reimbursement methods, HTAs at the national level are more common. **CONCLUSIONS:** Basic drivers of market access, such as health care spend, financing structure and regulatory policy create both independent and interdependent mechanisms that support access to new device technologies. Consideration of country level conditions and hurdles will inform device manufacturers' differential strategies to enter established and emerging markets.

PHP196

STAKEHOLDER INVOLVEMENT IN HEALTH TECHNOLOGY ASSESSMENT (HTA) OF NOVEL MEDICAL DEVICES

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HTA for medical devices follows the path of drugs in many countries. There are however substantial differences that should be considered when evaluating medical devices. Drummond (2009) describes six important differences. Medical devices: 1) are often diagnostic therefore requiring to consider their related therapeutic effects; 2) have faster product cycles often making trial results outdated; 3) performance depend on users' skills and complementary investments in training and equipment; 4) innovation may cause a shift from one in-patient setting (operating room) to another (cathlab) or to an out-patient setting with substantial cost-effects; 5) are manufacturer specific, making it difficult to draw conclusions about product class effects; 6) innovation may be difficult to protect with patents thus encouraging imitation with resulting falling prices. In addition to issues 1-6, regulatory approval of a device does not require the same level of evidence as for drugs. Despite initial poor evidence, decisions on health care resource-use based on cost-utility (QALY) need to be made throughout the product lifecycle. This can be achieved by involving stakeholders in regular, timely data exchange for model updating, considering issues 1-6 above. As medical devices directly affect several stakeholders, their respective treatment costs from accounting systems can be used (4). As product registries are continuously updated the improving performance due to new devices and user learning is reflected (2-3). According to regulatory requirements manufacturers must evaluate their product performance and notify competent authorities of adverse events. Such data should update cost-utility evaluations relating to manufacturer specific patient morbidity (5). Furthermore as outcomes data are increasingly captured by devices directly or apps and electronically transferred to electronic health records, the burden on manufacturers to administrate registries may be lessened (2). As medical devices are regularly procured in tenders, their product prices should be used (6). In turn HTA outcomes should inform tenders.

PHP197

OPPORTUNITIES AND LIMITATIONS OF SUSTAINABILITY INDICES IN SATISFYING THE NEEDS OF HEALTH TECHNOLOGY PURCHASERS SEEKING OBJECTIVE AND UNBIASED INDICATORS OF ENVIRONMENTAL AND SOCIETAL IMPACTS

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OBJECTIVE: To establish the extent to which existing sustainability indices provide pertinent and transparent evidence of the environmental and social impacts of health technology providers. **METHOD:** A search was undertaken to identify a comprehensive list of sustainability indices for study. For each of these the following criteria were identified; target constituency, specific environmental or social domains being measured, criteria for inclusion, data sources and ranking or scoring methodology. **RESULTS:** The majority of indices were found to be focused on the needs of investors rather than purchasers. The indices either measured specific environmental or social domains such as carbon efficiency, water risks and social impacts, or provided a broader measure of sustainability by combining environmental, social and governance issues together in a single metric. Incorporation within an index often required inclusion in pre-existing non sustainability criteria against which additional sustainability measures were applied. Data used within the indexes reviewed were found to have been derived from publically available sources such as websites and company reports, or from data submitted by the organisations under evaluation to rating research groups. Few of the indices published a level of methodological transparency that could provide sufficient visibility in order to understand how they are derived. **CONCLUSION:** There remains a latent need among purchasers for a verifiable method of measuring sustainability of providers. In order for a sustainability index to provide utility in the comparison of health technology providers the following criteria must be met; The index should be open to all Health Technology providers, methods used by the index to measure performance should be transparent. None of the current sustainability indexes reviewed fulfilled these criteria. Further study is needed to identify the environmental and social domains of importance to purchasers and the best approach for deriving this data.

