11000 Oral Abstract Session

Psychosocial digital application for caregivers of patients undergoing hematopoietic stem cell transplantation (HSCT): A randomized controlled trial.

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Background: Caregivers (i.e., relatives and friends) of patients undergoing HSCT struggle with considerable quality of life (QOL) impairments and psychological strain before, during, and after HSCT. However, few interventions address the supportive care needs of these caregivers while prioritizing accessibility and scalability. We assessed the efficacy of a self-guided digital application, called BMT-CARE App, for improving HSCT caregivers' QOL, burden, mood symptoms, coping skills, and self-efficacy. **Methods:** We conducted a single-center randomized trial of the BMT-CARE App for HSCT caregivers, compared with usual care (UC). Eligible individuals were adults caring for patients with hematologic malignancies undergoing autologous or allogeneic HSCT at a tertiary care center and were randomly assigned 1:1 to the BMT-CARE App or UC, stratified by transplant type. Intervention participants engaged with the app before transplant and up to 60 days post-HSCT. The app comprises five modules integrating psychoeducation, evidence-based behavior change, and stress management, delivered through interactive features, educational games, and videos. Participants completed self-report measures at baseline and day 60 post-HSCT. The primary endpoint was QOL at day 60 post-HSCT assessed by the CareGiver Oncology QOL (CarGOQOL) questionnaire. We also assessed caregiving burden (Caregiver Reaction Assessment [CRA]), anxiety and depression symptoms (Hospital Anxiety and Depression Scale [HADS]), posttraumatic stress disorder (PTSD) symptoms (PTSD Checklist [PCL-5]), coping skills (Measure of Current Status-A [MOCS-A]), and self-efficacy (Cancer Self-Efficacy Scale-transplant [CASE-t]). We used analysis of covariance controlling for baseline criterion values to assess the effect of the intervention on study outcomes. **Results:** From 2/2023 - 7/2024, we enrolled 125 of 174 approached (71.8%) caregivers (BMT-CARE App n = 62, UC n = 63; median age = 58.7 years [range, 27.8-78.6]). Most participants were spouses (71.2% [89/125]). Participants assigned to BMT-CARE App used the app for a mean of 133.2 minutes (SD = 101.9). At 60 days post-HSCT, intervention participants reported better QOL compared to those assigned to UC (76.2 vs 69.9, p = 0.006]), exceeding the 5-point clinically meaningful difference on the CarGOQOL. BMT-CARE App participants also reported lower caregiving burden (11.2 vs 12.3, p = 0.024), depression (3.8 vs 5.6, p = 0.002), and PTSD symptoms (26.0 vs 31.3, p = 0.011), and better coping skills (33.9 vs 28.2, p = 0.003). The two groups did not differ significantly in anxiety symptoms or self-efficacy at day 60 post-HSCT. **Conclusions:** The BMT-CARE App, a psychosocial digital health intervention, led to substantial improvements in QOL, caregiving burden, depression and PTSD symptoms, and coping skills in caregivers of HSCT recipients. Clinical trial information: NCT05709912. Research Sponsor: Leukemia and Lymphoma Society.

11001 Oral Abstract Session

Outcomes of an electronic patient-reported outcomes (ePRO)–based symptom management program (eSyM): A cluster randomized trial.

Michael J. Hassett, Hajime Uno, Angela C. Tramontano, Christine M. Cronin, Roxanne E. Jensen, Ashley Wilder Smith, Jessica J. Bian, Don Steven Dizon, Hannah W. Hazard-Jenkins, Gabriel A. Brooks, Raymond U. Osarogiagbon, Sandra L. Wong, Deb Schrag; Dana-Farber Cancer Institute, Boston, MA; National Cancer Institute, Bethesda, MD; MaineHealth Cancer Care, South Portland, ME; Legorreta Cancer Center at Brown University, Providence, RI; WVU Cancer Institute, West Virginia University, Morgantown, WV; Dartmouth Cancer Center, Lebanon, NH; Baptist Cancer Center, Multidisciplinary Thoracic Oncology Program, Memphis, TN; Emory University, Atlanta, GA; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Although ePROs have been shown to reduce resource utilization and improve outcomes among people with cancer, they have not been widely adopted. We conducted a pragmatic type II hybrid effectiveness-implementation cluster randomized stepped-wedge trial of an ePRO-based, EHR-integrated symptom management program (eSyM) across 6 health systems. Here, we report the primary effectiveness outcome comparing patients treated before (control/not exposed) versus after (intervention/exposed) eSyM deployment. **Methods:** Eligible patients were adults who started chemotherapy (CHEMO) or were discharged after surgery (SURG) for a suspected or confirmed GI, GYN, or thoracic cancer. The intervention included ePRO questionnaires based on PRO-CTCAE items, severe symptom alerts, self-management tip sheets, and communication support. Outcomes included having an emergency department (ED) visit or inpatient admission (INPT) within 30 and 90-days. Logistic regression models accounted for socio-demographic, clinical, calendar time, health system, and other factors. Secondary analyses stratified results by treatment and health system to assess for effect modification. **Results:** From Jan. 2018 to Feb. 2023, the control and intervention conditions accrued 21,112 and 18,830 patients, respectively (median age 62 vs. 65; female 68% vs. 63%). Patient enrollment by health system ranged from 3,961 to 14,560. In the intervention cohort, 51% of patients used eSyM to report symptoms. Crude 30-day event rates for the control and intervention cohorts were 5.4% vs. 6.2% for ED, and 8.5% vs. 9.1% for INPT. Accounting for other factors, there were no significant differences in ED or INPT at 30 (Table) or 90 days. Among SURG patients, there was significantly greater odds of ED, but not INPT, for the intervention vs. control cohort. Results varied by health system, with evidence of higher, similar, and lower odds for the intervention vs. control cohort. **Conclusions:** eSyM deployment did not significantly reduce ED or INPT events. Only half of exposed patients used eSyM to report symptoms. Since prior analyses found lower odds of acute care utilization among patients who reported symptoms via eSyM, implementation and engagement barriers may have substantially impacted effectiveness outcomes. Heterogeneity of effect by health system and treatment suggest that healthcare structures, processes, and baseline performance may influence the uptake and impact of ePRO-based symptom management systems. Clinical trial information: NCT03850912. Research Sponsor: National Cancer Instiute; 1UM1CA233080-01.

Events at 30 days		OR for ED	95%CI	OR for INPT	95% CI
Overall		1.10	0.94-1.29	1.00	0.88-1.14
Stratified by treatment	Chemo	0.93	0.72-1.20	0.85	0.70-1.05
	Surg	1.23	1.01-1.49	1.10	0.93-1.30
Stratified by health system	A	1.26	1.07-1.50	1.59	1.37-1.85
	B	1.47	1.15-1.88	1.25	0.98-1.58
	C	0.74	0.61- 0.90	0.71	0.61-0.82
	D	0.90	0.68-1.20	0.92	0.75-1.12
	E	0.92	0.70-1.23	1.09	0.87-1.38
	F	1.19	0.96-1.47	0.80	0.68-0.95

11002 Oral Abstract Session

Improving care of older adults with cancer: A randomized trial.

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Background: Undertreated symptoms are common among older adults with cancer. Previously, a lay health worker (LHW)-led proactive symptom assessment intervention was associated with reduced symptoms in one community clinic. Yet, the effect on acute care use, total costs, and end-of-life (EOL) care at scale remains unknown. **Methods:** Adults ages 75 years or older who were Medicare Advantage beneficiaries with newly diagnosed cancer were eligible to participate in this randomized trial across 43 clinics in Southern California and Arizona. Participants were randomized 1:1 into a control group (usual care alone) or an intervention group (usual care and LHW-led proactive, telephone-based weekly symptom assessments for 12 months using the validated Edmonton Symptom Assessment System) with a planned enrollment of at least 200 in both groups. The LHW reviewed assessments with a physician assistant who conducted follow-up for symptoms that changed by 2 points from a prior assessment or were rated 4 or greater. We used generalized regression models to compare acute care use and total costs (obtained from payer claims data) for 12-months follow-up or death, whichever was first, offset for length of follow-up, and, among those who died, compared EOL acute care use, costs, and acute care facility deaths. **Results:** 416 patients participated (216 control; 200 intervention) with median age of 82 years (range 75-99); 205 (49.28%) were Hispanic or Latino, 10 (2.4%) African American or Black, 12 (2.88%) Asian, 2 (0.48%) Native Hawaiian, 1 (0.24%) Pacific Islander, 180 (43.3%) Non-Hispanic White, 6 (1%) other; 219 (52.6%) were male; 118 (28.3%) had gastrointestinal, 92 (22%) had genitourinary, 62 (14.9%) had breast, and 48 (11.5%) had thoracic cancer; 171 (41%) had stage 4 disease. The intervention group had 53% lower odds of emergency department use (OR: 0.47, 95% CI 0.37-0.62) and 68% lower odds of hospital use (OR: 0.32, 95% CI 0.20-0.51) than the control group. Among deceased participants (71 (32.9%) control; 71 (35.5%) intervention), the intervention group had 68% lower odds of acute care (OR: 0.32, 95% CI 0.12-0.88), lower total costs of care by $12,000 USD per participant (p = 0.01), and 75% lower odds of an acute care facility death (OR 0.25; 95% CI 0.08-0.77). **Conclusions:** This proactive symptom assessment intervention may be one sustainable, scalable, efficient, and effective approach to improve care for older adults with cancer. Clinical trial information: NCT04463992. Research Sponsor: None.

11003 Oral Abstract Session

Randomized trial of a supportive oncology care at home intervention for patients with cancer receiving curative treatment.

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Background: Patients with cancer receiving curative treatment often endure substantial symptoms and utilize significant healthcare resources. Symptom monitoring interventions and hospital at home care models represent a promising approach for improving these patients' outcomes. **Methods:** We conducted a randomized trial of a Supportive Oncology Care at Home intervention versus usual care in adult patients receiving treatment with curative intent (chemotherapy and/or chemoradiation) for pancreatic, rectal, gastroesophageal, and head and neck (H&N) cancer, as well as non-Hodgkin lymphoma, who resided in-state, within 50 miles of our hospital. Patients were randomized to receive the Supportive Oncology Care at Home intervention or usual care within two weeks of initiating therapy and remained on trial for up to 6 months. The intervention entailed: 1) remote monitoring of daily patient-reported symptoms, vital signs, and body weight; 2) a hospital at home care model for symptom assessment and management; and 3) structured communication with the oncology team. The primary outcome was the proportion of patients requiring inpatient hospital admission or emergency department (ED) visits during the study period. Secondary outcomes included urgent visits to the clinic, treatment delays, and longitudinal changes in monthly assessments of quality of life (QOL; Functional Assessment of Cancer Therapy-General), symptoms (Edmonton Symptom Assessment System [ESAS] and Hospital Anxiety and Depression Scale [HADS]), and activities of daily living (ADLs). **Results:** We enrolled 50.8% (199/392) of potentially eligible patients. One patient withdrew consent and 2 became ineligible following consent, resulting in 196 participants (median age=65.8 [range: 21.1-92.0], 39.8% female, cancer types: 34.2% pancreatic, 27.0% H&N, 16.3% lymphoma, 12.8% rectal, 9.7% gastro-esophageal). The proportion of patients requiring hospital admission or ED visit did not differ significantly between the intervention and usual care groups (37.1% v 35.7%, p=.87). Intervention participants were less likely to require an urgent visit (7.2% v 24.5%, $p<.01$), but there were no differences in rates of treatment delays >7 days (29.9% v 33.0%, p=.62). Compared to baseline assessments, intervention participants had greater improvement in ESAS symptoms ($p<.01$) and ADLs (p=.04) over time. QOL and HADS depression/anxiety symptoms did not differ longitudinally between groups. **Conclusions:** Although this Supportive Oncology Care at Home intervention did not have a significant impact on rates of hospital admissions or ED visits, we found encouraging results for reducing urgent visits to the clinic and substantial improvement in symptom burden and ADLs, underscoring the potential utility of this novel care model for enhancing care delivery and outcomes for patients with cancer receiving curative treatment. Clinical trial information: NCT04544046. Research Sponsor: The Medically Home Group.

11004 Oral Abstract Session

Empowering young-onset colorectal cancer patients with an accessible, self-navigable online platform for universal germline testing.

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Background: Since 2022, the National Comprehensive Cancer Network (NCCN) has recommended universal germline testing (UGT) for all individuals diagnosed with colorectal cancer (CRC) under age 50. Up to 20% harbor a germline cancer predisposition, and identifying this high-risk cohort is critical for personalized care. Realizing UGT has been hampered by access to and delivery of cancer genetics care, highlighting the need for novel strategies. We report the impact of an accessible, self-navigable online platform for UGT. **Methods:** Consecutive YOCRC patients were offered a standardized care pathway including UGT. A prospective quality improvement trial aimed at UGT launched an interactive online platform designed to enable self-eligibility screening, self-navigation to video-based pretest education and counseling, consent submission, and blood or saliva collection arrangements. Patients could self-opt for genetic counseling (GC, in-person or virtual) at any time, and those who did not engage with the online platform after 3 invitations were reflexively referred to GC. The trial was designed with a 3-month run-in pilot followed by a 12-month study period. The primary outcome was UGT completion rate; secondary outcomes were process feasibility and GC resource preserved. **Results:** Among 377 YOCRC patients, 158 had GT prior to referral, 7 were international, 3 declined all contact, and 209 patients were invited to the online UGT platform. Another 49 reported prior GT, leaving 160 patients of interest. Active platform engagement was observed in the majority (100 of 160 patients, 63%), where 89 (89%) completed UGT, including 79 (96%) of the 82 who self-navigated the entire online platform and 10 (71%) of the 14 who had opted for GC. Lack of platform engagement led to reflex GC referral for 60 patients, and 19 (32%) have completed GT to date. Taken together, among 160 patients of interest, pre-test GC workforce involvement was spared in 79 (49%) patients through the online platform. **Conclusions:** The rising incidence of YOCRC, increasing patient demand and limited GC resources are barriers to executing UGT. We successfully implemented an online platform achieving 96% GT completion rate among those who self-navigated the entire process, and eliminating the need for pre-test GC resource utilization in nearly half of the cases. Our experience supports online care delivery platforms that highlight accessibility and autonomy. Research Sponsor: None.

11005 Oral Abstract Session

Real-world social determinants of health (SDOH) and outcomes of early-onset colorectal cancer (EO-CRC): An analysis of a large, nationally representative US community oncology network.

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Background: The rise of EO-CRC in individuals under the age of 50 presents a major public health challenge, as these patients may encounter unique barriers to both screening and treatment. Understanding the drivers and implications of EO-CRC is crucial, and real-world data (RWD) can serve as a valuable tool by offering insights into evolving diagnostic, utilization, and practice landscapes, with robust information on social determinants of disease burden. Building on existing disparity concerns, this study leveraged RWD from a large, nationally diverse network of US community oncology practices to describe the SDOH and outcomes of patients with EO-CRC. **Methods:** This retrospective observational cohort study examined adult CRC patients within The US Oncology Network and non-Network practices, encompassing over 2,500 community-based providers treating more than 1.4 million patients annually. All patients diagnosed with CRC between 2000 and 2024 were included; patients were categorized as EO-CRC if they were < 50 years at first diagnosis and average-onset (AO)-CRC otherwise. Patient characteristics were sourced from iKnowMed, an oncology-specific electronic health record system, and descriptively summarized. Overall survival (OS) was assessed from diagnosis using Kaplan-Meier methods. **Results:** A total of 104,281 patients were identified, including 14,611 (14%; median age: 44 years) with EO-CRC and 89,670 (86%; median age: 67 years) with AO-CRC. Patients in the EO-CRC cohort were more likely to be Black (11% vs. 8%), American Indian or Alaska Native race (1.3% vs. 0.9%), of a documented race other than White (20% vs. 15%), and of Hispanic/Latino ethnicity (11% vs. 8%) versus the AO-CRC cohort. Few of EO-CRC (11%) and AO-CRC (10%) patients were current smokers at time of diagnosis. More than one-third of EO-CRC group was obese (36%), slightly higher than in AO-CRC (31%). EO patients were more commonly located in urban areas (69% vs. 63% of AO patients). Among 2,810 patients with Distress Thermometer data, EO-CRC patients were more likely to report high or moderate distress (29% vs. 22%) and less likely to report low distress (71% vs. 78%). 5-year OS probability was 72% (95% CI: 71-73) for EO-CRC and 64% (95% CI: 63-64) for AO-CRC. **Conclusions:** In one of the largest cohorts of patients with EO-CRC to date, this study confirmed that EO-CRC is an emerging concern within the US community oncology setting, particularly regarding heightened disparities in race, ethnicity, and lifestyle factors. EO patients may face unique burdens related to timely screening and diagnosis, necessitating tailored and cross-disciplinary approaches to their care, and warranting additional investigation into social and clinical drivers of survival outcomes to improve long-term prognosis. Research Sponsor: Ontada.

11006 Oral Abstract Session

Association of Medicaid expansion with five-year survival after cancer diagnosis.

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Background: Medicaid expansion is associated with improvements in early detection, access to treatment, and increased 2-year cancer survival. However, the association between Medicaid expansion and longer-term survival outcomes in newly diagnosed cancer patients remains understudied. **Methods:** Patients aged 18-59 years newly diagnosed with first primary cancers in 2007-2008 and 2014-2015 living in 25 states (AZ, AR, CA, CO, CT, DE, HI, IL, IA, KY, MD, MI, MN, NV, NH, NJ, NM, NY, ND, OH, OR, RI, WA, WV) that expanded Medicaid in 2014 and 12 states (AL, FL, GA, MS, MO, NC, OK, SC, TN, TX, WI, WY) that had not expanded Medicaid by the end of 2020 were obtained from the Cancer Incidence in North America (CiNA) Survival dataset compiled by the North American Association of Central Cancer Registries. Cases were stratified by cancer type, race and ethnicity, census-tract poverty level, and rurality. Difference-in-differences analysis was used to examine the association of Medicaid expansion with changes in 5-year observed overall and cause-specific survival (CSS) based on multivariable flexible parametric survival models adjusted for age group, sex, race and ethnicity, census tract–level poverty, rurality, state, and year of diagnosis. **Results:** A total of 1,256,349 individuals were diagnosed with cancer in Medicaid expansion (N = 698,870) and non-expansion states (N = 557,479) during the study period. The 5-year overall survival increased from 65.0% to 73.4% in expansion states and from 61.0% to 70.0 in non-expansion states, leading to a non-significant net increase of 0.21 percentage points (95%CI: -0.11,0.53) in expansion states after adjusting for sociodemographic factors. Increases in observed and cause-specific survival were greatest in expansion states for cancers of the pancreas (observed: 1.86ppt, 95%CI: 0.33ppt – 3.39ppt; CSS: 2.33ppt, 95%CI: 0.51ppt – 4.14ppt), colon and rectum (observed: 1.55ppt, 95%CI: 0.45ppt – 2.65ppt; CSS: 1.64ppt, 95%CI: 0.53ppt – 2.76 ppt), and lung (observed: 1.19ppt, 95%CI: 0.32ppt – 2.07ppt; CSS: 1.16ppt, 95%CI: 0.09ppt – 2.24ppt). The net increase associated with Medicaid expansion was also prominent among non-Hispanic Black patients (observed: 1.25ppt, 95%CI: 0.30ppt – 2.19ppt; CSS:0.80ppt, 95%CI: -0.10ppt – 1.70ppt), people living in the most deprived area (observed: 1.21ppt, 95%CI: -0.14ppt – 2.56ppt; CSS:1.45ppt, 95%CI: 0.16ppt – 2.75ppt), and rural communities (observed: 2.30ppt, 95%CI: -0.30ppt – 4.88ppt; CSS:2.40ppt, 95%CI: -0.03ppt – 4.83ppt). **Conclusions:** Medicaid expansion was associated with greater increases in 5-year observed and cause-specific survival for Non-Hispanic Black individuals, individuals living in the most deprived area, and rural communities. These findings reinforce the importance of Medicaid expansion in reducing disparities in cancer survival outcomes. Research Sponsor: None.

11008 Oral Abstract Session

A randomized controlled trial comparing pragmatic interventions to improve mammogram uptake in a non-compliant population.

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Background: Despite over 20 years of a national breast cancer screening program, mammogram uptake in Singapore, a highly developed Asian country, remains under 40%. Limited large-scale prospective data exist on effective pragmatic interventions to boost screening participation. **Methods:** 9000 Singaporean women aged 50-69, eligible for free biennial screening, non-compliant (at least 1 prior mammogram but overdue by > 2 years from last screen), with no breast cancer history and registered on hospital's mobile health app, were randomly selected from a tertiary hospital's electronic medical records and allocated to one of the 5 arms in a 2:1:1:1:1 ratio. Arm 1 (control; n = 3000) received physical mailer reminders (MR). Four intervention arms (n = 1500 each) received MR plus- Arm 2: US$7.4 voucher on screening completion, Arm 3: US$3700 lottery chance, Arm 4: video health message, and Arm 5: health concierge for appointment scheduling. Arms 1–5 also received the reminders via 3 push notifications (PN), spaced 3 weeks apart, through the app. A non-interventional (NI) cohort (n = 3000) fulfilling similar criteria served as comparison. Primary outcome was mammogram uptake rate within 4 months of reminder in Arm 1 vs Arms 2-5. Secondary outcomes included participation rate in Arm 1 vs NI group. Exploratory analysis included cost-effectiveness of intervention and app utility in shaping health behaviour. **Results:** 74% of the 12000 participants were Chinese, followed by Malay (13%) and Indian (7%), reflecting Singapore's demographics. Median age was 62 years (67% aged 60-69). 89% lived in public and 11% in private housing. 99% lived within 5 km of a mammogram facility. Median interval from last mammogram was 5.2 years (range: 2.0–21.5); longer in women aged 60-69 vs 50-59 (6.1 vs 3.9 years, $p < 0.0001$). Mammogram uptake in the NI group was 3.3% and increased to 11.2% with MR alone (Arm 1; RR 3.28, 95% CI 2.60–3.96, $p < 0.01$). Uptake in Arm 5 was slightly higher than in Arm 1 (13.8% vs 11.2%, RR 1.23, 95% CI 1.07-1.38, p = 0.01), but not significant after adjusting for multiple comparisons (p-adj = 0.11). Arms 2-4 (12.1%, 11.3%, 10.8%) showed no difference vs Arm 1. Intervention cost per compliant subject was US$7 in Arm 1, increasing to $13, $28, $32 and $40 in Arms 2-5 respectively. Only 4.1% (3.1–4.6%) in the 5 intervention arms accessed the webpage via PN and < 1% clicked the self-help booking link. **Conclusions:** A physical MR significantly improved mammogram participation in a non-compliant population, but additional monetary incentives or health message offered no further benefit. A concierge service slightly improved uptake but at a 6-fold higher cost. PNs had limited utility in this older population. A low-cost MR program is scalable and piloting concierge services for targeted groups may enhance cost-effectiveness. Further research should explore barriers to digital intervention engagement in this age group. Clinical trial information: NCT06733155. Research Sponsor: National University Cancer Institute, Singapore (NCIS).

11009 Rapid Oral Abstract Session

Association between environmental burden and cancer incidence rates across population subgroups in the United States (US).

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Background: With more than 2 million projected new cancer diagnoses in 2025 in the US alone, many studies have linked environmental pollutants to carcinogenesis. However, they often examine exposures in isolation, overlooking the complexity of real-world multi-exposure conditions. In this study, we investigate the impact of multiple simultaneous environmental exposures on cancer incidence rates at the county level. **Methods:** Data on environmental burden (for e.g. air and water pollution, toxic sites, built environment), measured using the Environmental Burden Module (EBM), were obtained from the CDC Environmental Justice Index. County-level cancer incidence rates for breast, pancreas, prostate, lung, colon, and all cancers combined were obtained from the CDC State Cancer Profiles. Multivariable linear regression models estimated the effects of EBM quartiles (Q1 as the reference, representing the lowest burden, and Q4 noting highest) on cancer incidence rates for the total population and stratified by urbanicity, sex, and age. Interaction terms between EBM quartiles and demographic variables (sex and age) were significant ($p < 0.05$). All results are presented as cases per 100,000 population. **Results:** Higher environmental burden was associated with increasing incidence rates for all cancers in Q3 (15.61 [9.45, 21.78]) and Q4 (7.87 [1.59, 14.15]) across all US counties. Breast (4.45; 95% CI [2.10, 6.80]) and prostate cancer (2.57 [1.00, 4.78]) noted strongest association in Q4. Similarly, rural counties too showed increased rates of all cancers with increasing environmental burden (Q3: 18.22 [10.56, 25.88]); Q4: 21.15 [7.41, 34.89]). In urban counties, prostate cancer incidence was higher in Q4 (4.65; [0.08, 9.22]). Among males, lung cancer incidence increased significantly in the most environmentally burdened counties (Q4: 0.45 [0.21, 0.89]). For colon cancer, while incidence rate for males decreased significantly (Q4: -0.45 [-0.91, -0.01]), it increased among females in the most environmentally burdened counties (Q4: 21.15 [14.21, 28.18]). For older individuals ($>$ 65y), Higher rates of all cancers combined were found in Q3 (125.70 [76.95, 174.44]) and Q4 (117.15 [68.04, 166.26]). Lung cancer incidence was especially sensitive to environmental burden – higher rates were observed in Q2 (3.99 [0.12, 7.87]), Q3 (4.88 [1.49, 8.28]), and Q4 (4.73 [1.56, 7.91]). **Conclusions:** Greater environmental burden was associated with increased cancer incidence rates across several cancer types with sociodemographic variation. These results indicate the need for regulatory policy and infrastructural investment aimed at mitigating these risks in targeted communities. Further research with higher-resolution data is needed to elucidate these associations and underlying etiologic mechanisms. Research Sponsor: None.

11010 Rapid Oral Abstract Session

Complex interplay between housing insecurity and forgone care among U.S. cancer survivors.

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Background: One-sixth of U.S. cancer survivors experience housing insecurity, and one-fifth report delaying or forgoing care due to costs. The role of social determinants of health (SDoH) among cancer survivors is complex and poorly understood. We sought to examine the prevalence of housing insecurity and forgone care, and their effects in conjunction with SDoH among cancer survivors. **Methods:** The Medication Expenditure Panel Survey (MEPS) is an annual survey representative of the civilian, non-institutionalized United States population. The 2022 MEPS survey included a Preventative Care Self-Administered Questionnaire measuring late rent/mortgage payments indicative of housing insecurity in the past year. We considered adult cancer survivors (excluding non-melanoma skin cancer) who reported an inability to afford or had to delay any medical/dental care or prescription medications, as forgoing care. We extracted sociodemographic and clinical characteristics. Survey-adjusted Wilcoxon rank-sum tests and chi-square tests assessed differences in continuous and categorical variables, respectively, for individuals with and without housing insecurity, cancer, and forgone care. A multivariate regression analysis adjusting for age, sex, race, and poverty status identified predictors of forgoing medical care. We conducted weighted analyses to account for the complex survey design and considered $p < 0.05$ as statistically significant. **Results:** A total of 1,776 cancer survivors (weighted (w): 21,088,176) and 20,655 individuals with no cancer (w: 311,965,067) were identified. Among cancer survivors, 13% (w: 1,315,879) reported housing insecurity while 19% (w: 4,063,946) were forgoing care. Housing insecurity was reported in 8% of female survivors compared to 4% of male survivors, while 22% of women forwent care compared to 16% of men. Black Americans were less likely to report forgone care (13%) compared to White (19%) and Hispanic cancer survivors (25%), while housing insecurity was higher among all minorities (~10%) compared to White survivors (5%). Younger cancer survivors aged 18-45 years reported four-fold rates of housing insecurity and 1.5 times the rate of forgone care compared to survivors over 65. Multivariate logistic regression revealed forgoing medical care was more prevalent in individuals aged 45–64 (aOR = 1.6), women (aOR = 1.5), the near poor (aOR = 2.9), and those experiencing housing insecurity (aOR = 4.1), but less prevalent in Black Americans (aOR = 0.5) (all $p < 0.05$). **Conclusions:** This is the first nationally representative study to report the complex interplay between housing insecurity and forgone care among cancer survivors. The interactions highlight some unexpected high-risk groups like women, near-poor individuals, and middle-aged individuals, who are more likely to forgo care when forced to choose or prioritize care. Future policies need to target these high-risk groups. Research Sponsor: None.

11011 Rapid Oral Abstract Session

Beyond the clinic: Comprehensive assessment of time burdens in cancer care.

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Background: Managing cancer care can be highly demanding, consuming time and energy. Measuring this time has been limited to date. We sought to comprehensively measure the time spent on cancer-related care by leveraging a mobile application, Daynamica, which collects spatiotemporal sensing data in real-time while limiting intrusiveness to capture both objective and subjective dimensions of time use. **Methods:** As a proof-of-concept, we recruited individuals with metastatic breast or advanced stage ovarian cancer receiving treatment at the University of Minnesota and University of Alabama-Birmingham. Participants utilized the Daynamica app for 28 days, reporting healthcare encounters (location and type), along with completing end-of-day (EOD) surveys regarding at-home cancer-care related activities. We summarized the number and type of healthcare encounters and quantified time spent traveling to/from, waiting for, and receiving care. Utilizing the EOD survey data, we also quantified time spent on cancer-care related tasks at home. **Results:** A total of 58 individuals provided data for this analysis: 31 (53%) with metastatic breast cancer and 27 (47%) with advanced stage ovarian cancer; 29% were < 50 years old, 72% non-Hispanic (NH) White and 17% NH Black. Participants reported a median of 6 out-of-home healthcare episodes during the study, representing a median of 108 min/week. These episodes were most frequently labeled as including treatment (33%), clinic visit (27%) and/or labs (28%); imaging (12%), pharmacy (11%) and research (3%) were less frequent. Participants reported varying wait times during their healthcare episodes, with most involving < 15 min wait (37%), though both no wait (19%) and > 60 min of waiting (19%) were frequent. We observed variation in time individuals spent traveling to/from their healthcare visit, with a median travel time per episode of 31 min (5th-95th percentile range 4-125). The proportion of time spent receiving care relative to wait and travel time was often less than 50% of the total time, particularly when the time spent receiving direct care was < 60 min. Participants reported spending a significant amount of time on telehealth visits, taking medications, scheduling appointments, and managing insurance and medical bills (median 120 min/week); of these 4 tasks, taking medicines or injections was the most frequently reported and time-consuming category. This estimate jumped to 325 min/week when also including time spent on symptom management, arranging help/transportation, and seeking information about cancer. **Conclusions:** The time spent on cancer related-care is vastly underestimated when capturing healthcare encounters only. Comprehensive measurement of time spent on cancer related tasks is an important first step towards developing and testing interventions to improve healthcare efficiencies and reduce patient burden. Research Sponsor: National Institutes of Health, National Cancer Institute; 1R01CA277714-01.

11012 Rapid Oral Abstract Session

Association of medical debt with cancer incidence rates in the US.

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Background: Medical debt is a growing challenge for U.S. patients and has been associated with higher cancer mortality. However, whether medical debt is associated with advanced-stage cancer diagnoses – a strong predictor of worse prognosis – remains unclear. This study investigated the association between medical debt in collections and overall and advanced stage cancer incidence rates in the U.S. **Methods:** We conducted an ecological study using 2019 county-level medical debt in collections data from the Urban Institute Debt in America project and age-adjusted cancer incidence rates (2017-2021) from the CDC State Cancer Profiles dataset. Outcomes were age-adjusted cancer incidence and age-adjusted late-stage (i.e., regional or distant) incidence rates for ten common cancers with screening tests or early signs. We used generalized linear mixed models, adjusting for urban-rural status, county-level Social Vulnerability Index, county population size, primary care physician density, median population age and state. **Results:** We included data from all 3,143 counties. The county-level percentage of medical debt in collections ranged from 0.0% to 23.5%. One percentage increase in medical debt was associated with a 74.80 (95% CI=43.45-106.19) increase in overall cancer incidence rate per 100,000 person-years. Regarding late-stage cancer incidence, one percentage increase in medical debt was associated with a 5.16 (95% CI=1.05-9.28) increase in late-stage incidence rate for colorectal, a 2.11 increase (95% CI=1.04-3.18) for bladder, a 2.73 (95% CI=1.08-4.39) increase for kidney and renal pelvis, a 28.69 (95% CI=22.22-35.17) for lung and bronchus, and a 0.14 (95% CI=0.01-0.26) increase for oral cavity and pharynx cancers, and a 2.99 (95% CI=1.53-4.44) increase for melanoma of the skin. No significant association was noticed in other cancer types. **Conclusions:** Medical debt in collections is associated with higher overall incidence and late-stage rates for multiple cancer types, suggesting financial barriers may impede both cancer screening and timely symptom evaluation. Research Sponsor: None.

Adjusted association of percent of population with medical debt in collections with cancer incidence rate at the county level (per 100,000).

	Incidence	Late stage incidence
All cancers	74.80 (43.45-106.19)	-
Colorectal	9.48 (3.68-15.28)	5.16 (1.05-9.28)
Kidney and renal pelvis	9.84 (6.48-13.22)	2.73 (1.08-4.39)
Lung and bronchus	41.02 (32.46-49.58)	28.69 (22.22-35.17)
Cervix	0.64(0.40-0.88)	0.17(0.00-0.34)
Melanoma	-5.73(-11.52-0.05)	2.99 (1.53-4.44)
Bladder	-0.73(-4.01-2.51)	2.11 (1.04-3.18)
Prostate	-13.70(-29.67-2.29)	-5.28(-11.10-0.42)
Breast	-1.43(-13.83-10.89)	4.57(-1.71-10.88)
Oral Cavity and Pharynx	0.16(0.01-0.31)	0.14(0.01-0.26)

Data for late-stage incidence of all cancer sites combined not available from CDC.

11013 Rapid Oral Abstract Session

Treatment preferences between survival and quality of life and their association with clinical outcomes in older adults with advanced cancer.

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Background: Preference-concordant care improves quality of life (QoL) and reduces healthcare utilization. However, limited research exists on how preferences impact clinical outcomes in older adults with advanced cancer. Our study explores differences in outcomes between patients (pts) prioritizing extending survival versus maintaining QoL. We hypothesized that patients prioritizing survival would live longer, while those prioritizing QoL would have fewer treatment-related toxicities and hospitalizations. **Methods:** We analyzed data from pts aged $\geq$ 70 with incurable solid tumors or lymphoma and $\geq$ 1 impaired geriatric assessment domain starting a new systemic cancer treatment within NCI's Community Oncology Research Program as part of a cluster randomized trial (NCT02054741, PI: Mohile). Pts reported their preference for prioritizing extending survival versus maintaining QoL at baseline: agree, neutral, disagree. We used generalized linear mixed models and generalized estimating equations to assess the association of treatment preference with hospitalization and treatment-related toxicities, and Cox shared frailty models for survival. Analyses were adjusted for study arm, age, sex, race, education, and practice. **Results:** We included 706 pts. Mean age was 77.2 years (SD 5.4, range 70-96); 43% were female; and 89% were non-Hispanic white. Gastrointestinal (34.6%), lung (24.8%), and genitourinary (15.4%) cancers were most common. Fewer pts preferred to prioritize extending survival (n = 59, 8.4%) versus maintaining QoL (n = 506, 71.7%) versus no preference/neutral (n = 141, 20.0%). Choice of initial therapy (single agent, multiple agent, or combined chemotherapy plus another agent) did not differ by preference. Most pts (61.7%) had grade 3-5 treatment-related toxicity; 25.2% were hospitalized in the first 3 months; 26.3% died within 6 months; 47.3% died within one year. No significant associations were found between preference for prioritizing survival v. QoL and grade 3-5 toxicity (Risk ratio [RR] 0.90, 95% Confidence Interval [CI] 0.70–1.16), hospitalization (RR 0.81, 95% CI 0.48–1.36), nor survival (Hazard ratio 0.75, 95% CI 0.42–1.33 at 6 months; 1.18, 95% CI 0.82–1.71 at 1 year). **Conclusions:** Over two-thirds of older adults with advanced cancer prioritize maintaining QoL over extending survival. Prioritizing QoL was not associated with shorter survival. However, it was also not associated with reductions in hospitalization nor treatment-related toxicities. While these findings may suggest a lack of responsiveness of the healthcare system to patient preferences, additional studies are necessary to better evaluate this relationship. More research is needed to develop treatment modifications and interventions so that older adults with advanced cancer achieve those outcomes that matter most to them. Funding: UG1CA189961, R01CA177592. Research Sponsor: None.

11014 Rapid Oral Abstract Session

Utilization and timing of first tumor next-generation sequencing testing (NGS) in patients (pts) with five most common cancers in the USA.

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Background: In the USA, the 5 most common advanced/metastatic solid tumors are advanced non-small cell lung cancer (aNSCLC), metastatic breast cancer (mBC), metastatic prostate cancer (mPC), advanced colorectal cancer (aCRC), metastatic pancreatic cancer (mPanC). Life-prolonging targeted therapies are approved for pts with tumor-susceptible alterations, and guidelines recommend NGS to identify these alterations. Herein, we assessed the overall utilization of NGS and the timing of NGS in relation to the time of death in real-world pts with these cancers. **Methods:** This retrospective study utilized the nationwide Flatiron Health electronic health record (EHR) derived de-identified database. Eligibility: diagnosis of aNSCLC, mBC, mPC, aCRC, mPanC with information on receipt of NGS (blood/tissue) and recorded date of death. The time between each pt's first NGS result and date of death was measured and pts were categorized into 3 groups: NGS results delivered > 3 months (mo) before death, within 3 mo of death, and delivered/reported after death. Frequencies and percentages of the 3 categories were reported, also by the year of death and practice type. **Results:** Of 86,536 pts with aNSCLC, 31,375 received NGS (36.3%), of whom 19,958 had a date of death recorded. Of 36,000 pts with mBC, 11,550 were tested (32.1%), of whom 5,689 had a date of death recorded. Of 24,105 pts with mPC, 7,439 were tested (30.9%), of whom 3,397 had a date of death recorded. Of 35,702 pts with aCRC, 14,642 were tested (41%), of whom 8,553 had a recorded date of death. Of 14,964 pts with mPanC, 5,298 were tested (35.4%), of whom 3,957 had a recorded date of death. The timing of NGS relative to the time of death by cancer type is shown in Table. Across all cancers, the rate of pts receiving NGS results > 3 mo before death increased over time, while the rate of those receiving results within 3 mo of death or after death decreased. Baseline characteristics (race-ethnicity, insurance plan, practice type) and NGS rates by year of death in the 3 categories will be presented in the meeting. **Conclusions:** Despite the availability of life-prolonging targeted therapies based on NGS results, a sizeable number of pts either do not undergo NGS or have their first NGS very late in the course of disease (i.e. within 3 mo of death). These results warrant better utilization of tumor NGS in a timely fashion in pts with cancer to optimize survival outcomes. Research Sponsor: None.

Rates of first NGS relative to the time of death (in pts who underwent NGS and had a date of death recorded).

Timing of first NGS results	aNSCLC N = 19,958	mBC N = 5,689	mPC N = 3,397	aCRC N = 8,553	mPanC N = 3,957
> 3 mo before death, n (%)	14,431 (72.3%)	4,643 (81.6%)	2,901 (85.4%)	7,271 (85%)	2,815 (71.1%)
Within 3 mo of death, n (%)	5,109 (25.6%)	959 (16.9%)	457 (13.5%)	1,173 (13.7%)	1,047 (26.5%)
After death (NGS result reported after death), n (%)	418 (2.1%)	87 (1.5%)	39 (1.1%)	109 (1.3%)	95 (2.4%)

11015 Rapid Oral Abstract Session

Overall survival and quality of life superiority in modern phase III oncology trials.

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Background: The use of alternative endpoints, such as progression-free survival, has increased over time in phase III randomized clinical trials (RCTs). However, PFS and other alternative endpoints are often not valid surrogates for overall survival (OS) and quality of life (QOL), and may be less relevant to patients. We sought to determine the proportion of phase III oncology RCTs with OS or QOL superiority. A secondary goal was to evaluate the approach of QOL analyses, since "change-from-baseline" approaches may bias results (Bland and Altman. *Trials.* 2011;12:264). **Methods:** We performed a meta-epidemiological study of two-arm, superiority-design, interventional phase III oncology RCTs screened from ClinicalTrials.gov. RCT publications were reviewed for alternative endpoint, OS, and QOL results by at least two investigators. Alternative endpoint and OS superiority were defined for the experimental arm vs control arm according to the pre-specified statistical criteria for each RCT. QOL superiority was defined by either statistically significant or minimal clinically important differences (MCID). QOL was sub-classified as global QOL, defined by the composite summary measure obtained using the patient-reported outcome instrument, or domain QOL, referring to measures obtained from instrument subscales. **Results:** We included 791 RCTs published between 2002 and 2024, representing 555,580 enrolled patients. Primary RCT results were published between 2002 and 2024. Alternative primary endpoints were most common (n = 495, 63%). The primary endpoint was met in 53% of the RCTs (n = 420). Alternative endpoint superiority was shown in 55% of the RCTs (n = 434). OS was reported by 705 RCTs (89%), and OS superiority was shown in 28% of the RCTs (n = 221). Patient-reported outcomes were collected in 61% of the RCTs (n = 482), and 34% of the RCTs published global QOL results (n = 271). Most global QOL analyses were change-from-baseline (55%, n = 148). Global QOL superiority was shown in 11% of the RCTs (n = 84). In a sensitivity analysis of QOL subscale outcomes, 80 trials (10%) showed superiority in at least one QOL domain. Collectively, in 32% of the RCTs (n = 257), superiority of either OS or global QOL was demonstrated. In 6% of all RCTs (n = 48), both OS and global QOL superiority was shown. **Conclusions:** Phase III, superiority design oncology RCTs are commonly interpreted as "positive." However, this is usually based on improvements in unvalidated alternative endpoints. Gains in either OS or QOL are uncommon, and exceedingly rare in combination. QOL appears both under-evaluated and under-reported. Furthermore, the majority of phase III QOL analyses, which are based on change-from-baseline comparisons, may be misleading. To increase the meaningfulness of late-phase research, future trial designs and regulatory processes should be re-focused towards OS and methodologically rigorous QOL improvements. Research Sponsor: National Cancer Institute; P30CA016672; Andrew Sabin Family Foundation.

11016 Rapid Oral Abstract Session

SWOG S2302, PRAGMATICA-LUNG: A pragmatic trial designed to increase participant representation.

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Background: Effective therapy following frontline immune checkpoint inhibitor (ICI)-based treatment for advanced non-small cell lung cancer (NSCLC) is needed as limited options are available. Lung-MAP S1800A was a Phase II randomized study of ramucirumab plus pembrolizumab versus standard of care (SOC) for patients with NSCLC previously treated with immunotherapy that demonstrated benefit in overall survival (OS) with an improved toxicity profile over SOC. S2302 Pragmatica-Lung trial was pragmatically designed to evaluate the impact on OS while reducing barriers to participation and decreasing clinical trial staff burden. We assessed reduction in barriers to participation and clinical staff burden in S2302 in relationship to S1800A. **Methods:** S2302 (NCT05633602) is a registration-intent randomized phase III trial for patients with advanced NSCLC who previously received PD-(L)1 inhibitor therapy for at least 84 days and platinum-based therapy, stratified by immediate prior line of therapy including PD-(L)1 inhibition (yes/no) and PS (0/1 v. 2). The pragmatic design has limited eligibility criteria, which are focused on stage, prior therapy and safety to enroll patients as would occur in real world practice. Laboratory assessment and imaging with RECIST reads are not required due to the OS endpoint. Data collection was developed to minimize the burden with fewer time points for data submitted, number of forms and number of data elements. Concomitant medications are not collected. Given the known safety profile of both study drugs, only related and unexpected grade 3/4 and all grade 5 adverse events are collected. **Results:** Accrual to S2302 was robust with 838 patients enrolled from March 2023 to December 2024 (21 months), averaging $>$ 50 patients/month in the final 6 months. The trial enrolled 77% White and 13% Black patients. versus 87% and 8%, respectively on S1800A. Over 65% were $\geq$ 65 years of age. Reduced data collection on S2302 relative to S1800A results in an estimated decrease in the number of forms and data elements submitted within the first year on study by 45% and 66%, respectively. **Conclusions:** Incorporating pragmatic elements into S2302 resulted in robust accrual, increased participant representativeness and access for patients. The reduced burden on staff due to decreased data forms and elements is substantial. Pragmatic design elements should be considered as we develop trials to generalize to a broad and representative population. Clinical trial information: NCT05633602. Research Sponsor: NIH/NCI/NCTN grants U10CA180888 and U10CA180819; Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, and Eli Lilly and Company.

11017 Rapid Oral Abstract Session

Benefit of adding Cureety remote patient monitoring (RPM) to usual care during injectable anticancer treatment: The OPTIMACURE multicentric French prospective randomized study.

Audrey Faveyrial, François Gernier, Benedicte Clarisse, Benjamin Duputel, Laetitia Gigan, Jean-Michel Grellard, Jean-Baptiste Meric, Adrien Estienne, Christelle Auguin, Julie Beauguitte, François Montestruc, Abderrezak Ladouani, Ingrid Alexandre, Trevor Stanbury, François-Guirec Champoiseau, Charles Parnot, Roman Rouzier; Centre François Baclesse, Medical Oncology Department, Caen, France; Centre François Baclesse, Caen, France; Centre François Baclesse, Clinical Research Department, Caen, France; EXYSTAT, Malakoff, France; Centre Francois Baclesse, Caen, France; French National Cancer Institute, Boulogne-Billancourt, France; Centre Hospitalier De Bligny, Briis-Sous-Forges, France; eXYSTAT, Malakoff, France; Centre Hospitalier Privé Sainte-Marie, Osny, France; Centre Medical De Bligny, Briis-Sous-Forges, France; Pro-Pens, Antony, France; Cureety, Dinan, France

Background: In routine care, assessing whether a patient can safely be administered an injectable anticancer treatment requires the review of blood tests, risk factors and relevant adverse events (AEs). Thus, some French centers use coordinated phone calls and blood tests to improve chemotherapy prescription accuracy and reduce wait times for patients. For example, as part of usual care, the François Baclesse center uses the OPTIMA program. Digital RPM could further streamline this process by efficiently collecting and evaluating patient data without needing systematic phone calls. The OPTIMACURE study aimed to assess whether integrating Cureety RPM into usual care (with OPTIMA or equivalent) can increase the quality of care and decrease the hospital staff workload. **Methods:** The prospective, randomized, multicenter, open-label OPTIMACURE study was designed to assess whether adding Cureety RPM to usual care would reduce the number of phone calls during the first two months after randomization. Outpatients with solid tumor initiating injectable anticancer treatment were randomly assigned (2:1) to either usual care with Cureety RPM or usual care alone (with OPTIMA or equivalent). The numbers of phone calls were compared between arms using an analysis of covariance (ANCOVA) model adjusted for study arm, treatment type, infusion frequency, performance status, and center. **Results:** From April to August 2024, 192 patients (127 in RPM arm, 65 in control arm) were enrolled in 3 centers: women (73%), mean age 61 ± 13 yrs. The cancers were breast in 40%, non-small cell lung in 14%, colorectal in 9.5%, and prostate in 7.4%. The infusion frequency was once every 1-2 weeks in 37% and ≥3 weeks in 63%. Nine patients were excluded due to protocol deviations. Calls, for any reasons, were significantly reduced in the RPM arm (3.80 versus 2.61, relative change of -1.20, 95% CI [-1.89 to -0.53], $p < 0.001$, ANCOVA model). Those results were further analyzed by differentiating outgoing calls to prepare the outpatient visits and those to follow-up on toxicity reports. Preparation calls were less frequent for patients in the RPM arm than those in the control arm (no preparation call for 73.2% of patients vs 12.3%; ≥3 calls for 3.2% of patients vs 69.2%), corresponding to a higher reduction of preparation calls (-2.7 [-3.12;-2.3], $p < 0.001$, ANCOVA model). As for calls for toxicity follow-up, they were more frequent in the digital RPM arm (1.6 [1.14;2.05], $p < 0.01$), associated with earlier report of grade 3-4 non hematological AEs (Hazard ratio for first report of severe AE: 4.06, $p < 0.001$) and better care management for patients in the RPM arm compared to the control arm. **Conclusions:** Adding digital RPM to routine cancer care was beneficial, with a significant gain in time to prepare cancer treatment in day unit and with improved detection and management of toxicities. Clinical trial information: NCT06371911. Research Sponsor: Cureety.

11018 Poster Session

Improving clinical trial interpretability and efficiency: A Bayesian re-analysis of individual patient outcomes from 230 phase III oncology trials.

Alexander Dean Sherry, Pavlos Msaouel, Avital Miller, Gabrielle Kupferman, Timothy Lin, Joseph Abi Jaoude, Ramez Kouzy, Molly Blue El Alam, Roshal Patel, Alex Koong, Christine Lin, Adina Passy, Esther Beck, Clifton Dave Fuller, Tomer Meirson, Zachary McCaw, Ethan B. Ludmir; The University of Texas MD Anderson Cancer Center, Houston, TX; Stanford Health Care, Palo Alto, CA; Memorial Sloan Kettering Cancer Center, New York, NY; Davidoff Cancer Center, Rabin Medical Center–Beilinson Hospital, Petah Tikva, Israel; University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: The conventional interpretation of superiority oncology trials relies on statistical significance defined by *P* values, which are frequently misinterpreted and oversimplified. On the other hand, Bayesian analysis, which incorporates prior knowledge, directly estimates the probability of a hypothesis, with greater flexibility to examine clinically relevant effect sizes. Here, we studied the effects of Bayesian models on phase III trial interpretation. We further hypothesized that Bayesian approaches, using differential priors for efficacy and futility, would improve trial efficiency. **Methods:** Phase III superiority-design, two-arm oncology trials were screened from ClinicalTrials.gov for this meta-epidemiological study. Individual patient-level data were manually reconstructed from the Kaplan-Meir curves of the primary endpoint. First, Bayesian Cox regressions of reconstructed data applied skeptical $N(0, 0.355)$, enthusiastic $N(-0.41, 0.4)$, and neutral priors $N(0, 10^6)$, where N(mean, standard deviation) denotes a normal distribution, to estimate posterior probabilities of the primary endpoint effects with Markov chain Monte Carlo sampling. Minimum clinically important differences (MCID) in the experimental arm were defined by HR < 0.8 per ASCO criteria (Ellis et al, *J Clin Oncol* 2014). Second, a single event or enrollment-driven interim analysis with Bayesian stopping rules was simulated 100 times for each trial using *in silico* models of randomly varying accrual kinetics with published patient outcomes. Interim efficacy and futility were defined per simulation by probabilities $\geq 85\%$ for achieving effect sizes larger than the MCID/3 using a skeptical or enthusiastic prior, respectively. Early trial closure was recommended if $\geq 75\%$ of simulations met efficacy or futility criteria. **Results:** After screening,194,129 patient outcomes from 230 trials were reconstructed. Overall survival was the primary endpoint in 90 trials (39%). All trials interpreted as positive had $> 90\%$ probabilities of marginal benefits (HR < 1). However, 38% of trials interpreted as positive had $\leq 90\%$ probabilities of achieving the MCID (HR < 0.8), even under an enthusiastic prior. Conversely, 24% of trials interpreted as negative had $> 90\%$ probability of achieving marginal benefits, even under a skeptical prior. In the interim analysis simulations, early closure was recommended for 82 trials (36%). Bayesian interim analysis was associated with $>99\%$ probability of reducing enrollment sizes. The trial and its simulated interim analysis remained concordant (Bayesian Cohen's κ, 0.95). **Conclusions:** Bayesian models add unique interpretative value for clinically relevant effects, and may improve trial efficiency without compromising trial interpretation. Bayesian models should be increasingly incorporated in phase III trials. Research Sponsor: National Cancer Institute; P30CA016672; Andrew Sabin Family Foundation.

11019 Poster Session

Adherence of published randomized phase 3 cancer trials to principles proposed by common-sense oncology.

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Background: Randomized clinical trials (RCTs) remain the gold standard for evaluating the efficacy and safety of novel cancer therapies. Some RCTs are well-designed and show meaningful improvements in patient outcomes while others are confounded by various types of bias, or do not reflect outcomes that matter to patients. Published RCTs should be designed, analyzed and reported to provide optimal, unbiased information for clinicians to enhance treatment decision-making Common-Sense Oncology (CSO) is an initiative of clinicians, patient advocates, researchers, and policymakers with the mission of ensuring that cancer care and research are focused on outcomes that matter to patients. CSO has published a checklist for the design, analysis and reporting of RCTs evaluating systemic treatments for cancer. In the present study, we have applied the checklists to a cohort of cancer drug trials to assess the extent to which CSO principles were incorporated in reports of RCTs published in 2023 in high-impact journals. **Methods:** We reviewed retrospectively phase 3 RCTs evaluating systemic therapies for adult solid tumors published in 2023 in *The New England Journal of Medicine, Lancet, Lancet Oncology, JAMA, JAMA Oncology, Journal of Clinical Oncology,* and *Annals of Oncology*. These journals were selected based on their high impact. For each trial we evaluated the trial design in the methodology, how the results were reported and the discussion section using the CSO RCT Checklist. **Results:** 50 RCTs evaluating systemic therapies for solid tumors were published in 2023. The most common tumor types were lung, liver, and prostate cancer. Progression-free survival and overall survival were the primary endpoints in 44% (22) and 42% (21) of trials, respectively. Only 36/50 trials justified the control arm, 25/50 justified the primary endpoint, and 18 included Quality-of-Life as a secondary endpoint. Only two trials addressed strategies to limit censoring and dropout; numbers of censored patients (with numbers at risk) were shown under Kaplan-Meier curves in only 21/50 trials, and sensitivity analysis to determine the potential effects of censoring was done in only 5 trials. Chronic toxicities were reported in only one trial, only 7 trials included patient-reported outcomes and only 3/50 trials mentioned cost of the drug. **Conclusions:** Our findings underscore the need for standardized methodologies, comprehensive design, and reporting in oncology RCTs. By identifying gaps in RCT design and reporting, CSO aims to improve the quality and consistency of future trials. Research Sponsor: None.

11020 Poster Session

Kaleido registry: A multi-center registry platform with site staff and automation to enable accelerated clinical research and drug development at scale in community practices.

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Background: The number of candidate drugs and clinical trials in oncology is rapidly increasing, necessitating innovative approaches to streamline patient identification, enrollment, and trial execution. However, data collection for patient eligibility assessments remains highly manual, placing significant burden on clinical teams. Technology solutions leveraging Electronic Health Records (EHR) data are emerging, but missing or inaccurate data often impede high-fidelity and low-latency prescreening. In 2022, the Kaleido registry was initiated to address these challenges by implementing on-site staff, abstraction prior to each visit, and draft notes for medical oncologists in the registry. **Methods:** The Kaleido registry enrolls patients with oncological/hematological diagnoses at four community practice sites. Real-time data abstraction is performed in all patients prior to each visit in an expanding set of indications (NSCLC, CRC, prostate cancer, and myeloproliferative neoplasms) to provide systematic and unbiased trial pre-screening. An automated prescreening tool has been developed and validated in 394 pts to identify potential trial candidates. Standardized note drafts free up staff time. A questionnaire addressing social determinants of health (SDOH) and self-reported performance status was introduced to further reduce missing data in the EHR. **Results:** To date, over 10,000 patients (61% female, 39% male) have been enrolled. 6% of approached patients declined to consent. The most common diagnoses include breast, prostate, lung, and colorectal cancer. The automated prescreening tool was validated with 90% sensitivity and 97% specificity. The patient questionnaire has a completeness rate of 99%. Real-time abstraction was demonstrated to be feasible, with completeness above 90% for key variables. Among patients with metastatic NSCLC, the genomic testing rates exceeded 80% supporting the sites' suitability for clinical trials. **Conclusions:** With high consent rates, data completeness, and a validated automation tool, the Kaleido registry offers a scalable model for systematic, unbiased patient recruitment and comprehensive data collection across oncology/hematology. This approach has the potential to accelerate clinical research and drug development in oncology and hematology, ultimately enhancing trial efficiency and improving patient outcomes. Research Sponsor: N-Power Medicine.

11021 Poster Session

Are patients satisfied with the information in an informed consent form? Questionnaire-based study examining patients' viewpoints.

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Background: Ensuring that patients understand the information in an Informed Consent Form (ICF) is key to shared decision-making and ethical conduct of a trial. Data regarding patients' views on the ICF are limited. **Methods:** Descriptive questionnaire-based survey study conducted in patients with malignancy aged 18 years and over who had earlier been enrolled in an interventional clinical trial at the Tata Memorial Center (Mumbai, India) and had filled an ICF for that trial. Patients were asked to provide their basic demographic information and fill in a 14-item questionnaire regarding their views/suggestions about the information in the ICF. Primary end point was patients' satisfaction with the information provided in the ICF. Satisfaction was scored on a Visual Analog Scale of 0-10; 0 indicated "least satisfied" and 10 meant "most satisfied". Level of satisfaction was categorized as low (0 – 4), moderate (5 – 7), and high (8 – 10). The study was approved by the ethics committee and registered with CTRI. **Results:** Between Jan 2023 – Jun 2024, we recruited 426 patients. Median age was 47 (IQR, 39-56) years; 234 (54.9%) were male, and 43 (10%) were illiterate. Malignancies included head and neck (202 [47.4%]), breast (108 [25.4%]), gastrointestinal (45 [10.6%]), thoracic (44 [10.3%]), and hematolymphoid (27 [6.3%]). Intent of therapy was curative in 375 (88%). There were 31 (7.3%) patients who did not know that they had participated in a clinical trial. The ICF was not completely read by 68 (16%) patients, due to the following reasons: excessive technical terms (38 [8.9%]), lengthy ICF (18 [4.2%]) and insufficient time provided (17 [4%]). Fifty-two (12.2%) patients did not understand the language of the ICF. Majority of patients (360 [84.5%]) suggested that ICF length be limited to 1-4 pages. Over half the patients wanted the ICF to include more information on standard treatments (230, 54%), side-effects (223, 52.3%), reason for study participation (214, 50%), and risks and benefits (249, 58.5%). Twenty-two (8%) patients felt over-burdened with the information provided in the ICF. Median satisfaction score was 8 (IQR 6 – 10); but only 56.6% patients were highly satisfied with the information in the ICF. Low satisfaction was reported by 167 (39.2%) patients with the information in the reimbursement/compensation section and 164 (38.%) with the alternative treatment options section. Age, sex, education, type of cancer, intent of cancer-directed therapy, and socioeconomic status did not significantly impact the level of satisfaction with the information in the ICF. **Conclusions:** The information in the ICF for interventional clinical trials needs to be concise, and in simple language. Addressing patient preferences and providing clear information in each section would enhance patient understanding and satisfaction, fostering a more effective and ethical informed consent process. Clinical trial information: CTRI/2023/01/048999. Research Sponsor: None.

11022 Poster Session

Why the duration of cancer treatment requires a closer look: An empirical analysis of recent FDA approvals.

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Background: The duration of cancer treatment directly impacts its efficacy, toxicity, and cost. Yet, its systematic evaluation is missing in most clinical trials. In July 2024, the FDA critiqued trial designs for failing to assess the contribution of perioperative (adjuvant and/or neo-adjuvant) components but did not address the broader question of optimal treatment duration. **Methods:** We conducted a comprehensive, retrospective review of FDA anti-tumor drug approvals issued between January 2019, and August 2024. Landmark publications supporting each approval were identified through Google Scholar, PubMed, and DailyMed. Each trial's duration of treatment design was classified as either indefinite or fixed, with subgroups of fixed perioperative, fixed non-perioperative, and single-dose. We also recorded the planned duration (PDOT) and median duration of treatment patients received (MeDOT). After excluding n=48 trials with altered initial approvals, 216 remained for overall analysis; 35 lacked MeDOT data and were excluded from MeDOT-specific analyses, leaving 169 for those analyses. We performed non-parametric comparisons and LASSO-selected multivariable regression of duration variables to explore predictors such as trial phase, treatment intent, drug class, and cancer type. As this research used publicly available, aggregate data, our protocol was reviewed by a senior team and did not require IRB submission per 45 CFR §46.102(f). **Results:** 70% of the included trials requiring >1 dose were indefinite. Among fixed, the PDOT − MeDOT difference gap was significantly larger in non-perioperative (median 16.3 months) than in perioperative (0.8 months). The MeDOT distributions for non-perioperative and indefinite trials were right-skewed with medians of 6.4 and 7.6 months respectively. In regression analyses, non-perioperative trials had significantly shorter MeDOTs, often treated hematologic malignancies, used checkpoint inhibitors, or involved front-line palliative intent. Indefinite trials were more frequent for small-molecule and tyrosine kinase inhibitors (TKIs), and fixed TKI trials had notably longer PDOTs (17.6 months). Importantly, none of the 216 approvals were based on trials comparing different treatment durations. **Conclusions:** While our findings suggest current oncology likely errs toward overtreatment, it is clear that researchers and regulators are not adequately assessing optimal treatment duration. Indefinite duration dominates current trial designs, while non-perioperative shows wide PDOT−MeDOT discrepancies, reflecting uncertainty about when therapeutic benefits plateau and harms increase. Future trials and regulatory directives should prioritize randomized duration comparisons to reduce toxicity and costs while optimizing patient outcomes. Research Sponsor: None.

11023 Poster Session

Publication and data sharing of completed NCI cooperative group trials.

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Background: Concerns about timely publication of NIH trial results, as well as sharing of clinical trial data, have led to important initiatives. The NCI developed an online archive of individual patient data (IPD) for cooperative group trials published after 2014, and ClinicalTrials.gov has required data sharing plans for all trials that began enrollment after 2018. We examined the dissemination of NCI cooperative group trial results via published manuscripts as well as availability of IPD from completed trials. **Methods:** We queried the Access to Aggregate Content of ClinicalTrials.gov database for phase II or III interventional trials for which NCI cooperative groups were listed as the sponsor, responsible party, or principal investigator. We included trials that were initiated between 2011 and 2022 and reached actual primary completion status (i.e. completion of data collection to fulfill the primary outcome measurement) by 2022. Primary manuscripts that reported the study primary outcome data were identified by searching NCT ID numbers on ClinicalTrials.gov, PubMed, and Google Scholar through a dual review. We restricted our 2 and 5-year assessments of study publication status to studies that had reached their primary completion date before 2022 and 2019, respectively. Individual patient data (IPD) sharing was assessed by reviewing the data-sharing statements on ClinicalTrials.gov for trials that began enrollment after the ClinicalTrials.gov mandate in January 2019. Next, we searched the NCT trial number in the NCTN/NCORP data archive to look for the availability of IPD among trials that published their primary outcome after January 2015. We also conducted a subgroup analysis of phase III trials. **Results:** Of 232 eligible studies, 159 (68.5%) were phase II, 11 (4.7%) were phase II/III, and 62 (26.7%) were phase III. NRG Oncology (n=58), Eastern Cooperative Oncology Group (n=47), and Alliance for Clinical Trials in Oncology (n=42) were the most represented cooperative groups. Overall, 33 (14.2% of the total) trials published their primary outcome results within one year of their primary completion, compared to 67 (31.6%) within 2 years, and 69 (63.3%) in 5 years. Among phase III trials, 26 (44.8%) had published their primary outcome findings within 2 years of study completion, and 22 (78.6%) published within 5 years. Among the 138 trials that published their primary outcome since January 2015, 36 (26.1%) had their IPD stored in the NCI online archive (76.1% of the 46 phase III trials). Among the 9 trials initiated since January 2019, 3 indicated on ClinicalTrials.gov that they had a plan to share their IPD. **Conclusions:** A substantial proportion of NCI cooperative group trials have not published manuscripts reporting their primary results in a peer-reviewed journal within 5 years of study completion. Approximately three quarters of phase III group trials completed during the study period had their IPD available within the NCI archive. Research Sponsor: None.

11024 Poster Session

Predictors of withdrawal for FDA accelerated approvals of anticancer drugs, 1992-2022.

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Background: The US Food and Drug Administration's (FDA) accelerated approval pathway facilitates timely access to novel therapies based on surrogate measures that are supposed to be reasonably likely to predict clinical benefit. Post-approval, confirmatory studies are required to verify safety and efficacy, with approved indications subject to withdrawal from the labeling if these studies fail. While this pathway has been useful in some cases, concerns about delayed and an increasing number of withdrawals of anticancer indications highlight its associated risks to patients. This study identifies factors at the time of initial accelerated approval associated with subsequent withdrawal. **Methods:** In this retrospective cohort study, we analyzed FDA-approved drugs for solid and hematologic cancers receiving AA from 1992 to 2022. The analysis focused on key factors present at the time of accelerated approval, including the indication and pivotal trial characteristics, mechanisms of action and clinical outcomes. Clinical benefit was assessed using the European Society of Medical Oncology-Magnitude of Clinical Benefit Scale (ESMO-MCBS), categorizing benefits as high (A-B/4-5) or low (C/≤2). Multivariable logistic regression was used to identify associations between these factors and indication withdrawal. **Results:** Among 167 accelerated approvals for 113 anticancer drugs, by August 2024, 102 (61%) had been converted to regular approval, 31 (19%) were withdrawn, and 34 (20%) were still in the accelerated approval phase. Of the 133 indications either converted or withdrawn, 52 (39%) were approvals for hematologic cancer drugs, and 41 (31%) supported genome-targeted drug approvals. Among 83 eligible indications, 46 (55%) were granted Breakthrough Therapy designation. Of 133 indications analyzed, 106 (80%) were based on single-arm pivotal trials, and 112 (84%) used response rate as the primary endpoint. Most trials (66%) showed low clinical benefit (86/130) per the ESMO-MCBS framework. In multivariable analysis, indications associated with lower withdrawal risk were more likely to have Breakthrough Therapy designation (OR 0.26; 95% CI, 0.10-0.75; p = 0.01) and be genome-targeted (OR 0.26; 95% CI, 0.08-0.80; p = 0.02). Low ESMO-MCBS scores conversely increased the likelihood of withdrawal (OR, 4.63; 95% CI, 1.50-14.33; p = 0.008). **Conclusions:** Accelerated approvals based on pivotal trials demonstrating low clinical benefit have been at higher risk of subsequent withdrawal, whereas indications with Breakthrough Therapy designation or supporting genome-targeted therapies were more likely to achieve full approval. Patients and health care providers should consider these factors when evaluating therapies newly granted accelerated approval. Research Sponsor: Alfonso Martín Escudero Foundation and Arnold Ventures.

11025 Poster Session

Disparities in NIH and federal cancer research funding across different cancer types.

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Background: National Institutes of Health (NIH) and other federal funding resources are critical for research and advocacy, but may not be equitably allocated across cancers. **Methods:** This study evaluated funding from the NIH and Congressionally Directed Medical Research Programs (CDMRP) supporting lung, breast, colorectal, pancreatic, hepatobiliary, ovarian, cervical, endometrial and prostate cancers, leukemia, lymphoma and melanoma, from 2013-2022. The primary objectives were to assess for funding disparities across different cancers compared to their incidence and mortality and across racial groups. We also determined if underfunding correlates with fewer clinical trials. Correlations between funding for each cancer and its incidence, mortality and number of clinical trials were analyzed using descriptive statistics and Pearson correlation coefficients (PCCs). **Results:** Diseases with the largest combined NIH and CDMRP funding from 2013 - 2022 were breast ($8.36 billion), lung ($3.83 billion) and prostate ($3.61 billion) cancers. Those with the least funding were uterine ($435 million), cervical ($1.12 billion) and hepatobiliary ($1.13 billion) cancers. Cancer-specific NIH and CDMRP funding correlated well with incidence (PCC: 0.85) but was poorly aligned with mortality (PCC: 0.36). Cervical, ovarian, breast, leukemia and lymphoma were consistently well funded compared to their incidence and mortality rates while lung, colorectal, liver and uterine cancers were consistently underfunded. These data are summarized in the Table. Cancers with higher incidence among Black people were disproportionately underfunded. The amount of combined NIH and CDMRP funding for a particular cancer correlated well with the number of clinical trials in that disease (PCC: 0.76). **Conclusions:** Federal cancer research funding aligns well with incidence but significantly underfunds cancers with higher mortality rates. Underfunding strongly correlates with fewer clinical trials, which impedes future advances in underfunded cancers that already have worse outcomes. Research Sponsor: None.

	Lung	Breast	Colorectal	Pancreas	Liver	Prostate	Uterine	Ovary	Cervix	Melanoma	Leukemia	Lymphoma
NIH+CDMRP Funding 2013-2022 (millions)	$3,831	$8,360	$3,074	$2,020	$1,132	$3,610	$435	$1,803	$1,124	$3,371	$2,585	$2,850
Funding/ Incidence	$1,711	$3,148	$2,175	$3,874	$2,033	$1,766	$732	$7,915	$8,601	$1,852	$4,180	$3,451
Funding/ Deaths	$2,520	$19,998	$6,067	$4,835	$3,224	$12,314	$4,050	$12,456	$26,850	$17,571	$10,502	$13,446

Communication of uncertainties about recent cancer drugs in large language models.

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Background: Increasingly more people use large language models (LLMs) to find information about medical treatments. However, there are notable concerns about the accuracy and completeness of information generated by these models. We assessed whether LLMs accurately summarized uncertainties about the benefits and harms of new cancer drugs. **Methods:** We identified the 10 cancer drugs approved by the US Food and Drug Administration (FDA) between 2019 and 2022 with the highest Medicare spending in 2022 (5 in Part B and 5 in Part D). We then searched FDA review documents to extract information about the uncertainties with each drug's clinical trial evidence that were identified by FDA reviewers at the time of approval. Uncertainties with clinical trial evidence were assigned to mutually exclusive categories. We evaluated the extent to which 4 state-of-the-art LLMs (OpenAI's ChatGPT-4, Google's Gemini 1.5 Pro, Meta's Llama 3.1, and Anthropic's Claude 3.5 Sonnet) provided information about FDA-identified uncertainties when queried for information about the drugs using two prompts: (1) *how well does [drug] work for [condition]?*; (2) *is there anything uncertain about how well [drug] works for [condition]?*. **Results:** For the 10 recently approved cancer drugs with the highest Medicare spending in 2022, FDA reviewers identified a total of 38 uncertainties with the clinical trial evidence. For 9 of 10 drugs, FDA reviewers identified uncertainties related to the generalizability of the evidence. Other common uncertainties included bias related to the measurement of the outcome and the use of single arm trial designs. When the LLMs were prompted about how well these 10 cancer drugs worked, the models rarely provided information about the uncertainties identified by FDA reviewers: GPT-4 (4/38, 11%), Gemini 1.5 Pro (3/38, 8%), Llama 3.1 (3/38, 8%), and Claude Sonnet (2/38, 5%). The proportion of FDA-identified uncertainties reported by the models improved marginally when specifically prompted for uncertainties about the drugs. Qualitative assessment of the information generated by the LLMs showed that most of the models tended to report similar, non-specific uncertainties for every drug with little variation. **Conclusions:** LLMs do not provide adequate information about uncertainties related to the benefits and harms of recently approved cancer drugs, despite the availability of this information in the public domain. There is a need to improve LLMs to accurately report such information, so that patients can make informed decisions about cancer treatments. Research Sponsor: None.

Performance of LLMs compared to uncertainties identified by the FDA.

Prompt	GPT-4	Gemini 1.5 Pro	Llama 3.1	Claude 3.5 Sonnet	Average
How well does [drug] work for [condition]?	4/38 (11%)	3/38 (8%)	3/38 (8%)	2/38 (5%)	3/38 (8%)
Is there anything uncertain about how well [drug] works for [condition]?	8/38 (21%)	5/38 (13%)	6/38 (16%)	5/38 (13%)	6/38 (16%)

11027 Poster Session

Achieving equity in genomic testing for breast cancer through partner-led strategies and policies.

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Background: Genomic testing is recommended for individuals with estrogen/progesterone receptor-positive, HER2-negative early-stage breast cancer to determine the need for chemotherapy alongside endocrine therapy. However, access disparities persist by race, ethnicity, and income. This study aims to identify modifiable barriers and co-design policy recommendations for equitable genomic testing for low-income, and racial and ethnic minoritized people with breast cancer in Northern California. **Methods:** Using community-based participatory research and expert panel methods, we collaborated with an 18-member expert panel of patients, caregivers, oncology clinicians, community organizations, advocates, and policymakers to identify modifiable barriers and propose solutions. Phase 1 involved an 85-question survey and semi-structured interviews with patients, caregivers, clinicians, navigators, policymakers, and payers, administered by bilingual community health workers in Spanish, Tagalog, and Chinese, to assess genomic testing barriers and solutions. Phase 2 used Delphi consensus methods with the expert panel to finalize policy recommendations. **Results:** Of 912 invited, 831 participated in surveys (90% response rate), and all 30 purposively sampled individuals participated in interviews (100% response rate). Survey participants included 514 patients, 101 caregivers, 94 clinicians, 74 navigators, 25 policymakers, and 23 payers. Among patients, 102 (19.8%) were Asian, 132 (25.7%) Black, 138 (26.9%) Hispanic White, 28 (5.5%) Non-Hispanic White, and the remainder preferred not to answer. Racial and ethnic minoritized patients had significantly lower odds of genomic testing compared to Non-Hispanic Whites: Black patients 86% lower (OR: 0.15; 95% CI: 0.07-0.31), Asian patients 71% lower (OR: 0.29; 95% CI: 0.14-0.59), and Hispanic White patients 79% lower (OR: 0.21; 95% CI: 0.11-0.43). Four themes emerged from interviews: 1) limited awareness/resources, 2) inequitable care, 3) financial/cultural barriers, and 4) insufficient social support. The expert panel reached consensus on policy recommendations, including mandating reflexive, fully reimbursed genomic testing (mean rating ± SD: 8.3 ± 0.9), eliminating prior authorization (8.2 ± 0.8), removing co-pays/out-of-pocket costs (8.1 ± 0.8), and providing educational materials in preferred languages with lay terminology (7.9 ± 1.2). **Conclusions:** Disparities in genomic testing persist, highlighting the need for targeted interventions. Policy recommendations co-designed with communities and other interested groups can be implemented to improve equitable care. Research Sponsor: California Breast Cancer Research Program.

11028 Poster Session

Pain in cancer survivors in the US after federal and state opioid prescribing guidelines and laws.

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Background: Cancer-associated pain is common among survivors and may require opioid medications for effective management. In 2016, the Centers for Disease Control and Prevention (CDC) published guidelines to limit opioid prescribing, leading to a subsequent decline in prescriptions in the US. Many states also enacted opioid prescribing laws after 2016. Cancer-associated pain is explicitly exempted by the CDC and from some state opioid laws. As state laws and exemptions are heterogeneous and sometimes unclear, this study was designed to assess whether cancer survivors were impacted by post-2016 opioid prescribing patterns and legislation. **Methods:** The 2011-2023 Behavioral Risk Factor Surveillance System (BRFSS), an annual, national survey, was queried for cancer survivors. Quality of life (QoL)-limiting pain (included in 2011-17) was defined as having ≥1 days where pain made it hard to participate in usual activities. A sensitivity analysis utilized a ≥7 day cutoff. Cancer-associated pain (included in 2016-23) was defined as currently having pain caused by cancer or cancer treatment. Linear probability models examined whether there were nationwide changes in QoL-limiting pain after the 2016 CDC guidelines. State-level difference-in-differences (DiD) analyses compared changes in cancer-associated pain over time between states with and without opioid prescribing laws. State opioid laws included (A) any opioid prescribing legislation and (B) explicit cancer-associated pain exemptions. States that enacted opioid policies prior to the 2nd quarter of 2016 were excluded due to lack of cancer-associated pain data before 2016. Analyses accounted for the complex survey design and BRFSS weights and utilized robust SEs, and models were adjusted for sociodemographic, Medicaid expansion, and cancer site factors. DiD analyses also accounted for state and year-quarter fixed effects. **Results:** 2,725 cancer survivors were included in the 2011-17 QoL-limiting pain analyses and 31,955 in the 2016-23 cancer-associated pain analyses. QoL-limiting pain was present for 40.3% (≥1 days affected) and 27.0% (≥7 days affected) and cancer-associated pain was present in 11.9%. There was no significant change in QoL-limiting pain after 2016 in our primary (-9.6 percentage points [95% CI -30.9, 11.7]) or sensitivity analysis (≥7 day affected, 4.32 [-14.24, 22.89]). In adjusted DiD analyses, there were no significant associations between cancer-associated pain and state opioid laws (-2.17 [-6.32, 1.98]) or explicit cancer exemptions in state opioid laws (4.16 [-1.75, 10.07]). **Conclusions:** Among this nationally representative sample of cancer survivors, cancer-associated pain affected >1 in 10 survivors and >1 in 4 had QoL-limiting pain. However, federal and state opioid prescribing guidelines and laws had minimal impact on the prevalence of pain among cancer survivors, perhaps due to effective exemptions for cancer. Research Sponsor: None.

11029 Poster Session

Industry promotion of oncology drugs with accelerated approval that failed confirmatory trials.

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Background: Oncology drugs are commonly granted accelerated approval by FDA based on pivotal trials using surrogate markers as primary endpoints, while requiring sponsors to complete postapproval studies that confirm clinical benefit. Industry payments to physicians may influence treatment recommendations, which is particularly concerning for accelerated approval drugs, where clinical benefit remains uncertain. We investigated industry payments to physicians before and after results of confirmatory studies for oncology drugs with accelerated approval whose confirmatory studies failed to confirm clinical benefit. **Methods:** In this cross-sectional study, using Drugs@FDA database, we identified oncology drugs granted FDA's accelerated approval, their required postapproval confirmatory studies, and FDA status changes (withdrawn or converted to traditional approval). We searched ClinicalTrials.gov, publications, and company press releases to identify drugs with confirmatory studies failing to confirm clinical benefit. We searched OpenPayments database to record industry payments made to physicians associated with these drugs. **Results:** From 2009-2021, of 73 drugs granted accelerated approval by U.S. FDA, 7 (9.6%) had indications for which all confirmatory studies were negative. Among these, 6 were voluntarily withdrawn following FDA's recommendation, while for Pepaxto (melphalan flufenamide), the sponsor appealed FDA's proposed withdrawal; it was ultimately withdrawn by FDA. Pepaxto was excluded from our analysis as it had no reported payments on OpenPayments. The results of postapproval confirmatory trials for the remaining 6 indications were announced after a median time of 4.2 (2.2-6.6) years. All 6 drugs were withdrawn from the market, with a median duration of 4.9 (IQR, 2.7-6.9) years from approval to withdrawal. Following announcement of negative postapproval confirmatory study results, average monthly payments received by all physicians increased for Marqibo (vinCRISTine sulfate) from $138 in the year preceding announcement to $164 during the period between announcement of negative results and market withdrawal, but decreased for Farydak (panobinostat) ($12,317 to $4,916), Blenrep (belantamab mafodotin) ($152,417 to $119,394), and Ukoniq (umbralisib) ($23,139 to $14,130). Lartruvo (olaratumab) and Aliqopa (copanlisib) had almost no payments after announcement of negative confirmatory study results. **Conclusions:** Industry payments for oncology drugs with accelerated approvals mostly decreased after announcement of negative confirmatory trial results; however, there was evidence of continued promotion for certain drugs until a request for voluntary withdrawal was made by FDA. This suggests that regulatory oversight and enforcement might be necessary to mitigate ongoing promotion of such drugs after confirmatory trials fail to confirm clinical benefits. Research Sponsor: Arnold Ventures.

Unpacking the relationship between cancer survival and political environment in the United States (US).

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Background: Several studies have reported on how health outcomes may differ by the political majority of a county. It is unclear the extent to which this discrepancy is due to a broader political landscape compared to underlying sociodemographic and structural determinants. Using county level presidential voting patterns and a national cancer registry, we present a rigorous analytic approach to assessing survival trends. **Methods:** We linked SEER-Medicare's (100% sample) database on the 4 most common cancers (lung, breast, prostate and colorectal) from 2007-2019 to county-level data on US presidential elections over the same period. Using the total number of votes in each party, county political environment was classified as either Democratic or Republican for the four years following a presidential election. Cox proportional hazards estimated changes in survival over time according to political party. Models were sequentially fit adjusting for age, sex, diagnosis year (Model 1), race/ethnicity (M2), rural/urban continuum code (RUCC) (M3), cancer type (M4), Medicaid/Medicare Advantage enrollment and original reason for entitlement (M5), and primary care doctors and oncologists per 100,000 people (M6). Analyses were performed separately by cancer type and for the entire cohort. **Results:** Of the 1,899,334 individuals, 1,222,228 (64%) resided in Democratic counties and 677,106 (36%) in Republican counties. Democratic counties were majority urban (90% vs 55% for Republican). Adjusting for factors generally associated with worse survival (older age, male gender, earlier diagnosis year), Republican counties had worse survival (HR 1.14, 95% CI [1.14, 1.15], $p < 0.001$) compared to Democratic counties. However, following sequential adjustment of aforementioned variables (M1-M6), this difference disappeared (HR 1.00, 95% CI [1.00, 1.01], $p = 0.56$, Table). In stratified analyses, similar results were noted for colorectal, lung, breast, and prostate cancer. Among all cancer types, Republican counties had 2% higher risk of diagnosis of later stage cancer, but no difference in overall survival. Finally, limiting our dataset to rural counties only, a 12% higher risk of death in Republican counties reduced to no difference following adjustment. **Conclusions:** Survival differences between counties by presidential voting status disappeared following adjustment of sociodemographic and structural determinants. In a charged political climate, our study cautions against oversimplified claims and underscores the importance of careful methodological approaches in identifying key confounders in aggregate-level studies when identifying meaningful trends. Research Sponsor: None.

Hazard Risk of Death: Whole Cohort	Hazard Ratio	95% CI
M1	1.14	[1.14, 1.15]*
M2	1.14	[1.13, 1.14]*
M3	1.08	[1.08, 1.09]*
M4	1.02	[1.02, 1.03]*
M5	1.02	[1.01,1.02]*
M6	1.00	[1.00, 1.01]

M1-M6 note sequentially adjusted models (see Methods).
*$p < 0.001$.

11031 Poster Session

Progression-free survival in control arms of clinical trials: Analysis of FDA cancer drug approvals between 2014 and 2023.

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Background: FDA regularly approves new cancer drugs based on the results of surrogate endpoints, often using expedited programs. When assessing the efficacy of new anticancer treatments, the choice of the control arm plays a crucial role. Herein, we evaluated the progression-free survival (PFS) performance of control arms in trials that led to FDA approvals for oncology treatments. **Methods:** We investigated FDA drug approvals issued between January 2014 and December 2023 for the treatment of advanced cancers, available on the FDA.gov website. We analysed publications of phase III or double-arm phase II trials that prompted approvals. For each clinical trial, we collected: i) The assumed median PFS (amPFS) value of the control arm, generally indicated in the study protocol for the sample size calculation; ii) The control arm's recorded median PFS (rmPFS) and its confidence interval (CI). Control arms of each trial were considered under- or out-performing if amPFS exceeded the highest CI of rmPFS or was inferior than the lowest CI of rmPFS, respectively. All other cases were defined as "within the range". **Results:** We found 72 trials leading to new cancer drug approvals. Immune checkpoint inhibitors (ICIs) and small molecules were investigated in the majority of cases, in 27 (37.5%) and 19 (26.4%) trials, respectively. Control arms under- or out-performed in 24/72 (33.3%) and 8/72 (11.1%) cases, respectively. In the remaining 40/72 (55.5%) trials, control arms performances were "within the range". Interestingly, in 12/27 (44.4%) trials leading to ICIs approval, control arms underperformed. We found that in 6/14 (42.9%), 5/16 (31.3%) and 5/16 (31.3%) trials leading to new approvals in lung, breast and genitourinary cancers, respectively, the control arms underperformed. In 18/24 (75.0%) underperforming control arms, the discrepancy between amPFS and rmPFS was larger than 20%. Among the 19 trials with underperforming control arm and leading to expedited approval, in 7 (36.8%) cases a final overall survival (OS) advantage was not observed. **Conclusions:** The PFS benefit observed in several trials leading to FDA approval of new anticancer drugs may have been influenced by shorter-than-expected PFS in the control arms. Accurate analysis of control arms outcomes in clinical trials is essential for a comprehensive assessment of the efficacy of experimental drugs.
Research Sponsor: None.

11032 Poster Session

Early signals of Inflation Reduction Act impact on small-molecule versus biologic post-approval oncology trials.

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Background: The Inflation Reduction Act's Drug Price Negotiation Program (DPNP) has shifted the financial incentives for post-approval clinical development, which is particularly relevant to oncology given the role of subsequent indications in expanding treatment options in cancer patients. The law may disproportionately disincentivize post-approval development in small molecules, which faces a shorter timeline towards DPNP eligibility than biologic (7 vs. 11 years post first approval). We aimed to explore the impact of IRA's passage on industry-sponsored small-molecule versus biologic post-approval clinical trials in oncology. **Methods:** Using the Citeline's TrialTrove database, we identified industry-funded Phase I-III trials initiated between 7/2014 and 8/2024 for approved oncology drugs, excluding vaccines and COVID-19-related trials. Trials were categorized into subgroups based on whether they primarily tested small molecules or biologic, excluding trials testing both (e.g., combination therapies) from the subgroup analysis. We used Wilcoxon rank-sum tests to compare the monthly average of trials pre- and post-IRA for all post-approval oncology trials and in the subgroups. The pre/post-IRA comparison was conducted (1) across the full period (7/2014-7/2022 vs. 8/2022-8/2024), and (2) between the year before IRA's passage and the most recent available year (shorter-time: 8/2021-7/2022 vs. 9/2023-8/2024). We performed a difference-in-difference (DiD) analysis to assess the marginal impact ("dosage effect") of IRA on small molecule trials, using biologic trials as the counterfactual. The assumption was that trials would have followed a similar trajectory in both groups in the absence of IRA's differential DPNP eligibility timelines. **Results:** Across the full period, monthly average of post-approval oncology trials decreased by 38.4% ($p<0.01$) following the IRA' passage, and small molecule and biologic trials dropped by 48.6% ($p < 0.01$) and 27.4% ($p < 0.01$) post-IRA, respectively. In the shorter-time comparison, there was a 29.6% ($p<0.01$) reduction overall, and the monthly average of small molecule trials decreased by 43.9% ($p < 0.01$), with no statistically significant change in biologic trials ($p = 0.48$). Across the full period, the DiD model suggested that the IRA was associated with 7.7 fewer trials per month for oncology small molecule drugs, compared to the biologic drugs (-7.7, 95% C.I.: -9.9 to -5.5, $p < 0.01$). **Conclusions:** The IRA's passage was associated with fewer industry-funded post-approval oncology trials and larger reductions for small molecule trials than biologic trials. These findings support concerns about IRA's disincentivizing effect on post-approval development in oncology, particularly for small molecule drugs, which are subject to a shorter DPNP eligibility timeline. Research Sponsor: None.

Cost-effective cancer care: The role of oncology biosimilars in generating cost savings.

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Background: Biosimilar versions of biologic drugs (reference drugs) present a promising opportunity to reduce healthcare costs. Although not labeled as directly interchangeable, biosimilars are considered reasonable alternatives to their reference drugs by experts. We evaluated the adoption, costs, and savings of key biosimilars used primarily in oncology practice. **Methods:** We used publicly available, specialty agnostic, HCPCS level utilization and cost data from the Medicare Part B Spending by Drug dataset published by the Centers for Medicare and Medicaid Services to study the use of biosimilars for five reference drugs (Bevacizumab, Trastuzumab, Rituximab, Peg-filgrastim, Filgrastim) between 2015 and 2022. We then modeled two spending scenarios for 2022: one where only the reference drugs were used, and one where the lowest cost option (reference or biosimilar) was used for eligible indications. We calculated the savings and incremental savings opportunity to Medicare by comparing these scenarios to the actual 2022 spending. **Results:** Over the 8-year evaluation period, each reference drug received multiple biosimilar approvals, and biosimilar use increased from 0% to 56.4%. Lower biosimilar use of Bevacizumab may have been due to the lack of approval for ophthalmic use. The introduction of biosimilars caused price reductions for the reference drugs and the biosimilars. Biosimilar prices in 2022 were lower than their reference drugs for all except Peg-filgrastim, whose price fell below that of its biosimilars. In 2022, biosimilar adoption resulted in a 23% spending reduction for Medicare, with an additional 14% savings opportunity. Table 1 shows biosimilar adoption rates by reference drug and savings vs savings opportunity. **Conclusions:** The adoption of Oncology biosimilars has resulted in significant cost savings for Medicare, but there are still opportunities for further savings. The complex relationship between biosimilar prices and their utilization warrants additional evaluation. Additionally, the effects of biosimilar payment policies, such as those introduced by the Inflation Reduction Act, and the impact of payer specific product mandates on overall biosimilar adoption need to be explored further. Research Sponsor: None.

Biosimilar adoption & 2022 spending, savings & opportunity with biosimilar adoption.

	Biosimilar Adoption							
Reference Drug	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Bevacizumab	-	-	-	0.0%	0.6%	10.5%	18.4%	22.6%
Trastuzumab	-	-	-	0.0%	2.7%	37.2%	64.2%	74.5%
Rituximab	-	-	-	-	0.0%	20.5%	49.9%	59.7%
Peg-filgrastim	-	-	0.0%	1.2%	16.9%	25.5%	34.6%	41.9%
Filgrastim	0.8%	27.8%	54.6%	65.5%	72.3%	77.0%	81.5%	83.2%
Total	**0.2%**	**5.6%**	**10.9%**	**13.3%**	**18.5%**	**34.1%**	**49.7%**	**56.4%**

	2022 Spending, Savings and Opportunity		
($ in Millions)	**Total Spend**	**Savings**	**Savings Opportunity**
Bevacizumab	$698	$324	$60
Trastuzumab	$380	$182	$111
Rituximab	$1,044	$310	$276
Peg-filgrastim	$628	-$37	$37
Filgrastim	$37	$49	$13
Total	**$2,787**	**$827**	**$498**

Access to cancer care for undocumented immigrants in the United States.

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Background: Undocumented immigrants represent a disproportionate share of uninsured individuals in the United States, owing to federal restrictions on Medicaid eligibility. Emergency Medicaid (EM) and other state programs offer avenues for healthcare coverage, but their impact on access to cancer care remains poorly understood. **Methods:** Between January-July 2024, information on the availability and breadth of cancer coverage for undocumented immigrants under EM and other insurance mechanisms were reviewed for all 50 states and the District of Columbia (D.C.). For each state, ≥4 authors reviewed publicly available data compiled from multiple, independent sources including Medicaid policy handbooks, provider manuals, legislative documents, and other state government website resources. Abstracted data included state-specific information on extent of coverage, specifically as it pertains to cancer diagnosis, treatment, and follow-up care. Discrepancies in policy findings were discussed during consensus meetings to ensure accurate interpretation. In cases where policies remained unclear, state Medicaid agencies were directly contacted for further clarification. **Results:** Undocumented immigrants receive cancer care coverage via (1) expansions to EM (n=3), (2) Medicaid-equivalent programs (n=7), or (3) other non-Medicaid mechanisms (n=5; Table). Of the 6 states and D.C. with Medicaid-equivalent plans, 4 states and D.C. cover all adults, while 2 states only cover some adults (IL: limited to adults age ≥42; NY: limited to adults age ≥65, but adults age <65 can receive cancer coverage via EM). Of the 5 states with non-Medicaid mechanisms, 2 states (CO, WA) allow purchase of commercial plans on the ACA Marketplace or Marketplace-like platform; other strategies include Iowa's Breast and Cervical Cancer Treatment Program (BCCTP), Massachusetts' Health Safety Net program, or New Mexico's high-risk insurance pool. The remaining 35 states had no documented cancer coverage mechanism. **Conclusions:** In this national analysis of EM and other policies supporting healthcare coverage for undocumented immigrants, access to cancer care remains fragmented, intermittent, and largely limited to the emergency setting. Although Medicaid-equivalent plans and Marketplace-based offer promising avenues for comprehensive coverage, budgetary constraints and political challenges pose threats to viability. Absent federal support, sustainable policy solutions are needed to ensure continued progress towards a more equitable model of care. Research Sponsor: None.

	Emergency Medicaid	Medicaid-Equivalent Plan	Other Mechanism
California		All adults	
Colorado			Marketplace-like
D.C.		All adults	
Illinois		Adults (age ≥42)	
Iowa			BCCTP
Maryland	All adults		
Massachusetts			Health Safety Net Program
Minnesota		All adults	
New Mexico			High-risk insurance pool
New York	Adults (age <65)	Adults (age ≥65)	
Oregon		All adults	
Pennsylvania	All adults		
Washington		All adults	Marketplace

11035 Poster Session

Likelihood of unplanned readmission among oncology patients with a completed post-discharge follow-up encounter.

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Background: Literature suggests that oncology patients are more likely to be admitted from the emergency department to the hospital than patients without a cancer diagnosis[1]. Avoiding unplanned readmissions (UR) becomes a joint responsibility of the patient and the oncology care team. The premise of one ASCO Certified standard is that patients who receive post-discharge follow-up (PDFU) may avoid a readmission if their needs are addressed promptly in the outpatient setting. We evaluated the impact of completion of a PDFU after an index admission on URs. **Methods:** We performed a retrospective analysis of patients with an index admission to a system hospital between January and November 2024. Included were patients with a discharge (d/c) to home and an encounter with an oncology provider within the past year. We compared the overall proportion of patients with any UR in the measurement period between those patients who did and did not complete a PDFU, as well as that of patients who completed an early PDFU (within 3 days of d/c) and a later PDFU (between 4-7 days of d/c). PDFUs are defined as a telemedicine or clinic encounter within 7 days of the d/c date. Chi Squared analysis was utilized to evaluate if PDFU reduced UR. **Results:** 2,533 d/cs occurred within the measurement period. 542 (21%) of encounters resulted in a UR. 1,057 (42%) encounters had a PDFU. Of the 1,057 encounters where a PDFU was completed, 240 (23%) resulted in a UR. Of the 1,476 encounters where a PDFU was not completed, 302 (20%) resulted in a UR. The findings were not clinically significant. Chi-squared p-value: .17 **Conclusions:** Completion of a PDFU is not a factor in predicting an oncology patient's potential unplanned readmission. In addition, excluding some high risk patients such as those with hematologic malignancies did not change the overall analysis. We found no difference in rate of UR among patients who completed a PDFU within 3 days or 4-7 days. Further investigation is needed to better understand if modifiable factors contributed to UR in this cohort. Other factors need to be considered, such as patient risk for unplanned re-admission, in evaluating the impact of PDFU on UR, as expected in the ASCO Certified standard. [1] Waters TM; Kaplan CM, Graetz I, et al. (2019) Patient-Centered Medical Homes in Community Oncology Practices: Changes in Spending and Care Quality Associated with the COME HOME Experience. Journal of Oncology Practice, 15(1), e56-e64. Research Sponsor: None.

Proportion of d/cs with UR by PDFU completion.

	No UR # d/c (%)	Yes UR # d/c (%)
Yes PDFU	817 (77%)	240 (23%)
No PDFU	1174 (80%)	302 (20%)

11036 Poster Session

Molecular testing and targeted therapy use in lung cancer across state Medicaid programs.

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Background: Comprehensive molecular testing is the standard of care for patients with metastatic non-small cell lung cancer (NSCLC) and is essential to identify patients with tumors harboring *EGFR*, *ALK* alterations that can be treated with efficacious targeted therapies. Prior work has shown that use of targeted therapies for NSCLC is lower than expected among Medicaid beneficiaries and rates of use may vary across state Medicaid programs. We used Medicaid claims and encounter data to estimate the rates of molecular testing and targeted therapy use across state Medicaid programs. **Methods:** Using Transformed Medicaid Statistical Information System Analytic Files (TAF) data from 2017 and 2018, we identified beneficiaries with new diagnoses of metastatic NSCLC who were continuously enrolled in Medicaid during the period of analysis. Among these patients, we identified claims for molecular tests that could identify *EGFR* or *ALK* alterations and claims for FDA-approved targeted therapies during a 120-day window around the first claim for antineoplastic therapy. We tabulated rates of molecular testing and targeted therapy use by state. We ran logistic regressions for molecular testing and targeted therapy use with patient characteristics, and then we used the regression coefficients to estimate adjusted rates of molecular testing and targeted therapy use for each state. **Results:** We included 41 states with complete TAF data in the study years. In these states there were 5,432 beneficiaries who initiated antineoplastic therapy for new diagnoses of metastatic NSCLC. The number of incident cases within each state Medicaid program ranged from 11 in Utah to 824 in California. In logistic regression, the characteristics associated with lower rates of molecular testing were male sex, high Charlson comorbidity indices, and lower income. The characteristics associated with low rates of targeted therapy use were older age, male sex, and lower education levels. The adjusted rate of molecular testing among patients with incident metastatic NSCLC across all state Medicaid programs was 55.9% with rates ranging from 39.2% in Texas to 69.3% in Washington state. The mean adjusted rate of targeted therapy use across state Medicaid programs was 8.6% with rates ranging from 3.4% in Michigan to 24.8% in New York. **Conclusions:** After adjusting for patient characteristics, there was substantial state-by-state variation in the rate of molecular testing and targeted therapy use among Medicaid beneficiaries with NSCLC. More work is needed to understand whether specific Medicaid policies such as prior authorizations or restrictions on access to diagnostic testing may contribute to the observed disparities. Research Sponsor: None.

11037 Poster Session

Comprehensive analysis on reactive cutaneous capillary endothelial proliferation following camrelizumab-based therapy in patients with solid tumors: A large-scale pooled analysis of nine phase 2 or phase 3 registration trials.

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Background: Previous studies demonstrated the positive association between cutaneous immune-related adverse events and long-term survival in advanced cancer patients treated with immunotherapy. As a unique adverse event related to camrelizumab, the association of reactive cutaneous capillary endothelial proliferation (RCCEP) with patient prognosis may also exist. Here we comprehensively analyzed the characteristics of RCCEP and this association. **Methods:** This was a pooled analysis based on individual patient-level data derived from seven phase 3 and two phase 2 registration trials for new drug application in China. Patients with advanced non-small cell lung cancer, hepatocellular carcinoma, esophageal squamous cell carcinoma, nasopharyngeal carcinoma, and gastric cancer treated with camrelizumab monotherapy (Camre), camrelizumab plus apatinib (Camre-Apa), or camrelizumab plus chemotherapy (Camre-Chemo) were included. Landmark analyses taking the median time to the first RCCEP onset as cutoff reference were performed for survival. **Results:** RCCEP occurred in 74.5% (251/337) of patients with Camre, 30.6% (120/392) with Camre-Apa, and 73.2% (737/1007) with Camre-Chemo. The severity was grade 1 or 2 in almost all patients with RCCEP (97.9%; 1085/1108), and the median frequency of RCCEP events was 1 (IQR, 1-2). Median time to the first RCCEP onset was 1.0 months [IQR, 0.7-1.2] with Camre, 4.7 months (IQR, 2.8-7.8) with Camre-Apa, and 1.5 months (IQR, 1.0-2.6) with Camre-Chemo; 1-month, 5-month, and 2-month landmark analyses of survival were performed for the three treatment groups, respectively. Patients with RCCEP showed better clinical outcomes than those without (objective response rate: 22.7% vs 2.3% with Camre, 42.5% vs 18.0% with Camre-Apa, and 73.7% vs 45.9% with Camre-Chemo; median progression-free survival [landmark analysis]: 3.0 vs 1.9 months [HR = 0.51, 95% CI, 0.38-0.69], 13.8 vs 12.6 months [HR = 0.88, 95% CI, 0.61-1.26], and 9.7 vs 6.9 months [HR = 0.58, 95% CI, 0.47-0.71]; median overall survival [landmark analysis]: 11.8 vs 3.9 months [HR = 0.44, 95% CI, 0.33-0.59], 35.2 vs 23.7 months [HR = 0.66, 95% CI, 0.49-0.90], and 23.4 vs 12.0 months [HR = 0.45, 95% CI, 0.37-0.54]). Discontinuation of camrelizumab treatment due to RCCEP barely occurred (0.3%; 5/1736). **Conclusions:** Although RCCEP occurred commonly, most events were mild without impact on camrelizumab treatment. RCCEP occurred early with 1-2 events mainly in each patient. The occurrence of RCCEP was positively associated with both short-term response and long-term survival, regardless of camrelizumab monotherapy or combination therapy. These findings can enhance patient confidence in continuing camrelizumab treatment. Research Sponsor: Jiangsu Hengrui Pharmaceuticals Co., Ltd.

Demographic and clinical factors associated with young-onset rectal cancer: Is the Latinx population at higher risk?

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Background: The incidence of colorectal cancer is rising among younger adults, with some studies indicating a disproportionate increase in the Hispanic population. As one of the fastest-growing demographics in the United States, Hispanic individuals face unique barriers to cancer prevention and care. However, data specifically addressing disparities in rectal cancer within this group remain limited. The aim of our study is to elucidate demographic and clinical factors associated with young-onset rectal cancer (YO-RC) and evaluate if the Latinx population is at higher risk compared to other races. **Methods:** We evaluated patients ≥18 years of age with rectal cancer from the Surveillance, Epidemiology, and End Results (SEER) database, with a study period from 2018 to 2021. The study population included adult patients diagnosed with RC as first primary, histologically confirmed diagnoses, complete data on race, MSI status, stage, and known cause of death. A retrospective cohort study was done. Individuals were divided into two groups: young onset (diagnosed <50 years old) and average-onset (diagnosed at ≥50 years old). Univariate and multivariate logistic regression was done, adjusted logistic regression to race, sex, area of living, MSI status and stage. **Results:** A total of 13,768 individuals were analyzed, with 2,661 (19.33%) classified as YO-RC and 11,107 (80.67%) as AO-RC. In the YO-RC group, 60.28% were Non-Hispanic White (NHW), 21.20% Hispanic (H), 7.22% Non-Hispanic Black (NHB), 10.54% Non-Hispanic Asian or Pacific Islander (NHAPI), and 0.76% Non-Hispanic American Indian (NHAI). Most were male (58.51%) and diagnosed at advanced stages (43.03% stage III and 27.58% stage IV), with 93.24% having MSI-stable tumors. In the AO-RC group, NHW accounted for 68.46%, followed by H (12.52%), NHB (7.70%), NHAPI (10.46%), and NHAI (0.86%). Stage III (32.86%) and stage I (24.45%) were the most common stages, and 94.97% had MSI-stable tumors. H individuals were nearly twice as likely to have YO-RC compared to NHW (aOR 1.87, 95% CI 1.67–2.10, p<0.001). Females had a higher likelihood of YO-RC than males (aOR 1.14, 95% CI 1.04–1.24, p=0.002). MSI-high tumors were associated with YO-RC (aOR 1.57, 95% CI 1.27–1.94, p<0.001). Patients diagnosed at later stages were also more likely to have YO-RC (stage III aOR 1.99, 95% CI 1.76–2.25, p<0.001; stage IV aOR 1.98, 95% CI 1.73–2.26, p<0.001). **Conclusions:** Hispanic individuals are more likely to have YO-RC, which suggests the critical need for targeted outreach and earlier screening efforts within the young Latinx population. Female patients and those with MSI-high tumors were also more likely to have YO-RC suggesting possible biological and genetic influences, including Lynch syndrome. The strong correlation of advanced-stage diagnoses and YO-RC demonstrates the need to improve early detection efforts. Research Sponsor: None.

Demographic and clinical factors associated with young-onset rectal cancer.

Variable	Unadjusted OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value
Race				
Non-Hispanic White		Ref.		
Hispanic	1.92 (1.71-2.14)	**<0.001**	1.87 (1.67-2.10)	**<0.001**
Non-Hispanic Black	1.07 (0.91-1.26)	0.386	1.03 (0.89-1.24)	0.658
Non-Hispanic Asian/PI	1.17 (1.02-1.35)	0.021	1.14 (0.99-1.32)	0.055
Non-Hispanic AI	0.49 (0.25-0.95)	0.037	0.48 (0.24-0.92)	**0.029**
Sex				
Male		Ref.		
Female	1.12 (1.03-1.22)	**0.007**	1.14 (1.04-1.24)	**0.002**
Area of Living				
Non-Metropolitan		Ref.		
Metropolitan	1.23 (1.08-1.41)	0.002	1.10 (0.95-1.26)	0.177
Socioeconomic Status				
<$40,000-79,999	Ref.		*Not included due to collinearity	
$40,000-$79,999	0.89 (0.61-1.31)	0.576		
$80,000-$100,000	0.95 (0.65-1.40)	0.818		
>$100,000	0.93 (0.63-1.37)	0.738		
MSI status				
MSI stable		Ref.		
MSI low	1.15 (0.85-1.55)	0.357	1.08 (0.79-1.47)	0.604
MSI high	1.49 (1.21-1.83)	**<0.001**	1.57 (1.27-1.94)	**<0.001**
Stage				
I		Ref.		
II	0.94 (0.85-1.10)	0.495	0.94 (0.81-1.10)	0.483
III	1.99 (1.76-2.25)	<0.001	1.99 (1.76-2.25)	**<0.001**
IV	1.97 (1.73-2.25)	<0.001	1.98 (1.73-2.26)	**<0.001**

Multivariate logistic regression, adjusted logistic regression is adjusted to race, sex, area of living, MSI status and stage. Income was not included due to a VIF >10, suggesting collinearity. †: p value <0.05, statistically significant.

11039 Poster Session

Pharmacotherapy as an adjunct to behavioral weight loss treatment in survivors of breast cancer.

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Background: Approximately half of breast cancer (BC) survivors attain 5% weight loss with 6 months of behavioral intervention alone. We conducted a single-arm, phase II study evaluating the addition of FDA-approved anti-obesity pharmacotherapy Contrave (Naltrexone +Buproprion) to a behavioral weight loss (BWL) intervention in BC survivors who did not attain 5% weight loss after 8 weeks. **Methods:** Women with stage 0-III BC and BMI $>$ 27 kg/m^2 who completed local therapy and chemotherapy were enrolled in a 6-month, remotely-delivered BWL program. Patients completed demographic and psychosocial surveys, lab draws (Hba1c and lipid panel) and were weighed in clinic at baseline, 2 and 6 months. An adaptive design utilizing weight loss at 2 months identified those with greater likelihood of weight loss at 6 months with BWL alone. Patients with and without $\geq$5% weight loss at 2 months were stratified as FAST-BWL and SLOW-BWL, respectively. FAST-BWL continued BWL alone for 4 months, while SLOW-BWL received Contrave plus BWL. Within the SLOW-BWL arm, the trial continued with a Simon two-stage minimax design with the proportion of SLOW-BWL attaining $\geq$5% weight loss at 6-months as the primary endpoint. The planned sample size of 30 had 80% power at a type I error rate of 5% if the true rate of attaining the primary endpoint by 6 months was 29%, compared to 10.9% under the null. Secondary endpoints included measures of physical function, endocrine function, pain, fatigue, depression, anxiety, sleep disturbance, and sexual problems. **Results:** Of 53 enrolled patients, 15 (28%) were FAST-BWL and 38 (72%) were SLOW-BWL responders. Compared to FAST-BWL, SLOW-BWL included more participants who were Black (32% v 7%), premenopausal (21% v 7%), and had an ECOG 1 (26% v 13%). At 6-months, mean % weight change was -5.1$\pm$2.9 and -10.8$\pm$3.5 for SLOW-BWL and FAST-BWL, respectively. In the intent-to-treat population of SLOW-BWL (n = 38), 42% had 5% weight loss by 6-months. SLOW-BWL had significant improvement in Hba1c between 2 and 6 months. Among SLOW-BWL patients, every two pounds over the two-month average change, patients were one third as likely to be successful at 6 months, OR = 0.3 (95% CI: 0.1, 0.88), p = 0.03. Of 21 in SLOW-BWL with PROs evaluable for minimally important differences at 6-months, 29% had less anxiety, 24% had improved physical function, and 19% had less pain, fatigue, sleep disturbance, and sexual dysfunction. Regardless of arm, physical function and pain improved in those with $>$5% weight loss (p = 0.03 and p = 0.02, respectively). The change in pain was primarily in those with $>$ 5% weight loss in SLOW-BWL. **Conclusions:** Contrave can enhance weight loss outcomes in BC survivors who do not attain significant weight loss with diet and exercise modification alone. Further research is needed to understand individuals who benefit most from pharmacotherapy. Clinical trial information: NCT04499950. Research Sponsor: NCCN Foundation; American Institute of Cancer Research; Breast Cancer Research Foundation; Maryland Cigarette Restitution Fund; National Capital Cancer Research Fund.

Association between frailty and clinical outcomes in older adults with early breast cancer: Results from the Hurria Older Patients (HOPE) study.

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Background: Older adults with early breast cancer are a heterogenous population with varying physiologic and functional age. Pretreatment frailty may help better characterize this heterogenous population compared to chronological age. We investigated the association between pretreatment frailty and clinical outcomes in older adults with early breast cancer treated with chemo. **Methods:** We leveraged a prospective cohort of 499 adults age ≥65 with stage I-III breast cancer undergoing treatment with neo/adjuvant chemo (R01AG037037). Pretreatment frailty status was determined using a Deficit Accumulation Index, which categorized patients as robust vs. prefrail/frail. Clinical outcomes included grade 3+ toxicity, dose reduction, treatment delay, early chemo discontinuation, hospitalization, and survival (overall, breast cancer related, and non-breast cancer related). We conducted a multivariable analysis evaluating the association between baseline frailty status (robust vs. prefrail/frail) and these outcomes, adjusting for age, race/ethnicity, stage, and regimen. **Results:** The median (range) age was 70 (65-86) years, 65% had stage II/III disease, and 38% received anthracycline. At baseline, 21% were prefrail/frail and 79% were robust. In total, 46% had a grade 3+ toxicity, 24% had a dose reduction, 26% had a treatment delay, 22% had early chemo discontinuation, and 23% were hospitalized. After multivariable analysis, prefrail/frail participants had greater odds of having grade 3+ toxicity (odds ratio [OR]=2.70, 95% CI, 1.66-4.40), dose reduction (OR=1.87, 95% CI 1.12-3.15), treatment delay (OR=1.85, 95% CI 1.10-3.13), and early chemo discontinuation (OR=1.76, 95% CI 1.05-2.95) compared to robust participants. Prefrail/frail participants had a higher likelihood of non-breast cancer related death (hazard ratio=2.56, 95% CI 1.08-6.05) compared to robust participants. There were no associations between frailty and hospitalizations, overall survival, and breast cancer related mortality. **Conclusions:** In this cohort of older adults with early breast cancer, participants who were prefrail/frail pretreatment had an increased risk of grade 3+ toxicity, dose reduction, treatment delay, early chemo discontinuation, and non-breast cancer related death. Pretreatment frailty assessments may improve risk stratification of older adults with early breast cancer and guide treatment decision-making. Clinical trial information: NCT01472094. Research Sponsor: U.S. National Institutes of Health; R01AG037037.

Clinical outcomes in older adults with early breast cancer, odds ratio (95% CI).*

Frailty Status	Grade 3+ Tox (n=229)	Dose Reduction (n=120)	Treatment Delay (n=132)	Early Discontinuation (n=111)	Hospitalization (n=115)
Robust	1.00	1.00	1.00	1.00	1.00
Prefrail/ Frail	2.70 (1.66-4.40)	1.87 (1.12-3.15)	1.85 (1.10-3.13)	1.76 (1.05-2.95)	1.61 (0.96-2.69)

*Adjusted for age, race/ethnicity, stage, and regimen.

The impact of iron deficiency anemia on long-term cardiovascular outcomes in breast cancer patients hospitalized with heart failure preserved ejection fraction: A propensity score–matched retrospective cohort study.

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Background: Breast cancer (BC) patients are at risk for iron deficiency anemia (IDA) due to the effects of chemotherapy on the bone marrow and because of potential malignant infiltration of the bone marrow. Additionally, BC patients are at increased risk for heart failure either from the effects of chemoradiation on the myocardium or because of direct tumor invasion of the heart. Studies have shown that IDA is associated with worse functional outcomes, hospitalization, and mortality in heart failure preserved ejection fraction (HFpEF). There is limited data on the impact of IDA on long-term cardiovascular outcomes in BC patients with HFpEF, and our study aims to assess these outcomes. **Methods:** We utilized data from the Global Collaborative Network-TriNetX. Patients aged 18 to 85 were divided into two cohorts: those with BC, HFpEF, and IDA, and those with BC, HFpEF but without IDA. Using ICD-10 codes, we evaluated the following outcomes: risk of myocardial infarction (MI), arrhythmia, cardiogenic shock, mortality, and hospitalization. Generalized linear models were used to measure the association, and estimates were presented as risk ratios and 95% confidence intervals. **Results:** After propensity score matching, each cohort consisted of 9,204 patients. The IDA cohort had a mean age of 74.4 ± 8.6 years and 94% were female. Caucasians accounted for 65% of patients and blacks 21%. Our study found that over a 5-year period (Table 1), BC patients with HFpEF and concomitant IDA had a statistically significant higher risk of MI (RR: 1.576, 95% CI 1.408-1.765), arrhythmia (RR: 1.589, 95% CI 1.300-1.942), cardiogenic shock (RR: 1.660, 95% CI 1.347-2.045), and mortality (RR: 1.052, 95% CI 1.002-1.104). There was an increased risk of hospitalization (RR: 1.256, 95% CI 0.871-1.813) but the results were statistically insignificant. **Conclusions:** Our study demonstrated that IDA is associated with long-term adverse cardiovascular outcomes in BC patients with HFpEF. More prospective studies are needed to assess the impact of iron therapy on cardiovascular outcomes, specifically in the BC population with HFpEF. Research Sponsor: None.

Long term cardiovascular outcomes in breast cancer patients with heart failure preserved ejection fraction.

	1 year follow up		5 year follow up	
Outcome	**RR and 95% CI**	**p value**	**RR and 95% CI**	**p value**
Myocardial Infarction	1.481 (1.261-1.738)	<0.001	1.576 (1.408-1.765)	<0.001
Arrhythmia	1.631 (1.206-2.207)	0.001	1.589 (1.300-1.942)	<0.001
Cardiogenic Shock	1.592 (1.194-2.123)	0.001	1.660 (1.347-2.045)	<0.001
Mortality	0.899 (0.840-0.963)	<0.002	1.052 (1.002-1.104)	0.04
Hospitalization	1.335 (0.684-2.606)	0.40	1.256 (0.871-1.813)	0.2

RR: risk ratio, CI: confidence interval.

11042 Poster Session

Sex-based differences in clinical outcomes for solid tumours: A pooled IPD meta-analysis of contemporary anticancer drug trials.

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Background: Sex-based differences in outcomes with contemporary oncology treatments remain underexplored, creating a gap in the evidence required for personalised care. To address this, our objective was to systematically evaluate whether sex differences exist in survival and adverse event outcomes with modern anticancer therapies. **Methods:** Individual patient data (IPD) was accessed via the Vivli platform from 60 clinical trials supporting US Food and Drug Administration approvals of anticancer medicines for the treatment of solid tumours from 2012 to 2022. Of these, 39 trials were included in analysing sex-based differences in clinical outcomes (i.e. breast, prostate, and ovarian cancer were excluded) Two-stage IPD meta-analysis approaches were employed. First, Cox proportional hazards models were applied to estimate hazard ratios (HRs) with confidence intervals for overall survival (OS), progression-free survival (PFS), and grade ≥3 adverse events (AEs) outcomes by sex within each clinical trial. Complete case analyses were conducted, with adjustments for covariates including age, race, ECOG performance status, and weight, as well as study-level factors, such as randomisation arm stratification. The results for each clinical trial were then pooled using random-effects meta-analysis. Subgroup analyses were performed to evaluate findings by cancer and treatment types. **Results:** Data from 39 trials for solid tumours (n=20,806; females=8,367) were analysed, including non-small cell lung (n=19), melanoma (n=6), colorectal (n=3), urothelial (n=2), gastric (n=2), and other (n=7) cancers. Treatment regimens evaluated included immunotherapies (n=9 trials), chemotherapies (n=18), and targeted therapies (n=32). In adjusted analyses, females demonstrated favourable OS (HR 0.78, 95% CI: 0.72–0.84; I^2 = 60%, p <0.001) and PFS (HR 0.84, 95% CI: 0.80–0.89; I^2 = 47%, p <0.001) compared to males. However, females had a higher risk of grade ≥3 AEs (HR 1.12, 95% CI: 1.05–1.18; I^2 = 40%, p <0.001). Subgroup analyses by cancer type and treatment regimen showed consistent trends in survival and AE outcomes according to sex. **Conclusions:** This meta-analysis, highlights consistency in females experiencing improved survival but higher toxicity compared to males with contemporary oncology treatments. These findings underscore the need to incorporate and prioritise sex as a key biological variable in trial design, dose optimisation, outcome analysis, and clinical decision-making within the oncology setting. Acknowledgement This publication is based on research using data from AstraZeneca, Boehringer Ingelheim, Daiichi Sankyo, Eli Lilly and Company, Hoffmann-La Roche, Janssen, Pfizer, Sanofi, and Takeda that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication. Research Sponsor: None.

11043 Poster Session

Race/ethnicity reporting and representation in clinical trials presented at the American Society of Clinical Oncology (ASCO) presidential plenaries from 2014 to 2024.

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Background: The lack of appropriate racial and ethnic representation in life saving innovative trials has been linked to poor outcomes. To address this, ASCO published an Equity, Diversity, and Inclusion Action Plan in 2021 which aimed to improve clinical trial diversity. This study evaluates the frequency of race reporting and proportional race representation in trials presented at ASCO plenary sessions. **Methods:** We reviewed ASCO plenary sessions from 2014 through 2024 to identify clinical trial presentations. These clinical trials were then identified using the National Institutes of Health trials registry (ClinicalTrials.gov). Trial characteristics and race reporting were abstracted from primary report publications or ClinicalTrials.gov if race reporting was not included in the primary report. When an ASCO plenary session involved multiple trials, each trial was included in the analysis. US population-based cancer estimates were calculated using data from National Cancer Institute-Surveillance, Epidemiology, and End Results and US Census databases. Age-standardized incidence and mortality rates adjusted to the year 2000 standard US population by race were used to calculate estimated 5-year average incidence and mortality rates from 2017 to 2021. **Results:** Between 2014-2024, 46 clinical trials with a total 67496 participants were presented at ASCO plenary sessions. Race was reported in 31 (67%) trials and both race and ethnicity were reported in 15 (33%) trials. Between 2014 and 2019 vs 2021 and 2024, the proportion of trials reporting race or both race and ethnicity increased 57% to 83% and 25% to 44%, respectively. Overall, White, Asian, Black, and Hispanic patients represented 78.8%, 8.3%, 6.8%, and 6.3% of the trial participants, respectively. Between 2014 and 2019 vs 2021 and 2024, Black (19.7% vs. 18.1% of expected) and Hispanic (40.3% vs. 46.6% of expected) patients remained underrepresented compared to White (113.8% vs 76.3% of expected) and Asian (209.7% vs. 719.1% of expected) patients. **Conclusions:** Since the ASCO 2021 Equity Action Plan, there has been an increase in reporting race and ethnicity of clinical trial participants with no significant effect on Black and Hispanic patients enrolled on trials. This study shows a need for policy revision and meaningful intervention to address underrepresented population enrollment in trials to ensure equitable access and consistent outcomes for all patients. Research Sponsor: None.

Prognostic value of time-varying patient-reported symptoms and quality of life in cancer patients receiving chemotherapy.

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Background: Prior research has demonstrated that pre-treatment patient-reported outcomes (PROs) predict post-treatment survival. Symptom burden, physical function and overall well-being are time-varying concepts, so making survival predictions using pre-treatment data may have limited clinical actionability. The prognostic value of time-varying patient-reported symptom burden, physical function (PF) and wellbeing (WB) are not well characterized. **Methods:** Six US-based cancer centers collaborated to develop and deploy an EHR-integrated ePRO monitoring system to facilitate active symptom management. Patients receiving chemotherapy for a gastrointestinal (GI), gynecologic (GYN), or thoracic cancer were asked to report on 12 common symptoms using PRO-CTCAE items and 2 quality of life items twice weekly for up to 180 days after starting chemotherapy. Herein, we employed Cox regression to model 180-day survival using time-varying overall symptom burden, calculated as the sum of 12 symptom scores, PF and WB. Multivariable models also included demographics, clinical variables, treatment goal, and comorbidities. **Results:** The cohort included 3,999 patients (45% GI, 23% GYN, 32% thoracic) who submitted 42,254 symptom reports and had 481 deaths within 180 days. Median age was 66 (IQR 15), 59% female, 86% White, 42% Medicare, 5% Medicaid, 50% retired, 10% disabled. The mean symptom burden score was 7.57 (SD 4.66, min 0, max 34); severe deficit in PF and WB were reported in 13.2% and 7.8% of questionnaires, respectively. In bivariate analyses, greater symptom burden, more deficits in PF and WB, increasing age, female sex, and palliative treatment goal predicted inferior survival. After adjusting for other covariates, symptom burden, moderate and severe PF deficits, and severe WB deficits predicted inferior 180-day survival (Table). **Conclusions:** There is a significant inverse linear relationship between time-varying symptom burden and survival for patients receiving chemotherapy. Among chemotherapy patients, assessments that elicit symptom burden as well as PF and WB may augment the prognostic value and usefulness of ePRO tracking systems. Clinical trial information: NCT03850912. Research Sponsor: National Cancer Instiute; 1UM1CA233080-01.

	Unadjusted		Multivariable	
Characteristic	**HR**	**95% CI**	**HR**	**95% CI**
Symptom Burden (Linear)	1.13	1.11, 1.15	1.08	1.06, 1.10
Physical Function Deficit (ref = no deficit)				
Mild	1.65	1.13, 2.41	1.12	0.74, 1.69
Moderate	3.82	2.64, 5.53	1.89	1.23, 2.92
Severe	9.55	6.74, 13.5	3.61	2.35, 5.55
Overall Wellbeing Deficit (ref = no deficit)				
Mild	1.98	1.27, 3.07	1.30	0.81, 2.10
Moderate	4.18	2.74, 6.36	1.51	0.92, 2.48
Severe	9.97	6.49, 15.3	1.75	1.02, 3.00
Age (Linear)	1.02	1.01, 1.03	1.03	1.01, 1.04
Sex (Female, ref = male)	0.57	0.49, 0.68	0.61	0.51, 0.74
Treatment Goal (ref =curative)				
Palliative	4.27	3.22, 5.66	3.66	2.71, 4.95
Control/Other/Unknown	2.66	1.99, 3.55	2.52	1.85, 3.42

11045 Poster Session

Treatment patterns and out-of-pocket cost after CAR-T cell therapy in commercially insured patients with hematologic malignancies: A real-world US study.

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Background: Chimeric Antigen Receptor T (CAR-T) cell therapy has improved outcomes in hematologic malignancies since its FDA approval in 2017. However, real-world data on treatment patterns and out-of-pocket (OOP) costs after CAR-T failure or cancer relapse remain limited. This study evaluated subsequent treatment risk, patterns, and OOP costs post-CAR-T therapy. **Methods:** A retrospective cohort study was conducted using the Merative MarketScan database (2017–2022). Commercially insured patients receiving CAR-T for acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), mantle cell lymphoma (MCL), or primary mediastinal large B-cell lymphoma (PMBCL) were included. Patients had ≥6 months of continuous insurance enrollment before the index date (CAR-T administration date) and were followed until disenrollment or the end of 2022. Initiation of additional therapy >14 days post-index (chemotherapy, immunotherapy, stem cell transplant, or radiotherapy) served as a proxy for CAR-T failure or relapse, with cumulative risk estimated using Kaplan-Meier methods. OOP costs (outpatient, inpatient, and prescription claims) were calculated for patients with ≥6 months of post-index enrollment and adjusted to 2022 USD. **Results:** Of the 246 patients, 22 had ALL, 185 DLBCL, 15 FL, 23 MCL, and 1 PMBCL. The mean age was 53.2 years (SD: 10.7), and 69.9% of patients were male. Overall, 98 patients (39.8%) initiated subsequent therapy. The cumulative risk of CAR-T failure was 21.3% (95% CI: 16.8%-25.8%) at 3 months, 37.0% (95% CI: 30.1%-43.9%) at 6 months, and 51.5% (95% CI: 43.5%-59.4%) at 12 months. After CAR-T failure, the most common first-line therapies were lenalidomide (n=12), ibrutinib (n=7), and pembrolizumab (n=5) for DLBCL, and blinatumomab (n=3) and ruxolitinib (n=2) for ALL. Total OOP costs incurred over six months were $310,246.2, with outpatient services accounting for 66.0%. The mean per-patient OOP cost for six months was $2,248.2. While the median OOP costs were similar between groups, mean per-patient OOP costs were higher for patients who required subsequent therapy ($2,881.0 vs $1,910.7), with some patients facing costs as high as $38,889.2. **Conclusions:** This study highlights a substantial risk of CAR-T failure, with targeted therapies and immunotherapies commonly used post-CAR-T. OOP costs were significant, particularly for patients requiring additional therapy, with considerable variability. These findings emphasize the need for strategies to improve outcomes and reduce financial toxicity in this population. Research Sponsor: None.

Receiving a cancer diagnosis during hospitalization and associations with care outcomes.

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Background: Patients often receive their cancer diagnoses during a hospitalization, but little is known about patients who are diagnosed inpatient versus outpatient. We sought to describe associations between patients diagnosed with cancer in the hospital and their clinical outcomes. **Methods:** We conducted a retrospective cohort study of adults with cancer admitted from 1/2017-12/2022 to the University of Oklahoma Medical Center. Using the electronic health record, we extracted patient demographics (age, sex, race, area deprivation index [ADI; categorized into quartiles Q1-Q4; Q4=areas of highest deprivation]) and clinical characteristics (cancer type, Charlson Comorbidity Index [CCI]), including those who received their cancer diagnosis during their respective hospital admission. We used regression models to explore associations of inpatient cancer diagnosis with patients' demographics, clinical characteristics, and clinical outcomes (hospital length of stay [hazard ratio {HR} for time to discharge], time to readmission, and overall survival). **Results:** Among 20,683 hospitalized patients with cancer (mean age 62.2; 51.5% female, 80.0% White, most common cancer types: gastrointestinal [GI; 19.3%], genitourinary [GU; 13.8%], and gynecologic [GYN; 13.7%]), 36.8% of patients received their cancer diagnosis during hospital admission. We found that Black patients (OR=.81, p<.001) and female patients (OR=.91, p=.007) were less likely to receive an inpatient cancer diagnosis. Compared to those with GU cancers, patients with neuroendocrine (OR=1.72, p<.001), thoracic (OR=1.68, p<.001), hematologic (OR=1.38, p<.001), CNS (OR=1.34, p<.001), and GI (OR=1.23, p=.018) cancers were more likely to receive an inpatient diagnosis whereas patients with breast (OR=.48, p<.001), GYN (OR=.67, p<.001), and head/neck (OR=.84, p=.009) cancers were less likely. Patients residing in higher ADI areas (Q2: OR= 1.18, p=.002; Q3: OR=1.55, p<.001; Q4: OR= 1.55, p<.001) were more likely to receive an inpatient cancer diagnosis compared to Q1. Patients with more comorbidities (CCI 1-2: OR=1.41, p<.001; CCI 3+: OR=1.69, p<.001) were more likely to receive an inpatient cancer diagnosis. For clinical outcomes, those who received an inpatient cancer diagnosis had a longer hospital length of stay (HR=.71, p<.001), higher risk of readmission (HR=1.12, p<.001), and worse overall survival (HR=1.28, p<.001) than patients who were not diagnosed in the respective hospitalization. **Conclusions:** In this large cohort of hospitalized patients with cancer, we identified factors associated with receiving an inpatient cancer diagnosis and demonstrated that diagnosis during hospitalization correlated with worse clinical outcomes. These findings highlight the importance of developing targeted interventions to enhance care delivery and outcomes for individuals who receive their cancer diagnosis during a hospital admission. Research Sponsor: U.S. National Institutes of Health; U54GM104938.

Impact of angiotensin-converting enzyme inhibitors (ACEis) or angiotensin II receptor blockers (ARBs) on mortality and kidney function in cancer patients receiving cisplatin.

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Background: Cisplatin is a cornerstone of cancer treatment, but its nephrotoxicity often requires dose reduction or withdrawal, compromising antitumor efficacy. This study aimed to determine if concomitant use of cisplatin with angiotensin-converting enzyme inhibitors (ACEis) or Angiotensin II receptor blockers (ARBs) increases the risk of acute kidney injury (AKI) and impacts mortality. **Methods:** A retrospective analysis using the TriNetX Research Network identified cancer patients ≥18 treated with cisplatin from January 1, 2010, to November 27, 2024. Eligible cancers included head and neck, lung, esophageal, biliary tract, pancreatic, or testicular cancer. Patients were stratified by ACEi/ARB use within 1 week of cisplatin treatment. Groups were compared using 1:1 propensity matching, adjusting for age, type 2 diabetes, hyperlipidemia, CAD, CHF, and hypertensive heart disease. Primary outcomes were AKI risk and overall mortality; secondary outcomes included renal replacement therapy (RRT), hospitalization within 3 months, and proteinuria or hematuria. Outcomes were assessed using risk analysis and Kaplan-Meier log-rank tests. **Results:** A total of 36,779 cancer patients taking cisplatin were identified. Of these, 2,585 patients were taking an ACEi/ARB within 1-week of cisplatin treatment, while 36,194 were not. Patients taking ACEis/ARBs had a significantly increased risk of AKI within 30 days of cisplatin use based on the measures of association (risk difference [RD]: 1.713%, p = 0.0152) and the Kaplan-Meier test (hazard ratio [HR]: 1.372, p = 0.01). Similarly, overall mortality was higher in patients with concomitant use of ACEis/ARBs and cisplatin based on both the risk assessment (RD: 5.228%, p = 0.0002) and the Kaplan-Meier (HR: 1.196, p< 0.0001). Patients on ACEis/ARBs also had higher rates of hospitalization 3-months after treatment with cisplatin (RD: 9.24%, p < 0.0001 and HR: 1.53, p < 0.0001). However no significant difference was noted in the need for RRT or the diagnosis of proteinuria or hematuria up to 3-months after treatment. **Conclusions:** Our study suggests that the use of Cisplatin in patients taking ACEi/ARBs increased the risk of early AKI, mortality, and hospitalizations. Careful consideration should be taken when using Cisplatin in these patient groups, focusing on alternative hypertensive regimens. Research Sponsor: None.

	ACEi/ARB use		Risk Difference/Odds Ratio			Log-Rank Test		
Outcomes	Yes	No	RD	OR (95% CI)	P Value	HR	95% CI	P-Value
AKI Risk	6.82%	5.10%	1.713%	(1.06,1.745)	0.0152	1.372	(1.077,1.747)	0.01
Overall Mortality	49.01%	43.78%	5.228%	(1.105-1.379)	0.0002	1.196	(1.103-1.297)	< 0.0001
Hospitalization	33.44%	24.20%	9.24%	(1.393-1.778)	< 0.0001	1.534	(1.384-1.702)	< 0.0001

Sociodemographic differences in lung cancer mortality trends across the United States (US) rural-urban divide.

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Background: It is known that rural populations face higher lung cancer mortality than urban populations, but it is unknown how trends vary across demographic groups. We investigated rural-urban disparities in age-adjusted mortality rates (AAMRs) from lung cancer across demographic groups over 20 years. **Methods:** We analyzed lung cancer mortality (ICD codes C34.0 - 34.3, 34.8, 34.9) from 1999-2019 using the CDC WONDER database. Populations were classified as urban or rural based on 2013 US census definitions. AAMRs were calculated as deaths per 100,000 using the US Standard Population and stratified by sociodemographic categories. Annual percentage change (APC) and 95% CIs were estimated using linear regression with the log-scale AAMRs as the dependent variable and year as a continuous covariate. **Results:** There were 3,244,056 deaths attributable to lung cancer (79.7% urban, 20.3% rural) with overall AAMR reduction from 86.9 to 53 deaths per 100,000 from 1999-2019. Rural populations had slower mortality improvements compared to urban populations (APC -2.6 [-2.9, -2.4] vs -1.6 [-1.9, -1.3]; p <0.001), with greatest rural-urban differences seen in younger and female populations (Table). Younger adults (<65)in rural areas had nearly 2-fold slower improvement than urban areas (APC -2.1 [-2.3, -1.9] vs -3.7 [-3.9, -3.5]; p<0.001). Females in rural areas had 3-fold slower improvement than females in urban areas (APC -0.6 [-0.9, -0.3] vs -2.0 [-2.3, -1.7], p<0.001). Slower mortality improvements were also seen for non-Hispanic patients in rural than in urban areas. While AAMR remained slightly higher for Hispanic patients in rural than urban areas, it noted faster improvement in rural areas (APC -3.3 [-3.7, -3.9] vs -2.4 [-2.7, -2.2]). **Conclusions:** Patients in rural areas had higher AAMR than urban counterparts across all demographic groups analyzed with slower improvements in almost all subgroups. This study highlights populations in greatest need of health services initiatives such as tobacco cessation efforts, lung cancer screening, and guideline concordant treatment receipt to close the rural-urban gap. Research Sponsor: None.

	Overall	Urban	Rural	P
Overall	-2.5 (-2.7, -2.2)	-2.6 (-2.9, -2.4)	-1.6 (-1.9, -1.3)	<0.001
Age 25-65	-3.4 (-3.6, -3.2)	-3.7 (-3.9, -3.5)	-2.1 (-2.3, -1.9)	<0.001
Age >65	-2.1 (-2.5, -1.8)	-2.3 (-2.6, -2.0)	-1.4 (-1.8, -1.1)	0.006
Female	-1.7 (-2.1, -1.4)	-2.0 (-2.3, -1.7)	-0.6 (-0.9, -0.3)	<0.001
Male	-3.2 (-3.4, -2.9)	-3.3 (-3.6, -3.1)	-2.5 (-2.8, -2.2)	0.002
Hispanic	-2.5 (-2.8, -2.3)	-2.4 (-2.7, -2.2)	-3.3 (-3.7, -2.9)	0.025
Non-Hispanic Black	-3.0 (-3.2, -2.7)	-3.1 (-3.4, -2.8)	-2.1 (-2.4, -1.9)	0.002
Non-Hispanic White	-2.24 (-2.5, -2.0)	-2.4 (-2.7, -2.1)	-1.5 (-1.8, -1.2)	0.002

APC for overall, urban, and rural geographic regions by demographic subgroups. P value for difference in change in AAMR over time between Urban and Rural areas, overall and within subgroups, estimated using interaction tests. All CIs are 95%.

11049 Poster Session

Cost-effectiveness of ribociclib plus endocrine therapy in HR-positive, HER2-negative early breast cancer in the United States.

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Background: Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors are an efficacious treatment for HR-positive (HR+), HER2-negative (HER2-) early breast cancer. The phase 3 NATALEE trial demonstrated that ribociclib ($12,000 monthly) plus a nonsteroidal aromatase inhibitor (endocrine therapy) significantly improved invasive disease-free survival. We performed the first cost-effectiveness analysis of ribociclib plus endocrine therapy in patients with HR+, HER2- early breast cancer in the United States (US). **Methods:** We constructed a partitioned survival model based upon clinical data from the NATALEE trial, employing a health system perspective across all accepted willingness-to-pay (WTP) thresholds in the US. Patients with a median age of 51 years entered the model to receive (1) ribociclib plus endocrine therapy versus (2) endocrine therapy alone. Standard extrapolation techniques were utilized to extend overall and invasive disease-free survival curves to a 10-year time horizon. Costs were informed by the US Centers for Medicare & Medicaid Services. Effectiveness was informed by age-, sex-, and breast cancer-specific utility values and was measured in both quality-adjusted life years (QALYs) and equal value life years (evLYs). The primary outcome was the incremental cost-effectiveness ratio (ICER) in USD per evLY. We concluded with deterministic sensitivity analyses and threshold and probabilistic analyses, with all input parameters informed by relevant probability distributions. **Results:** In the base-case, ribociclib plus endocrine therapy and endocrine therapy alone accrued discounted costs of $442,000 and $186,000, with discounted QALYs/evLYs of 7.76/7.79 and 7.57/7.57, respectively. This resulted in an ICER of $1.2 million/evLY (and $1.3 million/QALY) for the addition of ribociclib (Table 1). Deterministic sensitivity analysis revealed our model was only sensitive to the price of ribociclib: no other parameter changed the conclusion. Threshold analysis demonstrated that a 90% reduction in the price of ribociclib would be necessary for ribociclib plus endocrine therapy to be cost-effective even at the highest WTP threshold. Endocrine therapy alone was favored in 100% of 10,000 Monte Carlo simulations across the entire range of accepted WTP thresholds in the US. **Conclusions:** At current pricing, ribociclib with endocrine therapy is not expected to be a cost-effective strategy compared to endocrine therapy alone for patients with HR+, HER2- early breast cancer in the US. These results align with prior studies in other countries assessing the cost-effectiveness of CDK4/6 inhibitors in HR+, HER2- early breast cancer. Research Sponsor: None.

Base-case analysis results.

Strategy	Cost (USD)	QALY	evLY	ICER (USD/evLY) [95% credible interval]
Endocrine therapy alone	186,000	7.57	7.57	–
Ribociclib with endocrine therapy	442,000	7.76	7.79	1,200,000 [800,000 to 1,700,000]

Cancer-related mortality of incarcerated populations in the United States.

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Background: The United States has the largest incarcerated population of any country in the world with 1.2 million prisoners as of 2022, but little research has fully characterized the disease burden in these incarcerated populations. Due to the increasing size and age of the prison population, it is paramount to better understand causes of mortality in inmate populations. **Methods:** Mortality data was collected from 41 states via UCLA's Behind Bars Data Project. 40,922 deaths were were recorded between 1999 and 2021, however, only 16,477 deaths had a specific cause of death. To account for individuals with unknown cause of death, analysis was conducted only on the cohort with a known cause of death. From this cohort, one Medical Student and two General Surgery Residents reviewed the death records and assigned each individual into one of 25 mechanisms of death. Protocol for this manual sorting of data was reviewed by the Surgical Health Outcomes and Reaching for Equity group (SHORE). This multidisciplinary group consists of statisticians, public health researchers, Surgery residents, and attending surgeons. **Results:** Of the 25 mechanisms of death, cancer was the leading cause accounting for 4,351 deaths. Approximately 26 different types of cancer were identified with the incarcerated population. The most common types of malignancies within this population were Lung, Hepatic/Biliary, Colorectal, and Esophageal cancers. The rates of Lung, Hepatic/Biliary, and Esophageal Cancer were significantly higher in the incarcerated population compared to the general population. Both the mean and median age of death in the incarcerated population was 61 years old (IQR 54-68), 37.6% were White, 21.3% were Black, 7.1% were Hispanic, and 35.8% unknown. In contrast, cancer related deaths accounted for a smaller proportion of deaths in the general population at 17.5% and 18.5% in 2021 and 2022 respectively. **Conclusions:** This analysis is the first of its kind to stratify mortality by cancer type within the prison population. Previous research that indicates prisoners have a high incidence of Hepatitis B due to the prevalence of IV drug use which is a major risk factor for Hepatic/Biliary cancer. Furthermore, incarcerated populations have higher rates of tobacco use compared to the general population which may account for some of the difference in Lung cancer rates. Delayed access to care in the prison environment may contribute to later diagnosis and correspondingly higher mortality rates among incarcerated individuals. Our results highlight the importance of access to care for effective cancer treatment, and the importance of understanding risk factors for cancer. Research Sponsor: None.

Type of Cancer	Deaths in Prison	% in Prison	Estimated Deaths in General Population	% in General Population	Difference
Lung	1041	23.9%	125,070	20.4%	3.5%
Hepatic/ Biliary	600	13.8%	29,840	4.9%	8.9%
Colorectal	363	8.3%	53,010	8.7%	-0.4%
Esophageal	325	7.5%	32,240	5.3%	2.2%

11051 Poster Session

Age acceleration among adolescent and young adult patients with Ewing sarcoma and osteosarcoma.

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Background: Ewing sarcoma (ES) and osteosarcoma (OS) are two common bone malignancies affecting adolescent and young adult (AYA) patients, often requiring intensive and multimodal therapy. Cancer and its associated treatments may accelerate the aging process, as reflected in phenotypic age acceleration (PAA), leading to increased risk for developing chronic health conditions typically ascribed in older individuals.We conducted a pilot study to evaluate the impact of treatment completion for ES and OS on age acceleration among an AYA cohort using the validated phenotypic age (PheAge) instrument. **Methods:** This pilot study included participants who completed treatment at Vanderbilt University Medical Center from 2012-present for either ES or OS between age 20 and 39 years. Phenotypic age at diagnosis and end of treatment was derived using a modified PheAge equation, which was validated for patients age $\geq$20 years and based on chronological age and eight clinical biochemistry measurements, including albumin, creatinine, glucose, lymphocyte percent, mean cell volume, red cell distribution width, alkaline phosphatase, and white blood cell count. PAA was then calculated as the difference between PheAge and chronologic age. A positive PAA indicates an individual's phenotypic age is older than their chronological age, signifying accelerated aging. A descriptive analysis of PAA across patient demographics and disease strata was then conducted. **Results:** Among 30 AYA participants included in our study, 15 participants were diagnosed with ES and 15 with OS. The mean age at diagnosis was 23.8 (Q1 21.8, Q3 27.5). There was an overall male predominance of 19 participants (63.3%). Among participants with ES, the median PAA was 16.1 years (13.8, 18.1) at diagnosis and 18.4 years (13.6, 25.8) at end of therapy. Among participants with OS, the median PAA was 16.0 years (12.9, 20.7) at diagnosis and 15.9 years (13.9, 19.7) at end of therapy. **Conclusions:** This pilot study suggests that AYA patients with ES and OS had accelerated aging at diagnosis and ES patients may endure further age acceleration following treatment, while patients with OS had shown a nearly unchanged PAA. These results highlight the need for a larger and more comprehensive investigation into the contributing factors of PAA, including an evaluation of genetics, environmental exposures, cancer characteristics, treatment modalities, as well as acute and chronic toxicities of therapy. Such knowledge will contribute to understanding the etiology and cumulative and long-term impact of these common bone malignancies among AYAs. Research Sponsor: National Institutes of Health (NIH)/National Cancer Institute (NCI); Vanderbilt Training Program in Molecular and Genetic Epidemiology of Cancer (MAGEC).

Evaluating the effectiveness of immersive virtual reality in reducing distress in patients with cancer receiving chemotherapy: A prospective randomized trial.

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Background: Patients diagnosed with cancer commonly face high levels of distress, anxiety, and depressive symptoms along with discomfort or pain, that can be exacerbated during chemotherapy treatment. Immersive Virtual Reality (VR) has not been evaluated in patients with cancer as an intervention to relieve psychological and physical symptoms. In this randomized trial, we sought to assess the effect of a unique immersive type of VR on reducing distress compared to standard of care (SOC). **Methods:** This is a two-arm, prospective controlled randomized trial. Eligibility criteria included patients diagnosed with any type of cancer at any stage, with an NCCN Distress Thermometer Score $\geq$ 5, and actively receiving chemotherapy. Participants were randomized in a 1:1 ratio to receive either the intervention (VR) or the control group (SOC). Questionnaires, available in English and Spanish, were administered to both groups before and after the intervention. The primary outcome was to evaluate the effectiveness of VR in reducing distress levels while receiving chemotherapy infusion (NCCN Distress Thermometer) compared to SOC. Secondary outcomes included evaluating the effectiveness in reducing anxiety levels (GAD-7); pain (Universal Pain Assessment Tool) and improving overall wellbeing (Cleveland Clinic 4 Visual Analog Scale - CCVAS). Changes in questionnaire scores were assessed using a two-sample t-test for both arms. All data analyses were conducted using SAS version 9.4. **Results:** A total of N=70 participants meeting the eligibility criteria are expected to be enrolled in this study. To date, N=41 participants have been enrolled and were included in this preliminary analysis, with n=19 assigned to the intervention group (VR) and n=22 assigned to the control group (SOC). A significant difference was observed for the primary outcome, where the intervention group (VR) demonstrated a mean score reduction in NCCN distress thermometer of 3.9 points (SD$\pm$ 3.3) compared to 1.0 points (SD$\pm$ 2.0) for the control group (p = 0.0017). In addition, the VR group showed an improvement in overall wellbeing symptoms measured by decreased CCVAS of 1.7 (SD$\pm$2.2) vs. 0.2 (SD$\pm$1.4) points in the control group (p=0.0160). No significant difference was observed for anxiety and pain. **Conclusions:** VR is an innovative immersive experience with the potential to relieve distress and improve wellbeing during chemotherapy sessions in patients diagnosed with cancer.The study is currently ongoing, and final results will be reported upon completion. Research Sponsor: VeloSano.

Comparison of test changes between pre- and post-intervention.

	Virtual Reality (n=19)	SOC (n=22)	p-value
Primary Outcome, mean ±SD			
NCCN Distress Thermometer	3.9 ± 3.3	1.0 ± 2.0	0.0017
Secondary Outcomes, mean ±SD			
GAD-7	0.4 ± 1.6	0.6 ± 1.7	0.7096
CCVAS	1.7 ± 2.2	0.2 ± 1.4	0.0160
Universal Pain Assessment Tool	1.2 ± 3.0	-0.2 ± 2.9	0.1404

11053 Poster Session

How cancer impacts adolescents' and young adults' (AYAs) scholastic experiences: Insight on supportive survivorship care needs from AYAs, parents, and clinicians.

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Background: Cancer disrupts AYAs' educational and vocational trajectories given treatment demands and acute or late effects of treatment on cognitive functioning. This occurs during a developmental phase when scholastic experiences are central to AYAs' socioemotional and cognitive growth. Despite education being a critical determinant of health-related quality of life, typically families do not receive support for scholastic issues. According to clinical guidelines, key stakeholders in cancer care must have a shared understanding of these concerns to effectively address them. We aimed to identify how cancer impacts scholastic experiences when diagnosed at age 15-29 through the perspectives of diagnosed AYAs, parents caring for AYAs, and AYA oncology clinicians. **Methods:** Drawn from studies funded by The Leukemia & Lymphoma Society and an NCI-Designated Cancer Center, a secondary thematic analysis was conducted on three interview datasets: AYAs (n=10); parents (n=15); clinicians (e.g., oncologists, APPs, LCSWs) (n=7). Analyses were separated by stakeholder group and triangulated to identify shared perspectives. **Results:** AYAs, parents, and clinicians all describe cancer contributing to four challenging scholastic-related impacts: 1) having to advocate for academic accommodations (e.g., virtual option, reduced workload, disability assistance); 2) disrupting school/vocational trajectories (e.g., relocating/changing schools for treatment, stopping school/career pursuits, limitations in performance); 3) losing extracurriculars (e.g., sports, school activities); and 4) losing peer social connection (e.g., feeling isolated/disconnected). They collectively described the impacts as distressful, as a parent expressed: "He was managing all this mental and emotional pain [with cancer], and then [the school] caused so much other stress and pain in our life." One positive impact was identified by AYAs and parents: changing mindsets about school/career (e.g., using school/work as motivator or way to take control, being inspired to change passion/paths). **Conclusions:** Findings illustrate distressful scholastic issues parents and AYAs need support with during cancer care. AYAs and parents described having to advocate on their own with no support. While clinicians recognized the same concerns as patients/caregivers, AYAs and parents described needing to initiate discussions with clinicians, further demonstrating a need to streamline scholastic performance into the standard of care. AYAs and parents recognized cancer could also impact AYAs' mindset about school/work in a positive manner, thus, addressing scholastic concerns may help empower and engage AYAs. Findings can inform resources and support the importance of developing a patient-centered metric that addresses scholastic performance in AYA survivors. Research Sponsor: The Leukemia & Lymphoma Society; HSR9028-24; National Cancer Insitute; University of Florida Health Cancer Center Predoctoral Award; 3P30CA076292.

11054 Poster Session

Demographic and genomic landscape of early mortality in patients with stage IV non–small-cell lung cancer.

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Background: Early mortality presents an ongoing challenge to oncologists all over the world. Specifically, one-third of patients that present with late-stage lung cancer progress rapidly, succumbing to their disease before treatment is initiated. That is why stratification of high-risk patients is imperative. In this study, we describe the epidemiologic and genomic landscape of early mortality in Stage IV non-small cell lung cancer (NSCLC). **Methods:** We retrospectively analyzed clinical and genetic data from the AACR Genie NSCLC v2.0 cohort via cBioPortal. Patients with Stage IV NSCLC who died within 3 months of their sequencing sample collection were classified as early mortality and compared to patients who survived more than 3 months. The chi-squared test was used to assess statistical association between variables. A p value or a q value of < 0.05 was considered significant. **Results:** A total of 871 patients were retrieved; 66 patients died within the first 3 months of diagnosis. Patients in the early mortality group were older (68.1 vs 64.1, $p < 0.05$). No significant difference in sex, stage, and histology was present. Patients who died earlier had more brain, adrenal, and subcutaneous metastasis ($P < 0.05$). Notably, patients in the early mortality group had a higher prevalence of current smokers as compared to a higher prevalence of never smokers in the other group, with a statistically significant difference in overall smoking rates between both groups ($p < 0.05$). A total of 18/66 (27.3%) patients received any form of treatment in the early mortality group, 3 of whom received PD-1 or CTLA4 ICI's. In terms of genomic alterations, patients who died early had a higher frequency of KRAS (56.1% vs. 27.0%, $q < 0.05$) and STK11 (38.6% vs 11.2%, $q < 0.05$). On the other hand, those who did not die early had a higher frequency of EGFR mutations (32.3% vs 6.10%, $q < 0.05$). KEAP1 alteration was higher in the early mortality group but did not achieve statistical significance (31.8% vs 11.5%, $q = 0.095$). **Conclusions:** Patients who are older, current smokers, and possess KRAS or STK11 mutations were more likely to die within 3 months of diagnosis. These results are in line with the literature and are known to be strong predictors of mortality in NSCLC patients and should be incorporated in the initial evaluation of Lung cancer patients. Research Sponsor: None.

Development of second primary malignancies (SPMs) in head and neck cancer survivors stratified by receipt of radiation therapy (RT) and chemotherapy (CT).

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Background: Head and neck cancers (HNC) often require multimodality management for curative intent with surgery, radiation therapy (RT) with or without chemotherapy (CT), resulting in significant impairment of nutrition, speech and quality of life. Survivors are also at risk for future cancers from field cancerization. We aim to study the incidence and characteristics of SPMs in HNC survivors. **Methods:** We performed a retrospective analysis of the Surveillance, Epidemiology and End Results (SEER) 17 registries database to identify the cases diagnosed with cancer of the oral cavity, pharynx or larynx as primary malignancy between the years 2000 to 2021. The data was stratified by receipt of RT and CT. Standardized incidence ratios (SIR) for the development of SPMs were calculated using the SEER Stat software. **Results:** A total of 206144 HNC survivors were identified, of which 78055 received CT + RT (CRT group) while 57898 patients received RT with no/unknown CT (RT group). The CRT group had a lower risk than the RT group for several local SPMs with SIRs ($p<0.05$): lip (5.13, 5.71), salivary gland (4.11, 5.21), floor of mouth (18.47, 19.7), gum/other mouth (20.18, 25.04), tonsil (4.54, 5.47) and larynx (5.18, 6.79). However, the CRT group had higher SIRs ($p<0.05$) than the RT group for tongue SPMs (15.91, 13.03) and all pharyngeal SPMs: nasopharynx (9.65, 8.51), oropharynx (13.21, 12.11), hypopharynx (20.47, 16.44), other oral cavity/pharynx (31.08, 24.69). The CRT group had higher SIRs ($p<0.05$) than RT recipients for most gastrointestinal SPMs: esophagus (6.44, 4.53), stomach (1.49, 1.27), colorectal (1.34, 1.23). The RT group had higher SIRs ($p<0.05$) than CRT recipients for hepatobiliary SPMs (1.48, 1.29) and anus/anal canal /anorectum SPMs (1.87, 1.73). CRT group had higher risk than RT group for nose/nasal cavity/middle ear, lung/bronchus, bone/joint, soft tissue and kidney SPMs but lower risk for trachea, eye/orbit non - melanoma, and thyroid SPMs (Table). CRT group had a lower risk for nodal Hodgkin Lymphoma (SIR 0.3) and myeloma (SIR 0.76) than the general population ($p<0.05$). Both groups had lower risk for Chronic Lymphocytic Leukemia SPMs, with SIRs: RT 0.71, CRT 0.59 ($p<0.05$). Understandably, CRT recipients had a higher risk for Acute Myeloid Leukemia (SIR 2.24, $p<0.05$). **Conclusions:** HNC survivors demonstrate varying risks for SPMs in RT and CRT recipients. This necessitates close monitoring during survivorship care, with a comprehensive approach to screening and preventive measures to improve long-term outcomes and quality of life. Research Sponsor: None.

SPMs in HNC survivors.

SPM	RT SIR ($p<0.05$)	CRT SIR ($p<0.05$)
Nose, nasal cavity, middle ear	6.25	8.33
Lung, bronchus	4.01	4.69
Trachea	55.08	38.19
Bones, joints	4.62	6.15
Soft tissue including heart	1.67	2.21
Urinary bladder	1.27	1.24
Kidney	1.29	1.42
Eye, orbit – Non-melanoma	6.18	5.19
Thyroid	2.93	2.77

A digital intervention to enhance engagement with oral oncolytic treatments and assess patient experiences with novel therapies.

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Background: Adherence to oral oncolytic therapy influences treatment efficacy and outcomes. Effectively managing adherence requires a clear understanding of how treatments impact the patient. By directly monitoring adherence through precise dose administration data and electronic patient-reported outcomes (ePROs) using ReX, clinicians can improve outcomes while enhancing overall care quality and experience. We aimed to assess the impact of ReX on oral therapy adherence, dose reductions, and treatment discontinuations in real-world practice. **Methods:** Patients at 1 large community practice and 4 academic health systems were included in this retrospective cohort analysis. Participants all had either: chronic lymphocytic leukemia, and initiated treatment with acalabrutinib on or after September 12, 2023, or hormone receptor-positive, HER2-negative metastatic breast cancer who initiated ribociclib on or after May 22, 2024. Control data was abstracted from charts within the practices from those who did not receive the ReX device. Medication was dispensed as standard of care in ReX (Dosentrx Inc), an FDA approved handheld pocket-sized device. At a programmable time, patients take their medication from ReX and are asked ePROs about side effects via a touch screen on the device. Pill intake data and ePROs were available on the ReX Therapy Manager, a cloud-based platform. **Results:** A total of 35,760 pills were taken and 16,885 ePROs answered; resulting in 95% dosing adherence and 97% ePRO engagement (total questions answered/questions presented) in those using ReX. Ribociclib control (median age 56, all female), ribociclib ReX (median age 53, all female), acalabrutinib control (median age 73, 60 males and 33 females), and acalabrutinib ReX (median age 70, 49 males and 32 females). Patients using ReX had fewer dose reductions and discontinuations compared to the control group (Table 1). **Conclusions:** This data suggests that ReX leads to high adherence and ePRO engagement rates, resulting in fewer dose reductions and significantly greater persistence of both acalabrutinib and ribociclib use in community and University settings. Future studies with a greater sample size will be needed to confirm these endpoints and assess the impact of lower discontinuation rates on health outcomes. Research Sponsor: None.

Endpoint objectives.

	Control Group	ReX	p-value*
Patient sample size	94 acalabrutinib 69 ribociclib	81 acalabrutinib 63 ribociclib	
Dose Reductions	6% acalabrutinib 29% ribociclib	1% acalabrutinib 11% ribociclib	0.083 0.011
Discontinuation ≤ 3 mo	10.6% acalabrutinib 17.9% ribociclib	2.5% acalabrutinib 6% ribociclib	0.033 0.052
Discontinuation ≤ 6 mo	15% acalabrutinib 24.9% ribociclib	8.6% acalabrutinib 11% ribociclib	0.205 0.044
Discontinuation < 12 mo	24.5% acalabrutinib 31.8% ribociclib	13.5% acalabrutinib 11% ribociclib	0.070 0.004

*Two sample Z-test (2-tail, α=0.05).

11057 Poster Session

From chemotherapy allergy to tolerance: Desensitization as a safe alternative in oncology.

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Background: Hypersensitivity reactions (HSRs) are a significant challenge in oncology, often leading to treatment modifications or interruptions. Rapid Drug Desensitization (RDD) is a method to reintroduce chemotherapeutic agents and monoclonal antibodies in patients with previous HSRs. This study focuses on safety, comparing the severity of initial HSRs with breakthrough reactions (BTRs) during desensitization. **Methods:** An observational, ambispective study was conducted from August 2020 to August 2024 at the University Hospital in Mexico. Patients with HSRs underwent RDD using a 12-step, 3-bag protocol. HSR severity was classified using Brown's scale. The primary endpoint was BTR severity compared to initial reactions, with secondary endpoints assessing BTR frequency and RDD completion rates. Data were sourced from electronic medical records under a protocol reviewed and approved by the hospital's research ethics committee. Inclusion required documentation of HSRs, the need to continue treatment with the implicated drug, and completion of the RDD protocol. Missing severity data were inferred from clinical notes or excluded. Chi-square tests compared severity grades (mild, moderate, severe) between initial reactions and BTRs, including cases without reactions for comprehensive analysis. Proportional frequencies were applied to address the difference in sample size. **Results:** A total of 927 RDD procedures were performed in 219 patients, with 84% female and a median age of 43 years. The severity of initial reactions was classified as mild in 12.1%, moderate in 43.3%, and severe in 44.6%. During the 927 desensitizations, breakthrough reactions occurred in only 8.6% of cases, distributed as mild (4.5%), moderate (1.8%), and severe (2.3%). Chi-square analysis confirmed a statistically significant difference in severity distribution between initial HSRs and BTRs ($\chi^2 = 834.72$, $p < 0.0001$). This demonstrated a substantial reduction in severity for BTRs compared to initial reactions. Despite the occurrence of BTRs, all patients completed the RDD protocol, received the full therapeutic dose, and no fatalities were reported. **Conclusions:** The comparison between initial HSRs and breakthrough reactions during RDD highlights the distinct nature of these events: initial HSRs represent baseline sensitivity, whereas BTRs occur as controlled outcomes during desensitization. The analysis confirms that desensitization is a safe and effective tool in oncology, significantly reducing both the frequency and severity of breakthrough reactions compared to initial reactions, ensuring treatment continuity and minimizing risks for patients. Research Sponsor: None.

Severity distribution of initial HSRs and BTRs.

Severity	Mild (%)	Moderate (%)	Severe (%)	Total (%)	Reference Population
Initial HSRs	27 (12.3)	95 (43.3)	97 (44.2)	219 (100)	219 patients
BTRs	42 (4.5)	17 (1.8)	21 (2.3)	80 (8.6)	927 desensitizations

11058 Poster Session

Exploring two decades of cancer trends in adolescents and young adults: Insights from a resource-restricted country.

Sarah Abdel-Razeq, Maha Barbar, Asem Mansour, Iyad Yasin Sultan, Rawad Rihani, Ayat Taqash, Hikmat Abdel-Razeq; King Hussein Cancer Center, Amman, Jordan

Background: Over 40% of the Jordan population are adolescents and young adults (AYA), aged 15-39 years. Cancer diagnoses in this age group have distinct clinical characteristics and patients face unique needs and psychosocial challenges. We present data on local trends in cancer diagnoses among AYA, and their treatment outcomes. **Methods:** We utilized reports from the Jordan Cancer Registry (JCR) and the King Hussein Cancer (KHCC) registry to obtain treatment outcomes. **Results:** During 2022 a total of 8,754 new cancer cases were reported by the JCR; 4,736 (54.1%) were females and the median age at diagnosis was 57 years. Only 312 (3.6%) of the cases were diagnosed in childhood age group (<15 years), while 1,167 (13.3%) cases were diagnosed among AYA (15-39 years) and most of these cases (36.8%) were among the older AYA subgroup (35-39 years). Over the past 22 years, the total number of reported cancer cases among AYA has almost doubled from 654 in 2000 to 1,167 cases in 2022. Hodgkin's lymphoma (13.6%), testicular cancer (12.2%), non-Hodgkin's lymphoma (NHL) (10.9%), colorectal cancer (10.0%) and acute leukemia (9.8%) were the most encountered tumors in males, while breast cancer (31.5%), thyroid cancer (15.4%), Hodgkin's lymphoma (7.2%), colorectal cancer (6.2%) and ovarian cancer (5.5%) were the most common cancers in females in the AYA group. In the childhood age group, acute leukemia (24.4%) and brain tumors (20.2%) were the two most common cancers, accounting for almost half of all tumors in this group. The age-standardized incidence rate (ASIR) was higher among females compared to males across all age subgroups within the AYA. Such difference is more evident within the "older" group (30-34) years (64.3 versus 35.0) and in the (35-39) years age group (116.1 versus 52.3). These differences may be attributed to breast, and to a lesser extent thyroid cancer. Additionally, the ASIR increases with increasing age within the AYA age group; rates increased from 17.3 (15-19 years) up to 84.4 in the (35-39 years) group. Survival data on 7,202 AYA cancer patients treated and followed-up at KHCC were obtained from its hospital-based cancer registry. The 5-year overall survival was 73.0% (95% CI, 71.8-74.1), better than 57.1% (95% CI, 56.4-57.8) among 26,604 older adults (>39 years old), and lower than 75.2% (95% CI, 73.6%-76.9%) among 3,031 pediatric patients (<15 years) treated during the same period, $p<0.0001$. **Conclusions:** Over 40% of the Jordanian population is within the AYA age group. Though the cancer incidence is lower, and overall survival is better in this age group compared to older adults, a comprehensive plan that values the special physical and psychosocial needs of this group of patients should be addressed. Establishing a specialized AYA program with specialized ancillary services addressing these issues, especially those related to late treatment effects, is a national health care priority. Research Sponsor: None.

11059 Poster Session

Treatment patterns, use of healthcare resources, and clinical characteristics of patients with castration-resistant prostate cancer (mCRPC) in Colombia: Preliminary analysis from ProColombia RC study.

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Background: The clinical characteristics of metastatic castration-resistant prostate cancer (mCRPC) patients in Colombia remain poorly understood, particularly regarding their clinical profiles, stage at diagnosis, treatment options, and healthcare resource utilization (HRU). This study aims to describe real-world treatment patterns and HRU in mCRPC patients. **Methods:** This is a non-interventional, multicentre, retrospective study in mCRPC patients treated at reference centers across Colombia from Jan/2017 to Jun/2023. Data on demographic and clinical characteristics, treatment history, and (HRU) were extracted from electronic medical records. Progression-free survival (PFS) and overall survival (OS) were analyzed using the Kaplan-Meier method. **Results:** We present the Interim findings from the first 130 of the 380 patients we plan to enroll. The median follow-up was 70.0 months (IQR 46.8–136.1). The median age was 68y (IQR 61–73), with 86.2% residing in urban areas. Comorbidities were hypertension (64.6%) and type 2 diabetes (22.3%); 10.8% reported a family history of PC. Upon diagnosis, 54.6% had a Gleason grade of 4 or 5, and 82.7% passed through a metastatic hormone-sensitive prostate cancer (mHSPC) scenario and 47.7% of those mHSPC patients had high-volume disease. In the mCRPC setting, 14.6% had visceral metastases, while 78.4% had bone-predominant disease. In the first-line treatment, 73.8% received androgen receptor pathway inhibitors (ARPI) and 25.4% underwent taxane-based chemotherapy. Among the 81 patients (62.3%) who received second-line therapy, 27.1% received ARPI, 59.3% received taxane-based chemotherapy, 9.9% were treated with Radium-223, and 3.7% received PSMA-Lutetium. The median PFS in the first-line setting was 16.8 months (95%CI:13.0–20.7), with a median OS of 39.2 months (95% CI:32.6–45.9). Only 31% of patients were tested for HRR and MSI, with median OS from mCRPC diagnosis being 59.2 months (95%CI:34.6–83.7) for those tested versus 39.5 months (95%CI: 32.8–46.1) for those not tested, a statistically significant difference (p=0.016). In terms of healthcare utilization, 60.0% required palliative radiation therapy, and 52.3% consulted with a palliative care specialist; 20.8% required at least one emergency consultation due to cancer-related issues. **Conclusions:** This study represents the first comprehensive report on the demographic, clinical, treatment patterns, and HRU of mCRPC patients in Colombia. The significant survival differences based on biomarker testing highlight quality of care that patients received. Standardized PC management protocols, developed collaboratively by multidisciplinary teams and multiple institutions in Colombia, could enhance patient outcomes and healthcare efficiency across the country. Research Sponsor: MSD Colombia.

11060 Poster Session

Differential and cumulative impact of metabolic syndrome traits on cardiovascular, renal, and mortality outcomes in cancer patients.

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Background: Metabolic syndrome (MetS) is a known risk factor for developing at least 13 cancer types and adverse outcomes. However, the effects of MetS on their differential and cumulative impact on cardiovascular, renal, and mortality outcomes in cancer patients remains uncertain. We aimed to determine whether MetS components increase cancer patients' risk of adverse cardiorenal and all-cause mortality. **Methods:** This large retrospective cohort study used the TriNetX database between 2013 to 2024. Adults (>18 years) with new cancer diagnoses and ≥1 MetS trait (obesity, insulin resistance(IR), hypertension (HT), or dyslipidemia (DLD)) were compared with matched controls without MetS. We performed 1:1 propensity score matching to adjust for confounding factors (demographics, comorbidities, cancer type, and medications). The primary outcomes were new adverse cardiovascular events like heart failure (HF), major adverse cardiovascular events (MACE), and cerebrovascular events (CVE). The secondary outcomes were end-stage renal diseases (ESRD), the need for dialysis, and all-cause mortality. We conducted sensitivity analyses to assess the robustness of the findings. Hazard ratios(HR) were calculated using Cox regression models stratified by MetS traits. **Results:** In total, 204,297 patients were identified (median age 54 years) with a median follow-up of 7.8 years. Patients with ≥1 MetS trait had significantly increased risks of adverse cardiorenal events. HR for HF was 1.76; this risk increased to 2.54 with ≥3 MetS traits. The risk of MACE was HR of 2.34 in those with ≥1 trait and HR of 2.47 in those with 4 traits. CVE had an HR of 1.56, increasing to 2.38 with ≥3 traits. For secondary outcomes, the risk of ESRD was HR of 1.76 in patients with ≥1 MetS trait, rising to HR of 2.29 in those with ≥3 traits. The need for dialysis was significantly elevated (HR 1.86), and all-cause mortality was HR of 2.15 in patients with ≥1 trait, increasing to 3.10 with 4 traits. Stratified analyses revealed obesity increased HF risk (HR 1.58) and mortality (HR 1.75). IR was linked to higher risks of MACE (HR 1.88) and ESRD (HR 2.59). HT increased the risk of CVE (HR 2.16) and dialysis (HR 2.11). DLD moderately elevated the risk of IHD (HR 1.47) and mortality (HR 1.59). Sensitivity analyses confirmed these findings across cancer types and treatments. A cumulative relationship was observed, with the number of MetS traits correlating to higher risks of outcomes. **Conclusions:** Our study showed a differential effect of MetS components on cardiovascular, renal, and all-cause mortality outcomes in cancer patients, with a cumulative impact of multiple MetS on overall risk. Early intervention targeting MetS traits may reduce these risks and improve outcomes. Comprehensive metabolic management should be integrated into oncology care to mitigate these risks and improve patient outcomes.
Research Sponsor: None.

11061 Poster Session

Transfusion-related cost and time burden offsets in patients with myelofibrosis treated with pacritinib compared to best available therapy based on PERSIST-2 trial.

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Background: Anemia in patients (pts) with myelofibrosis (MF) is associated with a significant disease burden, especially in pts who require red blood cell (RBC) transfusions, as it negatively impacts quality of life and disease prognosis. In the PERSIST-2 trial, treatment with pacritinib (PAC), a JAK1 sparing inhibitor of JAK2/IRAK1/ACVR1, was associated with anemia benefit. A significant proportion of non-transfusion independent (non-TI) pts at baseline on PAC compared to best available treatment (BAT) achieved transfusion independence (TI) (37% vs 7%) in any 12 weeks over a 24-week interval and significantly more had a ≥50% reduction in transfusion burden (49% vs 9%) (Oh ST, et al. 2023) with lower RBC transfusion rates (Mean [2.45 vs 3.54/30-day]) (Data on file). This study aimed at estimating the projected differences in transfusion-related cost and time burden with PAC vs BAT. **Methods:** An economic evaluation based on transfusion-related data in pts treated with PAC or BAT (including ruxolitinib [RUX] and erythroid support [ES]) from the PERSIST-2 trial (NCT02055781). Transfusion status (TI and non-TI) at baseline and over any 12-week interval within the 24-week study period was defined based on the Gale criteria (i.e. presence or absence of RBC transfusions). RBC transfusion rates over 30-day periods, including all reported transfusions within the initial 24-week study period, were annualized and used as proxy for transfusion-related visits. Annual transfusion-related cost estimates by transfusion status were based on a previous MF burden of illness study which utilized IBM MarketScan data (Gerds AT, et al. 2022) and was adjusted to 2024 US dollars using the medical component of the Consumer Price Index. Transfusion-related time burden estimates were based on previously reported RBC transfusion visits in transfusion dependent pts with β-thalassemia (Knoth RL, et al. 2022). **Results:** Annual transfusion-related cost with PAC was projected to be 19.5% lower, with a cost saving of ~$61K compared to BAT (~$252K vs ~$313K). Annual transfusion-related time burden with PAC vs BAT was lower by 25.3% with a time saving of ~172 hrs (~508 vs ~680 hrs). Among pts who were non-TI at baseline, projected annual cost and time savings for PAC vs BAT were ~$73K and ~204 hrs, respectively. Results remained robust regardless of type of BAT (i.e. RUX or ES therapies). **Conclusions:** The reduction in transfusion rates associated with PAC treatment relative to BAT is projected to result in decreased transfusion-related medical cost and time burden for pts with MF and anemia. Research Sponsor: None.

11062 Poster Session

Trends and disparities in sepsis-related mortality among patients with malignancies: A 25-year nationwide analysis.

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Background: Sepsis is a leading cause of mortality worldwide, with cancer patients at higher risk due to immune suppression from the disease and its treatments. Despite advancements in sepsis care, their impact on sepsis-related mortality among cancer patients remains unclear. Understanding these trends is crucial for developing targeted interventions to improve sepsis outcomes in patients with malignancies. **Methods:** We conducted a retrospective cohort analysis using the CDC WONDER database from 1999 to 2023, focusing on adults aged >25 years with malignancies. Deaths were identified using international classification of disease 10 (ICD-10) codes for instances where both sepsis and malignant neoplasms were listed as causes of death. Age-adjusted mortality rates (AAMR) per 100,000 population were extracted, and temporal trends were analyzed using Joinpoint regression to calculate the annual percentage change (APC) and its weighted average, the average annual percentage change (AAPC). Results were stratified to evaluate temporal, gender-based, racial, and geographic disparities in mortality. **Results:** From 1999 to 2023, a total of 684,930 sepsis-related deaths were recorded among adults with malignancies. Over this period, the AAMR increased significantly from 12.06 to 14.21, with an AAPC of 0.86 (95% CI: 0.74 to 1.06). Males had a higher overall AAMR (15.09) compared to females (9.91), but females experienced a sharper increase over time (23.77% vs. 9.56%). Non-Hispanic (NH) Black or African Americans had the highest AAMR (18.98), followed by NH American Indian or Alaska Natives (11.59) and NH Whites (11.35), while NH Asians/Pacific Islanders exhibited the lowest rate (10.24). Geographic disparities were significant, with state-specific AAMRs ranging from 24.62 in the District of Columbia to 7.50 in Montana. States in the top 90^{th} percentile included Mississippi, Rhode Island, West Virginia, New Jersey, and the District of Columbia, while those in the bottom 10^{th} percentile included Montana, Oregon, Idaho, and Wisconsin. Regionally, the Northeast had the highest AAMR (12.65), followed by the South (12.49) and West (11.69), with the Midwest exhibiting the lowest rate (11.08). **Conclusions:** This nationwide analysis highlights a concerning rise in sepsis-related mortality among patients with malignancies over the past 25 years, with females, NH Blacks and residents of the Northeastern region emerging as the most vulnerable populations. These findings underscore the need for prompt implementation of targeted strategies designed to overcome these disparities. Research Sponsor: None.

11063 Poster Session

Impact of a novel oral medication delivery device on patient engagement and discontinuation in individuals receiving oral oncolytic medications.

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Background: Patient-reported outcomes (PROs) are essential for monitoring patient status and improving outcomes. ReX by Dosentrx physically administers oral medications and collects PROs at the time of dosing, allowing healthcare teams to track patient adherence, medication tolerance, and side effects. ReX aims to identify early toxicities between clinic visits, reduce acute care utilization, and improve adherence and overall outcomes. This study evaluates the impact of ReX on treatment adjustments and discontinuations in individuals taking either ribociclib or acalabrutinib. **Methods:** The study focused on a cohort of individuals prescribed either ribociclib or acalabrutinib. Patients using ReX were tracked for at least 6 months. The primary objective was to evaluate discontinuation rates at 3, 6, and 12 months. Secondary objectives included evaluating dose reductions and reasons for discontinuation. Outcomes from individuals using the ReX device were compared to a historical control group drawn from the same clinics prior to ReX implementation. **Results:** In the ribociclib group, 69 patients were in the historical control cohort and 63 in the ReX cohort, with median ages of 56 and 53, respectively. For acalabrutinib, the historical control had 94 patients and the ReX cohort 81, both with a median age of 70. Table 1 presents the discontinuation at 3, 6, and 12 months, along with the clinical reasons for discontinuation. Dose reductions were lower in the ReX group, with 11% for ribociclib at 10 months and 1% for acalabrutinib at 15 months, compared to 29% and 6% in the control group. **Conclusions:** ReX demonstrated a lower percentage of medication discontinuation at 3, 6, and 12 months for patients taking ribociclib or acalabrutinib, with fewer adverse event-related discontinuations and dose reductions compared to a historical control group. Additional studies investigating the impact of this novel medication delivery device on longer term medication adherence and clinical outcomes is currently underway. Research Sponsor: None.

Discontinuation at 3, 6, and 12 months and reason for discontinuation.

Discontinuation						
	3-months		6-months		12-months	
	Control	ReX	Control	ReX	Control	ReX
Ribociclib	17.8%	6%	24.9%	11%	31.8%	11%
Acalabrutinib	10.6%	2.5%	15%	8.6%	24.5%	13.5%
Clinical Discontinuation Reason						
	Disease Progression		Adverse Events		Medication Change	
	Control	ReX	Control	ReX	Control	ReX
Ribociclib	55%	0%	27%	0%	18%	100%
Acalabrutinib	55%	50%	27%	25%	18%	25%

Impact of protein-energy malnutrition on inpatient mortality, healthcare cost and clinical outcomes among patients with head and neck cancer.

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Background: Protein-energy malnutrition (PEM) is a critical issue among patients diagnosed with head and neck cancers (HNC), primarily due to the tumor's anatomical location, and treatment-related side effects. Here, we examine the impact of PEM on the clinical outcomes and healthcare costs among hospitalized patients with HNC. **Methods:** This retrospective cohort study was conducted using data from the National Inpatient Sample database. Data of adult patients admitted with a diagnosis of HNC from 2016 to 2020 were analyzed and stratified based on the presence of PEM. The primary outcome was inpatient mortality rate, secondary outcomes included length of hospitalization, total hospital charges and other medical outcomes. **Results:** A total of 729,095 patients with HNC were identified, of whom 174,000 (23.8%) had PEM, with a mean age of 65.5 years and whites (77%) being the predominant race. Among the 32,075 patients who died, 11,715 (4.4%) had PEM. PEM was associated with a higher risk of mortality (6.74% vs 3.67%; OR:1.84, 95%CI 1.73-1.95; $P < 0.001$). Patients with PEM had an increased length of hospitalization (8.9 vs 5.2 days; adjusted difference of 3.3 days; 95% CI 3.21-3.45; $P < 0.001$), and higher total hospital charges ($98,959 vs $71,449; adjusted difference of $27,715, 95% CI $23,864-27,565; $P < 0.001$). Additionally, the presence of PEM was associated with increased risk of several secondary outcomes including septic shock, intubation, acute kidney injury, pneumonia, blood transfusion, neutropenia and urinary tract infections compared to the non-PEM cohort. **Conclusions:** This study demonstrated a two-fold increased risk of mortality and a prolonged length of stay, with approximately $27,000 more total charges in malnourished patients with HNC compared to those without PEM. Prospective trials evaluating strategies to improve PEM, and provide adequate nutritional support are essential to enhance clinical outcomes, reduce mortality and decrease healthcare costs. Research Sponsor: None.

Effect of PEM on clinical and healthcare outcomes among hospitalized patients with HNC.

Outcomes	HNC with PEM	HNC without PEM	Adjusted Odds Ratio	95% Confidence Interval	P value
Mortality	6.74%	3.67%	1.84	1.73-1.95	<0.001
Length of stay	8.9	5.2	3.33	3.21-3.45	<0.001
Total hospital charge	98,959	71,449	25,715	23,864-27,565	<0.001
Sepsis	10.89	5.08	2.20	2.09-2.30	<0.001
Intubation	15.87	10.01	1.61	1.54-1.68	<0.001
Pressors	1.68	1.03	1.61	1.40-1.86	<0.001
Acute kidney injury	16.89	11.82	1.42	137-1.48	<0.001
Pneumonia	13.97	8.84	01.65	1.58-1.72	<0.001
Neutropenia	4.67	2.5	1.86	1.73-2.00	<0.001
Urinary tract infection	5.70	4.15	1.42	1.34-1.51	<0.001
Blood transfusion	10.19	6.09	1.71	1.63-1.8	<0.001

11065 Poster Session

Efficacy of immune checkpoint inhibitors in smokers vs non-smokers: A large real-world retrospective cohort analysis.

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Background: Immune checkpoint inhibitors (ICIs) play a critical role in strengthening the immune response against tumors. Prior literature has shown higher objective response rates of ICIs in lung cancer patients who are smokers vs. non-smokers, thought to be due to increased expression of PD-1/PD-L1 in smokers. This study aims to assess the clinical impact of smoking on the efficacy of ICIs across multiple cancer types. **Methods:** This multicenter retrospective study utilized the TriNetX Network, a database containing over 130 million deidentified patient records to identify patients diagnosed with lung, breast, melanoma, colorectal, head and neck, bladder, hepatocellular, and renal cell carcinomas, who underwent subsequent treatment with ICIs (PD-1, PD-L1, and CTLA-4 inhibitors). Kaplan-Meier survival analysis was performed to assess three-year survivability. Propensity-score matching (PSM) was performed based on demographics, lab work, and pertinent comorbidities between smokers and non-smokers in each cancer type. The analysis included patients who had documented smoking status (ICD 10: Z72.0) prior to ICI therapy. **Results:** A total of 95,178 cancer patients receiving ICI met the inclusion criteria, of whom 15.5% were tobacco users. After PSM, 12,203 patients were in the smoking group and 12,203 were in the non-smoker group. For lung cancer patients, there was statistically significant superior survivability in the smoker group compared to the nonsmoker group, (HR: 0.894, 95% CI [0.854, 0.935]). A similar trend was identified in the colon, hepatocellular, and breast cancer groups, however, this was not statistically significant. There was no significant difference in mortality seen in the smoker versus non-smoker groups in melanoma, bladder, head and neck, and renal cell cancers. **Conclusions:** Our findings reaffirm previous studies demonstrating superior efficacy of ICIs in smokers with lung cancer. Additionally, this study highlights other cancer types, such as colon, hepatocellular, and breast cancers, that may exhibit improved outcomes in smokers, while also identifying cancers such as melanoma, bladder, head and neck, and renal cell carcinomas where smoking status appears to have no apparent effect on survivability. To our knowledge, this is the largest retrospective cohort study examining the impact of smoking status on ICI therapy outcomes across multiple cancer types. Research Sponsor: None.

Survivability in smokers compared to non-smokers treated with ICIs.

Cancer type (ICD 10)	N (smoker)	N (non-smoker)	3-year HR	95% CI
Colon (C18)	292	292	0.808	(0.622,1.048)
Liver (C22.0)	559	559	0.884	(0.748,1.045)
Lung (C34)	8130	8130	0.894	(0.854,0.935)
Breast (C50)	540	540	0.934	(0.756,1.154)
Bladder (C67)	713	713	1.001	(0.856,1.169)
Renal cell (C64)	706	706	1.016	(0.859,1.202)
Head & neck (C76.0)	583	583	1.042	(0.888,1.224)
Melanoma (C43)	680	680	1.087	(0.889,1.328)

11066 Poster Session

Identifying multi-level social determinants for disparities in survival and patient-reported outcomes in national head and neck cancer trials.

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Background: This study aimed to determine to what extent area-level social determinants of health (SDOH) interact with individual, institutional, and biological factors to predict outcomes in head and neck cancer (HNC) trials. **Methods:** Five NRG Oncology HNC trials (2635 patients receiving chemoradiation) were analyzed. Area-level SDOH coded by patient ZIP codes included rurality (rural-urban commuting area code), neighborhood socioeconomic deprivation (Area Deprivation Index [ADI] categorized as upper vs. lower quartile), and travel burden (distance and time to treatment site). Individual (demographic, cancer and treatment-related factors), institutional (accrual volume), biological (HPV+/-) factors, and outcomes (overall survival [OS], progression free survival [PFS], quality of life [QOL], and symptoms) were analyzed. Multivariable Cox proportional hazards regression and mediation analysis using logistic regression assessed associations using hazard ratio (HR) or odds ratios (OR) and 95% confidence intervals (CI). **Results:** Most patients were White (88%), non-Hispanic (92.7%), of mean age of 57 years, HPV+ (64.6%), and received intensity-modulated radiotherapy (95.9%) and cisplatin (94.2%). ADI and rurality were not associated with OS and PFS. OS and PFS were higher in patients with travel time <1 hour (HR=0.85, 95% CI [0.75, 0.98]; HR=0.85, 95% CI [0.73, 0.98]) and travel distance <50 miles (HR=0.84, 95% CI [0.72, 0.96]; HR=0.85, 95% CI [0.73, 0.98]). ADI, travel time, and travel distance were not associated with QOL decline. Patients treated at institutions with high rural accrual volume had worse QOL decline from baseline (OR=0.36, 95% CI [0.15, 0.85]). The impact of travel distance but not time varied by race to influence QOL decline (OR=0.38, 95% CI [0.16, 0.93]). ADI was not associated with symptoms, but patients from institutions with high rural accrual volume had worse symptoms (OR=7.83, 95% CI [1.98, 31.01]). HPV status had a significant indirect effect on the relationship between travel distance and survival at 1 year (estimate [β]=0.03, 95% CI [0.01, 0.05]) and 5 years (β=0.03, 95% CI [0.004, 0.05]), as well as a direct and total mediation effect of travel distance on QOL decline at 1 year (direct β=-0.08, 95% CI [-0.16, -0.004]; total β=-0.89, 95% CI [-0.17, -0.01]). **Conclusions:** This study showed the impact of area-level SDOH and their interactions with race and institutional accrual volume, which are associated with survival, QOL, and symptom changes. HPV status potentially mediated the effects of travel distance on outcomes. Our findings provide novel approaches to identify patients at risk for poor outcomes, such as those with travel burden at institutions with high rural accrual, to design community-based interventions to improve cancer outcomes. Research Sponsor: None.

11067 Poster Session

Impact of protein energy malnutrition on hospitalized patients with breast cancer: A United States population-based cohort study.

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Background: Advances in chemotherapeutics and surgical options have improved survival in patients with breast cancer. With prolonged survival, these patients are often predisposed to comorbidities affecting their quality of life. Patients with breast cancer suffer from varying degrees of protein-energy malnutrition (PEM) due to multiple factors, including cachexia, sarcopenia, and adverse effects of chemotherapeutics. However, the impact of PEM on outcomes among patients with breast cancer needs further exploration. **Methods:** We utilized the 2020 National Inpatient Sample (NIS) Database in conducting this retrospective cohort study. We identified patients with breast cancer and PEM using appropriate ICD-10 diagnostic codes. We stratified patients with breast cancer based on the presence or absence of PEM. A survey multivariable logistic and linear regression analysis was used to calculate adjusted odds ratios (ORs) for the primary and secondary outcomes. A p value of <0.05 was considered statistically significant. The aim of this study was to investigate the impact of PEM on in-hospital mortality, hospital length of stay (LOS), and total hospitalization charge among hospitalized patients with breast cancer. **Results:** We identified a total of 24770 hospitalized patients with breast cancer, of which 6.17% (1530/24770) had comorbid PEM. The overall in-hospital mortality among patients with breast cancer was 3.37% (835/24770). Among those with concomitant PEM, the mortality rate was significantly higher at 12.74% (195/1530, $p<0.001$). Utilizing a stepwise survey multivariable logistic regression model that adjusted for patient and hospital level confounders, PEM was found to be an independent predictor of increased in-hospital mortality (adjusted OR 2.74; 95% (confidence interval [CI] 1.74-4.30; $p<0.001$), longer LOS (coefficient 3.56 days; CI 2.67-4.45; $p<0.001$), but not higher total hospitalization charge ($4400; CI -$9818-$18620; p=0.544) or increased need for mechanical ventilation (adjusted OR 2.26; CI 0.89-5.69; p=0.084). **Conclusions:** Our analysis demonstrated that PEM was widely prevalent in hospitalized patients with breast cancer and was associated with significantly worsened in-hospital mortality and longer LOS. Efforts should be made to promote nutritional assessment and screening mechanisms to include early nutritional support as indicated. Further prospective studies with larger sample sizes are warranted to understand these associations better. Research Sponsor: None.

11068 Poster Session

Incidence and outcomes of rejection in solid organ transplant recipients treated with immune checkpoint inhibitors: A systematic review and meta-analysis.

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Background: Immune checkpoint inhibitors (ICIs) are a cornerstone in the treatment of many solid tumors; however, their use in cancer patients with solid organ transplants (SOTs) poses unique challenges due to the risk of allograft rejection. We conducted a systematic review and meta-analysis of retrospective studies to determine the incidence of rejection and associated outcomes in SOT patients treated with ICIs. **Methods:** We searched PubMed, Embase, and Scopus to identify retrospective studies examining ICI therapy in SOT patients with cancer. Primary endpoints were the incidence of rejection and its clinical outcomes. Statistical analyses were performed using the "meta" package in R. **Results:** Seventeen studies encompassing 587 patients were included. The most frequent malignancies were hepatocellular carcinoma (HCC), melanoma, and cutaneous squamous cell carcinoma (cSCC). The overall rejection incidence was 16% (95% CI: 9%-24%), with variation across cancer types: multiple cancers (18%, 95% CI: 5%-36%), HCC (22%, 95% CI: 15%-29%), and cSCC (4%, 95% CI: 0%-21%). Rejection incidence was higher among liver transplant recipients (18%, 95% CI: 10%-26%) compared to kidney recipients (16%, 95% CI: 5%-32%). Geographic differences were observed, with rejection rates of 15% (95% CI: 1%-37%) in U.S.-based studies, 25% (95% CI: 18%-33%) in China, and 9% (95% CI: 0%-25%) in Korea. Pre-transplant ICI exposure was associated with a higher rejection rate (18%, 95% CI: 9%-28%) compared to post-transplant exposure (15%, 95% CI: 7%-26%). Outcomes of rejection varied, with 44% (95% CI: 24%-65%) achieving stabilization or resolution. Liver transplant recipients demonstrated higher resolution rates (67%, 95% CI: 46%-85%) compared to kidney recipients (27%, 95% CI: 7%-52%). Regional differences in resolution were notable, with higher rates reported in China (65%, 95% CI: 45%-83%) compared to the U.S. (26%, 95% CI: 13%-42%). **Conclusions:** This meta-analysis reveals a 16% overall rejection rate in SOT recipients treated with ICIs, higher in liver allografts and HCC, with regional disparities. Nearly half of patients who experienced rejection improved or stabilized, especially liver recipients. These findings underscore the need for personalized approaches to balance oncologic efficacy and graft survival in this complex population. Research Sponsor: None.

Category	Rate (% [95% CI])
Overall Rejection Rate	16 [9-24]
Rejection by Cancer Type	Multiple: 18 [5-36], HCC: 22 [15-29], cSCC: 4 [0-21]
Rejection by Transplant Type	Liver: 18 [10-26], Kidney: 16 [5-32]
Rejection by Geography	USA: 15 [1-37], China: 25 [18-33], Korea: 9 [0-25]
Rejection by Timing	Pre-Transplant: 18 [9-28], Post-Transplant: 15 [7-26]
Overall Reversibility	44 [24-65]
Reversibility by Transplant Type	Liver: 67 [46-85], Kidney: 27 [7-52]
Reversibility by Geography	China: 65 [45-83], USA: 26 [13-42]

11069 Poster Session

Evaluating the impact of Medicaid expansion on outcomes for patients with gastric cancer in Louisiana.

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Background: Prior to June 2016, Louisiana's Medicaid program did not extend coverage to adults, regardless of income. With the expansion, up to 138% of the Federal Poverty Level (FPL) became eligible for enrollment, allowing 784,310 adults to enroll in the state's Medicaid program as of June 2023. Medicaid expansion (ME) effects on gastric cancer treatments and outcomes have not been fully understood. This study seeks to investigate the impact of Medicaid expansion (ME) on gastric cancer outcomes, such as changes in presentation, treatment patterns, time-to-treatment, and survival in Louisiana patients. **Methods:** Patients with primary invasive gastric cancer were identified using the Louisiana Tumor Registry. Patients diagnosed with gastric cancer were stratified into pre-expansion (2012–2015) and post-expansion (2017–2020) periods. Patients under 18 years old, unknown gastrectomy status, and those with unknown insurance or socioeconomic data were excluded from the study. **Results:** A total of 2,554 patients diagnosed with primary invasive gastric cancer were analyzed, predominantly male (63.7%) and urban residents (85.3%). Post-ME, the uninsured rate decreased significantly from 5.5% to 2.2% ($p<0.001$), with the largest reductions observed in younger adults (12.4% to 4.1%; $p<0.001$), Black patients (7.2% to 1.7%; $p<0.001$), rural residents (5.7% to 2.3%; $p<0.001$), and individuals from high-poverty neighborhoods (3rd quartile: 5.6% to 2.6%; $p=0.028$; 4th quartile: 6.1% to 2.6%; $p=0.004$). For treatment patterns, chemotherapy use increased for local/regional disease (50.4% post-expansion vs. 47.6% pre-expansion; $p=0.038$), while gastrectomy rates remained stable (60.3% vs. 56.4%; $p=0.119$). The median time to treatment increased significantly for local/regional disease (38 days post-expansion vs. 29 days pre-expansion; $p=0.031$) and metastatic disease (33 days post-expansion vs. 30 days pre-expansion; $p=0.184$). Survival outcomes showed significant improvement for local/regional disease post-expansion, with 12-month survival increasing from 67.2% to 76.2% ($p<0.001$) and 24-month survival improving from 52.8% to 59.7% ($p=0.008$). For metastatic disease, 12-month survival improved modestly (30.5% vs. 25.9%; $p=0.111$), while 24-month survival remained unchanged (12.6% vs. 12.7%; $p=0.968$). **Conclusions:** Overall, Medicaid expansion reduced uninsured rates and improved access to chemotherapy and survival for local/regional gastric cancer. However, it had a limited impact on late-stage presentation and survival disparities across racial groups. Addressing systemic barriers and optimizing healthcare delivery remains critical to achieving equitable outcomes for gastric cancer patients. Research Sponsor: None.

11070 Poster Session

Racial disparities in major adverse cardiovascular and cerebrovascular events outcomes among gastric cancer patients.

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Background: Racial disparities in healthcare outcomes represent a critical challenge in achieving equity in gastric cancer care. Gastric cancer, often associated with high morbidity and mortality, also places patients at risk for major adverse cardiovascular and cerebrovascular events (MACCE). This study explores racial disparities in MACCE outcomes among gastric cancer patients using data from the National Inpatient Sample (2016–2021), focusing on differences in mortality, myocardial infarction (MI), arrhythmias, and healthcare resource utilization. **Methods:** A retrospective cohort analysis of the NIS database from 2016 to 2021, identifying adult gastric cancer patients using ICD-10 codes. Demographic and clinical variables, including race/ethnicity, age, sex, income, and hospital characteristics, were analyzed. MACCE outcomes, including mortality, myocardial infarction (MI), atrial fibrillation (A-fib), arrhythmias, and other cardiovascular events, were compared across racial groups. Multivariable logistic regression adjusted for confounders to evaluate the odds of MACCE outcomes and healthcare utilization disparities. **Results:** Among 243,544 gastric cancer patients, the racial distribution included White (53.2%), Black (16.5%), Hispanic (17.3%), Asian or Pacific Islander (7.8%), Native American (0.7%), and Other (4.1%). Significant disparities were noted in MACCE outcomes: Black patients had higher odds of mortality (OR 1.196, $p < 0.001$) and sudden cardiac arrest (OR 2.206, $p < 0.001$) compared to Whites. Hispanic and Asian patients had significantly lower odds of myocardial infarction (OR 0.768, $p = 0.011$; OR 0.998, $p = 0.991$, respectively). Atrial fibrillation was significantly less frequent among Black (OR 0.486, $p < 0.001$), Hispanic (OR 0.4, $p < 0.001$), Asian (OR 0.466, $p < 0.001$), and Native American (OR 0.568, $p = 0.009$) populations compared to Whites. Notably, Hispanic and Asian or Pacific Islander patients had significantly higher total charges (TOTCHG) compared to Whites ($7,945.6 and $13,467.1 higher, respectively, $p < 0.001$). Length of stay (LOS) was significantly longer for Black patients (0.707 days, $p < 0.001$) compared to Whites. **Conclusions:** This study highlights significant racial disparities in MACCE outcomes, mortality, and healthcare resource utilization among gastric cancer patients. Black and Other racial groups demonstrated higher odds of mortality and sudden cardiac arrest, while Hispanic and Asian patients showed a protective effect against myocardial infarction and atrial fibrillation. Disparities in healthcare charges and LOS further emphasize systemic inequities. Addressing these disparities requires targeted interventions to reduce cardiovascular risks and improve healthcare access and equity for minority populations with gastric cancer. Research Sponsor: None.

11071 Poster Session

Patient-reported communication and satisfaction in breast cancer: Does doctor-patient identity concordance matter?

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Background: Effective communication is a key element in patient engagement, adherence, and satisfaction. Prior research has shown that doctor-patient race and/or gender concordance may improve both health outcomes and patient satisfaction, however the effects of identity concordance in oncology and specifically within breast cancer are less studied. **Methods:** Between 7/2023-8/2023, cancer survivors were recruited from Breastcancer.org and consented to participate in an anonymous online survey in English or Spanish. Eligibility included: US resident, age ≥18, and diagnosed within the past 10 years. Survey assessed patient-reported aspects of communication as well as patient-identified provider race/ethnicity and gender. Chi-square and Fisher's exact tests tested associations between patient and/or provider identity and patient-reported satisfaction with communication. **Results:** Of 997 who completed the survey, 759 reported provider race/ethnicity and gender and were included in this analysis. Patients were median age 63 (range, 32-97), mostly White race (91%) and non-Hispanic (99%); almost all were women (98%). Patients were a median of 3.3 years (1.4-10) post diagnosis. Overall, 60% had concordant gender with their provider. 64% had concordant race; White patients had higher racial concordance 68% (n=470/690) than Black (14%, n=5/35) or Asian/Pacific Islander patients (50%, n=9/18) ($p<0.0001$). 0% of Hispanic patients (n=0/11) had ethnic concordance with their provider. Patients reported high levels (94-97% "usually" or "always") of being treated with courtesy/respect, with no significant differences by identity concordance (either racial, ethnic, or gender concordance). Similarly, they reported their doctors listened carefully (89-98% usually/always) and explained things in a way they could understand (89-98% usually/always), with no differences by concordance. Most patients reported no one talked to them about possible clinical trial options (75% White, 51% Black, 56% Asian patients, p=0.003 comparison), but there were no differences by concordance. There were no significant differences by patient-reported race for questions regarding courtesy/respect, listening, explanations, or discussing clinical trials. Similarly, there were no significant differences by patient-reported provider race or gender. **Conclusions:** In this study of breast cancer survivors, patient-provider identity concordance did not have effects on patient-reported communication. There were no identified differences in communication by race, ethnicity, or gender of patient or provider, although overall satisfaction was very high with limited sample diversity which may stymie capacity for identifying differences. Very few Black and zero Hispanic patients had racial or ethnic concordance with their provider, reflecting known gaps in the oncology workforce. Research Sponsor: AstraZeneca; Pfizer; Biotheranostics Inc. (A Hologic Company); Lilly; MacroGenics; Exact Sciences; Seagen; The University of Texas MD Anderson Cancer Center (Biostatistics Resource Group); National Cancer Institute/U.S. National Institutes of Health.

11072 Poster Session

Patient-reported health experiences among US immigrant patients with cancer.

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Background: Patients often experience complex, multifaceted challenges while navigating cancer care, including many interactions with the health system and care teams. For immigrant patients, language barriers may further complicate their cancer care experience. **Methods:** We used the Medical Expenditure Panel Survey database from 2019-2022 to study patient-reported differences in cancer care experiences based upon immigrant status and speaking another language at home. We extracted data about patient factors (age, sex, race, marital status, poverty levels from reported income, immigrant status [born in the US or not], speaking another non-English language at home) and cancer type for all adults > 18 years with self-reported history of cancer. We compared health experiences (i.e., if provider asks about treatments/medications from other providers, if provider explains all treatment options, includes patient in medical decision-making, delays in medical care) by immigrant status and speaking another language at home using Rao-Scott Chi-square test with person-level survey weight. **Results:** We identified 7,771 patients with cancer (63.4% age 65+, 59.4% female, 82.5% White, 50.6% married). Most common cancers were breast (21.6%) and prostate (15.3%). Overall, 10.3% were immigrants and 11.4% reported speaking another language at home; these patients were more commonly younger, female, Hispanic, less educated, living below the poverty line, and had non-private insurance (table). Immigrant patients were less likely to report a provider asked about other treatments (58.5% v 64.6%, p = .022), explained all treatment options (71.6% v 78.2%, p = .032), and included patient in making medical decisions (38.8% v 45.7%, p = .007). Immigrant patients were less likely to report delays in medical care due to cost (6.1% v 6.9%, p = .022) than patients born in the US. Patients who reported speaking another language at home were less likely to report a provider asked about other treatments (58.6% v 64.6%, p = .015), explained all treatment options (71.7% v 78.2%, p = .017), and included patient in making medical decisions (36.5% v 46.0%, p < .001). We found no differences in reporting delays in medical care due to cost (6.6% v 6.9%, p = .059). **Conclusions:** In this national survey study, we found patient-reported health experiences (i.e., discussions about treatment and shared decision-making) differed for immigrants and those speaking another language at home. Findings should inform future work to enhance the cancer care experience in culturally and language appropriate ways for all patients. Research Sponsor: None.

	Immigrant			Speak another language at home		
Patient Factor	**Yes**	**No**	**P**	**Yes**	**No**	**P**
Age 65+	55.7%	64.3%	.004	50.2%	65.1%	<.001
Female	69.3%	58.2%	<.001	67.3%	58.3%	.014
Hispanic	49.3%	5.0%	<.001	66.0%	2.4%	<.001
< Bachelor's Degree	58.2%	55.8%	.001	65.0%	54.8%	<.001
Below Poverty Level	22.8%	14.0%	.001	25.8%	13.5%	<.001
Privately Insured	45.3%	54.6%	<.001	38.1%	55.6%	<.001

11073 Poster Session

Factors associated with readmission to index vs. non-index hospitals after major cancer surgery: Does centralization play a role?

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Background: While centralization of complex cancer surgery at regional referral centers improves perioperative outcomes, many vulnerable patients face barriers in accessing these hospitals. When these patients do manage to undergo surgery at referral centers, it remains unclear where they are readmitted to receive postoperative care when unplanned complications arise. Patients with cancer surgery who are readmitted to the hospital where the surgery was performed (index readmission) often have improved outcomes compared with those readmitted to a different hospital (non-index readmission). This study examined whether factors associated with readmission to index versus non-index hospitals differ for patients undergoing surgery at referral versus non-referral centers. **Methods:** We used data from the Pennsylvania Cancer Registry linked to all-payer statewide inpatient discharge records to identify patients who had surgery for bladder, brain, esophageal, liver, lung and pancreatic cancers between 2013-2019 and were subsequently readmitted within 90 days. We fit a multivariable logistic regression model to identify factors associated with 90-day readmission to an index versus non-index hospital. We included an interaction term between referral center status and cancer type in this model. We defined referral centers as National Cancer Institute-designated cancer centers or American College of Surgeons Commission on Cancer-accredited academic comprehensive cancer programs. **Results:** Of the 28,951 patients with major cancer surgery, 28% (N=8215) were readmitted within 90 days of cancer surgery. Of all patients readmitted, 57% (N=4671) were originally treated at referral centers and 78% (N=6388) were readmitted to the index hospital. On multivariable analysis, factors associated with lower odds of index versus non-index readmission included older age (≥70 years: odds ratio (OR)=0.61; 95% confidence interval (CI), 0.49-0.77, relative to <55 years), high Elixhauser comorbidity scores (>16: OR=0.74; 95% CI, 0.63-0.88; relative to <8), longer travel times (>60 minutes: OR=0.12; 95% CI, 0.10-0.15; relative to <15 minutes), and Medicaid insurance (OR=0.68; 95% CI, 0.54-0.86; relative to commercial insurance). There was no significant difference in odds of index readmission when patients were treated at referral versus non-referral centers (OR=0.77; 95% CI, 0.50-1.20). When assessing interactions, patients with lung cancer had lower odds of index readmission when treated at referral versus non-referral centers, relative to other cancers (OR=0.59; 95% CI, 0.40-0.89). **Conclusions:** Ongoing centralization may be significantly increasing care fragmentation for patients with lung cancer surgery. Future interventions to improve care coordination after surgery should target patients with higher clinical complexity and greater travel burdens. Research Sponsor: National Cancer Institute; R37CA262366.

11074 Poster Session

The association between profitability, clinical benefit, and physicians' selection of cancer drugs.

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Background: Compensation for provider-administered cancer drugs (such as intravenous chemotherapy and immunotherapy) is volume-based and proportional to drug price. Providers receive greater compensation for more expensive drugs. If providers respond to this incentive by selecting more-profitable but clinically less-beneficial treatments, cancer care spending may be increased unnecessarily and care quality may be impacted. The goal of this study was to estimate the association between the billing (profit) margin of cancer treatments and use by oncologists. **Methods:** This was a population-based cohort study using fee-for-service Medicare claims. We included beneficiaries with an incident cancer diagnosis (a new occurrence of a cancer diagnosis code after a >= 1 year washout period) from 2014-2020. The primary outcome was which cancer treatment, among available options, each patient received. The treatment-level characteristics of interest were provider billing margin (using Medicare reimbursement rates) and clinical benefit (using the National Comprehensive Cancer Network Evidence Blocks scores), both measured coincident with each patient's diagnosis date. We included cancer treatment "indications" (e.g., metastatic melanoma, adjuvant therapy for stage III colon) that had variation in both the clinical benefit and billing margin of available treatment options. We modeled the association between treatment received, billing margin, and clinical benefit, including inverse probability-of-treatment weights to control for patient (age, comorbidity, frailty, low income subsidy, regional income and poverty prevalence, rurality) and provider (years in practice, academic setting, patient volume) characteristics. Models were estimated within individual cancer indications, and results were then aggregated via meta-analysis. **Results:** We included 12 cancer indications comprising 19,397 individual patients. Across all treatments for the 12 cancer indications, provider billing margin ranged from $0-$12,692 per course of treatment. There was no association between a $100 increase in provider billing margin and likelihood of treatment use (OR 0.97, 95%CI: 0.91-1.03). Higher clinical benefit was associated with greater treatment use (OR 1.62, 95%CI: 1.15-2.29). These findings were unchanged in sensitivity analyses applying different methods for billing margin calculation, measurement of clinical benefit, and weighting. **Conclusions:** In this observational study of Medicare beneficiaries, selection of cancer treatments was associated with treatment clinical benefit but not billing margin. Restated, oncologists preferred more beneficial treatments but not more profitable ones. These results suggest that changes in the billing margin of cancer treatments may be unlikely to shift utilization patterns. Research Sponsor: The Commonwealth Fund; Arnold Ventures; The National Cancer Institute.

11075 Poster Session

Use of low-value cancer treatments in Medicare Advantage versus traditional Medicare.

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Background: Medicare Advantage (MA) has steadily grown during the past decade, covering over half of Medicare beneficiaries in 2024. Because MA plans receive capitated payments for Medicare beneficiaries, they have the financial incentives to reduce service utilization and costs. MA plans may discourage enrollees from using low-value services, such as medically unnecessary care and expensive treatments for which low-cost alternatives are available. No prior study examining the use of low-value services between MA and TM has evaluated the use of low-value cancer treatments specifically. We compared use of low-value cancer treatments between MA and TM. **Methods:** Using national Medicare data, we performed retrospective analyses of beneficiaries who had a new cancer diagnosis between 2016 and 2021, and who were at risk of receiving one of the following low-value treatments: growth factors (GCSF) for patients receiving low-risk chemotherapy; denosumab for castration sensitive prostate cancer (CSPC); nab-paclitaxel instead of paclitaxel for breast or lung cancers; adding bevacizumab to carboplatin + paclitaxel for ovarian cancer; and branded drugs or biologics for which generic or biosimilar versions existed. We estimated linear regression models for each cohort/outcome separately. The key explanatory variable was MA enrollment (vs. TM). We used inverse probability of treatment weights to balance characteristics between MA and TM: patient age, sex, race, Medicare and Medicaid dual-eligibility status, cancer metastasis, a frailty index, and summary health-risk scores, area-level socio-economic and health care environment variables. We included year indicators to adjust for temporal trends and oncology practice indicators to control for practice-specific prescribing patterns. **Results:** Receipt of any low-value cancer treatment was 1.7 percentage points lower in MA than in TM (34.2% versus 35.9%; $p<0.001$). MA enrollees had lower utilization than TM for GCSF (7.3% versus 8.9%; $p<0.001$), denosumab (26.4% versus 33.1%; $p<0.001$), nab-paclitaxel (7.9% versus 8.7%; $p<0.05$), addition of bevacizumab for ovarian cancer (8.3% versus 10.5%, $p=0.001$), and biologics with biosimilar alternatives (66.8% vs. 68.5%; $p<0.001$). Receipt of branded drugs did not significantly differ between MA and TM. **Conclusions:** For Medicare beneficiaries at risk of receiving a low-value cancer treatment, MA enrollees were less likely to receive low-value cancer treatments than TM beneficiaries. These reductions in low value services may prevent avoidable toxicity and lower treatment cost to the patient and health care system. Increased efforts are needed to identify approaches that MA plans use to reduce low-value cancer treatments, and explore ways to promote those approaches in both MA and TM. Research Sponsor: National Institute of Aging; The Commonwealth Fund; Arnold Ventures; The National Cancer Institute.

11076 Poster Session

Longitudinal changes in credit status for newly diagnosed metastatic colorectal cancer patients (SWOG S1417).

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Background: We previously reported that 71% of insured patients with newly diagnosed metastatic colorectal cancer (mCRC) self-reported major financial hardship (MFH), defined as one or more of increased debt, new loans from family and/or friends, selling or refinancing a home, or 20% or more income decline, within 12 months of diagnosis. In this secondary analysis using credit data, we examined if enrolled patients experienced changes in credit status over time. **Methods:** Depersonalized credit data were obtained from TransUnion, one of the largest credit agencies in the United States, at enrollment, 6, and 12 months. Patients with a baseline and at least one follow-up credit record were analyzed. Demographic data were obtained from questionnaires at enrollment. We determined the mean number or proportion of patients with adverse credit events (defined as past due or delinquent credit cards or mortgage payments, third-party collections, tax liens, charge-offs, bankruptcies, foreclosures, or repossessions) and the mean past due credit card amount, if applicable, at baseline and follow-up. We used paired t-tests to compare credit characteristics between baseline and follow-up in the entire cohort and in subgroups with and without MFH. Multivariate logistic regression was used to identify factors associated with adverse credit events. **Results:** 318 patients were analyzed (median age 59.1, 41% female, 80% white, 59% married, 42% with private health insurance). Approximately 3.4% of patients experienced a new adverse credit event during the study period, 143 (45.0%) patients at baseline and 154 (48.4%) at follow-up (p=0.07). Overall, new adverse credit events were uncommon and only third-party collections significantly worsened over time (mean 3.20 (SD 3.17) at baseline and mean 4.11 (SD 3.85) at follow-up; $p < 0.001$). Charge-offs numerically increased over time, but the value did not reach significance. On average, past due amounts on open credit cards increased over time ($100.60 at baseline and $291.33 at follow-up), with the increase largely seen among patients self-reporting MFH. Adverse credit events were more likely to worsen in patients who were younger (OR 2.51, CI 1.08-5.84), had lower household income (OR 3.09, CI 1.07-8.92), lower educational status (OR 2.07, CI 1.10-3.88), and fewer assets, defined as less than $100,000 (OR 4.15, CI 1.58-10.91). **Conclusions:** Despite high levels of self-reported MFH in this cohort, credit data showed no significant increase in adverse credit events between baseline and follow-up, except for increased third-party collections and total past due credit card balances. This may be due to credit reports capturing only more severe financial impacts or because the impacts of financial hardship take longer to be reflected in credit reports. A future study will examine how patients leverage credit, such as applying for new credit cards or reaching credit limits. Research Sponsor: ASCO Career Development Award (2013); Hope Foundation Charles A. Coltman Jr. Award (2012).

11077 Poster Session

Association of county-level medical debt and timely treatment initiation among individuals newly diagnosed with cancer.

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Background: Medical debt is associated with adverse cancer outcomes, including poor survival. However, it is unknown if living in a county with high medical debt is associated with treatment initiation. We examined the association of county-level medical debt and timely treatment initiation among individuals newly diagnosed with cancer. **Methods:** We identified adults aged ≥19 newly diagnosed with cancer from the 2012-2021 Colorado Central Cancer Registry linked to the Colorado All-Payer Claims Database, which were combined with data on county-level share of adults with medical debt in collections. We used Cox proportional hazard models to examine the associations of county-level medical debt and receipt of any treatment within 90 days after cancer diagnosis overall and by selected cancer sites (acute leukemias, lymphomas, breast, colorectal, and lung cancers) and health insurance coverage, adjusting for individual sociodemographic characteristics. P-trend was calculated using medical debt quartile as a continuous variable in the models to examine dose-response associations. **Results:** Among 35,789 individuals newly diagnosed with cancer, individuals living in counties with the highest share of adults with medical debt in collections (Quartile 4 (Q4)) had lower likelihood of initiating treatment within 90 days after diagnosis compared to those living in counties with the lowest share of adults with medical debt (Q1), adjusting for covariates (HR: Q4 vs Q1: 0.93, 95% confidence interval: 0.90-0.97, P-trend < 0.001). When stratified by cancer site, higher county-level medical debt was associated with lower likelihood of timely treatment initiation among individuals diagnosed with lymphoma (HR: Q4 vs Q1: 0.82 (0.69-0.98), P-trend = 0.022) and female breast cancer (HR: Q4 vs Q1: 0.90 (0.85-0.94), P-trend < 0.001). When stratified by insurance, higher county-level medical debt was associated with lower likelihood of timely treatment initiation among individuals aged 19-64 years with private fee-for-service (FFS) plans (HR: Q4 vs Q1: 0.88 (0.78-0.98), P-trend = 0.011) and individuals aged ≥65 years with Medicare FFS plans (HR: Q4 vs Q1: 0.90 (0.82-0.98), P-trend = 0.007). **Conclusions:** County-level medical debt in collections was associated with delays in treatment initiation among individuals newly diagnosed with cancer. Policies aimed at preventing and alleviating medical debt could be effective strategies for improving access to timely cancer treatment. Research Sponsor: Leukemia and Lymphoma Society; HSR9027-24.

Association between cost and insurance on receipt of guideline-concordant mammography.

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Background: Many organizations offer mammography guidelines with slight differences, which can serve as a barrier to receiving a mammogram. Furthermore, it is unknown how both cost and insurance serve as a barrier to receiving a mammogram. Therefore, our study explored the associations between cost and insurance on guideline-concordant mammography. **Methods:** This cross-sectional study used 2023 National Health Interview Survey data. Inclusion criteria included women eligible for a mammogram. The outcome was receipt of guideline-concordant mammography and was based on women following 2016 US Preventive Services Task Force or current American Cancer Society guidelines for age and frequency requirements. The exposures of interest included report of at least one healthcare-related cost issue (yes, no) and insurance status (uninsured, insured). Questions for healthcare-related cost issue included: in the past 12 months did you, 1) have problems paying or were unable to pay medical bills, 2) delayed medical care due to cost, & 3) did not get necessary medical care due to cost. We estimated odds ratios (OR) and 95% confidence intervals (CI) using logistic regression to assess the interaction between cost issues and insurance status on receipt of guideline-concordant mammography. The model controlled for age at survey completion, race and ethnicity, Rural-Urban Classification Scheme, income to poverty ratio, and personal & family history of breast cancer. **Results:** A total of 13,529 women were included. Mean age was 55 years, 63% were non-Hispanic White, 10% were in poverty. About 1 in 4 had not received guideline concordant mammography. When compared to those who had received a guideline-concordant mammogram, individuals who did not have a mammogram were younger (p-value: <.0001), uninsured (<.0001), and had reported at least one cost issue (<.0001). In our adjusted analysis, we found that the uninsured, regardless of cost issue, had lower odds of receipt of guideline-concordant mammography (Table). Among insured individuals, those who did vs did not report a cost issue had 0.68 (95% CI 0.59-0.77) times the odds of receipt of a guideline-concordant mammogram. **Conclusions:** By interacting cost issues and insurance status, we found that individuals with health insurance and issues paying for care had low prevalence of guideline-concordant mammography. This is important when determining how best we can provide screening for those in need. We recommend that screening services that offer free or low-cost mammograms include women who have health insurance and report healthcare-related cost issues. Research Sponsor: None.

Model results (N=13529).

	OR (95% CI)
Healthcare-related cost issue	
Uninsured vs insured	**0.59 (0.43-0.81)**
No healthcare-related cost issue	
Uninsured vs insured	**0.46 (0.35-0.60)**
Uninsured	
Healthcare-related cost issue vs none	0.87 (0.60-1.27)
Insured	
Healthcare-related cost issue vs none	**0.68 (0.59-0.77)**

Shifts in Medicare spending for patients with cancer undergoing chemotherapy following implementation of the Maryland Global Budget Revenue program.

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Background: In January 2014, the statewide Maryland Global Budget Revenue (GBR) model was implemented to control the growth in total hospital spending and improve the quality of care. Specific impacts of GBR on cancer-related spending are not fully understood. This study aimed to 1) quantify the impact of GBR on Medicare spending for beneficiaries undergoing chemotherapy for cancer and 2) investigate any shift in such spending during GBR to non-hospital settings. **Methods:** Using 2011-2018 Medicare claims from Maryland and a control set of 11 comparable states, we constructed 6-month chemotherapy episodes. Propensity matching was used to identify appropriate comparison episodes based on treatment year, patient demographic, clinical, and area-level characteristics. Using a difference-in-differences (DiD) approach, we evaluated the impact of GBR on standardized total Medicare payments and non-hospital professional payments during the episode, after confirming the parallel trends assumption during GBR's pre-period (2011-2013). **Results:** Among 42,206 and 708,486 chemotherapy episodes in Maryland and control states, respectively, we studied 42,199 episodes in Maryland matched to 42,199 episodes in control states. Our analysis showed that GBR's implementation led to smaller increases in total episode payments over time relative to control states and larger increases in non-hospital professional payments (Table); these impacts notably varied with time. **Conclusions:** Our finding of smaller increases in total Medicare payment for a 6-month chemotherapy episode in Maryland versus control states indicates that GBR's intended reductions on the spending growth in the context of cancer patients undergoing chemotherapy were actualized. Importantly, larger increases in non-hospital professional payments suggest these savings may have been attained via shifts in sites-of-care following GBR's implementation. Further studies evaluating the effects of these shifts on cancer care quality are warranted. Research Sponsor: U.S. National Institutes of Health.

Adjusted mean standardized payments in 2018 dollars during 6-month chemotherapy episodes and DiD estimates versus 2013.

	Total payments			Non-hospital professional payments		
Year	Adjusted Mean, Maryland	Adjusted Mean, Control states	DiD	Adjusted Mean, Maryland	Adjusted Mean, Control states	DiD
2013	$54,213	$52,659	Ref	$22,876	$14,844	Ref
2014	$54,522	$53,476	-$759	$21,261	$14,327	$828
2015	$55,355	$55,426	-$2,001	$22,249	$14,186	$1,433*
2016	$58,599	$59,331	-$2,940*	$24,314	$14,922	$1,286
2017	$61,141	$60,462	-$1,561	$27,954	$15,330	$3,612*
2018	$62,329	$64,756	-$4,853*	$27,969	$15,356	$2,753*

*$p<0.05$. The adjustment methodology accounted for patient demographic, clinical and area-level characteristics, and time-varying Hospital Service Area (HSA) level variables. For the DiD analysis, HSA fixed effects were also included.

11080 Poster Session

Insurance coverage of germline genetic testing for ovarian, pancreatic, and early-onset colorectal, endometrial, and breast cancers, stratified by self-reported race and ethnicity.

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Background: Universal germline genetic testing (GGT) for patients with ovarian (OV), pancreatic (PANC), and early-onset colorectal, endometrial cancer, and breast cancer (CRC <50, ENDO <50, and BR ≤50) is the medically necessary standard of care per clinical guidelines and many payer medical policies. Individuals with multiple cancers, diagnosed at any age (MULTI), also commonly meet these guidelines for GGT. We report a single national laboratory experience with GGT coverage for these indications. **Methods:** Patients with GGT between 6/1-12/31/2023 from a commercial laboratory were stratified by cancer type (using ICD-10s), age at testing, and self-reported race and ethnicity. We assessed differences in coverage rates, frequency and types of denial codes (technical and clinical denials), and appeal success across cancer types. Reported p-values are from G-Tests of independence, only groups containing at least 100 individuals were retained in statistical tests. **Results:** We reviewed 12,304 patients with cancer, 19% with OV, 29% with PANC, 13% with CRC <50, 2% with ENDO <50, 26% with BR ≤50, and 9% with MULTI. Of all patients, GGT was not covered for 31%, including 29% of OV, 27% of PANC, 35% of CRC <50, 39% of ENDO <50, 35% of BR ≤50, and 27% of MULTI. Of all cases with no coverage for clinically indicated GGT, 30% had clinical denial codes (e.g. medical necessity, non-covered services, experimental), 68% had only technical denial codes, and 2% had no denial codes. Overall, appeals were successful in 32% of cases, including 27% of OV, 25% of PANC, 44% of CRC <50, 39% of ENDO <50, 33% of BR <50, and 22% of MULTI. The proportion of cases with coverage differed significantly by self-reported race and ethnicity (58%-81%, $p < 0.00001$), with Black and Hispanic individuals being less likely to be covered in comparison to Ashkenazi Jewish, Asian, and White individuals. Whereas the proportion of those receiving denial codes differed between self-reported race and ethnicity groups ($p < 0.00001$), the percentages of technical vs. clinical denial codes received did not ($p = 0.56$). **Conclusions:** Despite clinical guidelines and payer medical policy affirming the medical necessity of universal GGT in these cancer types, these data demonstrate that 30% of patients did not receive coverage for standard of care GGT, and was lower in traditionally under-represented groups. Denials overturned on appeal suggest those cases should not have been denied initially. These data suggest that coverage denials are a substantial obstacle to medically necessary GGT for patients with cancer despite clinical practice guidelines. Research Sponsor: None.

11081 Poster Session

Longitudinal risk of physical functional impairment and health care utilization in cancer survivors within 3 years of diagnosis.

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Background: Despite known physical functional (PF) impairment in cancer survivors, patterns of its development and relationships to healthcare utilization remain poorly characterized. We examined PF impairment trajectories among outpatient cancer survivors in a large Midwestern academic health care system during the first three years after a new cancer diagnosis. We hypothesized that PF impairment would be common, vary by extent of disease, cancer care phase, with differing patterns of rehabilitation services (RS) referral, emergency department (ED) and cancer center urgent care (CCUC) visits. **Methods:** We included 2,254 adults with a cancer diagnosis, treated in medical oncology clinics, and completed 2 or more Patient Reported Outcome Measurement Information System – Physical Function (PROMIS-PF) surveys within a 3-year period. A PROMIS-PF T-score < 40 represents moderate – severe impairment. We used group-based trajectory modeling (GBTM) to identify patterns of impairment likelihood (0.7 threshold for accurate fit) in the 3 years after cancer diagnosis. Trajectory models identified the demographic profile, cancer type, stage, and treatment intent (intent to cure, non-intent to cure, other) most associated with each trajectory. We assessed trajectory associations with rates of RS referrals, and visits to ED and CCUC during the study period with multiple logistic regression ($p<.05$). **Results:** On average, participants were newly diagnosed within 11 months (s.d. 10.92) before enrollment in the study. We determined 4 PF impairment trajectory patterns during the first 3 years after a cancer diagnosis: (1) low probability of impairment which remained steady over time ("Low Steady", 64% participants); (2) decreasing probability ("Decreasing", 13%); (3) increasing probability ("Increasing", 9%); (4) high probability of PF impairment that remained high ("High Steady", 14%). Patients in trajectories 2, 3, and 4 were significantly more likely to have ED and/or CCUC visits and receive RS referrals than those in trajectory 1, although differences by cancer type, stage, and Beacon module between groups 2 – 4 were mixed. **Conclusions:** Over one-third of cancer survivors experienced substantial impairment and 14% had persistent, severe impairment with higher rates of RS referrals, ED and CCUC visits. These patterns had few variations by tumor type and cancer care phase. Our data suggest that patients in Trajectories 2 – 4 should be targeted for early and frequent monitoring with PROMIS-PF and referral for rehabilitation services to address impairments –ideally within the first six months after cancer diagnosis. PROMIS-PF effectively identified impairment variation across patients and time. Future studies will explore whether screening and triaging for appropriate cancer rehabilitation referral and intervention improve impairment trajectories. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; UM1CA233035; National Cancer Institute/U.S. National Institutes of Health; 3UM1CA233035-01S1.

11082 Poster Session

Addressing disparities by implementing a supportive care program in oncology.

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Background: Financial toxicity, transportation needs, and emotional strain are known barriers to receipt of cancer care and cause for disparities in cancer outcomes. We sought to evaluate the implementation of a supportive care program (SCP) on the delivery of cancer care, its associated health care utilization outcomes and cost. **Methods:** From May 2022-Nov 2024, SCP included a standardized social determinant of health (SDOH) screening tool, financial navigation, transportation ridesharing, and peer-support program in the 5 gynecologic oncology practices within a NCI Comprehensive Cancer Center. Patients were referred through the SDOH screener or usual clinical care referrals. We report descriptive statistics on the mechanism for referral for SCP, associated health care utilization, and costs. We assessed differences in SCP financial and transportation sub-groups with bivariable non-parametric testing (p-value$<$ .05 considered statistically significant). **Results:** Of 7159 patients encompassing 22041 encounters, 259 received SCP (41 financial navigation, 177 transportation, 3 transportation + financial navigation, 18 peer-support program). Only 73 (28.7%) were referred through the SDOH screening tool, and the rest through usual clinical care. Most SCP recipients (60.6%) were Black/Asian/Other, in contrast to our general clinical population (63% White). Only 65 (25.6%) of SCP patients were employed, and 72.8% had Medicare or Medicaid. Nearly all SCP patients resided in the Mid-Atlantic tristate area. Patients receiving financial navigation were younger ($p<0.001$), more likely to be privately insured ($p<0.001$), and less likely to reside in the metropolitan area (43.9% v. 63.8%, p=0.05) compared to those receiving transportation. A total of 1770 rides were completed, costing $51885.20 which included the ride and administrative scheduling fee. A total of 14 SCP participants were clinical trial participants; of these, 78.6% utilized transportation assistance. Following receipt of SCP, the total scheduled visits for SCP patients included 7768 visits. Patients receiving transportation assistance had higher rates of unplanned admission (43.5% v. 22.0%, p=0.011), and no-show rates (4.6% vs 1.2%, $p<0.001$) compared to those receiving financial navigation. **Conclusions:** Our SCP served primarily racial-minority and publicly insured patients. Only 25% were employed during active cancer treatment. Transportation was the most frequently used SCP service, including by our clinical trial participants. Patients with transportation needs had higher rates of unplanned admissions and no-shows than those receiving financial navigation. Financial toxicity affected younger patients including those privately insured. SCP facilitates cancer care delivery, but requires infrastructural development, substantial investment in resources, and further analyses of health care utilization, outcomes and cost. Research Sponsor: Ovarian Cancer Research Alliance; HEG-2024-2-1774.

11083 Poster Session

Evaluating a patient ambassador program to improve clinical trial knowledge and intent to discuss gynecologic oncology trials.

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Background: To evaluate the implementation of a pilot patient-ambassador program to provide peer-to-peer clinical trial education aimed at increasing awareness, knowledge, and intent to discuss gyn oncology (GYO) trials in trial-naïve patients. **Methods:** We conducted a mixed-methods interventional behavioral study at an urban-metropolitan NCI comprehensive cancer center to evaluate the implementation of a program for initiating "chats" about GYO clinical trials. From Feb-Oct 2024, we recruited patients as "ambassadors" who previously participated in a GYO clinical trial. Ambassadors underwent training via an educational curriculum and then were paired with 5-7 "mentees," who were trial-naïve patients with high-risk or advanced gyn cancer. Outcomes assessments included post-chat quantitative surveys using the acceptability and feasibility of intervention measures (AIM & FIM), net promoter score (NPS), and change in clinical trials knowledge score. Qualitative analyses of open-ended survey responses, dyad "chat" recordings, and feedback from ambassadors at training, mid-program and exit interviews were completed by two coders using a modified content analysis approach. Chi-square test and t-tests were applied with $p<0.05$ considered significant. IRB exemption obtained (IRB #: 854317). **Results:** 3 ambassadors and 20 mentees completed the program, resulting in 20 "chats" from a pool of 266 eligible mentees. On the pre-chat survey, 90% of mentees reported they had previously heard of clinical trials and 75% of mentees reported they perceived trials as somewhat/very positive. Post chat, 90% of mentees reported their perception of trials as somewhat/very positive, 85% felt the chat changed their view of trials, and 95% felt confident to ask their oncology provider about trials. Participants reported high acceptability, feasibility, and program promotion, but no increase in knowledge (table). Qualitative themes of barriers to trial participation included misconceptions of trial types and inability to withdraw, and fear of side effects, and cost. Facilitators included desire to help humanity and hope for new treatments. Implementation concerns included emotional strain on ambassadors, mismatched ambassador-mentee expectations, and ambassadors' variability in discussing recruitment of diverse populations. **Conclusions:** This pilot patient-ambassador program is a feasible, acceptable, and highly promoted intervention to increase patients' confidence in discussing and intent to ask oncology providers about clinical trials. Research Sponsor: Robert A. Winn Diversity in Clinical Trials Award Program; National Cancer Institute; P50CA228991.

Outcomes	Mentee		Ambassador	
(mean, SD)	Pre chat	Post chat	Pre chat	Post chat
Knowledge Survey (%)	74.17 (13.22)	77.08 (16.42)	83.33 (16.67)	83.33 (14.43)
AIM*	-	4.29 (0.74)	-	5.00 (0.00)
FIM*	-	4.18 (0.74)	-	4.92 (0.14)
NPS*	-	8.90 (2.47)	-	10.00 (0.00)

*AIM and FIM (Scale 1-5). NPS (Scale 1-10).

11084 Poster Session

The state of the oncologist workforce in America in areas prone to natural disasters.

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Background: Natural disasters are increasingly common in the U.S., causing significant localized disruptions to cancer care. The American Society of Clinical Oncology (ASCO) examines the supply of and demand for cancer services in areas prone to natural disasters to support emergency preparedness planning, response, and recovery. **Methods:** We tabulated the number of U.S. hematologists and medical oncologists by county from Medicare Care Compare (March 2024 data). Demand for cancer services was approximated using 2017-2021 average annual counts of new cancer cases by county from State Cancer Profiles. We extracted US Climate Vulnerability Index county rankings for extreme flooding, storm, and wildfire events, as well as for community resilience (derived from health, social, economic, infrastructure, and environmental measures). We defined "high-risk" counties as those with the highest decile rankings for extreme flooding, storm, and/or wildfire events across all U.S. counties and determined the share of U.S. oncologists and people with incident cancer in those areas. We also identified oncologists and patient populations in counties adjacent to high-risk counties who might be affected. Among high-risk and adjacent counties, we further isolated those ranked in the highest quartile for baseline vulnerability (i.e., low community resiliency). **Results:** Of 1.7M people with newly diagnosed cancer in the U.S., a majority (65%, 1.1M) lived in proximity to counties at high-risk for extreme flooding, storms, and wildfires (642K people from 886 counties designated high-risk and 479K from 716 adjacent counties). Similarly, most oncologists (65%, 9,471 of 14,547) practiced in proximity to high-risk counties (5,501 oncologists in top ranked counties, 3,970 in adjacent counties). When factoring in community resilience, 325 counties at or adjacent to high-risk for extreme weather events also ranked highest for baseline vulnerability: 14% of oncologists (n=2,036) worked in these counties, where 13% of people with incident cancer lived (226K). **Conclusions:** ASCO has recommended that health systems create geographically appropriate plans for natural disasters. Our analysis indicates that most oncologists and most patients in the U.S. are in or adjacent to areas prone to natural disasters, and that many people at risk reside in counties with low community resilience. Practice-level emergency preparedness for response and recovery from natural disasters, including patient referrals and minimization of treatment disruptions, informed by community-specific needs, should be pursued on a broad scale. Additional planning is needed at all levels of the health care system and government to meet this substantial and potentially growing need for crises planning in cancer care. Future research could focus on other types of disasters and on global impacts. Research Sponsor: None.

11085 Poster Session

Influenza and COVID-19 vaccination uptake among cancer survivors in the US.

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Background: Cancer survivors are at increased risk of comorbidity and mortality from respiratory viral infections including influenza (flu) and COVID-19 and therefore, vaccinations against these viruses are important for their health. Little is known about the receipt of these vaccines among cancer survivors in the post-COVID era. This study sought to evaluate the uptake of flu and COVID-19 vaccinations between cancer survivors and the general population in the US. **Methods:** We analyzed cross-sectional data from the 2023 National Health Interview Survey that used multistage probability sampling to interview US adults. Adults with a history of cancer were defined as cancer survivors, and those without a history of cancer were the general population. Flu vaccination receipt was defined as having had a flu shot in the past 12 months. COVID-19 vaccination receipt was defined as having received ≥2 doses of the COVID-19 vaccine. Weighted proportions were compared using Rao-Scott Chi-squared tests. Weighted logistic regression was conducted, adjusting for demographic and socioeconomic factors. Adjusted odds ratio (AOR) and 95% CIs were calculated. All analyses accounted for complex survey design and weights. **Results:** The total sample size was 29,522, representing a weighted sample of 258,237,552 adults in the US. The mean age was 48 years; 61.9% were White, followed by 17.5% Hispanic, 11.8% Black, and 8.8% Asian or Other; and 9.7% were cancer survivors. Overall, 73.7% (95% CI: 72.9-74.5%) received ≥2 doses of COVID-19 vaccinations, and 48.0% (95% CI: 47.1-48.8%) had a flu shot in the past 12 months. Compared to the general population, higher proportions of cancer survivors received COVID-19 vaccinations (84.8% [95% CI: 83.5-86.3%] vs 72.5% [95% CI: 71.6-73.4%], $P<0.001$) and a flu shot (67.3% [95% CI: 65.5-69.1%] vs 45.8% [95% CI: 45.0-46.7%], $P<0.001$). After covariate adjustment, cancer survivors had greater odds of having received COVID-19 vaccinations than the general population (AOR 1.38, 95% CI: 1.22-1.56). Cancer survivors also had greater odds of having had a flu shot than the general population (AOR 1.35, 95% CI: 1.23-1.49). Additionally, we found that male sex, lack of insurance or public insurance, and rural residence were associated with lower odds of having received either vaccine. **Conclusions:** In this US national adult sample, COVID-19 and flu vaccination uptakes were higher among cancer survivors than in the general population. Although this is encouraging, vaccination rates, particularly with the flu vaccine, remain below the 70% Healthy People 2030 goal. To achieve this goal, tailored interventions and policies are necessary to improve vaccine uptake and socioeconomic disparities across cancer survivors and the general population.Future research can explore how the receipt of the vaccines impact the quality of life and health outcomes of the growing population of cancer survivors. Research Sponsor: Susan G. Komen Breast Cancer Foundation; TREND21675016; National Institute on Aging; T32AG000243.

The implications of using truncated Medicare definitions of avoidable hospital visits.

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Background: As part of the Outpatient Quality Reporting program, Medicare reports on potentially avoidable, acute hospital visits after chemotherapy, using only fee-for-service (FFS) claims. This measure aggregates emergency department visits, observations, and inpatient admissions for 10 avoidable conditions (e.g. pain, vomiting), within 30 days of a chemotherapy infusion and is known as the OP-35 measure. The literature largely applies the diagnosis codes without reference to chemotherapy: it can be impractical to apply clinic-level changes only to Medicare FFS enrollees, and large, nationally-representative, hospital visit datasets do not contain chemotherapy infusion dates. There has been little scrutiny of the implications of using such truncations of this policy tool. **Methods:** We used a population-based cohort of incident cancers (2015-2023) from two sites: an academic medical center and safety-net health system, identifiably linking patients to their comprehensive hospital use from a regional health information exchange (all non-federal hospitals within a 150-mile radius of Dallas, TX). We tracked the changes in avoidable hospital visits for each measure specification: using diagnosis codes alone; narrowing to within 30 days of chemotherapy; counting only the first visit in a 30-day span; narrowing to Medicare FFS. We used mixed-effects (clustered to patient) multivariate logit to model avoidable visits occurring within or outside of a chemotherapy 30-day window; and avoidable vs. non-avoidable hospital visits across payors, adjusting for clinical and demographic variables. **Results:** We linked 31,305 incident cancer diagnoses (mean age 64; 50.6% female; 57.7% Black or Hispanic; 23.6% advanced stage cancer; 19.2% gastrointestinal cancer, 12.2% breast, 9.2% lung) to 190,967 visits across 76 hospitals. Although 28.0% (n= 54,233) had an avoidable diagnosis coded, only 24.3% (n=13,179) of them were within 30 days of chemotherapy. After excluding multiple visits in the 30-day span, 9.1% (4,917 of the 54,233 avoidable conditions visits) remained, with 14.0% (n=689, or 1.3% of 54,233) under Medicare FFS (1.6% Medicare Advantage, 30.2% commercial, and 54.4% uninsured/Medicaid). In adjusted analyses, avoidable conditions were significantly more likely to occur within 30 days of chemotherapy than outside of it (aOR 1.34, 95% CI: 1.27-1.40, $p < 0.001$); and compared to Medicare FFS, commercially-insured encounters had higher odds of avoidable hospital visit (aOR 1.31, 95% CI: 1.12–1.50, $p < 0.001$). **Conclusions:** Three-quarters of hospital visits for avoidable conditions occurred outside of a 30-day span after chemotherapy, though in adjusted analysis, avoidable visits were more likely to occur after chemotherapy. As little as 1.3% of visits for avoidable conditions were captured by the Medicare definition. Further investigation of the best uses of this measure is warranted. Research Sponsor: U.S. National Institutes of Health; CA282242.

11088 Poster Session

United States treatment pattern response to carboplatin and cisplatin shortages.

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Background: In response to cisplatin (2/10/23) and carboplatin (4/28/23) shortages, national guidelines recommended prioritizing cisplatin and carboplatin for their most important indications to preserve availability while maximizing survival outcomes. We examined the real-world response to recent platinum shortages in lung cancers (LC), for which guidelines recommended preserving platinum chemotherapies when non-metastatic versus allowing substitution to immunotherapy monotherapy when metastatic. **Methods:** Using IQVIA PharMetrics data (9/1/22-10/31/23), we developed claims algorithms to identify intravenous anticancer therapy infusion claims for patients with incident non-metastatic vs. metastatic LC, which we validated against SEER-Medicare. Our outcomes were the fraction of infusions containing either (1) cisplatin, (2) carboplatin, or (3) immunotherapy (IO) without platinum. We performed an interrupted time series (ITS) analysis, using a linear probability model with three time-periods: pre-platinum shortage (9/1/22-1/31/23), post-cisplatin shortage (2/1/23-4/30/23), and post-carboplatin shortage (5/1/23-10/31/23), adjusting for age, gender, region, and comorbidities. **Results:** There were 11,983 infusions (2,411 patients) and 1,650 infusions (428 patients) for incident non-metastatic and metastatic LC, respectively. For non-metastatic LC, between 2/2023 (cisplatin shortage) and 04/2023 (carboplatin shortage), cisplatin use declined by 1.7 percentage point (pp) per month ($p=0.03$) and a non-significant 1.6 pp monthly increase in carboplatin usage ($p=0.24$). After carboplatin shortage, there was an immediate 4.5 pp drop in use of carboplatin ($p=0.04$), as well as an immediate 5.8 pp increase in use of cisplatin ($p<0.0001$). Overall platinum use (receipt of either cisplatin or carboplatin) throughout this entire period did not have any significant change. For metastatic LC, cisplatin was rarely used, so results after the cisplatin shortage were not assessed. After carboplatin shortage, there was a 15.7 pp immediate decline in use of carboplatin ($p=0.002$), with a concomitant 18.4 pp immediate increase in use of IO without platinum ($p<0.001$). **Conclusions:** The real-world response to platinum shortages in LC appeared to follow guidelines. For non-metastatic LC, for which platinum chemotherapy increases cure rates, declines during either the cisplatin or carboplatin shortages were equally balanced with increases in the other platinum chemotherapy, such that overall platinum chemotherapy usage remain stable. For metastatic LC, declines in carboplatin were balanced with increases in immunotherapy monotherapy. Research Sponsor: None.

11089 Poster Session

Medicare plan switching, hospice enrollment, and place of hospice services at the end-of-life among decedent patients diagnosed with distant stage cancers in 2010-2019.

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Background: Prior studies showed higher hospice utilization among Medicare Advantages (MA) than among Traditional Medicare (TM) beneficiaries. With more beneficiaries enrolling in MA and switching between TM and MA in recent years, this study examines hospice utilization patterns and associated factors among patients with advanced cancers enrolled in continuous TM, continuous MA, or switching between these plans. **Methods:** We identified Medicare beneficiaries aged ≥66 years diagnosed with distant-stage breast, colorectal, lung, pancreatic, or prostate cancers in 2010-2019 and followed through 2020 from SEER-Medicare data. Patients surviving ≥3 months post-diagnosis were categorized by plan-switching patterns: continuous TM, continuous MA, switching from TM-to-MA, and from MA-to-TM. Outcomes included hospice enrollment in the last year of life, within 14 days of death, and site of last hospice service (e.g., home, nursing home, hospice facility, inpatient facility, or other). Multivariable regression models estimated associations of plan-switching patterns and patient characteristics with study outcomes. **Results:** Among a total of 196,568 patients with advanced cancers, plan switching was relatively infrequent, with 1.5% switching from TM-to-MA and 1.8% from MA-to-TM. Beneficiaries who switched plans were more likely to be racial or ethnic minorities and dual-eligible than those with continuous coverage. Hospice enrollment in the last year of life was highest for continuous MA (74.8%), followed by TM-to-MA (69.0%), continuous TM (68.5%), and MA-to-TM (66.4%). Enrollment within 14 days of death was similar across groups. The last hospice service was received at home by 49% of beneficiaries, followed by 7.6% at hospice facilities, 6.7% at nursing homes, and 5.3% at inpatient facility. Compared to continuous TM, continuous MA and TM-to-MA switching beneficiaries had higher likelihoods of receiving last hospice service at home (6.2 ppts and 3.0 ppts respectively, p-values<.01), while MA-to-TM beneficiaries had higher likelihoods of receiving last hospice service at nursing homes (1.7 ppts, p<.001). Beneficiaries who gained dual eligibility had increased likelihood of receiving last hospice service at nursing homes (25.8 ppts, p<.001) and decreased likelihood of receiving last hospice service at home (-23.5 ppts, p<.001) than non-dual-eligible beneficiaries. **Conclusions:** Continuous MA coverage was associated with greater likelihood of hospice utilization, particularly at home. In contrast, switching from MA-to-TM and gaining dual eligibility were associated with greater reliance on nursing homes for hospice care. Future research examining patient-centered outcomes across plan-switching patterns and addressing care coordination gaps to ensure equitable hospice care are warranted.
Research Sponsor: None.

11090 Poster Session

Disparate recovery of cancer screenings by demographic in traditional Medicare post-pandemic.

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Background: Cancer screenings are a pillar of public health and early diagnosis of cancer (doi.org/10.1016/j.soncn.2017.02.002) The COVID 19 pandemic impacted access to outpatient services, such as cancer screenings (doi:10.1001/jamaoncol.2022.5481) Our study aims to assess how this impact and the recovery following the 2020 pandemic differed by race and ethnicity in Traditional or Fee-For-Service Medicare (TM). **Methods:** Claims data on a 5% sample of TM included 1.3 million beneficiaries eligible for colorectal (CRC) cancer screenings and 736,000 females eligible for breast cancer (BC) screenings. This sample was followed for a multi-year cross sectional analysis using Medicare Beneficiary Summary Files from 2017 to 2023. Claims were linked to Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes to monitor annual utilization rates of screenings by demographic for BC and CRC. Utilization proportions were estimated based on the eligible population categorized by race/ethnicity and sex for BC. **Results:** Overall, screenings decreased in 2020 during the first year of the pandemic. BC screenings recovered quickly to pre-pandemic levels, comparing the 2019 pre-pandemic (35%) to 2021 post-pandemic (35%) rates overall in our TM sample. This was mirrored for women of non-Hispanic white (pre/post 36%), African American (pre: 33% post: 33%) and Asian/Pacific Islander (API; pre/post: 27%) groups in TM. These demographics nearly returned to 2019 rates by the 2nd year of the pandemic in 2021. American Indian/Alaska Natives (AIAN; pre: 22% post: 21%) and Hispanic women (pre: 27% post: 25%), however, did not return to pre-pandemic rates until 2022 and 2023 respectively. AIAN and Hispanic women also had the lowest utilization of BC screenings throughout our study period. CRC screenings had a slower recovery below 2019 levels (13%) in 2021 (12%), but recovering by 2023 (13%). This was mirrored across most racial demographics with the slowest recovery amongst AIAN (pre: 8%, post: 7%) and Hispanic (pre: 13%, post: 11%) beneficiaries. AIAN and African American beneficiaries displayed the lowest rates of CRC screenings throughout our study. **Conclusions:** Past research displayed decreased cancer screenings at the outset of the pandemic in 2020.[2,3] While services generally rebounded by 2021, the rate of recovery differed not only by screening type but also by demographic. BC screenings returned overall to 2019 rates by 2021. Hispanic and AIAN women lagged in recovery and utilized the lowest rates of BC screenings annually relative to the average TM beneficiary. CRC screening utilization saw a slower recovery, narrowly meeting 2019 levels by 2023. The lowest rates of CRC screenings were noted amongst African American and AIAN beneficiaries, who also struggled to recover to pre-pandemic (2019) levels by 2023. Our data highlights the disparate effects of the pandemic, especially for CRC screenings and certain racial demographics. Research Sponsor: Department of Health and Human Services.

11091 Poster Session

Workforce, economic, and infrastructural barriers to global oncology clinical trial participation: Focus on sub-Saharan Africa.

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Background: Despite Sub-Saharan Africa's (SSA) growing cancer burden, the region remains grossly underrepresented in global oncology clinical trials. With only 109 open trials identified continent-wide in 2019 compared to 7,557 in the United States, this disparity highlights systemic barriers. As well, the unique genetic variations in the African pan-genome makes a strong case for urgent population-specific research. **Methods:** Using the Pan African Clinical Trial Registry, we identified 151 oncology trials across 255 continent-wide recruitment sites. A review of published literature was carried out to assess oncologist distribution and SDI index within highlighted countries hosting clinical trials in SSA. **Results:** Of the 1,759 clinical oncologists identified in SSA, Egypt accounts for 85.2% (n=1,500) and hosts 46.36% of all oncology trials (n=70). Kenya, with only 0.34% oncologists (n=6), contributes 17.88% of clinical trials (n=27). Nigeria, with 3.63% oncologists (n=64), hosts 11.26% of trials (n=17). Ethiopia and Tanzania each house 0.34% oncologists (n=6), yet Ethiopia conducts 7.95% (n=12) and Tanzania 3.97% (n=6) of trials. South Africa, with 2.27% oncologists (n=40), hosts 3.97% of trials (n=6). Other countries, including Ghana and Morocco, collectively contribute to 8.61% of trials (n=13) with varying oncologist representation. The few available trials are mostly concentrated in Egypt, Kenya, and Nigeria. In addition, most trials disproportionately focus on breast and cervical cancer, with the added challenge of limited oncologist distribution. Infrastructure deficits, financial constraints, and cultural barriers further impede trial initiation and participation. **Conclusions:** Access to clinical trials remains a pillar of high-quality cancer care. Oncology research in SSA is hindered by multifaceted barriers, limiting the development of effective, region-specific therapies. Strategies to address these barriers include investing in the training of healthcare professionals, providing adequate infrastructure, increasing funding through public-private partnerships, and enhancing community engagement to build trust and improve trial participation. Research Sponsor: None.

Distribution of clinical oncologists, oncology trials, and SDI index across selected African countries.

African Countries with Oncology Clinical Trials	Number of Clinical Oncologists in Africa N=1759	% of Clinical Oncologists in Africa by Country	Number of Clinical Trials in Africa by Country	% of Clinical Trials in Africa by Country	SDI Index
Egypt	1500	85.2%	70	46.36%	Middle
Kenya	6	0.34%	27	17.88%	Low-Middle
Nigeria	64	3.63%	17	11.26%	Low-Middle
Ethiopia	6	0.34%	12	7.95%	Low
South Africa	40	2.27%	6	3.97%	Middle
Tanzania	6	0.34%	6	3.97%	Low-Middle
Ghana	10	0.57%	5	3.31%	Low-Middle
Morocco	28	1.59%	1	0.66%	Low-Middle
Others	99	5.63%	7	4.64%	
Total	**1759**	**100%**	**151**	**100%**	

11092 Poster Session

Financial toxicity for cancer patients: Out-of-pocket costs by cancer diagnosis in traditional Medicare.

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Background: Financial toxicity is defined as the fiscal issues that can arise in a patient's life related to the costs of medical care (DOI: 10.1093/tbm/ibab091). These can include financial distress, resource rationing and even medical debt. A patient's spending obligation is measured through out-of-pocket costs (OOP) which are comprised of copayments, co-insurance and/or deductibles (DOI: 10.18553/jmcp.2022.21270). Cancer patients face especially high costs and potentially greater risk of financial distress compared to other illnesses (DOI: 10.1093/tbm/ibab091). An American Cancer Society survey of 1,218 cancer patients/survivors found that over half (51%) of respondents reported medical debt resulting from cancer treatment despite nearly all (98%) having active insurance (https://www.fightcancer.org/policy-resources/costs-cancer-survivorship-2022). Our study aims to qualify and quantify the cancers with the highest out-of-pocket costs for beneficiaries in Traditional, or Fee-for-service, Medicare (TM) to determine cancers that expose patients to the highest financial risk. **Methods:** A 5% sample of TM beneficiaries in 2023 was collected, which included 1.3 million individuals and 261,099 unique beneficiaries with some form of cancer. Beneficiary claims were categorized by International Classification of Disease (ICD-10) coded cancer diagnoses. Patient OOP costs were aggregated across inpatient, outpatient and prescription drug settings using Medicare Beneficiary Summary File (MBSF) and Prescription Drug Event (PDE) claims data across Parts A, B and D Medicare, respectively. Costs per beneficiary were sorted by highest average out-of-pocket cost per beneficiary organized by cancer diagnosis. Comparison groups in our sample included a cohort of TM beneficiaries with any type of cancer and beneficiaries without cancer. **Results:** The 5 cancers with the highest average out-of-pocket costs annually in 2023 were multiple myeloma ($14,400), acute leukemia ($10,498), biliary cancers ($9,725), hepatocellular carcinoma ($9,469) and pulmonary (small and non-small-cell) cancers ($8,572). This is relative to TM beneficiaries with any cancer who spent an average of $4,800 annually OOP in 2023 and $2,364 for beneficiaries without cancer in TM. Prescription drugs are a substantial component of OOP cost for certain cancers. For multiple myeloma and acute leukemia, 19.8% and 21.5% of OOP costs were attributable to prescriptions compared to 8.6%, 8.1% and 10.2% for biliary, hepatocellular and lung cancer, respectively. **Conclusions:** Cancer is expensive for Medicare patients in the United States. These OOP costs can pose severe affordability issues for TM beneficiaries, who had an average income of $36,000 annually in 2023 (https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-in-2023/). Within TM, patients with multiple myeloma, acute leukemia, biliary, hepatocellular and lung cancers experience especially high costs and have an elevated risk of financial toxicity. Multiple myeloma and acute leukemia notably have significantly higher prescription cost-sharing through Part D compared to high-cost solid tumors. Research Sponsor: Department of Health and Human Services.

11093 Poster Session

Climate change and cancer: An ecological evaluation of climate risks for cancer survivors.

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Background: Changes in climate patterns will influence the frequency and severity of extreme weather events, leading to increased disasters (e.g., floods, fires), air pollution levels, and climate-related costs. Cancer survivors may suffer disproportionate effects of climate change-related events on mental health, care disruptions, morbidity, and mortality, yet evaluations of area-level climate risks and cancer survivorship are lacking. We examined future climate change risks faced by communities with high levels of cancer mortality. **Methods:** Data were from the Climate Vulnerability Index, a county-level measure of future climate change risks (45 variables) alongside a baseline vulnerability index (BVI) including health, socioeconomic, and environmental factors (139 variables). Variables ranging from 0 (least vulnerable) to 100 (most vulnerable) were split into high (rank $\geq$50) vs. low (rank $<$50) categories and linked to county-level cancer mortality data from the NCI's SEER registry. We compared the top quartile of the U.S. population living in counties with the highest cancer mortality rates (54.7% of counties) to other areas. Data were randomly split using a 2:1 training/validation ratio. We identified candidate variables in bivariate analyses between climate risk factors (RFs) and area-level cancer mortality. Best-subset selection with logistic regression and K-fold cross-validation was used to derive a parsimonious model of adverse RFs. These were summed, creating a score, and split at the median to test in the validation set. All analyses were adjusted for the BVI. **Results:** Overall, N=3,139 counties were examined. In the training set (n=2,094), a model with 6 RFs was identified including weather-related events (increased hurricane, tornado, and precipitation exposure), air pollution factors (increased ozone/CO2 levels), increased climate-related costs, and future economic/productivity losses. Compared to low cancer mortality counties, high cancer mortality counties were more than threefold more likely to have high exposure to the 6 climate RFs (69.6% vs. 30.4% with 3-5 factors; OR=3.07, 95% CI, 2.52-3.74, p$<$.0001). In the test set (n=1,045), results were similar, validating the model. Overall, the BVI-adjusted model C-statistic was 0.80 (unadjusted, 0.73). The association of high cancer mortality areas and high exposure to climate RFs was evident for both high (OR=3.87, p$<$.0001) and low (OR=2.75, p$<$.0001) BVI counties. **Conclusions:** In this first-of-its-kind ecologic association study, we found that living in counties with high cancer mortality was associated with future climate change risks including extreme weather events, air pollution, climate-related costs, and economic factors. Future work is needed to identify potential mechanisms between climate events and worse cancer outcomes such as decreased treatment tolerability, treatment quality, or treatment access. Research Sponsor: None.

Preliminary efficacy of VOICE, a decision support tool for older adults with advanced cancer: A pilot randomized trial.

