVIDENTIARY REQUIREMENTS FOR DRUGS AND DEVICES: OPPORTUNITIES AND CHALLENGES

Tsoi B[1], Masucci L[2], Campbell K[1], Drummond M[3], O'Reilly D[1], Goeree R[1]
[1]*PATH Research Institute, McMaster University, Hamilton, ON, Canada,* [2]*Health Quality Ontario, Toronto, ON, Canada,* [3]*University of York, Heslington, UK*

OBJECTIVES: To describe and evaluate theoretical frameworks and practical examples to harmonize processes and evidentiary requirements in health technology assessment (HTA) and regulatory approval. **METHODS:** A systematic review was conducted to identify relevant scholarly work and policy documents relating to harmonization or alignment of HTA and regulatory processes. Bibliographies were screened by two independent reviewers and websites were evaluated to identify additional relevant documents. To supplement the literature search, semi-structured interviews were conducted with key international stakeholders from a broad range of perspectives including HTA, regulators, academics and payers. **RESULTS:** A considerable degree of overlap exists between HTA and regulatory approval, and harmonization of certain aspects is possible. Various theoretical models have been put forth and there have been a number of practical attempts reported that have drawn to varying degrees on these theories. Based on the international review, approaches to harmonize can be categorized into those: 1) focused on reducing uncertainty in the evidentiary requirements (e.g. early dialogue, alignment of evidentiary requirements); 2) focused on aligning the timeframe and other logistical aspects in the review process (e.g. adaptive licensing, parallel licensing); or 3) a mix of the above two (e.g. pre-market trial development). These strategies can further be classified on a spectrum based on their expected level of structural and organizational change required to implement them into the existing regulatory-HTA processes. Passive processes require less radical structural and operational changes while active processes require greater restructuring. **CONCLUSIONS:** Harmonization of regulatory and HTA processes may be feasible for both pharmaceutical and non-pharmaceutical health technologies. Greater harmonization benefits patients, manufacturers and all levels of the health care system. However, attempts at harmonization so far have raised numerous legal, political and practical issues. These challenges must be considered when introducing a harmonized framework into the existing regulatory and HTA framework.

PHP32

FACTORS ASSOCIATED WITH ONLINE PHARMACY USE IN A NATIONALLY REPRESENTATIVE SAMPLE

Brown JD, Li C
University of Arkansas for Medical Sciences, Little Rock, AR, USA

OBJECTIVES: To examine factors associated with online pharmacy use in a nationally representative sample. **METHODS:** Data were from the 2002-2009 Medical Expenditure Panel Survey. Individuals who participated in the survey for two years and had ≥1 prescriptions were included. Online pharmacy use was assessed by "pharmacy type" variables for medications reported in prescription data files. Univariate analyses of online use were performed with sociodemographic information, medications classes, disease states, Charlson Comorbidity Index (CCI), prescription insurance coverage, and health care expenditures and utilization. Significant variables and variables that have been shown to be associated with internet use for health information were further adjusted in a multivariate logistic regression model predicting online pharmacy use. STATA survey commends were used to account for complex survey design. **RESULTS:** A total of 449 online users were identified across 8 panels of MEPS representing a weighted prevalence of 0.66% and population estimate of nearly 1.5 million. After adjusting for sociodemographic differences, higher nondrug health care expenditures (log-transformed) [OR=1.09 (1.01-1.18)], prescription expenditures (log-transformed) [OR=1.25 (1.14-1.37)], having five or more prescriptions [OR=5.19 (1.639-16.43)], and use of erectile dysfunction medications [OR=2.28 (1.06-4.90)] were associated with more online pharmacy use. Black race [OR=0.48 (0.31-0.74)] and Medicaid coverage [OR=0.29 (0.17-0.52)] were inversely related to online pharmacy use. Among common "internet drugs of abuse"; including stimulants, sedatives, and narcotic medications, only narcotic medications were associated with online pharmacy use [OR=0.67 (0.50-0.90)] in the multivariate regression analysis. **CONCLUSIONS:** Using nationally representative data, this study showed that age, race, insurance coverage, health care expenditures and number of prescriptions are predictors for online pharmacy use.

PHP33

KENTUCKY PHYSICIAN OPINIONS OF THE POTENTIAL RECLASSIFICATION OF PSEUDOEPHEDRINE AS A LEGEND DRUG

Goodin AJ, Freeman PR, Talbert J, Monson K, Blumenschein K
University of Kentucky, Lexington, KY, USA

OBJECTIVES: Pseudoephedrine (PSE) is used as a precursor in the illicit production of methamphetamine. Several policies have been adopted to control access to PSE, including tracking of sales, quantity restrictions and, in two states, the reclassification of PSE as a Schedule III controlled substance. In 2012, the Kentucky Legislature considered a controversial bill proposing the reclassification of PSE as a legend drug available by prescription only. The purpose of this study is to assess physician opinion of the proposed legislation. **METHODS:** A simple random sample of 2000 licensed physicians in Kentucky were mailed a survey that solicited opinions on the proposed PSE legislation. Non-responders were contacted via reminder postcards twice between June and July of 2012 and were offered the option to complete a survey electronically. Response frequencies were calculated and logistic regression was used to analyze the impact of physician characteristics such as confidence in the ability to identify legitimate PSE use, practice type, urbanicity, legislation awareness, and estimated frequency of PSE demand on likelihood of PSE legislation support. **RESULTS:** Excluding bad addresses, 243 surveys were returned (response rate=12.5%). Physician support for legislation to reclassify PSE as a legend drug was mixed, with 41.3% in support, 40.5% in opposition and 18.2% unsure. Physicians supporting the legislation most commonly cited reduced risk of methamphetamine abuse (55.5%) as reason for support. Physicians who reported being confident in their ability to identify legitimate PSE use were more likely to express support (p=0.026), as were those reporting low estimated requests for PSE during peak allergy/flu season (p=0.002). Physicians in urban counties were less likely to express support (p<0.001). **CONCLUSIONS:** These findings suggest that Kentucky physicians are divided on the issue of PSE reclassification and that physician characteristics influence opinion. The potential impact on physician behavior should be considered when evaluating PSE policy options.

PHP34

ASSESSMENT OF THE MECHANISMS OF ACTION OF NEW PHARMACEUTICALS APPROVED BY THE FDA BETWEEN 1980 AND 2011

Kwon S, Araujo-Lama L, Montagne M, Seoane-Vazquez E
MCPHS University, Boston, MA, USA

OBJECTIVES: Mechanism of action (MOA) is the description of a biochemical event, usually indicative of the drug's pharmacological activity. The U.S. Food and Drug Administration (FDA) requires MOA to be described on the drug's label. The MOA is important because it assists health providers in understanding the therapeutic applications and possible adverse reactions of a drug. This study assessed the MOA of new drugs and biologics approved by the FDA between 1980 and 2011. **METHODS:** Information was collected from drug labels available online