PCN325
WHAT MAKES A PHARMACEUTICAL PRICING & REIMBURSEMENT PROCESS PATIENT-CENTRIC? A COMPARATIVE ANALYSIS OF 11 SYSTEMS
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OBJECTIVES: To find how 11 pricing & reimbursement (P&R) processes assess the value of innovative medicines to provide sustainable and timely patient access. BACKGROUND: In November 2014, the UK Minister for Life Sciences announced the Innovative Medicines and Medical Technology Review to consult various stakeholders on how to improve access to medicines in England. METHODS: Eleven processes were analysed focusing on oncology: Australia, Belgium, Canada, England, France, Germany, Italy, Netherlands, New Zealand, Scotland and Sweden. The decision-making process split into eight steps: regulatory approval, health technology assessment, appraisal, reimburse- ment decision, price negotiations, decision enforcement, routine access and later access. Data collected was based on the IFPMA guidelines and the AHTAN frameworks [Hutton et al. 2006] [Allen et al. 2013]. The analysis relies on a pro- posed definition of patient-centricty, assuming that value creation for patients should determine the reward of other stakeholders [Porter 2010]. It was designed to be a pragmatic guide for identifying and assessing available RWE-sources. Patient-registries containing detailed data are good sources for RWE gathering, but in countries without national registries, data collection from clinical practice is still a feasible alternative for RWE collection.

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WHAT LIFECYCLE MANAGEMENT LESSONS CAN WE LEARN FROM PD-1 IMMUNO-ONCOLOGY THERAPIES?
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OBJECTIVES: To understand the early lifecycle management strategies of inno- vative oncology immunotherapies, specifically the PD-1 drugs pembrolizumab (Keytruda, Merck) and nivolumab (Opdivo, Bristol-Myers Squibb), for application in disease areas. METHODS: Targeted secondary research using combina- tions of key words (‘PD-1’, ‘Keytruda’, ‘Opdivo’, ‘FDA’, ‘Pembrolizumab’, ‘Nivolumab’, ‘Approval’, ‘Immuno-oncology’) identified source literature, which was abstracted and analyzed qualitatively. Key themes were discussed in a consensus meeting and implications of findings were theorized. RESULTS: Several lifecycle management strategies were identified from secondary research, including indication expansion, patient segmentation using biomarkers, and combining with other drug treatments. Product launches of pembrolizumab and nivolumab were reviewed, receiving accelerated approval from the FDA for advanced melanoma in late 2014. Nivolumab subsequently received approval for NSCLC in May 2015, where- as pembrolizumab has been approved under FDA Priority Review for the same indication as of June 2015. Nivolumab is also under Priority Review in combination with ipilimumab (Yervoy, Bristol-Myers Squibb) for melanoma. Both PD-1 therapies are in numerous clinical trials with other oncology indications and are of high interest. CONCLUSIONS: The reward of other stakeholders determines the reward of other stakeholders in a specific therapeutic area including value creation and reimbursement for patents with a specific genetic biomarker, which is predictive of response across the range of cancers.

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DELAY IN DIAGNOSIS OF BREAST CANCER IN GREECE: FINDINGS FROM A QUALITATIVE STUDY
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OBJECTIVES: Research findings point to the existence of delays in symptom rec- ognition, diagnosis and treatment of breast cancer. The present study aimed at identifying reasons for delay in breast cancer diagnosis in Greece. METHODS: A qualitative study performed in December 2014, using a semi-structured interview guide. Recruitment was performed through a patients’ organization. Women with a diagnosis of primary or secondary breast Ca after 2011, residing in Athens, and who had completed treatment were eligible for the study. The interviews were recorded with participants’ written consent and were transcribed and content analyzed using a model of patient and provider delay. RESULTS: 23 women participated. Delays were detected in all intervals of the patient pathway. Although most participants performed annual breast cancer screening tests, some women had not undergone screening the year previous to their diagnosis due to financial and personal reasons. In the majority of cases women were symptomatic, however, they delayed treatment seeking due to a lack of confidence in a delayed presence of a breast lump is the main symptom that caused non-delayers to seek medical attention. Women who had delayed consulting with a physician despite having found a breast lump gave the following reasons: misattributing their symp- tom to benignity, non-breast-feeders (women with a diagnosis of primary breast cancer) and other personal health problems, depression or denial and financial barriers to visiting a specialist. The study also identified delays in diagnosis attrib- uted to the healthcare providers, in some cases physician(s) did not suspect malignancy. CONCLUSIONS: Delayed diagnosis of breast cancer among women participating in the study is attributed to both patient and provider behavior. Our findings indicate that raising awareness and educating both patients and health care providers is important. However, further research is necessary to identify the extent of the problem and confirm these results.

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A PRAGMATIC APPROACH TO DATA SOURCE SELECTION FOR USE IN REAL-WORLD EVIDENCE (RWE) GENERATION
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OBJECTIVES: Real-world evidence (RWE) can be gathered from various sources, including existing registries, claims data or medical records. The challenge is select- ing the best RWE-source for answering specific research questions. As data sources collect different data elements, the best RWE collection approach for gathering the necessary data will differ per country. The objective was to test a systematic approach to selecting the best RWE-source per indication. Methods: A qualitative study. Our approach consisted of two workstreams: assessment of existing RWE-sources and inventory of data elements collected in clinical practice. We selected oncology and gynecology as the target area. The first step of workstream one is a targeted literature search to identify RWE-sources. Database owners were surveyed on their data. A scoring algorithm was developed to prioritize RWE-sources on the number and type of relevant data elements. Finally, the most promising databases were selected. RESULTS: Data collection was performed on 112 variables on their score and collaboration possibilities. For workstream two, a small sample of practicing physicians were interviewed on what data is routinely collected in clinical practice. The results from the 2 workstreams were combined to analyse per country which collection approach is optimal for RWE generation for answering specific research questions. RESULTS: We identified 327 national or regional general oncology registries. Almost each country has database collection information on diagnosis and survival data, but databases collecting information on treatment and response to treatment are rare. Interviews revealed that medical records typically collect detailed information on diagnosis, treatment and response, although specific details were absent across countries. The method proposed a practical guide for identifying and assessing available RWE-sources. Patient-registries containing detailed data are good sources for RWE gathering, but in countries without national registries, data collection from clinical practice is still a feasible alternative for RWE collection.

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FROM DIAGNOSIS TO TREATMENT AND SURVIVAL: THE EMOTIONAL JOURNEY OF PATIENTS WITH BREAST CANCER
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OBJECTIVES: Breast cancer has important economic, psychological and social impact for the patients, their families and the health system. Our aim was to record the emotional trajectory of breast cancer patients during the different treatment stages. METHODS: A qualitative study was performed in December 2014, using a semi-structured interview guide. Participants were recruited through a patient organization. Women with a diagnosis of primary or secondary breast Ca after 2011, residing in Athens who had completed treatment were eligible