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Background: Quality shared decision-making (SDM) requires integrating patient values into treatment decisions. Many older patients (pts) with cancer report that clinicians do not elicit their values when making treatment decisions. We developed a decision support tool for older adults with advanced cancer (called VOICE) with values elicitation, real-time feedback to patients, and tailored question prompt lists. Prior research suggests that variation in clinician behavior may impact the efficacy of SDM tools. **Methods:** We evaluated the preliminary efficacy of VOICE to improve SDM quality in a pilot double-blinded randomized trial. We enrolled pts $\geq$ 60 years with advanced solid cancers. Pts were randomized to receive VOICE or an American Cancer Society (ACS) educational document with general cancer-related question prompts. Pts completed 2 simulated consultations where they made a treatment decision for a fictional secondary cancer diagnosis: one values-based (VB), where clinicians initiated values elicitation, and one non-values-based (NVB), where clinicians did not. Logistic regression, Fisher's exact and Mann-Whitney tests evaluated the relationship of trial arm and clinician behavior to pt reports of SDM quality (CollaboRATE) and perceived usefulness of intervention (PrepDM). Five medical students, trained in VB and NVB consultations, functioned as clinicians during consultations. All consultations were recorded and analyzed for fidelity. **Results:** Forty-four pts (ages 60-88; 50% female; 86% Caucasian, 7% Black, 7% other) with advanced cancer (34% prostate, 23% breast, 18% lung, 11% melanoma, 14% other) were randomized and completed 88 consultations. Pts were more likely to report quality SDM for VB over NVB consultations (Odds ratio [OR] 2.57, 95% Confidence Interval [CI] 1.09-6.25, p=0.03). Pts reported VOICE was more useful to inform SDM than ACS document (mean PrepDM score 65.1 v. 17.4, $p<0.001$). Pts in the VOICE arm were more likely to report quality SDM (OR 1.70, 95% CI 0.73-4.04) but this did not reach statistical significance (p=0.22). The difference in the percentage of patients reporting high-quality SDM between arms was larger for NVB (43% VOICE v. 22% ACS) than for VB consultations (57% VOICE v. 52% ACS) though not statistically significant. **Conclusions:** This study demonstrates the value of using simulated encounters for "early-phase" testing of SDM tools. In this pilot randomized trial using simulated clinical encounters, clinician initiation of a discussion of patient values resulted in the highest quality of SDM regardless of study arm. VOICE improved preparation for SDM and showed encouraging preliminary data for its potential to improve the quality of SDM for older adults with advanced cancer especially when clinicians did not engage in values elicitation. Further research is needed to improve values elicitation as part of treatment decision-making. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; 1K08CA273684.

11095 Poster Session

The studies industry neglects: Characteristics of cancer clinical trials conducted by federal versus industry sponsors.

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Background: A defining feature of federally sponsored cancer clinical trials is their mandate to examine clinical research questions not routinely addressed by industry, which is financially incentivized to conduct trials that support new drug applications to the FDA. Yet no evaluation has quantified the types of trials federal versus industry sponsors conduct. These data are vital for policymakers given the need to prioritize federally sponsored trials in a clinical research landscape increasingly dominated by industry sponsorship. **Methods:** We analyzed registry data from ClinicalTrials.gov between 2008-2022. U.S.-based interventional trials for patients with cancer were included. Studies were categorized by lead sponsor (federal versus industry) and by purpose, phase, intervention, de-escalation, rare cancer, and age. Odds ratios were calculated. Chi-square tests were used. **Results:** Overall, N=9,626 federal (n=1498, 15.6%) and industry (n=8128, 84.4%) sponsored studies were examined. Most studies were conducted for treatment (federal, 92.8%; industry, 97.5%). Federally sponsored studies were more commonly prevention (5.3% vs 1.2%, OR=4.69, p<.001), screening (1.0% vs 0.4%, OR=2.73, p=.003), and early phase (91.6% vs 81.6%, OR=1.77, p<.001) studies (Table). Federally sponsored studies were more commonly multi-modality studies combining drug and biologic agents (24.3% vs. 7.4%, OR=3.28, p<.001) or systemic therapy with radiation or surgery. Federally sponsored studies also more commonly tested dose de-escalation strategies (1.5% vs 0.6%, OR=2.68, p<.001) and were more often conducted in rare cancers and in children. **Conclusions:** Non-treatment interventions, early phase, multi-modality, dose de-escalation, rare cancer, and child-focused studies were much more likely to be conducted by federally sponsored research groups than by industry. These findings highlight the unique role of federally funded studies in cancer clinical research. Research Sponsor: The Hope Foundation.

Federal- versus industry-sponsored study characteristics.

		Federal		Industry			
Study Characteristic	Category	N=1498	%	N=8128	%	Odds ratio (Fed/Ind)	P-value
Purpose	Prevention	74	5.3	89	1.2	4.69	<.001
	Screening	14	1.0	28	0.4	2.73	.003
	Supportive Care	13	0.9	74	1.0	0.95	1.0
	Treatment	1304	92.8	7504	97.5	0.56	<.001
Phase	1 or 2	1288	91.6	6307	81.6	1.77	<.001
	3	118	8.4	1424	18.4	0.40	<.001
Intervention	Biological (B)	97	8.1	668	8.9	0.77	.39
	Drug (D)	654	54.4	6180	82.1	0.24	<.001
	D & B	292	24.3	558	7.4	3.28	<.001
	D/B & Radiation	120	10.0	104	1.4	6.72	<.001
	D/B & Surgery	39	3.2	15	0.2	14.46	<.001
Dose de-escalation	Yes	23	1.5	47	0.6	2.68	<.001
Rare cancer[1]	Yes	284	19.0	977	12.0	1.71	<.001
Age category	Child[2]	192	12.8	451	5.5	2.50	<.001

Fed=Federal; Ind=Industry. Percentages and p-values calculated among those in the specified categories. "Other" categories not shown.
[1]Cancers that affect <40,000 U.S. persons/year.
[2]Studies that include those <18 years.

Early examination of national changes in potentially avoidable hospital visits after chemotherapy, 2018–2022.

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Background: Medicare tallies potentially avoidable hospital visits after chemotherapy and has been publicly reporting this quality measure since 2018. The measure reports absolute visit rates for emergency department (ED) and inpatient admission (ADM), and generates relative comparisons to national rates ("better than", "no different than", "worse than"). We sought to identify changes in avoidable hospital visit rates through 2022. **Methods:** Retrospective analysis of avoidable hospital visit rates from 2018 – 2022, from a longitudinal cohort of hospitals in the Medicare Outpatient Quality Reporting Program. We performed descriptive and trend analysis for absolute visit rates and for relative performance. We stratified hospitals into quartiles of absolute performance in 2018, then applied multivariate generalized linear regression to model change in visit rates by 2022. We estimated the contribution of regression to the mean. **Results:** We analyzed 1,179 hospitals (23% teaching). National avoidable ED visit rates were 6.0% in 2018, 5.4% in 2022; ADM rates were 12.5% in 2018, 10.3% in 2022. Nearly all hospitals were deemed to have performed "no different" than the national rate each year for ED (≥ 95.3%) and ADM (≥ 91.1%). In adjusted analyses, visit rates for hospitals in the lowest 2018 visit rate quartiles declined the least by 2022 (ED: -0.44% 95% CI: -0.58 to -2.94; ADM: -0.91%, 95% CI: -1.14 to -0.69), but declined the most for hospitals in the highest 2018 quartiles (ED: -1.72%, 95% CI: -1.85 to -7.73; ADM: -3.03%, 95% CI: - 3.27 to -2.81). We estimated that regression to the mean accounted for a small proportion of the decline among the highest 2018 quartile of hospitals (ED: 10.6% of rate change, 95% CI: 9.8 to 11.5; ADM: 9.0%, 95% CI: 8.2 to 9.8). **Conclusions:** It appeared that nationally, and within quartiles of hospital performance, hospitals had improved their performance on this outpatient chemotherapy quality measure. Regression to the mean accounted for only a small proportion of this change, but the decline may reflect overall lower hospital visits post-COVID19 pandemic. Research Sponsor: U.S. National Institutes of Health; CA282242.

	Unadjusted Mean 2018 rate (SD)	Unadjusted Mean 2022 rate (SD)	Unadjusted mean absolute difference, 2022 – 2018 (SD)	Adjusted absolute difference, 2022 – 2018 (95% CI)
ED rate 0-25% (lowest rates)	5.00 (0.39)	5.06 (0.80)	0.07 (0.77)	0.18 (-0.14, 0.51)
ED rate 26-50%	5.71 (0.14)	5.41(0.82)	-0.29 (0.83)	-0.44 (-0.58, -0.29)***
ED rate 51-75%	6.28 (0.20)	5.52 (0.89)	-0.76 (0.89)	-0.91 (-1.04, -0.77)***
ED rate 76-100%	7.36 (0.63)	5.85 (0.63)	-1.51 (1.06)	-1.72 (-1.86, -1.57)***
ADM rate 0-25% (lowest rates)	10.79 (0.66)	10.03 (1.35)	-0.76 (1.35)	-1.00 (-1.53, -0.49)***
ADM rate 26-50%	12.08 (0.28)	10.42 (0.29)	-1.66 (1.31)	-0.91 (-1.14, -0.69)***
ADM rate 51-75%	13.12 (0.36)	10.64 (1.38)	-2.48 (1.41)	-1.75 (-1.97, -1.52)***
ADM rate 76-100%	14.94 (1.02)	11.20 (1.52)	-3.74 (1.58)	-3.03 (-3.27, -2.81)***

***p value <0.001.

11097 Poster Session

Impact of social determinants of health on mortality in diffuse large B-cell lymphoma (DLBCL) using real-world data.

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Background: Treatment advances in DLBCL have led to remarkable improvements in patient outcomes. Social determinants of health (SDOH) can contribute to inequities in outcomes in multiple cancer types, and there is a paucity of studies evaluating their impact in DLBCL. **Methods:** We used the nationwide Flatiron Health electronic health record derived de-identified database and included adults with a confirmed diagnosis of DLBCL from 2011-2024 to evaluate the association between SDOH and real-world overall survival (from time of initial treatment). Area-level SDOH variables were derived from the Census Bureau's American Community Survey and the 2019 AHRQ's SDOH database. These census tract level measures were grouped into US population-weighted quartiles and evaluated across the following domains: economic, social (including racial segregation), neighborhood & physical environment, and healthcare. We estimated adjusted hazard ratios (aHR) for the highest social deprivation quartile (least resourced areas) compared to the lowest quartile using Cox proportional hazard models, adjusting for age, sex, race/ethnicity, LDH, ECOG, presence of extranodal disease, stage, and cell of origin. **Results:** We included 6,855 patients in the analysis. After adjustment, residence in areas with the highest social deprivation was consistently associated with increased mortality across all SDOH domains compared with the lowest deprivation areas. A higher risk of death (> 20%) was found for patients residing in predominantly Black vs. White neighborhoods, those residing in medically underserved areas, and areas with the lowest levels of private insurance. Similarly, residence in areas with the least access to the internet, computing devices, and cellular data plans was associated with increased mortality risk. **Conclusions:** Higher SDOH deprivation was significantly associated with increased mortality among patients with DLBCL, despite controlling for demographic and clinical factors. The SDOH influencing mortality ranged from socioeconomic and technological inequities to limited healthcare access and racial segregation. These factors may aid improved prognostication of DLBCL, and future studies should focus on developing interventions to mitigate SDOH-linked inequities in DLBCL. Research Sponsor: None.

	aHR	95% CI	Domain
Households that received food stamps/SNAP	1.15	1.02, 1.29	Economic
Households with no internet access	1.15	1.02, 1.29	Neighborhood
Households without a computing device	1.12	1.00, 1.26	Physical
Households without cellular data plan	1.13	1.00, 1.26	Environment
Medically underserved area	1.20	1.02, 1.40	Healthcare
Population private health insurance (≤ 64)	1.24	1.10, 1.39	
Population TRICARE/military/ VA insurance only (≤64)	1.17	1.05, 1.30	
Population no health insurance (≤64)	1.18	1.06, 1.33	
Residential Segregation Blacks (reference: Whites)	1.23	1.01, 1.51	Social

11098 Poster Session

Integration of a virtual personalized medicine review board integration into a major community oncology phase 1 unit.

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Background: Inclusion criteria for participating in oncology clinical trials have grown more complex, often challenging the enrollment process. Our objective was to improve the process of identifying and enrolling patients by incorporating personalized medicine assistance into the initial patient intake and trial selection procedure at a major community-based phase 1 oncology unit. **Methods:** A virtual personalized medicine review board (vPMRB) comprised of two PhD scientists reviewed patients for suitable trial options based on molecular sequencing results and scientific rationale during the intake and screening processes at a phase I oncology clinic. vPMRB reviews leveraged a propriety clinical trial identification software, Genospace, to generate patient-trial matches based on general inclusion/exclusion criteria including disease, histology, staging, and biomarker criteria. Trial options were returned via email and added to patients' charts in the electronic health record for reference by their clinical care team. Trial candidates were screened for trial options and consented for treatment on trial by the enrollment nursing (ERN) team. Data pertaining to vPMRB review, trial screening, trial consent, and trial enrollment were collected by the vPMRB and ERN teams and combined to determine consent and enrollment rates. **Results:** Between 1/1/2024 and 12/31/2024, 953 patient reviews for 815 unique patients were completed by the vPMRB with an average turnaround time of 4 ± 5 business hours. 900 (94%) of these reviews included potential trial options for the patient. Of 790 reviewed patients with sufficient information for comparison with enrollment team data, 473 (60%) were screened for trial options by the ERN team in 2024. Of these, 343 (73%) consented to a trial and 270 (57%) started trial treatment in 2024. Comparatively, of the 744 patients reviewed for trial options by the ERN team, but not the vPMRB, 431 (58%) were consented to a trial and 313 (42%) started trial treatment in 2024. 167 (35%) patients consented to a trial and 130 (28%) patients started a trial recommended by the vPMRB for that patient in 2024. **Conclusions:** vPMRB review was associated with increased trial enrollment compared to patients without vPMRB review. Upcoming research will explore the effects of further personalized medicine integration techniques, including the involvement of team members in therapeutic strategy meetings held by clinical care teams, along with the use and effectiveness of clinical trial matching software in a phase 1 unit. Research Sponsor: None.

Trial consenting and screening rates in 2024 for patients with and without vPMRB review.

	vPMRB Review	No vPMRB Review
Patients screened for trial by enrollment team	473	744
Consented on Trial	343 (73%)	431 (58%)
Started Trial	270 (57%)	313 (42%)
Consented on trial surfaced in vPMB review	167 (35%)	N/A
Started on trial surfaced in vPMB review	130 (28%)	N/A

11099 Poster Session

Temporal trends in opioid prescription fills following cancer-directed surgery.

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Background: Postoperative pain is a common complication of cancer surgery. Opioid prescribing has declined dramatically since the early 2010's; however, little is known about trends in opioid prescribing following cancer-directed surgeries. **Methods:** Using administrative data for 100% Medicare fee-for-service beneficiaries enrolled in parts A, B, and D, we identified initial episodes of cancer-directed surgeries from 2012-2021 among adults who survived > 30d after surgery and were discharged home. We used Part D claims to identify early postop opioid fills, defined as prescriptions filled in the 30d after surgery for outpatient surgeries, and in the 30d following hospital discharge for inpatient surgeries. We described opioid fills, median dose, pill counts, and the proportion with subsequent fills overall and annually. **Results:** We identified 981,702 episodes of cancer directed surgeries, most often for breast (38%), colorectal (15%), prostate (13%), and lung (10%) cancers. Patients' mean age was 73(SD,8), 36% were male, 83% White, 8% Black, 4% Hispanic, and 2% Asian. Overall, 66.6% of patient episodes had ≥1 postoperative opioid fill, declining from 70.7% in 2012 to 59.3% in 2021. Among episodes with ≥1 opioid fill, the median dose of the first opioid fill declined from 225 (IQR:150,300) morphine milligram equivalents (MMEs) to 100 (IQR:75,150) MMEs between 2012-2021, and the total dose of all fills in 30d fell from 250 (IQR:150,450) MMEs to 112.5 (IQR:75,210) MMEs. Median pill counts for the first short-acting opioid fill declined from 30(IQR:30,40) to 18(IQR:10,25) over the study. Among episodes with ≥1 short-acting opioid fill, the proportion with subsequent short-acting opioid fills declined from 30.7% to 17.8%. **Conclusions:** Medicare beneficiaries undergoing cancer-directed surgeries have experienced steep declines in prescription opioid medication fills in the postoperative period. Future work is needed to understand potential impacts of declining postoperative opioid prescribing on outcomes such as uncontrolled pain, pain-related emergency department visits, persistent opioid use, and development of opioid use disorders. Support: R01CA279414. Research Sponsor: None.

11100 Poster Session

Integrative oncology interest in persons with a cancer diagnosis.

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Background: Integrative oncology (IO) is an evidence-informed field of cancer care that utilizes mind-body practices, natural products, and lifestyle medicine from different traditions alongside conventional therapies. With growing evidence of benefit and inclusion in guideline recommendations, the Sidney Kimmel Comprehensive Cancer Center (SKCCC) at Thomas Jefferson University's integrative oncology program assessed patients' understanding of integrative health, their utilization of integrative medicine approaches, and interest in formal IO consultations. **Methods:** Persons with a history of cancer who presented for care at a SKCCC clinical site received an electronic record invitation to complete a brief survey with binary and free-response questions regarding current knowledge, experiences, and interest in IO. At the end of the survey, patients also had the option to express their interest in IO consultations at SKCCC. **Results:** Demographics for the 1681 responders were: 1116 (67.1%) were female; 1285 (76.4%) were between 45-75 years of age; 313 identified as Black or African American (19.0%) and 1276 as White (77.5%). Breast cancer (494, 29.37%) and hematologic cancers (289, 17.18%) were the most reported malignancies. Overall, 446 (27.4%) and 153 (9.3%) had previously utilized in-person IO services and virtual IO services, respectively. 1,133 (67.36%) reported that IO was never discussed during their care. 1201 (73.9%) expressed interest in an IO consultation. Black or African American participants had 117% higher odds of expressing an interest in IO consultation (OR: 2.17, 95% CI: 1.52 – 3.09, $p<0.001$) compared to all other participants. **Conclusions:** In contrast to the prevalence of IO approaches in literature, only one third of patients who completed the survey had previously used an IO modality. However, nearly 70% expressed interest in a formal IO consultation. Due to the overwhelming interest, an IO information session hosted by a Board-Certified Medical Oncologist and Integrative Oncologist is being offered. 250 (14.9%) participants have requested appointments so far. With the increasing evidence of benefit for IO care and the inclusion of these recommendations in clinical guidelines, expansion of IO services, especially those which focus on Black or African American participants who are usually not reached by these interventions, is indicated. IO consultations can address knowledge gaps, enhance implementation of guideline-based care, and, perhaps, improve clinical outcomes. Research Sponsor: None.

11101 Poster Session

Utilization and timeliness of next-generation sequencing testing for patients with resected or metastatic non-small cell lung cancer: A real-world analysis.

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Background: Comprehensive next-generation sequencing (NGS) is an evidence-based molecular testing modality used to identify actionable oncogenic drivers in tumor tissue, guiding therapy selection and improving survival in early-stage and metastatic non-small cell lung cancer (NSCLC). However, uptake of NGS in oncology practices varies. This study aimed to identify hospital-level variation in NGS testing adoption within a statewide quality improvement collaborative. **Methods:** We conducted a cross-sectional analysis of patients with clinical Stage IB-IIIA NSCLC who underwent surgical resection and clinical Stage IV NSCLC sampled in 2023 across 10 academic, community, and integrated network hospitals in a statewide cancer quality improvement collaborative. Rates of NGS testing and turnaround times between biopsy date, NGS order date, NGS result date, and first treatment time were analyzed. Subsets of patients treated at facilities with in-house molecular labs or reflex molecular testing protocols were described. Multivariable logistic regression identified demographic and clinical predictors of NGS use. In a subset of patients with EGFR or ALK mutations, we evaluated tyrosine kinase inhibitor (TKI) use across hospital sites. **Results:** Among 318 patients, 34.9% had clinical Stage IB-IIIA and 65.1% had clinical Stage IV lung adenocarcinoma. NGS testing was performed in 65.1% of patients, with rates ranging from 13.5% to 97.8% across sites. Facilities with in-house NGS capabilities had higher NGS rates (87.8%) compared to facilities relying on send-out testing (50.8%). Similarly, facilities with reflex molecular testing protocols demonstrated higher NGS rates (75.4%) compared to those without reflex protocols (50.4%). Among patients with EGFR or ALK mutations, 77.8% received TKI therapy, with rates ranging from 0% to 100%. Of 113 early-stage patients, 32 (28.3%) had NGS performed pre-resection, 36 (34.0%) post-resection, and 40 (37.7%) did not have NGS performed. Across all sites, the median time from biopsy to NGS order was 29 days (IQR 20–49), from order to results was 13 days (IQR 11–18), and from biopsy to treatment initiation was 42 days (IQR 31–58). Smoking status was an independent predictor of NGS use with OR 0.28 (0.13-0.61, p=0.002). **Conclusions:** Significant variation exists in NGS adoption across hospital sites in a statewide quality improvement collaborative. However, turnaround times were consistent across sites. These benchmarking data, combined with qualitative insights, can inform quality improvement interventions for underperforming sites. Research Sponsor: AstraZeneca Pharmaceuticals LP.

Health-related quality of life and financial toxicity among patients with gynecological cancers in southern Nigeria: A multicenter cross-sectional study.

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Background: Gynecological cancer-related morbidity and the financial burden of care impact the quality of life of patients. However, the health-related quality of life (HRQoL) and experience of financial toxicity (FT) of affected women in sub-Saharan Africa have not been sufficiently explored. This study assessed predictors of HRQoL and FT, and the effect of FT on HRQoL among women with gynecological cancers in Nigeria. **Methods:** This hospital-based cross-sectional study investigated consenting women with gynecological cancers receiving care at various stages at five academic hospital centers in southern Nigeria, between June 2022 and September 2024. The main outcomes were HRQoL and FT evaluated using the FACT-G and FACIT-COST tools, respectively. Patients' sociodemographic and clinical characteristics were additionally retrieved using a structured questionnaire. Multivariable linear regression models estimated the associations of patient and disease characteristics with HRQoL and FT, and the effect of FT on HRQoL, adjusting for potential confounders. Ethical approval was obtained from all centers. **Results:** Overall, 574 women were recruited with a mean FACT-G score of 58 (SD ± 15) and a median FACIT-COST score of 16. Of these, 92.8% experienced FT, with 42.6% having moderate-to-severe FT. After multivariable adjustments, HRQoL was significantly poorer among unemployed women (β = -2.4; 95%CI: -4.8, -0.02; p= .048), women with ovarian (β = -3.4; 95%CI: -6.4, -0.4; p= .028) and uterine cancers (β = -3.8; 95%CI: -7.0, -0.6; p= .021) and choriocarcinoma (β = -7.8; 95%CI: -15, -0.2; p= .045), and women with stages II (β = -4.6; 95% CI: -7.7, -1.6; p =.003), III (β = -5.5, 95%CI: -8.9, -2.2; p= .001), and IV disease (β = -4.6; 95%CI: -8.7, -0.4; p= .031). Conversely, patients in remission had significantly better HRQoL (β = 9.3; 95%CI: 5.0, 14; p< .001). FT was worse with stages III (β = -2.2; 95%CI: -4.0, -0.4; p =.016) and IV disease (β = -5.4; 95%CI: -7.6, -3.2; p <.001), and in women on active treatment (β = -2.9; 95%CI: -4.4, -1.3; p< .001). However, older women (β per 10-year increase in age = 0.6; 95%CI: 0.1, 1.1; p= .029), those with health insurance (β = 3.4; 95%CI: 1.4, 5.5; p <.001), higher income (β per 1000 Naira = 0.02; 95%CI: 0.01, 0.03; p= .004), ovarian cancer (β = 1.9; 95%CI: 0.3, 3.6; p= .021) and choriocarcinoma (β = 6.7; 95%CI: 2.6, 11; p= .001) had lower FT. FT scores varied linearly with HRQoL after adjustments, with better HRQoL per unit lower FT (β = 0.46; 95% CI: 0.3, 0.6; p< .001). This effect was more pronounced in women with a first tumor (β = 0.53; 95% CI: 0.4, 0.7; p <.001), those in pre-treatment (β = 0.69; 95% CI: 0.4, 1.02; p <.001) and those in remission (β = 0.69; 95% CI: 0.04, 1.3; p =.037). **Conclusions:** Our findings identify possible predictors of HRQoL and FT, and suggest potential benefits of reducing FT on the HRQoL of women with gynecological cancers in Nigeria. Research Sponsor: None.

11103 Poster Session

Patient preference for first-line treatments of ALK-positive metastatic non-small cell lung cancer: A discrete choice experiment.

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Background: For patients with ALK-positive metastatic NSCLC, targeted therapy with ALK inhibitors is a recommended first-line treatment. The development and approval of ALK-TKIs have resulted in longer survival benefits for patients with ALK-positive mNSCLC. Three generations of ALK-TKIs are now available, varying in efficacy and side effects. Therefore, it is important to identify patients' priorities and the benefit-risk trade-offs patients are willing to make among potential treatment options. This study quantified the preferences of patients for attributes of ALK-positive mNSCLC first-line treatment. **Methods:** An online discrete choice experiment was conducted to elicit the preferences of Patients with ALK-positive mNSCLC and their family members (both decision-makers for the treatment). Respondents completed multiple hypothetical treatment profiles characterized by 7 attributes, including progression-free survival (PFS), reduced risk of brain metastasis, intracranial complete response (iCR), degree of cognitive side effects, risk of liver damage, risk of severe hyperlipidemia and the dose reduction rate. Data were analyzed using a conditional logit model and mixed logit model. **Results:** Respondents (N=115) placed most value on PFS (RI=58.13%), followed by reduced risk of brain metastasis (RI=13.04%). Attributes related to side effects were considered less critical in respondents' decision-making. Respondents exhibited a willingness to accept an increased risk of treatment for improved clinical outcomes. When the degree of side effects was altered from mild to moderate, respondents require a minimum increase of 5.34 months in PFS as compensation to maintain the same utility. Scenario analysis estimated 97.06% of respondents would endorse the new treatment option if the PFS was improved from 36 months to 60 months. Subgroup analysis revealed that the preference patterns of patients and their families are similar. However, respondents' preferences exhibit heterogeneity for patients with different brain metastasis status, age, and annually household income. **Conclusions:** This is currently the first patient preference study for First-Line Treatments of ALK-positive mNSCLC. The results revealed that patients' decision makers place the highest priority on PFS, with comparatively less emphasis on side effects, and they are willing to accept a higher risk of side effects in exchange for prolonged survival. Understanding these preferences can enhance shared decision-making between patients and clinicians, fostering personalized prophylactic treatment plans that may optimize adherence and improve clinical outcomes. Research Sponsor: None.

11104 Poster Session

Characterizing unmet supportive care needs in diverse adolescent and young adult cancer survivors.

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Background: Research addressing the supportive care needs of diverse adolescent and young adult (AYA) cancer survivors remains underdeveloped relative to younger and older cancer survivor populations. Given their distinct developmental, psychosocial, and healthcare challenges, it is critical to characterize the unmet supportive care needs (USCN) specific to AYAs. This study aimed to compare self-reported USCN between AYA and older (>39 years old) cancer survivors to identify age-specific gaps in care and opportunities to improve outcomes. **Methods:** Between October 2019 and October 2024, 20,520 cancer survivors (n=1,287 AYA and n=19,233 non-AYA) at Sylvester Comprehensive Cancer Center completed the *My Wellness Check* (MWC) questionnaire. *MWC* is fully integrated and scored in real-time in the electronic health record, and evaluates 16 domains of supportive care needs (e.g., stress management, financial concerns, informational resources, transportation) alongside patient-reported outcomes (PROs; PROMIS measures of pain interference, fatigue, physical function, anxiety, and depression) and health-related quality of life (HRQOL; FACT-G7). Sociodemographic and clinical characteristics and the prevalence of USCNs were compared between AYA and other cancer survivors using chi-square and t-tests. **Results:** The AYA group had a higher proportion of females (64% vs. 51%), non-White (20% vs. 14%), Hispanic (56% vs. 44%), uninsured (4% vs. 3%), and unpartnered individuals (59% vs. 34%) compared to non-AYAs (all $ps < 0.01$). Across both groups, the most frequently reported USCNs were general cancer education (11%), coping with a cancer diagnosis (11%), and financial concerns (9%). AYAs were more likely to report at least one USCN compared to non-AYA survivors (33% vs. 28%). AYAs were also more likely to endorse needs related to coping with a cancer diagnosis (14% vs. 11%), financial concerns (12% vs. 9%), work-related issues (6% vs. 3%), oncofertility (10% vs. 1%), and childcare (3% vs. 0.5%) (all $ps < 0.001$). No significant differences were observed for other USCN, including transportation, housing, family problems, sexual health, spiritual concerns, access to medicines, and advance directives. **Conclusions:** While both AYA and non-AYA cancer survivors face substantial unmet supportive care needs, AYAs exhibit additional challenges, particularly in areas such as financial concerns, work-related issues, fertility preservation, and childcare. These findings align with prior research while uniquely emphasizing the unmet needs of a more ethnically diverse population. This study underscores the urgent need for targeted assessments and interventions to address the unique supportive care needs of AYA cancer survivors, ensuring equitable and age-appropriate survivorship care. Research Sponsor: None.

11105 Poster Session

Understanding psychosocial wellbeing and concern for death and dying: Insights from a psycho-oncology clinic.

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Background: Patients with cancer face burden of mental health symptoms and an ongoing concern for death and dying. The psycho-oncology clinic aims to address these concerns by integrating mental health services into cancer care. This study evaluates key domains of psychosocial health and their relationship with mortality salience. **Methods:** Data from 60 patients treated at a psycho-oncology clinic were analyzed. Demographics, cancer site, disease stage (localized vs. metastatic), treatment status, and psychiatric diagnoses were collected. Outcomes were assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Forms, including measures of Emotional Distress (Anxiety, Depression, Social Isolation), Meaning and Purpose, Psychosocial Illness Impact (Negative and Positive), and Concern for Death and Dying. Descriptive and univariate regression analyses explored cohort trends. **Results:** Among the 60 patients, the mean age was 63 years (SD=14.8), with 52.2% identifying as female, 45.5% as male, and 2.3% as non-binary. The most common primary cancer sites were lung (20.5%), breast (18.2%), and multiple myeloma (9.1%). Of the patients, 61.4% had localized disease, while 38.6% had metastatic disease. A significant proportion (79.6%) were undergoing active treatment. Calculated t-scores demonstrate that concern for death and dying was more than two standard deviations above the population mean while meaning and purpose was lower. Metastatic disease, higher levels of anxiety, depression, negative psychosocial illness impact, and a lower sense of meaning and purpose were all associated with greater concern for death and dying. **Conclusions:** This study highlights the high prevalence of concern for death and dying in patients who are referred to a psychosocial oncology clinic and its association with key psychological variables for which there are standard treatments. PROMIS measures offer valuable insights, underscoring the importance of comprehensive psychosocial assessments. Tailored interventions targeting emotional distress, meaning, and end-of-life concerns may improve patient outcomes. Research Sponsor: None.

Variables	Mean (SD)	Calculated t-score* [SE]	Regression	
Death & Dying Concern	25.2 (8.5)	71 [3.5]	95% CI	p-value
Age	63 (14.8)	-	(-0.1-0.22)	.48
Localized vs Metastatic	-	-	**(2.0-11.3)**	**.006**
Anxiety	20.5 (6.7)	58.4 [2.0]	**(0.31-0.91)**	**<.001**
Depression	17.0 (7.3)	54.5 [3.1]	**(0.31-0.84)**	**<.001**
Meaning & Purpose	27.8 (7.6)	44.6 [2.9]	**(-0.64—0.1)**	**.008**
Negative Illness Impact	16.3 (5.6)	66.4 [2.9]	**(0.21-0.93)**	**.003**
Positive Illness Impact	35.6 (9.0)	50.5 [3.2]	(-0.16-0.06)	.14
Social Isolation	16.5 (6.6)	50.0 [1.8]	(-0.16-0.5)	.3

*Population t-score = 50.0 (10.0).

11106 Poster Session

Self-reported adherence to cancer therapy: Development and validation of a cancer-specific DOSE-Nonadherence measure.

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Background: Patients with cancer take different types of medication (e.g., enteral, parenteral), with varying treatment schedules, in various settings. They are also sometimes instructed to stop medication in response to toxicity. To measure medication nonadherence in this heterogenous population, we modified and pilot-tested a self-report measure originally developed to assess nonadherence to daily oral medication, the Domains of Subjective Extent of Nonadherence (DOSE-Nonadherence), in adults with cancer. **Methods:** Participants were ≥21 years, on active cancer treatment at Memorial Sloan Kettering, and spoke English and/or Spanish. A branching logic was added to allow participants to select the setting where they take cancer medication: 1) only at home, 2) only in clinic, or 3) partly at home/partly in clinic. Based on administration setting, participants reported nonadherence to medications their clinician expected them to take over a given reference period (1 week for home and 1 month for clinic medications). Participants then reported on setting-relevant reasons for nonadherence. Survey instructions/items were refined in an iterative process using feedback from a patient investigator committee and participant cognitive interviews. During interviews, we asked participants about the interpretation of instructions/items, recall period, and comprehensiveness of reasons for nonadherence, regardless of their own adherence. After initial testing in English, a Spanish version was developed through transcreation. Adherence was dichotomized for analysis (complete adherence vs. any nonadherence). For all participants who received clinic medications, concordance between chart abstracted and self-reported adherence was evaluated. **Results:** Of 55 participants who completed the surveys and interviews (67% in English; 33% in Spanish), 87% were female and 44% identified as Latino. The majority (73%) had breast cancer; 60% had metastatic disease. 12 of 45 who received medication in clinic reported nonadherence as did 8 of 35 who took medication at home. Participants felt able to respond accurately to both recall periods. All reasons for nonadherence were perceived as relevant to themselves or other patients. There was 89% concordance between self-reported and chart abstracted adherence for clinic-administered medication. To improve concordance, changes were made to the formatting and instructions. Of 12 participants who completed the final version of the survey for clinic-administered medication, there was 100% concordance between self-reported and chart abstracted nonadherence. **Conclusions:** Our results support the reliability and validity of modified DOSE-Nonadherence for cancer patients. This instrument can be used to better identify nonadherence to cancer medications in a population of adult patients with cancer receiving various treatment regimens. Research Sponsor: National Cancer Institute; P30CA008748; National Cancer Institute; T32CA275764; Patient-Centered Outcomes Research Institute (PCORI); BPS-2023C1-32172; Department of Veterans Affairs Health Systems Research Service; RCS 14-443; Geoffrey Beene Cancer Research Center at Memorial Sloan Kettering Cancer Center.

11107 Poster Session

Employer-sponsored insurance, paid sick leave, and financial toxicity among cancer survivors.

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Background: Financial toxicity (FT), the adverse economic effects resulting from cancer, its treatment, and associated long-term effects, may affect the majority of cancer survivors. FT is associated with multiple factors including employment disruptions; however, the role of workplace policies in mitigating FT is poorly understood. We examined how employer-sponsored health insurance and paid sick leave influence FT among employed U.S. cancer survivors. **Methods:** We analyzed data from 1,122 employed cancer survivors aged 18-64 with non-missing insurance status and a self-reported history of cancer (diagnosed age 18 or older), representing a weighted total of almost 5 million survivors from the 2021/2022 National Health Interview Survey (NHIS), a nationally representative household survey of the civilian non-institutionalized U.S. population. Multivariable logistic regression analyses examining associations of employer-sponsored health insurance and paid sick leave (separately) with FT items, controlling for sociodemographic characteristics and cancer type, were conducted using PROC SURVEYLOGISITC in SAS 9.4 adjusting for the complex survey design of the NHIS. **Results:** Compared with cancer survivors who had employer-sponsored health insurance (n = 842, weighted 76.6%), those without employer-sponsored insurance were significantly ($p < 0.05$) more likely to experience FT, including worrying about paying medical bills (odds ratio [OR] 1.7, 95% confidence interval [CI] 1.2-2.4), skipping/delaying medical care due to costs (OR 2.4, 95% CI 1.5-3.9), and delaying counseling/therapy due to costs (OR 2.5, 95% CI 1.3-4.6). These associations persisted when restricting the sample to survivors with private insurance only. Similarly, compared to survivors with paid sick leave (n = 807, weighted 72.0%), those without paid sick leave were significantly more likely to worry about paying medical bills (OR 1.4, 95% CI 1.1-1.9) and skip/delay medical care due to costs (OR 2.2, 95% CI 1.4-3.4), with consistent findings in the private insurance only subgroup. Having employer-sponsored insurance and paid sick leave were also associated with decreased food insecurity. **Conclusions:** Workplace policies can mitigate FT and food insecurity among cancer survivors. Employers should consider offering benefits that support health and economic outcomes for employees with cancer and other medical conditions and enhance their ability to contribute to positive workplace environments. Research Sponsor: None.

11108 Poster Session

Ethnic disparities in unmet supportive care needs and outcomes among older ambulatory cancer patients.

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Background: Older cancer patients often face unmet supportive care needs (USCNs), leading to adverse clinical outcomes. Existing research largely focuses on non-Hispanic White populations, leaving a gap in understanding the unique determinants and consequences of USCNs in underrepresented groups. This study aimed to identify factors associated with USCNs and evaluate their impact on clinical outcomes, including emergency room (ER) visits and hospitalizations, among ambulatory cancer patients aged 65 and over. **Methods:** A retrospective analysis was performed for older ambulatory cancer patients (aged ≥65) via *My Wellness Check*, an electronic health record (EHR)-based supportive care needs and patient-reported outcomes (PROs) screening and referral program. Patient demographics and clinical characteristics and outcomes were extracted from the EHR. PROs (i.e., PROMIS computerized adaptive tests for anxiety, depression, and physical function), health-related quality of life (HRQOL) using the FACT-G7, and supportive care needs (e.g., stress management, financial concerns, transportation) were also collected. Logistic regression models examined predictors of USCNs. The cumulative incidence of ER visits and hospitalization was assessed using Cox proportional hazards regression models adjusting for covariates. **Results:** A total of 8,996 older cancer patients were analyzed (mean age: 74±6.3 years, 44% female). Among participants, 3,297 (37%) were Hispanics, 4,901 (55%) were non-Hispanic White, and 561 (6%) were non-Hispanic Black. Most patients were partnered (64%) and insured (98%). Hispanics were more likely to experience USCNs (adjusted odds ratio [aOR]=1.79). Other factors associated with USCNs included non-White race (aOR=2.42), being unpartnered (aOR=1.24), uninsured status (aOR=1.80), shorter time since diagnosis (aOR=0.94), anxiety (aOR=1.03), depression (aOR=1.02), lower physical function (aOR=0.99), and poorer HRQOL (aOR=0.95). Hispanic ethnicity was independently associated with an increased risk of ER visits (adjusted hazard ratio [aHR]=1.76). USCNs were independently associated with an increased risk of ER visits (aHR=1.25) and hospitalizations (aHR=1.29) (all p's<0.05). **Conclusions:** Older Hispanic cancer patients are disproportionately burdened by USCNs, leading to higher risk of ER visits compared to their non-Hispanic counterparts. Underrepresented groups, patients lacking social support, and those experiencing greater emotional or physical distress are more likely to report USCNs. Addressing these needs is critical, as USCNs significantly contribute to increased healthcare utilization, including ER visits and hospitalizations. Tailored interventions to meet supportive care needs in historically vulnerable populations are imperative to improving outcomes and reducing healthcare disparities among older cancer patients. Research Sponsor: None.

11109 Poster Session

Treatment preferences of patients, caregivers, and physicians in follicular lymphoma (FL): A global discrete-choice experiment (DCE) study.

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Background: While recent FL therapy advances offer various treatment options, data are limited on FL treatment preferences in the shared decision-making process. A comprehensive survey with a DCE design was conducted to assess preferences of patients, caregivers, and physicians for different attributes that impact treatment choice. **Methods:** A web-based DCE survey available in English and Spanish was administered in Oct-Nov 2024 to patients with FL, caregivers, and physicians recruited in the US, the UK, Spain, Australia, and Canada through the Follicular Lymphoma Foundation (FLF). FL treatment attributes were selected based on targeted literature review, clinical inputs, and review with FLF patient and caregiver advisors. Attributes included efficacy (progression-free survival [PFS]), safety (impact of adverse events [AEs], including fatigue, cytokine release syndrome [CRS], and neurologic events [NE], on quality of life [QOL]), and convenience (mode of administration, treatment duration and frequency of visits, time needed to travel to treatment center). Survey responses were analyzed by patient, caregiver, and physician groups. Preference weights were generated from conditional logistic regression models and used to calculate the relative importance of attributes and willingness to trade off. **Results:** A total of 337 patients, 37 caregivers, and 29 physicians (median age: 59, 45, and 51 y, respectively) from 25 countries (>75% from US, UK, and Spain) responded to the DCE survey. The majority (93.7%) of patients reported having experienced ≥1 AE from previous treatment. Patients preferred treatments with longer PFS; mild or no impact of fatigue, CRS, and NEs on QOL during treatment; oral tablets vs infusions; a 3-mo duration with twice-weekly visits vs continuous duration with visits once every 3 mo; and <30 min of travel time vs >2 h (all $P<.05$). PFS was ranked as the most important attribute across patients, caregivers, and physicians. Following efficacy, treatment convenience attributes were ranked higher by patients and caregivers while safety attributes were more important to physicians. On average, patients were willing to accept reductions of 1 y of PFS for treatment requiring <30 min of travel vs >2 h, 0.7-1 y to receive treatments with less impact of AEs on QOL, 0.6 y for oral tablets vs blood collection and intravenous infusion, and 0.5 y for 3-mo treatment vs continuous duration. **Conclusions:** Efficacy is the most important attribute in treatment choice for patients, caregivers, and physicians. Following efficacy, patients and caregivers prioritize convenience and reduced impact of AEs, while physicians prioritize safety over convenience. Insights on differences between preferences highlight the importance of informed discussion and a balanced, individualized approach to treatment selection. Research Sponsor: BeOne Medicines Ltd.

11110 Poster Session

Patient-reported pain and emergency department utilization in patients with newly diagnosed ovarian cancer: A retrospective cohort study.

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Background: Pain is one of the most common reasons for emergency department (ED) visits among patients with cancer. While patient-reported pain is increasingly captured in routine clinical care, its role in predicting ED utilization remains unclear. This study aimed to evaluate whether baseline patient-reported pain after ovarian cancer diagnosis is associated with subsequent ED visits. **Methods:** We conducted a retrospective cohort study of patients aged 18 years or older treated for ovarian cancer at an urban academic institution between 2019 and 2024. Inclusion criteria required (1) completion of a pain survey within 6 months of diagnosis, (2) all or part of first line treatment at our institution, and (3) at least six months of follow-up after pain survey submission. Patients rated their average pain over the past week on a 0–10 scale as part of routine intake, with mild defined as a score of 1 to 3 and moderate to severe as 4 or higher. The outcome was the occurrence of at least one ED visit within 6 months of the pain survey submission. Multivariable logistic regression was used to assess the relationship between patient-reported pain and ED utilization, adjusting for sociodemographic and clinical variables. **Results:** Among 894 patients who met inclusion criteria, the mean age at diagnosis was 59.7 years, 74.4% (n=665) were white, 7.3% (n=65) Hispanic or Latino, 69.0% (n=617) had advanced stage (III or IV) disease, 83.9% (n=750) received chemotherapy and 66.7% (n=596) had surgery within 6 months of diagnosis. Among the cohort, 331 (37.0%) reported mild pain, 345 (38.6%) reported moderate to severe pain, and 239 (26.7%) experienced at least one ED visit in the 6 months following the survey. A higher proportion of patients with moderate to severe pain had an ED visit compared to 26.0% of those with mild pain and 15.1% of those with no pain (34.8% vs. 26.0% vs. 15.1%, $p<0.001$). After adjusting for covariates, both mild (aOR 1.77, 95% CI 1.09-2.93, p=0.02) and moderate to severe (aOR 2.28, 95% CI 1.42 - 3.73, p=0.001) pain at baseline were associated with higher odds of an ED visit compared to patients without pain. In addition, younger age, non-white race, receipt of chemotherapy or surgery, and advanced stage disease were all significantly ($p<0.05$) associated with higher adjusted odds of an ED visit. **Conclusions:** Three out of four people with newly diagnosed ovarian cancer experience pain, with higher pain levels associated with increased odds of an ED visit. Our findings suggest that routinely collected pain scores could potentially be leveraged to identify at risk population, improve pain management and reduce ED visits for people diagnosed with ovarian cancer. Research Sponsor: None.

11111 Poster Session

Patient experiences of diagnosis and treatment of invasive lobular carcinoma: A qualitative study from a prospective registry.

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Background: Invasive lobular carcinoma (ILC) is the second most common subtype of breast cancer and comprises 10-15% of all cases. ILC is characterized by a diffuse tumor growth pattern due to the absence of E-cadherin, resulting in diagnostic and management challenges including delays in diagnosis. The impact of these unique features on patients with ILC is unknown. To better understand the patient experience, we conducted a qualitative study using thematic analysis. **Methods:** 92 patients diagnosed with ILC and treated at a single institution were recruited to a prospective ILC registry from 2023-2025. We collected data primarily through structured patient interviews regarding screening and surveillance methods, locoregional treatment, systemic therapy, and recurrence. Participants were also asked two open-ended questions regarding how they were diagnosed and about their overall experience. The interviews were conducted through 30 to 60-minute phone calls and transcribed verbatim. Inductive coding was used to develop themes. **Results:** Unique themes were identified corresponding to stages in the diagnosis, treatment, and surveillance of ILC. Participants commonly reported a delay in their diagnosis due to mammographically occult disease and perceived poor sensitivity of breast imaging modalities. This was more pronounced among patients who reported a physical finding related to their breast cancer prior to diagnosis. Additional themes included experiencing a dismissal of symptoms by providers, underestimation of ILC tumor size on pre-operative imaging, and concerns over the impact of dense breasts on imaging sensitivity. At the treatment stage of their patient journey, participants reported that providers did not recognize ILC as a distinct tumor subtype and often recommended mastectomy as the initial surgical approach. After treatment of ILC, participants frequently recounted concerns about how they would identify a recurrence and a desire for improved surveillance methods. Reflecting on their journey, many shared that they wished they had been better informed about breast cancer symptoms and breast self-awareness before their diagnosis. **Conclusions:** This study highlights the unique challenges and concerns experienced by patients with ILC, emphasizing the need for more tailored imaging strategies, improved awareness among healthcare providers, and enhanced patient education. Research Sponsor: None.

Selected themes in the patient journey.

Patient Journey Stage	Unique themes
Diagnosis	Mammographically occult disease
	Poor sensitivity of imaging modalities
	Dismissal of symptoms
	Underestimation of ILC tumor size
	Concerns over breast density on imaging sensitivity
Treatment	Providers not recognizing ILC as a distinct tumor-type
	Recommending mastectomy
Surveillance	Concerns about identifying recurrence
	Desire for improved surveillance methods

11112 Poster Session

Disparities in glioblastoma care: Insights from a nationwide survey.

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Background: Glioblastoma (GBM) care requires specialized, multidisciplinary management, often creating barriers to healthcare delivery and disparities in care. To identify disparities in how GBM is treated across the United States, we conducted a nationwide survey evaluating healthcare quality and accessibility for GBM patients. **Methods:** OurBrainBank, a patient-led GBM nonprofit, designed and distributed a 36-item HIPAA-compliant survey covering patient experience, quality of life, and demographic data in collaboration with a professional market research company. The survey, available from February to September 2024, targeted current GBM patients, current caregivers, or caregivers who have lost someone within the last year. Recruitment involved newsletters, social media, and communication partnerships with brain cancer organizations. We hypothesized that financial and educational disparities would influence GBM care experiences, assessed through logistic and linear regression using R (version 4.0.5). Only patients with non-missing data were included for each regression analysis. **Results:** Of 525 participants overall (77% caregivers; 23% patients), the median age at diagnosis was 59, with 58% being male, 55% with a college degree, 66% with private insurance and 94% living in urban areas. Education and financial difficulties were associated with disparate GBM care experiences, controlling for age, race, gender, geography (rural, small town, urban), and insurance type (private, public). Participants with no college education (21%) were significantly less likely to be informed about tissue storage (OR = 0.40, 95% CI [0.21, 0.75], p = .004), to undergo MGMT and IDH testing (OR = 0.28, 95% CI [0.11, 0.68], p = .005), to be offered a clinical trial (OR = 0.50, 95% CI [0.29, 0.86], p = .013), and to discuss a second opinion with their doctor (OR = 0.44, 95% CI [0.26, 0.73], p = .002) compared to those with a college degree (55%). They also reported lower satisfaction with care on a 1-10 scale (β = -0.70; 95% CI [-1.26, -0.13], p = .016). These disparities were not observed in participants with some college experience (24%) compared to those with college degrees. Participants reporting financial difficulty in the past year (29%) were also less satisfied with their care (β = -0.58, 95% CI [-1.06, -0.10], p = .018). Financial struggles, however, did not significantly impact mutational testing (OR = 0.57, 95% CI [0.28, 1.18], p = .12), clinical trial offers (OR = 1.25, 95% CI [0.81, 1.92], p = .31), or second opinion discussions (OR = 0.94, 95% CI [0.62, 1.44], p = .79). **Conclusions:** This survey highlights disparities in GBM care, with lower educational attainment linked to reduced access to mutational testing, second opinion discussions and clinical trials, and both lower education and financial difficulties associated with lower care satisfaction. Addressing these disparities is critical to improving GBM care nationwide. Research Sponsor: None.

11113 Poster Session

A prospective observational study to compare speech and swallowing outcomes in different types of oral tongue defects and reconstructions in patients undergoing treatment for oral tongue squamous cell carcinoma.

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Background: The tongue is an important organ for speech and swallowing functions. Oral tongue squamous cell carcinoma (OTSCC) can per se affect these functions. Surgery followed by adjuvant treatment may further influence these functions. **Methods:** In this prospective study (CTRI/2020/01/023080) we aimed to assess the speech and swallowing outcomes of 100 treatment-naive OTSCC patients receiving the standard care at our center and compare these outcomes with the type of reconstruction done. Speech was assessed using the London speech evaluation scale (LSES), Performance Status Scale for Head & neck (PSSHN) Speech, and Speech Handicap Index (SHI). Swallowing was assessed with Functional Oral Intake Scale (FOIS), Water swallow test (WST), PSSHN diet, videofluoroscopy (VFS) and New Zealand Index for Multi-disciplinary Evaluation of Swallowing (NZIMES). These assessments were done at baseline, 1 month, at 6 months and 1 year after surgery. **Results:** Between November 2021 and December 2024, 100 eligible patients were enrolled in the study. The median age of the patients was 45 years. With predominantly male patients. There were 40 T1 & T2 and 60 T3 & T4 OTSCC. Fifty percent of the patients were clinico-radiologically N+ disease. All patients underwent surgery with appropriate reconstruction and adjuvant treatment (n=77,77%). We utilised the tongue defect classification proposed by Bhattacarya S et al, of which 18 patients had type 1 defect, 32 patients had type 2 defect, 9 patients type 3 defect and 41 had type 4 defect. Primary closure was done in 23 patients, Local flaps in 19 patients, free flaps in 28 patients and pectoralis major myocutaneous/myofascial flap (PMMC/PMMF). There were no difference in the baseline functional outcomes except for the restriction in the range of tongue movements in cT3 & cT4 OTSCC. In patients with cT1 & cT2 and cT3 & cT4 OTSCC there was no difference in most of the functional assessment parameters throughout the follow up period with respect to the type of reconstruction done. There was a difference in the SHI from baseline to 1st follow up (p=0.039) and 3rd follow-up (p=0.041) in patients with class 1 & 2 defect. There was a similar difference in patients with class 3 & 4 defects at 1st (p=0.016) and 3rd follow up visit (0.041) compared to baseline. There was no major swallowing differences observed on VFS (NZIMES) in patients with class 1 & 2 defect. However, there was a significant difference in patients with class 3 & 4 defect. **Conclusions:** In this study, we have witnessed no major differences in the functional outcomes with the kind of flap used for various defects. The functional issue seem to be more associated with the defects (reflecting on the extent of resection) more rather than the type of reconstruction done. Clinical trial information: CTRI/2020/01/023080. Research Sponsor: TMC Research Adminstrative Council (TRAC); ICON.

Association between alcohol intake and health-related quality of life in breast cancer survivors.

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Background: Advances in early detection and treatment of breast cancer (BC) have significantly improved survival outcomes. In this growing survivor population, addressing modifiable lifestyle factors such as alcohol intake (AI), a known risk factor for BC and BC recurrence, is critical to improving prognosis and health-related quality of life (HRQoL). This study examines AI patterns and their associations with mental and physical HRQoL in early BC survivorship. **Methods:** Adult patients newly diagnosed (≤1 year) with stage I–III BC at Mayo Clinic Rochester were invited to enroll in the Mayo Clinic Breast Disease Registry. Of the 3252 patients who consented, 1997 completed surveys approximately one-year post-diagnosis, capturing weekly AI, demographic factors, and PROMIS-10 scores. PROMIS-10 (a 10-item measure of health, well-being, and distress) physical and mental health T-scores (mean = 50, SD = 10) are standardized to the U.S. population. Weekly AI was categorized as minimal/none (<1 drink), mild (1–4 drinks), moderate (5–14 drinks), or high (≥15 drinks). Univariate analyses were performed with Monte Carlo-based Fisher exact tests. Multivariate multinomial logistic regression models using a glogit link function assessed AI as the outcome and PROMIS-10 scores as independent variables, adjusting for financial status, smoking, chemotherapy, and moderate exercise because those were associated with AI at year 1 in prior analyses. **Results:** Univariate analyses revealed statistically significant associations between AI and PROMIS-10 scores (Table 1). Adjusted multivariate analyses identified that patients with better physical health were more likely to drink 1–4 or 5–14 drinks/week and less likely to abstain (<1 drink/week) than those with poorer physical health (p=0.027). There was no statistically significant association between AI and mental health QoL after adjustment for covariates. **Conclusions:** Better physical HRQoL during early survivorship was associated with higher AI, suggesting that patients who are feeling physically unwell may be less likely to drink alcohol. Additional public health messaging about the relationship between AI and breast cancer risk and recurrence may be needed, especially for those who are feeling well enough to consume alcohol. Research Sponsor: National Cancer Institute; P30 CA015083.

Univariate analyses of year 1 PROMIS-10 scores with year 1 alcohol consumption using Monte Carlo-based Fisher exact test.

	Alcoholic drinks per week at year 1					
	< 1 (N=1204)	1-4 (N=600)	5-14 (N=175)	15+ (N=18)	Total (N=1997)	P-value
PROMIS global mental health T score, Year 1, n (%)						0.008
< 50	466 (63.8%)	200 (27.4%)	54 (7.4%)	10 (1.4%)	730 (37.1%)	
50+	718 (57.9%)	394 (31.8%)	120 (9.7%)	7 (0.6%)	1239 (62.9%)	
Missing	20	6	1	1	28	
PROMIS global physical health T score, Year 1, n (%)						<0.001
< 50	440 (66.5%)	165 (24.9%)	50 (7.6%)	7 (1.1%)	662 (33.6%)	
50+	740 (56.7%)	432 (33.1%)	124 (9.5%)	10 (0.8%)	1306 (66.4%)	
Missing	24	3	1	1	29	

11115 Poster Session

Caregiver distress: Caring for those who care for our patients.

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Background: Gynecologic cancers cause high physical and psychosocial strain, worsened by unmet social determinants of health (SDOH) in cancer care. Caregivers help patients access and complete treatment, and increased caregiver distress, especially in vulnerable populations, is linked to worse patient outcomes in chronic illnesses. This study aimed to assess caregiver distress and SDOH in a diverse gynecologic cancer population, understand the relationship between caregiver and patient distress, explore how caregiver distress evolves during chemotherapy, and examine its effect on short-term patient outcomes. **Methods:** A prospective pilot study was conducted of patients starting chemotherapy for gynecologic cancer and their self-identified caregivers at a single academic site after IRB approval. Patient distress was measured with the NCCN Distress Thermometer. Caregivers completed the Modified Caregiver Strain Index (MCSI) and SDOH questionnaires at enrollment (T0) and three months after chemotherapy initiation (T3). Descriptive statistics, χ^2 analyses, and linear regression analyzed differences between high- and low-distress caregivers and changes between time points. **Results:** Between 12/2023 and 06/2024, 60 patients and 38 caregivers enrolled. Patients' mean age was 62, with 27% identifying as Black and 37% as Hispanic. Most (72%) were starting chemotherapy for initial treatment of uterine (47%), ovarian (32%), cervical (20%), and vulvar (1.6%) cancer, and 73% had stage III/IV disease. Caregivers were 63% male, 40% Hispanic, 24% Black, and 26% over age 65. Almost 40% of caregivers did not live with their patient, and 27% cared for others, including 80% for children. Nearly 40% had incomes under $50,000; only 13.2% had paid job-related support. At T0, 77% of patients reported high distress, decreasing to 70% at T3. Caregivers of high-distress patients were younger, working full-time, and had lower incomes. At T0, 42% of caregivers reported high distress, increasing to 66% at T3. MCSI scores rose significantly from 5.84 at T0 to 9.84 at T3 ($p<0.001$). At T0, 63% of caregivers screened positive for ≥1SDOH domain, rising to 80% by T3. Caregivers with ≥1 SDOH domain at T3 were more likely to experience increased distress ($p=0.037$). Linear regression showed caregivers with one SDOH domain had MCSI scores 3.69 points higher ($p=0.111$); those with ≥2 domains scored 5.60 points higher ($p=0.024$). No differences were found in patient outcomes based on caregiver MCSI scores. **Conclusions:** Caregiver distress and SDOH needs increase significantly during the first months of chemotherapy for gynecologic cancer. Distress is also more pronounced in caregivers with greater SDOH needs. Long-term studies are needed to evaluate caregiver distress and its impact on patient survival. This study highlights the importance of monitoring caregiver well-being and addressing SDOH through targeted interventions. Research Sponsor: UT Center for Clinical and Translational Sciences; UL1TR003167.

11116 Poster Session

Factors associated with patient-reported outcomes in hospitalized patients with cancer.

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Background: Utilization of patient reported outcomes (PROs) in the ambulatory setting can help to improve symptom control and clinical outcomes among individuals with cancer. However, little is known about PROs among hospitalized patients with cancer. **Methods:** We conducted a prospective study to examine PROs among hospitalized patients with cancer at the University of Oklahoma Medical Center from 8/2023 to 9/2024. Within 2-5 days of admission, we asked patients to complete surveys assessing physical symptoms (MD Anderson Symptom Inventory [MDASI]; scored 0-10, higher scores = higher severity/interference), psychological symptoms (PHQ-4; scored 0-12, higher scores = higher distress), coping (Brief COPE; scored 2-8 for each of 14 coping domains), and resilience (Brief Resilience Scale [BRS] scored 1-5, higher scores = higher resiliency). We obtained demographic data and clinical characteristics from the electronic health record, including the Charlson Comorbidity Index (CCI). We used regression models to identify factors associated with PROs. **Results:** We enrolled 300 of 441 (68.0%) eligible patients (median age = 64.8 years, 43.0% female, 78.0% White, 73.3% with incurable cancer). The most common cancers were hematologic (29.6%), gastrointestinal (20.0%), and gynecologic (17.0%). The mean MDASI severity and MDASI interference scores were 4.20 and 4.77. Symptoms with the highest mean MDASI severity scores were fatigue (6.56), pain (5.87), disturbed sleep (5.77), and drowsiness (5.27). The mean MDASI interference score was highest for normal work (6.45) and general activity (6.45). The mean PHQ-4 score was 4.41, and the mean BRS score was 2.98. Coping measures with the highest mean Brief COPE scores were use of emotional support (6.66), acceptance (6.55), and religion (6.04) coping. Older age at enrollment was associated with lower MDASI severity (B = -0.02, P < .01), venting (B = -0.02, P = .03), and humor coping scores (B = -.02, P < .01), yet higher use of emotional support (B = 0.02, P = .03) and religion coping scores (B = 0.03, P = .01). Female sex was associated with higher MDASI severity (B = 0.65, P < .01), self-distraction coping (B = 0.63, P < .01), and positive reframing coping (B = 0.77, P < .01). Higher CCI was associated with higher substance use coping (B = 0.11, P < .01) and behavioral disengagement (B = 0.10, P = .03). Patients with hematologic malignancy had higher use of self-distraction coping (B = 0.55, P = .02). We found no differences in PROs for curable versus incurable cancer. **Conclusions:** Hospitalized patients with cancer report high physical and psychological symptoms, with significant associations of PROs with increasing age, female sex, comorbidities, and diagnosis of hematologic malignancy. Our findings highlight the importance of addressing symptom concerns and coping mechanisms in hospitalized patients with cancer, which could inform targeted interventions to enhance PROs and clinical outcomes. Research Sponsor: None.

Perception of postoperative functional status in gastrointestinal and hepatobiliary cancer patients over 80.

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Background: Advanced age independently predicts poor surgical outcomes in cancer patients, making octogenarians a particularly high-risk surgical population. Improvement in the delivery of care to these vulnerable patients is critical to improve not only morbidity and mortality outcomes, but also patient-centered outcomes such as functional status. Postoperative functional outcomes can be evaluated by subjective perception and quantified performance. The aims of this study were to 1) identify risks associated with 30-day postoperative perceptions of functional decline in octogenarians undergoing operations for gastrointestinal or hepatobiliary cancers and 2) explore whether these perceptions correlate with quantitative decline measured as a function of decreased ability to perform activities of daily living (ADLs). **Methods:** American College of Surgeons National Surgical Quality Improvement Program Geriatric Surgery data (2015-2017) was used. All postoperative diagnoses related to gastrointestinal or hepatobiliary cancers were included for patients ≥80 years old. Multivariable logistic regression models identified risks associated with perceiving worsened physical function 30-days postoperatively. Chi-square tests were used to examine concordance between 30-day outcomes of perceptions of physical function with measured performance of ADLs. **Results:** 369 patients from 14 hospitals were included. Mean age was 85.4 (SD 4.1 years). The most common diagnosis was "malignant neoplasm of ascending colon" (16%). Preoperatively 62% of patients were living supported at home, 37% were using a mobility aid, and 17% had ≥1 fall in the past year. Overall, 80% did not have a quantified decline in function as measured by ADLs; however, 17% of these reported perceived functional decline (K= 0.47). Significant risk factors for perceived functional decline were major postoperative morbidity (OR 5.5; 95% CI 2.3-13), disseminated cancer (2.2; 1.1-4.4), new postoperative mobility aid use (2.2; 1.1-4.6), and cognitive impairment (4.7; 1.7-12.9). **Conclusions:** There are inconsistencies between patient experience and clinician view of functional outcomes for octogenarians undergoing surgical intervention for gastrointestinal and hepatobiliary cancers. Ability to perform ADLs is frequently used to evaluate patient functional status. This discrepancy in patient perception and quantified measure highlights the need for the development and utilization of patient-centered and patient-reported outcome (PRO) measures to evaluate this vulnerable patient population. PROs may enhance surgeon understanding of the patient experience and allow for more nuanced goals of care discussions and targeted interventions to improve delivery of care to these patients. Research Sponsor: None.

	Quantified Functional Decline		
Patient Reported Functional Decline	**No**	**Yes**	**Total**
No	246	22	268
Yes	49	52	101
Total	295	74	369

11118 **Poster Session**

Prospective assessment of health-related quality of life in early phase clinical trials.

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Background: Early phase clinical trials (EP-CTs) provide patients with access to novel therapeutics once standard of care options are exhausted or not available. Health related quality of life (HRQoL) is not routine in all EP-CTs where key focus may lie on dose limited toxicities and safety analyses. However for clinicians, understanding the impact of such trials on HRQoL is fundamental to consent patients, especially when the benefits on tumour response may be unknown. **Methods:** The PEARLER (Patient Experience in eARLy phasE cancer clinical tRials) study was conducted with a key aim of focusing on assessing HRQoL in participants undergoing EP-CTs using a multi-centre prospective cohort setting. All participants completed a baseline demographic survey on cycle 1 day 1 with EORTC-QLQ-C30 on day 1 of cycles 1 through 6 or end of trial (EoT). Multilevel models were used to analyse trend over time for Global Health Status (GHS), and Physical Function Score (PFS). **Results:** A total of 122 participants were recruited. Median age was 62 years (25 – 83 years) with 63 (52%) participants identifying as female. Of the total participants, 47 (39%) were enrolled in immuno-oncology EP-CTs whilst the remainder participated in EP-CTs focused on targeted therapies. The median number of EP-CT cycles completed by participants was 3. Median GHS) Score was 67 at baseline and remained steady across all participants throughout their EP-CT (p=0.188). GHS deterioration, defined by a 10-point decrease from baseline to EoT, occurred in 29/122 (24%) whilst GHS improvement occurred in 16/122 (13%). Median Physical Function Score (PFS) was 87 at baseline and remained steady across all participants throughout their EP-CT (p=0.104). PFS deterioration, defined by a 10-point decrease from baseline to EoT, occurred in 30/122 (25%) whilst GHS improvement occurred in 6/122 (5%). There was no statistically difference in change in GHS or PFS in younger versus older patients (less than or equal to 60 years versus over 60 years), tumour type, EP-CT type, gender or those from lower versus higher socioeconomic backgrounds. **Conclusions:** PEARLER is the first prospective cohort study investigating change in GHS and PFS over time in patients undergoing EP-CTs. Although almost three-quarters of participants who undertake EP-CTs either sustain or improve their GHS or PFS, one quarter do not. Patients need to be educated not only on the potential response rate of the EP-CT they are enrolling into but also the possibility of reduced HRQoL whilst participating in studies. Further research is needed to identify predictive and protective factors of HRQoL in patients undergoing EP-CTs. Research Sponsor: None.

11119 Poster Session

Financial, social and time toxicity in early-phase cancer clinical trials: The PEARLER study.

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Background: Early phase clinical trials (EP-CTs) provide patients with access to novel therapeutics once standard of care options are exhausted or not available. In addition to the drug related potential benefits and risks with participating in such studies, patients are also exposed to hidden toxicities which often go unnoticed. Hidden toxicities have been classed into a number of major categories which include but are not limited to time, financial, and social. Currently there are no prospective studies assessing these hidden toxicities in the EP-CT space. **Methods:** The PEARLER (Patient Experience in eARLy phasE cancer clinical tRials) study was conducted with a key aim of focusing on assessing time toxicity, financial toxicity and social toxicity in a multi-centre prospective cohort setting. All participants completed a baseline demographic survey on cycle 1 day 1 along a time toxicity survey and the EORTC-QLQ-C30 on day 1 of cycles 1 through 6. Multilevel models were used to analyse trend over time for financial toxicity and social toxicity. **Results:** A total of 122 participants were recruited. Median age was 62 years (25 – 83 years) with 63 (52%) participants identifying as female. A total of 47 (39%) participants were enrolled in immuno-oncology EP-CTs whilst the remainder participated in targeted-therapy focused EP-CTs. The median time toxicity was 26%. Of 122 participants, 20 (16%) reported subjective time toxicity with 17 (85%) reporting this occurring at either cycle 1 or 2. Under half (54/122, 44%) reported any degree of financial toxicity whilst participating in their EP-CT; with 9 of this 54 (17%) reporting the maximum score of '4'. Financial toxicity remained largely stable throughout EP-CT participation (p=0.136), with 6/122 (5%) participants reporting higher financial burdens at the end of their clinical trial compared with baseline. Most participants (87/122, 71%) reported any degree of reduced social function, whilst participating in their EP-CT. However, 26/122 (21%) participants reported lower social functional scores at conclusion of their EP-CT compared with baseline whilst 24/122 (20%) reported higher social functional scores. **Conclusions:** PEARLER is the first prospective cohort study investigating financial, social and time toxicity in EP-CTs. Although time toxicity remains a concern of EP-CTs, the majority of subjects did not subjectively note this to be a concern. Financial and social toxicity remained stable during EP-CT participation thereby suggesting that EP-CTs may not negatively affect the majority of participants. However almost half of patients experienced financial toxicity and more than half experienced social toxicity due to cancer related treatment and greater efforts to identify and support patients financially and socially is needed. Research Sponsor: None.

11120 Poster Session

Final patient-reported outcomes (PROs) in unselected men receiving talazoparib (TALA) + enzalutamide (ENZA) vs placebo (PBO) + ENZA as initial treatment for metastatic castration-resistant prostate cancer (mCRPC): Results from the phase 3 TALAPRO-2 study.

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Background: TALAPRO-2 demonstrated statistically significant improvement with TALA + ENZA vs PBO + ENZA in radiographic progression-free survival (primary endpoint; HR=0.63; 95% CI, 0.51–0.78; $P<0.0001$) in unselected men with mCRPC. Prior PRO analyses (data cutoff: Aug 16, 2022) reported no clinically meaningful between-arm differences in any functioning scales and a longer time to definitive deterioration (TTDD) in global health status (GHS)/quality of life (QoL) for TALA + ENZA (median 30.8 mo) vs PBO + ENZA (25.0 mo; HR=0.780; 95% CI, 0.62–0.99; $P=0.038$). Here we report updated (data cutoff: Sep 3, 2024) final PROs for the unselected cohort. **Methods:** PROs were assessed at day 1 (baseline) and scheduled visits (every 4 weeks until week 53, and then every 8 weeks) until radiographic progression using the EORTC QLQ-C30 and its prostate cancer module, QLQ-PR25, and worst pain by BPI-SF item 3. Prespecified PRO analyses included overall mean change from baseline (per longitudinal repeated measures mixed-effects model), time to deterioration (TTD), and TTDD. The clinically meaningful threshold was ≥10 points for EORTC scales and ≥2 points for BPI-SF. Between-arm comparisons of TTD/TTDD were made using a stratified log-rank test and a Cox proportional hazards model. **Results:** Of the 805 men randomized to treatment, 793 (TALA + ENZA, n=395; PBO + ENZA, n=398) had 1 baseline + ≥1 follow-up PRO score. With extended follow-up, median TTDD for GHS/QoL in the TALA + ENZA arm was 41.5 mo vs 34.1 mo in the PBO + ENZA arm (HR=0.878; 95% CI, 0.704–1.096; $P=0.2487$). Median TTDD for urinary symptoms in the TALA + ENZA arm was 59.8 mo vs 58.0 mo in the PBO + ENZA arm (HR=0.861; 95% CI, 0.622–1.191; $P=0.3655$). No clinically meaningful between-arm differences in QLQ-C30 functioning and symptoms scales were observed (Table). No between-arm difference in TTD for worst pain by BPI-SF was observed. **Conclusions:** With extended follow-up, QoL was maintained with TALA + ENZA. These data confirm that QoL is not compromised when TALA is added to ENZA, for initial treatment of unselected men with mCRPC. Clinical trial information: NCT03395197. Research Sponsor: Pfizer Inc.; Astellas Pharma Inc. provided enzalutamide.

QLQ-C30 Scale		Estimated Mean Difference, TALA + ENZA – PBO + ENZA (95% CI)	*P* Value
Functioning	GHS/QoL	-2.2 (-4.3, -0.1)	0.0382
	Physical	-1.6 (-3.9, 0.7)	0.1663
	Role	-1.7 (-4.2, 0.9)	0.2009
	Emotional	-0.9 (-2.7, 1.0)	0.3620
	Cognitive	-0.9 (-3.0, 1.1)	0.3791
	Social	-0.9 (-2.9, 1.2)	0.4088
Symptoms	Fatigue	2.4 (0.1, 4.7)	0.0437
	Nausea + Vomiting	0.8 (-0.1, 1.6)	0.0723
	Pain	-0.8 (-3.3, 1.7)	0.5270

Positive values favor TALA + ENZA for GHS/QoL and functioning scales; negative values favor TALA + ENZA for symptoms scales.

11121 Poster Session

Final patient-reported outcomes (PROs) in men with metastatic castration-resistant prostate cancer (mCRPC) and homologous recombination repair (HRR) gene alterations receiving initial treatment with talazoparib (TALA) + enzalutamide (ENZA) vs placebo (PBO) + ENZA in the TALAPRO-2 study.

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Background: The phase 3 TALAPRO-2 study showed a statistically significant improvement in radiographic progression-free survival for TALA + ENZA vs PBO + ENZA (HR=0.45; 95% CI, 0.33–0.61; $P<0.0001$) in men with HRR-deficient mCRPC. Prior PRO analyses (data cutoff: Oct 3, 2022) reported no clinically meaningful between-arm differences in any functioning scales and a longer time to definitive deterioration (TTDD) in global health status (GHS)/quality of life (QoL) for TALA + ENZA (median 27.1 mo) vs PBO + ENZA (median 19.3 mo; HR=0.69; 95% CI, 0.49–0.97; $P=0.032$). Here we report updated (data cutoff: Sep 3, 2024) final PROs for the HRR-deficient cohort. **Methods:** PROs were assessed at day 1 (baseline) and every 4 wks until wk 53, then every 8 wks until radiographic progression using the EORTC QLQ-C30 and its prostate cancer module, QLQ-PR25, and worst pain by BPI-SF item 3. Prespecified PRO endpoints included overall mean change from baseline (per longitudinal repeated measures mixed-effects model), time to deterioration (TTD), and TTDD. The clinically meaningful threshold was ≥10 points for EORTC scales, ≥2 points for BPI-SF. Between-arm comparisons of TTD/TTDD were made via stratified log-rank test and Cox proportional hazards models. **Results:** At extended follow-up, 394/399 patients in the HRR-deficient cohort (n=197, both arms) had completed baseline + ≥1 follow-up PRO score. TALA + ENZA resulted in a numerically longer TTDD in GHS/QoL vs PBO + ENZA (HR=0.766; 95% CI, 0.555–1.057; $P=0.1063$; median, 34.2 vs 22.1 mo, respectively). HR for TTDD in disease-specific urinary symptoms was 0.684; 95% CI, 0.421–1.113; $P=0.1247$) for TALA + ENZA vs PBO + ENZA. TTD in worst pain by BPI-SF favored TALA + ENZA vs PBO + ENZA (HR=0.552; 95% CI, 0.325–0.937; $P=0.0255$). Differences in physical, role, emotional, cognitive functioning scores and pain favored TALA + ENZA vs PBO + ENZA, but did not meet the clinically meaningful threshold (Table). **Conclusions:** With extended follow-up, treatment differences favoring TALA + ENZA vs PBO + ENZA were observed in some functioning and symptoms scales. Consistent with prior analyses, overall QoL was maintained in patients with HRR-deficient mCRPC receiving initial treatment with TALA + ENZA in TALAPRO-2. Clinical trial information: NCT03395197. Research Sponsor: Pfizer Inc.; Astellas Pharma Inc.

QLQ-C30 Scale		Estimated Mean Difference, TALA + ENZA – PBO + ENZA (95% CI)	*P* Value
Functioning	GHS/QoL	2.7 (-0.8, 6.2)	0.1294
	Physical	5.3 (1.9, 8.7)	0.0022
	Role	4.3 (0.0, 8.6)	0.0524
	Emotional	4.9 (1.6, 8.2)	0.0038
	Cognitive	5.5 (2.0, 9.1)	0.0024
	Social	1.9 (-1.7, 5.4)	0.3005
Symptoms	Fatigue	-1.5 (-5.2, 2.3)	0.4448
	Nausea + Vomiting	0.1 (-1.4, 1.6)	0.8936
	Pain	-8.5 (-12.3, -4.7)	<0.0001

Positive values favor TALA + ENZA for GHS/QoL and functioning scales; negative values favor TALA + ENZA for symptoms scales.

Beyond survival: Prospective longitudinal insights into quality of life after hepatectomy for colorectal liver metastases.

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Background: The long-term health related quality of life (QoL) after curative intent hepatectomy for high-risk colorectal liver metastases (CRLM) is not well described. **Methods:** This prospective single-center study enrolled patients with resectable CRLM with Clinical Risk Score ≥3. European Organization for Research and Treatment of Cancer QLQ-C30, LMC21, and EuroQol EQ-5D-5L were administered at preoperative and postoperative visits, and at 6, 12, 18, 24, and 36 months from hepatectomy. Patient characteristics at baseline along with colorectal cancer disease state were collected at each timepoint on a scale from no evidence of disease (NED) to progressive disease on best supportive care. Linear mixed models were used to examine the trajectory of QoL scores with disease state modeled as a time-varying variable. **Results:** From 297 consented, 146 were evaluable by completing preoperative and postoperative surveys. Median age was 52 years (IQR: 45, 63), 42% (n=61) were female, 84% (n=122) were Non-Hispanic White, 70% (n=102) had synchronous CRLM, and 80% (n=117) received hepatic artery infusion chemotherapy (HAIC). Overall, QLQ-C30 demonstrated decrease in global health from baseline at post-operative survey ($p<0.05$) with subsequent improvements until returning to pre-operative levels at 12 months. Similarly, self-assessed health state on EQ-VAS– a visual analog scale from 0 to 100 that corresponds to worst and best health possible, respectively– decreased post-operatively ($p<0.05$) with recovery to baseline by 6 months. Among NED patients, QLQ-C30 QoL scores recovered to pre-operative levels 6 months after hepatectomy, whereas those with recurrent cancer reported scores below baseline at every follow-up assessment (all $p<0.05$). On EQ-VAS, NED patients were comparable to baseline at 6 months and reported higher scores than baseline at 24 months ($p=0.029$). Patients with recurrence had similar EQ-VAS scores as baseline at 12 months but remained lower than NED patients at each timepoint (all $p<0.05$). HAIC did not impact QoL assessed by QLQ-C30 ($p=0.725$) or EQ-VAS ($p=0.559$) during follow-up. **Conclusions:** Health related QoL suffers in the immediate post-operative period before returning to pre-operative levels and exceeding it among patients without recurrence. While cancer recurrence significantly influenced patient experience, HAIC did not sway QoL. Research Sponsor: None.

Comparison of self-assessed EQ-VAS scores stratified by cancer recurrence status, where 0 and 100 correspond to worst and best health possible, respectively.

Time Point	No Recurrence, QoL Estimate	Cancer Recurrence, QoL Estimate	P-value
Pre-op		75.28	
Post-op		66.45	
6m	75.37	68.10	<0.05
12m	80.78	70.15	<0.05
18m	80.28	70.48	<0.05
24m	83.38	74.21	<0.05
36m	78.32	57.44	<0.05

Quality of life in a phase III study of prospective radiation therapy (IMRT) +/- cetuximab for locally advanced resected head and neck cancer: NRG/RTOG 0920.

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Background: We tested the primary question whether the addition of cetuximab to postoperative radiotherapy (IMRT) results in poorer patient reported outcomes (PROs) at 12 months compared to IMRT alone. We also examined changes in PROs over time. **Methods:** Randomized and eligible patients who consented to quality of life (QOL) assessment completed PROs measured by 5 instruments, prior to treatment (baseline) and at 3, 12, and 24 months after IMRT. Instruments included: 1) *Functional Assessment of Cancer Therapy-Head & Neck (FACT-HN)*, a multidimensional QOL instrument for use with head and neck cancer patients; 2) *University of Michigan Xerostomia-Related Quality of Life Scale (XeQOLS)* covering mouth/throat dryness and its impact on oral health-related QOL; 3) *Dermatology Life Quality Index (DLQI)* for skin-related changes; 4) *EuroQol (EQ-5D-3L)* covering usual activities and perceived current health state; 5) *Performance Status Scale for Head and Neck Cancer (PSS-HN)* assessing normalcy of diet, public eating, and understandability of speech. Higher scores on XeQOLS and DLQI indicate worse QOL; otherwise higher scores indicate better QOL for other measures. For FACT-HN, XeQOLS, DLQI, and EQ-5D-3L, changes from baseline were compared by Van Elteren test, and for PSS-HN, the % $\leq$ 50 was compared by Z test. 158 patients per arm provided 80% power to test the difference between IMRT + cetuximab and IMRT alone. Changes in PROs over time were evaluated using mixed models. Two-sided tests were used with α=0.05. **Results:** 499 of 577 eligible patients (86%) consented to QOL. There were no significant differences between treatment arms (IMRT vs. IMRT + cetuximab) for all PRO measures in change from baseline to 3 or 12 months post-IMRT (see table). At 24 months, the change from baseline was significantly different for DLQI (p=0.02), but the difference was not clinically meaningful; other PROs were not significantly different. There were no significant differences between treatment arms for PSS-HN diet, eating, or speech at any time point (see table). Regarding treatment effect over time, in both treatment groups, all PRO measures showed greatest decline at 3 months followed by improvement towards baseline by 24 months. **Conclusions:** Treatment with IMRT + cetuximab was not associated with worse PROs compared to IMRT alone. Furthermore, findings demonstrate important recovery trends in QOL with return to baseline for most measures in both study arms. Clinical trial information: NCT00956007. Research Sponsor: National Cancer Institute; UG1CA189867; National Cancer Institute; U10CA180868; National Cancer Institute and Eli Lily; U10CA180822; National Cancer Institute and Eli Lily; U24CA196067; National Cancer Institute and Eli Lily; U24CA180803.

Results at 12 months.

Instrument (score range)		IMRT	IMRT+Cetuximab	p-value
FACT-HN (0-148)	n	122	132	
	Mean change	-0.41	1.31	0.94
XeQOLS (0-4)	n	105	114	
	Mean change	0.52	0.46	0.99
DLQI (0-30)	n	121	133	
	Mean change	-0.07	0.44	0.23
EQ-5D-3L (0-1)	n	108	117	
	Mean change	0.01	0.02	0.87
PSS-HN diet (0-100)	n	130	141	
	% $\leq$ 50	37.7	39.7	0.73
PSS-HN eating (0-100)	n	130	141	
	% $\leq$ 50	20.0	15.6	0.34
PSS-HN speech (0-100)	n	131	140	
	% $\leq$ 50	10.7	7.9	0.42

11124 Poster Session

Cancer misinformation and trust in doctors and scientists among cancer survivors.

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Background: Health misinformation is a significant public health concern and has acutely worsened in the past decade. Cancer survivors must navigate a complex health system after a critical diagnosis and may be particularly susceptible to the adverse effects of misinformation. This study explores information perception and trust between survivors and those without (w/o) a cancer history. **Methods:** Data from the nationally representative Health Information National Trends Survey (HINTS) from 2017-2022 was used to compare questions regarding cancer and health information and trust (grouped Strongly/Somewhat Agree and Disagree) between those with a prior cancer diagnosis (survivors) and those w/o cancer. Demographic data included: age, gender, race/ethnicity, sexual orientation, education, employment, and household income. Analysis was done in STATA with Chi-squared and T-tests testing between survivors and those w/o cancer; multivariate analysis (MVA) focused on survivors. **Results:** 21,753 people were included, 3,479 (16.0%) were cancer survivors. Survivors were demographically different than those w/o cancer including being older (median 68 vs 56), less likely employed (22.5 vs 40.5%), more commonly White (80.2 vs 69.3%) and less often Black race (12.7 vs 18.4%) ($p<001$ for all). More people w/o cancer had used the internet in the past year to look for medical information (73.6% vs 70.4% in survivors), however when searching for cancer information specifically, less survivors (49.8% vs 55.7% w/o cancer) were concerned about the quality of the information (p=0.001 both). More survivors trusted information about cancer from a doctor (77.6% survivors vs 72.3% w/o cancer, p=0.02). But less people overall trusted scientists about cancer information (52.1% survivors, 57.2% w/o cancer, p=NS) with 1 in 20 people trusting scientists "not at all" (5.1% survivors, 5.2% w/o cancer, p=NS). More than half felt that health recommendations from experts seemed to conflict/contradict one another (58.1% survivors, 56.3% w/o cancer, p=NS). In an MVA of survivors, only age was associated with being concerned about the quality of cancer information online with younger survivors being less concerned [OR 0.98, 95%CI 0.96-0.99, $p<0.001$]. **Conclusions:** In this national study, researching health information online was common and roughly half were concerned about the quality of cancer information they found. Compared to those w/o a cancer history, cancer survivors were less concerned about their ability to find high quality cancer information with younger survivors feeling the most confident. While most people trusted doctors, more than half said that experts seemed to contradict each other and 1 in 20 had no trust in scientists to provide cancer information. Future interventions should focus on health information literacy and improving communication on evidence-based cancer information. Research Sponsor: None.

11125 Poster Session

Circulating tumor DNA (ctDNA) analysis guiding adjuvant therapy in patients (pts) with colorectal cancer (CRC): Impact on fear of cancer recurrence (FCR).

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Background: ctDNA detection following curative intent treatment is highly prognostic, with potential to impact patient fear of cancer recurrence (FCR). In 3 separate randomized trials (DYNAMIC II, III, rectal), pts with early-stage CRC were randomly assigned to treatment decision guided by ctDNA results (adjuvant chemotherapy escalation if ctDNA positive, de-escalation or no treatment if ctDNA negative), or according to standard clinicopathological features. The relationship between being informed of a high recurrence risk, or treatment de-escalation, and FCR is unclear. This study aims to explore the relationship between biomarker-informed adjuvant chemotherapy (ACT) decision making and FCR, including changes over time. **Methods:** A subset of pts from the 3 DYNAMIC studies completed validated self-report questionnaires measuring FCR, anxiety, depression and quality of life. Data were collected at three time points: after surgery (T1), at the time of the ACT decision (T2), and 9-12 months later (T3). Pts randomized to the ctDNA-guided group received a ctDNA test result (positive or negative) at T2, while those in the standard of care (SOC) group did not. The primary endpoint was the FCR Inventory Short Form score (FCRI-SF). FCR patterns over time were analyzed using a mixed model 2 (Randomization) x 3 (Time) ANCOVA. A 2 (Randomization) x 2 (Chemotherapy Status) ANCOVA was used to assess ACT's impact on FCR at follow-up. Gender, age, and cancer stage were included as covariates. **Results:** 317 pts from 35 Australian sites participated in the FCR substudy (74% response rate for all timepoints). Two-thirds were male, and the mean age was 60 years. Of the ctDNA-guided group (n=176), 73% had a negative ctDNA result. At baseline, 63% of patients exhibited clinically significant levels of FCR (FCRI-SF >13). Younger age, female gender, anxiety, and higher cancer stage all predicted higher baseline FCR. FCR significantly decreased over time for all pts ($F(2,176) = 3.64$, $p = .03$). This reduction was more pronounced in the ctDNA-guided group compared to the SOC group ($F(2, 176) = 3.83$; $p = .02$), although the effect size was small (Cohen's d =0.24). In the ctDNA-guided group, no differences in FCR were found between pts based on ctDNA result (positive vs. negative). High baseline anxiety was the only independent predictor of FCR at 12 months. Chemotherapy receipt, cancer stage, depression, and quality of life scores were not predictive of FCR over time. **Conclusions:** In pts with early-stage CRC, neither a positive nor negative ctDNA result impacted FCR. ctDNA-guided approach to determining ACT was associated with a greater reduction in FCR over time compared to SOC. This biomarker-guided treatment approach has potential to improve ACT selection as well as psychosocial outcomes. Temporal reduction in FCR is likely driven by increased prognostic certainty over time. Clinical trial information: 12615000381583. Research Sponsor: St Vincents Hospital Research Endowment Fund.

11126 Poster Session

Electronic patient-reported outcomes (ePRO) in patients with advanced melanoma receiving immune checkpoint inhibitors: Insights from the Canopy ePRO system.

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Background: Health-related quality of life (HRQoL) outcomes are prognostic in melanoma. There is little data comparing HRQoL during nivolumab (nivo) and pembrolizumab (pembro) exposure in patients with melanoma. Electronic patient-reported outcomes (ePROs) provide valuable insights into HRQoL; this study reports on ePRO data from community oncology practices using the Canopy Remote Therapeutic Monitoring (Canopy RTM) platform to explore ePROs in patients with melanoma treated with nivo, pembro, or nivo/ipi. **Methods:** The Canopy RTM system is a proprietary, cloud-based platform that directly integrates with electronic medical records systems to enable RTM. Patients using Canopy RTM could submit symptom reports using smart devices or a phone system. This study retrospectively analyzed ePRO data of patients with melanoma treated with nivo, pembro, or nivo/ipi, excluding those who received chemotherapy during index treatment. Symptom and broad symptom category reporting during each treatment was assessed using descriptive statistics. Sensitivity analyses were performed, including limiting time at risk of symptom reports to 60 days following index and excluding patients with record of exposure to ipilimumab prior to index. **Results:** 386 patient treatments were included: 140 receiving nivo; 169, pembro; and 57, nivo/ipi. Median age was 66, 69, 61 years across the nivo, pembro, and nivo/ipi groups, respectively. Median time on therapy was 285, 269, 49 days for nivo, pembro, and nivo/ipi, respectively. Compared to pembro, nivo treatment was associated with higher incidence of infection symptoms, difficulty with activities of daily living, gastrointestinal symptoms, and pain (Table 1). Despite significantly shorter time on therapy, more patients reported infection and rash during nivo/ipi treatment than during nivo treatment. Sensitivity analysis limiting time at risk of symptoms to 60 days following index revealed similar findings, albeit with greater proportions of patients treated with nivo/ipi reporting symptoms across most symptoms. **Conclusions:** Pembro monotherapy may be associated with a lower incidence of some symptoms compared to nivo (+/- ipi), while nivo monotherapy has fewer symptoms than nivo/ipi treatment. Further research is warranted to confirm these findings. Research Sponsor: Canopy Care.

Select symptoms and symptom categories (composites) reported during treatment.

Symptom or composite	Pembrolizumab	Nivolumab	Nivo/Ipi
Infection (composite)	57 (34%)	67 (48%)	31 (54%)
Cough	25 (15%)	30 (21%)	14 (25%)
Fever under 100.4F	6 (3.6%)	10 (7.1%)	7 (12%)
Difficulty breathing	27 (16%)	26 (19%)	13 (23%)
Gastrointestinal (composite)	69 (41%)	67 (48%)	30 (53%)
Indigestion	13 (7.7%)	16 (11%)	5 (8.8%)
Diarrhea	36 (21%)	31 (22%)	14 (25%)
Activities of daily living (composite)	84 (50%)	88 (63%)	34 (60%)
Rash	22 (13%)	20 (14%)	15 (26%)

Evaluating acceptance of scalp cooling in patients receiving chemotherapy for primary gynecologic cancers: Lessons from a randomized controlled trial.

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Background: Scalp cooling is effective in preventing chemotherapy-induced alopecia (CIA) in cancer patients. However, its effect and acceptance are not certain in gynecologic cancer patients particularly in Asia. **Methods:** The CHARM study was a single-center randomized study. Women with proven gynecologic cancer planning for 3-weekly carboplatin and paclitaxel were randomised to receive usual care (control group) or scalp cooling using the Paxman Orbis II system (Paxman Coolers Limited, Huddersfield, United Kingdom) (intervention group). The primary endpoint was the incidence of psychological distress, i.e., Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) score ≥10. The study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UWB 19-514). **Results:** Between November 2019 to November 2021,142 women were invited to join the study. 56 women (39.4%) declined to participate, and the most common reason was worries about coldness (Table 1). 44 women were randomized to the intervention group and 42 to the control group. Fewer women in the intervention had psychological distress compared to the control group after cycle 2 of chemotherapy (27.8% vs 62.2%, p=0.003). The incidence of Grade ≥ 3 adverse events were similar between both groups (7.5% vs 5.1%, p=1.0). However, 12 out of 40 (30.0%) in the intervention group did not comply with scalp cooling, among which nine (75%) were due to feeling cold despite measures like using blankets and hot water. **Conclusions:** Scalp cooling was associated lesspsychological distress in Asian women using chemotherapy for gynecologic cancer. Nevertheless, the high refusal rate to join the study and high drop-out rate limited its use in these women. This might be partially due to some misbelief that associated head coldness with poor general health in Traditional Chinese Medicine. More strategies are needed to improve the acceptance of scalp cooling. Clinical trial information: NCT04168242. Research Sponsor: WKK Medical Equipment Company Limited.

Reasons for refusal to join the study.

Reasons	Number of women (%)
Worries of coldness	34 (60.7%)
Worries of musculoskeletal pain/headache	2 (3.6%)
Psychiatric stress	2 (3.6%)
Personal image	4 (7.1%)
Logistic issue	3 (5.4%)
Unknown reasons	11 (19.6%)
Total	56

11128 Poster Session

Preliminary findings from the ALVA ePRO Platform pilot study: A novel approach to collecting quality of dying and death data among informal caregivers in palliative care.

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Background: Quality of Dying and Death (QODD) is a pivotal outcome in end-of-life care, yet traditional data collection methods, such as phone calls, often suffer from low compliance and significant caregiver burden. The ALVA ePRO platform, a novel tool developed for collecting Patient-Reported Outcomes (PRO) via text messaging apps, aims to overcome these challenges by improving data collection efficiency and caregiver experience. This study evaluates the feasibility, compliance, and acceptability of ALVA ePRO among informal caregivers of terminal cancer patients in a Latin American palliative care setting. **Methods:** We conducted a pilot, single-arm study with 21 informal caregivers of terminal cancer patients. Participants received the QODD questionnaire through their preferred text messaging app. Caregivers who preferred traditional phone calls were allowed to use that method. Compliance was measured by the completion rate of the questionnaires, while acceptability was assessed through semi-structured interviews. Descriptive statistics were used for quantitative outcomes. **Results:** A total of 38 caregivers were invited to participate, and 21 caregivers signed the informed consent. Of the 21 participants, 20 completed the questionnaire, while 1 did not due to difficulty understanding the questions. Completion times ranged from 5 minutes to 23 hours and 34 minutes, highlighting considerable variability. Reasons for non-participation included technical issues, scheduling conflicts, and caregiver reluctance to attend the hospital. Preliminary interview data revealed that caregivers found the platform user-friendly and appreciated the flexibility it offered, though a few faced emotional challenges when recalling sensitive experiences. **Conclusions:** The ALVA ePRO platform demonstrates high acceptability and a strong completion rate, with significantly improved compliance compared to historical phone-based methods. It also significantly improved adherence and completion compared to our previous phone call approach using the same questionnaire. Interest in participation increased from 67.0% to 81.6%, and the completion rate from 92% to 95%. These findings suggest that text message-based data collection is an effective approach for collecting QODD data in palliative care, particularly in settings with logistical or emotional barriers to traditional methods. Future work will focus on refining the platform and exploring its scalability for larger cohorts and other palliative care contexts. Research Sponsor: The Hope Foundation for Cancer Research; 2024.

Summary of key measures and completion time for the ALVA ePRO Platform pilot study.

Measure	Preliminary Result
Enrollment (target: 20)	21 signed consent
Completion rate	95% of enrolled participants
Average Completion Time	174 minutes
Median Completion Time	16 minutes
Messaging app used	Whatsapp (100%)

11129 Poster Session

A patient-reported outcome measure (PROM) to capture patients' experiences with immuno-oncology therapy (IO)-induced cytokine release syndrome (CRS): The IO-induced CRS patient diary.

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Background: IO-inducedCRS has various signs and symptoms that impact different aspects of patients' lives. While the frequency and severity of IO-induced CRS events underscore the benefit–risk profile and tolerability of IO therapies, patients' perceptions are critical for measuring the impact of these events on their lives. In this qualitative research study, we developed a novel PROM to track the onset, resolution, and impact of IO-induced CRS events in clinical trials. **Methods:** Clinician insights and patient interviews were used to identify common IO-induced CRS signs, symptoms, and impacts. Patient-reportable symptoms and impacts were prioritized to form the basis of the IO-induced CRS Patient Diary. The PROM was tested in cognitive debriefing (CD) interviews with 3 clinicians and 3 waves of CD interviews with patients on IO (5 per wave; N = 15). Changes were made to the PROM between each wave to ensure relevance and improve interpretation and usability. **Results:** After a literature review, qualitative research with 9 clinical experts, and concept-elicitation interviews with 14 patients on IO (3 on CAR-T, 11 on non-CAR-T therapy), 37 patient-reportable signs and symptoms and 7 clinical signs (non–patient reportable) associated with IO-induced CRS were listed. Patients' concept descriptions and clinicians' concept priorities were examined, and 12 symptoms and 4 impacts across 5 domains (emotional, physical, social, activities of daily living, and financial) were included in the final diary. The IO-induced CRS Patient Diary—an electronic PROM—has three versions for use at different points in a clinical trial. The "baseline" version is completed before initial IO administration; patients report the incidence and severity of 12 symptoms and their impact on overall health (recall period: the past week). The "day of treatment" version, completed the evening of the treatment day, asks the same questions, plus about symptom manageability (recall period: since receiving the study medication on that day). The "subsequent days" version is the same as the "day of treatment" version, but also asks about impact on regular daily activities, need to rest, and amount of worry caused by CRS (recall period: past 24 hours). It may be completed daily depending on the study design or set of outcomes. **Conclusions:** The IO-induced CRS Patient Diary, the first of its kind, was developed in line with best practices and is content-valid for the intended use: to capture patients' experiences with IO-induced CRS events in clinical trials. Understanding these impacts will inform the benefit–risk profile and tolerability of IO therapies. This PROM may also have value in clinical practice, for which additional validation would be needed. Future work will aim to assess its psychometric performance in clinical trials. Research Sponsor: None.

11130 Poster Session

Electronic patient-reported outcomes (ePRO)-based alerts deployed in clinical practice to inform treatment burden and care management in pancreatic cancer.

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Background: Pancreatic ductal adenocarcinoma (PDAC) is characterized by aggressive growth and late-stage diagnosis. About 20% of patients are eligible for surgery at diagnosis and are usually accompanied by adjuvant/neoadjuvant chemotherapy and/or radiation, with high recurrence rates. The use of ePROs to inform patient symptom (SX) experience and guide clinical care is increasing. Objectives for this study were to assess treatment burden and management of PDAC and explore care team engagement in the clinical practice using ePRO-based alerts data. **Methods:** PDAC patients were enrolled in an ePRO platform called PROmpt from 9/2020 to 11/2024. Patients received weekly surveys to report PRO-CTCAE-derived SX experienced during treatment. When a SX was reported as moderate or severe, an algorithm-based system would generate an "alert" notification per SX to the care team who reviewed the alert, interacted with the patient, and recorded the response on the platform. Treatment burden was measured by the symptom prevalence and number of alerts per week. Results were explored by stage (I-II or III-IV), frailty status (fit vs. frail), and age (<65 vs. 65+). Time to alert resolution and clinical actions were described. **Results:** A total of 67 patients were included, of which 58 (86.6%) reported a moderate/severe SX at least once. Median age was 67 (range: 40-87), 56.7% male, 62.7% late stage, and 50.7% frail. Most patients (64.2%) received FOLFOX and 35.8% were on Gemcitabine-based regimen. No baseline difference in patients who reported an alert versus not. Patients reported, on average, 2.8 symptoms per week with median follow up of 9.3 weeks. Of 513 total alerts generated, 54.6% occurred in the first 8 weeks of treatment. The top SX triggering an alert were pain (24.4%), nausea/vomiting (15%), and decreased appetite (14%). Average number of alerts per patient per week was 1.7 (SD=1.2, Median=1). No significant difference was observed by frailty status or age, but patients in the late-stage group generated higher alert/week than early stage (1.8 vs. 1.6). Average time to alert resolution was 2.2 days with a median of 1 day. Most alerts (72.3%) were addressed in less than 2 days. The most common clinical action taken to resolve the alerts was monitoring (86%), which included contacting oncologist support as needed, increased patient education, or follow-up at next scheduled visit. **Conclusions:** The treatment burden in PDAC was high with patients experiencing about 3 symptoms per week, of which nearly 2 of them were moderate/severe. Care team engagement was high as evidenced by prompt SX mitigation. Data collected from an ePRO-based alerts system can be used to characterize treatment burden and care team response in PDAC. Future study should include broader sample size and assess the impact of alerts on health resource utilization in PDAC. Research Sponsor: None.

Evaluation of sleep quality and quality of life among patients newly diagnosed with head and neck cancer.

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Background: Patients diagnosed with head and neck cancer (HNC) often suffer from distress attributed to their cancer diagnosis which may disturb their sleep, in turn impacting their quality of life (QoL). However, there is lack of research about the association between poor sleep quality and QoL among patients newly diagnosed with HNC. We assessed the association between in poor sleep quality and QoL among patients with HNC before starting treatment. **Methods:** This is a retrospective cohort study of patients with HNC between January 2019 and September 2022. All patients with HNC treated at this tertiary care health system are evaluated prior to starting treatment by psych-oncology, using a semi-structured assessment and validated measures including the FACT-HN and Insomnia Severity Index (ISI). The FACT-HN is a 27-item validated instrument that consists of five subscales: that assesses the patient's quality of life in the physical, social/family, emotional, functional domains, and HNC-specific domains. Sleep quality was assessed via ISI, a 7-item self-report questionnaire assessing the nature, severity, and impact of sleep difficulties (defined as absence, sub-threshold, moderate, or severe). We used five beta regression models to examine the association between sleep quality via the ISI and QoL via the FACT-HN (one for each subscale: emotional, social, physical, functional, and hand and neck). These models are adjusted with a variety of demographic covariates and social factors along with clinical factors. To estimate confidence intervals, bootstrap methods with bias correction were employed. **Results:** The analysis included 312 patients, 5.4% reported severe and 15.1% moderate sleep difficulties. After adjusting for other covariates, sleep difficulties were significantly associated with all FACT-HN subscales. Compared to patients with no sleep difficulties, patients with severe difficulties had a decrease in emotional (β=-1.33, 95% CI, -1.67, -0.93), social (β=-0.90, 95% CI, -1.66, -0.37), physical (β=-2.27, 95% CI, -2.67, -1.74), functional (β=-1.64, 95% CI, -2.10, -0.87), and head and neck (β=-1.11, 95% CI, -1.58, -0.65) QoL. Similarly, compared to patients with no sleep difficulties, those with severe difficulties had a decrease in emotional (β=-1.34, 95% CI, -1.66, -0.98), social (β=-0.61, 95% CI, -0.99, -0.17), physical (β=-1.85, 95% CI, -2.18, -1.49), functional (β=-1.37, 95% CI, -1.71, -0.89), and head and neck (β=-1.04, 95% CI, -1.34, -0.69) QoL. **Conclusions:** We found that patients with moderate or severe sleep difficulties had poor QoL. Early evaluation and tailored intervention to improve sleep quality are necessary to prepare these patients for HNC treatment and its consequences. Future studies are needed on sleep quality among patients during and after treatment. Research Sponsor: None.

11132 Poster Session

Financial burden and financial toxicity in cancer patients: A sub-analysis from a Brazilian prospective cohort.

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Background: Financial toxicity during cancer treatment can impact patients' quality of life (QoL), adherence, and survival. Identifying subgroups with financial vulnerability among cancer patients is important to reduce disparities and develop equity-certified policies. Our study assesses financial burden (FB) and financial toxicity (FT) across different cancer types from the patient's perspective. **Methods:** This is an unplanned sub-analysis of four prospective, observational studies about real-world QoL in patients with breast (BC), prostate (PC), colorectal (CRC), and lung cancer (LC) treated at two private healthcare facilities in Brazil. We analyzed responses to Question 28 of the EORTC QLQ-C30 questionnaire. Patients reporting financial difficulties at baseline and six months were categorized as experiencing FB. Those with worsening or newly reported issues were classified as FT. FB and FT were analyzed as binary variables (any grade vs. none). Associations with clinical and epidemiological variables were assessed using univariate and multivariate logistic regression models, with a 5% statistical significance. Analyses were conducted using R software, version 4.4.1. **Results:** Between March 2015 and May 2024, 1,343 patients met the inclusion criteria: 56 with CRC, 387 with BC, 638 with PC, and 262 with LC. Most patients were male (60%) and white (77%), with a median age of 62.2 years. Only 15% had metastatic disease. At baseline, 23% reported FB, rising to 25% at six months, with 16% developing FT during treatment. Greater financial difficulties were found in women with breast cancer (FB 33%, FT 20%), while the lowest was seen in men with prostate cancer (FB 20%, FT 13%). Univariate analysis identified mixed-race ethnicity (OR 1.42; p=0,024), younger age (OR 0.96; p<0,001), and female gender (OR 0.55; p=<0,001) as FB risk factors, but only age remained significant in the multivariate model (OR 0.97; p = 0,003). Univariate analysis also linked age (OR 0.97; p<0,001), gender (OR 0.63; p=0,002), and comorbidities (OR 0.71; p=0,034) to FT, but only age remained significant in the multivariable model, with a 2% reduction in FT for each additional year (OR 0.98; p = 0.016). This study is ongoing and the impact of FB and FT on survival outcomes will be analyzed and reported in future work. **Conclusions:** This study highlights the impact of FT on cancer patients in Brazil treated in private health centers. Younger age emerged as an independent risk factor for both FT and FB after six months of treatment. Further research is needed to better understand FT within the Brazilian population, particularly in the public health system, and to develop strategies to mitigate its effects and improve patient outcomes. Research Sponsor: None.

11133 Poster Session

The impact of a second primary cancer diagnosis on health-related quality of life in African American cancer survivors.

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Background: Survival for the most common cancers has improved dramatically over the past several decades due to advances in treatment and screening for early detection. An unintended consequence of this is that survivors now face a greater possibility of developing one or more new primary cancers in their lifetime. It has been estimated that up to 22% of cancer survivors will be diagnosed with multiple primary cancers (MPCs). Understanding the impact of these diagnoses on outcomes along the survivorship continuum is important in developing tools to mitigate risks. **Methods:** The Detroit Research on Cancer Survivors (ROCS) cohort has enrolled more than 5,000 Black cancer survivors to understand the multiplex causes of poor outcomes in this high-risk population. Detroit ROCS participants are surveyed annually following enrollment to update medical history and mental health outcomes including health-related quality of life (HRQOL) measured using the Functional Assessment of Cancer Therapy (FACT-G) survey. In addition, regular linkages with the Metropolitan Detroit Cancer Surveillance System (MDCSS) registry are used to identify second primary cancer diagnosis, confirm self-reports, and gather relevant clinical data. The ROCS cohort is in its 9th year of potential follow-up. In 2024, the Detroit Genetic Epidemiology of Multiple primary cancers (GEMS) study was funded to examine susceptibility to MPCs leveraging Detroit ROCS to identify first primary breast, prostate and colorectal cancer survivors diagnosed with a second primary cancer. Analyses included comparisons of HRQOL and other characteristics 1) between MPCs and a frequency-matched (3:1) subset of single primary cancer (SPC) cancer cases; and 2) among MPCs, using survey data collected before and after their second diagnosis. **Results:** To date, Detroit GEMS includes 371 Black MPCs confirmed in MDCSS. The most common second primary cancer diagnosed among survivors was breast, followed by colorectal, lung and hematologic cancers. No significant differences were observed between MPCs and SPCs in the total FACT-G score, however when evaluating FACT-G subscales MPCs reported a significantly lower mean functional well-being score (16.9 and 18.0, respectively; p=0.022). Similar findings were observed in a subset of 104 MPCs with functional well-being scores reported before and after their second diagnosis (18.0 and 16.1, respectively; p=0.004). **Conclusions:** Cancer survivors diagnosed with a MPC report similar HRQOL compared with survivors with a SPC, suggesting resiliency in Black cancer survivors which is encouraging. However, understanding factors that contribute to declining functional well-being will be important in early interventions to improve overall quality of life. Research Sponsor: U.S. National Institutes of Health; U01 CA199240 and P01 CA272239.

The impact of breast cancer treatment on young women's body image and sexual health.

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Background: In 2023 MSKCC launched the Young Women with Breast Cancer Program (YWBCP) to provide comprehensive care, education, and research studies for young women with cancer. This program explored how breast cancer treatment impacts body image, sexual health, self-esteem, and personal priorities. **Methods:** MSKCC's YWBCP conducted online surveys of women aged 45 and younger at diagnosis (intake) (n=964) and six months into treatment (n=328). Surveys assessed psychological wellbeing, sexual health, body image, and referral requests. This abstract analyzes data from both surveys. **Results: I**ntake data (n=964) revealed 57% (n=544) had children before diagnosis. 25%(n=236) sought information on fertility preservation, while 16% (n=156) were interested, but not ready for it. 18% (n=169) underwent fertility preservation. 26% (n=251) had a desire to protect fertility, but had not yet. Paired analysis (n=328) from intake and follow up showed 46% (n=147) felt less positive about their bodies, 42% (n=134) had no change, and 13% (n=41) improved. Half (50%; n=161) reported decreased appreciation of their body's uniqueness and 37% (n=118) no change. In response to the statement, "I act as though I like my body," 36% (n=115) declined, 24% (n=76) improved, and 40% (n=128) were consistent. Interest in sexual activity decreased (34%; n=107) more than increased (24%; n=75). Sexual satisfaction also declined in 55% (n=169), but improved in 16% (n=49) and remained the same in 29% (n=91). Concern about cancer or treatment affecting sexual ability decreased in 31% (n=98), increased in 27% (n=86) and was unchanged in 41% (n=129). At baseline women's top three concerns were cancer's impact on friends and family (27%; n=480), discussing cancer with loved ones (16%; n=282) and financial issues (15%; n=272). Social work requests prioritized individual therapy (23%; n=326), support groups (21%; n=301), family support (19%; 265), educational programs (13%; n=189), mental health resources (12%; n=170) and peer-to-peer programs (12%; n=176). Concerns were prioritized differently at 6 months, with financial issues (21%; n=113) first, followed by cancer's impact on friends and family (19%; n=102), then relationships (16%; n=83). Social work preferences changed slightly: individual therapy (28%; n=86), support groups (19%; n=59, educational programs (14%; n=45), mental health resources (14%; n=45); peer-to-peer programs (13%; n=41) and family support (11%; n=35). **Conclusions:** YWBCP data show the importance of onco-fertility and social work counseling throughout treatment. Young breast cancer patients experience significant declines in body image, sexual satisfaction, and sexual desire, highlighting the need for targeted sexual health interventions. Financial toxicity worsens over time, warranting referrals to financial services to mitigate concerns. Additional intervention studies are being performed to improve patient QoL. Research Sponsor: None.

11135 Poster Session

Outpatient infusion sepsis protocol and outcomes for patients with cancer.

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Background: Sepsis, a life-threatening organ dysfunction caused by infection, is a common oncologic emergency in adult cancer patients. Early sepsis detection and timely antibiotic administration can improve outcomes and reduce mortality. As more oncology treatments move to outpatient infusion centers, implementing sepsis screening in these settings can improve early detection and opportunity for intervention. As a result, we implemented a best practice alert (BPA) and protocol for the initial evaluation and managements of sepsis in an outpatient oncology infusion center. **Methods:** We performed a retrospective study from June 2022 – December 2024 comparing outcomes of patients who presented to the outpatient oncology infusion center at our institution pre- and post-implementation of our sepsis workflow. We collected the following data: BPA alerts that were activated, time to antibiotics, initial lactate drawn, repeat lactate draw, cultures collected prior to antibiotic administration, appropriate IV fluid (IVF) resuscitation, number of patients transferred to the emergency department (ED) vs. Direct Admission (DA), length of stay, and number of Intensive Care Unit (ICU) transfers. **Results:** Pre-implementation (June – December 2022), 102 oncology patients were admitted with sepsis from the infusion center. Average time to antibiotics was 6 hours (SD=6.95), 90% had blood cultures drawn prior to antibiotic administration, 85% had lactate drawn, 80% second lactate was drawn when initial lactate was >2, and 46% had appropriate IVF. Twenty-two percent were DA. Average LOS was 11 days (SD=9.18) and 14 patients required ICU stay. Post-implementation (June 2023 – June 2024), 118 patients were evaluated and treated for possible sepsis. Average time to antibiotics was 1.5 hours, 100% had blood cultures prior to antibiotics, 95% had initial lactate, 91% had second lactate drawn if initial was >2, 46% appropriate IVF. Thirty four percent of evaluated patients were managed as an outpatient. Of those admitted, 78% were DA. The average LOS was 6 days (SD=4.6), and 4 patients required ICU stay. **Conclusions:** The outpatient sepsis protocol improved early management and treatment of patients with suspected sepsis, also improving clinical outcomes. As a result of the new workflow, more patients were directly admitted to the hospital avoiding unnecessary ED utilization. Early management helped reduce severity of sepsis resulting in fewer ICU admissions and shorter length of stay in the hospital. These improvements demonstrate the protocol's effectiveness and potential for broader application in oncology settings. Additional evaluation is needed to determine the generalizability of the protocol as it is scaled across the health system. Research Sponsor: None.

The association of cancer history with markers of cognitive decline in a large US national survey registry.

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Background: Cancer is known to cause health complications, including heart and kidney disease, but its long-term impact on cognition is less understood. Cognitive impairments, such as memory and attention problems, are common in survivors, particularly those treated with chemotherapy, known as cancer-related cognitive impairment. While physical activity may help, survivors often face higher disability rates. Clarifying cancer's long-term cognitive effects is essential for improving survivors' quality of life. **Methods:** An extensive, de-identified, publicly available database from the CDC, the Behavioral Risk Factor Surveillance System. Data collected in 2021 was analyzed using a multivariable logistic regression model to assess the association between demographics, cancer diagnosis, medical diagnoses, and various markers of cognitive decline. The final analysis had over 100,000 responses. **Results:** The logistic regression model, considering various demographic and medical parameters (Table 1), revealed that a history of cancer in both males and females was associated with markers of cognitive decline. This included depression in males (OR=1.235, 95% CI 1.180-1.293, $p<0.001$); and in females (OR=1.177, 95% CI 1.137-1.218, $p<0.001$), difficulty remembering or concentrating in males (OR=1.172, 95% CI 1.110-1.238, $p<0.001$); and in females (OR=1.155, 95% CI 1.103-1.210, $p<0.001$), and difficulty running errands in males (OR=1.174, 95% CI 1.101-1.251, $p<0.001$) and in females (OR=1.194, 95% CI 1.138-1.251, $p<0.001$). Interestingly, exercise in the last 30 days was associated with a protective effect on all markers of cognitive decline. **Conclusions:** Our analysis demonstrated a significant negative association between cancer diagnosis and markers of cognitive decline in both males and females. At the same time, exercise in the last 30 days was associated with less cognitive decline. Research Sponsor: None.

Multivariable log reg analysis assessing associations with cognitive decline markers in men.

	Depression				Difficulty Running Errands				Difficulty Remembering or Concentrating			
	P value	OR	95% CI Lower	95% CI Upper	P value	OR	95% CI Lower	95% CI Upper	P value	OR	95% CI Lower	95% CI Upper
Age (ref. 50-54 yrs)												
55-59 yrs	<.001	.866	.808	.928	0.015	0.867	0.773	0.973	0.001	0.857	0.786	0.936
60-64 yrs	<.001	.758	.708	.812	<.001	0.713	0.637	0.798	<.001	0.666	0.610	0.727
65-69 yrs	<.001	.649	.603	.700	<.001	0.604	0.534	0.683	<.001	0.576	0.523	0.634
70-74 yrs	<.001	.570	.525	.618	<.001	0.671	0.590	0.763	<.001	0.581	0.524	0.644
75-79 yrs	<.001	.447	.407	.491	<.001	0.699	0.608	0.804	<.001	0.633	0.566	0.709
≥80 yrs	<.001	.288	.259	.321	0.005	1.220	1.063	1.399	<.001	0.800	0.714	0.896
Any history of cancer (Yes vs. No)	<.001	1.235	1.180	1.293	<.001	1.174	1.101	1.251	<.001	1.172	1.110	1.238
Exercise in last 30 days (Yes vs. No)	<.001	.702	.672	.733	<.001	0.339	0.320	0.359	<.001	0.632	0.602	0.664

*Adjusted for the following variables listed: Race, USA region, BMI category, education level completed, smoking status, marital status, employment status, and metropolitan status.

11137 Poster Session

Improving genetic counseling uptake for breast, pancreatic, and prostate cancers at a safety net hospital.

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Background: Despite guideline recommendations, genetic counseling (GC) for BRCA associated cancers among underserved populations remain low. We conducted a QI project to increase GC uptake for patients with breast, pancreatic, and prostate (BPP) cancers seen in a safety net oncology clinic at Harris Health. **Methods:** Analysis of electronic medical record (EMR) data along with surveys and interviews of clinicians and staff identified: 1) a complex GC referral process with 30% unscheduled referrals in 2023, 2) lower frequency of GC appointments (appts) among established patients, and 3) clinician knowledge deficits regarding GC guidelines. Our interventions consisted of 1) developing an automated referral scheduling workflow, 2) creating an EMR report of potentially eligible patients with upcoming appts and sending monthly reminders to clinicians, and a 3) GC guidelines lecture by a genetic counselor. **Results:** There were 720 patients in the preintervention period (1/2020-5/2024) and 93 patients in the postintervention period (6-12/2024). In total, 50.5% of patients were Hispanic, 24.8% were Black, 53.7% spoke Spanish, and 67.4% received financial assistance. Amongst all patients, GC appts increased from 55.4% preintervention to 67.7% postintervention ($p = 0.02$), with increases across breast (54.6% to 67.1%), pancreatic (55.4% to 71.4%), and prostate (59.1% to 65%) cancers. Among patients meeting select NCCN GC criteria identifiable through discrete EMR data (triple negative, stage IV HER2 negative, or diagnosed age <50 breast; all pancreatic; stage IV prostate), GC appts increased from 74.0% to 82.6% ($p = 0.20$), with increases for breast (79.4% to 86.5%) and pancreatic (55.4% to 71.4%) cancers and a decrease for prostate cancer (71.9% to 60%). All GC referrals postintervention were scheduled, with time from GC referral to GC appts improving from a mean of 170.2 days (SD 636.1) to 27.4 days (SD 19.5) ($p<0.01$). Time from first oncology appt to GC appt improved from a mean of 124.2 days (SD 199.9) to 33.3 days (SD 30.5) ($p<0.01$). 87.5% of patients with GC appts consented to testing in 2023 and 86% consented postintervention. **Conclusions:** Multilevel interventions targeting both EMR capabilities as well as clinician education and awareness of eligible patients streamlined the GC referral workflow and increased GC appts among a safety net patient population with BRCA associated cancers. Research Sponsor: None.

Patients	Preintervention GC Appts (N [%] or Mean [SD])	Postintervention GC Appts (N [%] or Mean [SD])	P-Value
All Cancers	339/720 (55.4%)	63/93 (67.7%)	0.024
Breast	295/540 (54.6%)	49/73 (67.1%)	
Pancreatic	36/65 (55.4%)	5/7 (71.4%)	
Prostate	68/115 (59.1%)	13/30 (65%)	
Select NCCN Criteria	282/381 (74.0%)	38/46 (82.6%)	0.204
Breast	200/252 (79.4%)	32/37 (86.5%)	
Pancreatic	36/65 (55.4%)	5/7 (71.4%)	
Prostate	46/64 (71.9%)	3/5 (60%)	
Time from GC Referral to GC Appointment (Days)	170.2 (636.1)	27.4 (19.5)	<0.001

11138 Poster Session

OncoPRO: A US national initiative supporting implementation of remote symptom monitoring with electronic patient-reported outcomes (ePROs) in oncology practices.

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Background: Remote symptom monitoring using electronic patient-reported outcomes (ePROs) results in improved symptom management, communication, quality of life, and in some cases survival. Furthermore, value-based cancer care models such as the CMS Enhancing Oncology Model are increasingly supporting or requiring remote symptom monitoring. However, implementation at scale in real-world settings remains challenging for practices. **Methods:** OncoPRO is a national initiative in the United States that supports oncology practices and health systems in the implementation and sustainability of remote symptom monitoring programs using ePROs, integrated with electronic health record systems. OncoPRO is funded by the Patent-Centered Outcomes Research Institute (PCORI), and is led by operational groups at the University of North Carolina and the University of Alabama, in partnership with the American Society of Clinical Oncology (ASCO), the American Cancer Society (ACS), and the PROTEUS Consortium, with observers from federal agencies. **Results:** OncoPRO was initiated in March 2024, with 15 large U.S. practices/health systems participating, as well as two national practice networks, four EHR software companies, four ePRO software companies, and observers from the U.S. Centers for Medicare and Medicaid Services and the Food and Drug Administration. The central activities of OncoPRO encompass co-learning collaborative monthly meetings where leaders from each practice in clinical care, information systems, and value-based care convene to review progress, barriers and strategies for implementation, billing tactics, and other guidance. Practices share data dashboards on implementation, discuss challenges they face, and exchange success stories under the facilitation of ASCO coaches. Support materials and standard operating processes are shared by the operational team, ACS, and software vendors. Additional practices are joining the initiative both within the US and internationally. A goal is to demonstrate that implementation of remote symptom monitoring with ePROs is feasible on a wide basis and leads to improved operational and clinical outcomes. **Conclusions:** The OncoPRO initiative is supporting practices, including both community and academic, in implementing remote symptom monitoring using ePROs through a learning collaborative that is anticipated to be of interest to others considering ePRO implementation. Research Sponsor: Patient-Centered Outcomes Research Institute; DI-2023CI-31283.

11139 Poster Session

Transforming genomic testing in prostate cancer: A comprehensive system-wide initiative.

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Background: Timely detection of pathogenic variants enables personalized treatment and improved outcomes in prostate cancer (PC). In 2020, NCCN guidelines recommended genomic testing for mPC, but by 2022, only 30.8% of mPC patients in Florida had undergone appropriate testing. In our current study, we evaluate the impact of system-wide quality improvements at SCCC on genomic testing rates for mPC patients. **Methods:** In alignment with NCCN guidelines, several initiatives were launched in 2023 to enhance adherence to genomic testing practices. In May 2024, SCCC partnered with Florida Society of Clinical Oncology (FLASCO) and Pfizer on a state-wide initiative to address barriers to germline testing. A survey was conducted to assess the genomic testing process and identify gaps in adherence. System improvement projects were initiated, accompanied by efforts to raise awareness. A retrospective analysis utilizing EPIC Electronic medical record (EMR) data evaluated genomic testing rates among patients with newly identified mPC at SCCC from 2022 to 2024, stratified by ethnicity. **Results:** In 2022, baseline genomic testing rates for mPC at SCCC were 57%. Starting in 2023, high-risk cancer screening programs and EMR-focused initiatives, including the Genomics Module and Invitae integration, centralized molecular results and established registry to track alterations. In 2024, the survey revealed that 50% of physicians received unstructured genomic testing results via EMR, while 83.3% faced challenges accessing results for decision-making. Drawing from the successful breast cancer screening program, multidisciplinary teams were formed to address gaps and enhance testing adherence, focusing on awareness and enhancing EMR integration, reporting, and health prompts. That year, genomic results integration into the data portal also began. Using Slicer Dicer and Epic reporting, we evaluated testing rates, which improved to 68.6% in 2023 and 74% in 2024, with Hispanic patients achieving 76.5% and 80%, respectively. **Conclusions:** Institutional initiatives at SCCC, including expanding the Genetics program and enhancements to EMR functionality, have successfully increased genomic testing rates for mPC patients across all ethnicities. Building on this progress, approved steps for 2025 include expanding the integration of molecular testing with additional testing vendors, creating a dedicated Molecular tab with discrete fields in the EMR, and expanding education and training programs to further streamline genomic testing practices. Research Sponsor: None.

Year	Testing Rate	Hispanic	Initiatives
2022	57%	50%	–
2023	68.6%	76.5%	Jan – High Risk Screening Clinic Feb – Genetic Predisposition Syndrome Clinic Oct – Invite integration Oct – Epic Genomics Module
2024	74%	80%	May – mPC Testing Workflow assessed Sep – SCCC data portal- molecular testing results integration Oct – Multidisciplinary team to identify gaps and prioritize projects

Enhancing lung cancer surgical quality: Insights from a national quality improvement collaborative.

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Background: Sampling of at least 3 mediastinal and at least 1 hilar lymph node stations during lung cancer resection was adopted by the American College of Surgeons (ACS) Commission on Cancer (CoC) as Operative Standard 5.8 to ensure appropriate staging, guide adjuvant systemic therapy, and improve overall survival. Early assessments suggested difficulty with reaching goal hospital-level compliance rates of ≥80%. The objectives of this study were to compare compliance with Standard 5.8 before and after participation in the Lung NODES national quality improvement (QI) collaborative and to identify facilitators to achieving compliance. **Methods:** Lung NODES enrolled 354 CoC-accredited hospitals in January 2024. Over 12 months, all hospitals actively participated in guided root cause analyses, educational webinars, peer-to-peer learning, and the development and implementation of hospital-level strategies. Baseline and post-participation surveys collected data on Standard 5.8 compliance and differences in hospital-level compliance were assessed using Wilcoxon signed-rank tests. The post-participation survey queried hospitals on facilitators to achieving compliance. **Results:** The number of hospitals achieving ≥80% compliance with Standard 5.8 increased from 144 (40.7%) to 238 (67.2%) from baseline to post-participation, respectively. Hospital-level median compliance increased from 67.8% (IQR 42.9-90) to 90.5% (IQR 70-100), $p<0.001$. All hospital types had an increase in mean absolute difference in compliance, with the largest increase seen for community hospitals (25.4%, STD 43.5) (Table). For the 114 programs that newly achieved compliance, facilitators included surgeon buy-in (83.3%), proactive specimen labeling (76.3%), and multidisciplinary communication (73.7%). **Conclusions:** Participation in Lung NODES was associated with higher compliance with Standard 5.8 irrespective of hospital type, suggesting that national QI collaboratives may represent an effective large-scale approach to address gaps in cancer care delivery. Research Sponsor: None.

Operative standard 5.8 compliance by hospital type at baseline and after participation in Lung NODES.

Hospital Type	Baseline Compliant Programs n (%)	Final Compliant Programs n (%)	Baseline Compliance Median (IQR)	Final Compliance Median (IQR)	Absolute Difference in Compliance Mean (STD)
Academic N= 50	19 (38.0)	38 (76.0)	68.7 (35.0-90.0)	88.9 (80.0-100)	20.0 (29.8)
Community N=32	10 (31.3)	21 (65.6)	56.3 (23.6-83.8)	93.4 (66.7-100)	25.4 (43.5)
Comprehensive Community N=147	55 (37.4)	97 (66.0)	65.0 (42.9-89.5)	91.7 (66.7-100)	17.5 (30.3)
Integrated Network N=102	51 (50.0)	68 (66.7)	78.6 (50.0-92.2)	90.2 (70.6-100)	12.8 (29.0)
Other N=23	9 (39.1)	14 (60.9)	69.0 (40.0-81.7)	84.6 (60.0-100)	13.2 (35.1)

11141 Poster Session

Systematic communication model to facilitate conversations about metastatic breast cancer.

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Background: For patients with metastatic breast cancer (mBC) understanding their stage and treatment goals is essential to engage in shared decision-making. However, patient-physician communication challenges often hinder discussions about this information. This study evaluated a systematic communication model designed to guide conversations on mBC and to ease oncologists' experience when conveying this delicate information. **Methods:** Patents starting 1st-line mBC treatment were included at 7 referral centers in Mexico. During the consultation in which mBC was disclosed, their oncologists followed a 9-step communication model that facilitated and promoted conversations about mBC stage, treatment, and prognosis, considering each patient's information preferences. After 3-10 days, patients completed a survey assessing understanding of their mBC stage and treatment, and satisfaction. Oncologists also completed a survey exploring their experience providing the information. This study was funded by Pfizer. **Results:** 50 patients were included by 10 oncologists. Patients' median age was 55 yrs (IQR 15); most had ≤high school education (55%) and had recurrent mBC (63%). After receiving information through the communication model, 78% of patients were aware that their BC was metastatic, 56% that mBC is not curable, 76% that their treatment's main objective was to improve their lifespan and quality of life, and 70% that their treatment had no established end date. Patients reported having discussed their prognosis with their oncologist in 54% of cases, most of which considered this information was very useful for: making treatment decisions (94%), preparing for the future (92%), and keeping hope (92%). Overall, most (78%) were satisfied with the way in which they received information about their mBC. As for oncologists' experience, they considered the communication model was very helpful to better convey the incurability of mBC (76%), treatment objectives (82%), and prognosis (42%). With all patients, oncologists were very satisfied (46%) or satisfied (54%) after implementing the model. They felt anxious in 2% of cases, stressed in 2%, confident in 90%, and calm in 90%; their distress thermometer score was ≥4/10 in 26% of consultations. Of note, oncologists reported not completing ≥1 step of the model in 44% of consultations, mostly due to limited time (46%) and forgetfulness (29%). Compared to their usual practice, they considered that the model did not affect (42%) or moderately increased (50%) the duration of the consultation. **Conclusions:** Both patients and oncologists were highly satisfied with the way in which mBC information was disclosed through the communication model. Oncologists particularly recognized the model as a valuable aid for these conversations. Yet, prognosis was discussed with a limited proportion of patients, underscoring the need for further efforts to ease approaching this topic. Research Sponsor: Pfizer.

Epidemiologic patterns and mortality outcomes in young lung cancer non-smokers: A National Inpatient Sample analysis (2016–2021).

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Background: While the incidence and mortality of smoking-related lung cancer have declined, cases among individuals who have never smoked (LCINS) are increasing, particularly among women and younger populations. LCINS often presents with distinct pathology features, unique genetic mutations, and a higher prevalence of early-onset disease. Despite these distinctions, limited evidence exists regarding the epidemiology and mortality outcomes of LCINS. This study aims to compare sociodemographic differences and mortality outcomes among early- and late-onset lung cancer, stratified by smoking status. **Methods:** We performed a pooled cross-sectional analysis using the National Inpatient Sample (NIS) from 2016 to 2021. Lung cancer patients, identified by ICD-10 codes (C34.x), were stratified by age ($\leq$50 years and $>$ 50 years) and smoking status (current, former, and non-smokers). Comorbidities were assessed using the Elixhauser Comorbidity Index. Descriptive statistics and multivariable logistic regression analyses were used to compare mortality outcomes, with statistical significance defined as $p < 0.05$. Analyses were performed using STATA MP 18. **Results:** A total of 199,798 lung cancer hospitalizations were identified, representing 998,990 weighted discharges across the U.S. Of these, 1.47% were young non-smokers ($\leq$50 years), 1.33% young smokers, 26.63% older non-smokers ($>$ 50 years), and 25.8% older smokers. Young non-smokers were more likely to be female (60.8% vs 50.4% of the general population) and non-white (49.2% vs 23%), with a notably higher prevalence of Asian (11.4% vs 3.3%) and Hispanic (15.1% vs 4.8%) individuals. Young non-smokers had fewer health conditions compared to the general population, with a lower mean Elixhauser Comorbidity Index (19.38 vs 20.63) and lower prevalence of chronic pulmonary disease (16.5% vs 51.3%). However, they had a higher prevalence of metastatic disease (55.8% vs 40.8%). Inpatient mortality was higher in young non-smokers (7.2%) compared to young smokers (5.2%), and higher in older non-smokers (9.1%) than older smokers (5.0%). Multivariable logistic regression showed a statistically significantly increased mortality for young non-smokers compared to young current smokers (OR 1.58, 95% CI 1.26–1.99, $p < 0.01$), and similarly for older non-smokers (OR 1.72, 95% CI 1.42–2.08, $p < 0.01$), after adjusting for age, sex, race and other confounders. **Conclusions:** LCINS, particularly in early onset cases, represents a distinct subgroup with unique sociodemographic and clinical characteristics, including a higher prevalence of non-white individuals, fewer comorbidities, and an increased mortality rate. The higher mortality may reflect the advanced stage at presentation and poorer prognosis of LCINS, suggesting potential differences in disease mechanisms compared to smoking-related lung cancer. These findings highlight the need for tailored screening strategies and personalized treatment approaches for the LCINS population. Research Sponsor: None.

11143 Poster Session

Real-world assessment of breast cancer risk following hormonal therapy in endometriosis: A Global Collaborative Network propensity score matched analysis.

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Background: Research suggests endometriosis, an estrogen-dependent condition, may be a potential risk factor for breast cancer (BC) development. While oral contraceptives are the standard treatment, their efficacy is limited in symptom control. This study examines the relationship between hormonal therapy (HT) prescribed for endometriosis management and BC risk. **Methods:** Using TriNetX Global Collaborative Network, we compared 41 029 endometriosis patients receiving HT against 111 429 control patients without HT. We excluded patients with prior contraceptive use or neoplasm diagnosis. Through propensity score matching, we created 38 311 balanced pairs, accounting for demographics (age, race), medical history (pelvic disease, family cancer history, hypertension, diabetes), and clinical factors (pregnancies, body mass index). Additional analyses were conducted by type of HT: progestins (36 156 matched pairs) and LHRH analogues (7 700 matched pairs). BC incidence was measured using hazard ratios, starting 6 months post-endometriosis diagnosis. We evaluated the rate of pregnancies and we also conducted an analysis to assess the risk of major cardiovascular events according to HT treatment for endometriosis, including stroke, cardiac ischemia, thrombosis, and pulmonary embolism. **Results:** The matched cohorts had a mean age of 34 years (standard deviation 9.3). The study population was predominantly white (60%), with lower representation of Black American (10%) and Asian (3%) patients, while race was unknown for 19% of participants. Among patients with endometriosis treated with HT, 262 of them developed BC compared to 239 cases in the control group with a hazard ratio (HR) of 1.18 (95% CI 1.0–1.4, p = 0.064), showing no significant age-related differences. LHRHa treatment was associated with higher BC incidence (66 versus 36 cases, HR 1.7, 95% CI 1.14–2.6, p = 0.009). Age-stratified analysis of LHRHa patients showed no differences for those under 30 and 40 years, while patients under 50 showed a non-significant increase (25 versus 19 cases, HR 1.28, 95% CI 0.70–2.32, p = 0.42). Progestin treatment showed marginally increased BC risk (243 versus 216 cases, HR 1.2, 95% CI 1.0–1.4, p = 0.05) without age-related differences. Patients in the control group not receiving HT presented a lower chance to get pregnant (HR 1.32, 95% CI 1.3–1.4). No significant differences were observed in terms of major cardiovascular events. **Conclusions:** While overall HT showed no clear link to BC risk, both progestins and LHRHa were associated with increased risk. These findings warrant further investigation, particularly since these medications are typically prescribed to endometriosis patients with severe symptoms who share common reproductive and hormonal risk factors with BC. Research Sponsor: None.

11144 Poster Session

Comprehensive genomic profiling in AYA cancer patients.

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Background: Cancer types in Adolescents and Young Adults (AYA) vary by age. Since many AYA cancers are classified as rare, patients continue to face limited therapeutic options. This study evaluates the utility of comprehensive genomic profiling (CGP) and genome-matched therapies for AYA cancer patients, considering age-specific variations using a nationwide database. **Methods:** We analyzed data from 2,325 AYA patients (aged 15–39) who underwent CGP between 2019 and 2023. The genomic landscape and treatment status were assessed. Patients were classified into two groups: those with cancer types that are more common in those under 30 years of age and those categorized as other. Parameters were compared between the two groups. **Results:** The median age was 33 years, with *TP53* being the most frequently altered gene. Overall, 275 patients (12%) were administrated for treatment based on CGP. Cytotoxic agents were suggested when no actionable molecular targets were identified. However, there was no significant difference in overall survival (OS) between patients who received the recommended therapies and those who did not (40 vs. 33 months, $p = 0.07$). A generational comparison of cancer incidence identified 6 cancer types that were more prevalent in patients under 30 years of age: bone, peripheral nervous system, central nervous system, germ cells, adrenal gland, and soft tissue (collectively referred to as 6 specific cancer types). Among patients with the 6 specific cancer types (N = 824), *TP53* and *STK11* were the most frequently altered genes, whereas *TP53* and *KRAS* predominated in patients with other cancers (N = 1501). Treatment administrations, including cytotoxic agents, based on CGP were made for 50 patients (6.1%) and 225 patients (15%), respectively ($p < 0.01$). Among these, 28 patients (56%) with the 6 specific cancer types and 54 patients (24%) with other cancers did not receive genome-matched therapies ($p < 0.01$). Regarding OS, patients with other cancers who received the recommended therapies had significantly longer OS than those who did not (41 vs. 30 months, $p < 0.01$). However, in patients with the 6 specific cancer types, there was no significant difference in OS between those who received the recommended therapies and those who did not (38 vs 44 months, $p = 0.33$). **Conclusions:** The prognostic benefit of CGP may be limited for rare cancers that are prevalent among the younger generation, as fewer opportunities for receiving genome-matched therapies. Research Sponsor: AYA Oncology Alliance (AYAKEN).

11146 Poster Session

Hospice utilization in Veterans with newly diagnosed metastatic prostate cancer.

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Background: Treating men with metastatic castration-sensitive prostate cancer (mCSPC) using androgen deprivation therapy (ADT), with or without treatment intensification, is highly palliative and leads to survival measured in years. In contrast, hospice provides end-of-life support when estimated life expectancy is ≤6 months, which rarely applies to men with newly diagnosed mCSPC. Although traditionally, patients transition to hospice when cancer treatments have been exhausted, the VA allows hospice enrollment during cancer treatment. This study investigates factors associated with hospice enrollment for Veterans within the first six months after diagnosis of mCSPC. **Methods:** We conducted a retrospective cohort study utilizing the VA Corporate Data Warehouse, an extensive database of medical records from 130 VA facilities, linked to Medicare data. Patients newly diagnosed with mCSPC between January 1, 2023, and June 17, 2024, were identified using a validated natural language processing tool. Veterans with prior orchiectomy, receipt of ADT the prior year, or without primary care visits the two years prior to diagnosis were excluded. Our primary outcome was hospice enrollment within six months of metastatic diagnosis. Multivariate logistic regression was used to estimate adjusted odds ratios (aOR) and 95% confidence intervals (CI), adjusting for clinical and socioeconomic variables, including neighborhood disadvantage as measured by area deprivation index (ADI). **Results:** We identified 3429 Veterans with mCSPC, with a mean age of 76 years, 30% of whom were Black. Overall, 11% (n = 391) of Veterans were referred to hospice within the first six months following mCSPC diagnosis. Older age and higher level of frailty were associated with greater odds of hospice enrollment within 6 months (aOR 1.84, 95% CI 1.59-2.14 per 10 years; aOR 4.79, 95% CI 3.74-6.13 for those with moderate/severe frailty versus not frail or mild frailty, respectively). Single Veterans (aOR 1.41, 95% CI 1.11-1.80) and those without additional healthcare insurance (aOR 2.22, 95% CI 1.74-2.85) also had greater odds of hospice referral. Neighborhood-level disadvantage was significantly associated with hospice enrollment: Veterans living in the most deprived neighborhoods (ADI 80–100) had higher odds of hospice referral compared to those in the least deprived neighborhoods (ADI 0–20) (aOR 2.97, 95% CI 1.90-4.73). **Conclusions:** Social determinants of health, including neighborhood-level disadvantage and lack of insurance coverage were strongly associated with Veteran hospice enrollment within six months of mCSPC diagnosis. However, since a unique benefit of VA cancer care allows hospice enrollment in concert with cancer treatment, more work needs to be done to understand whether hospice enrollment is being used primarily for social support or for end-of-life care in men with a highly treatable condition. Research Sponsor: Department of Veterans Affairs, HSR&D; Project Number: IIR 22-215.

11147 Poster Session

Association of MammaPrint and clinical outcomes by race among 5000 individuals with HR+HER2- early stage breast cancer enrolled in FLEX.

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Background: Black women with hormone receptor-positive (HR+), HER2-negative (HER2-) early stage breast cancer (EBC) have a 38% higher mortality rate than White women, a disparity not fully explained by social determinants of disease. Previous research demonstrating unequal performance of gene expression (GE) assays across racial groups has raised concerns that GE assays may underestimate risk of recurrence in Black patients (pts). Compared to other GE assays, the MammaPrint (MP) 70 gene signature consistently classifies a higher proportion of Black pts as High Risk compared with White pts. This analysis examines real world data and survival stratified by MP and self-reported race in pts with HR+HER2- EBC enrolled in FLEX. **Methods:** The ongoing FLEX (NCT03053193) trial enrolls pts undergoing standard of care MP testing, classifying tumors as Low, High 1 (H1), or High 2 (H2) risk of recurrence. BluePrint defines molecular subtypes as Luminal, Basal, or HER2. Clinical differences were assessed with Chi-squared or Fisher's exact tests. Distant recurrence-free interval (DRFI), defined per STEEP criteria, was compared by race and MP using Kaplan-Meier estimates and log rank tests. **Results:** Among 5142 pts analyzed, 9.6% were Black and 90.4% were White. Node positive (30.4% vs 21.9%; $p < 0.001$) and Grade 3 disease (25.3% vs 14.1%; $p < 0.001$) were more common among Black pts. Black pts had significantly higher incidences of H1 (43.1%), H2 (18.3%), and Basal (9.3%), and lower rates of Low (38.5%) Risk tumors, compared with White pts (H1: 36.6%; H2: 7.4%; Basal: 3.3%; Low: 56.6%; $p < 0.001$). Black pts had higher rates of neo/adjuvant chemotherapy (CT) (52.9% vs 40.3%; $p = 0.003$) and use of an anthracycline-taxane regimens (43.0% vs 35.4%: $p = 0.001$) compared with White pts. However, despite a 61.4% incidence of H1/H2 risk disease among Black pts, only 52.9% received CT. In contrast, White pts had a 44.0% H1/H2 incidence and 40.3% received CT. Among all pts, 4-year DRFI was lowest for H2 (90.7%), 96.7% for H1, and 98.8% for Low Risk ($p < 0.001$). DRFI for Black pts was 98.3% for Low, 95.5% for H1, and 90.2% for H2 ($p = 0.005$). For White pts, DRFI was 97.9% for Low, 96.9% for H1, and 89.8% for H2 ($p < 0.001$). Among CT treated pts, DRFI was comparable for Black ($n = 186$) and White ($n = 1130$) pts with H1 (96.0% vs 96.4%) and H2 (90.3% vs 90.6%) tumors. **Conclusions:** Black pts have a higher prevalence of H2/Basal and higher risk clinical features in the nationwide prospective FLEX Registry trial. Black pts with HR+HER2- MP H1/H2 EBC were less likely to receive neo/adjuvant CT than White pts with H1/H2 tumors. This highlights a critical gap in real-world practice where Black pts may be undertreated. However, clinical outcomes are equivalent among similarly treated Black and White pts across MP risk groups. MP classifies fewer EBCs as Low Risk in Black pts, and this classification is accurate as 4-year DRFI is excellent in these pts. Clinical trial information: NCT03053193. Research Sponsor: Agendia, Inc.

11148 Poster Session

Adherence to vaccination recommendations in the adult cancer population.

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Background: In 2024, the American Society of Clinical Oncology (ASCO) published a strong recommendation that clinicians should ensure that all adults with cancer are up to date on seasonal and age- and risk-based vaccinations. The recommended vaccines are drawn from CDC guidelines and include annual influenza, COVID-19, Tdap, Hepatitis B, Zoster (shingles), and Pneumococcal vaccines for all adults, and RSV and HPV for specific groups. Recent studies have found that patients undergoing treatment for cancer had lower COVID-19 vaccination rates mediated by area-level social determinants of health; to our knowledge, rates of adherence to and mediators of other recommended vaccinations in the adult cancer population have not been adequately quantified. **Methods:** We used data from the nationally representative National Health Interview Survey (NHIS) from 2019-2023 to evaluate vaccination rates among individuals with a history of cancer. We identified all individuals aged ≥50 with a diagnosis of cancer within the past 5 years and extracted data on self-reported receipt of three vaccines: annual influenza, pneumonia, and shingles vaccinations. We adjusted for age, race, sex, insurance type, education, US census region, metropolitan statistical area, and used ordinal logistic regression to model determinants of greater degrees of vaccination. **Results:** Between 2019 and 2023, only 30.6% (95% CI [29.3, 31.9]) of all adults aged ≥50 with cancer reported receiving all three studied vaccines. Individually, 69.6% (95% CI [68.2, 71.0]) received the influenza vaccine, 58.4% (95% CI [56.9, 59.9]) received the pneumococcal vaccine, and 42.5% (95% CI [41.0, 44.0]) received the shingles vaccine. The likelihood of receiving more vaccines increased with age (for age 65-74: OR 4.16, CI [3.63, 4.76], $p < 0.001$; for age 75+: OR 5.33, CI 4.62-6.15, $p<0.001$), whereas variables associated with receiving fewer recommended vaccines included being Hispanic (OR 0.70, CI [0.52, 0.93], $p=0.01$) or Black (OR 0.61, CI [0.49, 0.77], $p<0.001$), having Medicaid (OR 0.77, CI [0.63, 0.95], $p=0.01$), and having high school education or less (OR 0.65, CI [0.59, 0.73], $p<0.001$). We did not find a significant association between living in a non-metropolitan area and vaccination receipt. **Conclusions:** Between 2019 and 2023, less than one-third of respondents aged ≥50 years diagnosed with cancer within 5 years reported receiving all three appropriate age-related vaccinations. Race-ethnicity, lower socioeconomic status, and lower education were all associated with receiving fewer of the recommended vaccinations. In order to meet ASCO recommended guidelines, efforts to improve vaccination uptake among adults with cancer may need to include targeted interventions for these at-risk populations. Research Sponsor: None.

11149 Poster Session

Association between body mass index and overall survival in veterans receiving immune checkpoint inhibitors.

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Background: While obesity is a well-established risk factor for cancer development, patients with obesity paradoxically demonstrate better survival rates compared to those with normal body mass index (BMI) in certain malignancies. Studies suggest this phenomenon extends to patients receiving immune checkpoint inhibitors (ICI), with emerging evidence showing improved progression-free and overall survival across multiple cancer types. Despite recognition of this relationship, its magnitude and consistency in real-world populations remain uncertain. The Veterans Affairs (VA) healthcare system, with its comprehensive electronic health records and distinctive demographic composition, presents a unique opportunity to validate these findings in routine clinical practice. **Methods:** We conducted a retrospective analysis using the VA Corporate Data Warehouse, selecting de-identified patients who received ICI therapy between March 2011 and June 2024 (VA COIN grant #1I50HX004009, IRB #1575166). From an initial cohort of 37,863 veterans, we chose a random 20% subset (n = 7,302) for preliminary analysis. We extracted demographic data (age, sex, race), vital signs for BMI calculation, cancer diagnoses (ICD-9/10 codes), and ICI records. BMI categories were: underweight (< 18.5 kg/m^2), normal (18.5-25 kg/m^2), overweight (25-30 kg/m^2), and obesity ($>$ 30 kg/m^2). We calculated overall survival from ICI initiation to death or last follow-up. Survival analyses included Kaplan-Meier methodology with Cox proportional hazards models. **Results:** The cohort of 7,302 veterans was predominantly male (97%) and White (74%), with most patients aged 65-75 years (51%). Pembrolizumab (45%) and nivolumab (29%) were the most frequently prescribed ICIs. Survival was significantly associated with BMI class (log-rank test $p < 0.01$). Using normal BMI (18.5-25, n = 2,422) as reference, Cox proportional hazards analysis showed progressively lower mortality risk with increasing BMI, ranging from 13% reduction in overweight patients (HR 0.87, 95% CI 0.82-0.93) to 27% reduction in patients with BMI 35-40 (n = 481, HR 0.73, 95% CI 0.65-0.83, $p < 0.01$). Underweight patients showed increased mortality risk (HR 1.31, 95% CI 1.15-1.51). **Conclusions:** The 27% mortality reduction among patients with higher BMI demonstrates a clinically meaningful survival advantage in immunotherapy outcomes and suggests BMI might be an important factor in risk stratification and treatment discussions. The increased mortality risk in underweight patients may reflect cancer-related cachexia. These findings, derived from a large cohort of veterans, corroborate the obesity paradox in cancer immunotherapy and suggest potential applications for personalized immunotherapy approaches. Research Sponsor: None.

Impact of palliative chemotherapy in hospitalized patients with advanced solid tumors.

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Background: The role of palliative chemotherapy (PC) in patients with advanced solid tumors and poor performance status (PS) remains uncertain since this population is underrepresented in clinical trials. Retrospective studies of patients with an Eastern Cooperative Oncology Group-Performance Status (ECOG-PS) > 2 consistently demonstrate poorer survival and increased treatment-related toxicities. This study aimed to evaluate the clinical impact of PC in hospitalized patients and its association with PS and outcomes. **Methods:** This retrospective chart review was conducted between January 2018 and July 2024 across a five-hospital health system. The primary endpoint was overall survival (OS), defined as the time from the first dose of inpatient chemotherapy to death or last follow-up. Secondary outcomes included in-hospital mortality, length of stay, 30- and 60-day mortality, and toxicity. Continuous variables were compared using the Mann-Whitney *U* test or the two-sample t-test and categorical variables were compared using the Chi-squared or Fisher's exact test. Time to event data were assessed using the Kaplan-Meier method. A p-value < 0.05 was considered statistically significant. **Results:** A total of 383 patients were included in this study. Of these, 227 patients had an ECOG-PS ≤ 2, and 156 patients had an ECOG-PS > 2. The median age was 60 years, and 57% were female. Common primary tumor sites included gastrointestinal, gynecologic, and lung. At presentation, 288 patients were chemotherapy-naïve, and 88% were hypoalbuminemic. The median OS was 188 days. Patients with an ECOG-PS ≤ 2 had a significantly longer median OS compared to those with an ECOG-PS > 2 (293 vs 77 days, $p<0.0001$). Mortality rates were higher in patients with ECOG-PS > 2 during the index hospitalization (17% vs 6%, p=0.0005), at 30 days (24% vs 14%, p=0.015), and at 60 days (36% vs 21%, p=0.001). Despite these differences, bleeding and infection rates were similar between groups. Median duration of hospitalization was 13 days, with significantly longer stays observed in patients with poor PS (16 vs 10 days, $p<0.0001$). Although toxicity rates were comparable overall, patients with ECOG-PS > 2 experienced significantly higher rates of thrombocytopenia (39% vs 25%, p=0.018) and neutropenia (40% vs 27%, p=0.028). In univariate analysis, significant predictors of shorter survival included ECOG-PS > 2 ($p<0.0001$), age > 60 (p=0.0097), Charlson Comorbidity Index ≥ 8 (p=0.02), hypercalcemia (p=0.0014), and hypoalbuminemia (p=0.0014). In multivariate analysis, all factors except age > 60 remained independent predictors of shorter survival. **Conclusions:** PC in hospitalized cancer patients with ECOG-PS > 2 was associated with shorter survival, longer hospital stays, and higher rates of early mortality. These findings emphasize the importance of careful patient selection and the need for further research to optimize care strategies in this population. Research Sponsor: None.

11151 Poster Session

Association of co-administration of a vaccine with immune checkpoint inhibitors with survival.

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Background: Patients undergoing chemotherapy are less likely to complete recommended routine vaccination. Vaccination during immune checkpoint inhibitor (ICI) therapy elicits a significant cytokine response, which could enhance antitumor effects. This study investigates whether co-administration of vaccination with ICI improves cancer patient survival. **Methods:** Using the California Immunization Registry and Scripps Health's electronic medical record, we validated vaccination status for patients at a large healthcare system in San Diego and conducted an observational cohort study of all ICI recipients from January 1, 2018, to June 1, 2024. Overall Kaplan-Meier survival curves were compared between patients who received vaccination within 100 days of ICI initiation and those who did not using log rank test. Subgroup analyses focused on patients with stage IV non-small cell lung cancer (NSCLC) and stage IV melanoma. The ICI cohort was propensity matched 1:1 by demographics to non-cancer patients to evaluate immunization rates. **Results:** 1,854 ICI-treated patients and 1,854 matched patients without cancer were identified for analysis. Vaccination within 100 days of ICI initiation was associated with improved overall survival (HR: 0.43, 95% CI: 0.37 – 0.49, $p<.0001$). Among NSCLC patients ($n=241$), overall survival improved when any vaccination was administered within 100 days of ICI initiation (HR 0.37, $p<.0001$), with benefits observed specifically for COVID-19 (HR: 0.43, $p<.0001$) and influenza (HR: 0.38, $p<.0001$) vaccinations. Similarly, melanoma patients ($n=216$) demonstrated improved overall survival with COVID-19 (HR: 0.53, $p=.0214$) and influenza (HR: 0.59, $p=.0468$) vaccinations. Findings remained robust upon censoring deceased unvaccinated patients within 100 days of ICI initiation to mitigate guarantee-time bias. No significant differences were observed in demographics, BMI, smoking status, medical comorbidities, PD-L1 expression (for NSCLC), or LDH levels (for melanoma) between patients who had received a vaccine within 100 days of ICI initiation and those that did not, that would otherwise explain this difference in mortality. There was no difference between the vaccinated and unvaccinated groups in terms of vaccination-related infection mortality. Active ICI patients were more likely to receive routine vaccinations than non-cancer patients (Influenza 2023 OR: 1.51, $p=.0016$), though vaccination rates have declined since their 2020 peak (Influenza vaccination rate: 2020, 71%; 2023, 59%). **Conclusions:** Co-administration of vaccination with ICI therapy improves survival, independent of infection-related outcomes. The associated cytokine response from vaccination during ICI therapy may enhance antitumor effects. Vaccination rates among ICI-treated patients have declined since 2020, highlighting the need for interventions to improve uptake and outcomes. Research Sponsor: NIH CTSA; K12TR004410.

11152 Poster Session

Trends in place of death among breast cancer patients in the United States (1999–2023): A 25-year analysis of racial and regional disparities.

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Background: Breast cancer is the second most prevalent cancer among women in the United States, associated with significant morbidity and mortality related to treatment. The place of death (PoD) significantly influences patient and caregiver preferences, access to home-based supportive care, and the overall cost of caregiving. This study evaluates trends in PoD for patients with breast cancer in the U.S. from 1999 to 2023 using data from the CDC WONDER (Wide-ranging Online Data for Epidemiologic Research) database. **Methods:** We conducted a comprehensive analysis of data from the CDC WONDER database covering the period from January 1, 1999, to December 31, 2023. Deaths attributed to breast cancer were identified using the International Classification of Diseases-10th Revision (ICD-10) code C50. We collected demographic data to calculate descriptive statistics based on race, PoD, census region, and home and hospice utilization over the past 25 years. **Results:** Our analysis revealed a total of 1,047,098 breast cancer-related deaths from 1999 to 2023. Among these, 513,231 deaths (49.01%) occurred in home or hospice facilities (H&H), while 471,297 deaths (45.01%) were reported in medical facilities and nursing homes (M&N). The proportion of H&H deaths increased from 37.1% in 1999, peaked at 62.6% in 2020, and then declined to 56.9% in 2023. Racial disparities were evident, with all racial groups experiencing an increase in percentage of H&H mortality from 1999 to 2023. Black or African American individuals exhibited the highest relative percentage increase at 66.04%. In 2023, the highest rates of H&H mortality were observed in white patients (58.99%), followed by Hispanic patients (56.36%), American Indian or Alaska Native patients (50.51%), and Black or African American patients (48.90%). Regional analysis indicated that all regions saw an increase in H&H mortality from 1999 to 2023, with the Midwest showing the highest relative percent increase at 60.58%. In 2023, the South had the highest percentage of H&H mortality (59.80%), followed by the West (58.45%), Midwest (55.53%), and Northeast (49.33%). **Conclusions:** The trends in place of death for breast cancer patients over the past 25 years highlight significant shifts in mortality patterns, with increasing reliance on home and hospice care, particularly among certain racial and regional groups. These findings highlight the need for targeted interventions to improve access to palliative care services and support for patients and caregivers, particularly in underserved populations and regions. Research Sponsor: None.

Regional trends in disability adjusted life years (DALYs) and mortality of pancreatic cancer among older adults (70+): A global burden of disease study (1990–2021).

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Background: Pancreatic cancer is a major health challenge, particularly for older adults, with significant regional disparities in its burden over the decades. This study analyzes 30-year trends in pancreatic cancer DALYs and deaths among older adults across regions. **Methods:** We used Global Burden of Disease (GBD) data (1990–2021) to analyze age-standardized DALYs and deaths for individuals aged 70+. Trends were assessed using AAPCs and APCs, stratified by region and socio-demographic index (SDI). **Results:** Regions with lower SDI (e.g., Sub-Saharan Africa, South Asia) showed higher AAPCs, indicating greater increases in DALYs and deaths compared to high-income regions (e.g., North America, Western Europe). Low-middle SDI regions, Central Asia, and Southeast Asia saw significant increases in deaths, while Southern Latin America and the Caribbean experienced slight declines. In Eastern Europe, pancreatic cancer DALYs and deaths increased at an AAPC of 1.45% and 1.50%, respectively, showing a moderate but concerning rise in burden. Meanwhile, Central Sub-Saharan Africa experienced a sharp increase, with DALYs and deaths rising at an AAPC of 2.10% and 2.15%. In contrast, Oceania saw only a slight increase, with DALYs and deaths rising at an AAPC of 0.50% and 0.55% showing a relatively stable burden compared to other regions. The highest death rates are observed in High-income Asia Pacific (109.30 in 2021) and Southern Latin America (85.01 in 2021), while the lowest death rates are in South Asia (12.17 in 2021) and Low SDI regions (14.00 in 2021). For DALYs, the highest rate was 1462.27 per 100,000 population in High-income Asia Pacific in 2016, while the lowest rate was 131.06 per 100,000 population in South Asia in 1990. **Conclusions:** The burden of pancreatic cancer among older adults is increasing at a faster rate in regions with lower socio-demographic development, while more affluent areas are seeing relatively stable trends. These stark disparities highlight the urgent need for focused healthcare efforts, better distribution of resources, and stronger preventive measures in regions where the impact of pancreatic cancer is growing most rapidly. Tackling these inequalities will demand global collaboration and customized strategies to lessen the rising toll of pancreatic cancer on older populations around the world. Research Sponsor: None.

Region	DALYs AAPC (%)	Deaths AAPC (%)	Trend
Western Sub-Saharan Africa	2.25 (2.22–2.28)	2.31 (2.28–2.35)	Highest increase, growing burden
North Africa & Middle East	1.67 (1.62–1.72)	1.77 (1.73–1.82)	Steady rise
Low-middle SDI Regions	1.59 (1.56–1.63)	1.65 (1.62–1.70)	Substantial increases
High-income North America	0.22 (0.18–0.26)	0.29 (0.25–0.32)	Lowest increases
Southern Latin America	-0.18 (-0.27–-0.10)	-0.03 (-0.08–0.02)	Decrease in burden
Caribbean	-0.12 (-0.21–-0.02)	-0.03 (-0.14–0.06)	Decrease in burden

Characterizing health related quality of life among individuals living with non-small cell lung in the United States: Findings from the Cancer Experience Registry.

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Background: Lung cancer is the second most common cancer and the leading cause of cancer-related deaths. Non-small cell lung cancer (NSCLC), which comprises ~85% of cases, is aggressive, often diagnosed late, and associated with significant symptom burden, and poor health-related quality of life (HRQoL) overall, as well as poor prognosis. However, the factors contributing to variation in HRQoL among NSCLC patients are poorly understood. This study aims to assess the role metastatic status and treatment history play in HRQoL. **Methods:** We conducted a retrospective analysis of Cancer Support Community's Cancer Experience Registry (CER) survey data collected between Feb 2015 – Nov 2023. The sample included 279 U.S. adults with NSCLC. HRQoL, specifically physical and psychological symptom burden and function, was assessed using the 7 domains of PROMIS29v2.0: anxiety, depression, pain, fatigue, sleep disturbance, physical function, and social function. Preliminary analyses (not shown here) found that non-metastatic patients were *more* likely to report higher pain, fatigue, and physical and social impairments compared to metastatic patients. We hypothesized that treatment history could partially explain this outcome: 62% of nonmetastatic patients reported history of surgery vs. 31% of metastatic patients. Thus, an interaction term (metastatic status x surgery) was created for further analysis in backward elimination linear regression models. **Results:** Participants were 68% women and 88% Non-Hispanic White, with a mean age of 64 (SD=10 years). The mean time since initial diagnosis was 5 years (SD=7). 16% were nonmetastatic with no history of surgery and 27% with a history of surgery; 39% were metastatic with no surgery and 18% with surgery. After adjusting for sociodemographic and clinical variables, treatment history showed associations with HRQoL, though findings were inconsistent in most groups. Those who were nonmetastatic without surgery reported more sleep disturbance (b = 3.58), those with clinical trial history reported less anxiety (b = -3.61), and those with immunotherapy reported less depression (b = -2.55). Metastatic individuals without surgery reported less pain (b = -3.75) and fatigue (b = -3.06) and better physical (b = 3.67) and social functioning (b = 4.19). Metastatic surgery group was not significant for any domains. **Conclusions:** Results underscore the complex factors that contribute to HRQoL in those with NSCLC. The findings emphasize the importance of a holistic, value-based care approach, considering not just survival but also patients' preferences and quality of life. A full understanding of treatment side effects and their implications for HRQoL is essential to aligning care with patient preferences. Future research should investigate how treatment history impacts HRQoL outcomes. Research Sponsor: Gilead Sciences.

Use of targeted therapy in patients with advanced non-small cell lung cancer in response to broad genomic profiling.

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Background: Broad genomic profiling (BGP) is increasingly performed for patients with advanced non-small cell lung cancer (aNSCLC) to inform the use of targeted therapy (TT). The approach to specific BGP results has evolved, alongside changes in evidence, FDA approval status, and professional guidelines. Limited data exist characterizing impact of BGP on treatment selection in a real-world patient population. **Methods:** We identified patients diagnosed with aNSCLC 2017–2023 using the nationwide deidentified Flatiron Health-Foundation Medicine aNSCLC Clinico-Genomic Database, containing data from ~280 US cancer clinics (~800 sites of care). We classified each patient's BGP results by contemporaneous FDA approvals and NCCN guidelines, categorizing findings as actionable with on-label TT (first- [1L] vs. later-line [2+]), potentially actionable with off-label TT (NCCN recommended vs. not recommended), or not actionable. We then categorized actual 1L treatments received relative to these standards. **Results:** Of 5781 patients with aNSCLC who underwent BGP testing (Table), on-label 1L TT was used in 13.1% of patients, while 3.3% (1.3% guideline recommended + 2.0% not recommended) received off-label 1L TT. Overall, 17.6% had a 1L targetable alteration (74.5% of whom received on-label TT), while 6.0% had a 2L+ on-label targetable alteration (9.7% received TT in 1L, against label + recommendation). In addition, 4.7% had a potentially actionable alteration with recommended off-label TT (11.4% of whom received off-label 1L TT), while an additional 23.3% had potentially actionable alterations without recommended TT (4.3% received off-label TT in 1L, against NCCN recommendation). **Conclusions:** In this cohort of patients with aNSCLC, half had actionable or potentially actionable BGP results. One in four patients with 1L actionable findings did not receive corresponding on-label 1L TT (potential missed opportunity), while one in ten with 2L+ actionable findings received TT as off-label 1L treatment in contrast to guidelines (potential indication creep). 1L off-label TT use was uncommon and largely guideline discordant. Research Sponsor: U.S. National Institutes of Health; 5R01CA280359-02; National Cancer Institute/U.S. National Institutes of Health; T32CA233414.

First-line treatments by mutation actionability in patients with advanced non-small cell lung cancer, as recommended (Rec'ed) by contemporaneous clinical guidelines.

Mutation Category	On-Label TT	Rec'edOff-Label TT	NOT Rec'ed Off-Label TT	Non-Targeted Systemic Therapy
Actionable, TT 1st Line N = 1018 (17.6%)	758 (74.5%)	44 (4.3%)	≤5 (≤0.5%)	≥211 (≥20.7%)
Actionable, TT 2nd Line N = 349 (6.0%)	.	.	34 (9.7%)	315 (90.3%)
Potentially actionable – Off-Label TT Rec'ed N = 273 (4.7%)	.	31 (11.4%)	≤5 (≤1.8%)	≥237 (≥86.8%)
Potentially actionable – Off-Label TT NOT Rec'ed N = 1348 (23.3%)	.	.	58 (4.3%)	1290 (95.7%)
Not actionable N = 2793 (48.3%)	.	.	16 (0.6%)	2777 (99.4%)
TOTAL N = 5781	**758 (13.1%)**	**75 (1.3%)**	**115 (2.0%)**	**4833 (83.6%)**

Cells ≤5 patients censored; TT = targeted therapy.

11156 Poster Session

Real-world outcomes in patients living with HIV with lung cancer and treated with immune checkpoint inhibitors.

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Background: Lung cancer is one of the most common non-AIDS defining cancers in People Living with HIV (PLWH) and a leading cause of cancer death in PLWH. PLWH were initially excluded from clinical trials of immune checkpoint inhibitors (ICIs) due to concerns for safety and efficacy. Little is known about the real-world rates of immune-related adverse events (irAEs) and survival outcomes in PLWH with lung cancer treated with ICIs. **Methods:** Adults (age≥18) diagnosed with lung cancer and treated with ICIs between 2015-2021 were identified from the Merative MarketScan database, which contains de-identified healthcare claims of > 250 million patients in the US. We categorized patients into two cohorts based on HIV status: People Living with HIV (PLWH) and those without HIV (PLWoH). We evaluated rates of irAEs and Kaplan-Meier (KM) survival analysis estimated overall survival (OS) in both cohorts; survival function was calculated from first ICI treatment to death or last follow-up. We used the log-rank test to assess statistical differences in survival between the cohorts. **Results:** 21,259 people with lung cancer and treated with ICIs were identified, and 105 were identified as PLWH. More PLWH treated with ICIs were male (81.9%) and younger (median age 61 yrs) than PLWoH (53.4%, 64 yrs). There was no significant difference in median OS of PLWH (343 days) and PLWoH (364 days, p=0.62). PLWH experienced a similar rate of irAEs (53.3%) as PLWoH (54.6%). Most patients experienced one irAE (55.36% PLWH, 54.33% PLWoH). PLWH experienced irAEs in up to 3 organ systems, and PLWoH in up to 7 organ systems. The most common irAEs in PLWH were neurologic (41.07%), endocrine (39.29%), and renal (32.14%). In PLWoH, endocrine (52.26%), renal (34.93%), and cutaneous (27.82%) were the most common. Patients who experienced irAEs had statistically significantly improved OS in both cohorts compared to those without irAEs (both p<0.0001). **Conclusions:** We found similar rates of irAEs and OS in a large, real-world population of PLWH with lung cancer treated with ICIs, and people without HIV and lung cancer treated with ICIs. Further research is needed to improve early identification of lung cancer in PLWH and identify predictors of toxicities. Research Sponsor: National Cancer Institute; U54CS254566.

ARIMA prediction model for mortality caused by metastatic cancers in the United States population up to the year 2050: A CDC WONDER Database analysis.

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Background: Metastatic cancers are the leading cause of mortality in the United States (US). In this study of death certificates, obtained from data registry spanning from 1999 to 2024, we examined mortality trends among individuals suffering from any metastatic cancer in US. **Methods:** Our aim was to analyze the trends in mortality among US residents by demographic characteristics and predict future years based on the existing data by Autoregressive Integrated Moving Average (ARIMA) forecasting modeling. The national mortality data from the multiple causes of death files in the CDC WONDER Database were queried by applying the ICD-10 codes as C77-C79 for secondary cancers. Trends in age-adjusted mortality rate (AAMR) were assessed and results were expressed as average annual percentage changes (AAPC) from Join point regression. **Results:** There were a total of 2,098,842 deaths due to metastatic cancers in US from 1999-2024 with a crude mortality rate of 25.97 per 100,000 population, about 52% of them being males and 48% were females. Mortality rates (AAMR) continue to trend down from 1999-2008 in both gender, but showed an increase from 2009 onwards with females showed significant AAPC of +0.44. ARIMA predictive model exhibits a significant decline of mortality rates up to the year 2050 in Black population (AAMR: 24.45), Northeast region (AAMR: 10.84) and metropolitan areas (AAMR: 19.93). **Conclusions:** These findings provide valuable insights of mortality patterns among US population with metastatic malignant diseases. Certain sub-groups with specific demographic and geographic characteristics such as White Population, non-metropolitan areas and those belonged to West region had higher future prediction of AAMR. Research Sponsor: None.

ARIMA forecasting model for predicting AAMR in metastatic cancer population in U.S.

Variables	AAMR in 1999	Lowest AAMR (year)	AAMR in 2024	AAPC	ARIMA forecast (2050)
Total	27.65	18.34 (2008)	29.13	+0.30 (0.20 – 0.40)*	29.90
Gender					
Female	23.89	15.73 (2008)	26.23	+0.44 (0.34 – 0.54)*	26.04
Male	33.48	22.03 (2008)	33.19	+0.06 (-0.32 – 0.44)	32.31
Race					
White	27.74	18.70 (2008)	30.89	+0.51 (0.40 – 0.63)*	32.95
Black	35.32	21.30 (2014)	30.67	-0.54 (-1.43 – 0.36)	24.45
Hispanic	19.07	12.93 (2008)	21.68	+0.42 (0.30 – 0.55)*	24.68
Asian or Pacific Islander	16.32	11.60 (2008)	19.37	+0.54 (0.25 – 0.89)*	23.15
American Natives	20.35	15.19 (2005)	21.68	+0.33 (-0.15 – 1.15)	24.28
Census Region					
Northeast	27.29	15.62 (2014)	20.53	-1.03 (-1.57 – -0.49) *	10.84
Midwest	29.51	18.55 (2010)	31.96	+0.35 (0.21 – 0.47)*	30.74
South	28.23	19.18 (2008)	30.77	+0.43 (0.31 – 0.56)*	33.30
West	24.81	17.18 (2008)	30.72	+0.97 (0.77 – 1.19)*	39.18
Urbanization†					
Metropolitan	27.17	17.76 (2008)	24.66	-0.46 (-0.60 – -0.33) *	19.93
Non-metropolitan	29.87	20.73 (2010)	30.39	+0.02 (-0.75 – 0.80)	26.56

AAMR per 100,000 population.
†For urbanization, AAMR 1999-2020.
*P-value <0.05.

11158 Poster Session

Determinants of overall survival in the South African Breast Cancer and HIV Outcomes cohort.

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Background: Sub-Saharan Africa (SSA) has very low breast cancer (BC) survival. South Africa, unlike most SSA countries, is an upper middle-income country where patients are less burdened with cancer diagnostic and treatment costs. We aimed to provide five-year overall survival (OS) estimates and determinants among South African women with BC diagnosed and treated within the public health system. **Methods:** The South African Breast Cancer and HIV Outcomes prospective cohort study enrolled adult women recently diagnosed with invasive BC from four South African academic hospitals. We collected detailed sociodemographic, clinical, treatment, and outcomes data. Women were followed for five years or until December 31, 2023, whichever was earlier, and our primary outcome was five-year OS. Impacts of potential determinants on OS were assessed using individual Cox proportional hazard models focused on nine variable domains (*i.e.,* treating hospital, social status, BC risk factors, smoking, cardiovascular disease (CVD), HIV status, BC type, BC treatments, and age) and a combined model that also included adjustments for background mortality. **Results:** Between July 2015 and Feb 2019, we enrolled 2,838 women newly diagnosed with histopathologically confirmed invasive BC, of whom 58% had III or IV disease. At the end of follow-up, 1555 (55%) of the women had died, 1191 (42%) survived for five years, 33 (1%) were censored at study's end, and 59 (2%) were lost to follow up. The five-year OS was 44.3% (95% CI 42.5-46.2). In the full model, the variables with the largest impact on five-year survival were late-stage at diagnosis (HR 2.4 [95% CI 2.0-2.7] for stage III and HR 5.0 [95% CI 4.1-6.1] for stage IV disease, both compared with stage I/II) and differing degree of treatments received (no treatment received: HR 8.2 [95% CI 5.9-11.3]; chemotherapy and endocrine therapy: HR 1.9 [95% CI 1.4-2.6]; endocrine therapy only: HR 2.2 [95% CI 1.6-3.2]; chemotherapy only: HR 4.8 [95% CI 3.4-6.6]; surgery only: HR 3.0 [95% CI 1.9-4.8]; surgery and chemotherapy: HR 1.8 [95% CI 1.3-2.5], all compared with surgery and endocrine treatments). Other variables significantly associated with survival were treating hospital, relationship status, employment, education, family history of cancer, CVD, and HIV infection. **Conclusions:** Interventions to improve BC survival in South Africa's public health system should prioritize earlier diagnosis of cancer and expansion of the infrastructure supporting diagnostic and treatment services. Concurrently, South African BC patients with low socioeconomic status, HIV infection, and/or comorbid CVD are uniquely vulnerable and their barriers to accessing care must be better understood. Research Sponsor: National Institute of Health and South African Medical Research Counsel.

11159 Poster Session

Implementation and evaluation of multi-cancer early detection testing at the Dana-Farber Cancer Institute: A retrospective analysis of clinical outcomes and diagnostic pathways.

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Background: Early detection and interception of cancer is a growing field at the intersection of primary care and oncology. Technological innovation has facilitated the development of multi-cancer early detection (MCED) tests, which allow for the detection of a broad range of cancers in a single screening test. These tests are entering clinical practice as laboratory developed tests but little has been reported about their implementation. In 2023, Dana-Farber introduced an MCED Program to facilitate the evaluation of patients who have received MCED testing and to study novel MCED strategies. **Methods:** We conducted a retrospective chart review of patients seen at the Dana-Farber between 12/1/2023 and 12/1/2024 who had a cancer signal detected by a Grail Galleri MCED test. **Results:** Thirteen patients were evaluated for a positive cancer signal detected by the Grail Galleri MCED test. The median age was 62.7 (54.9-81.4), 61.5% (8/13) were male, and 84.6% (11/13) were white. Following diagnostic evaluation 76.9% (10/13) had a confirmed cancer diagnosis and 23.1% (3/13) were deemed false positives. The time from MCED test result to presentation at DFCI was a median of 25 days (6-368) and the median time to conduct the diagnostic evaluation was 23 days (5-104), which was shorter in true positive cases (15 days) compared to false positives (98 days). A total 6 of the 10 (60%) signal detected cases were solid tumors which included triple negative breast, testicular, liver, cholangiocarcinoma, tonsillar, and lung (non-smoker); and 4 (40%) cases were hematologic malignancies (3 lymphoma, 1 myeloma). Of the malignancies detected, 9 (90%) have no current screening guidelines. Screening mammography was up to date in the patient found to have triple negative breast cancer. Six cancers (60%) were diagnosed at stage I/II and 4 (40%) were stage III/IV. All 3 false positive cases received a repeat MCED test a median of 118 days (87-161) after the initial test and all had no signal detected at re-test. The median number of tests/procedures to reach diagnostic resolution was 4 for true positive cases (2-7) and 5 for false positive cases (4-6). All patients required advanced imaging. The first or second cancer signal origin was accurate in 90% (9/10). There were no issues encountered obtaining prior authorizations for diagnostic tests and no adverse events were reported. **Conclusions:** The majority of patients that presented with a positive MCED test were true positives with a cancer consistent with the cancer signal origin. Patients with signal detected tests were quickly adjudicated in our clinical program, although some patients initially experienced significant delays in finding a provider to work-up their test result. These findings support a role for dedicated cancer diagnostic clinical expertise in the evaluation of MCED tests. Research Sponsor: None.

Evaluation of large language model (LLM)-based clinical abstraction of electronic health records (EHRs) for non-small cell lung cancer (NSCLC) patients.

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Background: Abstraction is a critical step for converting clinical data from unstructured EHRs into a structured format suitable for real-world data analyses. Typically this is a manual, labor-intensive activity requiring substantial training. While prior work has shown that abstraction by humans is reliable, advances in LLMs may improve the efficiency of abstraction. We aim to measure the performance of LLMs in abstracting a diverse set of oncology data elements. **Methods:** Two clinical abstractors independently abstracted unstructured records of 222 advanced or metastatic NSCLC patients (mean: 248 pages per case). A two-stage LLM system balancing cost and comprehensiveness was used to abstract clinical elements for demographics, diagnosis, third-party lab biomarker testing, and first line (1L) treatment. The initial stage extracted 16 documents semantically similar to the abstraction query and input them, along with abstraction rules, into an LLM (GPT-4o). The LLM was instructed to provide both the abstracted field and a completeness assessment of provided context. If the first phase resulted in a low completeness score, the entire patient record was then input into a long-context LLM (Gemini-Pro-1.5) to re-attempt abstraction. Gwet's agreement coefficient (AC) was the primary measure of agreement between the LLM and each abstractor. Date agreement was calculated within ±30 days. **Results:** The LLM system yielded abstracted values for 90% of elements where both abstractors provided non-missing values. In these cases, the LLM also demonstrated high agreement with each abstractor (≥0.81 across all categories). Agreement was highest in demographic and diagnosis domains and lower for 1L treatment domain, which require deeper understanding of a patient's temporal journey. For elements where neither abstractor provided values, the LLM sometimes provided outputs (frequency: 4.9% for non-biomarker elements; 38.5% for biomarker elements). These discrepancies were primarily driven by nuances in abstraction rules; the LLM often included Tempus-tested biomarkers, while abstractors were more rigorous in abstracting only third-party biomarker results. **Conclusions:** LLMs show high completion rates and high agreement with human abstractors across a variety of critical abstraction fields. The use of LLMs may significantly reduce the burden of human abstraction and allow for large-scale curation of oncology records. Challenges in handling nuanced contexts underscore the need for careful refinement and evaluation prior to deployment. Research Sponsor: Tempus AI, Inc.

Domain	LLM agreement with abstractors (AC, min-max)
Demographic (birth date, sex, race, smoking status)	0.96-1
Diagnosis (stage, histology, year of diagnosis)	0.92-0.98
Third Party Biomarker (EGFR, ALK, ROS1, PDL1, BRAF, RET, NTRK)	0.87-1
1L Treatment (agents, initiation date)	0.81-0.86

11161 Poster Session

Real-world analysis of factors influencing turnaround time (TAT) for tissue comprehensive genomic profiling (CGP) in non-small cell lung cancer (NSCLC).

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Background: CGP is an integral part of the standard of care for many solid tumor malignancies, and especially for NSCLC, as testing informs first-line treatment selection at most stages. CGP TAT is understudied but has implications for appropriate treatment delivery and patient outcomes. **Methods:** In this retrospective cohort analysis, TAT was calculated for U.S. tissue CGP testing orders received between January 2021 and September 2023 at a centralized commercial molecular laboratory (Foundation Medicine, Inc., Cambridge, MA, USA). Ordering TAT (specimen collection to CGP ordering), Specimen TAT (CGP ordering to specimen receipt at testing lab), Molecular TAT (specimen receipt to results reporting), and Overall TAT (specimen collection to results reporting) were calculated. Cases were excluded if CGP was ordered >6 months after specimen collection or if missing TAT data. Descriptive statistics and linear regression modeling for association of TAT with available clinical and molecular factors were performed. **Results:** A total of 40,728 NSCLC biopsies from 547 institutions were included in the analysis. The median Overall TAT for all samples was 29.8 days (IQR: 21.7, 44.6). Median times for Ordering TAT, Specimen TAT, and Molecular TAT were 14.8 days (IQR: 8.4, 27.8), 3.2 days (IQR: 1.3, 6.2), and 9.0 days (IQR: 7.7, 11.0), respectively. Aggregating and calculating TAT at the institution level, the median Overall TAT was 40.6 days (IQR: 38.5, 43.8) versus 21.9 days (IQR: 20.7, 23.7) among the slowest and fastest Overall TAT quintiles, respectively; Ordering TAT [median 15.1, IQR: 11.6, 18.9] and Specimen TAT [median 3.9, IQR: 1.9, 5.1] contributed to this variability, while Molecular TAT [median 9.0, IQR: 8.6, 9.3] remained consistent. Higher institutional order volume was the strongest predictor of shorter Overall TAT (-6.59 days [95% CI: -7.46, -5.71] for institutions with [100-200) vs <20 orders, $P < .001$), largely driven by variability in Ordering TAT (-4.13 days [95% CI: -4.95, -3.31] for institutions with [100-200) vs <20 orders, $P < .001$) and Specimen TAT (-2.25 days [95% CI: -2.47, -2.04] for institutions with [100-200) vs <20 orders, $P < .001$). **Conclusions:** This study demonstrates that NSCLC CGP TAT is highly variable and is influenced by institutional factors, particularly higher institutional ordering volume. For patients with an established diagnosis, the time between specimen collection/diagnosis and CGP ordering likely represents the longest and most modifiable component of Overall TAT. This study raises the hypothesis that adoption of coordinated interventions, such as reflex testing, could reduce Ordering TAT, and thus Overall TAT, for many patients. Research Sponsor: None.

Assessing biosimilar entry in the market for biologic cancer drugs.

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Background: Biosimilars are biological drugs highly similar to and without clinically meaningful differences from their biological reference products. As of 2023, out of 39 biosimilars available in the US, 22 (56%) are indicated for cancer treatment (n=12) or supportive care (n=10). This study described the trends in uptake, pricing, and out-of-pocket (OOP) costs between 2014 and 2023. **Methods:** Using MarketScan claims data and Average Sales Price (ASP) data from the Centers for Medicare & Medicaid Services, we calculated quarterly ASP and the market share of reference products for treatment and supportive care biologics in the commercial and Medicare Part B markets, 2014 to 2023. We also estimated the average monthly out-of-pocket costs (deductible + copayment + coinsurance) before and after biosimilar entry. We identified biologics using Healthcare Common Procedure Coding System codes and adjusted costs to 2024 USD using the prescription drugs Consumer Price Index. **Results:** Analyses included 1,040,456 claims of 28 biological products (6 reference products and 22 biosimilars). On average, the ASP of reference products for treatment and support care decreased by 1.3% and 2.8% per quarter, respectively, after biosimilar entry. Market share of reference products declined over time after biosimilar entry, though the decline was smaller in the Medicare market than in commercial insurance market as of 2023 Q4. The average quarterly reduction ranged between 2.2% and 14.6% across reference products, with larger reduction for treatment drugs. Compared to monthly OOP averaging over 12 months before first biosimilar launch, monthly OOP costs of biologics (including reference and biosimilars) in 2023 fell for 4 reference drugs in the commercial market, and 5 in the Medicare market. **Conclusions:** Biosimilar entry has lowered the price and led to a substantial reduction in market share of biologic reference products, especially for cancer treatment drugs. Nevertheless, trends in OOP costs for biologics indicated biosimilars did not always lower financial burden for patients. Research Sponsor: None.

			Commercial insurance			Medicare Part B		
Drug	1st biosimilar entry	Reference product ASP quarterly change	Market share of reference product, 2023 Q4 (quarterly change)	Mean monthly OOP before biosimilar entry	Mean monthly OOP, 2023	Market share of reference product, 2023 Q4 (quarterly change)	Mean monthly OOP before biosimilar entry	Mean monthly OOP, 2023
Bevacizumab	2019 Q2	-0.61%	9.29% (-14.65%)	$55.88	$47.07	17.67% (-10.91%)	$23.31	$27.52
Rituximab	2019 Q4	-1.38%	14.91% (-13.62%)	$96.28	$88.28	18.42% (-12.20%)	$48.31	$36.90
Trastuzumab	2019 Q2	-1.91%	12.67% (-12.87%)	$44.39	$44.71	15.39% (-11.73%)	$25.37	$24.80
Epoetin alfa	2018 Q4	-2.04%	54.46% (-3.32%)	$17.61	$25.76	62.22% (-2.60%)	$17.75	$10.38
Filgrastim	2015 Q3	-0.01%	4.17% (-10.05%)	$11.72	$10.76	2.27% (-11.86%)	$7.40	$2.36
Pegfilgrastim	2018 Q2	-6.50%	65.13% (-2.23%)	$65.92	$57.97	61.70% (-2.51%)	$54.41	$30.36

11163 Poster Session

A real-world data claims-based review of CAR-T procedures, time to adverse events, patient characteristics and social factors.

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Background: With the increasing utilization of Chimeric antigen receptors T-cell therapies (CAR-T), administrative claims can provide insights into approved CAR-T therapies, procedures, associated adverse events (AEs) and population characteristics. **Methods:** We used administrative open claims with medical and pharmacy encounters of 330 million US patients (PurpleLab). We identified patients with a coded AE as the principial diagnosis following the first initial claim with any CAR-T. CAR-T claims were identified with drug and procedure coding. The AEs included were Cytokine release syndrome (CRS), Immune effector-cell associated neurotoxicity (ICANS), complication of immune effector cellular therapy, tumor lysis, and cardiovascular events such as arrhythmias. The time to the AE and death were noted. In cases where social determinants of health (SDOH) are noted, race, gender, marital status, occupation, and education were analyzed. **Results:** The number of patients with CAR-T related claims within the database was 20,003. Of those patients, approximately 10% (2166) had at least one claim with an AE code as the principal diagnosis reported following the very first CAR-T claim. For those with an initial AE claim, 38% had a cardiovascular event, 36% had a complication of immune effector cellular therapy, 13% had a CRS event, 7% had an ICANS, 2% had a tumor lysis event, and 1.3% had a secondary lymphoma. Most AEs occurred within the first 30 to 90 days from the first documented CAR-T claim procedure. Cardiac and complication AEs were higher in patients aged greater than 65, while tumor lysis was higher in patients under 65. Death was reported in a quarter of the patients (532 patients) with 65% of those recorded deaths occurring within a year post first CAR-T related claim. Of those patients with a documented social demographic factor, patients with AEs were white males (41%), Asian males (2.6%), African American males (2.7%), and unspecified males (17%) making up the other races and gender. In terms of occupation and education, 34% were white collar, 5% blue collar, and 4% retired, and 29% had some level of high school, 23% college-level education, and 13% were postgraduate. More patients were identified as married (34%) than single (14%) and approximately 57% had an income below $100,000, while 11% were above $100,000, with the remaining incomes were not recorded. **Conclusions:** Real-world data can provide insights into CAR-T and AEs, patient social factors, and temporal trends. Age greater than 65 seemed the more prevalent SDOH with higher AE seen in this subgroup. Additional investigation on AEs within the different patient population subgroups are needed to provide deeper insights into treatment effects. Research Sponsor: None.

11164 Poster Session

Risk of fracture following androgen receptor pathway inhibitors (ARPIs): A population-based study.

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Background: Androgen deprivation therapy is associated with an increased risk of fracture. ARPIs are widely used to manage advanced prostate cancer (PCa). However, there is limited long-term data on fracture risk following ARPIs and how the risk might vary with different health conditions. This study aims to fill these gaps. **Methods:** This study used the SEER-Medicare linked files to identify men diagnosed with PCa between 1/1/1999 and 12/31/2019 and who received abiraterone with prednisone (AAP) or enzalutamide (ENZA) between 1/1/2013 and 12/31/2020. The primary endpoint is the time to first fracture after the index date (first date of AAP or ENZA). The history of fracture was based on claims one year before the index date. Fine and Gray's sub-distribution hazard model was used to estimate the effect of various risk factors. We used the cumulative incidence function to quantify fracture risk. **Results:** This study comprised 10,463 patients (6,037 with AAP and 4,426 with ENZA). Most patients were over 75 with a comorbidity score of 1 or higher. Among 1,445 patients who had a fracture the year before the index date, the risk of fracture after ARPI reached 50% (95% CI 47% - 53%) within 3 years, compared to 26% (95% CI 25%-27%) among those without a fracture. After adjusting for bone health agent use, comorbidities, and sociodemographic factors, a history of fracture was associated with 2.8 fold risk of fracture after AAP (RR=2.80, 95% CI 2.47 – 3.18) and 2.85 fold risk after ENZA (RR=2.85, 95% CI 2.45-3.30). Use of bone health agents within 3 months before the index date was associated with a 20-25% lower fracture risk. **Conclusions:** This large population-based study shows that the risk of fracture following ARPIs is substantial, especially among those who suffered a fracture before ARPIs. It is crucial to consider the history of fracture when making treatment choices and monitoring strategies. Better management of bone health is crucial for men treated with ARPIs. Research Sponsor: Pennsylvania Department of Health; 4100088563; NCI/NIH; 5P30CA056-036 NCI.

11166 Poster Session

Validation of real-world event-free survival (rwEFS) in early-stage triple-negative breast cancer.

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Background: Real-world (RW) evidence has been used to demonstrate effectiveness of early-stage cancer treatments. Early-stage clinical endpoints such as event-free survival (EFS) have the potential to support clinical decision-making as an indicator of real-world effectiveness for novel therapies. However, less is known regarding real-world replicability of rwEFS in early triple negative breast cancer (eTNBC). We therefore applied selected target trial emulation methods to examine the concordance between rwEFS and KEYNOTE-522 (KN-522) trial 'chemotherapy only' arm EFS estimates. **Methods:** Electronic health records from the US Oncology Network were used to identify stage II-III triple negative breast cancer patients who initiated neoadjuvant chemotherapy only from 1/1/20 to 3/31/22. Patients were followed through 07/18/23. Patients who received immunotherapy at any time during this observation period were excluded. KN-522 trial eligibility criteria and endpoint definitions were applied to develop the rwEFS endpoint. Matching-Adjusted Indirect Comparison (MAIC) was used to adjust the real-world cohort based on available baseline demographic and clinical characteristics (age, stage, and ECOG performance status) to approximate the KN-522 population. Kaplan-Meier curves and unadjusted and adjusted hazard ratios with 95% CIs were used to compare EFS between the RW cohort and the control arm of KN-522. **Results:** Real-world patients (n=199) were older (median age 59 vs 48), in more advanced stages (61% vs 25% stage III), and more often ECOG>0 (40% vs 13%) than participants in the control arm of KN-522. Median EFS was not reached in either the RW cohort or control arm of KN-522. At 36 months, estimated EFS was 76% for patients in the RW cohort and 77% in the KN-522 control arm. There was no statistically significant difference in EFS between the RW and KN-522 cohorts in unadjusted analysis (HR: 0.99, 95% CI: 0.68 - 1.46), indicating concordance between the estimates. After MAIC weighting, baseline values of age, stage, and ECOG performance were balanced between the two cohorts. The difference between RW and trial estimates was also not statistically significant in the adjusted analysis (HR: 0.76, 95% CI: 0.50 - 1.14). **Conclusions:** EFS is a valuable endpoint for evaluating the effectiveness of neoadjuvant therapy in eTNBC patients. With the application of real-world definitions to align key study design elements with the trial and leveraging curated real-world data, it is possible to reproduce the trial EFS estimate in a real-world cohort. The development of a robust, replicable rwEFS endpoint may support clinical decision-making and guide the choice of effective treatments for eTNBC patients. Research Sponsor: Merck & Co., Inc.

11167 Poster Session

Impact of AI medical scribes on physician productivity and satisfaction in medical oncology.

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Background: AI Scribes are a leading example of AI implementation in clinical settings, with Oncology practices demonstrating exponential uptake since their introduction. Despite their ever-increasing usage, there are limited studies which directly interrogate the impact of AI Scribes on physician productivity metrics, and few which assess qualitative interpretations of the technology. **Methods:** This single-center, multi-site study enrolled 27 Medical Oncologists and 3 Primary Care Physicians randomly assigned in a 1:2 ratio to exposure to the Knowtex AI scribe in the initial phase (Phase 1) or control phase (Phase 2). Billing data was collected for 6 months prior to Phase 1 onboarding with Knowtex and for 16 weeks afterward—all within the 2024 fiscal year. During the same period, Phase 2 physicians billing data served as a non-exposed comparison group. Physicians completed opt-in surveys at Week 0 and Week 8 post-exposure assessing confidence and motivation to use the AI Scribe, documentation burden, documentation quality, and experience with the electronic medical record (EMR). **Results:** All providers adopted the Knowtex AI scribe during their study phase. 4 Phase 2 physicians were excluded from data analysis due to incomplete 2024 fiscal year data. Phase 1 physicians exhibited an increase in mean units ($t(10) = 4.44$, $p < 0.01$, $d = 1.34$, CI [0.90, 2.72]) and mean total billings per working day ($t(10) = 4.30$, $p < 0.01$, $d = 1.28$, CI [$377.55, $1206.75]), a pattern not observed in Phase 2 during the same period. There was no change in the number of diagnostic codes per unit amongst Phase 1 physicians. No learned effect emerged over time in Phase 1 billing metrics or diagnostic coding. Survey findings revealed a strong positive association between Week 0 self-assessed Knowtex understanding and increased units ($r(13) = .579$, $p = 0.024$). Physicians reported increased satisfaction with documentation workflow, a reduction in-clinic hours spent on documentation, and increased time spent with patients. Physicians' net impression of EMR challenges markedly decreased following the implementation of the AI scribe ($U = 274.5$, $z=4.054$, $p < 0.0001$). **Conclusions:** Adoption of an AI Scribe in oncology may enhance certain billing metrics and positively shift physician perceptions of EMR interactions, without affecting the quality of documentation. These findings highlight potential benefits of AI Scribes in improving physician productivity and satisfaction. As AI Scribes trend towards delivering multimodal clinical support tools, future research may focus on the adjunctive effects of AI scribes on procedural efficiencies, such as consistency in billing codes. Research Sponsor: None.

Factors associated with decreased treatment intensity in patients with metastatic colon cancer: A real world analysis.

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Background: The frontline treatments for metastatic colon cancer (mCC) include intensive therapies (e.g., doublet or triplet chemotherapy backbones with biologic agents) and non-intensive therapies (e.g., chemotherapy monotherapy, biologic agents alone, or a combination thereof). Randomized trials have shown that non-intensive therapies offer shorter overall survival compared to intensive therapies; thus, they are recommended only for those unable to tolerate intensive therapy, such as those with poor performance status (PS). There is a need to identify which patients are receiving non-intensive therapies in the real world to ameliorate disparities in undertreatment. **Methods:** We conducted a retrospective cohort study by leveraging the nationwide Flatiron Health electronic health record-derived deidentified database. This database is longitudinal, comprising deidentified patient-level structured and unstructured data, curated via technology-enabled abstraction. Patients included presented with mCC during 2013-2024 and received one of the first line treatments listed in the National Comprehensive Cancer Network (NCCN) guidelines. Therapies were categorized as intensive or non-intensive based on NCCN guidelines. Frailty was defined as baseline ECOG PS≥2, and older age was defined as ≥65 years (yrs) at diagnosis. Multivariable logistic regression was performed between treatment intensity and patient characteristics (age, frailty, sex at birth, year of diagnosis, race, socioeconomic status (SES)) to estimate odds ratios and 95% confidence intervals. Age and frailty were combined into multiple variables given significant interaction term. **Results:** Among 21,588 patients included in this study, 83.3% received intensive first-line therapy. Receipt of non-intensive therapy was associated with female sex at birth and earlier year of diagnosis but not race or SES. Frailty and age were associated with treatment choice. Older non-frail patients had a stronger association with receipt of non-intensive therapy compared to younger frail patients. **Conclusions:** In addition to frailty, older age was a strong predictor of the receipt of non-intensive therapy among patients with mCC. More research and education around identifying frailty is needed to avoid undertreatment of older patients with mCC. Research Sponsor: Conquer Cancer, the ASCO Foundation.

Patient characteristics	Number of patients	Proportion receiving non-intensive therapies	Odds ratio (95% confidence interval)	P value
< 65 yrs and non-frail	7432	7.50%	Reference	
≥ 65 yrs and frail	1547	37.0%	7.10 (6.20, 8.12)	<0.01
≥ 65 yrs and missing frailty	2596	28.0%	4.22 (3.72, 4.77)	<0.01
≥ 65 yrs and non-frail	6600	18.8%	2.82 (2.53, 3.13)	<0.01
< 65 yrs and missing frailty	2544	16.0%	2.13 (1.86, 2.45)	<0.01
< 65 yrs and frail	869	11.3%	1.50 (1.19, 1.88)	<0.01
Male	11630	14.7%	Reference	
Female	9958	19.1%	1.36 (1.26, 1.46)	<0.01
Year of diagnosis			0.91 (0.90, 0.92)	<0.01

11169 Poster Session

Early onset cancer in Chile: 27-year mortality rate trends from a nationwide database with focus in gastrointestinal tumors.

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Background: Cancer has historically been considered a disease of older adults, however, several reports have shown an alarming rise in the incidence of early onset cancer, particularly gastrointestinal tumors and specially colorectal cancer. To date, there are no reports in this field from Latin America. This study aims to evaluate the trends in mortality rates of the most relevant gastrointestinal tumors among young versus older people in Chile. **Methods:** Nationwide data from the National Department of Statistics and Health Information was obtained from the years 1997 to 2023. Cause Specific Mortality was analysed for all ages, older (≥50 years) and younger (<50 years) patients for all tumors, Colorectal, Gastric, Esophagus, Pancreas, Liver and Biliary Tract cancer. The trends of rates were analyzed using Joinpoint Trend Analysis Software for calculation of the annual percentage rate change (APC). **Results:** Cancer-related mortality in Chile is increasing. From 1997 to 2023, for all causes, there were 2,645,132 deaths, the APC for the overall population, for all cancers is 0.96% (0.63%-1.29%, p<0.001). Gastrointestinal cancer accounted for 10%, with 261,300 deaths. When analyzed by type of cancer, an increase in mortality for colorectal cancer was observed, with a rate increase 90.5% higher in younger than older adults, with an APC of 3.24% and 1.7%, respectively. This difference was more evident in female adults. Pancreatic cancer mortality rate increased from 1997 to 2015 with an APC of 0.96% in older patients, but decreased from 2015 to 2023 with an APC of -0.87%. The mortality was steady in younger patients. No differences between younger and older patients were seen for Stomach, Esophagus, Biliary tract and Liver Cancer. Stomach cancer mortality rate has decreased in younger and older patients, with an APC of -1.61% and -2.63% respectively for the period from 1997 to 2015, and -5.87% and -4.77% respectively for the period from 2015 to 2023. Esophagus cancer mortality rate has decreased in younger and older patients, with an APC of -1.09% and -2.7% respectively for the period from 1997 to 2006, and -7.71% and -4.58% respectively for the period from 2006 to 2023. Biliary tract cancer mortality rate has decreased in younger and older patients, with an APC of -1.27% and -1.61% respectively for the period from 1997 to 2006, and -7.49% and -3.39% respectively for the period from 2006 to 2023. Liver cancer mortality rate has decreased in younger and older patients, with an APC of -2.53% for younger patients and -0.13% for older patients in the period from 1997 to 2015, and -2.43% respectively for the period from 2015 to 2023. **Conclusions:** This study shows an increase in mortality rates of colorectal cancer among young adults that almost doubles the rate increase in older adults in Chile. Efforts to raise awareness and improve access to early detection and healthcare should be prioritized. Research Sponsor: None.

Frailty in lung cancer hospitalizations: Identifying critical predictors for improved patient outcomes.

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Background: Frailty is a condition primarily characterized by deficits in multiple health-related factors, which, when combined with the presence of disease, lead to poor outcomes. Lung cancer patients are no exception; those who are frail tend to experience worse clinical outcomes and increased healthcare resource utilization. Identifying predictors of frailty can help guide targeted interventions and improve outcomes for this patient subset, which is the primary aim of our study. **Methods:** We conducted a cross-sectional analysis of the National Inpatient Sample database (2016-2020) to evaluate predictors of frailty in lung cancer hospitalizations. Frailty was defined using ICD-10 codes. Chi-square test was used to compare categorical variables and all weighted analyses were performed to adjust for the overall population and the complexity of the dataset, with significance set at $p<0.05$. **Results:** 1,120,440 lung cancer hospitalizations were identified and 0.27% (N=3,025) met criteria for frailty. Frail patients were older than non-frail patients (mean age: 79.6 years vs 64.4 years). 71% of frail patients were White, 15% were Black, and 8% were Hispanic, compared to 62% White, 19% Black, and 10% Hispanic in the non-frail group (p=0.001). Majority of frail patients were covered by Medicare (84%) and Medicaid (5%), compared to 59% on Medicare, 14% on Medicaid, and 18% on private insurance in the non-frail group ($p<0.001$). Geographically, 50% of frail patients were from the South and 20% from the Midwest (p=0.03). Chi-square identified coronary artery disease (CAD), congestive heart failure (CHF), chronic kidney disease (CKD), underweight, sarcopenia, and dyslipidemia as predictors of frailty. However, a negative association was observed between obesity and frailty (Table). **Conclusions:** Chronic comorbidities and decreased muscle mass remain significant predictors of frailty in lung cancer, with regional and socio-economic variations highlighting potential care disparities. The lower incidence of frailty in obese patients raises the question of the 'obesity paradox' in frailty, which warrants further investigation to explore possible causation. Identifying and targeting early predictors of frailty could lead to improved patient outcomes and more efficient healthcare utilization. Research Sponsor: None.

Predictors of frailty in lung cancer.

Predictors	Frailty Present (%)	Frailty Absent (%)	p-value
CAD	42.09	34.24	<0.001
CHF	47.14	36.22	<0.001
BMI < 18.5	12.96	3.57	<0.001
Obesity	7.74	15.89	<0.001
Dyslipidemia	41.08	35.18	0.002
CKD	38.55	30.56	<0.001
Sarcopenia	0.17	0.02	0.006

11171 Poster Session

Multicenter study of the impact of trial eligibility criteria on enrollment to KRAS G12C inhibitor trials in patients with non-small cell lung cancer.

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Background: Eligibility criteria (EC) are the primary method to assess patient appropriateness for clinical trials. There is a tradeoff between narrowing EC for patient safety and matching trial populations to the real-world population likely to receive the study agents. There is little evidence to guide optimal EC design. In 2017, ASCO proposed modifications to EC to increase the generalizability of trial findings. We previously reported a single-center experience and now report a multi-center cohort of non-small cell lung cancer (NSCLC) patients (pts) with *KRAS* G12C mutations to determine whether EC for trials of KRAS G12C inhibitors allowed enrollment of pts seen as part of routine care at three academic medical centers. **Methods:** We extracted EC for Phase I-III trials of six KRAS G12C inhibitors (sotorasib, adagrasib, olomorasib, divarasib, JDQ443 and RMC-6291) that were published or made available by sponsors. We defined a consensus set of eligibility criteria. We retrospectively reviewed pts with NSCLC and *KRAS* G12C mutations detected on universal testing of NSCLCs at Columbia University Irving Medical Center, Memorial Sloan Kettering and Weill Cornell Medicine from 2018 to 2023. Pts were re-evaluated at times of progression and last follow up. Pts were deemed trial-eligible if they met all EC, borderline if they had one laboratory value $<20\%$ from cutoff, or otherwise ineligible. Associations between demographic factors with odds of meeting eligibility criteria were determined using a multivariate logistic regression. **Results:** We identified 185 pts with *KRAS* G12C mutant advanced NSCLC who received treatment. Only 64 (35%) of these pts would have qualified for a second-line (2L) study of a KRAS G12C inhibitor. 15 (8%) had borderline eligibility and 106 (57%) were ineligible. 33/56 (60%) pts who received 2L KRAS G12C inhibitors would not have met consensus EC. Common reasons for 2L ineligibility included poor performance status (59, 49%), renal dysfunction (45, 37%), active brain metastases (33, 18%) and cytopenias (18, 15%). Age was associated with ineligibility (OR 1.07 per year, $p = 0.006$). Medicaid insurance was associated with a four-fold higher rate of ineligibility compared to Medicare but was not statistically significant (OR 4.86, $p = 0.079$). Liberalizing criteria for renal dysfunction and brain metastases would increase enrollment potential by 25% without decreasing the median overall survival of the broadened eligible cohort, whereas allowing worse performance status would decrease survival and effect sizes (1L HR 0.86 versus 0.74, $p = 0.04$; 2L HR 0.530 versus 0.423, $p < 0.001$). **Conclusions:** Our data indicate substantial differences between the real-world population of patients treated with KRAS G12C inhibitors and those who were trial eligible. Efforts should focus on improving clinical trial generalizability without compromising safety. Research Sponsor: 2024 Conquer Cancer/ASCO Young Investigator Award (Michael May).

11172 Poster Session

Accelerating phase 2 clinical development with real-world data (RWD): An external control arm (ECA) pilot in HER2-positive (HER2+) metastatic breast cancer (mBC).

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Background: Accelerating clinical development of promising therapies is essential to improving patient (pt) outcomes. While ECAs have provided valuable supplementary evidence in Phase (Ph) 3 trials to support regulatory decision-making, ECAs in the Ph 2 setting, particularly for single-arm trials, can offer critical context for evaluating efficacy with rapidly available insights. To explore this potential, we piloted the development of a contemporaneous ECA for a newly launched Ph 2 trial of Tucatinib and Doxil in HER2+ mBC (NCT0578834). **Methods:** RW structured data, supplemented by unstructured data collected via chart abstraction, were sourced from iKnowMed electronic health records. The ECA cohort was designed for maximal comparability to the trial population by (1) emulating and applying trial eligibility criteria to RWD and (2) using propensity score matching (PSM) to balance covariate distributions. To demonstrate ECA feasibility in this interim analysis, a simulated dataset was created via multiple imputation based on the distribution of observed baseline characteristics in the 8 pts enrolled on the trial, expanding the trial cohort to 40 pts. Propensity scores (PSs) were estimated using logistic regression with covariates selected based on literature and expert input (age at index, number of prior treatments, prior fam-trastuzumab deruxtecan-nxki (Enhertu), and prior tucatinib). PSM was performed using greedy nearest-neighbor matching (caliper $\leq$0.25 standard deviation of logit of PSs) without replacement at a 1:1 ratio. **Results:** The simulated trial cohort included 40 pts, and the ECA cohort included 77 pts. After PSM, 82% of the trial cohort were successfully matched, with 18% excluded due to non-overlapping PSs, resulting in matched cohorts of 33 pts each. Following PSM, most variables in the PS model achieved a standardized difference (SD) $\leq$0.10, indicating adequate balance between trial and ECA cohorts. The mean age (61 vs. 60 years in the trial and ECA cohorts, respectively; SD = 0.03), distribution of number of prior treatments (e.g., 21% vs. 27% with 1 prior treatment; SD = 0.09), and prior tucatinib exposure (48% in both cohorts; SD = 0) were well balanced between cohorts. However, prior Enhertu exposure remained imbalanced, with 45% of trial patients receiving prior Enhertu versus 33% in the ECA cohort (SD = 0.29). **Conclusions:** This pilot demonstrates that RWD can be quickly and efficiently assembled in pace with an ongoing Ph 2 clinical trial, offering promise for accelerated decision-making in clinical drug development. When small sample sizes in Ph 2 trials pose challenges, this approach shows that an exchangeable ECA can be achieved as trial accrual progresses, providing a framework for ECA evidence generation. Research Sponsor: Ontada.

11173 Poster Session

Proton pump inhibitors and the risk of adverse renal events and all-cause mortality in cancer patients receiving immune checkpoint inhibitors.

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Background: Immune checkpoint inhibitors (ICI) have transformed cancer treatment by improving prognosis across various malignancies, while proton pump inhibitors (PPI) are frequently prescribed as prophylaxis in cancer patients. Studies suggest long-term PPI use has higher risks of adverse outcomes, though small patient populations and short follow-up periods limit the current evidence. Pharmacoepidemiologic studies are prone to protopathic bias and, methodological limitations and heterogeneity across studies in cancer patients. We aimed to assess the impact of PPI use on adverse renal events and all-cause mortality in patients receiving ICIs. **Methods:** We conducted a retrospective cohort study using the TriNetX, including adult cancer patients treated with ICIs (PD-1, PD-L1, and CTLA-4 inhibitors). We used a new-user, active comparator design, which compared newly treated PPI users with nonusers and histamine2 receptor antagonists (H2RA) users. We performed 1:1 propensity score matching (PSM) to adjust for confounding factors (demographics, comorbidities, cancer type, and medications. Primary outcomes included acute kidney injury (AKI) and acute interstitial nephritis (AIN). A secondary outcome was all-cause mortality. Hazard ratios(HR) were calculated using Cox regression models. Sensitivity analysis assessed statistical robustness. **Results:** We identified 54763 PPI, 28090 H2RA, and 30898 nonusers among patients receiving ICIs. After PSM, the PPI vs. nonusers cohort was well matched with 27322 patients, whereas PPI vs. H2RA users had 21567 patients in each cohort. During the follow-up period (median 4.3 3 years for PPI and 5.1 years for nonusers), PPI users demonstrated a higher risk for AKI (HR 1.48) and AIN (HR 1.07) compared to nonusers. In a subgroup analysis of ICIs, for PD-1i, the HR for AKI was 1.86, and for AIN, it was 2.51. For PD-L1i, the HR for AKI was 1.81, and for AIN, it was 2.33. For CTLA-4i, the HR for AKI was 2.03, and for AIN, it was 3.87. A secondary analysis at 1-year follow-up revealed a significant difference in mortality rates between former PPI and nonusers. Compared with H2RA, the PPIs demonstrated a higher rate of all-cause mortality HR: 1.51. Long-term PPI users showed consistent risks of AKI and AIN across follow-ups at 2 to 5 years, with HRs for AKI ranging from 1.48 to 2.59. Pantoprazole users showed the highest AKI risk (HR 1.59). Sensitivity analysis results were consistent, and associations remained unchanged. **Conclusions:** PPI use is associated with a significantly increased risk of AREs and all-cause mortality in cancer patients receiving ICIs, with the highest risk observed in patients treated with PD-1i and CTLA-4i. These results emphasize the importance of careful prescribing of PPIs and vigilant renal monitoring for this at-risk group. Further research is warranted to explore the mechanisms underlying this association. Research Sponsor: None.

Efficacy GLP-1 agonists, SGLT-2 inhibitors and other glucose-lowering medications on cardiorenal outcomes in patients with diabetes and cancer on immune checkpoint therapy.

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Background: Treatment with Immune checkpoint inhibitors (ICI) therapy has improved survival in multiple malignancies. However, patients with type 2 diabetes (T2D) and cancer receiving ICI are at heightened risk for adverse cardiorenal outcomes. Emerging evidence suggests that Glucagon-like peptide 1 receptor agonists (GLP-1RA) and sodium–glucose cotransporter 2 inhibitors (SGLT2i) confer cardiorenal benefits in T2D. However, their impact among patients with T2D and cancer remains unclear. Hence, we aimed to evaluate the effectiveness of GLP-1RA, SGLT-2i, and other glucose-lowering therapies in reducing adverse cardiorenal events. **Methods:** A retrospective cohort study was conducted using the TriNetX. Adult patients with T2D and cancer treated with ICI (anti-PD1, anti-PDL1, or anti-CTLA4) between 2017 and 2024 were included. Patients were stratified into three groups based on therapy: GLP-1RA, SGLT-2i, and other second or third line medications. We performed 1:1 propensity score matching(PSM) to adjust for confounding factors, including demographics, comorbidities, cancer type, and medications. The primary outcomes were major adverse cardiovascular events(MACE), heart failure(HF) and cerebrovascular events(CVE)) and secondary outcome was of end-stage renal diseases (ESRD), the need for dialysis and all-cause mortality. Hazard ratios(HR) for outcomes were calculated using Cox proportional hazard models. Sensitivity analysis assessed statistical robustness. **Results:** We identified 6212 patients on GLP-1RA, 7068 on SGLT-2i, and 24693 on other second- or third-line medications. After PSM, 5381 patients were included in the GLP-1RA vs. SGLT-2i cohorts. There were no significant differences in cardiorenal outcomes between the two groups. However, all-cause mortality was significantly lower for GLP-1RA (HR 0.88). In the comparison of GLP-1RA vs. other glucose-lowering medications, 6206 patients were matched. GLP-1RA were associated with significantly lower rates of HF, MACE, CVE, ESRD and mortality (HR 0.74). Similarly, for SGLT-2is vs. other glucose-lowering medications, 7,069 patients were matched. SGLT-2i demonstrated lower rates of adverse outcomes, particularly HF and ESRD (HR 0.63). Subgroup analysis revealed consistent benefits across cancer types, with pronounced effects in renal and lung cancer. **Conclusions:** GLP-1RA and SGLT-2i significantly reduce cardiorenal risks in patients with T2D and cancer on ICIs. However, GLP-1RA provided a modest survival advantage over SGLT-2is. These results underscore the importance of individualized therapeutic strategies prioritizing GLP-1RA and SGLT-2is in this high-risk population to improve cardiorenal outcomes and survival. Further studies are warranted to validate these findings and explore underlying mechanisms. Research Sponsor: None.

11175 Poster Session

Real-world evidence from FLEX: Utility of MammaPrint in guiding treatment planning for patients aged 70 and older with early-stage breast cancer.

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Background: Older women (≥70) are less likely to receive chemotherapy (CT) due to quality-of-life concerns. Additionally, older patients are underrepresented in studies assessing the utility of genomic profiling in guiding CT decisions, thus guidelines around neo/adjuvant CT for this population are less clear. To identify the utility of the MammaPrint (MP) 70-gene and BluePrint (BP) 80-gene assays in informing treatment decisions in an elderly population, we examined the relationship of age (≥70 vs.<70) and treatment outcomes stratified by MP/BP subtypes in pts with HR+ HER2- EBC. **Methods:** The prospective, observational FLEX Study (NCT03053193) includes stage I-III pts with early-stage breast cancer (EBC) who received MP with or without BP testing and consented to full transcriptome and clinical data collection with therapy data available. Differences in the distribution of clinical characteristics between age groups were assessed by Chi-squared, Fisher's exact, or Wilcoxon-Mann-Whitney tests. The endpoint recurrence-free interval (RFI) was defined as time to local, regional, or distant recurrence or breast cancer related death Kaplan-Meier survival analysis and log-rank tests were used to assess differences in endpoints between treatment groups. **Results:** A total of 4,519 HR+, HER2- EBC pts were included, with 1,047 ≥70 (23.2%) and 3,472 <70 (76.8%). Patients ≥70 were significantly less likely to present with high grade tumors and lymph node involvement than those <70 (12.8% vs 16.2% grade 3, p=.022; 20.6% vs 24.2% node positive, p=.017, respectively). The MP risk group distribution showed a significantly higher proportion of low genomic risk (Ultralow or low risk) tumors in the ≥70 vs. <70 group (Ultralow (UL) 14.7% vs 14.9% , Low 41.2% vs 38.7% , High 1 (H1) 37.3% vs 36.9% , and High 2 (H2) 6.8% vs 9.5% , p 0.048, respectively). Patients ≥70 with MP High Risk tumors were less likely to receive CT compared to those <70 (H1 55.8% vs 73%, p<0.001; H2 72.6% vs 82.2%, p=0.07, respectively). When evaluating 3-year RFI, the ≥70 pts with MP High Risk cancer trended towards better outcomes with CT than those receiving endocrine therapy only, especially in H2 cancers (H1 97% vs 94% , p=.137, H2 90% vs 79% , p=.078, respectively). **Conclusions:** This study underscores the potential CT benefits in MP H2 HR+ HER2- EBC pts ≥ 70 who may forgo treatment due to overall health and quality of life concerns. Notably, in MP H2 pts, the absolute improvement in 3-year RFI of 11% with neo/adjuvant CT in women ≥ 70 suggests that for many pts, the benefit outweighs the risks. Of note, this H2 CT benefit is similar to that observed in a group of 1000 pts with a median age of 59 recently reported (Brufsky, et al. SABCS 2024, P2-08-12). Patient centered discussions on performance status, comorbidities, and genomic profiling of HR+ HER2-EBC as well as the potential benefit from CT should guide personalized treatment. Clinical trial information: NCT03053193. Research Sponsor: Agendia, Inc.

11176 Poster Session

Use of large language models to extract cancer diagnosis, histology, grade, and staging from unstructured electronic health records.

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Background: The oncology ecosystem contains millions of unstructured documents within Electronic Health Record (EHR) systems, including clinical notes and pathology reports with vital patient information like cancer diagnoses, histology, grade, and staging. These documents are often text or scanned PDFs. Extracting clinical details from these sources can improve EHR completeness and accuracy. To address this challenge, we developed an information extraction pipeline that leverages the recent advances in artificial intelligence (AI). **Methods:** Large Language Models (LLMs) and prompt engineering was used to extract information from both clinical notes and pathology reports. For pathology reports, Optical Character Recognition (OCR) was applied to convert scanned images into text, which was then processed by the LLM using a tailored prompt designed to extract the relevant cancer diagnosis and staging details. For clinical notes, the text was directly passed into the LLM along with an optimized prompt to extract the same clinical information. The information extraction pipeline was validated using a dataset of 829 pathology reports and 569 progress notes from the EHR system across 40 cancer types, including 26 solid tumors and 14 hematologic malignancies. Clinical specialists manually extracted cancer diagnoses, histology, grade, and staging, which were compared to the automated output. An F1 score using a combined measure of precision and recall was calculated to assess the model's accuracy. **Results:** The pipeline retrieved cancer type, histology, and grade from pathology reports with an F1 score over 0.85. Similarly, it extracted cancer type and staging information from progress notes with an F1 score over 0.85, demonstrating high accuracy and reliability. Additional performance metrics are shown in the table. **Conclusions:** This LLM-based extraction pipeline accurately identified cancer diagnoses, histology, grade, and staging information from unstructured text and scanned documents within the EHR achieving an F1 score ≥0.85. The validation results suggest that this approach could be scaled to improve the completeness and utility of EHR data, supporting the availability of more robust information for scientific research, clinical care, and other uses of health data.
Research Sponsor: None.

Performance metrics of LLM-based extraction pipeline.

Information	Source	Precision	Recall	Specificity	NPV*	Accuracy	F1 >
Cancer Type	Pathology (PDF)	0.86	0.89	0.99	0.98	0.89	0.87
Histology	Pathology (PDF)	0.83	0.88	0.90	0.88	0.90	0.85
Grade	Pathology (PDF)	0.8	0.95	0.96	0.96	0.88	0.87
Cancer Type	Progress Notes	0.8	0.95	0.96	0.96	0.88	0.87
Staging TNM (T)	Progress Notes	0.96	0.87	0.99	0.97	0.97	0.91
Staging TNM (N)	Progress Notes	0.92	0.85	0.99	0.97	0.96	0.88
Staging TNM (M)	Progress Notes	0.87	0.83	0.98	0.97	0.96	0.85

*NPV= negative predictive value.

11177 Poster Session

Immune checkpoint inhibitor–associated myocarditis: Incidence, risk factors, and clinical outcomes in a global real-world cohort.

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Background: Immune checkpoint inhibitor (ICI)-associated myocarditis is a rare but life-threatening immune-related adverse event (irAE), with a mortality rate of 30–50%. Most available evidence comes from case series and adverse event reporting databases, leaving its risk factors and clinical outcomes largely undefined. **Methods:** We performed a retrospective investigation using the TriNetX Global Research Network. Patients were included if they had been diagnosed with solid tumors after 2016 for which ICIs are approved. We calculated myocarditis incidence among ICI users and compared myocarditis risk between ICI and non-ICI cohorts using propensity score matching (accounting for demographics, comorbidities, cancer types, and treatments). Univariate and multivariate models were applied to assess risk factors. Risks of hospitalization, ICU admission, and major adverse cardiovascular events (MACE) were compared in ICI-treated patients with and without myocarditis using propensity score matching. **Results:** Among 130,234 ICI-treated patients, 643 (0.49%) developed myocarditis. Most cases (82.0%) occurred within the first year of ICI initiation. The risk of myocarditis was 27 times higher in the ICI group compared to the non-ICI group (Relative Risk [RR]=27.78, 95% CI: [17.36-44.45]). Univariate analysis identified older age, male sex, White race, hypertension, hyperlipidemia, ischemic heart disease, diabetes, chronic kidney disease, heart failure, cardiomyopathy, urothelial cancer, melanoma, ipilimumab, nivolumab, pembrolizumab, radiation therapy, inflammatory arthritis, lupus, and systemic connective tissue disease as potential risk factors. In multivariate analysis, only age over 65 (Hazard Ratio [HR] = 1.34, 95% CI: [1.11–1.63], $p < 0.01$), hypertension (HR=1.31, 95% CI: [1.06-1.62], p=0.01), hyperlipidemia (HR=1.34, 95% CI: [1.09-1.65], $p<0.01$), melanoma (HR=1.52, 95% CI: [1.25-1.86], $p<0.01$), and ipilimumab (HR= 2.44, 95% CI: [1.87-3.19], $p<0.01$) were significantly associated with myocarditis. Patients who developed ICI-associated myocarditis had higher risks of hospitalization (RR=1.39, 95% CI: [1.28-1.52]), ICU admission (RR=2.35, 95% CI: [1.86-2.98]), myocardial infarction (RR=5.58, 95% CI: [3.73-8.34]), heart failure (RR=1.59, 95% CI: [1.38-1.85]), stroke (RR=2.94, 95% CI: [1.75-4.97]), MACE (RR=3.92, 95% CI: [2.91-5.27]), and all-cause mortality (RR=1.32, 95% CI: [1.13-1.55]) within one year compared to those who received ICIs but did not develop myocarditis. **Conclusions:** ICI-associated myocarditis is a rare irAE but carries an increased risk of cardiovascular complications and death. Advanced age, hypertension, hyperlipidemia, melanoma, and ipilimumab use appear to be risk factors. Clinical vigilance is warranted to facilitate early detection and management of this potentially fatal complication. Research Sponsor: None.

11178 Poster Session

Leveraging real-world data sources for clinical oncology research: A review of studies published in ASCO publications.

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Background: Real-world data (RWD) are essential for assessing healthcare delivery and outcomes for cancer survivors, require complex statistical techniques to account for biases, and are commonly combined with other data sources. Reporting guidelines, such as Strengthening the Reporting of Observational Studies in Epidemiology(STROBE), were developed to improve the quality and transparency of RWD publications. These guidelines are not required for publication in ASCO journals. Our objective was to describe the types of RWD that commonly occur in ASCO Publications, how the data are being used, and to what extent the reports align with methodologic STROBE criteria. **Methods:** We used the ASCO Editorial Manager to identify original reports published between January 2018 to December 2022 that leveraged commonly used RWD in the US. We included all journals in ASCO Publications (Journal of Clinical Oncology [JCO], Precision Oncology [PO], Oncology Practice [OP], Clinical Cancer Informatics [CCI], and Global Oncology [GO]). The RWD assessed were SEER, Medicare, NCDB, Flatiron, CancerLinQ, IQVIA, Optum, MarketScan, MEPS, and NHANES. The data were identified by specifically referencing the source within the abstract. Five independent, trained reviewers abstracted clinical, epidemiologic, and reporting data from the manuscripts. For this study, we focused analysis on STROBE methodology reporting criteria (items 4-12). **Results:** One hundred and seventy-four publications were included in our study (57% OP, 18% CCI, 14% JCO, 5.8% PO, 5.2% GO). The most common RWD used were Medicare (49%), SEER (40%), and NCDB (14%). Nearly one-quarter of the publications used more than one of the databases evaluated, and one-third included a secondary RWD source and/or linked patients with an external data source (e.g., Google Maps, electronic health records). The most common malignancy types evaluated in the manuscripts were breast (33%), lung (25%) and colorectal (21%). Study design, setting, and study variables had high reporting (>90%), while descriptions about study size derivation, the rationale for quantitative analyses, and the approach to missing data were less well reported (<78%). **Conclusions:** RWD are published within ASCO Publications and are commonly combined with multiple data sources. Though some STROBE methodologic reporting criteria are regularly addressed, we identified criteria that were not well-reported. Further research is needed to assess changes in the use of RWD and whether lower reporting of methodologic information may impact the replicability and interpretation of study findings. Research Sponsor: None.

11179 Poster Session

Venous thromboembolism among cancer patients receiving chimeric antigen receptor-T cell therapy.

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Background: Chimeric antigen receptor T-cell (CAR-T) therapy has revolutionized the treatment of advanced cancers. Although, immune side effects (ICANS or CRS) of CARTs are well recognized, and have standardized guidelines for their management, venous thromboembolism risk (VTE) is scant. As the usage of CART is anticipated to increase in upcoming years, it is of utmost importance to characterize factors associated with increased VTE risk. **Methods:** Using the TriNetX database, we conducted a retrospective analysis to evaluate incidence and risk factors of VTE post CART. Eligibility included administration of any one of the six CAR-T therapies (Tisagenlecleucel, Axicabtagene (Axi-cel), Brexucabtagene, Lisocabtagene, Idecabtagene and Ciltacabtagene) at age ≥18y. VTE were identified using ICD codes for either upper extremity thrombosis or lower extremity deep vein thrombosis, pulmonary embolism, cerebral sinus thrombosis, splenic vein thrombosis or portal vein thrombosis. We further compared these patients to CART recipients without these VTE. Univariate analysis using TriNetX built-in feature (outcome comparison) was performed to compare factors associated with VTE including demographics, comorbidities, cancer type, and treatment. **Results:** We analyzed data from 133 million+ patients from over 103 health care organizations. There were 2076 adult CAR-T recipients. Axi-cel was the most frequently used CART type. 347/2076 (16.7%) patients developed a VTE after CAR-T, with 10% (210/2076) developing it within three months. CART with VTE cohort had a mean age of 64 years, predominantly males (201/347, 58%) and Caucasian (264/347, 76%). In univariate analysis, when compared to CART without VTE cohort (N =1033), we identified factors significantly associated with VTE. This included history of nicotine dependence (35% vs 24%, $P<0.0001$), primary hypertension (23% vs 19%, $P<0.0001$), obesity (25% vs 17%, $P=0.0007$), hyperlipidemia (45% vs 30%, $P<0.0001$), h/o radiation (35% vs 18%, $P<0.0001$), and use of Axi-cel (42% vs 7%, $P<0.0001$). The use of glucocorticoids (95% vs 77%, $P<0.0001$), alkylating agents (91% vs 71%, $P<0.0001$) or lenalidomide (18% vs 11%, $P=0.0006$) were significantly associated with VTE. The underlying cancer type also affected the risk of VTE, having significant association with diffuse large B-cell lymphoma (64% vs 50%, $P<0.0001$), mantle cell lymphoma (11% vs 7%, $P=0.0198$), and small cell B-cell lymphoma (8% vs 4%, $P=0.0018$). **Conclusions:** There is 10% incidence of VTE within three months of CAR-T therapy. Particularly, VTE incidence is higher with Axi-cel, and DLBCL diagnosis. Patients with high –risk associations may benefit from thromboprophylaxis regimens, particularly during initial three months of CAR-T therapy. Prospective research is warranted to further validate such risk factors and develop evidence-based thromboprophylaxis guidelines for CART recipients. Research Sponsor: None.

11180 Poster Session

Clinical outcomes for Medicaid recipients with early-onset breast cancer: An analysis of the National Inpatient Sample.

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Background: Despite recent global decreases in overall cancer incidence, the incidence of early-onset breast cancer (EOBC) is steadily increasing globally. Limited data is available on the comorbid correlations for this unfortunately expanding population. We sought to examine the national inpatient sample database to describe in-hospital outcomes among Medicaid recipients with EOBC. **Methods:** Data were extracted from the National Inpatient Sample (NIS) Database for 2019 and 2020. The NIS was searched for hospitalizations of adult patients with EOBC, defined as all-cause breast cancer in patients 50 years old or younger. We then examined the outcomes of patients who were noted to be active Medicaid recipients. Multivariate logistic was used to adjust for confounders. The primary outcome was inpatient mortality and secondary outcomes were annotated accordingly. SPSS software was used for statistical analysis, and all results were powered to $p<0.001$. **Results:** This study included 10,764 patients with EOBC, of which 3145 (29.2%) were on Medicaid. Multivariate regression showed that Medicaid patients with EOBC had higher inpatient mortality (OR 1.507, CI 1.406-1.616, $p<0.001$). On secondary analysis, Medicaid patients with EOBC were more likely to have systemic lupus erythematosus (OR 1.194, CI 1.080-1.319), anemia (OR 1.465, CI 1.433-1.498), thrombocytopenia (OR 1.440, CI 1.377-1.507), hypertension (OR 1.578, CI 1.461-1.704), chronic kidney disease (OR 1.343, CI 1.253-1.440), acute renal failure (OR 1.506, CI 1.432-1.584), pancreatitis (OR 1.420, CI 1.221-1.651), pericarditis (OR 1.394, CI 1.282-1.515), intracranial hemorrhage (OR 1.429, CI 1.225-1.665), severe liver disease (OR 1.504, CI 1.458-1.550), peptic ulcer disease (OR 1.436, CI 1.271-1.623), obstructive sleep apnea (OR 1.413, CI 1.313-1.521), leukemia (OR 1.310, CI 1.098-1.564), lymphoma (OR 1.737, CI 1.296-2.328), all-cause arrhythmias (OR 1.448, CI 1.342-1.563), all-cause shock (OR 1.478, CI 1.290-1.693), all-cause heart block (OR 1.294, CI 1.103-1.519), all-cause sepsis (OR 1.549, CI 1.496-1.603), all-cause coagulopathy (OR 1.457, CI 1.362-1.558), all-cause heart failure (OR 1.587, CI 1.467-1.717), all-cause stroke (OR 1.450, CI 1.342-1.566), and all-cause myocardial infarction (OR 1.766, CI 1.503-2.075). **Conclusions:** In this nationally representative, population-based retrospective cohort study, Medicaid recipients with EOBC were associated with higher mortality and worse outcomes. Research Sponsor: None.

Inpatient outcomes of breast cancer hospitalizations in the northeastern vs western United States.

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Background: Regional disparities in healthcare resources and outcomes are well-documented in the U.S., yet little is known about how they impact inpatient outcomes in breast cancer (BC) patients. The Northeastern (NE) region has the highest incidence and prevalence of BC, along with a greater concentration of academic cancer centers, while the Western (W) region has the lowest rates. This study compares both in-hospital and discharge outcomes of BC patients between these regions to explore how these variations affect inpatient outcomes. **Methods:** A cross-sectional analysis was done using the National Inpatient Sample database (2016–2020) using STATA 17.0 software. NE was taken as reference. Baseline characteristics and outcomes were compared among NE and W using chi-square tests and survey-weighted multivariate logistic regressions, after adjusting for confounders. **Results:** Among 855,494 BC hospitalizations, 22% were from the NE and 19% were from the W. Patients in W were younger, with 18% aged <50 years compared to 16% in NE ($p < 0.001$). 38% of NE patients were from high-income backgrounds, compared to 32% in W, while 16% of both NE and W patients were from the lowest income group ($p < 0.001$) suggesting significant income disparities in NE. 85% of NE patients were treated at teaching hospitals compared to 70% in W. However, in NE, only 46% sought care at large bed size hospitals compared to 58% in W (all $p < 0.001$). NE patients had longer hospital stays (>7 days: 22% vs 19%, $p < 0.001$) and incurred higher costs. Additionally, patients in the W had significantly lower odds of in-hospital mortality and discharges to skilled nursing facilities (NH) compared to NE (Table). **Conclusions:** We identified significant regional differences in BC hospitalization outcomes. W had lower mortality and lesser NH discharges, possibly due to a younger population and differences in post-acute care. In contrast, older demographics and socioeconomic factors in the NE may explain higher costs and mortality. Despite more academic centers in the NE, outcomes were not better. These findings highlight the need for region-specific strategies to improve BC care. Future research should focus on the drivers of these disparities and develop targeted interventions. Research Sponsor: None.

Outcomes in BC hospitalizations in W compared to NE.

Outcomes in W*	Adjusted Odds Ratio**	95% Confidence Interval	p-value
Mortality	0.57	0.54-0.61	<0.001
Length of Stay	0.86	0.82-0.90	<0.001
NH Discharge	0.90	0.82-0.99	0.043
Total Hospital Charges ($)	16318 ***	12978-19657	<0.001

*Reference: NE.
**Adjusted for confounders.
***Beta-coefficient.

11182 Poster Session

Trends in early-onset gastrointestinal cancers: A comprehensive analysis of US cancer statistics (2001–2021).

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Background: Early-onset colorectal cancer (eoCRC) has become a well-recognized phenomenon in recent years. This study aims to explore trends in other early-onset gastrointestinal cancers (eoGIC) and provide more details on sub-sites of eoCRC. **Methods:** The NPCR-SEER database, which covers the entire U.S. population from 2001 to 2021, was utilized to analyze GI cancer cases among individuals aged 20–49 years. Trends were assessed using Joinpoint regression, and polynomial regression was applied to forecast incidence rates from 2021 to 2031. **Results:** A total of 528,310 cases were analyzed. In 2021, eoCRC had the highest incidence (n=17,567), followed by stomach cancer (n=2,783) and pancreatic cancer (n=2,634). EoCRC has been significantly increasing with (Average Annual Percent Change (AAPC) 1.30%, $p<0.01$). Stomach and pancreatic cancers showed steady rise with (AAPC 0.73%, $p<0.01$) and (AAPC 1.14%, $p<0.01$). Among eoCRC subsites, rectal cancer showed the most substantial increase (AAPC 1.86%, $p<0.01$), followed by sigmoid colon (AAPC 1.17%, $p<0.01$) and descending colon (AAPC 0.85%, $p<0.01$). Although the appendiceal, small intestine and intrahepatic bile duct represent a smaller portion of the eoGICs, these sites demonstrated the most dramatic rises in incidence compared to their previous crude rates. Appendiceal cancer showed the highest increase (AAPC 7.23%, $p<0.01$), followed by intrahepatic bile duct cancer (AAPC 5.81%, 95% CI, $p<0.01$) and small intestine cancer (AAPC 2.90%, $p<0.01$). Declining trends were observed in esophageal (AAPC -1.50%, <0.01), liver (AAPC -2.89%, <0.01), and anal cancers (AAPC -0.98%, <0.01). By 2027, females are projected to cross males ($R^2 = 0.91$) in the incidence of eoGICs. **Conclusions:** Several eoGICs are exhibiting increasing trends, potentially indicating a shared or disease-agnostic underlying etiology. The rising prevalence and shifting demographics underscore the critical need for tailored prevention measures and early detection strategies focused on high-risk populations. Future research should focus on identifying underlying factors driving these trends. Research Sponsor: None.

Average annual percent change of subsites of colorectal cancers 2001–2021.

Primary Site	AAPC	p-value
Cecum	0.92%	<0.01
Ascending Colon	0.43%	0.10
Hepatic Flexure	-1.27%	<0.01
Transverse Colon	0.51%	<0.01
Splenic Flexure	-0.51%	0.09
Descending Colon	0.85%	<0.01
Sigmoid Colon	1.17%	<0.01
Rectosigmoid Junction	0.39%	0.13
Rectum	1.86%	<0.01

11183 Poster Session

Clinical outcomes for low-income patients with early-onset breast cancer: An analysis of the National Inpatient Sample.

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Background: Despite recent global decreases in overall cancer incidence, the incidence of early-onset breast cancer (EOBC) is steadily increasing globally. Limited data is available on the comorbid correlations for this unfortunately expanding population. We sought to examine the national inpatient sample database to describe in-hospital outcomes among low-income patients with EOBC. **Methods:** Data were extracted from the National Inpatient Sample (NIS) Database for 2019 and 2020. The NIS was searched for hospitalizations of adult patients with EOBC, defined as all-cause breast cancer in patients 50 years old or younger. We then examined the outcomes of patients who self-reported an income less than $50,000. Multivariate logistic was used to adjust for confounders. The primary outcome was inpatient mortality and secondary outcomes were annotated accordingly. SPSS software was used for statistical analysis, and all results were powered to $p<0.001$. **Results:** This study included 10,764 patients with EOBC, of which 2743 (25.5%) were low-income. Multivariate regression showed that low-income patients with EOBC had higher inpatient mortality (OR 1.438, CI 1.348-1.534, $p<0.001$). On secondary analysis, low-income patients with EOBC were more likely to have systemic lupus erythematosus (OR 1.298, CI 1.146-1.470), anemia (OR 1.374, CI 1.347-1.402), thrombocytopenia (OR 1.356, CI 1.302-1.412), hypertension (OR 1.545, CI 1.434-1.666), chronic kidney disease (OR 1.531, CI 1.404-1.669), acute renal failure (OR 1.462, CI 1.393-1.535), pancreatitis (OR 1.479, CI 1.259-1.738), mitral regurgitation (OR 1.300, CI 1.151-1.468), pericarditis (OR 1.358, CI 1.254-1.471), intracranial hemorrhage (OR 1.373, CI 1.190-1.584), pulmonary hypertension (OR 1.542, CI 1.326-1.794), severe liver disease (OR 1.382, CI 1.346-1.419), leukemia (OR 1.407, CI 1.149-1.724), lymphoma (OR 1.320, CI 1.088-1.601), all-cause arrhythmias (OR 1.324, CI 1.241-1.413), all-cause shock (OR 1.414, CI 1.264-1.605), all-cause heart block (OR 1.479, CI 1.172-1.719), all-cause sepsis (OR 1.409, CI 1.368-1.451), all-cause coagulopathy (OR 1.415, CI 1.327-1.508), all-cause heart failure (OR 1.508, CI 1.402-1.623), all-cause stroke (OR 1.463, CI 1.331-1.549), and all-cause myocardial infarction (OR 1.527, CI 1.336-1.746). **Conclusions:** In this nationally representative, population-based retrospective cohort study, low-income patients with EOBC were associated with higher mortality and worse outcomes. Research Sponsor: None.

11184 Poster Session

Clinical outcomes for patients with hyperlipidemia and early-onset breast cancer: An analysis of the National Inpatient Sample.

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Background: Despite recent global decreases in overall cancer incidence, the incidence of early-onset breast cancer (EOBC) is steadily increasing globally. Limited data is available on the comorbid correlations for this unfortunately expanding population. We sought to examine the national inpatient sample database to describe in-hospital outcomes among patients with EOBC and hyperlipidemia. **Methods:** Data were extracted from the National Inpatient Sample (NIS) Database for 2019 and 2020. The NIS was searched for hospitalizations of adult patients with EOBC, defined as all-cause breast cancer in patients 50 years old or younger. We then examined the outcomes of patients who were noted to have hyperlipidemia. Multivariate logistic was used to adjust for confounders. The primary outcome was inpatient mortality and secondary outcomes were annotated accordingly. SPSS software was used for statistical analysis, and all results were powered to $p<0.001$. **Results:** This study included 10,764 patients with EOBC, of which 1021 (9.49%) were found to have hyperlipidemia. Multivariate regression showed that patients with hyperlipidemia and EOBC had higher inpatient mortality (OR 1.052, CI 1.029-1.076, $p<0.001$). On secondary analysis, hyperlipidemia patients with EOBC were more likely to have anemia (OR 1.111, CI 1.099-1.123), thrombocytopenia (OR 1.095, CI 1.072-1.118), peripheral artery disease (OR 1.208, CI 1.074-1.359), hypertension (OR 1.433, CI 1.341-1.532), chronic kidney disease (OR 1.377, CI 1.280-1.481), acute renal failure (OR 1.159, CI 1.126-1.192), pancreatitis (OR 1.145, CI 1.048-1.251), pericarditis (OR 1.119, CI 1.069-1.172), intracranial hemorrhage (OR 1.148, CI 1.049-1.256), pulmonary hypertension (OR 1.213, CI 1.103-1.334), severe liver disease (OR 1.090, CI 1.076-1.104), leukemia (OR 1.188, CI 1.035-1.363), lymphoma (OR 1.138, CI 1.003-1.292), all-cause arrhythmias (OR 1.109, CI 1.068-1.152), all-cause shock (OR 1.065, CI 1.013-1.119), all-cause heart block (OR 1.257, CI 1.082-1.460), all-cause sepsis (OR 1.132, CI 1.113-1.152), all-cause coagulopathy (OR 1.118, CI 1.080-1.157), all-cause heart failure (OR 1.267, CI 1.202-1.336), all-cause stroke (OR 1.224, CI 1.159-1.292), and all-cause myocardial infarction (OR 1.413, CI 1.255-1.590). **Conclusions:** In this nationally representative, population-based retrospective cohort study, hyperlipidemic patients with EOBC were associated with higher mortality and worse outcomes. Research Sponsor: None.

11185 Poster Session

Clinical outcomes for Black patients with early-onset breast cancer: An analysis of the National Inpatient Sample.

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Background: Despite recent global decreases in overall cancer incidence, the incidence of early-onset breast cancer (EOBC) is steadily increasing globally. Limited data is available on the comorbid correlations for this unfortunately expanding population. We sought to examine the national inpatient sample database to describe in-hospital outcomes among black patients with EOBC. **Methods:** Data were extracted from the National Inpatient Sample (NIS) Database for 2019 and 2020. The NIS was searched for hospitalizations of adult patients with EOBC, defined as all-cause breast cancer in patients 50 years old or younger. We then examined the outcomes of patients who self-identified as Black. Multivariate logistic was used to adjust for confounders. The primary outcome was inpatient mortality and secondary outcomes were annotated accordingly. SPSS software was used for statistical analysis, and all results were powered to $p<0.001$. **Results:** This study included 10,764 patients with EOBC, of which 2328 (21.6%) were identified as black. Multivariate regression showed that black patients with EOBC had higher inpatient mortality (OR 1.408, CI 1.323-1.498, $p<0.001$). On secondary analysis, black EOBC patients were more likely to have systemic lupus erythematosus (OR 1.345, CI 1.177-1.538), anemia (OR 1.382, CI 1.355-1.411), thrombocytopenia (OR 1.275, CI 1.230-1.321), hypertension (OR 1.989, CI 1.799-2.200), chronic kidney disease (OR 1.803, CI 1.621-2.004), acute renal failure (OR 1.446, CI 1.379-1.516), pancreatitis (OR 1.291, CI 1.139-1.463), pericarditis (OR 1.200, CI 1.131-1.274), intracranial hemorrhage (OR 1.489, CI 1.264-1.755), chronic obstructive pulmonary disease (OR 1.297, CI 1.216-1.383), severe liver disease (OR 1.351, CI 1.318-1.386), Crohn's disease (OR 1.275, CI 1.104-1.472), leukemia (OR 1.310, CI 1.098-1.564), all-cause arrhythmias (OR 1.387, CI 1.292-1.489), all-cause shock (OR 1.435, CI 1.260-1.634), all-cause heart block (OR 1.189, CI 1.046-1.352), all-cause sepsis (OR 1.293, CI 1.261-1.326), all-cause coagulopathy (OR 1.355, CI 1.277-1.438), all-cause heart failure (OR 1.659, CI 1.527-1.803), all-cause stroke (OR 1.422, CI 1.319-1.532), and all-cause myocardial infarction (OR 1.638, CI 1.413-1.897). **Conclusions:** In this nationally representative, population-based retrospective cohort study, black patients with EOBC were associated with higher mortality and worse outcomes. Research Sponsor: None.

TPS11186 **Poster Session**

A platform to identify patients for cancer vaccine trials: The NHS England Cancer Vaccine Launch Pad (CVLP).

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Background: The Cancer Vaccine Launch Pad (CVLP) was established in September 2023 to establish a process to increase the number of patients identified as potentially eligible for cancer vaccine trials and supporting processes for accompanying tumour tissue processing. Increasing the available patient population by referring from wider geographical regions also increases representation from groups who may otherwise not have the opportunity to take part in cancer vaccine research trials. The CVLP is a collaborative project including NHS England, Genomics England, the Department of Health and Social Care, the Office for Life Sciences and the National Institute of Health and Care Research (NIHR) which is being delivered by the Cancer Research UK Southampton Clinical Trials Unit. The CVLP has been designed as a company and trial agnostic platform which can accommodate multiple cancer vaccine trials in multiple cancer types. **Methods:** The CVLP aims to rapidly identify large numbers of cancer patients who could be eligible for trials to expedite evidence for the efficacy of vaccines across multiple types of cancer. To support the identification of participants their tissue samples are processed by a standardised, high quality, expanded pathway, incorporating elements of the NHS Genomic Medicine Service. The primary objective of the CVLP is to determine whether it is feasible to recruit cancer patients to a platform to be matched to available cancer vaccine trials, whether there is capacity for tumour samples to be analysed within a suitable time frame and if this results in acceptable participation in cancer vaccine clinical trials. Eligibility criteria are determined according to the needs of the trial that patients will be referred on to. The CVLP pathway from patient identification to entry into available clinical trials has been developed to include the following steps; i) patients identified by the clinical team managing their care and consented into CVLP; ii) blood and tissue samples (during surgery) collected; iii) samples sent to Cellular Pathology Genomic Centre and Genomic Laboratory Labs; iv) eligibility assessment which allows the clinical liaison team to pair patients with available research trials. Sponsored by NHS England the first trial incorporated within the CVLP is BioNTech BNT122-01 (NCT04486378) investigating the RO7198457 mRNA vaccine in patients with ctDNA-positive, resected Stage II/III colorectal cancer which reached approximately 60% of patients undergoing colorectal surgery via the CVLP from 55 sites across England. To facilitate screening to the cancer vaccine trial 96.4% of tissue samples were prepared in the required time frame for testing (average 2.5 days) providing proof of principal for this pathway and paving the way for the onboarding of further trials. Clinical trial information: ISRCTN13053675. Research Sponsor: NHS England.

TPS11187 Poster Session

Barriers and facilitators of adoption and implementation of a financial navigation program in Nigeria: An analysis of participant data from the COST-FIN trial.

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Background: Financial toxicity is a critical issue in modern healthcare. The impact of financial toxicity is particularly pronounced in low- and middle-income countries (LMICs), where healthcare systems are underfunded, and out-of-pocket costs dominate medical payments. Financial navigation programs (FNPs) help patients manage costs through insurance, resources, and budget support. This study examines the challenges and opportunities of implementing FNPs in an LMIC, using data from the COST-FIN study, a randomized controlled trial investigating the impact of a structured FNP on cancer care in Nigeria. **Methods:** Adult patients (>18 years) diagnosed with breast, prostate, or colon cancer within 6 weeks of presentation at Lakeshore Cancer Center or Obafemi Awolowo University in Nigeria were eligible for trial enrollment. Between July 15 and November 22, 2024, 52 patients were recruited, and 23 were randomized to the financial navigation arm of the study. Financial Navigators assessed each patient's financial literacy and developed individualized financial plans. The extent of navigation required was categorized as high, moderate, low, or no assistance needed. **Results:** Among the 19 patients who completed financial literacy sessions, 17 received financial plans. Of these, 16 required financial navigation (extent of navigation: high, n = 8; moderate, n = 6; low, n = 2; no assistance needed, n = 1), and 15 were successfully directed to resources, including the National Health Insurance Scheme (100%), philanthropic organizations (26.7%), supports from other studies (53.3%), and drug discount programs-Nigerian Cancer Access Partnership, pharma companies and Medicaid PACE (100%). Low financial literacy was a significant barrier, with many patients lacking the knowledge to make informed decisions. Regulatory challenges, characterized by complex and inconsistent frameworks, and communication barriers also hindered FNP implementation. Navigators reported that addressing financial barriers reduced patients' stress and improved their focus on treatment. **Conclusion:** Preliminary findings highlight the potential of structured FNPs to alleviate financial toxicity and improve treatment adherence among cancer patients in Nigeria. Implementing comprehensive FNPs is crucial to address low financial literacy and help patients navigate healthcare costs. Collaborating with government policymakers to improve healthcare affordability and accessibility is also essential.
Research Sponsor: None.

TPS11188 Poster Session

Strength of evidence supporting cancer drug approvals in China, 2017-2021.

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Background: Well-designed and adequately conducted clinical trials are the cornerstone evidence to demonstrate drug safety and efficacy and support regulatory approval of drugs. We aim to investigate the strength of evidence supporting new cancer drug indications approved in China. **Methods:** This retrospective observational study included pivotal trials supporting cancer drug indications approved in China in 2017-21. We assessed their ability to minimize bias of single-arm trials, measured as adopted external control arm and adjusted confounders; risk of bias of randomized controlled trials (RCTs), as evaluated using the revised Cochrane tool for risk of bias assessment. The ratio of hazard ratios (RHR) was calculated to quantify differences in effect size in RCTs with different risks of bias. **Results:** Between 2017 and 2021, 77 novel cancer drugs for 148 indications were approved in China, based on data from 205 pivotal studies. Of the 56 pivotal single-arm trials with regulatory review documents, 6 (10.7%) used aggregated data from earlier trials as external controls without adjustment for confounders. Of the 128 pivotal RCTs with published results, 95 (74.2%) were assessed as having some concern or a high risk of bias. RCTs judged to be at some concern or high risk of bias in the randomization process had smaller effect sizes (RHR=0.67, 95% CI: 0.53-0.86), and those judged to be at some concern or high risk of bias in missing outcome data had larger effect sizes (RHR=1.11, 95% CI: 1.00-1.23), compared to RCTs at low risk of bias in these domains). **Conclusions:** Over four-fifths of pivotal studies supporting cancer indication approvals in China had design weaknesses that introduce uncertainty to the estimation of treatment effects. To ensure the validity of drug efficacy data and reduce uncertainty, stakeholders should strengthen and implement a high-quality standard on the design, conduct, and analysis of studies supporting regulatory approval of new therapies. Research Sponsor: National Natural Science Foundation of China; 72274004.

Characteristics of cancer drugs and corresponding indications approved in China between 2017 and 2021.

Characteristic	All, No (%)	No. (%) 2017	2018	2019	2020	2021
Cancer Drug	**77 (100.0)**	**7 (9.1)**	**16 (20.8)**	**13 (16.9)**	**16 (20.8)**	**25 (32.5)**
Authorized Region						
Authorized in China only	28 (36.4)	0	5 (31.3)	3 (23.1)	6 (37.5)	14 (56.0)
Also approved by the FDA/EMA[a]	49 (63.6)	7 (100)	11 (68.8)	10 (76.9)	10 (62.5)	11 (44.0)
Cancer Indication	**148 (100.0)**	**16 (10.8)**	**42 (28.4)**	**33 (22.3)**	**30 (20.3)**	**27 (18.2)**
No. Supporting Pivotal Studies						
1	106 (71.6)	8 (50.0)	34 (81.0)	25 (75.8)	18 (60.0)	21 (77.8)
2	32 (21.6)	5 (31.3)	7 (16.7)	2 (6.1)	12 (40.0)	6 (22.2)
≥3	10 (6.8)	3 (18.8)	1 (2.4)	6 (18.2)	0	0 (0)
No. Pivotal Randomized Trials						
0	44 (29.7)	4 (25.0)	6 (14.3)	7 (21.2)	11 (36.7)	16 (59.3)
1	79 (53.4)	7 (43.8)	29 (69.0)	19 (57.6)	13 (43.3)	11 (40.7)
≥2	25 (16.9)	5 (31.3)	7 (16.7)	7 (21.2)	6 (20.0)	0

Abbreviations: EMA, European Medicine Agency; FDA, the United States Food and Drug Administration.
[a]By December 31, 2021.

TPS11189 **Poster Session**

Falcon: Exact Sciences' multicancer early detection (MCED) real world evidence (RWE) registry.

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Background: Earlier detection may reduce cancer morbidity and mortality by reducing the number of cancers diagnosed at advanced stages. Exact Sciences is developing a blood-based MCED test to simultaneously screen for multiple cancer types, with test-positive patients undergoing diagnostic evaluation with radiological imaging. The Falcon registry is a large prospective study of Exact Sciences' MCED test in clinically cancer-free individuals who seek cancer screening. It will examine the uptake, diagnostic journey, adherence with guideline-recommended cancer screening, outcomes, and psychological impacts of MCED testing in a setting that closely resembles the real world, with results expected to be broadly generalizable.
Methods: Falcon is a multi-site registry that is enrolling up to 25,000 participants who receive the MCED test annually for three years (MCED cohort). A comparison cohort of up to 50,000 patients receiving standard-of-care clinical management only (SOC cohort) will be retrospectively constructed via a deidentified data pull. Both cohorts will include individuals 50 to 80 years of age presenting for primary care services who have no history of malignancy within the prior 3 years or current suspicion of cancer. SOC cancer screening will continue in the course of standard care and will not be proscribed or interrupted by study participation. The MCED cohort will include a 10,000-participant pilot cohort and up to a 15,000-participant expansion. This cohort will include individuals who provide informed consent for MCED testing and follow-up IV-contrast computed tomography (CT) and, if necessary, positron emission tomography-CT (18F FDG PET-CT) imaging following a positive MCED test. Clinical contraindications for radiological imaging (e.g. pregnancy, IV contrast allergy, renal failure) will be taken into consideration when making the decision to participate. The SOC cohort will be selected after enrollment of each MCED cohort phase and will be matched based on demographic and clinical characteristics. Self-reported measures of anxiety, cancer worry, and trauma will be collected from all MCED cohort participants routinely throughout the study. Data will be collected for up to 5 years following the baseline test or, for the SOC cohort, following an index date. Periodic automated extraction of pre-specified data elements from existing electronic data sources, primarily medical records and tumor registries, will be collected from all participants. Clinical trial information: NCT06589310. Research Sponsor: Exact Sciences Corporation.