

they were completing it at their outpatient clinic. Such data collection must be tied to a transparent clinical purpose that patients see as an integral part of their health care. Other avenues for collecting outpatient drug toxicities outcomes should be investigated.

#### PCN229

##### THE USE OF SOCIAL MEDIA TO GENERATE HEALTH DATA FOR EFFECTIVENESS RESEARCH: A SCOPING REVIEW

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**OBJECTIVES:** Explore the use of social media for health data collection in effectiveness research in oncology. **METHODS:** We conducted a systematic review of scientific literature to assess health data collected via social media. Literature published in PubMed between January 2010 and April 2015 was included. Three reviewers screened studies for eligibility and extracted data. Based on included articles an explanatory and qualitative analysis was performed. **RESULTS:** Initially the search strategy identified 580 articles. Study inclusion criteria were met by 12 articles based on title and abstract, and by 4 articles based on the full paper. Two additional articles were included after evaluating the reference lists of included hits. Of the 6 included articles, four focused on identifying side effects to cancer treatments by using patient forum websites, one assessed the feasibility of disseminating a quality of life survey via a Facebook support group, and one focused on methodological considerations in analyzing data from Twitter. Several benefits of health data generated via social media were discussed, such as the ability to provide additional information on (unlabelled) side effects, the recruitment of a small sample of patients spread over a relatively wide geographic area, and the possibility to capture patient perspectives that tend to be more difficult to measure in clinical trials. Limitations of using social media to generate health data included validating authenticity of posts and users, duplicate and multiple posts, the volume of data available, selection bias (e.g. sicker or older patients may not be represented on social media) and incompleteness of data on patient characteristics. **CONCLUSIONS:** Limited literature is available on the actual use of health data from social media in effectiveness research in oncology. However, the potential of health data collected via social media is of increasing interest in the scientific community and should be further explored.

#### PCN230

##### THE IMPACT OF NON-MUSCLE INVASIVE BLADDER CANCER: QUALITATIVE RESEARCH WITH PATIENTS

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**OBJECTIVES:** To understand disease-related symptoms experienced by high-risk non-muscle invasive bladder cancer (NMIBC) patients, selected treatment patterns, patient satisfaction with their treatment and concern regarding future potential treatments. **METHODS:** Ten interviews were conducted with patients recruited at two urology clinics in the United States; patients were recruited by clinic staff. Patients were eligible to participate if they met one of the following three criteria: 1) were Bacillus Calmette-Guérin (BCG)-naïve treated with transurethral resection of bladder tumor (TURBT) ± intravesical chemotherapy; 2) had current or previous BCG treatment but were refractory or resistant to treatment; or 3) were BCG refractory or relapsing and whose next treatment option would be cystectomy but were prior to cystectomy. **RESULTS:** Participants were demographically representative of the patient population that seeks treatment for NMIBC. Nearly all interview participants reported visible hematuria as the symptom which led to their diagnosis. Other disease-specific symptoms were not frequently reported. All participants had received one or more NMIBC drugs (i.e., BCG, mitomycin, valrubicin), a procedure (i.e., TURBT, cystoscopy), or both. All participants reported transient medication side effects (e.g., painful urination, urgency, frequency) and/or catheter or stent adverse events (e.g., painful or burning urination, passing blood clots) following their procedure or surgery. Despite these findings, almost all participants were satisfied with their treatment. All patients were concerned about the possibility of cystectomy, should their disease progress, and were highly motivated to avoid this treatment. **CONCLUSIONS:** Patients reported disease and treatment-related symptoms; however, they were not severe enough to impact the patient's willingness to undergo intravesical therapy or diagnostic procedures. Further research is needed to better characterize the impact of timing and duration of treatment-related symptoms, as well as patient and caregiver perspective on additional bladder cancer therapies, especially when bladder sparing may be warranted.

#### PCN231

##### DO PATIENT REPORTED OUTCOMES (PRO) IN ONCOLOGY MATTER IN HEALTH TECHNOLOGY ASSESSMENTS (HTA)?

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**OBJECTIVES:** In parallel with increasing requests for PROs to be assessed in oncology trials, the European Medicine Agency (EMA) in 2014 published a reflection paper outlining their recommendations. The value PRO claims have to HTA Agencies is less clear. Our objective was to assess whether HTA agencies placed a similar valuation on PROs as the EMA. **METHODS:** Our focus was HTA agencies in key 3 European countries: Germany, the UK and France Cancer types were selected where they had a high number of HTA assessments: breast cancer (BC), non-small cell lung cancer (NSCLC), pancreatic cancer (PaC); prostate cancer (PC) and leukemias. Relevant HTA appraisals since January 2013 were identified using Quintiles' proprietary HTA Accelerator database. The drugs evaluated were compared to their respective European labels. **RESULTS:** Overall, 85 HTA submissions (AWMSG: 5; NICE: 7; SMC:

23; HAS: 28; G-BA: 11; IQWiG: 11) covering 31 oncology drugs were reviewed. Thirteen (42%) of these drugs had ≥1 PRO claims in their European label; corresponding HTA submissions also included PROs. Manufacturers presented PROs in 67.1% (57/85) of HTA submissions (BC: 72.7%; NSCLC: 100%; PaC: 0%; PC: 77.3%; leukemias: 43.5%). PROs were also presented in the HTA submissions of 8 drugs with no EMA PRO data. In HTA submissions, PROs assessing QoL (51/57, 89.4%) and pain (18/57, 31.6%) were the most common. Statistical significance was observed in 59.6% of the 52 submissions with available results. In the final HTA decision, PROs were mentioned for 43.9% of submissions, not mentioned in 35.1% and were not reviewed by the HTA body in 21.0% of submissions due mainly to methodological issues. **CONCLUSIONS:** Demonstrating a statistically significant improvement in PROs does not increase the chance of a positive HTA recommendation (65.5% vs 74.1% for submissions without PROs). The value that PRO claims in oncology have to payers needs to be further clarified.

