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WHAT MAKES A PHARMACEUTICAL PRICING & REIMBURSEMENT PROCESS PATIENT-CENTRIC? A COMPARATIVE ANALYSIS OF 11 SYSTEMS
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OBJECTIVES: To understand 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 was split into eight steps: regulatory approval, health technology assessment, appraisal, reimbursement decision, price negotiations, decision enforcement, routine access and later-stage reassessments. Data collection was based on the Hutton and Allen frameworks [Hutton et al. 2006] [Allen et al. 2013]. The analysis relies on a proposed definition of patient-centricity, assuming that value creation for patients should determine the reward of other stakeholders [Porter 2010]. It was designed to assess how each process delivers value for patients (equity of access, fulfilment of societal needs, fast access to innovation), the healthcare system (economic and financial sustainability) and the research-based industry (innovation reward). **RESULTS:** In patient-centric systems, the reimbursement decision tends to be solely based on the therapeutic value of the medicine. Cost considerations are generally addressed by price negotiations in a second stage. Other processes focus more on cost-effectiveness or budget impact (potentially with thresholds), which drives the reimbursement decision alongside clinical effectiveness; pricing and reimbursement are decided jointly. The English and Scottish processes are the only ones that have no price negotiations with manufacturers. **CONCLUSIONS:** Patient-centric P&R processes succeed in delivering value to major stakeholders by first deciding on the reimbursement status of a new medicine based on its value to patients. They then independently negotiate a price with manufacturers to ensure economic and financial sustainability for the healthcare system and innovation reward for the manufacturer.

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DELAYS 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 recognition, 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 was 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, there were difficulties in appraising symptoms as related to illness. The 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 symptom to benign conditions or breast-feeding, having competing priorities such as family and other personal health problems, depression or denial and financial barriers to visiting a specialist. The study also identified delays in diagnosis attributed to the healthcare providers, as 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 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 selecting 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 for identifying and selecting RWE-sources per indication. **METHODS:** Our approach consisted of two workstreams: assessment of existing RWE-sources and inventory of data elements collected in clinical practice. We selected oncology as test indication and the European Union 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 for answering specific research questions were selected based on their score and collaboration possibilities. For workstream two, a small sample of practicing physicians were interviewed on what data is routinely recorded in clinical practice. The results from the two 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 databases collecting 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 vary per country. **CONCLUSIONS:** The method tested represents 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 such 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 innovative oncology immunotherapies, specifically the PD-1 drugs pembrolizumab (Keytruda, Merck) and nivolumab (Opdivo, Bristol-Myers Squibb), for application across disease areas. **METHODS:** Targeted secondary research using combinations 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. Pembrolizumab and nivolumab - both holders of Breakthrough Therapy status - received accelerated approval from the FDA for advanced melanoma in late 2014. Nivolumab subsequently received approval for NSCLC in March 2015, while pembrolizumab was 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 for further oncology indications, and pembrolizumab has shown improved response rates in patients with a specific genetic biomarker, which is predictive of response across a range of cancers. **CONCLUSIONS:** In highly competitive therapeutic areas, manufacturers of innovative products need to consider multiple strategies for creating, maintaining, protecting and increasing product value. Demonstration of substantial improvements in clinical efficacy over the standard of care in one indication is not sufficient for 'success'. Earlier access through the FDA's Breakthrough Therapy designation and accelerated approval program is critical for first-to-market entrants. Expansion into both larger and more niche indications offers a complementary access strategy, while gaining a foothold in combination regimens provides opportunity for further product differentiation. Similar considerations apply to therapies that can treat several indications within a broader disease area.

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REAL WORLD EVIDENCE IN ONCOLOGY – STATUS QUO IN GERMANY
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OBJECTIVES: Observational studies can be useful to fill in gaps of randomized studies or when these cannot be conducted. Aim of this study was the assessment of available real world evidence (RWE) in oncology and the identification of research gaps for Germany. **METHODS:** A systematic literature search was conducted to evaluate the status quo of RWE in the field of oncology. Key words identifying health services research in combination with oncology in Germany were used in a search performed in the DIMDI (German Institute of Medical Documentation and Information) meta-database including all years up to 2015. The selected publications were classified by type of RWE study and further categorized by cancer types. **RESULTS:** In total, 80 publications were included and stratified by RWE approach and cancer type. Nine RWE categories were determined, including cancer registries, registry-linked data, health care claims, inpatient and outpatient data, and surveys. Most observational studies (56%) assessed oncologic health care by conducting surveys, followed by cancer registries (10%) and claims data (9%). Overall, 32 studies evaluated cancer in general, breast cancer was assessed in 15 studies, whereas 4 addressed prostate cancer, with remaining publications addressing other cancer types. Most observational studies were published in 2011 (18%). Assessments with cancer registries were published as of 2011, whereas there were no studies with claims data from 2012-2014. Specific care and treatment of cancer patients, including palliative care was considered in 23 publications. Almost all cancer types were assessed, except lymphoid and hematopoietic neoplasms. Moreover, claims data were hardly used. For surveys, it can be noted that the use increased from 2005 onwards. **CONCLUSIONS:** The available evidence shows that RWE data in oncology has not yet reached its potential to supplement randomized studies. Research gaps exist in terms of RWE treatment with new concepts and drugs.

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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 journey of patients with breast cancer 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 patients' organization. Women with a diagnosis of primary or secondary breast Ca after 2011, residing in Athens who had completed treatment were eligible