Biologic indicators of donor socioeconomic disadvantage and recipient mortality following allogeneic hematopoietic cell transplantation.

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Background: Allogeneic hematopoietic cell transplantation (HCT) carries significant risks, with low socioeconomic status (SES) being predictive of increased mortality. Our team recently discovered that socioeconomic disadvantage among unrelated HCT donors results in decreased recipient overall survival (OS) and increased treatment-related mortality (TRM) within a cohort from the Center for International Blood and Marrow Transplant Research (CIBMTR). We also demonstrated that upregulation of the stress- and SES-related gene expression profile termed the 'conserved transcriptional response to adversity' (CTRA) is associated with low SES and worse outcomes among HCT recipients. Here, we hypothesize that donor immunologic characteristics associated with neighborhood socioeconomic disadvantage (CTRA) will confer prognostic risk to HCT recipients as indicated by inferior long-term recipient outcomes. **Methods:** Among a subset of the above cohort for which donor whole blood samples were available from the CIBMTR repository, we evaluated whether donor cell CTRA gene regulation was associated with inferior HCT outcomes at 3 years in recipients being treated for hematologic malignancy. Multivariable models adjusted for donor and recipient characteristics evaluated associations between donor CTRA and recipient OS, TRM, disease free survival (DFS), relapse, and acute and chronic graft versus host disease. Results were considered significant if $P<0.05$. **Results:** We identified 263 donor-recipient pairs for study inclusion. Median recipient age at hematologic malignancy diagnosis was 53 years (range 19-77), 46% were female, and 54% had acute myeloid leukemia. Donors were 35% female and median age at donation was 31 years (range 18-60). In RNA sequencing data from HCT donors, greater CTRA expression was associated with reduced OS (covariate-adjusted HR=1.94/CTRA SD, 95% CI [1.01, 3.71], p=.046) which was driven predominately by increased TRM (adjusted HR=5.04, [2.20, 11.50], p=.0001). These clinical outcomes are consistent with those observed to be associated with donor SES in our prior work. Donor cell effects on transplant outcomes derived predominately from the pro-inflammatory component of the CTRA (OS: adjusted HR=1.67, [1.20, 2.33], p = .0026; TRM: adjusted HR=2.21, [1.21, 4.06], p=.010) and emerged above and beyond the effects of the recipients' own SES, as well as multiple other recipient disease, treatment, and demographic factors. Donor CTRA was not associated with relapse, DFS, or other transplant outcomes. **Conclusions:** For the first time, we show that transcriptome patterning among HCT donors, consistent with neighborhood SES disadvantage, results in adverse recipient HCT outcomes. These findings suggest that SES has a biologic impact at either the stem or immune cell level that persists even when transplanted into a new host. Research Sponsor: U.S. National Institutes of Health; U.S. National Institutes of Health.

6501 **Oral Abstract Session**

Evaluation of potential socioeconomic and racial/ethnic disparities in all-cause mortality in adolescent and young adult patients with cancer.

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Background: Adolescent Young Adult (AYA) cancer patients, aged 15-39, have historically been understudied. For older adults, socioeconomic (SES) and racial/ethnic disparities in mortality have been demonstrated, but less is known about survival disparities for AYA patients. Most existing studies do not account for the influence of insurance status and access to care. To address this gap, we evaluated the association of SES and race/ethnicity with overall mortality for AYA cancer patients who were members of an integrated health delivery system with relatively equal access to care. **Methods:** Patients diagnosed with cancer at age 15-39 years old in Kaiser Permanente Southern California between 2010-2018 were included. The fourteen most common AYA cancer types within our cohort were included (excluding thyroid cancer due to low mortality rate). The Neighborhood Deprivation Index (NDI) was used as a marker of SES. Patients were placed into NDI quartiles (Q1: least deprived-Q4: most deprived). Mortality rate per 1,000 patient years was calculated for each racial/ethnic group and NDI quartile. Multivariable cox model was used to estimate hazard ratios (HRs) for all-cause mortality. Models included race/ethnicity and NDI subgroup simultaneously, adjusting for sex, age and stage at diagnosis, and cancer type. **Results:** A total of 6,380 patients (59% female, median age: 33) were followed for a maximum of ten years. Racial/ethnic distribution was 45% Hispanic, 36% non-Hispanic White, 10% non-Hispanic Asian/Pacific Islander, 7% non-Hispanic Black, 2% Other/Unknown. Overall mortality was 21.8 deaths per 1,000 person years. Crude mortality rates were higher among Non-White racial/ethnic groups (Asian/Pacific Islander: 26.7, Black: 26.2, Hispanic: 25.6, Other/Unknown: 30.3) compared to White patients (16.4). In the adjusted model, Hispanic (HR=1.32, 95% confidence interval [CI] 1.03-1.50, p=0.004) and Black (HR=1.35, 95% CI 1.00-1.83, p=0.05) patients experienced significantly higher risk of all-cause mortality compared to White patients. No mortality differences were observed between Asian/Pacific Islander and White patients. Patients from more deprived neighborhoods had higher mortality risk (Q1: 19.9, Q2: 19.8, Q3: 24.1, Q4: 27.4). In the adjusted model, there was no significant difference in all-cause mortality between Q1 and Q2-Q4 [Q2 (HR=0.88, 95% CI 0.71-1.10), Q3 (HR=0.94, 95% CI 0.75-1.17), Q4 (HR=0.96, 95% CI 0.76-1.22)]. **Conclusions:** Our study suggests that for insured AYA cancer patients with similar access to care, Hispanic and Black patients have increased risk of all-cause mortality as compared to White patients, while no significant SES survival disparities were observed. These findings warrant further investigation, awareness, and intervention to address inequities in cancer care among vulnerable populations. Research Sponsor: None.

6502 **Oral Abstract Session**

Disparities in outcomes among hospitalized unhoused patients with cancer in the US.

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Background: Cancer is the 2nd leading cause of death among death among unhoused adults in the US. Use of aggressive medical interventions and costs during hospitalizations remains unstudied in the unhoused population. **Methods:** All hospitalized adults age ≥18 with a principal cancer diagnosis were identified in the 2016-2020 National Inpatient Sample (NIS). Logistic regression tested associations between unhoused status and: cost of care, mortality, and receipt of invasive procedures/systemic therapy. Adjusted analysis accounted for patient demographics, socioeconomic status, comorbidities, and effect modification of housing status by length of stay (LOS). **Results:** A total of 9,030 unhoused and 2,758,693 housed adults with cancer were included in the study. There were significant ($p<0.01$) differences in age <65 years (77% unhoused vs 41% housed), male sex (75% vs 53%), race (Black, 25% vs 13%; White, 58% vs 71%), and insurance type (Private, 6% vs 27%; Medicaid, 53% vs 11%). There were also differences by primary cancer diagnosis, with higher rates of lung (17% vs 14%) and liver (8% vs 3%) cancers. Unhoused persons received less chemotherapy inpatient (5% vs 7%) and fewer overall procedures (48% vs 58%), while experiencing longer LOS (median 6 vs 4 days). On adjusted analyses, unhoused adults were had lower odds of receiving invasive procedures (aOR [95% CI], 0.34 [0.27-0.42]) or systemic therapy (0.41 [0.20-0.85]); and were less likely to have a higher-than-median cost of stay 0.47 [0.39-0.57]). Additionally, unhoused adults were 35% and 20% less likely to have a higher-than-median cost of stay or die while hospitalized (95% CI 0.59 – 0.71 and 0.67 – 0.96, respectively). When accounting for the possibility of housing status being modified by LOS, unhoused persons remained significantly less likely than housed persons to receive inpatient procedures (aOR 0.38, 0.47, and 0.60 for short, medium, and long LOS, respectively; $p<0.001$ for each) or have high cost of stay (adjusted OR 0.55, 0.71, 0.70, $p<.001$ for each), though the differences by housing status were attenuated with longer length of stay. **Conclusions:** In this first nationwide analysis of hospitalizations among unhoused adults with cancer, unhoused patients remained significantly less likely to receive invasive procedures or systemic therapy. These disparities in inpatient management despite the higher prevalence of more aggressive cancers and comorbidities among the unhoused highlight missed opportunities to improve cancer care. Research Sponsor: None.

6503 **Oral Abstract Session**

Risk of early mortality in patients with cancer experiencing adverse financial events.

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Background: Patients with cancer are at higher risk for experiencing severe adverse financial events (AFEs) compared to similar individuals without cancer. Among persons with cancer, those experiencing bankruptcy have poorer survival. In this study, we sought to determine whether AFEs less severe than bankruptcy have an increased risk of death among patients with cancer. **Methods:** Records for all patients diagnosed with a solid tumor between 2013 and 2018 were identified through the Western Washington State SEER cancer registry and were linked to quarterly credit reports from TransUnion. Patients who survived at least 2 years from date of diagnosis were included. Cancer patients experiencing any AFE, defined as third-party collections, charge-offs, delinquent mortgage payments, tax liens, foreclosures, and repossessions within 2 years of diagnosis were compared with cancer cases who did not experience these events. After adjusting for age, sex, race, area deprivation index, rural/urban status, marital status, AFE at diagnosis, cancer type, and stage of cancer, we fit a Cox proportional hazards model to examine the relationship between AFEs and overall survival, and also fit a separate model for each cancer type. **Results:** A total of 64,637 patients were diagnosed with cancer between 2013 and 2018, and survived 2 years post-diagnosis. The overall population was 84% white, 53% female, and had a median age of 64. 12,698 patients experienced any severe financial event. The adjusted hazard ratio for mortality among patients who did versus did not experience an AFE was 1.22 (95% CI, 1.145-1.299, $p < 0.001$), with age >65, Asian/Pacific Islander race, greater area deprivation index, and higher stage of cancer associated with increased risk for mortality. Among differing cancer types, patients with prostate cancer who experienced an AFE had the highest risk of death compared with patients with prostate cancer who did not experience an AFE (HR 1.703,95% CI, 1.395 to 2.08, $p < 0.001$). **Conclusions:** Patients with cancer who experience severe AFEs within 2 years of diagnosis are at higher risk for mortality after adjusting for sociodemographic and clinical factors. When comparing within separate cancer groups, this association is strongest among patients with prostate cancer. Current analysis is limited by restricting population to those who survived at least 2 years after diagnosis; future work will expand population to include patients who died at any time point. Further research should investigate mechanisms for this increased mortality risk, to inform potential interventions and policy solutions, especially among the prostate cancer population. Research Sponsor: Kathryn Butler Foundation, Texas 4000 Foundation.

Cancer Type	HR	95% CI	p value
All	1.22	1.145 to 1.299	<0.0001
Prostate	1.703	1.395 to 2.08	<0.0001
Breast	1.18	0.993 to 1.403	0.0606
Colorectal	1.172	0.984 to 1.397	0.0759
Lung	1.169	0.998 to 1.37	0.0533
Other	1.149	1.049 to 1.259	0.0027

6504 **Oral Abstract Session**

Health insurance continuity and survival among children, adolescents, and young adults with blood cancer: An analysis based on SEER-Medicaid data.

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Background: Many previously uninsured patients do not receive Medicaid coverage until the point of, or after, cancer diagnosis, which may delay access to life-saving therapies. We examined whether continuous Medicaid coverage prior to diagnosis (vs. gaining Medicaid at, or after, diagnosis) provides a survival benefit in children and adolescents/young adults (AYAs) newly diagnosed with blood cancer. **Methods:** Using the linked SEER cancer registry-Medicaid enrollment data, we assessed coverage during the six months prior to, the month of, and the six months after cancer diagnosis (13-month window) in 29,873 children and AYAs (aged 0-39 years) diagnosed with blood cancer in 2006-2013. To measure insurance continuity, we categorized patients who had: (1) continuous Medicaid (enrolled for $\geq$6 months prior to through diagnosis), (2) newly gained Medicaid at/after diagnosis (enrollment only at or $\leq$6 months after diagnosis), (3) other patterns of noncontinuous Medicaid, (4) private insurance, (5) other insurance, or (6) uninsured/unknown insurance. The last three groups contain patients in SEER not linked to Medicaid enrollment data; these patients' insurance at diagnosis was available in SEER. Kaplan-Meier (KM) survival curve of 5-year overall survival was stratified by insurance continuity category. Associations between insurance continuity and survival were examined using Cox proportional hazard models, for all blood cancers combined and by cancer type (leukemia, lymphoma, myeloma). Models also adjusted for age, sex, race/ethnicity, rurality, neighborhood socioeconomic status, and diagnosis year. **Results:** Of our sample, 44.1% had private insurance, followed by Medicaid (28.3%), other insurance (9.6%), and no insurance (3.9%) or unknown insurance (14.1%). Of Medicaid-insured patients, 44.9% had continuous Medicaid, 38.9% gained Medicaid at/after diagnosis, and 16.2% experienced other noncontinuous patterns. The KM-estimated 5-year survival probability was 89.3% for privately insured patients, followed by other insurance (88.1%), continuous Medicaid (78.2%), other patterns of noncontinuous Medicaid (74.3%), and newly gained Medicaid at/after diagnosis (70.6%; $p<0.001$). In multivariable analysis, patients who newly gained Medicaid at/after diagnosis had a hazard ratio (HR) for death of 2.63 (95%CI=2.42-2.87), whereas patients with continuous Medicaid and those with other noncontinuous patterns had HRs of 2.08 (95%CI=1.90-2.28) and 2.31 (95%CI=2.04-2.60), respectively, compared to privately insured patients. This finding persisted across blood cancer types. **Conclusions:** Less than half of Medicaid-insured children and AYAs with blood cancer had continuous insurance coverage prior to and following cancer diagnosis. Lacking continuous Medicaid coverage was associated with inferior survival. Research Sponsor: The Leukemia & Lymphoma Society.

6505 **Oral Abstract Session**

Association of medical debt and cancer mortality in the US.

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Background: Medical debt is associated with non-medical and medical financial hardship, such as food and housing insecurity, as well as delaying or forgoing recommended health care. This study examines county level associations between medical debt and cancer mortality in the US. **Methods:** We conducted a county level ecological study, using 2018 medical debt data from the Urban Institute linked with 2015-2019 mortality data from the National Centers for Health Statistics. All US counties with non-missing information on medical debt and other covariates were included. Primary outcomes were age-adjusted mortality rates per 100,000 person-years for all malignant cancers and by cancer type. Multivariable linear mixed models were used to estimate the association of percent of population with medical debt with cancer mortality, adjusting for county level sociodemographic characteristics. Additional analyses examined the association between median amount of medical debt per person and cancer mortality for the subset of counties with these data. Models were weighted by county level population size, with standard errors clustered at the state level. **Results:** Among 2,943 counties, an average of 19.8% of the population had medical debt, ranging from 0% to 53.6% across counties. Higher percentages of the population with medical debt were observed in non-metro areas, counties with higher percentages of non-Hispanic Black people, adults without high school education, living below poverty level, uninsured, or unemployed. One percentage point increase in the population with medical debt was associated with a 1.12 (95% CI=1.02-1.22) increase in age-adjusted mortality rate (per 100,000 person-years) for all malignant cancers, a 0.47 (95% CI=0.43-0.52) increase for lung cancer, a 0.09 (95% CI=0.07-0.11) increase for colorectal cancer, and a 0.06 (95% CI=0.04-0.07) increase for female breast cancer. Among 1,949 counties with the amount of medical debt available, each $100 increase in median medical debt was associated with a 0.86 (95% CI=0.52-1.21) increase in age-adjusted mortality rate for all malignant cancers. Associations between increases in median medical debt and increased mortality rates were statistically significant for major cancer types. **Conclusions:** Medical debt is associated with significantly higher cancer mortality at the county level. Policies increasing access to affordable health care may improve cancer outcomes. Research Sponsor: None.

Association of medical debt and age-adjusted mortality rates.

Cause of Death	Any Medical Debt	Median Medical Debt, in hundreds
All malignant cancers	1.12 (1.02, 1.22)	0.86 (0.52, 1.21)
Lung and bronchus	0.47 (0.43, 0.52)	0.33 (0.18, 0.47)
Prostate	0.03 (0.02, 0.04)	0.03 (-0.002, 0.07)
Female breast	0.06 (0.04, 0.07)	0.05 (0.01, 0.09)
Colorectal	0.09 (0.07, 0.11)	0.06 (0.01, 0.11)

* Adjusted for county level education, racial/ethnic composition, metro status, uninsured and unemployment rates.

6506 **Oral Abstract Session**

The impact of single gene testing (SGT) on subsequent comprehensive genomic profiling (CGP) success in community oncology practice for advanced non-small cell lung cancer (NSCLC): Results from a prospective observational reference laboratory testing program.

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Background: CGP concurrently tests tumor tissue for guideline-recommended predictive biomarkers for optimal therapy selection and identification of clinical trials in NSCLC patients. A common practice in the community oncology setting is to first order SGT, then consider CGP when SGT results are negative or after treatment failure. Given the limited tissue available and the scope of alterations not tested by SGT, we sought to characterize the effects of prior SGT on subsequent CGP testing success, and therapeutic opportunities identified by CGP beyond SGT for NSCLC patients in the community setting. **Methods:** Reference laboratory information systems were used to prospectively contact clinicians across 80 community practices who ordered at least 1 SGT for guideline-recommended genomic variants in NSCLC. CGP was offered for their patients prior to SGT or upon receipt of negative SGT results. SGT included individual assays for *BRAF, EGFR, KRAS, MET exon 14 skipping* mutations; *ALK, RET,* and *ROS1* rearrangements; and PD-L1 IHC. CGP included DNA-seq for mutations, copy number variants in 523 genes including guideline-recommended genomic variants, MSI, and tumor mutational burden; RNA-seq for rearrangements/fusions/splice variants; and PD-L1 IHC. **Results:** Among a total of 580 NSCLC patients with CGP ordered (May 2021-December 2022), 168 (29%) had $\geq$1 SGT ordered prior to CGP (median=5). No patients had all SGT performed, with untested cases ranging from 10% for *ALK* to 90% for *MET exon 14*. The same FFPE tissue block was used for CGP in 150/168 (89%) of cases with prior negative SGT. Compared to CGP-only cases, CGP for cases with prior negative SGT was canceled twice as often at tissue review (16% vs 7%; p=.001), had higher DNA extraction failures (13% vs 8%; p=.09), and lower DNA sequencing success (70% vs 83%, p$<$.001). CGP detected guideline-recommended variants in 51% of all cases. Among prior negative SGT cases, frequencies were higher in genes where SGT was performed less often and is less sensitive than CGP RNA-seq (*RET* fusions, *MET exon 14* skipping). CGP also identified guideline-recommended variants in genes with no SGT offered during the study period (*ERBB2* mutations, *NTRK2/3* fusions), as well as variants with emerging evidence for FDA expedited program-designated clinical trial therapies in 28% of patients, including *NRG1* fusions and *BRAF* non-V600E, *KEAP1*, *KRAS* non-G12C, *NFE2L2, STK11,* and TP53 Y220C mutations. **Conclusions:** Prior negative SGT doubled subsequent CGP test cancellations for NSCLC due to tissue insufficiency and increased CGP DNA extraction failures. SGT practice in the community oncology setting does not meet practice guideline recommendations and negatively impacts the potential benefit of subsequent CGP for NSCLC patients. Research Sponsor: Eli Lilly and Company.

6507 **Oral Abstract Session**

Clinical value of timely targeted therapy (TT) for patients with advanced non-small cell lung cancer (aNSCLC) with actionable driver oncogenes (ADO).

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Background: Recent real-world studies observed that some aNSCLC pts with ADO initiated non-targeted therapy (non-TT) before biomarker test results became available. This study assesses the clinical impact of the timing of first line (1L) TT in aNSCLC pts with ADO. **Methods:** In a retrospective analysis of the nationwide Flatiron Health electronic health record-derived de-identified database, pts aged ≥18 years, diagnosed (Dx) with aNSCLC between 1/1/2015-10/18/2022, had ADO (ALK, BRAF, EGFR, RET, MET, ROS-1, or NTRK) based on biomarker testing ≤ 90 days of advanced Dx, and received 1L treatment (tx) were included. Cohorts were defined by tx patterns after test result: Cohort 1 received 1L TT ≤ 42 days; Cohort 2 initiated 1L non-TT before or after testing but switched to TT ≤ 42 days; Cohort 3 initiated non-TT before or after testing and did not switch to TT ≤ 42 days. Pts were followed from test results + 42 days until 11/30/2022 or death, whichever earliest. Multivariate Cox regression evaluated real-world progression-free survival (rwPFS) and overall survival (OS) between cohorts. **Results:** A total of 5156 aNSCLC pts with ADO were included: 79% were treated in the community setting and 56% received NGS testing. Most common ADO were EGFR and ALK for both Cohort 1 (78% and 13%) and Cohort 2 (67% and 24%); EGFR (39%) and BRAF (35%) for Cohort 3. Cohort 3 included more rare mutations (MET, NTRK, RET). Statistically significant differences were observed in gender, race/ethnicity, practice type, and area-level socioeconomic status across all cohorts. There was no significant difference in outcomes observed between Cohort 2 and 1, but significantly inferior outcomes in Cohort 3 vs 1. **Conclusions:** Our findings demonstrated better outcomes with upfront 1L TT vs non-TT in aNSCLC pts with ADO. The comparable outcomes between pts who received 1L TT after test result and pts who switched to TT ≤ 42 days of test result available underscore the importance of timely tx decisions based on ADO detection in lieu of tx-switch at progression. Opportunities remain to improve utilization of NGS to identify all ADO upfront to inform the appropriate 1L TT when indicated.
Research Sponsor: Genentech Inc./F. Hoffmann-La Roche.

Outcomes by tx pattern in aNSCLC pts with ADO.

	Median (95% CI) rwPFS, months	rwPFS adjusted Hazard Ratios (HRs)	Median (95% CI) OS, months	OS adjusted HRs
Cohort 1, n=3005 (reference group)	10 (10,11)	-	28 (27,29)	-
Cohort 2, n=162	13 (9,14)	0.92, p=0.374	26 (21,38)	0.96, p=0.731
Cohort 3, n=1989	6 (6,7)	1.18, p<0.001	21 (19,24)	1.12, p=0.018

6508 **Oral Abstract Session**

Practice- and provider-level inequities in next-generation sequencing (NGS) testing by race/ethnicity for patients (pts) with advanced non-small cell lung cancer (aNSCLC) treated in the community setting.

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Background: Inequities in NGS testing in pts with aNSCLC are well documented. Here, we examined elements of total inequity in NGS testing for pts with aNSCLC treated in the US community setting, in terms of within and between inequities at the practice and provider level. **Methods:** Using the nationwide, deidentified, electronic health record–derived Flatiron Health database, we studied pts with aNSCLC diagnosed in April 2018 or later and treated in the community setting. Testing quality was defined as an NGS result reported ≤60 days after advanced diagnosis. Total-practice inequity was the average percentage-point (pp) difference in the rate of testing quality for non-Latinx Black or Latinx pts compared with non-Latinx white pts. Within-practice inequity was the average pp difference in testing rates at a practice weighted by overall practice enrollment. Between-practice inequity was the covariance between a practice's overall testing rate and the extent of practice-level racial/ethnic underrepresentation. We estimated these inequities at the practice and provider levels using a Bayesian approach. **Results:** Our study included a total of 12,045 pts (9,981 non-Latinx white, 1,528 non-Latinx Black, and 536 Latinx pts). Both within- and between-practice inequities contributed to total inequity in NGS testing for non-Latinx Black and Latinx pts compared with non-Latinx white pts (Table). For non-Latinx Black pts, between-practice inequities were estimated as 57% (3.77 pp/6.56 pp) of the total inequity in NGS testing; for Latinx pts, the contribution of between-practice inequity was 39% (3.13 pp/8.01 pp). At the provider level, between-provider inequities were the dominant contributor to total inequity in NGS testing for both non-Latinx Black and Latinx pts, accounting for 86% (5.88 pp/6.87 pp) of total provider-level inequity for non-Latinx Black pts and 64% (5.36 pp/8.43 pp) for Latinx pts. **Conclusions:** Inequities within and between practices, as well as between providers, are meaningful contributors to total inequity in NGS testing. Additional healthcare equity initiatives are needed to identify potential causes for lagging practices/providers to address inequities in NGS testing. Research Sponsor: Genentech Inc./F. Hoffmann-La Roche.

Average percentage-point difference in NGS testing inequity in Pts with aNSCLC.

vs non-Latinx White pts (95% credible interval), %*	non-Latinx Black	Latinx
Practice level		
Total	6.56 (3.91, 9.17)	8.01 (3.81, 12.23)
Within	2.79 (−0.22, 5.72)	4.88 (−0.47, 10.18)
Between	3.77 (2.43, 5.13)	3.13 (−0.02, 6.24)
Provider level		
Total	6.87 (4.23, 9.46)	8.43 (4.17, 12.65)
Within	0.99 (−2.16, 4.11)	3.07 (−2.56, 8.56)
Between	5.88 (4.09, 7.65)	5.36 (1.73, 9.01)

* Negative values indicate higher NGS testing rate in non-Latinx Black or Latinx pts vs non-Latinx White pts.

6509 **Poster Discussion Session**

Strategies to increase accrual of underrepresented populations in Alliance NCTN trials.

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Background: Accrual of underrepresented populations (URPs-racial and ethnic minorities, women, rural populations, and younger and older populations) to clinical trials has been historically low, hampering progress in cancer treatment, symptom intervention and prevention for all. In 2018, the Alliance for Clinical Trials in Oncology (Alliance), as a part of the NCI's National Clinical Trials Network (NCTN) and a Research Base for the NCI Community Oncology Research Program (NCORP) began a multi-pronged strategy to increase accrual of underrepresented minorities by race and ethnicity (URMs) to both treatment and cancer control trials conducted by the Alliance. **Methods:** Alliance leadership set a goal of 20% accrual for racial and ethnic minorities to all trials in 2018. The Health Disparities Committee (HDC) implemented several strategies over time including leadership promotion/ expectation of goals; funding junior investigators and special projects focusing on URPs; working groups for specific populations in HDC; HDC co-chairs to selected protocols; translation services of patient facing materials; opening studies at NCORP Minority Underserved Sites; real time monitoring of accrual demographics, by Alliance and by site; protocols addressing aims for specific populations; closing protocol enrollment to majority populations; and increasing the study sample size to enroll additional minority participants to allow for analyzing intervention effects by subgroups. **Results:** Accrual data from 117 NCTN and NCORP trials led by Alliance was included from 2014-2022. Over time, accrual of racial and ethnic minorities increased from 13.6% to 25.3% for treatment and 13% to 21.5% for cancer control trials. This results in overall increase from 13.5 % to 23.6% of URMs for all trials, a 74.8% improvement. **Conclusions:** Intentional approaches to increase URMs has led to an increase in URM accruals to Alliance trials. Future strategies include implementation of the Alliance Patient Questionnaire to prospectively measure the prevalence of specific social determinants of health among patients enrolled to further expand the understanding and address the needs of unique population accrued to Alliance trials. In addition, accrual of women, rural populations, and younger and older adults (65+ years) are now being monitored over time to increase all URP accruals. Research Sponsor: U.S. National Institutes of Health.

6510 **Poster Discussion Session**

How patient-clinician education can strengthen partnerships and promote tangible actions to improve clinical trial diversity in breast and lung cancer trials.

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Background: Some of the greatest disparities in cancer care are related to clinical trial access for our patients. To address the racial/ethnic disparities in breast and lung cancer clinical trials, a tethered educational initiative was designed to empower patients, assess current clinician perceptions/practices, and improve awareness of real-world perspectives of clinical trials. **Methods:** Two, one-hour online, interactive, video-based programs were designed for patients, caregivers, and providers. This patient/caregiver program was hosted on CancerCoachLive and MedLive in November, 2022, while the provider program was hosted on ClinicalSeriesLive in December, 2022 and will remain on-demand until December 2023. This initiative was conducted in collaboration with TOUCH, the Black Breast Cancer Alliance, BlackDoctors.org, Moffitt Cancer Center, CancerCare, and the Lung Cancer Research Foundation. Herein, we report on an analysis from patients and providers regarding clinical trial diversity, behavioral impact, and qualitative insights. **Results:** As of data cut-off (02/10/23), 1,425 participants have engaged across both educational programs. Of participating patients, 46% were non-White (non-Hispanic), 36% were in remission, 36% were not on active treatment, and 29% were newly diagnosed. Following the program 81% were motivated to take one or more actions over the next two months: the most common actions being to research clinical trials (38%) or discuss clinical trials with a clinician (19%). Post-activity, 79% were confident to very confident discussing clinical trials with a clinician. Critical data related to clinician preferences was assessed and demonstrated a 23% increase in confidence from pre- to post-activity in improving diversity in clinical trial participation with preferences observed in both breast and lung cancers to offer clinical trials for newly diagnosed and second recurrence settings. Of those who are being offered clinical trials in the community setting, there was a higher likelihood for patients to be offered a clinical trial if their subtype was HER2+ breast cancer subtype or NSCLC with an actionable mutation. Data collection continues as this initiative is ongoing. Qualitative data including clinician write-in examples of behavioral impact and patient perspectives from the interviews will be shared. **Conclusions:** The outcomes discussed herein reveal a willingness from patients/caregivers to engage in clinical trial discussions and participate in clinical trials, if eligible. These educational programs positively impacted clinician motivation to address barriers to enrollment and clinical trial eligibility with their patients. Real-world accounts of patient experiences provide different perspectives that can help improve approaches to improve clinical trial diversity. Research Sponsor: Daiichi Sankyo Inc., Gilead Sciences, Inc., Merck & Co., Inc.; and Pfizer Inc.

6511 **Poster Discussion Session**

Mediators of racial/ethnic inequities in clinical trial participation among US patients with cancer, 2011-2022.

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Background: In 2024, the US Food & Drug Administration will require drug sponsors to implement plans to improve racial/ethnic diversity in clinical trials. While minoritized populations are less likely to participate in cancer trials, it is unknown whether social determinants of health (SDOH) explain these inequities. Here we identified SDOH factors that contribute to racial/ethnic inequities in clinical trial participation among patients with 22 solid and blood cancers. **Methods:** This retrospective study used the nationwide Flatiron Health electronic health record-derived de-identified database of adult patients with cancer (2011-2022). Area-level SDOH (*e.g.,* predominant race/ethnicity [proxy for segregation]) contextualizing where patients live were defined using the American Community Survey tract data. Patients were followed from cancer-specific diagnosis to clinical study drug receipt (proxy for trial participation), death, or last recorded activity. Associations of race/ethnicity and SDOH factors on trial participation were assessed using Cox proportional hazards models adjusted for clinical factors (diagnosis year, age, sex, performance status, stage, and cancer type). To elucidate which SDOH explain racial/ethnic inequities, mediation analysis was performed using nonlinear multiple additive regression trees models. **Results:** This study included 233,556 patients (median age: 68 years, 50.0% women; 65.6% non-Latinx [NL] White, 8.5% NL Black, 5.0% Latinx). Black and Latinx patients were more likely to live in marginalized areas (*i.e.,* disproportionately minoritized, low socioeconomic status, limited English proficiency, and low vehicle ownership) than White patients. Overall, 4.9% of patients participated in trials. Fewer patients from community practices or in marginalized neighborhoods participated in trials. Black (3.4%; hazard ratio [HR] 0.55, 95% confidence interval [CI]: 0.51- 0.60) and Latinx patients (3.6%; HR 0.57, CI: 0.52-0.63) were less likely to participate in trials than White patients (5.8%). Black-White trial inequities were substantially mediated (58%, CI: 47%-68%) by practice type (*e.g.*, community vs. academic center, 13%, CI: 10%-15%) and area-level SDOH (*e.g.*, segregation [33%, CI: 25%-44%] and vehicle ownership [12%, CI: 8%-15%]). Mediators explained 55% (CI: 38%-71%) of the Latinx-White trial participation inequity; area-level SDOH—including segregation (29%, CI: 13%-37%), limited English proficiency (15%, CI: 9%-25%), and vehicle ownership (8%, CI: 5%-12%)—were the most important mediators. **Conclusions:** SDOH factors, especially manifestations of structural racism such as segregation, explained a substantial proportion of racial/ethnic inequities in trial participation among patients with cancer. These findings can inform targeted efforts to increase racial/ethnic diversity in cancer trials. Research Sponsor: Flatiron Health.

6512 **Poster Discussion Session**

Comparison of incident breast cancer cases in the largest national US tumor registries.

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Background: National tumor registries, such as the NCDB (National Cancer Database) and SEER (Surveillance, Epidemiology, and End Results Program), have been used to explore numerous research questions related to trends in disease incidence, treatment patterns, and outcomes. However, some have criticized that they may not fully represent the general population. As such, we sought to compare the incident breast cancer cases in the NCDB and SEER to a national population cancer registry. **Methods:** All patients diagnosed with malignant or in situ breast cancer 2010-2019 were selected from the NCDB (Fall 2022 release) and SEER-22 (November 2021 release) and compared to breast cancer patient counts from the US Cancer Statistics Public Use Database (USCS, 2021 submission). Patient frequencies were summarized by age, sex, race/ethnicity, and year of diagnosis. Percent case coverage was estimated as the number of patients in the NCDB or SEER divided by the number of patients in the USCS. Chi-square tests were used to compare patient counts across data sources. **Results:** In total, the USCS database reported 3,047,509 patients diagnosed with breast cancer between 2010-2019, of which, 77.5% (N=2,362,477) were included in the NCDB and 46.0% (N=1,403,272) in SEER. Over time, case coverage steadily improved for the NCDB (72.8% in 2010 to 81.5% in 2019), while only a minor increase was observed in SEER (46.0% in 2010 to 46.6% in 2019). When compared to the USCS, case ascertainment was notably lower for individuals age $\geq$50 in both the NCDB and SEER (both $p<0.001$). The overwhelming majority of patients were captured by the NCDB (age $<$50: 81.7%; age $\geq$50: 76.6%) while SEER identified approximately half (age $<$50: 49.4%; age $\geq$50: 45.3%). Case ascertainment also varied significantly by patient sex across registries (both $p<0.001$). For male breast cancers, 84.1% were captured in the NCDB, only 77.5% of female patients were included. In contrast, case coverage in SEER was better for females than males (46.1% vs 43.5%). Notably, registries varied significantly by race/ethnicity (both $p<0.001$). Case coverage in the NCDB was highest for non-Hispanic White (78.2%), non-Hispanic Black (77.7%), and non-Hispanic Asian or Pacific Islander (72.5%) patients, and it was lowest for Hispanic (56.4%) and non-Hispanic American Indian/Alaska Native (41.1%). In SEER, case coverage was highest for non-Hispanic Asian or Pacific Islander (78.1%) and Hispanic (69.6%) patients, and it was considerably lower for all other subgroups (non-Hispanic Black 44.8%, non-Hispanic White 42.4%, and non-Hispanic American Indian/Alaska Native 36.6%). **Conclusions:** National US tumor registries provide data for a large sampling of breast cancer patients, and case coverage has improved over time. However, significant differences in case coverage were observed based on age, sex, and race/ethnicity, suggesting that analyses using these data sets should be interpreted with caution. Research Sponsor: U.S. National Institutes of Health.

6513 **Poster Discussion Session**

Big data in oncology: Challenges and solutions.

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Background: Oncology care is complex and often multimodal. With recent technological advances, only a fraction of data is structured feasibly for research. Here we present a step-by-step method of building a novel comprehensive pan-cancer oncology data model using standard data definitions and industry-standard benchmarks. **Methods:** A team of 133 members was assembled including a project manager, bioinformatic engineers, business analysts, biostatisticians, data stewardship experts, clinical curators, and quality assurance (QA) managers. We first identified data domains that capture a comprehensive patient journey, leveraging existing oncology data models as a starting point, including NAACCR, PRISSMM (Deb Schrag & Eva Lepisto), and mCODE (ASCO). A common data model was developed using standard terms plus 5-10 disease specific elements (DSE). REDCap was used as the database platform, as it is HIPAA compliant and allows customizations. The data was stored in AuroraDB using an architecture and products that provide scalability from both an integration and consumption perspective. **Results:** We identified 10 data domains, including 186 distinct elements: demographics (20), comorbidities (2); cancer diagnosis & staging (27), pathology (45), imaging (18), medications (11), oncology responses (11), radiation treatments (14), cancer surgeries (11), cancer genomic (19), tumor markers (8), and vitals (8). Standard ontologies were used, including ICD-0-3 histology codes, ICD-10 comorbidities codes, CPT cancer surgeries codes, and CTCAE 5.0 for toxicities. We identified a data steward for each tumor type across medical oncology, surgery, pathology, radiology, and radiation oncology domains who aided curator training and the identification of DSE. QA managers and analysts performed 20% source data verification. In addition, we built REDCap rules (applicable across a form), and complex queries (applicable across multiple forms). To support QA and clinical engagement, interactive Tableau dashboards were constructed. In addition, timing and quality errors were monitored via Tableau dashboards at the individual curator level to provide timely feedback, leading to improved data quality and curation efficiency in real time. The Medical oncology and radiology domains were the most time-consuming, whereas Cancer diagnosis was the most difficult to curate. **Conclusions:** We collected genomic and phenomic data for 15,579 patients across six tumor types to date. Collecting comprehensive oncology data across tumor types is possible but requires institutional support, collaboration between clinical & informatics teams, and a dedicated QA team. Research Sponsor: Memorial Sloan Kettering Cancer Center.

Tumor Type (15,579)	REDCap based rule (N)	Complex Queries (N)	Average time to complete a case (minutes)	Average number of forms per record
Lung (6,308)	224	66	196	50
Sarcoma (2,862)	228	50	269	56
Prostate (2,252)	134	50	346	72
Bladder (1,427)	198	54	235	60
Kidney (1,197)	227	61	193	58
Uterine (1,533)	224	48	123	42

Enhancement in line of therapy (LoT) derivation from real-world data (RWD) from electronic health records (EHR) via integration of medical claims data.

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Background: Clinical RWD derived from EHRs is becoming increasingly important for clinical research, trial design, regulatory decisions etc. These applications require identification of lines of therapy (LoT) which are typically not captured in EHR and must be abstracted from other clinical and medication data. EHR data has significant missingness which can be complemented with other data sources such as medical claims data. In this study, we demonstrate how our proprietary line of therapy algorithms for solid cancers show significant improvements when built using integrated EHR and claims data when compared to EHR data alone. **Methods:** For this analysis, ConcertAI's RWD360 dataset integrated with a large administrative open-claims dataset (>90% overlap) for 14 solid cancer indications (Breast, Bladder, Lung, Prostate, Pancreas, Melanoma, Liver, Head & Neck, Renal, Colorectal, Melanoma, Ovarian, Thyroid, Endometrial) was used. The date of advanced/metastatic diagnosis used as the index date for LoTs was derived from the EHR data and medications from both EHR and claims data were used. We ran our LoT algorithms on EHR data with and without claims data and evaluated the impact of integrating claims data on the quantity and quality of LoT output. **Results:** The inclusion of medication data from claims significantly increased (7-22%) the number of patients for which LoTs could be extracted from the EHR data. Furthermore, we observed increases in number of lines per patient, length of lines and medications per line across cohorts. The distance between index date and 1st line start date was shortened in a subset (2-12%) of patients as a result. In a small fraction of cases, we even observed removal of false lines as some of the lines moved to adjuvant/neoadjuvant setting by filling in missing medication from claims. Overall, 7-39% patients in the LoT cohorts were impacted by addition of claims. Results for a few cancer types are presented in Table 1. We also compared the top LoTs derived from the integrated dataset against the standard of care for that cancer and observed very good concordance. **Conclusions:** Deriving LoTs by integrating data from multiple data sources such as EHR and claims can significantly improve its accuracy. Research Sponsor: None.

Impact analysis of claims integration on LoTs for 5/14 solid cancer cohorts.

Cancer Indication	Breast	Lung	Prostate	Pancreas	Renal
# Pts with LoTs before claims integration	49826	53961	24309	12584	6639
# Pts with LoTs post claims integration	54557	57806	27191	13631	7478
# Pts added due to addition of claims	5034	3960	3019	1066	866
# False positive pts removed due to claims integration	303	115	137	19	27
# Pts with enhanced LoTs	18104	5421	9417	1461	1733
# Pts with decrease in days between index date and LoT start date	3680	1318	3018	308	442
# Total pts impacted	23441 (47.1%)	9381 (17.6%)	12436 (51.7%)	2527 (20.2%)	2626 (39.5%)

Pts, patients.

6515 **Poster Discussion Session**

End-of-life spending analysis of randomized trial of machine learning nudges to prompt serious illness communication among patients with cancer.

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Background: Early serious illness conversations (SICs) between oncology clinicians and patients in the outpatient setting may improve mood and quality-of-life among patients with cancer. However, the impact of early SIC "nudges" on end-of-life spending is unknown. **Methods:** This was a secondary analysis of a stepped-wedge randomized trial (NCT03984773) that randomized 9 medical oncology practices and their high-risk patients at a large academic institution to a behavioral intervention to increase SICs (performance reports and peer comparisons; precommitments for high-risk patients; weekly opt-out text prompts before high-risk encounters) vs. standard of care, between June 2019 and April 2020. We identified high-risk patients using a machine learning (ML) algorithm predicting 180-day mortality. This secondary analysis included 1187 (957 intervention, 230 control) patients with complete data who died by December 2020. We abstracted spending (defined as inflation-adjusted reimbursements for acute care [inpatient + ED], office/outpatient care, intravenous chemotherapy, other therapy [e.g. radiation], long-term care, and hospice) from the institution's accounting system; we captured spending at University of Pennsylvania inpatient, outpatient, and pharmacy settings. To evaluate intervention impacts on spending, we used a two-part model: first, logistic regression to model zero versus nonzero spending, and second, generalized linear models with gamma distribution and log-link function to model daily mean spending in the last 180 days of life. Models were adjusted for clinic and wedge fixed effects and clustered at the oncologist level. **Results:** Median age at death was 68 years (IQR 15.5), 317 (27%) patients were non-White, and 448 (38%) patients had a SIC prior to death. The intervention was associated with lower mean spending in the last 180 days of life (mean daily spending $377.96 [intervention] vs. $449.92 [control]; adjusted mean difference -$75.33, 95% CI -$136.42, -$14.23 , p = 0.016) (Table), translating to $13,559 total adjusted savings. Intervention patients incurred lower mean daily spending for chemotherapy (adjusted difference -$51.35, $p < 0.001$), office/outpatient care (-$14.59, $p < 0.001$), and other therapy (-$10.35, $p = 0.043$). The intervention was not associated with differences in end-of-life spending for acute care utilization, long-term care, and hospice. Results were consistent for spending in the last 30 and 90 days of life and after adjusting for age, race, and ethnicity. **Conclusions:** A ML intervention to prompt SICs led to end-of-life savings, driven by decreased chemotherapy and outpatient spending. Clinical trial information: NCT03984773. Research Sponsor: U.S. National Institutes of Health.

Unadjusted spending in last 180 days of life.

	Intervention	Control
Total Spending	$69,977	$82,110
Mean Daily Spending	$378	$450
· **Acute Care**	$202	$200
· **Outpatient**	$24	$39
· **Chemotherapy**	$113	$164
· **Other Therapy**	$29	$40

Biosimilar uptake and cost savings analysis before and after implementation of a pharmacist-driven substitution program within a National Community Oncology Network: One-year follow-up.

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Background: As of December 2022, 22 of the 40 biosimilar approvals in the United States, are used for the treatment of cancer or for the supportive care of patients with cancer. Our organization is a network of community oncology practices, representing 107 oncologists at 76 locations across 17 states. Because our network faces formulary selection and reimbursement challenges related to a diverse payor mix across multiple states, we sought to see the impact of utilizing regional clinical pharmacists (RCPs) to assist with selection of the most cost-effective biosimilar products. **Methods:** In October 2021, our network initiated an RCP-driven biosimilar substitution program, whereby the RCP acts as a liaison between providers and financial teams to evaluate existing drug orders and their financial impact. We previously presented data on the financial impact to payors and providers before and after implementation of the program from 4/1/2021 to 4/1/2022. This study evaluates the one-year results following program implementation. Additionally, outcomes related to biosimilar utilization as well as financial impacts to payors, patients, and providers were assessed. Payor savings is defined as the difference of the calculated 80% Medicare ASP+6 for the administered biosimilar compared to the originator; patient savings is defined as the difference of the calculated 20% Medicare ASP+6 co-insurance for the administered biosimilar compared to the originator; provider savings is defined as the difference between the invoiced cost of the biosimilar compared to the originator. **Results:** By the end of 2022, preferred product utilization was achieved for >90% of bevacizumab, trastuzumab, and rituximab orders. Use of the preferred pegfilgrastim product increased from <20% in 4/2021 to >60% by 12/2022. Use of filgrastim biosimilar product increased from <75% in 4/2021 to >90% by 4/2022, then decreased to 55% by 12/2022 due to trending ASP. Payor preference prevented biosimilar switching in approximately 34% of cases. **Conclusions:** Use of institution-preferred biosimilar products increased across all agents in this study after implementation of the RCP-driven biosimilar substitution program, except for filgrastim. Significant cost savings were noted for payors, patients, and providers. Barriers to switching to institution-preferred products included non-medical switching requirements by payors, patient assistance and compassionate use programs, and patient and/or provider preferences. Research Sponsor: Part of this research was made possible through a competitive independent medical education grant supported by Pfizer, Inc. All data, analysis, and content are independent of industry influence.

Time Period	Payor Savings	Patient Savings	Provider Savings	Total Savings
4/1/2021-9/30/2021	$8.0 million	$2.0 million	$11.3 million	$21.3 million
10/1/2021-4/1/2022	$10.8 million	$2.7 million	$10.6 million	$24.1 million
1/1/2022-12/31/2022	$26.4 million	$6.6 million	$23.5 million	$56.5 million

6517 **Poster Discussion Session**

The impact of adverse financial events on healthcare utilization and treatment costs at the end of life.

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Background: Patients with cancer are at higher risk of bankruptcy and other adverse financial events (AFEs) compared to similar individuals without cancer. However, little is known about how AFEs affect cancer care, particularly at the end of life (EOL). We investigated the association between AFEs, healthcare utilization, and healthcare costs at the EOL among patients with cancer. **Methods:** Western Washington Surveillance Epidemiology and End Results (SEER) cancer registry cases were linked to credit records from TransUnion and to claims from commercial payers and Medicare. Patients with AJCC Stage I-IV solid tumors who died between January 2013 and December 2019 and who had continuous enrollment in commercial or Medicare insurance for the 6 months prior to death were included. Emergency department (ED) and inpatient (IP) visits in the last 3 months of life, place of death, and mean healthcare costs per patient (paid by insurer) were compared between patients with versus without AFEs (charge-offs, third-party collections, tax liens, delinquent mortgage payments, foreclosures, or repossessions). A multivariate logistic regression analysis was used to evaluate the association between AFEs, ED or IP visits (>1 of either), and inpatient death, adjusting for socio-demographic factors, comorbidities, payer type, and cancer stage. Two-sample t tests were used to compare mean per-patient costs in the last 6 and 3 months of life among patients with versus without an AFE. **Results:** A total of 13,545 patients (median age 75, 54% male) were included, of which 15.6% experienced an AFE. Patients with AFEs were more likely to have multiple ED or IP visits (OR 1.19, CI 1.07-1.34) and die in a hospital (OR 1.37, CI 1.22-1.55) (Table). Younger age, higher Carlson Comorbidity Index (CCI), and being partnered were also associated with greater EOL healthcare utilization while race, sex, payer type, and cancer stage were not. Mean total healthcare costs were higher in patients with AFEs than those without in the last 6 months ($66,232, vs. $55,831, $p<0.0001$) and 3 months ($39,664 vs. $33,638, $p<0.0001$) of life. **Conclusions:** We demonstrated an independent association between AFEs as measured in credit records, increased EOL healthcare utilization, and greater per-patient costs in the months before death. These findings suggest that addressing patient financial hardship could improve their EOL experience and decrease healthcare costs. Research Sponsor: Kathryn Butler Foundation, Texas4000 Foundation.

Predictors of EOL healthcare utilization.

Predictors*	Multiple ED or IP visits	Inpatient death
AFE	1.19 (1.07-1.34), $p<0.002$	1.37 (1.22-1.55), $p<0.0001$
Age < 65	1.22 (1.06-1.40), $p<0.005$	1.19 (1.02-1.37), $p<0.023$
CCI > 1	1.27 (1.15-1.39), $p<0.0001$	1.31 (1.20-1.46), $p<0.0001$
Partnered	1.16 (1.06-1.26), $p<0.001$	1.17 (1.06-1.29), $p<0.001$

*Reference: no AFE, age 65+, CCI 0, no partner. Other predictors (not significant): race, payer type, cancer stage, and area deprivation index.

A multi-level system quality improvement project to reduce disparities in lung cancer screening: The Sylvester Lung Screening Project.

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Background: Racial disparities in lung cancer mortality and screening have been well documented in the USA. Annual screening with low dose Computed Tomography (CT) scans is completed in fewer than 6% of the eligible population. Research suggests that many factors contribute to low screening uptake, including barriers to care at patient, clinician, healthcare system, and community levels. In collaboration with the American Cancer Society, the University of Miami/ Sylvester Cancer Center underwent a multi-level system quality improvement (QI) project with the goal to decrease lung cancer screening disparities and improve guideline concordant lung cancer screening across the health care system. **Methods:** During the one-year multi-level QI project, interventions were put into place to increase lung cancer screening exams via improvements in EMR- identification of eligible patients, patient navigation and expanded provider education services in primary care clinics. Patient level interventions included a marketing campaign, patient navigation, and interpreters to address language barriers. The Patient-interface of the EMR 'Health Maintenance Gap' was optimized to alert eligible patients about screening. In addition, a full-time lung cancer screening navigator provided culturally competent, patient-centered counseling, while allowing for an increased capability to manage a higher volume of patients. Provider level interventions included teaching sessions about lung cancer screening and motivational communication skills, and BPA alerts. The primary outcome was the change in the number of screened patients. **Results:** With the implementation of these multi-level interventions, there was a twenty five percent improvement in the number of lung cancer screening exams completed during the project period January 2022- December 2022 compared to 2021 baseline, from 20 to 25%. The screening rate was highest among Hispanics (12%), followed by Blacks (8%), and Non- Hispanic Whites (NHW) (6%). The majority of LDCT results were Lung RADS Category 1 or 2 (93%). **Conclusions:** Multi-level interventions that target patients, clinicians, and the health care system can improve lung cancer screening rates in a short-term period. Developing patient-centered, culturally competent interventions is key to reducing disparities in lung cancer screening. This QI intervention was strengthened by tailoring intervention components to the educational primary care physicians and simplifying the referral process. Research Sponsor: American Cancer Society.

	Pre-Intervention (2021)	Post-Intervention (2022)
Eligible	**996**	**1323**
Screened (%)	**202 (20.3%)**	**334 (25.2%)**
Race/Ethnicity		
NHW	32/345 (9.3%)	32/492 (6.5%)
Hispanics	72/474 (15.2%)	66/547(12.1%)
Black	14/101 (13.9 %)	11/137 (8%)
Asian	1/20 (5%)	1/20 (5%)
Missing Ethnicity Data	5.6%	16.9%
LUNG-RADS		
0	0	0
1	10	19
2	175	292
3	14	16
4	3	7

6519 **Poster Discussion Session**

Guideline-concordant use of olanzapine as part of a 4-drug antiemetic regimen for high emetic risk chemotherapy across the state of Michigan.

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Background: Chemotherapy-induced nausea and vomiting (CINV) is a feared side effect of cancer treatment. If not adequately controlled, CINV can negatively affect both quality of life and increase the costs of care. Clinical practice guidelines from both ASCO and NCCN recommend inclusion of olanzapine as part of a 4-drug antiemetic regimen in patients receiving high emetic risk chemotherapy (HEC). Uptake of olanzapine has been low, however, in part due to oncologists' lack of familiarity with the medication, lack of awareness or agreement with the guidelines, and lack of olanzapine inclusion on prepopulated order sets. Current labeling of olanzapine as an antipsychotic poses an additional barrier. The purpose of this project was to increase guideline-concordant prescribing of olanzapine as part of a 4-drug antiemetic regimen in patients receiving HEC in practices that are part of the Michigan Oncology Quality Consortium (MOQC), a physician-led consortium of nearly 90% of oncologists in Michigan. **Methods:** In 2019, MOQC began measuring guideline-concordant HEC prophylaxis with a 4-drug regimen of olanzapine added to corticosteroids, a 5HT3RA, and an NK1RA as part of its measure set. A quality improvement intervention was initiated that consisted of 1) dissemination of baseline measure performance and regular reporting of practice and state-level performance to MOQC practices, 2) information support through sharing of guidelines at biannual meetings (2019, 2022) and state-wide CINV education to improve prescriber knowledge and beliefs and support the practices in updating prepopulated antiemetic order sets, and 3) addition of value-based reimbursement in 2021 to encourage practice change. Measure performance was assessed using ASCO's Quality Oncology Practice Initiative (QOPI) program. **Results:** The patient sample included 5,703 patients. MOQC practices increased the guideline-concordant prescribing of olanzapine as part of a 4-drug antiemetic regimen in patients receiving HEC round over round from R1 2019 to R1 2022 ($p<0.0001$). **Conclusions:** MOQC has facilitated increased use of olanzapine as part of a 4-drug antiemetic regimen in patients receiving HEC through practice education, reporting, and value-based reimbursement. Ongoing work will focus on practices with low uptake and on demonstrating the impact of this important practice change on patient outcomes. Research Sponsor: None.

The percentage of patients receiving olanzapine as part of a 4-drug antiemetic regimen for HEC over time.

Round	min (%)	Q1 (%)	median (%)	Q3(%)	max (%)	overall (%)	p-value
R1 2019	0	0	0	0	22	7	
R2 2019	0	0	0	10	43	13	3.12E-05
R1 2020	0	0	0	9	75	17	0.009
R2 2020				Data not available			
R1 2021	0	0	0	9	91	21	0.006
R2 2021	0	0	6	42	100	27	0.001
R1 2022	0	0	11	40	100	29	0.142

*Data is collected twice per year as designated by Round 1 (R1) and Round 2 (R2) in the table. P values show significance round-over-round.

Impact of a web-based decision aid on socioeconomically disadvantaged patients' engagement in decision making (Alliance A231701CD).

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Background: Increased patient engagement in decision making may mitigate disparities in breast cancer surgical care. Socioeconomically disadvantaged patients disproportionately experience barriers to engagement. Decision aids (DA) increase engagement by providing information, establishing role expectations during the consult, and increasing confidence in surgeon interactions. The objective was to test the effectiveness of a surgical web-based DA in increasing engagement among breast cancer patients in clinics that care for a high proportion of socioeconomically disadvantaged patients. **Methods:** A stepped wedge trial was conducted with 10 NCI Community Oncology Research Program clinics (Alliance for Clinical Trials in Oncology Research Base, 6/19-12/21). Clinics were randomized to time of transition from usual care (UC) to delivery of a web-based DA. Patients with stage 0-3 breast cancer eligible for surgery provided consent prior to a surgical consult. Socioeconomic disadvantage was assessed with the Area Deprivation Index measured at the zip+4 level and dichotomized. Patient engagement was measured by Patient's Self-Efficacy in Patient-Physician Interactions (PEPPI-5, follow-up survey) and count of Active Patient Behaviors (Street protocol, audio recorded consult). Intervention effects were tested with linear mixed-effects models, accounting for surgeon and clinic-level clustering, time, and enrollment post-COVID. Heterogeneity of treatment effect by socioeconomic disadvantage was assessed with an interaction term. **Results:** 573 patients enrolled. 44% (136/309) reviewed the DA. No significant difference in engagement was observed comparing DA and UC for PEPPI-5 (-0.80 [95% CI -2.13, 0.54], p = 0.24) or Active Patient Behaviors (2.52 [CI -4.11, 9.15], p = 0.46). Enrollment post-COVID was associated with increased Active Patient Behaviors (9.59 [CI 1.76, 17.43], p = 0.02) but no change in PEPPI-5 (-1.31 [CI -2.88, 0.26], p = 0.10). No heterogeneity of treatment effect was observed. **Conclusions:** In this trial conducted in clinics that serve diverse populations, no significant relationship was observed between a web-based DA and patient engagement. Conducting this stepped wedge trial during the pandemic was challenging. Future analyses will explore the impact of COVID on outcomes and effect of the decision aid for patients who reviewed it. UG1 CA189823; AHRQ R01HS025194; https://acknowledgments.alliancefound.org. Clinical trial information: NCT03766009. Research Sponsor: Agency for Healthcare Research and Quality; U.S. National Institutes of Health.

	Usual Care (n = 264)	Decision Aid (n = 309)
Age (years, median, range)	59 (30-87)	61 (27-90)
Race		
White	169 (64%)	207 (67%)
Black	60 (23%)	62 (20%)
Other	35 (13%)	40 (13%)
Socioeconomic Disadvantage	73 (28%)	59 (19%)
Enrollment Post-COVID	98 (37%)	281 (91%)
PEPPI-5 (n, median, range)*	239, 22.0 (7-25)	268, 22.0 (5-25)
Active Patient Behaviors (n, median, range)*	258, 17.5 (0-114)	301, 19.0 (0-112)

*Higher scores indicate higher engagement.

6521 **Poster Session**

Curating clinical trials: Helping patients find hope by exploring clinical trial opportunities.

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Background: Clinical trials are essential to the advancement of clinical therapies. However, only 5% of cancer patients enroll in clinical trials (CTs) due to limited accessibility. Given that greater participation in CTs is associated with better patient outcomes, patients from smaller centres are at a disadvantage. The Clinical Trials Navigators (CTN) program was established by Hamm (2022) to help patients in smaller communities navigate and enrol in CTs, resulting in clinical trial enrolment of 7% of patients. This study will provide updated results on the impact of the CTN program as it has expanded. **Methods:** Between March 2019 to September 2022, 241 patients were enrolled in the CTN program. Five Clinical Trials Navigators (CTNs) receive referrals from various sources: physicians, patients, and patient support groups. CTNs review medical information submitted and search five CT registries. Eligibility criteria is scrutinized. A second review of the CT list is conducted by two physicians to ensure accuracy. The number of potential trials is recorded at each step of review. Data collected includes: patient disease, stage, and number of prior therapies, time from referral to death, number of potential trials, number of trials that were phase I or phase II / III / IV, number of outgoing referrals, locations of the identified trials, and successful enrolment onto CTs. Patient information and results were inputted and analysed using REDCap. REB Category A approval has been granted on August 31, 2022. REB approval number is 22-439. **Results:** 41 Canadian cancer patients used the CTN program. The updated study found that 75.9% of patients were in stage IV of their disease, and 51% had at least two prior lines of therapy. 61.4% of patients deceased at last follow up, with a range of 0.3-37.5 months from CTN program referral to death, and a median of 5.9 months. CTNs identified a range of zero to 26 trials for each patient with a median of three trials: a range of zero to 10 phase I trials were found, and a range of one to eight phase II / III / IV trials were found. 25.5% of patients referred to a CT enrolled onto the recommended trial. The expanded CTN program resulted in CT enrolment of 8.5% of patients that follow-up information is available for. **Conclusions:** One quarter of patients referred to a CT by the CTN program were successfully enrolled, highlighting the CTN program as a successful tool to identify CTs for cancer patients and improve CT accrual. 8.5% of all patients with available follow-up information that participated in the CTN program were enrolled onto clinical trials. Further investigation into reasoning for early high mortality rates should be assessed. New initiatives to improve uptake of the CTN program are ongoing. Research Sponsor: Canadian Cancer Clinical Trials Network; Cancer Research Collaboration Fund.

6522 **Poster Session**

The Man Van: Mobile targeted case finding for prostate cancer.

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Background: Early intervention is potentially lifesaving in prostate cancer. The debate for screening continues with recent developments suggesting the arguments in favour are becoming stronger however, barriers to access remain. The Man Van project is designed to address these with a highly novel community-based targeting of high-risk groups on a mobile unit. **Methods:** A bespoke mobile health vehicle was moved to 8 community-based locations in areas of high deprivation indices in London, UK, inviting men for a health check consisting of: general health questionnaires, blood pressure, height/weight, HbA1c for diabetes and a PSA test. Telemedicine was used to inform patients of outcomes. Direct referrals to secondary care was performed. Community engagement was utilised to increase uptake using: primary healthcare centres, religious organisations and community centres. **Results:** Between December 2021 and December 2022, 618 men were seen at our Man Van clinics at a range of community settings (non-attendance rate 24%). The highest uptake was in locations where there was collaboration with primary care to recruit patients. The median age of attendees was 56 years, range 25-87. 43% of attendees were non-white (20% black). The median BMI was 27.7, range 16.2-50.5. 422 PSA tests were performed with 14 prostate cancers (3.3%) found till date. 9 (64%) of these cancers were grade group 2 (all $>$ 5% pattern 4) or 3. Of patients diagnosed with prostate cancer the median age was 59 years, range 48-73, 10 were black (71%), median PSA 6.85 g/L, range 0.81-45, median IPSS score was 9.5, range 2-31, median IIEF-5 was 16, range 1-25. The IPSS score was significantly higher ($P < 0.05$) in men diagnosed with prostate cancer. 1 bladder (G3pT1) and 1 oesophageal cancer (T3N2M1) were also found. 3 patients had either HGPIN or ASAP, 3 patients had renal stones, 2 urethral strictures were found. 334 HbA1c tests were performed with 18 diabetics diagnosed (5.4%). 46 patients (7.4%) required input for benign urinary symptoms and 20 for erectile dysfunction (3.2%). Primary care referrals were as follows: 171 for hypertension (27.6%), 43 for an elevated BMI (7.0%), 37 for mental health issues (6.0%), 43 for excess alcohol intake (7.0%), 51 for smoking cessation assistance (8.3%). Significantly more patients 45 years were referred for primary care follow-up versus $<$ 45 years ($P < 0.01$). Service evaluation questionnaires showed overwhelmingly positive support for the service. **Conclusions:** The Man Van initiative is a novel method of linking primary and secondary care for a range of health checks, including PSA. By improving community awareness and access in high-risk groups we demonstrate high uptakes for health checks including for prostate cancer and a willingness to engage with health improvement measures. As well as comparatively high levels of prostate cancers diagnosed at early stages, high levels of other health conditions were found; improving the economic value of the service. Research Sponsor: NHS England.

6523 **Poster Session**

Association of social vulnerability with delays in starting guideline-adherent adjuvant therapy among patients with head and neck cancer.

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Background: For patients with head and neck squamous cell carcinoma (HNSCC), initiation of postoperative radiation therapy (PORT) within 6 weeks of surgery is recommended by NCCN Guidelines and is the only Commission on Cancer Quality Metric for HNSCC due to the robust association of PORT delays with mortality and recurrence. Prior studies have identified that racial and ethnic minority and underinsured patients are at increased risk for PORT delay. However, no studies have examined the role of social vulnerability (i.e., social determinants of health such as education, housing, and transportation) in explaining disparities in PORT delay. To address this gap, this study seeks to evaluate the association of social vulnerability with delays in starting guideline-adherent PORT for patients with HNSCC. **Methods:** This is a multicenter retrospective cohort study of adult patients with HNSCC undergoing surgery at 3 urban academic centers followed by adjuvant therapy from 2018-2020. The primary outcome was delay in initiating guideline-adherent PORT (i.e., $>$ 6 weeks [42 days] postoperatively). Time-to-PORT (TTP) was analyzed as a secondary outcome. Census-tract level Social Vulnerability Index (SVI) scores were calculated as a national percentile rank (0 to 1) with higher scores indicating greater social vulnerability. Multivariable logistic regression (MLR) was used to evaluate the association of SVI with PORT delay. Kaplan-Meier curves and a log-rank test were used to evaluate differences in TTP between patients in the highest social vulnerability quartile (SVI $>$ 0.75) vs those in the lowest social vulnerability quartile (SVI $\leq$ 0.25). **Results:** The study included 505 patients undergoing surgery and adjuvant therapy. The mean age was 62.1 $\pm$ 11.9 years; 71% were male, 14% were Black and the most common tumor subsite was oral cavity (61%). The rate of PORT delay was 52% (95% CI 48-57%). Median TTP was 43 days (IQR 35-55 days). The mean overall SVI score was 0.48 $\pm$ 0.27. An increase in SVI of 0.25 was associated with a 33% increase in the odds of PORT delay (OR=1.33, 95% CI=1.08 to 1.63; p=0.0067) on MLR adjusted for facility, age, race, ethnicity, health insurance status, cancer subsite, rurality, and distance to the surgical facility. Patients in the highest SVI quartile had a significant increase in TTP relative to those in the lowest SVI quartile (log-rank p=0.012; median TTP = 47 and 42 days, respectively). **Conclusions:** In this multi-institution study, over half of patients with HNSCC experience delays in starting PORT. Increased census-tract level social vulnerability is associated with a greater risk of delayed initiation of guideline-adherent PORT. These data can be used to: 1) enhance existing risk prediction models and identify patients at-risk for PORT delay who might benefit from a targeted intervention and 2) improve institutional level risk-adjustment for case mix. Research Sponsor: U.S. National Institutes of Health; Triological Society/ American College of Surgeons; Hollings Cancer Center.

6524 **Poster Session**

Analysis and optimization of equitable US cancer clinical trial center access by travel time.

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Background: Racially minoritized and socioeconomically disadvantaged populations are underrepresented in cancer clinical trials. Data-driven, quantitative approaches are required to address this inequity. Here, we systematically analyze the geographical distribution of self-identified racial and socioeconomic demographics within commuting distance to cancer clinical trial centers and all hospitals U.S.-wide. **Methods:** We calculate self-identified racial and socioeconomic demographics of populations living within 30-, 60-, and 120-minute one-way driving commute times from U.S. cancer clinical trial centers and all U.S. hospitals. Data sources include the U.S. 2020 census (for race and socioeconomic data), OpenStreetMaps (for calculation of commuting times), NCT trial registry (for cancer clinical trial quantification), NCI Designated Cancer Centers List, Nature Index of Cancer Research Health Institutions and National Homeland Infrastructure Foundation-Level Data (for U.S.-wide hospital and cancer clinical trial center identification). Data analysis was conducted in R, and *Ggplot2* used for all data visualizations. **Results:** Analysis of clinical trial numbers between 2012–2022 identified 78 high-volume U.S. cancer trial centers. Compared to U.S. national averages, these centers are in areas with socioeconomically more affluent populations (+27.6K USD (95% CI +23.1 to 32.8K) median income unpaired mean difference; -0.073 (95% CI -0.063 to -0.084) deprivation index unpaired mean difference), with higher proportions of affluent self-identified White individuals (+10.1% unpaired mean difference (95% CI +6.8 to +13.7%)). The top 10^{th} percentile of all U.S. hospitals (N=7,623) show a range of absolute sum difference from 2.4% to 35% from equal racial representation of White, Black/African American and Asian/Mixed/Other groups. For each U.S. city above 500,000 inhabitants, we compile map overlays that display all prospective hospitals within commutable distance to racially diverse and socioeconomically disadvantaged populations. These maps may inform the design of future clinical trials or investigations in enrollment and retention strategies for clinical trials. **Conclusions:** Our analysis identifies biases in the sociodemographics of populations living within commuting distance to U.S.-based cancer trial sites and enables the determination of more equitably commutable prospective satellite hospital sites that could be mobilized for enhanced racial and socioeconomic representation in clinical trials. Other recruitment barriers still need to be tackled to ensure racial and socioeconomic demographics within the geographical vicinity of a clinical site can translate to equitable trial participant representation. Research Sponsor: Cold Spring Harbor Laboratory.

6525 **Poster Session**

Are enrollment criteria for phase II and III clinical trials in acute myeloid leukemia arbitrarily restrictive?

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Background: Ethical clinical research requires fair subject selection and a favorable risk-benefit ratio. Enrollment criteria can unfairly exclude patients if they are not based in safety. There are few data regarding variability within criteria, which can also represent unfair exclusion, or for acute myeloid leukemia (AML). **Methods:** We assessed enrollment criteria use and variability for frontline phase II and III therapeutic AML trials from 2010-2019 listed on Clinicaltrials.gov. Drug safety profiles were obtained from protocols, publications, and FDA labels. FDA publications guided a standardized abstraction and coding process. Associations between criteria and safety profiles were identified using X^2 and t-tests. Regression modeling identified differences in infectious disease (ID) exclusion by sponsor adjusted for trial phase, year, size, and safety profiles. **Results:** 190 trials were eligible; 159 (84%) were phase II and 32 (17%) phase III. Trials were sponsored by the National Institutes of Health (NIH; 50; 26%), industry (109; 57%), and academic investigators (AI; 108; 57%). Exclusions and variability are shown in the table. ID exclusions were for HIV (96; 51%) and hepatitis B (60; 32%) and C (64; 34%). Older adults were considered as over 60 (42 trials; 39%), 65 (23; 21%), 70 (13; 12%), or 75 years (18; 17%). There was no association between QTc limits and the use of QTc prolonging drugs (criteria presence p=0.2; mean 450 vs 474 ms, p=0.3) or renal function limits and nephrotoxic drugs (presence p=0.2; mean 1.65 vs 1.67 ULN, p=0.8). Hepatitis B and C exclusions were associated with the use of drugs linked to viral reactivation (OR 2.1 [95% CI 1.1,3.9], 2.0 [95% CI 1.1,3.7]). This was not the case for HIV (OR 1.2 [95% CI 0.7,2.2]). Industry sponsorship was independently associated with hepatitis B and C exclusion (OR 3.0 [95% CI 1.2,7.3], 3.3 [95% CI 1.4,4.7]) and AI sponsorship with HIV exclusion (OR 2.5 [95% CI 1.4,5.5]). **Conclusions:** There is substantial variability in enrollment criteria for AML clinical trials. Many criteria are related to risks, but some exclusions and variability are not clearly based in safety. Avoiding arbitrary exclusions will likely enhance trial representativeness and enrollment rates. Research Sponsor: Conquer Cancer Foundation of the American Society of Clinical Oncology; U.S. National Institutes of Health.

Criterion	Limit	Trials with Criterion (%)	Median	Interquartile Range	Coefficient of Variation*	Range
ECOG Performance Status	Upper**	162 (85%)	2	1-3	26%	1-3
WBC Count	Upper	31 (16%)	25 10^9/L	25-50	57%	10-100
Renal Function	Upper	128 (67%)	1.5 ULN	1.3-2.0	27%	0.8-2.5
AST/ALT	Upper	118 (62%)	2.5 ULN	2.5-3.0	24%	1.5-5
Bilirubin	Upper	130 (68%)	1.6 ULN	1.5-2.0	32%	1.0-5.0
QTc	Upper	48 (25%)	470 ms	450-480	4%	450-500
Left Ventricular Ejection Fraction	Lower**	70 (37%)	45%	45-50	9%	35-50
Prior Anti-cancer Therapy Washout Period	Lower	95 (50%)	14 days	14-28	47%	1-90
Prior Malignancy Washout Period	Lower	68 (36%)	24 months	12-36	63%	6-60

*Standard Deviation/Mean. **Among studies of fit patients.

6526 **Poster Session**

Evaluating social vulnerability impact on care and prognosis of head & neck-nervous system cancers in the US.

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Background: In the current literature, the association between social determinants of health (SDH) and head & neck-nervous system cancer (HNNsC) is limited by the narrow scope of SDH assessed and the broad classifications of HNNsC. Our study utilizes the CDC-Social Vulnerability Index (SVI) to assess both the individual and collective impact of four social determinant themes on various HNNsC in US adults. **Methods:** This study utilized the SEER database to evaluate 116,373 adult patients from 1975-2017 who presented with HNNsC. Patients were assigned SVI scores based on county-of-residence at the time of diagnosis, encompassing total-SVI score and 4 sub-scores of socioeconomic status, minority-language status, household composition, and housing-transportation. Using these scores, univariate linear regressions were used to assess patient care (months of follow-up) and prognosis (months of survival). **Results:** As total-SVI score increased, decreases in months of follow-up (MOF) and months of survival (MOS) were observed for many HNNsC tumors (p less than 0.001) when comparing the lowest to highest vulnerability cohorts. There was a decrease ranging from 3.55-36.6% in the MOF, with the largest decreases occurring in embryonal, anaplastic oligodendroglioma, and anaplastic ependymoma tumor types, with the largest sub-score contribution coming from socioeconomic status for these three disease classes. Similarly, there was a decrease ranging from 6.90-45.81% in the MOS, with the largest decreases occurring in anaplastic ependymoma, anaplastic astrocytoma, and pilocytic astrocytoma tumor types with the largest sub-score contribution coming from socioeconomic status for these three disease classes. Increases in vulnerability within SDH themes contributed significantly to these total-SVI trends in MOF and MOS, with each social determinant impacting different disease classes to varying extents. Socioeconomic status was the most impactful sub-score for MOF in nine of fourteen disease classes, followed by housing-transportation and household composition, each leading the impact of two of fourteen disease classes, and minority-language status leading the impact of one of fourteen disease classes. Similarly, socioeconomic status was the most impactful sub-score for MOS in eight of fourteen disease classes, followed by housing-transportation leading the impact of three of fourteen disease classes, household composition leading the impact of two of fourteen disease classes, and minority-language status leading the impact of one of fourteen disease classes. **Conclusions:** The results of this study show that with increasing social vulnerability, there is a significant decrease in both the care (follow-up) and the prognosis (survival) of US adults with HNNsC and highlight which SDH contributes more to disparities. Research Sponsor: None.

6527 **Poster Session**

Association of measures of socioeconomic deprivation with healthcare utilization in elderly patients enrolled in SWOG cancer clinical trials.

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Background: Reducing unplanned Emergency Room (ER) visits and hospitalizations is an important strategy for improving value. Patients enrolled in clinical trials are treated per protocol. While demographic factors have been associated with increased healthcare utilization, less is known about measures of socioeconomic deprivation (SD), which may be a proxy for structural barriers to access. We tested whether ER and hospital stays are more common among trials participants who live in areas of SD or have Medicaid insurance (MI). **Methods:** We examined ER visits and hospitalizations among cancer patients ≥65 years treated on SWOG clinical trials from 1999-2018 using trial data linked to Medicare claims. Neighborhood socioeconomic deprivation (NSD) was measured using patients' zip code linked to the Area Deprivation Index (ADI), measured on a 0-100 scale and categorized into tertiles (T1-T3). Higher ADI (T3) denotes areas of higher deprivation. Type of insurance was classified as Medicare alone or with Commercial, versus Medicare + MI. Outcomes were ER visits, hospital stays, and costs, all in the first year. Demographic, clinical, and prognostic factors were captured from trial records. Generalized estimating equations (GEE) were used, accounting for clustering by cancer type. Regression models were adjusted for age, race, and a study-specific prognostic risk score, and stratified by study and treatment. ADI and Insurance were considered separately to reflect neighborhood-level and individual-level measures of SD. **Results:** In total, N = 3,027 participants from 27 trials in bladder, breast, colorectal, lung, myeloma, and prostate cancers were analyzed. Median age was 71 years, 3% had Medicare + Medicaid and 22.3% were in the Highest ADI tertile. In all, 983 (32%) patients experienced hospitalization, and 1094 (36%) visited the ER. In multivariate GEE, patients living in more deprived areas were more likely to experience hospitalization (OR for ADI T3 compared to T1: 1.36, 95% CI, 0.95-1.94, p=.09) and to visit an ER (OR for ADI T3 compared to T1: 1.33, 95% CI, 1.08-1.63, p=.008). Overall, patients from the most deprived areas had a 61% increase in risk of either ER visit or hospitalization (OR for ADI T3 compared to T1: 1.61, 95% CI, 1.23-2.10, p<.001). Patients with MI were 86% more likely to visit an ER in the first year (OR 1.86, 95% CI, 1.49-2.33, p<.001. No increased risk of hospitalization was observed. **Conclusions:** Despite participation in cancer clinical trials, patients living in areas with higher deprivation or those with Medicare + MI had an increased risk of unplanned ER visits. These findings suggest that neighborhood deprivation and economic disadvantage may increase ER visits for socioeconomically vulnerable older patients with cancer. Efforts are needed to ensure adequate resources to prevent unplanned use of acute care in vulnerable populations. Research Sponsor: U.S. National Institutes of Health.

6528 **Poster Session**

Racial disparities in utilization of first line targeted therapies for metastatic breast cancer.

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Background: This study evaluated whether there were racial disparities in utilization (decomposed as change in proportion of eligible patients initiating therapy over time and time to treatment initiation (TTI)) to CDK4/6 inhibitors and pertuzumab since FDA approval as first line (1L) treatment for ER+/HER2- and HER2+ metastatic breast cancer (MBC), respectively. **Methods:** This cohort study used the nationwide Flatiron Health electronic health record-derived de-identified database. Included women were ≥18 years old, diagnosed with de novo or recurrent MBC, who received 1L therapy, and documented as non-Hispanic White (NHW) or non-Hispanic Black/African American (NHB). Two cohorts were generated for patients with ER+/HER2- MBC diagnosed 3/2015-10/2021 and HER2+ MBC diagnosed 7/2012-9/2021. We estimated temporal trends in the proportion of NHW and NHB patients receiving respective therapy using logistic regression with natural cubic splines for time trends and tested for changes in uptake over time within each group as well as differences in trends between groups. A similar model was used for TTI among treatment initiators, using linear regression models. In addition to time and race, regression models included age, ECOG performance status, insurance, Medicaid expansion status, practice type, and proportion of black patients per practice among patients who met both cohort criteria. **Results:** 8318 patients (NHW=7006; NHB=1312) met ER+/HER2- cohort criteria and 2321 (NHW=1915; NHB=406) met HER2+ cohort criteria. There was a significant change over time in the proportion of NHW ($p<0.0001$) and NHB ($p<0.0001$) initiating 1L CDK4/6 inhibitors (Table). Temporal trends were also significantly different between NHW and NHB ($p<0.0001$). Higher ECOG performance status (OR=0.85 per unit increase, 95%CI 0.80-0.90; $p<0.001$) and an increasing proportion of black patients seen at practice (OR=0.45, 95%CI 0.29-0.71; $p<0.001$) were independent predictors of lower odds of initiating CDK4/6 inhibitors. Overall, 43% NHW vs 41% NHB received pertuzumab respectively. There was no significant difference in uptake trends for pertuzumab between NHW and NHB (p=0.41). There was no significant difference in the temporal trends of TTI for either CDK4/6 inhibitors (p=0.74) or pertuzumab (p=0.84). **Conclusions:** Utilization of CDK4/6 inhibitors steadily increased over time, however > 25% of eligible patients did not receive the drug, and less than half of individuals who met indication for pertuzumab were prescribed it. Racial disparities were significant for oral CDK4/6 inhibitors but not for intravenous pertuzumab. Research Sponsor: Flatiron Health, Inc.

Percentage initiating 1L CDK4/6 inhibitors.

Year	2015	2016	2017	2018	2019	2020
NHW	46	60	69	73	72	48
NHB	41	50	57	62	66	43

6529 **Poster Session**

Healthcare coverage, access, and affordability among adult immigrant cancer survivors in the United States.

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Background: Cancer is a leading cause of morbidity and mortality among US immigrants; however, barriers to care remain understudied. This study assessed disparities in health insurance, health care access, and affordability among immigrant cancer survivors in the United States. **Methods:** Adult cancer survivors aged ≥18 years who participated in the 2019-2022 National Health Interview Survey were classified as 1) natives 2) foreign-born (FB) citizens or 3) noncitizens. Logistic regression tested for associations between nativity/citizenship and insurance, access (i.e., urgent care, emergency room [ER], hospital admissions), and affordability (assessed by social determinants of health [SDoH]: financial hardship, food insecurity, housing assistance). Separate models adjusted for demographics, socioeconomic status, and comorbidities. **Results:** A total of 8,923 adults (90% natives, 7% FB citizens, 3% noncitizens) were included in the study. There were baseline differences in age <65 (42% natives vs 61% FB citizens vs 76% noncitizens), female sex (57% vs 59% vs 73%), non-White race (15% vs 64% vs 77%), and Hispanic ethnicity (31% vs 62% vs 5%) between groups (all $p<0.05$). More noncitizens had household incomes <125% of the federal poverty line (12% vs 18% vs 35%). On adjusted analysis, noncitizens were 3x as likely as natives to be uninsured (2.99 [1.36-6.53]; $p=0.006$) and FB citizens were 2x as likely to have Medicaid (2.10 [1.35-2.35]; $p=0.001$). Financial hardship was 1.5x more common among FB citizens (1.50 [1.18-1.91]; $p<0.001$) while receipt of housing assistance was >2x more common among FB citizens (2.98 [1.82-4.88]; $p<0.001$) and noncitizens (2.37 [1.08-5.22]; $p=0.03$). While more FB citizens (18%) and noncitizens (33%) were food insecure (vs. 11%), there were no associations with nativity/citizenship (Table). There were no significant differences in health care access across groups. **Conclusions:** In this nationwide analysis of adult cancer survivors, although there were no differences in health care access/utilization, immigrants and foreign-born citizens had higher rates of uninsurance and affordability concerns—suggestive of barriers to care. This may portend worse health outcomes in cancer survivorship. Research Sponsor: None.

		Natives *N*=8,235	Foreign-Born Citizens *N*=559		Noncitizens *N*=129	
		Referent (%)	%	aOR (95% CI)	%	aOR (95% CI)
Insurance	Private	55	44	0.86 (0.67-1.09)	35	0.49 (0.30-0.81)
	Medicaid	9	**16**	**2.10 (1.35-2.35)***	31	1.87 (0.82-4.29)
	Uninsured	3	3	1.36 (0.67-2.77)	**21**	**2.99 (1.36-6.53)***
Access (utilization)†	Urgent care	28	25	0.90 (0.68-1.20)	22	0.69 (0.39-1.20)
	ER	28	28	0.97 (0.73-1.27)	30	0.92 (0.56-1.51)
	Hospital	18	20	1.12 (0.83-1.51)	17	0.98 (0.52-1.84)
Affordability (SDoH)	Financial hardship	41	**53**	**1.50 (1.18-1.91)***	64	1.31 (0.81-2.11)
	Food insecurity	11	18	1.30 (0.90-1.88)	33	1.41 (0.73-2.73)
	Housing assistance	3	**9**	**2.98 (1.82-4.88)***	**11**	**2.37 (1.08-5.22)***

*$p<0.05$; †within the last 12 months.

6530 **Poster Session**

Impact of free hospital-provided rideshare service on radiation therapy completion rates: A matched cohort analysis.

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Background: Radiation therapy (RT) is generally given in consecutive daily sessions over multiple weeks. This poses challenges for patients who face barriers such as limited access to public or private transportation, limited financial resources, lack of social support, and long distances to healthcare facilities. Delayed or incomplete RT increases risk for worse clinical outcomes. The potential of rideshare service, which uses a private vehicle for hire arranged through a phone-based application or website, to facilitate timely RT is understudied. **Methods:** Retrospective data was collected on patients who received RT at a single institution from 2017-2022. Patient demographic and treatment characteristics were compared between those who did and did not utilize free hospital-provided rideshare service. RT completion rates were analyzed for a 1:1 matched non-rideshare cohort using optimal matching with the scaled Euclidean distance metric, to balance age, sex, race, performance status, number of fractions prescribed, Area Deprivation Index (ADI), distance to treatment center, year of diagnosis, treatment site, intent, and modality. ADI is a validated composite measure of community-level socioeconomic deprivation. **Results:** Of 2,906 patients who underwent RT, 58 utilized free hospital-provided rideshare service. Rideshare utilizers had a lower median age (60 vs 66, $p = .02$), and were more likely to identify as Black or African American (60 vs 22%, $p < .0001$) compared to non-rideshare utilizers. Rideshare utilizers also had higher ADI scores (median 9 vs 5, $p < .0001$), indicating higher socioeconomic disadvantage, and travelled shorter distances for treatment (median 5.0 vs 14.7 miles, $p < .0001$). More rideshare utilizers underwent RT for curative intent (79 vs 50%, $p < .0001$), concordant with a higher number of fractions prescribed (median 28 vs 5, $p < .0001$) as well as longer treatment course duration (median 39 vs 13 days, $p < .0001$). The most common treatment sites were head and neck (31%) and breast / chest wall (22%) for rideshare utilizers, and pelvis (27%) and brain (21%) for non-rideshare utilizers ($p < .0001$). Volumetric modulated arc therapy followed by 3D conformal were the most common treatment modalities in both groups. The matched cohort analysis revealed that RT completion rates were significantly higher for rideshare vs non-rideshare utilizers at 96 vs 81% ($p = .01$) overall, and 98 vs 78% ($p = .01$) for patients undergoing treatment with curative intent. **Conclusions:** Even after adjustment for socioeconomic, clinical, and treatment characteristics, utilization of free hospital-provided rideshare service was associated with improved RT completion rates. These findings are notable as the majority of rideshare utilizers come from socioeconomically marginalized communities, and would otherwise be expected to face significant barriers to RT completion. Research Sponsor: None.

6531 **Poster Session**

Associations of loneliness and mortality risk among cancer survivors in the United States.

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Background: Loneliness (i.e., the subjective feeling of being isolated from others), has been linked to multiple adverse health outcomes, including chronic conditions such as heart disease, mental health disorders, and higher risk for early mortality. However, associations between loneliness and worse health outcomes have not been thoroughly examined in cancer survivors. This study examined associations between loneliness and mortality risk among cancer survivors in the U.S. **Methods:** Cancer survivors were identified from the 2008-2018 Health and Retirement Study, a nationally representative longitudinal survey conducted biannually among individuals aged ≥50 years, with follow-up was through December 31, 2020. Loneliness was measured at every 4 years using an abbreviated 11-item version of the UCLA Loneliness Scale Version 3. Example items include feelings of lacking companionship and isolation from others. Items were summed to create total loneliness scores, which were categorized into four levels: 11-12 (low/no loneliness), 13-15 (mild loneliness), 16-19 (moderate loneliness), and 20-33 (high loneliness). Time-varying Cox proportional hazard models were used to examine the association of loneliness and mortality risk among cancer survivors, while accounting for measurements at multiple time points. Sex, marital status, educational attainment, number of health conditions other than cancer, and year since cancer diagnosis were included in multivariable models. **Results:** Among 5808 person-years, there were 724 deaths during the study period. Compared to the low/no loneliness group, survivors reporting greater loneliness had higher hazard ratios (HR), indicating higher mortality risks; the highest HR observed was among the high loneliness group (HR:1.90, 95%CI:1.58-2.29), following a dose-response association (Table). HRs were attenuated after adjusting for sociodemographic characteristics, but findings were largely unchanged, and HRs remained highest for the high loneliness group (HR:1.71, 95%CI:1.39-2.12). **Conclusions:** Any elevated loneliness was associated with higher mortality risks among cancer survivors. Programs to screen for loneliness among cancer survivors and to provide social support to those in need are warranted. Research Sponsor: None.

Association of loneliness and mortality risk among cancer survivors.

Loneliness Score	Unadjusted HR (95%CI)	Adjusted HR (95%CI)
11-12	1	1
13-15	1.28 (1.00-1.63)	1.21 (0.92-1.58)
16-19	1.62 (1.33-1.98)	1.47 (1.19-1.82)
20-33	1.90 (1.58-2.29)	1.71 (1.39-2.12)

Outcomes of Black (B) versus White (W) patients (pts) with metastatic hormone-sensitive prostate cancer (mHSPC) treated with androgen deprivation therapy (ADT) with or without orteronel (Ort): Analysis of pt-level data from SWOG-1216 phase 3 trial.

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Background: Despite more aggressive prostate cancer (PCa) at presentation and higher mortality in real world, B pts with metastatic hormone resistant PCa did not have inferior outcomes than W pts when both were enrolled in clinical trials (PMID: 33951180). In the phase 3 S1216 trial, treatment with Ort, a novel CYP17 axis inhibitor, significantly improved progression-free survival (PFS) but not overall survival (OS) compared to bicalutamide (Bic) in pts with mHSPC receiving ADT. This trial enrolled the greatest number of B pts in a phase 3 trial in this setting to-date. We hypothesized that given comparable access to care as experienced in a clinical trial, outcomes in B pts would be similar to those of W pts in the mHSPC setting. **Methods:** Eligibility: Pts with mHSPC were enrolled. Only pts self-identifying as B or W were included in this analysis. PFS and OS for each group were estimated using Kaplan-Meier method. A multivariate analysis (MVA) adjusting for disease characteristics was conducted using a Cox proportional hazards model. **Results:** Among 1279 participants, 135 (10.6%) were B; 1077 (84.2%) were W. B and W were equally distributed between treatment arms, and had respectively similar proportion of pts with Gleason score ≥8 (61.3 vs 62.1%), Zubrod score ≥2 (5.1 vs 3.4%) and extensive disease (48.1 vs 48.7%). However, B pts, as compared to W, were younger (65.8 vs 68.4 yrs, p=0.001) and had a higher median baseline PSA (54.7 vs 26.7 ng/mL; p<0.001). PSA responses (≤ 0.2 ng/mL) at month 7 were similar in both groups (p=0.296). Overall, B vs W had similar median PFS (2.3 vs 2.9 yrs, p=0.71) and OS (5.5 vs 6.3 yrs, p=0.65). MVA confirmed similar PFS and OS after adjusting for known prognostic factors (Table). No interaction between race and treatment was observed (P-value interaction PFS= 0.77 and OS= 0.91). **Conclusions:** We demonstrate that even though B pts present with more aggressive disease in mHSPC setting, they did not have statistically significant worse OS and PFS than W pts and treatment effect was also similar for both racial groups. Equitable access to care may negate historical differences in outcomes among B vs W pts with advanced PCa. Funding: NIH/NCI/NCTN grant U10CA180888, U10CA180819; and Millennium Pharmaceuticals (Takeda Oncology). Univariate and MVA of PFS and OS. Research Sponsor: U.S. National Institutes of Health; Millennium Pharmaceuticals (Takeda Oncology).

	PFS			OS		
Characteristic	**HR[1]**	**95% CI[1]**	**p-value**	**HR[1]**	**95% CI[1]**	**p-value**
Race (Univariate; W vs B)	0.96	0.76-1.20	0.71	0.94	0.71-1.24	0.65
Race (W vs B)	1.12	0.88-1.42	0.4	1.01	0.75, 1.35	0.90
Treatment (Ort vs Bic)	0.58	0.50-0.68	<0.001	0.87	0.72, 1.04	0.14
Extensive disease (Yes vs No)	1.91	1.64- 2.23	<0.001	2.06	1.69, 2.50	<0.001
Gleason (≥8 vs <8)	1.24	1.06- 1.45	0.008	1.18	0.97, 1.43	0.10
Log PSA	1.21	1.16- 1.26	<0.001	1.14	1.08, 1.20	<0.001

[1]HR = Hazard Ratio, CI = Confidence Interval

6533 **Poster Session**

Selection biases in the systematic collection of breast biobank specimens.

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Background: A breast biopsy tissue biobank is a valuable resource for studying breast cancer biology and treatment response. However, underrepresentation of patient populations in biobanks limits the generalizability of findings. The aim of this study was to assess potential age and racial/ethnic disparities in the recruitment process for an institutional breast biopsy tissue bank. **Methods:** Ultrasound-guided (USG) research biopsy cores were collected immediately after routine clinical biopsy from January 2019 to October 2022 at a large academic center. Study eligibility included patients (pts) aged $>$ 18 years undergoing USG clinical breast biopsy with a radiographically evident mass $\geq$ 0.6 cm in the longest dimension. Eligible pts, identified by a research associate on the day of the biopsy, were invited to participate at the discretion of the radiologist performing the biopsy. Those approached either consented or declined a research biopsy. Demographic and clinical data of eligible pts were extracted from the EMR. **Results:** 2449 pts underwent USG breast biopsy and 1309 were deemed eligible for a research biopsy. Of the eligible population, 564 (43%) consented to the study, 322 (25%) declined, and 423 (32%) were not approached. Consented pts were younger compared to those who declined or to those not approached (median age 49, 51, and 51 years, respectively; p = .01). Comparison of study groups by age and race categories are shown in the table. Pts $>$ 70 were less likely to be approached compared to pts $<$ 70 (p = .01). However, The likelihood of pts being approached to consent did not differ significantly with age (p=.09). Of the eligible pts, 951 (73%) were White, 327 (25%) were non-White (10% Asian, 8% Black, 1% Hispanic, and 7% other race), and race was unknown for 31 (2%) pts. White and non-White pts were equally likely to be approached (p = .3). However, approached non-White pts were significantly less likely to consent compared to White pts (p =.01). Within the non-White population, Black pts were more likely to decline a research biopsy, with only 50% of approached Black pts consenting compared to 66% of White pts, 61% of Asian pts and 55% of pts of other race. **Conclusions:** We found disparities based on age and race/ethnicity in participation in a breast biopsy tissue biobank. Older pts were less likely to be offered participation but equally likely to consent when invited, while Black pts were equally likely to be offered participation, but less likely to consent when invited, compared to other racial subgroups. Our findings support targeted interventions to increase participation across diverse subgroups of pts. Research Sponsor: None.

	Age, n (%)			Race, n (%)			
	< 70	**> 70**	***p***	**White**	**Non-White***	**Unknown**	***p***
n	1090	219		951	327	31	
Approached	753 (69)	133 (61)	**.01**	653 (69)	215 (66)	18 (58)	.3
Not approached	337 (31)	86 (39)		298 (31)	112 (34)	13(42)	
n	**753**	**133**		**653**	**215**	**18**	
Consented	488 (65)	76 (57)	.09	433 (66)	119 (55)	12 (67)	**.01**
Declined	265 (35)	57 (43)		220 (34)	96 (45)	6 (33)	

* Asian, Black, Hispanic, Other.

6534 **Poster Session**

Beyond transportation: Financial hardship, food insecurity, and care access barriers among US cancer survivors with transportation barriers to care.

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Background: Health care payers and providers increasingly focus on addressing social determinants of health (SDoH) in order to reduce disparities in care and patient outcomes in the US. Transportation barriers to health care, a key SDoH, are associated with increased emergency department use and mortality risk among cancer survivors. Transportation barriers may also be associated with other potentially addressable aspects of SDoH and access barriers. To inform future interventions, we examined financial hardship and barriers to timely care among cancer survivors with transportation challenges in a nationally representative sample. **Methods:** We identified 18,140 adults with a history of cancer from the 2011-2018 National Health Interview Survey. Transportation barriers were defined as delay in care due to lack of transportation over the past 12 months. Primary outcomes included 1) medical financial hardship (FH) in any of the three following domains: material (problems paying medical bills), psychological (worrying about medical bills), and behavioral hardship (delaying/forgoing care due to cost); 2) food insecurity (worrying food would run out); and 3) delayed care due to other factors (long wait times, inability to get an appointment quickly). We estimated the proportion of survivors who report any financial hardship, food insecurity, or other factors that lead to care delays and compared the age-sex adjusted prevalence of these barriers among cancer survivors by whether or not they reported transportation barriers using logistics regression. **Results:** Of the 18,123 cancer survivors, 2.9% reported having transportation barriers to care. Survivors with transportation barriers experienced significantly higher financial hardship, food insecurity, or other factors that lead to care delays than survivors without transportation barriers (86.0% vs 45.3%, $p<0.001$). Additionally, survivors with transportation barriers were more likely to experience medical financial hardship (73.2% vs 38.3%, $p<0.001$), including material (50.3% vs 27.1%, $p<0.001$), behavior (57.5% vs 20.4%, $p<0.001$), and psychological (33.5% vs 15.4%, $p<0.001$) hardship than survivors without transportation barriers. Additionally, survivors with transportation barriers were more likely to experience food insecurity (43.9% vs 12.0%, $p<0.001$) and care delays due to other factors (45.6% vs. 11.6%, $p<0.001$). **Conclusions:** Most cancer survivors with transportation barriers to care also report struggling financially and experiencing additional barriers to timely care. Findings highlight the importance of screening and addressing social needs and comprehensive interventions to address barriers to care access in this vulnerable population. Research Sponsor: None.

6535 **Poster Session**

County-level jail incarceration and cancer mortality in the US.

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Background: Incarceration has been linked to poor community health outcomes, such as worse preterm births and mortality in the US, although little research has examined cancer outcomes. This study examined associations of county-level jail incarceration and cancer mortality. **Methods:** Annual county-level local jail incarceration rates (1990-2018) were obtained from the Vera Institute of Justice. We calculated annual county-level mortality rates (2000 -2019) with invasive cancer as the underlying cause of death (ICD-10 codes: C00-C97) using National Vital Statistics System. Associations of county-level jail incarceration and cancer mortality overall, and by sex, race, and common cancer sites were examined with generalized estimating equations with Poisson distribution and standard errors clustered at county level. To assess the short-, medium-, and long-term associations, we used lagged county-level incarceration rates by 1, 5, and 10 years prior to mortality rates in separate analyses. **Results:** Over the 20-year study period, each 1 per 1000 increase in county jail incarceration rate was associated with a 1.2% increase in cancer mortality rate in the short-term (model with 1-year lags, rate ratio (RR): 1.012, 95% CI: 1.009–1.015) and 1.1% increase in medium-term (5-year lags (RR: 1.011, 95% CI: 1.008–1.014) and 0.8% increase long-term (10-year lags (RR: 1.008, 95% CI: 1.004–1.012). After adjusting for county-level sociodemographic characteristics, the RRs were attenuated but remained statistically significant. Jail incarceration was associated with higher cancer mortality for all common cancers included in the study (Table) and for White people, but not for Black people. The magnitude of associations was similar for medium- and long-term effects (5- and 10-year lags, respectively). **Conclusions:** Higher county-level jail incarceration rates were associated with higher county-level cancer mortality rates, underscoring the collateral health consequences of mass incarceration. Efforts to identify interventions to decrease the cancer mortality burden in these communities are warranted. Research Sponsor: None.

Association of county-level incarceration and cancer mortality.

	Adjusted RR	95%CI
All cancers	1.007	1.004-1.009
Sex		
Male	1.007	1.004-1.009
Female	1.006	1.004-1.008
Race		
White	1.007	1.007-1.007
Black	1.000	0.997-1.003
Cancer Site		
Female breast	1.004	1.003-1.006
Colorectal	1.007	1.005-1.009
Prostate	1.004	1.002-1.007
Lung	1.009	1.006-1.012

*Model with 1-year lag of prior county-level incarceration rates.

6536 **Poster Session**

An intersectional approach to cervical cancer screening disparities by race/ethnicity and immigrant status.

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Background: Racial/ethnic minority and immigrant groups individually experience lower rates of cervical cancer (CC) screening. Although immigrants represent large proportions of racial/ethnic minorities, few studies have explored the interacting health consequences of these social categories. Intersectionality is a theoretical framework which recognizes that studying social categories independently cannot capture their cumulative effects on health. In the context of CC screening, only one study took this approach but did not analyze several important barriers to care. This study aims to analyze the joint influence of race/ethnicity and immigrant status on screening and identify barriers unique to each intersectional group. **Methods:** Data from the National Health Interview Survey years 2005, 2010 and 2015 were drawn from IPUMS. Analyses were restricted to those eligible for CC screening (n=17,941). Multivariable logistic regression was used to model the interactional effect of race/ethnicity and immigrant status on screening up to date (UTD) status adjusting for confounders. Variables reflecting socioeconomic status (SES), access to care, acculturation and language were separately included to see whether they explained identified disparities. Finally, amongst women not UTD on screening, reasons for this were analyzed. All analyses were adjusted for complex survey design. **Results:** US born Non-Hispanic Black women had higher odds of being UTD on screening (OR 1.63, 95% CI [1.23, 2.18]) while immigrant Non-Hispanic White (OR 0.45 [0.29, 0.7]), immigrant Asian (OR 0.29 [0.2, 0.42]) and immigrant Hispanic/Latinx women (OR 0.51 [0.39, 0.67]) had lower odds compared to US born Non-Hispanic White women. Adjusting for SES (OR 0.87 [0.65, 1.16]) and access (OR 1 [0.74, 1.36]) attenuated the ORs for immigrant Hispanic/Latinx women but not immigrant Asian and White women. Adjusting for acculturation attenuated the ORs for immigrant Hispanic/Latinx (OR 0.84 [0.58, 1.22]) and White women (OR 0.68 [0.42, 1.12]) only. Adjusting for language increased but did not attenuate the ORs for all immigrant groups. Analyses of reasons for not screening showed immigrant Non-Hispanic White, Black and Asian women had greater proportions selecting "Didn't need or know needed this test" versus other groups (10-12% vs. 5.4-8.4%). **Conclusions:** Immigrant status continues to explain much of the CC screening disparities previously attributed to race/ethnicity. SES and access to care remain important barriers for immigrant Hispanic/Latinx women but less so for other immigrant groups. This study reveals that acculturation is an important barrier for immigrant Non-Hispanic White and Hispanic/Latinx women, possibly representing disparities in knowledge. Language barriers may also contribute in all immigrant women. Further intersectional studies are needed to identify remaining barriers. Research Sponsor: None.

6537 **Poster Session**

Associations of cancer history, food insecurity, and nonmedical financial worry and mortality risk in the US.

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Background: Cancer survivors often face substantial out-of-pocket medical costs, which can adversely affect their financial well-being. Cutting expenses on food and housing to save money are common coping strategies. However, little is known about the extent to which food insecurities and non-medical financial worries affect mortality risk after consideration of medical financial hardship. **Methods:** The 2013-2018 National Health Interview Survey (NHIS) and the NHIS linked mortality files with vital status through December 31, 2019 were used to identify cancer survivors (ages 18-64: n=5,110; ages 65-79: n=4,949) and individuals without a cancer history (ages 18-64: n=115,643; ages 65-79: n=24,785). Medical financial hardship included 3 domains: material, psychological, and behavioral. Food insecurity (e.g., worry about food running out) and non-medical financial worries (e.g., paying for monthly bills and housing) were separately summarized and categorized as severe, moderate, and minor/none levels. Using age as the time scale, associations of cancer history, food insecurity and non-medical financial worry and mortality risk were examined with weighted Cox proportional hazards models. Adjusted models included medical financial hardship, sex, educational attainment, marital status, health insurance, comorbid conditions, and survey year. All estimates accounted for complex survey design. **Results:** In our sample, about 13.8% (ages 18-64) and 7.9% (ages 65-79) reported moderate to severe levels of food insecurity, respectively; 32.1% (ages 18-64) and 19.2% (ages 65-79) reported moderate to severe levels of non-medical financial worries, respectively. In adjusted analyses, cancer survivors had increased mortality risk. After controlling for medical financial hardship, food insecurity was associated with higher mortality risk in both age groups, following a dose-response relationship (Table); Non-medical financial worry was associated with higher mortality risk in the 65-79 age group (Table). **Conclusions:** Standardized and comprehensive assessment of financial hardship and other social needs, such food insecurity, is essential to identify and mitigate adverse economic impacts of cancer. Research Sponsor: None.

Adjusted associations of cancer history, food insecurity and non-medical financial worries and mortality risk.

		Ages 18-64			Ages 65-79		
		HR	95CI	P	HR	95CI	P
Cancer history	Yes	1.95	1.74 -2.19	<.001	1.18	1.09- 1.27	<.001
	No		ref			ref	
Medical financial hardship	3 domains	1.32	1.12- 1.57	0.001	2.15	1.75- 2.64	<.001
	1-2 domains	1.30	1.18- 1.43	<.001	1.59	1.48- 1.71	<.001
	0 domains		ref			ref	
Food insecurity	Severe	1.69	1.48- 1.92	<.001	1.57	1.33- 1.87	<.001
	Moderate	1.53	1.35- 1.72	<.001	1.42	1.25- 1.62	<.001
	Minor/ none		ref			ref	
Non-medical financial worries	Severe	1.08	0.91- 1.29	0.381	1.37	1.11- 1.69	0.003
	Moderate	1.02	0.90- 1.17	0.748	1.16	1.02- 1.32	0.027
	Minor/ none		ref			ref	

6538 **Poster Session**

The association between continuity of Medicaid enrollment and cancer survival in young adults diagnosed with cancer.

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Background: Disparities in young adult cancer survival between individuals with Medicaid and private insurance have been reported. To further understand the association between insurance-related access to healthcare and young adult cancer survival, we used Surveillance, Epidemiology, and End Results (SEER)-Medicaid linked data to test two hypotheses: 1) Those linked to Medicaid have lower cancer survival than those not linked, and 2) those with discontinuous enrollment in Medicaid around the time of diagnosis have lower survival than those with continuous enrollment. **Methods:** SEER-Medicaid linked data from 2006 to 2013 were obtained. Follow-up for vital status was through 2018. We included individuals diagnosed with a first malignant primary cancer diagnosed between 20 to 39 years. We excluded individuals who were linked to Medicaid enrollment records in multiple states during the same year. Individuals were defined as Medicaid-linked if they were linked to Medicaid in any U.S. state or the District of Columbia from 2006 to 2013. Medicaid enrollment was classified as continuous (enrolled within both the three months before and after diagnosis) and discontinuous (enrolled only within the 3 months before or after diagnosis or only at diagnosis). We used survival analysis methods including Kaplan-Meier (KM) curves and Cox Proportional Hazards (PH) regression models to evaluate survival differences in association with Medicaid linkage and enrollment timing after adjusting for race and a measure of census tract poverty. **Results:** Our analytic dataset included 137,259 young adults, among which there were 22,955 cancer deaths. KM curves showed consistently lower survival probabilities over time in young adults who linked vs. those not linked to Medicaid and in those with discontinuous vs. continuous enrollment ($p < .0001$). Adjusted Cox PH regression models indicated that those who linked to Medicaid had a 2.19 (95% CI 2.14-2.25) times higher hazard of death vs. those who did not link. Those with continuous and discontinuous Medicaid enrollment had a 1.91 (95% CI 1.84 to 1.99) and 3.32 (95% CI 3.19 to 3.45) times higher hazard of death, respectively, vs. those not linked to Medicaid. Similar patterns were consistently observed for specific cancer types. **Conclusions:** These results confirm an insurance-associated disparity in a national sample of young adult cancer patients and provide additional information on risks in association with Medicaid enrollment continuity. These results further support the critical need for consistent health insurance coverage in young adults and for additional research to understand social, economic, and access-related factors leading to lower survival in the Medicaid population. Lowering administrative burdens for Medicaid enrollment, eligibility, and renewal are potentially important strategies for improving cancer outcomes. Research Sponsor: None.

6539 **Poster Session**

Association of Medicaid expansion with timely receipt of treatment and survival among patients with HER2-enriched breast cancer.

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Background: HER2-enriched breast cancer (estrogen and progesterone receptors negative and HER2-positive) has no worse prognosis than other breast cancers if it is treated with HER2-targeted therapy. Medicaid expansion under the Affordable Care Act (ACA) has been shown to be associated with improved access to care and outcomes for many cancers, but its impact on care for HER2-enriched breast cancer is unknown. To fill this gap, we examined the association of Medicaid expansion with receipt of guideline-concordant treatment, time to treatment, and survival among newly diagnosed nonelderly women with HER2-enriched breast cancer. **Methods:** Women aged 18-62 years newly diagnosed with HER2-enriched breast cancer between 2010 and 2018 were identified from the National Cancer Database. Our primary outcomes included receipt of stage-based guideline-concordant treatment, initiation of treatment $<$60 days, and stage-specific 2-year overall survival. A difference-in-differences (DD) approach compared outcome changes following the expansion in Medicaid expansion vs. non-expansion states. A linear probability model estimated treatment outcome, and a flexible parametric survival model evaluated survival. All models were clustered at the state level and adjusted for age group, race/ethnicity, rurality of residence, zip code-level income, comorbidity, and diagnosis year. **Results:** A total of 31,354 patients with HER2-enriched breast cancer were included, including 19,255 in expansion states and 12,099 in non-expansion states. Compared to patients in expansion states, patients in non-expansion states were more likely to be racial/ethnic minorities, uninsured, and diagnosed at late-stage. Medicaid expansion was not significantly associated with changes in receipt of surgery for stage I-III disease but was associated with an increase of 4.42 percentage points (ppt, 95% CI: 0.09, 8.74) in receipt of chemotherapy/targeted therapy for stage IV disease, with an increase from 90.4% pre-expansion to 92.8% post-expansion in expansion states and a decrease from 93.7% to 91.9% in non-expansion states. Medicaid expansion was also significantly associated with a 2.41 ppt increase in initiating guideline-concordant treatment within 60 days (95% CI: 0.66, 4.17; 83.5% to 82.5% in expansion states vs. 86.6% to 83.7% in non-expansion states), and a 1.18 ppt increase in two-year survival rate (95% CI: 0.03, 2.33; 94.0% to 94.9% in expansion states vs. 94.3% to 94.1% in non-expansion states). The increase in two-year survival associated with Medicaid expansion was most prominent for stage III patients (DD=3.63 ppt; 95% CI: 0.64, 6.62). **Conclusions:** Medicaid expansion was associated with increased receipt of timely treatment and improved 2-year survival among nonelderly women newly diagnosed with HER2-enriched breast cancer. Research Sponsor: None.

Disparities in uptake of novel therapies for acute myeloid leukemia.

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Background: Multiple novel therapies have recently been approved to treat acute myeloid leukemia (AML). Inequities in the uptake of novel treatments have been seen in other cancers but are not known for this population. **Methods:** We performed a retrospective analysis of the nationwide Flatiron Health electronic health record (EHR)-derived deidentified database. We assessed sociodemographic associations with novel AML therapies use within two-years of Food and Drug Administration (FDA) approval from 1/2014-8/2022. Therapies were: glasdegib, venetoclax, ivosidenib, midostaurin, CPX-351, gilteritinib, enasidenib, and gemtuzumab ozogamicin (GO). Univariable associations were assessed using X^2 testing. Logistic regression modeling of community practices assessed associations between novel therapy receipt and sociodemographics adjusted by treatment year. Variable categories are shown. **Results:** Of 8081 patients in 280 clinics, 3102 (38%) received at least one novel therapy. The cohort was predominately older (69; interquartile range [57, 77]), male (56%), non-Hispanic (NH)-White (88%), and treated at a community practice (75%). There were 4808 patients treated within 24-months of a novel therapy approval, of which 1937 (40%) received a novel therapy. Venetoclax represented 59% of novel treatments prescribed. Bivariate associations were seen between novel therapy receipt within 24-months of approval and high SES and non-Hispanic (NH)-White race-ethnicity; similar associations were seen when assessed at the treatment regimen level. In a logistic regression model of community practices (N=2,459), older patients (OR 1.01; 95%CI 1.00, 1.02), females (OR 1.2; 95% CI 1.0,1.4), and those from high (vs low) SES (OR 1.4; 95%CI 1.1, 1.6) were more likely to receive novel therapy; there were no associations with sex or race-ethnicity. **Conclusions:** In this large national database of adults with AML, almost half received novel therapy within 24-months of FDA approval. Though there was no dichotomous difference in uptake by race-ethnicity in community practices, younger and more affluent patients were more likely to receive novel therapy, concerning for disparities in uptake. Research Sponsor: American Cancer Society; Conquer Cancer Foundation of the American Society of Clinical Oncology; U.S. National Institutes of Health.

	N	Overall Pts, N = 8,081	Overall Pts Receiving Novel Therapy, N = 3,102	X^2 p-value	N	Pts Treated Within 24 Months FDA Approval, N = 4,808	Pts Receiving Novel Therapy Within 24 Months FDA Approval, N = 1,937	X^2 p-value
Practice	8081			0.006	4808			0.001
Academic		1978 (24%)	788 (25%)			1273 (26%)	510 (26%)	
Community		5945 (74%)	2,237 (72%)			3443 (72%)	1373 (71%)	
Both		158 (2.0%)	77 (2.5%)			92 (1.9%)	54 (2.8%)	
SES (Yost Index Tertile)	5508			<0.001	3169			0.002
High		2234 (41%)	916 (44%)			1286 (41%)	564 (44%)	
Low		1987 (36%)	683 (33%)			1136 (36%)	418 (33%)	
Medium		1287 (23%)	502 (24%)			747 (24%)	296 (23%)	
Race-Ethnicity	6127			0.2	3657			0.078
Persons of Color		759 (12%)	264 (12%)			448 (12%)	158 (11%)	
NH-White		5368 (88%)	1993 (88%)			3209 (88%)	1271 (89%)	

Pts, patients.

6541 **Poster Session**

Talk, test, and take one click to curb prostate cancer mortality.

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Background: Prostate cancer remains the most commonly diagnosed cancer and the second leading cause of cancer-related death in men in the United States. BronxCare Health System (BCHS) serves the Bronx neighborhoods of Morris Heights, Fordham South, and Mount Hope, notable for the highest prostate cancer incidence rate in New York City as per the American Cancer Society Cancer Action Network report 2019, highlighting the need for prostate cancer screening among the patient population we serve. An anonymous voluntary paper survey was performed in 2019 at BCHS to determine primary care physician understanding and implementation of current PSA testing guidelines. The study showed that primary care providers at BCHS approach PSA testing in a wide variety of ways and screen a wide age range of patients suggesting a need for intervention. An electronic medical record (EMR) decision support tool activated during primary care visits for men aged 55-69 years was implemented beginning January 1, 2021 which facilitates the provider and patient engagement in a shared decision-making discussion. This a follow-up study to determine the effect of this EMR application on PSA order rates and prostate cancer diagnosis rates at BCHS. **Methods:** The total number of patients who had PSA and lipid panel (LP) screening were extracted from the EMR of BCHS for potentially eligible men (aged 55-69) seen during primary care visits during the years 2016-2022. LP is done annually as a part of routine screening for adults aged 55-69 and is taken as an equivalent of primary care visits. PSA screening rates were compared to LP screening rates to control for unforeseen variables. Similarly, the number of newly-diagnosed prostate cancers among the same population of men was extracted for the years 2016-2021. Data for 2022 is still not available. 2016-2020 are pre-EMR and 2021 and 2022 are post-EMR flag years. The pre and post-EMR flag PSA and prostate cancer diagnosis numbers were compared by calculating Z scores and p-values. **Results:** The year-wise PSA, LP, and newly-diagnosed prostate cancers (PC) are tabulated below. The proportion of men who had PSA testing among all men aged 55-69 who had LP testing in each pre-EMR flag year was compared to each post-EMR flag year. A significant increase ($p < 0.00001$) was noted in the proportion of men who had PSA screening after implementation of the EMR application. Similarly, the proportion of men with newly-diagnosed prostate cancer among all men aged 55-69 who had PSA screening significantly increased after EMR application ($p < 0.00001$). **Conclusions:** A decision support tool embedded in the EMR has been an effective approach in increasing prostate cancer screening rates and may help curb prostate cancer mortality in our patient population as early detection in right men at the right age has the potential to reduce prostate cancer mortality. Research Sponsor: None.

Year	LP	PSA	PC
2016	2531	728	91
2017	2561	651	82
2018	2834	686	80
2019	2972	792	79
2020	2917	877	73
2021	3359	2428	126
2022	3365	2246	NA

6543 **Poster Session**

Racial and ethnic disparities in employment of patients and caregivers following breast cancer diagnosis.

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Background: Breast cancer (BC) can negatively impact employment, risking healthcare benefits, financial security and quality of life, especially for underserved minority populations. To better understand the impact of BC diagnosis and treatment on employment, Breastcancer.org conducted an online survey. **Methods:** Between 6/7-7/12/2022, Breastcancer.org community members were recruited to participate in an anonymous survey in English or Spanish via email, social media, or website ads. Eligible participants were US residents, age $\geq$18, and diagnosed with BC within the past 10 years. Consented participants answered questions on socio-demographics, financial toxicity, and employment status. **Results:** Of 2,420 screened, 1,710 met eligibility, and 1,437 participated (84% participation rate). Mean age and time since diagnosis was 46 and 2 years, respectively; 75% were in active treatment for non-metastatic (89%) or metastatic (11%) BC. Patients identified as 60% White (n=868), 26.7% Hispanic (n=384), 8% Black (n=121), or 4% Other (n=64). 94% were women. BC negatively impacted employment for 92% of patients. Full-time employment went from 62% at diagnosis to 40% by the time of the survey. This was more pronounced in metastatic (56% to 25%) vs non-metastatic (63% to 42%) patients (p=0.015). 64% attributed employment changes to their diagnosis, noting reduced hours/income (40%), job change (26%), disability (13%), permanent job loss (13%), and/or early retirement (12%). 36% noted changes in their caregiver's employment status as well with 30% of caregivers having reduced hours/income, 30% taking time off work, and 27% changing jobs; 9% of caregivers had permanent job loss and 10% retired early. Hispanic patients were younger ($p<0.001$) and more likely to have young children ($p<0.001$) and take unpaid leave (p=0.02). (Table). BC diagnosis was also more likely to impact their caregiver's employment (58%, vs White 25% or Black 41% patients, $p<0.001$). **Conclusions:** Breast cancer can cause significant, lasting negative effects on employment status for patients and caregivers that can decrease financial security of the entire family unit. Hispanic patients and individuals with metastatic disease appear to be at highest risk. Legislative protections and financial support may be required to mitigate the significant financial toxicity of a cancer diagnosis, especially for the most vulnerable. Research Sponsor: Gilead Sciences Inc., Pfizer Inc., Lilly.

	Total (n=1,437)	Hispanic (n=384)	Non-Hispanic White (n=1,282)	Non-Hispanic Black (n=121)	Other (n=64)
Age (mean, yrs)	46	38*	50	46	49
Time since Dx (mean, yrs)	2	2	3	2	3
Children <18	55%	83%*	43%	57%	53%
Employment after Dx (% Change)					
Full-time	40% (-22%)	36% (-25%)	41% (-22%)	46% (-17%)	42% (-19%)
Part-time	19% (+6%)	23% (+10%)	17% (+5%)	18% (+7%)	13% (+2%)
Retired	13% (+4%)	2% (+1%) *	19% (+5%)	10% (+3%)	14% (+3%)
Unpaid leave	8% (+5%)	13% (+10%)*	6% (+4%)	6% (+3%)	3% (+3%)
Unemployed	6% (+4%)	7% (+4%)	5% (+4%)	6% (+3%)	8% (+2%)

* $p\leq0.05$.

Depression, systemic inflammation, and exposure to discrimination among sexual and gender minority (SGM) cancer survivors.

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Background: Our prior research shows that SGM cancer survivors experience high rates of depression, due in part to exposure to discrimination. Depression among cancer survivors in general has been linked to markers of systemic inflammation including peripheral blood interleukin (IL)-6, tumor necrosis factor alpha (TNFα), and C-reactive protein (CRP). To date, no studies have examined the association of these markers with depression among SGM cancer survivors in the context of discrimination. **Methods:** Cross-sectional patient-reported data and serum samples were collected from 66 SGM cancer survivors (see Table). Depression was assessed by the Patient Health Questionnaire (PHQ)-9, discrimination by the Harassment, Rejection, and Discrimination Scale (HHRDS), IL6 and TNFα by multiplex assay, and CRP by ELISA. We used a clinical cut-point for depression of 10 on the PHQ-9, indicating moderate depressive symptoms, and assessed associations between continuous variables using bivariate correlations and multivariate linear regressions. **Results:** More SGM cancer survivors exceeded the clinical cut-point for depression (15.9%) than cancer survivors in prior general population samples (11.3%). Higher depression among SGM cancer survivors was associated with higher levels of exposure to discrimination (r=0.28, p=0.03), TNFα (r=0.30, p=0.02), and CRP (r=0.39, p=0.002); exposure to workplace discrimination, specifically, was associated with higher levels of CRP (r=0.32, p=0.02). In multivariate models controlling for demographic and clinical characteristics, CRP remained a significant predictor of depression (β=0.34, p=0.01). **Conclusions:** This study replicates prior findings of high levels of depression among SGM cancer survivors. It provides preliminary evidence that markers of inflammation, specifically CRP, are uniquely predictive of depression among SGM cancer survivors in the context of exposure to discrimination. These findings need to be replicated in larger samples and evaluated for potential use in providing supportive cancer care to SGM survivors. Research Sponsor: U.S. National Institutes of Health.

Sample characteristics (N=66).	
Sexual orientation	
Bisexual	3 (4.5%)
Lesbian/Gay	62 (94%)
Another orientation	1 (1.5%)
Gender identity	
Cisgender man	21 (31.8%)
Cisgender woman	44 (66.7%)
Transgender man	1 (1.5%)
Race/Ethnicity	
Black	2 (3.0%)
Latino	2 (3.0%)
Non-Latino White	62 (94.0%)
Age, mean (range)	56 (28-78)
Employment Status	
Employed	44 (66.7%)
Retired/disabled/unemployed	22 (33.3%)
Cancer type	
Breast	27 (40.9%)
Prostate	8 (12.1%)
Endometrial	6 (9.1%)
Lymphoma	6 (9.1%)
Other	19 (28.8%)
Months since treatment, median (range)	6 (0-170)
Depression, mean (s.d.)	5.24 (4.63)
Discrimination, mean (s.d.)	22.22 (9.40)
IL6, mean (s.d.)	8.69 pg/mL (16.79)
TNFα, mean (s.d.)	4.25 pg/mL (1.46)
CRP, mean (s.d.)	0.20 mg/mL (0.34)

6545 **Poster Session**

Association of major adverse financial events and later stage cancer diagnosis in the US.

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Background: Studies have documented an increased risk of bankruptcy and other financial hardships for individuals following a cancer diagnosis in the US. Few studies, however, have examined how patients' financial situation prior to cancer diagnosis is associated with cancer stage at diagnosis. This study assessed the prevalence of the specific major adverse financial events (AFEs) of bankruptcies, liens, and evictions prior to cancer diagnosis and their association with later stage diagnosis. **Methods:** Individuals aged 21 to 69 years diagnosed with cancer during 2014-2015 were identified from the SEER population-based registries for Seattle, Louisiana and Georgia. Registry data were linked with LexisNexis consumer data to identify patients with a history of court-documented AFEs. All AFEs occurring at any time prior to cancer diagnosis were identified. The association of AFEs and later stage cancer diagnoses (Stages III/IV) was assessed with sex-specific multivariable logistic regression. **Results:** Among 101,649 individuals diagnosed with cancer linked to LexisNexis data, 36,791 (36.2%) had a major AFE reported prior to diagnosis. The most recent event occurred a mean of 7.8 years prior to diagnosis. For individuals with an AFE, one-third experienced multiple events. Within each registry, AFEs were most common among non-Hispanic Black, unmarried, and low-income individuals. However, even in the highest income group, 27% had a prior AFE. Individuals with prior AFEs were more likely to be diagnosed with later stage cancer than individuals with no prior AFE (males-odds ratio (OR) 1.09; 95% CI, 1.03 to 1.14; $P < .001$ and females-OR 1.11; 95% CI, 1.06 to 1.17; $P < .0001$), after adjusting for age, race and ethnicity, marital status, income prior to diagnosis, registry, and type of cancer. The association between a major AFE and later stage diagnosis was observed regardless of when the event occurred relative to cancer diagnosis. **Conclusions:** In this novel cancer registry, LexisNexis consumer data linkage, we found that one-third of individuals newly diagnosed with cancer had a pre-diagnosis bankruptcy, lien, or eviction. Individuals with these AFEs were more likely to have later stage diagnosis, even after accounting for traditional measures of socioeconomic status, such as income. The prevalence of pre-diagnosis AFEs underscores patient financial vulnerability at the time of their cancer diagnosis, even before experiencing any subsequent financial burden associated with cancer treatment. Our findings are especially timely, with growing efforts by health care providers to screen and address patient social needs as part of oncology care. Research Sponsor: None.

Racial disparities in cancer mortality in patients with gastrointestinal malignancies following Medicaid expansion.

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Background: Racial minorities experience disparities in receipt of cancer treatment and survival. The optional Medicaid expansion provision of the Affordable Care Act provided federal funding to participating states to improve healthcare access for disadvantaged populations by expanding Medicaid eligibility criteria. This study aimed to investigate the effect of Medicaid expansion on racial disparities in mortality among patients with gastrointestinal malignancies. **Methods:** A cross-sectional cohort study of patients with pancreatic ductal adenocarcinoma (PDAC), colorectal cancer (CRC), and gastric adenocarcinoma (GC) of any stage was conducted using the National Cancer Database (2009-2019). Difference-in-difference analysis (DID) was performed to compare adjusted 2-year mortality separately among Black and White patients residing in Medicaid expansion states (MES) and non-expansion states (non-MES) before (2009-2013) and after (2014-2019) expansion. Differences in receipt of surgery and chemotherapy were also evaluated. **Results:** A total of 86,052 patients were included for analysis, including 19,188 patients with PDAC, 60,404 with CRC, and 6,460 with GC. Two-year mortality decreased among Black patients with PDAC residing in MES compared to non-MES following expansion (DID -9.4%, $p<0.001$) (Table). Mortality also decreased among Black and White patients with CRC in MES compared to non-MES following expansion (DID -4.2%, $p < 0.001$ and -2.9%, $p = 0.047$). Among patients with GC, Black patients in MES experienced a marked reduction in mortality compared to non-MES (DID -7.7%, $p = 0.07$). Both Black and White stage 3-4 PDAC patients had an increase in receipt of chemotherapy in MES following expansion (DID 3.7%, p=0.28 and DID 2.7%, p=0.20). Rates of surgery, but not chemotherapy receipt, increased among Black patients with stage 4 CRC in MES following expansion (DID 5.7%, p=0.03 and 1.0%, p=0.66, respectively). A greater increase in receipt of chemotherapy was observed among Black patients with stage 4 GC in MES than in non-MES (DID 11%, p=0.06). **Conclusions:** Medicaid expansion was associated with a greater reduction in 2-year mortality rates for Black patients residing in MES than for those in non-MES. Existing racial disparities in mortality remained the same or worsened in non-MES but in almost all cases were mitigated in MES following Medicaid expansion. Research Sponsor: U.S. National Institutes of Health.

Difference in adjusted 2-year mortality in black compared to white patients in expansion (MES) and non-expansion states (non-MES) following medicaid expansion.

		2009-2013		2014-2019		DID*	P-Value
		Non-MES	MES	Non-MES	MES		
Pancreas (%)	White	81.4	78.2	69.9	67.5	0.7	0.65
	Black	77.0	77.8	74.6	66.0	-9.4	< 0.001
CRC* (%)	White	29.0	28.3	27.2	22.3	-4.2	< 0.001
	Black	32.4	29.5	30.4	24.6	-2.9	0.047
Gastric (%)	White	69.8	61.9	61.3	57.1	3.7	0.23
	Black	67.9	62.2	62.7	49.2	-7.7	0.07

*Difference in difference (DID); colorectal cancer (CRC).

6547 **Poster Session**

What is your preferred language? Evaluating equal access to oncology clinical studies for non-English-speaking participants.

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Background: Oncology clinical research studies (CRS) are essential for developing new therapies and improving patient outcomes, yet the lack of diversity among research participants remains an issue. The logistical complexity of participating in CRS, lack of funding, limited location of study sites, socioeconomic barriers, and the exclusion of non-English speakers (NES) likely contribute to this lack of diversity. In this study, we sought to evaluate what proportion of oncology CRS exclude NES. **Methods:** We searched ClinicalTrials.gov on December 28, 2022, to identify registered oncology CRS in the most prevalent cancer types: breast, lung, colorectal, and prostate cancers. Only US based studies were included. We reviewed the inclusion and exclusion criteria of each study and identified those that excluded NES. Trials with available informed consent forms (ICFs) were examined to evaluate length, available languages, and readability. Descriptive analysis and chi-squared tests were used to explore associations between study characteristics and the exclusion of NES. **Results:** We identified 12,393 CRS, of which 2527 were excluded due to duplicates listed under more than one cancer type. Of 9866 evaluable studies, 1195 (12%) explicitly excluded NES individuals from participating. Of these, 161 (13%) allowed Spanish-speaking participants. Breast cancer trials had the highest proportion of CRS which excluded NES (17%), followed by trials in colorectal (13%), prostate (9%), and lung (7%) cancer. When analyzed by funding sources, studies funded by academic institutions had the highest proportion of CRS that excluded NES individuals (24%) compared to 15% of NIH funded, 19% of other government-funded, and 2% of industry-funded studies ($p<0.001$). Compared to interventional studies, observational research studies were more likely to exclude NES (11% vs 20%; $p<0.001$). Notably, most CRS did not have ICFs available online. Of the 242 (2%) studies that had ICFs available for review, only 3 (1%) had ICFs available in another language – all of which were in Spanish. Furthermore, many ICFs were lengthy, with a median of 11 pages (range 1-54), and complex, with a median readability of 12th grade Flesch Kincaid level (range 6-26). **Conclusions:** Many oncology CRS, especially those funded by academic institutions, exclude NES, impacting 1 in 10 individuals in the US. This exclusion is not always explicit, making it likely that our findings underestimate the issue. Requiring English proficiency for research study participation will continue to contribute to the underrepresentation of historically excluded populations and NES patients with cancer from clinical trials and other research studies. Eliminating exclusionary criteria based on language and providing adaptive resources for NES participants is crucial for ensuring that oncology research is inclusive and grounded in equity. Research Sponsor: None.

6548 **Poster Session**

Sexual orientation and gender identity data collection among NCI community oncology research program (NCORP) practices: A 5-year landscape update.

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Background: National organizations (ASCO, ACS, ACCR) have advocated for routine collection of sexual orientation and gender identity (SOGI) in cancer clinics to advance cancer health equity. In 2017, only 24% of NCI Community Oncology Research Program (NCORP) practices collected sexual orientation (SO) data, while 10% collected gender identity (GI) data; recent progress in collection is unknown. **Methods:** In 2022, NCORP practices again completed a Landscape Assessment to assess research capacity (funding support from 2UG1CA189824) and were asked whether they routinely collect SOGI data in the electronic health record (EHR). The proportions of practices reporting collection of SO and/or GI data and population level differences over time were calculated using Fisher's exact tests. Univariate associations between SOGI data collection and site-related variables were evaluated using logistic regression; significant associations were then tested in separate multivariate logistic regression models. **Results:** 271 practices responded to the Landscape Assessment; 42% (114) reported that they routinely collect SO data, 58% (157) reported that they collect GI data; both were significantly higher than 2017 ($p<0.001$). Compared to other regions, practices in Northeastern states were significantly more likely to report collecting GI, but not SO. Practices with higher proportions of White patients were also more likely to collect GI ($p < 0.001$). Practices with community outreach staff were more likely to collect SO (Table 1). There were no significant differences in SOGI collection by Medicaid/Medicare patients, new cancer cases per year, or practice ownership. In both 2017 and 2022, sites in Southern states were less likely to collect GI than sites in other regions. **Conclusions:** Progress was made in SOGI collection between 2017 and 2022, but fewer than half of NCORP sites routinely collect SOGI data, in spite of national guidelines. Further examination of the cultural context of SOGI collection could inform efforts to improve data collection in the South and other regions. The lack of data on sexual and gender minority patients in the EHR contributes to health inequity and deficiencies in patient-centric care. Research Sponsor: U.S. National Institutes of Health.

		Univariate			Multivariate	
Variable	Comparison Group	Collection Reported to Occur N (%)	Collection Reported to Not Occur N (%)	P	Odds Ratio (95% Confidence Interval)	P
Gender Identity		N=157	N=114			
Practice Group Region	Midwestern	70 (45%)	44 (39%)	0.023	REF	0.045
	Western	32 (20%)	18 (16%)		1.39 (0.63, 3.13)	
	Northeastern	19 (12%)	7 (6%)		2.08 (0.73, 5.91)	
	Southern	36 (23%)	45 (40%)		0.59 (0.30, 1.16)	
Percent New White Patients		83 (17%)	74 (22%)		1.03 (1.02, 1.05)	<0.001
Sexual Orientation		N=112	N=159			
Staff Dedicated to Community Outreach		29 (25%)	23 (14%)	0.02	2.07 (1.12, 3.81)	0.02

6549 **Poster Session**

Patient-level interventions to increase guideline concordant treatment among Black breast cancer patients: Can they close the racial gap in survival after diagnosis?

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Background: While we have seen impressive improvements in breast cancer (BC) survival over the last few decades, substantial racial disparities persist. Inequities in the receipt of guideline-concordant treatment contribute to worse survival in Black BC patients. Previous studies have shown that patient-level disparity reduction interventions (e.g., patient navigation) can significantly increase guideline-concordant treatment receipt among Black patients, with positive spillover effects in nonBlack patients. The aim of this study was to estimate the potential impact of disparity reduction interventions on racial inequities in survival after BC diagnosis in North Carolina. **Methods:** We used data from the Cancer Information and Population Health Resource, which links multipayer claims to North Carolina's cancer registry for biological women diagnosed with BC in 2004-2017. We calculated Black/nonBlack disparities in the receipt of chemotherapy (CTx) within 4 months of diagnosis for patients ages <70 with hormone-receptor negative stage Ib-III BC (CTx cohort; N=2223) and the receipt of endocrine therapy (ET) within 12 months of diagnosis for stage I-III hormone receptor-positive BC (ET cohort=16220). We then simulated the potential increase in the proportion of patients receiving CTx and ET if proven patient-level disparity-reduction interventions were implemented across the state. Based on the literature, we assumed that the effects of these interventions in increasing treatment receipt would be same in the CTx and ET cohorts. We estimated the effect of this potential increase in CTx and ET receipt on 10-year overall survival using cohort-, race-, and treatment receipt-stratified Markov models. We report confidence bounds representing 95% of simulation results. **Results:** Over the 2004-2017 period, 72.9% and 70.8% of Black patients in our cohorts received CTx and ET, respectively. This was significantly lower than among nonBlack patients ($p<.05$). State-wide implementation of disparity reduction interventions could increase CTx and ET receipt among Black patients to 86.7% (80.9-92.5%) and 84.2% (78.5-89.9%), respectively. As a result, the racial 10-year survival gap would decrease from 9.4 to 8.1 (5.7-10.5) percentage points in the CTx cohort, and from 6.2 to 5.4 (4.0-6.7) percentage points in the ET cohort. **Conclusions:** Patient-level interventions can reduce disparities in guideline-concordant-treatment receipt. However, increases in treatment receipt alone would not be enough to close the racial survival gap, suggesting that, in isolation, patient-level interventions are unable to eliminate disparities. Action on the structural factors that disadvantage Black BC patients is needed. Our team is conducting community-engaged work to share and interpret these findings. Research Sponsor: American Cancer Society; Pfizer.

6550 **Poster Session**

Disparities in clinical trial enrolment at a Canadian comprehensive cancer centre: A 15-year retrospective study.

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Background: Disparities in clinical trials limit the generalizability of study findings and perpetuate disparities in treatment access and outcomes, but there is a paucity of data in the Canadian context. The objective of this study was to examine disparities in cancer clinical trial enrollment at a large, comprehensive Canadian cancer center. **Methods:** We conducted a retrospective cohort study of clinical trial enrollment among all newly diagnosed cancer patients (N=154,880) at the Princess Margaret Cancer Centre in Toronto, Canada (2006-2021). Multivariable Bayesian hierarchical logistic regression with random effect for most responsible physician was used to examine the correlates of clinical trial enrollment, comparing the population of enrolled and non-enrolled patients. Odds ratios were adjusted for patient variables (sex, age at diagnosis, language, geography, primary care provider), and census tract-level marginalization (residential instability, material deprivation, dependency, ethnic concentration), disease variables (cancer site and disease stage at diagnosis), and provider variables (most responsible physician (MRP), and MRP's sex, language, medical training, and department). **Results:** Overall, 11.2% of patients enrolled (n=17,400) in a clinical trial, with 5-, 10-, and 15-year cumulative incidences of 12%, 15%, and 18%, respectively. Small, but significant differences were observed between enrollees and the overall patient population. Lower odds of enrollment were observed in patients who were female (adjusted odds ratio [AOR], 0.82; 95% confidence interval [CI], 0.78-0.86; $p<.001$), $\geq$65 years (AOR vs <40, 0.61; 95% CI, 0.56-0.65; $p<.001$), non-English language speakers (AOR vs English, 0.72; 95% CI, 0.67-0.77; $p<.001$), lived $\geq$250 km away from the cancer center (AOR vs <15km, 0.71; 95% CI, 0.62-0.80; $p<.001$), or lived in areas with greater material deprivation (AOR, 0.94; 95% CI, 0.93-0.96; $p<.001$) or higher ethnic concentration (AOR, 0.96; 95% CI, 0.94-0.98; $p<.001$). Greater odds of enrollment were found in patients with metastatic disease (AOR, 1.19; 95% CI, 1.13-1.25; $p<.001$) and in those with a primary care provider (AOR, 1.69; 95% CI, 1.55-1.85; $p<.001$). **Conclusions:** Disparities were observed in clinical trial enrollment, despite a publicly funded health care system. While broader prospective data collection efforts are critical to better understand the influence of patient, provider and system factors on clinical trial enrollment, these findings suggest the need for targeted strategies to increase diversity in clinical trial access. Research Sponsor: Princess Margaret Cancer Centre.

6551 **Poster Session**

The intersection of neighborhood-level disadvantage and overall lung cancer survival.

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Background: Despite recent advances in lung cancer therapeutics leading to considerable improvement in survival, disparities continue to persist among socially disadvantaged populations. Although the reasons underlying this phenomenon are uncertain, we posit that neighborhood-level factors could play a role. Furthermore, neighborhood disadvantage may lead to epigenetic changes which promote malignant progression. This study aimed to determine the effects of neighborhood-deprivation index (NDI), a validated 13-factor-based measure, that combines income, education, employment, and housing in a neighborhood, on lung cancer mortality. **Methods:** A retrospective cohort study assessed the relationship of NDI with survival weighted by age, stage, and DNA methylation among biopsy-proven lung cancer from two U.S. medical centers, Johns Hopkins University and the University of Illinois Chicago, between 2008-2020. In our analysis, U.S.-standardized NDI values for each year of sample collection were computed at the U.S. census tract level and categorized into quartiles. Participants' residential addresses were geocoded to U.S. census tracts and linked to NDI quartiles. DNA extraction from liquid biopsy samples was performed for quantification of DNA methylation. **Results:** The study included 184 lung cancer patients, with 89 in the low-deprivation group and 95 in the high-deprivation group. The high-deprivation group had a higher percentage of females (57% vs. 48%), a higher percentage of African Americans (AA) (50% vs. 36%), a lower pack-year smoking history (30 vs. 39 median pack-years), and a higher percentage with stage IV disease (28% vs. 20%) than the low-deprivation group. Overall, NDI was significantly higher among AA when compared with Whites (p=0.003) and associated with lung cancer stage at diagnosis with an odds ratio of 1.17 (p=0.02). There was a significant correlation between DNA methylation and stage for HOXA7, SOX17, ZPF42, TAC1 and HOXA9. Only HOXA7 DNA methylation correlated with NDI (p=0.003).The high-deprivation group had a significantly shorter survival duration compared to the low-deprivation group, with a 1-year survival rate of 79% vs. 90%, a 2-year survival rate of 70% vs. 84%, and a 5-year-survival rate of 51% vs. 73% (p=0.02). After adjusting for age at diagnosis, stage, and DNA methylation status, belonging to the high-deprivation group was associated with a higher mortality risk with a hazard ratio of 2.02 (p=0.04). **Conclusions:** Neighborhood-level socioeconomic status and DNA methylation may be associated with late stage lung cancer at diagnosis; whereas NDI shows a potential association with shorter survival and increased mortality risk. Higher neighborhood deprivation among AA suggests that changes in health care policy that account for neighborhood-level indices of socioeconomic deprivation may enable more equitable improvement of lung cancer mortality. Research Sponsor: The University of Illinois at Chicago - Department of Surgery Start-up Funds.

6552 **Poster Session**

Impact of the COVID-19 pandemic on insurance transitions among commercially insured cancer patients in Washington state.

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Background: Insurance transitions following cancer diagnosis can disrupt care and impact outcomes. The COVID-19 pandemic impacted employment for millions of Americans, threatening their ability to maintain insurance. Using a large database linking commercial insurance to cancer registry records, we evaluated insurance transitions among newly diagnosed cancer patients in the pre- and post-COVID periods. **Methods:** We linked Western Washington SEER cancer registry records and enrollment records from two commercial insurers covering 3 million persons and Medicaid in Washington State. Eligible persons were ages 18-63 and commercially insured in the 12 months prior to their first cancer diagnosis. Post-diagnosis follow-up periods were stratified into pre-COVID (January 2017 – February 2020) and post-COVID (March 2020 - December 2020). We created logistic regression models to look at factors associated with (1) disenrollment for any reason and (2) transition to Medicaid, accounting for age, sex, race, year of diagnosis, cancer site, AJCC stage, comorbidities, and Area Deprivation Index (ADI), and diagnosis during the pandemic. **Results:** Among 5,458 newly diagnosed solid tumor patients enrolled in commercial plans pre-COVID, 16.9% disenrolled for any reason over 12 months following diagnosis. Among disenrollees, 10.0% transitioned to Medicaid. Patients with Lung, Oral, and Myeloma cancers had the highest disenrollments (21.2%, 21.0%, and 19.3% respectively). Among the 1,224 diagnosed post-COVID, 9.7% disenrolled for any reason. Among those who disenrolled, 21.0% enrolled in Medicaid. Patients with Leukemia, Melanoma, Oral, and Gynecologic cancers had the highest disenrollments (23.3%, 14.5%, 13.6%, and 13.6% respectively). In logistic regression, persons diagnosed after the pandemic were less likely to disenroll compared to the pre-pandemic period (Table). Transitions to Medicaid was not greater post-Pandemic. Advanced stage, comorbidity, and living in high ADI regions were significantly associated with transitioning to Medicaid. **Conclusions:** Newly diagnosed cancer patients with commercial insurance during the COVID-19 pandemic were substantially less likely to disenroll than those diagnosed before the pandemic. The findings may reflect pandemic-related preferences for job stability during a time of personal and societal crisis. Research Sponsor: Andy Hill Care Fund.

Factors [Only significant associations shown]	Any Disenrollment Estimate (95% CI)	Transition to Medicaid Estimate (95% CI)
AJCC stage (ref = in situ)		
4	1.13 (0.82, 1.56)	3.21 (1.38, 7.46)
Post-COVID period (ref = Pre-COVID)	0.52 (0.42, 0.64)	1.20 (0.75, 1.89)
Comorbidity Score (ref = 0)		
2+	1.10 (0.81, 1.50)	2.30 (1.25, 4.24)
ADI (ref = 1)		
8	1.42 (1.02, 1.96)	4.14 (1.80, 9.55)
9	1.01 (0.65, 1.56)	7.05 (3.03, 16.40)
10	1.26 (0.80, 1.98)	4.57 (1.68, 12.46)

6553 **Poster Session**

Translated consent documents (CDs) and use in non-industry sponsored studies (NISS).

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Background: Patients (pts) from historically underrepresented groups often have limited English proficiency (LEP). One challenge specific to obtaining consent from these pts to participate in clinical trials is the need for translated CDs. CD translation leads to enrollment delays and increases costs to study sponsors. We hypothesized that NISS, for which the principal investigator pays translation costs, would consent proportionately fewer pts with a primary language other than English and pts with LEP compared to industry sponsored studies (ISS). **Methods:** Pts' primary language and English proficiency were assessed for all 12,082 consent events with appropriate available data at the Jonsson Comprehensive Cancer Center from 2013 to 2018. Pts with LEP were pts (or parent/guardian for pediatric pts) who had a primary language other than English, and the electronic health record indicated that the pt required a translator within 6 months of the consent date. CD language was documented per chart review when available, and when not, languages of available IRB-approved CDs were evaluated. The proportion of consent events for pts with a primary language other than English and with LEP were compared between NISS and ISS using generalized estimating equations, and the odds of signing CDs in the pts primary language were evaluated by multivariable analyses. Discrepant CD language data was evaluated by McNemar's test. All analyses were performed using SAS 9 (SAS Institute, Cary, NC, USA). **Results:** Pts with a primary language other than English represented 8.1% of consent events in ISS vs 4.4% in NISS ($p<0.001$) and 5.5% vs 2.8% ($p<0.001$) for pts with LEP. Pts with a primary language other than English represented 4.5% vs 1.2% of consent events utilizing CDs in the pts' primary language in ISS vs NISS ($p<0.001$) and 3.7% vs 0.9% ($p<0.001$) for pts with LEP. On multivariable analyses, the odds for pts with a primary language other than English of signing CDs to a NISS was 0.74 (CI, 0.63-0.94, p=0.005), and of signing CDs in their primary language was 0.38 (CI, 0.27-0.52, $p<0.001$) compared to pts whose primary language was English. The odds for pts with LEP of signing CD to a NISS was 0.74 (CI, 0.58-0.95, p=0.02), and signing CDs in their primary language was 0.35 (CI, 0.25-0.50, $p<0.001$) compared to pts whose primary language was English. Of 52 pts who signed CDs for both $\geq$1 NISS and $\geq$1 ISS, 18 signed in discrepant languages, with 16 of those 18 signing translated CDs for the ISS but not the NISS (p=0.002). **Conclusions:** Although the role of cost as an effect driver cannot be proven in a retrospective analysis, consistent with our hypothesis, the proportion of consent events utilizing appropriately translated CDs for pts with a primary language other than English and pts LEP was lower in NISS vs ISS, driven by lower odds of signing CDs and lower frequency of signing translated CDs. Approaches that reduce translation costs for investigators should be investigated. Research Sponsor: Jonsson Comprehensive Cancer Center Seed Grant.

6554 **Poster Session**

Examining clinical trial eligibility for oncology patients with human immunodeficiency virus (HIV): A global cross-sectional analysis.

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Background: People Living with HIV (PLWH) are at higher risk of developing cancer, and malignancy is the most common cause of death in PLWH in the USA. In 2017 a joint research statement by the American Society of Clinical Oncology and Friends of Cancer Research (ASCO-FCR) examined trial inclusivity, stating PLWH should not be excluded from clinical trials due to HIV positivity alone without justification. It also provided guidance for designing trial inclusion criteria using CD4 count, use of antiretroviral therapy (ART), ART-related drug interactions and HIV-associated complications. To review incorporation of ASCO-FCR recommended wording and current compliance, we examined global eligibility for PLWH in clinical trials. **Methods:** Clinicaltrials.gov was searched on 15 Nov 2022 for open and recruiting trials worldwide, using terms 'advanced cancer' and 'interventional'. Trials lacking systemic treatment were deemed non-evaluable. Evaluable studies' eligibility criteria were manually reviewed for specific criterion excluding PLWH or diagnosis/history of immunodeficiency (outright exclusion). Therapy type and study phase were captured and their relationships to outright exclusion were significance tested using odds ratios (OR) with 95% confidence intervals (CI). **Results:** The search rendered 2388 evaluable clinical trials. Eligibility criteria outrightly excluded PLWH in 1194 (50%) , of which 1113 (93%) were early phase trials (Phase 0-2). 206 evaluable trials (8.6%) permitted inclusion of PLWH aligned with ASCO-FCR guidance, including 3 (0.1%) with a cohort for PLWH. AIDS-defining illness was an exclusion criterion in 27 trials (1%), and specific interactions to ART in 10 (0.4%). Early phase trials had a significantly higher likelihood of outright exclusion of PLWH when compared with late phase trials (OR 2.98; 95% CI 2.16-4.11, $p<0.0001$). Trials investigating immunomodulatory agents were more likely to outrightly exclude PLWH than those investigating other drug classes (OR 1.60; 95% CI 1.36-1.88, $p<0.0001$). Criteria which may implicitly exclude PLWH were identified, including 204 (8.5%) citing active/chronic/severe infection, 189 (7.9%) listing CYP and P-gp interaction criteria and 3 (0.1%) "immunodeficiency". **Conclusions:** Despite adequate time to incorporate, most currently recruiting oncology clinical trials do not use ASCO-FCR guidance for including PLWH. Half of evaluated trials excluded PLWH without reason. Early phase and immunotherapy trials were significantly more likely to exclude PLWH without exception, despite data to support immunotherapy use for PLWH. Covert inclusionary barriers exist in criteria that lack HIV-specific guidance, and this may further exclude PLWH. Consideration of recommendations and guidance in eligibility criteria for oncology trials is critical to address current inequities in care for PLWH and cancer.
Research Sponsor: None.

6555 **Poster Session**

Disparities in lung cancer screening in a diverse urban population and the impact of a community-based navigational program.

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Background: Lung cancer (LC) is the leading cause of cancer death in the US in both men and women; causing 25% of all cancer deaths. Annual lung cancer screening (LCS) with a low-dose CT (LDCT) in high-risk individuals (aged 50-80 with a >20 pack-year smoking history) decreases LC deaths by 20% and is recommended by USPSTF. Despite the efficacy, uptake of LDCT remains low at 6% nationally, and 13% in Rhode Island. Patient (pt) and provider perceived barriers, along with racial, ethnic and socioeconomic disparities widen the gap. We evaluated the implementation of a LCS navigation program at an urban community health center (CHC) with a multiethnic, socioeconomically underserved population. **Methods:** A bilingual (English and Spanish speaking) pt navigator was integrated into routine clinic practice at a large primary care CHC group, across 4 sites, starting in January 2022. The navigator's role was to assess pt and provider awareness of the LCS process, assess for systemic barriers, and provide navigational support for the LDCT process. Pts eligible for LCS at the CHC from 1/2022 to 12/2022 were retrospective examined; 50 to 80 years and a >20 pack-year smoking history. The navigator administered a questionnaire to assess barriers to LDCT and demographic variables. **Results:** A total of 360 eligible pts were seen across the CHC practice in 2022, of which 149 (41.4%) agreed to undergo LDCT after counseling and shared decision making and 28% of these (n 101) completed LDCTs. 153 of the eligible pts completed the survey questionnaire. Of these, 50% were females; 40% were Hispanic/Latinx, 40% were non-Hispanic/Latinx and 22% declined to answer. Majority, 61% were white, 10% African American/Black and 28% declined to answer. A sizeable proportion were non-English speaking (34%) and resided in cities with Rhode Island's lowest per-capita incomes (Pawtucket 48%), Central Falls (32%) and North Providence/Providence (10%). In assessing barriers to LCS, 46% of pts were not aware of the LCS process and 44% were unaware that LCS was covered by health insurance; 58% of eligible pts did not recall their PCP discussing LCS. Of the LDCTs resulted available at the time of analysis, 84% were Lung RADS-1 and 16% Lung RADS-4 category. **Conclusions:** Our study highlights the unique barriers to LCS in an urban multiethnic community. While access to LCS remains an issue, pt awareness of the lung cancer screening process was the major barrier. A patient navigation program is critical to the success of LCS in a community, by providing education to patients and providers and the necessary logistical support needed in the LDCT process. With a community based navigational program, we demonstrate a significant increase in lung cancer screening rates in our population to 28% as compared to the state LCS rate of 13%. *(Supported by the Robert A. Winn Diversity in Clinical Trials Career Development Award).* Research Sponsor: Win CDA Diversity in Clinical Trials Career Development Award.

6556 **Poster Session**

Racial disparity in dose intensity of early-stage breast cancer chemotherapy.

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Background: There are persistent, entrenched racial disparities noted in breast cancer outcomes. A basis for these disparities can be racial inequality for stage matched Black vs. White women in receiving early-stage breast cancer (ESBC) chemotherapy dose intensity of, at minimum, 85% or more of chemotherapy (historic gold standard) within prescribed timeframe. Our study measured dose reductions, early terminations, and overall dose intensity of ESBC chemotherapy in urban breast cancer centers and compared by race. **Methods:** Using a longitudinal, comparative descriptive design, treatment characteristics were measured in women receiving ESBC cancer chemotherapy in seven cancer centers in Western PA and Eastern Ohio. Dosing scheduled was calculated per patient chemotherapy prescription. Actual dose was measured as percentage of chemotherapy received / prescribed in "prescribed time," meaning exact, ideal time to complete chemotherapy calculated from dose initiated without delay, dose reduction or early stoppage. The second measurement, "in any time," measured chemotherapy completed over any course of time, incorporating delays and reductions. Results were dichotomized according to 85% of prescribed dose for both outcomes and compared by patient self-reported race (Black or White). **Results:** This study was conducted from August 2017 through June 2022. N=260 patients, race self-reported as 100 Black (38.5%) and 160 White (61.5%). Overall, n=36 (13.8%) had early termination of therapy. Early termination was more common for Black patients, 21%, vs 10% for White patients (p=.04). N=100 (38.3%) of all patients had some dose reduction, racially divided by 46.4% of Black patients vs. 34.3% of White patients, NS. By projected endpoint, Black patients received 77% (SD 24.1) of prescribed chemotherapy; White patients 86.7% (SD 16.6), p=.001. By "in any time" endpoint, Black patients received 86.5%, (SD 22.8) of prescribed therapy, White patients received 93.5% (SD 13.2), p=.002. By "in any time" measurement, 15% of White patients and 25% of Black patients did not receive the gold standard of 85% of prescribed chemotherapy. N= 7 of delays or terminations were due to disease progression, or poor response, and rarely, (n=4) to patient nonadherence. Largely, delays and early cessation were due to chemotherapy toxicity. **Conclusions:** Racial disparities in dose intensity and alterations of prescribed ESBC chemotherapy must be eliminated. Further examining the racial differences around dose delays and early chemotherapy termination, including racial barriers to patient- clinician communication around chemotherapy related toxicity, is essential to ensure equitable ESBC care and outcomes. Research Sponsor: U.S. National Institutes of Health.

6557 **Poster Session**

A quantitative synthesis of disparities in the inclusion of racial/ethnic minorities and older women in breast cancer trials.

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Background: Trials that inadequately include underrepresented minority (URM) populations widen inequities in cancer care. We assessed reporting patterns, representation, and trends of URM representation in breast cancer (BC) trials. **Methods:** We analyzed all phase 2/3 trials for age disparity and trials recruiting from the US for racial/ethnic disparity amongst BC RCTs (1990-2021). Enrollment-incidence ratios (EIR), which compare trial proportions (TP) from age subgroups against global estimates of incidence in the corresponding age group (from Global Burden of Disease) and racial/ethnic subgroups against US-population-based incidence in the corresponding racial/ethnic group (from SEER 22), were calculated. Individual-trial EIRs were pooled using random-effects meta-analyses. EIRs of <0.80 indicated meaningful underrepresentation, while EIRs >1.20 indicated meaningful overrepresentation. Meta-regression was used to explore associations between key trial characteristics and EIR, and trends in EIR over the last three decades. **Results:** Of 842 global trials with 490,657 participants, 232 (27.6%) reported the number of participants in specific age strata and 144 (17.1%) reported outcomes by age. Only 60 trials recruited exclusively from the US. Of these, 41 (68.3%) reported race and 24 (40.0%) reported ethnicity, and 2 (3.3%) analyzed outcomes by race. Older adults aged $\geq$65 years (TP: 24.3%; EIR: 0.53 [95% CI: 0.47-0.60]) and Hispanic women (TP: 5.3%; 0.54; 0.40-0.75) were underrepresented across global trials and US-only trials respectively. Black women were significantly underrepresented in trials that led to FDA approval (0.38; 0.25-0.58) but not in US-only trials. Stratified analysis by BC subtype (with subtype-specific population incidence) showed underrepresentation of Black women in US-only trials for HER2+ BC (0.66; 0.47-0.93), Hispanic women in ER+ BC (0.42; 0.20-0.90), Asians in triple-negative BC (0.24; 0.11-0.53), and older women in HER2+ BC (0.35; 0.31-0.40) and triple-negative BC (0.36; 0.29-0.45). From 1990-2021, the representation of older women declined significantly (meta-regression coefficient for EIR: -0.4 per 10 years), while Black and Hispanic representation showed no significant change. Black ($p = 0.02$) and Hispanic representation ($p = 0.05$) worsened significantly in larger trials. **Conclusions:** Published reports of BC trials do not consistently report the inclusion of URM. Older and Hispanic women were consistently underrepresented, whereas Black women were underrepresented in large, practice-changing trials. Research Sponsor: None.

Representation of each subgroup given as an EIR with a 95% confidence interval.

	US-only	Trials that led to FDA approval
White	0.97 (0.95-1.00)	0.85 (0.74-0.96)
Black	1.02 (0.75-1.39)	0.38 (0.25-0.58)
Asian	1.27 (0.63-2.56)	2.59 (1.85-3.63)
Hispanic	0.54 (0.40-0.75)	0.67 (0.42-1.07)

6558 **Poster Session**

Disparities in intensity of care at the end-of-life for patients with gastrointestinal cancer.

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Background: Racial/ethnic minority patients experience disparities along the cancer continuum. Studies show that racial/ethnic minorities with cancer have higher rates of intensity of care at the end-of-life (EOL) compared to non-Hispanic Whites (NHW). Less is known whether disparities in intensity of care at EOL exist among racial/ethnic minority patients with a gastrointestinal (GI) cancer. **Methods:** Using the California Cancer Registry linked to hospital discharge data, we conducted a retrospective study of patients ≥18yrs with upper GI, pancreatic, or colorectal cancer who died from 2005-2018. We evaluated if race/ethnicity was associated with EOL intensity of care defined as hospital/ED visit or death, ICU, intubation, CPR & dialysis within 14-days of death. We used logistic regressions to calculate odds ratios adjusting for age, socioeconomic status (SES), insurance, geography, stage, comorbidities, and NCI-designated centers. **Results:** 189,837 patients with GI cancer died: 41,389 (21.8%) with upper GI, 46,554 (24.5%) with pancreatic & 101,894 (53.7%) with colorectal cancer. 118,995 (62.7%) were NHW, 14,146 (7.5%) Black, 33,802 (17.8%) Hispanic & 22,894 (12.1%) Asian/Pacific Islander (API). Median age was 74.6 yrs, 54.1% male, 85.9% lived in urban areas, 48.9% had Medicare, 16.1% had low SES & 35.7% had Stage 4. Black, Hispanic, and API patients compared to NHW had higher odds of intensity of care at EOL (Table). **Conclusions:** This study shows disparities in intensity of care at the EOL among racial/ethnic minorities with GI cancers. Solutions are urgently needed to reduce such disparities in care. Research Sponsor: National Institute on Minority Health and Health Disparities of the National Institutes of Health under Award Number K23MD013474; Conquer Cancer Foundation of the American Society of Clinical Oncology.

Cancer	Race/ Ethnicity	Hospital Admission	ED visit	Hospital/ ED Death	ICU admission	Intubation	CPR	Dialysis
Upper GI	Black	1.95 (1.56-2.42)	1.59 (1.36-1.86)	1.36 (1.11-1.66)	1.38 (1.21-1.58)	1.48 (1.30-1.69)	1.71 (1.39-2.11)	1.58 (1.22-2.03)
	Hispanic	1.37 (1.22-1.55)	1.30 (1.18-1.43)	0.99 (0.89-1.12)	1.00 (0.91-1.11)	1.02 (0.93-1.12)	1.21 (1.03-1.41)	1.49 (1.24-1.79)
	API	1.31 (1.15-1.48)	0.74 (0.67-0.83)	1.41 (1.26-1.58)	1.09 (0.98-1.21)	1.13 (1.02-1.24)	1.18 (1.00-1.41)	1.47 (1.24-1.79)
Pancreatic	Black	1.53 (1.28-1.82)	1.66 (1.43-1.93)	1.40 (1.18-1.66)	1.60 (1.38-1.85)	1.61 (1.39-1.85)	2.04 (1.63-2.56)	1.55 (1.2-2.0)
	Hispanic	1.20 (1.07-1.35)	1.10 (0.98-1.23)	0.98 (0.87-1.10)	1.03 (0.90-1.17)	1.03 (0.91-1.16)	0.97 (0.78-1.20)	1.30 (1.06-1.60)
	API	1.17 (1.03-1.33)	0.82 (0.72-0.94)	1.51 (1.34-1.70)	1.30 (1.14-1.49)	1.35 (1.19-1.54)	1.07 (0.83-1.36)	1.13 (0.89-1.44)
Colorectal	Black	1.25 (1.11-1.41)	1.47 (1.32-1.62)	1.30 (1.15-1.46)	1.44 (1.33-1.56)	1.47 (1.36-1.59)	1.86 (1.66-2.10)	1.84 (1.63-2.09)
	Hispanic	1.43 (1.30-1.58)	1.14 (1.05-1.23)	1.11 (1.02-1.21)	1.04 (0.97-1.11)	1.09 (1.02-1.16)	1.17 (1.06-1.30)	1.54 (1.38-1.71)
	API	1.33 (1.21-1.47)	0.74 (0.68-0.82)	1.41 (1.29-1.54)	1.19 (1.10-1.27)	1.22 (1.14-1.31)	1.16 (1.03-1.30)	1.51 (1.34-1.70)

NHW=Reference.

6559 **Poster Session**

Source of funding and enrollment disparity in cancer clinical trials.

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Background: Recent findings that Black and Hispanic patients were significantly underrepresented in industry-sponsored prostate cancer trials warrant a detailed investigation across cancer types to assess the association between funding source and enrollment disparities. **Methods:** Phase II/III clinical trials in prostate, breast, colorectal, and lung cancers reporting age, gender, race/ethnicity, and reporting NIH or industry as the funding source were considered eligible for inclusion. For age, and gender analysis, all trials were considered eligible. For race/ethnicity analysis, trials recruiting from the United States (US) were considered eligible. Enrollment-incidence ratios (EIR) comparing trial proportion from age/gender or racial/ethnic subgroups against global cancer incidence in the corresponding group (from Global Burden of Disease) or US-population-based incidence in the corresponding racial/ethnic subgroup (from SEER 22), were computed. Trial-level EIRs were pooled using a random-effects model and subsequently stratified by funding source. A univariate meta-regression was conducted to assess the temporal changes in EIR by each funding category. **Results:** Of 42,390 studies initially identified, 2234 trials (1989-2021) met the eligibility criteria. Regarding age, 361 (16%) trials reported age categories by 65 years threshold. Of 698 trials recruiting from the US, 498 (71%) reported race, and 198 (28%) reported ethnicity. Regarding representation, older adults were under-represented (EIR: 0.66; 95% CI: 0.62-0.70) in the industry but not in NIH-sponsored clinical trials (0.79; 0.62-1.00). Regarding gender, no significant disparity was observed regarding the enrollment of men and women in colorectal and lung cancer clinical trials. In terms of race, there was a greater under-representation of Black patients in industry sponsored trials (0.29; 0.26-0.32) as compared to NIH-sponsored clinical trials (0.65; 0.57-0.74) [P_{int} <0.01]. Asian patients were significantly overrepresented in industry sponsored trials (3.17; 2.69-3.74) but not in NIH sponsored clinical trials (1.43; 0.85-2.41) [P_{int} <0.01]. Hispanic patients were significantly under-represented in both, industry (0.27; 0.22-0.34) and NIH-sponsored clinical trials (0.35; 0.22-0.55) [P_{int} 0.32]. Secondary analyses including trials recruiting exclusively from the US, and analyses by specific cancer types showed consistent results. