Admissions with comorbid diabetes formed 12.6% (45) of patients who died in the hospital. The length of stay was significantly higher for admissions with a primary diagnosis (9.2 days) compared to those with secondary diagnoses (7.8 days). Only 40% of admissions with a primary or secondary diagnosis of CRC of which 27.4% were indicating advanced disease and possibly failure of timely screening. Diabetes was the most common comorbid condition and further investigation in diabetes is needed to check screening behavior and access to screening centers.

OBJECTIVES: There is no evidence about real medical practice in oncology in Mexico. The objective of this study was to explore current medical practices of colorectal oncologists in the management of five malignancies: breast, non-small cell lung (NSCL), colon, rectum and kidney cancer. METHODS: A specific instrument for these malignancies was designed, validated and applied to Mexican oncologists. Information requested reflects stages-specific treatment and disease management, including surgery and drugs used, as well as frequency of prescription, discontinuation and factors that determines them in public and private health care institutions, between January and December 2009. RESULTS: 30 oncologists were included: 63.3% from Instituto Mexicano del Seguro Social and 20.0% from Instituto Nacional de Cancerología. 73.3% of all oncologists have public and private practices. Tamoxifen (adjuvant hormone therapy) and 5-fluorouracil/leucovorin/cyclophosphamide (adjuvant, neoadjuvant and palliative chemotherapy) are the most frequently drug schemes used in breast cancer, with no differences between public and private practices (p < 0.05). At least 85.0% of NSCL cancer cases are diagnosed in IIB and IV stages; combination chemotherapy (platinum/etoposide) is highly prescribed in NSCL cancer patients undergoing radiotherapy or non-resectable disease. Colon cancer is diagnosed in stages III/IV(58.0%) and IV (14.0%); 20.0% of colon cancer patients undergoes surgery (left or right hemicolectomy). Drug availability and medical guidelines recommendations drive prescription to treat colon cancer. Surgery in rectum cancer is applied at stages IIIB or IV (range: 17.6%, 20.0% and 16.9%, respectively). Rectum cancer presents drive prescription to treat colon cancer. Surgery in rectum cancer is applied at stages IIIB or IV (range: 17.6%, 20.0% and 16.9%, respectively). Rectum cancer presents.

Abstracts

TREATMENT PATTERNS OF MALIGNANT ONCOLOGISTS IN FIVE DIFFERENT CANCERS Tienen-Téllez LMC, Vargas-Valencia J, Martínez-Fonseca J, Sotelo-Guzmán M

Mould-Quedado I

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OBJECTIVES: There is a lack of knowledge about real medical practice in oncology in Mexico. The objective of this study was to explore current medical practices of colorectal oncologists in the management of five malignancies: breast, non-small cell lung (NSCL), colon, rectum and kidney cancer. METHODS: A specific instrument for these malignancies was designed, validated and applied to Mexican oncologists. Information requested reflects stage-specific treatment and disease management, including surgery and drugs used, as well as frequency of prescription, discontinuation and factors that determine them in public and private health care institutions, between January and December 2009. RESULTS: 30 oncologists were included: 63.3% from Instituto Mexicano del Seguro Social and 20.0% from Instituto Nacional de Cancerología. 73.3% of all oncologists have public and private practices. Tamoxifen (adjuvant hormone therapy) and 5-fluorouracil/leucovorin/cyclophosphamide (adjuvant, neoadjuvant and palliative chemotherapy) are the most frequently drug schemes used in breast cancer, with no differences between public and private practices (p < 0.05). At least 85.0% of NSCL cancer cases are diagnosed in IIB and IV stages; combination chemotherapy (platinum/etoposide) is highly prescribed in NSCL cancer patients undergoing radiotherapy or non-resectable disease. Colon cancer is diagnosed in stages III/IV(58.0%) and IV (14.0%); 20.0% of colon cancer patients undergoes surgery (left or right hemicolectomy). Drug availability and medical guidelines recommendations drive prescription to treat colon cancer. Surgery in rectum cancer is applied at stages IIIB or IV (range: 17.6%, 20.0% and 16.9%, respectively). Rectum cancer presents.

TREATMENT PATTERN OF METASTATIC TRIPLE NEGATIVE BREAST CANCER IN COMMUNITY PRACTICE

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OBJECTIVES: Triple negative (TN) breast cancer (BC) is a subtype of BC characterized by its unique molecular profile and aggressive clinical behavior, lacks satisfactory standard therapies. Little is known about how patients with TNBC were treated in community practice. This study was conducted to identify treatment patterns of first-line chemotherapy (CT) of TNBC using data from community practices. METHODS: Data from the National Cancer Database (NCDB) and the ION 2003–2008 were used to identify patients with stage IV TNBC treated with at least one of the following agents: CT, bevacizumab (BBV), cetuximab (CTX), or trastuzumab (THZ). The NCDB is a validated database that provides overall survival at 5 years and individual survival at 3 years according to BC stage and treatment lines. Bevacizumab (range: 5–8%) and bevacizumab (range: 2–4%) use remained relatively stable during the observation period, whereas interferon-α1b and temsirolimus was used rarely (<1%) and everolimus was not used at all. CONCLUSIONS: Pharmacologic agents were increasingly used to treat mRCC patients in recent years. Targeted therapies have become the standard curative treatment. The aim of this study is to examine colorectal cancer treatments in community practice. A specific instrument for colorectal malignancies was designed, validated and applied to Mexican oncologists. Information requested reflects stages-specific treatment and disease management, including surgery and drugs used, as well as frequency of prescription, discontinuation and factors that determine them in public and private health care institutions, between January and December 2009. RESULTS: 30 oncologists were included: 63.3% from Instituto Mexicano del Seguro Social and 20.0% from Instituto Nacional de Cancerología. 73.3% of all oncologists have public and private practices. Tamoxifen (adjuvant hormone therapy) and 5-fluorouracil/leucovorin/cyclophosphamide (adjuvant, neoadjuvant and palliative chemotherapy) are the most frequently drug schemes used in breast cancer, with no differences between public and private practices (p < 0.05). At least 85.0% of NSCL cancer cases are diagnosed in IIB and IV stages; combination chemotherapy (platinum/etoposide) is highly prescribed in NSCL cancer patients undergoing radiotherapy or non-resectable disease. Colon cancer is diagnosed in stages III/IV(58.0%) and IV (14.0%); 20.0% of colon cancer patients undergoes surgery (left or right hemicolectomy). Drug availability and medical guidelines recommendations drive prescription to treat colon cancer. Surgery in rectum cancer is applied at stages IIIB or IV (range: 17.6%, 20.0% and 16.9%, respectively). Rectum cancer presents.

CANCER – Conceptual Papers & Research on Methods

IMPROVING ASCERTAINMENT OF VITAL STATUS USING SOCIAL SECURITY DEATH MASTER FILE (SSDMF) AND THE NATIONAL DEATH INDEX (NDI)

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BACKGROUND: Ascertainment of vital status is critical to studies in many disease areas especially in oncology. Two commonly used sources for mortality are SSDMF and NDI, with NDI considered the gold standard. Limitations identified in previous studies are under-ascertainment associated with the former; time lag (1–2 years) and higher cost associated with the latter. OBJECTIVES: To compare ascertainment of vital status by consolidating mortality data from SSDMF and NDI vs. either source alone. METHODS: Patient identifiers for a cohort of 3764 cancer patients from a large US claims database were submitted to SSDMF (cutoff February 2009) and NDI (cutoff December 2007) to obtain vital status. Matching to SSDMF utilized SSN alone or a combination of last name, first name and birthdate. Matching to NDI utilized combinations of SSN and/or patient name, birthdate, and state of residence. For patients with a death date found in NDI, a variable indicating a true or false match was provided by NDI based on the probabilistic score. We derived the death date via a stepwise approach by utilizing all match results from either source. RESULTS: Of 3764 patients, SSDMF returned a match for 901 (24%) patients using SSN alone, and 1088 (29%) patients using the combination. From the NDI, 946 (25%) patients had a “true” match, 1408 (37%) had a “false” match, and remainder were considered alive. Comparing SSDMF and NDI results utilizing both true and false NDI matches, we derived death dates for 1326 patients, with a match in 47% and 40% more compared to SSDMF by SSN alone or NDI true match, respectively. Eight patients had claims following death date and were considered false matches. CONCLUSIONS: Utilizing all match results from SSDMF and NDI identified significantly more deceased patients compared to either source alone. Misclassification of living patients as deceased appears minimal as verified by claims.
lematic. There is no single ICD-9 code to identify FN; therefore an algorithm must be created to identify FN patients. Previously published algorithms are generally comprised of 3 main codes: (1) neutropenia (primary designation ICD-9 code 288.01) (2) fever (ICD-9 790.86) (3) infection. However, the primary designation of neutropenia is not always the case. As a result, when assessing the impact of neutropenia in the neupropic cancer patient can often be difficult to confirm due to the lack of neurophil and typical clinical symptoms and signs; the febrile response may also be blunted. Therefore, the FN algorithm may use neutropenia alone, likely identifying patients with neutropenia alone in addition to those with FN. FN was defined as primary or secondary diagnosis of neutropenia or infection during the first chemotherapy course; 41% of cancer patient newly initiating chemotherapy were classified as having FN. When the FN definition was narrowed to primary or secondary diagnosis of neutropenia and other infection or fever 2% infection data was classified as having FN; when the definition was broadened to diagnosis of neutro- penia or fever or infection or a procedure code for infection treatment 64.7% were classified as having FN. There is a strong need to validate the coding associated with submitting medical claims for the treatment of FN in cancer patients receiving che-motherapy in real-world practice in order to utilize claims data to investigate FN.

PCN158
A METHOD TO INCREASE SAMPLE SIZE BY REMOVING THE CONTINUOUS ENROLLMENT REQUIREMENT
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OBJECTIVES: To introduce a method where the continuous enrollment requirement can be removed to increase the sample size and correct for incomplete informa-
tion with an advanced statistical technique. METHODS: The inverse probability weight least squares model is used to estimate the outcomes from a sample that does not require continuous enrollment in the inclusion criteria. This method involves two steps: probabilities are estimated using a non-parametric approach, and standard errors of the outcomes regression are adjusted for the first step estimation. RESULTS: To demonstrate the technique, we used U.S. claims data. Patients with incidents of lung cancer were used. A total of 236 patients were identified without the continuous enrollment requirement of one year after diagnosis. With the continuous enrollment requirement, our sample size would be 87. Incomplete cases were more likely to have surgery and higher rates of comorbidities. R-squared increased 25% with the inverse probability weighted technique. Standard errors decreased with 35% and therefore improved the precision of our estimators. CONCLUSIONS: The con-
tinuous enrollment requirement does not have to be applied for pharmacoeconomic studies. Results might be biased if there are substantial differences between complete and incomplete observations. Even though there are no differences, removing this requirement increases the sample size and provides efficient estimators, especially in rare events.

PCN159
HFS 14: A SPECIFIC QUALITY OF LIFE SCALE FOR PATIENTS WITH HAND-FOOT SYNDROME
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BACKGROUND: Hand-foot syndrome or Hand-Foot skin reaction is a common adverse effect of certain chemotherapy agents, such as capecitabine or pegylated docorubicin, where it is estimated to occur in 50% of cases. OBJECTIVES: To introduce a method where the continuous enrollment requirement can be removed to increase the sample size and correct for incomplete information with an advanced statistical technique. METHODS: The inverse probability weight least squares model is used to estimate the outcomes from a sample that does not require continuous enrollment in the inclusion criteria. This method involves two steps: probabilities are estimated using a non-parametric approach, and standard errors of the outcomes regression are adjusted for the first step estimation. RESULTS: To demonstrate the technique, we used U.S. claims data. Patients with incidents of lung cancer were used. A total of 236 patients were identified without the continuous enrollment requirement of one year after diagnosis. With the continuous enrollment requirement, our sample size would be 87. Incomplete cases were more likely to have surgery and higher rates of comorbidities. R-squared increased 25% with the inverse probability weighted technique. Standard errors decreased with 35% and therefore improved the precision of our estimators. CONCLUSIONS: The continuous enrollment requirement does not have to be applied for pharmacoeconomic studies. Results might be biased if there are substantial differences between complete and incomplete observations. Even though there are no differences, removing this requirement increases the sample size and provides efficient estimators, especially in rare events.

PCN160
PATIENT-REPORTED OUTCOMES SUPPORTING ONCOLOGY PRODUCT LABELING CLAIMS: TRENDS AND CHALLENGES
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The FDA has advocated the PRO Draft Guidance released in 2006 as the main vehicle for evaluating PRO and HRQOL claims in oncology product approvals. Additionally, FDA-affiliated researchers have identified factors inhibiting acceptance of HRQOL-based claims for oncology product labels, including: trial design, missing data, multi-
plecy, and inconsistent findings of HRQOL data. The views of the FDA on PRO and HRQOL claims are extensive per its own guidance, which puts forth detailed, restric-
tive requirements on use. These matters clarify why the FDA has not yet allowed the utilization of PRO or HRQOL data as primary evidence to support an oncology product approval. In contrast, the EMEA since its establishment in 1995 has con-
ducted authorizations without an explicitly defined approach for evaluating HRQOL and other PRO data. Further, a reflective paper released in 2005 offered only broad recommendations on HRQOL labeling claims. As a result, the use of PRO or PRO data in the review process is based more broadly on its relevance to a given drug and overall assessment of the study in the eyes of the reviewers. The varying approaches between the FDA and the EMEA partly stem from divergent underlying organizational characteristics. The FDA enforces laws regarding medical product quality. Alternatively, the EMEA serves as a coordinating body, leaving enforcement responsibility to member states. Consequently, the EMEA provides more generic advice, whereas the FDA insists on rigorous criteria for conceptual and study design issues surrounding PRO claims. Otherwise, the EMEA is more likely to accept well-established PRO and HRQOL measures, whereas the FDA is inclined to request new PRO measures that explicitly satisfy the agency’s most recent evaluative stand-
ards. Finally, the FDA places greater focus on symptom-based endpoints reflecting the direct consequences of treatment, whereas the EMEA is more willing to accept global HFQOL claims.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PD1B
ASSOCIATION BETWEEN GLYCOXYLATED HEMOGLOBIN AND CARDIOVASCULAR OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A NESTED CASE-CONTROL STUDY
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OBJECTIVES: To describe the association between the three-year average glycoxylated hemoglobin (AIC) and cardiovascular outcomes in adults with type 2 diabetes mellitus (T2DM). METHODS: In this nested case-control study, 245,416 adults (≥18 years) with T2DM were identified among members of Kaiser Permanente Southern Califor-
ia. Type 2 diabetes patients had at least two ICD-9 diagnosis codes for T2DM (250, x0, 250.x2) and either AIC > 7.5% or prescriptions for hypoglycemic agents from 2002-2007. Using hospital records and death certificates, cases were defined as patients with a nonfatal MI, nonfatal stroke, or death due to cardiovascular (CV) causes (MI, stroke, heart failure, arrhythmia, sudden cardiac death) during the period included 395 days pre/210 days post from the index date. Four controls from the T2DM pool were matched to each case based on age, sex and index date (date of the case defining event). A conditional logistic regress-
ion model was used to estimate the odds-ratio (OR) of cardiovascular events compar-
ing patients with an average AIC ≤ 6% and those with average AIC > 8% to patients with average AIC between 6–8%, considered ‘near A1C target’. A1C categories were assigned to each patient based on average A1C over the three years prior to the index date. RESULTS: A total of 44,628 controls were matched to 11,137 cases. After adjusting for CV related medications, comorbidities, and other confounders, patients with an average AIC ≤6% were 50% more likely to experience a CV event than the ‘near A1C target’ T2DM patients (OR = 1.50, 95% CI 1.33–1.65, p < 0.0001). Patients with an average AIC > 8% experienced a 14% increase in odds of a CV event (OR = 1.14, 95% CI 1.03–1.26, p = 0.01). CONCLUSIONS: Compared to those with mean A1C levels between 6–8%, patients with T2DM who achieved mean A1C levels of ≤6% or failed to decrease their A1C below 8% over a 3-year period are at increased risk for cardiovascular events.

PD2B
THE IMPACT OF ORAL ANTIDIABETICS ON WEIGHT IN THE ELDERLY WITH TYPE 2 DIABETES MELLITUS IN THE AMBULATORY SETTING
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OBJECTIVES: To assess the impact of oral antidiabetics agents on weight change in Type 2 Diabetes Mellitus (T2DM) patients age 65 years and older. METHODS: An electronic medical record, General Electric Centricity research database, containing the ambulatory health records of US patients was used to conduct a historical cohort study of the T2DM elderly patients identified by ICD-9 codes, OAD prescription or both. Six months of continuous OAD monotherapy activity was required, and study participants must have been age (≥65) and meet the inclusion criteria. OAD readings were mandated, at baseline, and follow up. Data were analyzed using ANOVA with Tukey test to correct for multiple comparisons. RESULTS: A total of 2720 patients with a primary diagnosis of T2DM were included in the study. The overall mean age was 72.7 years. Statistical significant differences between users of different OADs at baseline were found for diastolic blood pressure (p = 0.0009), and age (< 0.001). The most prescribed OAD medications were metformin (58.9%), glipizide (14.5%) and glimepiride (7.7%). The overall mean change in AIC level was 2.92% (p < 0.001) units and weight change was -0.89 lb. Significant differences in BMI units change were found for metformine users (-2.17), sulfonylureas users (-1.06), and glimepiride users (-0.89). CONCLUSIONS: An association was found between the OAD use and