PHP198

FROM SCIENCE TO SERVICE: THE ONTARIO PATIENT REPORTED OUTCOMES OF SYMPTOMS AND TOXICITY (ON-PROST) RESEARCH UNIT

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Research suggests that routine collection of Patient Reported Outcome Measures (PROMs) can contribute to clinical decision-making and improve health, but their systematic implementation in Ontario, outside the Edmonton Symptom Assessment (ESAS), has not yet occurred. While ESAS is a valid symptom screening tool, it does not allow customization to disease specific symptoms or toxicities nor does it reflect the multidimensional impact of cancer on physical, emotional and social health. Reaching consensus on a core set of PROMS for each of these domains is critical to improving health and monitoring the impact of cancer. However, applying numerous PROMs is burdensome to patients and evaluators. We are now moving forward to make routine PROM data collection a reality in the cancer system. On-PROST aims to improve the patient experience of cancer and the quality of care through the routine collection of a standardized set of (PROMs) for use in clinical care, and to advance the science of cancer treatment through research across the cancer continuum. Based on initial consensus for the implementation of core PROM data (PROMs-Cancer Core), we will develop a cohesive research agenda and foster the development, standardization and implementation of core PROMs relevant across cancer populations for research use and clinical practice. On-Prost focuses on five cancer research areas: Health Services Research; Biomarker Research; Radiation Oncology; Palliative and Supportive Care; and the PROMs-Cancer Core items. We plan to develop national and international partnerships, and to foster the development, standardization and implementation of core PROMs relevant across cancer populations and for disease specific purposes for routine clinical care and trials. Our goal is to foster common PROMs with multiple purposes, including performance and impact of cancer reporting, that will help deliver personalized quality care and treatment, and will concretely impact on cancer control and policy over the next five years.

PHP199

THE IMPACT OF THE GERMAN PHARMACEUTICAL MARKET REORGANISATION ACT (AMNOG) ON THE GERMAN REFERENCE PRICE MARKET – TRENDS TWO YEARS AFTER THE INTRODUCTION OF THE AMNOG

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With the introduction of the German Pharmaceutical Market Reorganisation Act (**German:** "Arzneimittelmarktneuordnungsgesetz" (AMNOG)) in January 2011, pharmaceutical entrepreneurs have to present a dossier to demonstrate the additional benefit of a new pharmaceutical at product launch in the German market. Pharmaceuticals failing to demonstrate additional benefit against the standard of care in the corresponding indication can be included in an existing reference price group or even trigger the building of a new one. Top-selling reference price markets with many newcomers or price-aggressive competitors are at risk of a repeated examination through the federal joint committee (G-BA) in short intervals, resulting in a frequent updating of the reference price. This triggers a cascade, the so called "Kellertreppeneffekt" (Race to the Bottom), which could result in a rapidly decreasing reference price. One parameter of interest to assure an adequate security of supply is the measure value 160, assuring that at least 20% of packages and 20% of prescriptions are available at a lower price than the new reference price. To avoid the cascade, alternative, lower measure values, such as the measure value 100, can be applied. The measure value 100 is feasible for reference price groups with a large amount of products which are free of patients' copayment. Pharmaceuticals are normally free of patients' copayment if the product price is 30% lower than the corresponding reference price. The focus of our presentation is to analyze the impact of the AMNOG on 10 top-seller reference price groups and to evaluate further adjustments to the reference price level of these groups through varying measure values. Furthermore, additional parameters of interest influencing the reference price level will be considered.

PHP200

EFFECTIVE DEMAND FOR A HEALTH LITERATE HEALTH CARE SYSTEM - EVIDENCE FROM IRISH SURVEY DATA

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Health literacy (HL) research has mainly focused on the skills and abilities of individuals in the health care setting. For the past 20 years, most research has been conducted in North America. However, HL is now gaining political support at European Union level. This presentation is concerned with attitudes that nationally representative survey respondents in Ireland have towards improving their health by seeking a more health literate health care system. Two waves of the Survey of Lifestyle, Attitudes and Nutrition (SLAN 1998 & 2002) were used in this analysis. The primary focus of this study was to look across the socioeconomic gradient and see whether Irish health policymakers should invest in HL as a health inequalities or a public health issue. A secondary objective was to look at preventive health care utilization (General health check-up, blood pressure check-up, blood cholesterol check-up) using the HL variable as the main independent variable stratified by gender and medical card eligibility.

The constructive dependent variable (termed 'effective demand for a health literate health care system') showed that 46% of respondents desired at least one attribute on a health literate health care system. Various multivariate logistic regression models used social class grouping, medical card eligibility, level of education and employment status as the main socioeconomic gradient variables. No discernible trend emerged among the socioeconomic variables. This suggests that HL should be viewed as a public health issue with a policy focus at a system level. Consistently, females (OR 1.15; 95%:1.04 -1.28) were more likely than males to seek a health literate health care system. However, males without a medical card with an effective demand for health literate health care system were more likely to get a general check-up (OR 1.23; 95%:1.03 -1.47). The investment in making the system more user-friendly would benefit all in society and not those stigmatized as having low literacy.

PHP201

CAN RISK MANAGEMENT PLANS (RMP) CONTRIBUTE TO HEALTH TECHNOLOGY ASSESSMENT (HTA) AND KNOWLEDGE OF SAFETY IN EVERYDAY MEDICAL PRACTICE?