reimbursement methods, HTAs at the national level are more common. **CONCLUSIONS:** Basic drivers of market access, such as health care spend, financing strategies and mandatory 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requiring to consider their related therapeutic effects; 2) have faster product cycles often making trial results outdated; 3) are manufacturer specific, making it difficult to draw conclusions about product class effects; 4) innovation may cause a shift from one in-patient setting (operating room) to another (cathlab) or to an outpatient 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 and product price constraints are updated the improved 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). Further more 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 transparent and objective 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 impact. However, there was limited 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 indices 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 visibil ity 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 indices 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-PF) RESEARCH UNIT**

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Research on an ongoing 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. It does not 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 FROM data collection a reality in the cancer system. On-PF2013 aims to improve the patient experience of care 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 international consensus for the implementation of core PROMs 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-PF focuses on cancer research and care delivery. The core PROMs-Cancer Core include: 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 for research use and 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 ("Gesetzentwurfsneuordnungsgesetzes" (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 at corresponding indications will not be included in the price group or even trigger the building of a new one. Top-selling reference price markets with many newcomers or price-competitive 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, ensuring 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 10% 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**

**EVIDENCE FROM IRISH SURVEY DATA**

Coughlan D

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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 at- tribute of a health literate health care system. However, males without a medical card with an effec tive demand for health literate health care system were more likely to get a general check-up (OR 1.23; 95% CI 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?**


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In 2011, the German Pharmaceutical Market Reorganisation Act (AMNOG) was introduced to allow the German Federal Joint Committee (G-BA) to acquire additional data to support its reference price setting process. This process often leads to an increasing number of new products being transmitted to the G-BA, with a large amount of products which are free of patients’ copayment. The pharmaceutical entrepreneur has to show that their product meets at least the level of evidence set by the AMNOG in order to be included in a product group or they can even trigger the building of a new one. This presentation focuses on the impact of the AMNOG on 10 top-seller reference price groups in terms of differences in fees and evidence levels 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 10% 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.