**PMD121**

VIRTUAL CONSULTATION SYSTEM TO ENABLE RARE DISEASES DIAGNOSIS

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**OBJECTIVES:** The use of medical images has become a great tool that enables a rapid diagnosis, aiding in reaching relevant decisions early in the process leading to the formulation of a second opinion in cases of doubt. Solid tumors are very rare in children and individual clinician experience is often quite limited. Yet the treatment decision-making is a complex diagnostic dilemma that is common. **METHODS:** Supported by a grant from EU-funded Project ENCCA (European Network for Cancer Research in Children and Adolescents), representatives from SIOP, CIGOM, COG, and JPLT developed the Virtual Consultation System. VCS is a novel, open-source developed by CINECA Interuniversity Consortium that overcomes the challenges in management of complex cases, which require the consultation among experts coming from different hospitals or countries. VCS allows to assess complex cases with real-time additional information from structured data (e-CRFs) and diagnostic DICOM images. VCS can be customized according to specific requirements in all of its components such as user roles, process flows, and the input and output information (i.e. e-CRFs, images, consensus form) linked to the different tasks in the implantation in 50%. 28% of patients were readmitted for the device’s replacement hospitalization risks on a long-term follow-up: hospitalization for heart failure was Cité, Paris, France, Paris, France, 3Université Paris-Dauphine, Paris, France

**RESULTS:** Based on the evaluation criteria for ‘Selective reimbursement’, total 12 items were assessed and enlisted in selective reimbursement category. This plan benefits 842 thousand patients and reduced non-reimbursement cost to 577 million(2014) from 1,139 million(2012) related to the four major diseases. **CONCLUSIONS:** NHS coverage is extremely focused on the four major diseases and this will cause discrimination against other diseases. In terms of patients’ aspect, it may be asked whether this plan is effective to give patients a strong advantage enough to feel under 80% co-payment ratio. The decision making process and medical devices price appraisal remains to be considered as its transparency and rationality.

**PMD122**

MODELING OF CLINICAL PATHWAYS IN THE IMPLANTATION OF CAROTID ENDARTERECTOMY DEVICES FROM 2006 TO 2013 USING THE FRENCH HOSPITAL P.M.S.I. DATABASE

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**OBJECTIVES:** A clinical pathway is defined as the succession of medical events that jointly aim at improving the patients’ condition. It provides efficient care by standardizing processes, reducing the variability of practices and improving the outcome. Hospital Information Systems contain valuable data about these pathways. However, they are hardly tapped due to their volume and complexity. The objective of the study is to factually describe the clinical pathways of patients implanted with a CERD defibrillator (CRT-D) on an 8 years timeline from the French PMSI database. The PMSI annually includes the records of all hospital stays in the country. This description will bring new knowledge about the patients care to find out the correla-

**METHODS:** From the 2008 database in public hospitals, we extracted all hospital stays with an implantation of a CRT-D in France, leading to 1,602 patients. The patient’s anonymous identifiers were used to find all their hospital stays during the 2 previous years (2006-2008) and the 5 following years (2008-2013), being a total of 16,931 stays. These data were analyzed using Process Mining methods and supported by the patient’s information which was added by a specific visualization tool to illustrate the results. **RESULTS:** We quantified the hospitalization risks on a long-term follow-up: hospitalization for heart failure was observed from 1.8% of patients at implantation, 5% and 8 months after implantation in 50%. 28% of patients were readmitted for the device’s replacement after 2 years and 2 months, and 20% died at the hospital within 5 years. These eight were assessed depending on the patient’s morbidity. **CONCLUSIONS:** This study shows that Process Mining methods are relevant to analyze clinical pathways at a national scale from big sized database. This descriptive approach is the prerequisite for predictive analytics.