#### PCN232

##### DEVELOPMENT OF A PATIENT-REPORTED OUTCOME (PRO) ASSESSMENT OF CORE NON-SMALL CELL LUNG CANCER (NSCLC) SYMPTOMS

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**OBJECTIVES:** Lung cancer is the leading cause of cancer-related mortality worldwide. Patients experience symptoms throughout the course of their disease which detrimentally affect their health-related quality of life (HRQOL). The assessment and monitoring of changes in NSCLC symptoms is increasingly important in clinical trials when making treatment comparisons between therapies. The objective was to develop a brief assessment of core symptoms appropriate for use in clinical trials. **METHODS:** This non-interventional, cross-sectional qualitative study consisted of conducting individual interviews with NSCLC patients. Patients aged ≥18 years with stage IIB-IV NSCLC participated in individual interviews to provide descriptions of NSCLC symptoms, including severity, frequency and change over time. **RESULTS:** 17 treatment-naïve patients (mean age=68yrs) were recruited for concept elicitation interviews. The most common spontaneously reported symptoms of NSCLC were cough (58.8%), shortness of breath (47.1%), chest pain (47.1%) and fatigue (29.4%). These symptoms were included in the initial 12-item version of the Symptoms In Lung Cancer (SILC) scale. An additional 10 post-treatment patients (mean age=63yrs) participated in cognitive interviews to ensure that the items were correctly interpreted, relevant, and disease-related (i.e., not treatment-related). They overall found the SILC easy to complete and interpreted most of the items as intended. Items related to fatigue were removed as post-treatment patients found these concepts difficult to attribute to their disease, and were reported by less than a third of treatment-naïve patients. The final 9-item SILC uses a 5-point verbal response scale (higher scores indicating greater severity/frequency), a 7-day recall period, and assesses 3 core symptom concepts: chest pain (severity and frequency), cough (severity and frequency), dyspnea (while lying down/sitting, standing, walking, carrying a light load and when walking up an incline). **CONCLUSIONS:** SILC is an easy-to-use and concise tool to assess the core symptoms of disease in NSCLC patients.

#### PCN233

##### CANCER IS ASSOCIATED WITH INTRAOPERATIVE AND POSTPROCEDURAL COMPLICATIONS AND DISORDERS

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**OBJECTIVES:** The risk of nosocomial infections plays important role especially for patients with severe sicknesses and lengthy hospital stays. To better understand associated risk factors, real world evidence data from primary care patients was analyzed. **METHODS:** 5,817 primary care patients from 982 general practices (GP) with first diagnosis of intra- or postoperative complications ("IPC") (in digestive system (ICD 10: K91) or circulatory system (ICD 10: I97)) were identified during the index period 04/2010-03/2015 from the Disease Analyzer database, Germany). Furthermore, 5,817 controls were included after individual matching (1:1) to study cases on age, gender, type of health insurance (private or statutory) and the physician. **RESULTS:** Study patients in both groups were 64 yrs old on average, 3% were female. The share of patients with cancer diagnosis was higher in the case than in the control group (21.5% versus 5.8%, p<0.001), e.g. significant differences were identified in shares of breast cancer (7.3% versus 1.0%, p<0.001) or cancer of digestive organs (8.4% versus 0.9%, p<0.001). There were no significant differences in the shares of prostate, skin and respiratory organ cancer. In multivariate regression models, newly diagnosed IPC were significantly associated with cancer (Odds ratio, OR, 95%CI: 4.58, 4.03-5.20), as well as with breast cancer (8.51, 6.41-11.29) and cancer of digestive organs (10.49, 7.87-14.00) among others. **CONCLUSIONS:** This study suggests that cancer diagnosis might be a risk factor for the development of IPC. More specifically, certain tumors, like breast cancer or cancer of digestive organs are more likely to be associated with IPC than others (e.g. prostate or skin cancer). Potential reasons for this observations, e.g. differences in therapy duration or frequency and complexity of surgical procedures, have to be investigated.

#### PCN234

##### TRANSLATION AND LINGUISTIC VALIDATION OF THE MODIFIED MYELOPROLIFERATIVE NEOPLASM SYMPTOM ASSESSMENT FORM - TOTAL SYMPTOM SCORE (MMPN-SAF TSS) FOR USE IN 26 COUNTRIES

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**OBJECTIVES:** Symptom burden is critical for assessing therapeutic efficacy in myelofibrosis, characterized by splenomegaly, abdominal and constitutional