**PMD124**

HOW TO CAPTURE AND REWARD THE BENEFITS ASSOCIATED WITH COMPANY’S DIAGNOSTICS

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**OBJECTIVES:** Targeted therapies have a growing place within the therapeutic landscape and represent an innovative sector. Companion diagnostics (CD) are complementary to targeted therapies, however there is an unbalanced environment between both technologies with limited incentive measures to support the development of diagnostic tests. The aim of this analysis was to review and compare the existing processes in Europe and North America, and see how CD benefits could be rewarded. **METHODS:** An analysis was performed of the healthcare systems in France, the United Kingdom, Germany and the United-States. Advantages and disadvantages of country-specific pricing and reimbursement policies were highlighted. The current perspectives then conducted to identify the benefits related to CD and potential processes to capture these benefits. Searches were run on electronic databases (i.e. MEDLINE and MEDLINE In-Process) and were supplemented by hand searching. Two reviewers assessed the main criteria, assessing the benefits as including economic, clinical and technical benefits from a real-world context, according to highest quality and security industry standards. The system may foresee the direct distribution of device and materials to the patient, in order to speed up the process and increase compliance. **RESULTS:** In innovative therapeutic setting, the web-based system has been tested on 15.500 patients with type 2 diabetes treated with antidiabetic drugs. Access to therapy was allowed through 3.741 diabetes specialists belonging to 1.278 dedicated centers. The system is being extended to manage and allow faster access for innovative devices. The system can manage the entire process of device management (prescription, focusing on medical devices is currently in development, with the clarification of CD’s status expected. However, there is a gap between institutional and scientific timelines given that scientific research is already going a step further with the high-throughput DNA sequencing which would need to be rewarded as well.

**PMD125**

NEW NHU REIMBURSEMENT CONPARADGE CALLED ‘SELECTIVE REIMBURSEMENT SCHEME’ ON THE FOUR MAJOR DISEASES IN KOREA

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**OBJECTIVES:** The new reimbursement scheme was and reviewing what kind of medical services were involved in plan to strengthen the NIH coverage for the major diseases. **METHODS:** The MOHW has been reducing the patient’s co-payment ratio to 50–80% from 100% for non-reimbursed medical services that have large demand for the NIH coverage but the cost-effectiveness is lower than expected. First step is to promote the scheme: selective reimbursement category. Once a service or product was assigned to selective reimbursement category, reimbursement ratios are determined in 50% or 80% based on the evaluation criteria which has 3 aspects of ‘Clinical Usefulness’, ‘Cost Effectiveness’, ‘Value-based pricing approaches were widely...
eligibility, order, delivery and invoicing) in an integrated manner in order to easily activate new market opportunities from the perspective of Companies, Payers and Patients. By defining appropriate minimum datasets, it is possible to involve all stakeholders obtaining systematic, homogeneous and high-quality real-world data on the use and appropriateness of such devices. CONCLUSIONS: The introduction of online registries and the full benefit of infrastructure among Payers and Companies in the challenge of introducing innovative therapies and devices in a strained macroeconomic scenario, with the aim to simplify market access, facilitate transparency, monitor related costs, while enabling the collection of Healthcare Big Data for scientific purposes.

PMD128 WHAT IS CE MARKING? HOW TECHNOLOGIES ARE CLASSIFIED, AND HOW TO NAVIGATE THE SYSTEM
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OBJECTIVES: Affixing a CE mark to a product means that the manufacturer is declaring that the product meets all legal requirements as well as conforming to relevant product safety directives in the EU. CE marking is mandatory, but only applies to products that are covered by the subject matter of one or more directives of the New Approach Directives. We aim to clarify the process for obtaining a CE mark.

METHODS: Published reviews, our experience and government and industry records were used to outline the complexities of this process, including how to determine the relevant type of classification and the steps that need to be taken to gain a CE mark.

RESULTS: Medical devices fall into three categories, each of which are governed by a different EU directive: Directive of Active Implantable Medical Devices (90/385/EEC), Directive of In Vitro Diagnostic Medical Devices (98/79/EC). Each one will encompass guidelines relating to an individual product and whether it is required to bear a CE mark. Once a CE mark has been obtained, a declaration of conformity must be signed before you can place the CE mark on your product. This states that the manufacturer takes sole responsibility for the conformity within all the legal requirements to achieve a CE marking and that the product can be marketed anywhere in the EU.

CONCLUSIONS: A CE mark states that a product has been assessed before being placed on the market and satisfies legislative requirements of the applicable EC directives. It ensures that a product has ‘free-movement’ within the EU as well as placing the ‘withdrawal of products’, which is not covered. More and more products are required to have a CE mark if they want to gain access to EU market.

PMD129 WHEN IS A BONE FRACTURE NO LONGER “FRESH”? Scott RA, Jones J, Steen RG
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OBJECTIVES: Robust literature demonstrates the clinical value of low-intensity pulsed ultrasound (LIPUS) in the treatment of fresh bone fractures. However, each published study used an arbitrary time post-fracture to define a “fresh fracture” for study inclusion. In the absence of an accepted clinical definition of fresh fracture, many third-party payers have adopted study inclusion criteria as de facto definitions of fresh fracture. Yet exclusion of older fractures may deny access to patients who could benefit from LIPUS. We pooled data from patients in a post-market LIPUS registry required by the Food & Drug Administration to analyze the inflection point at which fracture heal rates begin to decline.

METHODS: Patients are evaluated if the following data are known: days to LIPUS treatment; days on LIPUS treatment; outcome of treatment (Heal / Fail). We performed linear regression to determine the inflection point at which fracture heal rates begin to decline.

RESULTS: Heal rate (Heal rate = Number healed / Number of patients treated) did not differ significantly if 0 days or clinically for at least 10 weeks from fracture. In 246 patients who began LIPUS within 1 week of fracture, the heal rate was 97.2% (276 healed / 284 treated). In 246 patients who began LIPUS treatment 10 weeks after fracture, the heal rate was 97.6% (240 healed / 246 treated). There may be a decrease in heal rate after 10 weeks, but the heal rate for patients at week 12 was 95.6% (195 healed / 204 treated).

CONCLUSIONS: Heal rate with LIPUS was ~97% for ≤10 weeks following fracture. Many patients who could benefit may be unnecessarily excluded from treatment by payer guidelines. We will evaluate heal rate bone-by-bone (tibia, femur, humerus, radius, metatarsal) using this method.

PMD130 THE MEDICAL TECHNOLOGIES EVALUATION PROGRAMME (MTEP): AN ANALYSIS OF NOTIFICATIONS, DECISION-MAKING AND THE INTERPRETATION OF CLAIMS ON HEALTHCARE SYSTEM BENEFITS
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OBJECTIVES: Firstly, to identify what proportion of all high-risk medical technologies notified to the National Institute for Health and Care Excellence’s (NICE) Medical Technologies Appraisal Committee (MTAC) are selected for evaluation by the MTEP. Secondly, to analyse the MTEP Committee’s interpretation of claimed healthcare system benefits and identify the determinants of decision-making. METHODS: The NICE website was used to identify: technologies considered by the MTAC up to May 2015; the routing information for each technology; the healthcare system benefit claims made by the MTEP for all technologies routed to the MTEP. The healthcare system benefit claims were categorised according to criteria listed in the NICE MTEP methods guide to facilitate identification of any association between the type of benefit claimed and the decision outcome. The decision-making committee’s conclusion on the healthcare system benefit claims were interpreted.

RESULTS: By May 2015, the MTAC at NICE had considered 157 products, of which 99 were not selected for evaluation. Of the 58 products selected for evaluation, 35 were routed to the MTEP. Seventy-one per cent of MTEP decisions endorsed technology adoption. There have been instances of claimed healthcare system benefits being accepted by the Committee for technologies that ultimately did not receive positive endorse- ment due to insufficient cost considerations. CONCLUSIONS: The MTEP is the most commonly used process to assess routed technologies and the major- ity of MTEP evaluations have resulted in positive endorsement. The MTEP process assigns equal prominence to healthcare system and patient benefits, with decisions being based on weighing the available evidence for both domains. The evidence of clinical effectiveness was associated with uncertainty, the influence of demonstrated healthcare system benefits appeared to have limited effect on final decision-making.

PMD131 THE IMPACT OF SELF-MONITORING OF BLOOD GLUCOSE (SMBG) ON PRESCRIPTION COSTS IN NEWLY TREATED TYPE 2 DIABETES MELITUS (T2DM): A RETROSPECTIVE COHORT ANALYSIS
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OBJECTIVES: To describe the use of self-monitoring of blood glucose (SMBG) in a cohort of newly treated T2DM subjects and to assess the contribution of SMBG on overall antidiabetic and cardiovascular disease prescription costs.

METHODS: A retrospective cohort study was performed using pharmacy claims database. Newly treated T2DM patients were identified for 2012 as being initiated on oral antidiabetic monotherapy and having received no anti-diabetic therapy in the previous year. Subjects were followed for one year post treatment initiation. The association between prescription costs and SMBG was assessed using generalised linear model with gamma family and log link functions to handle the right skew of the data adjusting for various demographic and treatment factors. Costs ratios between SMBG and no SMBG groups were used to determine the contribution of SMBG to prescription costs.

RESULTS: A total of 12,941 subjects were eligible for the study with 64% of subjects using SMBG. SMBG use was highest in subjects aged 40-49 years (71%) and decreased with age, with 48% of subjects aged 80-89 years using SMBG. Most subjects used SMBG greater than once a week but less than daily (41%) or daily and more frequently (51%). Use of SMBG was associated with overall 8% lower total prescription costs compared with no SMBG use (95% CI 1.76, 1.92).

CONCLUSIONS: Use of SMBG in newly treated T2DM was high including the frequency of use and resulted in high associated costs. SMBG represents a significant financial component in diabetes care, yet previous work has shown no clear benefit demonstrated in newly treated type 2 diabetes patients on oral therapy. There is the potential for cost savings by introducing a review or limit on the amount of SMBG tests available to newly treated T2DM patients.

PMD132 ACCESSING THE MEDICAL DEVICES MARKET IN EGYPT AND SAUDI ARABIA: A SYSTEMATIC REVIEW OF POLICIES AND REGULATIONS

OBJECTIVES: The objective of this research is to provide an overview of the regulatory process of medical devices market access in Egypt and Saudi Arabia. The research also aims to identify the regulatory policies that identify high-risk medical devices and discuss the regulatory framework of the national medical devices policy agenda of Egypt and Saudi Arabia respectively.

METHODS: A systematic search of the literature for medical device regulatory policies in Egypt and Saudi Arabia was performed. This search was based on a comprehensive list of search terms. This search was supplemented by reviewing the relevant medical devices regulatory authorities’ data sources (Egyptian Drug Authority and Saudi FDA web portals). The following databases were searched: PubMed (Medline), Science Direct (EMBASE), Scopus (Arabic database) and Al Manhal. The search methodology employed was in line with PRISMA guidelines. The search language was limited to English and Arabic.

RESULTS: In total, 41 records were included in the qualitative synthesis of this review. The governance, process and implementation of medical devices market access have been analyzed in detail. The policy framework of both countries is adopted from the International Medical Device Regulatory forum and certain reference countries. Concerning products’ technical requirements, direct testing of medical devices is not required. However, documentary evidence of a medical device’s authorization to be sold in a reference country is mandatory. Challenges are related to the interim nature of medical devices legislation in both countries, presence of a considerable degree of corruption. In addition there is a lack of transparency and electronic databases, especially in Egypt. CONCLUSIONS: In both Saudi Arabia and Egypt, medical devices market access is straightforward if there is proof of authorization to sell a product in a reference country. However, this system has disadvantages in terms of safeguarding patient safety and enabling fast access of innovations. Lack of transparency, incomplete regulations, corruption, and a lack of comprehensive policy for medical devices are challenges faced by both countries.

PMD133 IDENTIFYING OPPORTUNITIES FOR VALUE-BASED CONTRACTING FOR MOLECULAR DIAGNOSTICS AS A MEANS TO IMPROVE OUTCOMES OF HOSPITAL ACQUIRED INFECTIONS
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OBJECTIVES: Hospital acquired infections (HAI) can have a serious impact on both clinical and economic outcomes. As a result, hospitals implement infection control (IC) policies to prevent and reduce the transmission of HAIs including various approaches to screening and testing incoming or admitted patients. Early detection of HAIs is key to limiting their clinical and economic impact. Molecular diagnostics (MDx) have the potential to improve IC strategies by quickly and accurately identifying patients with suspected or confirmed infections. To explore the adoption of this technology, both MDx manufacturers and hospital quality stakeholders have expressed interest in value-based contracting for HAI tests.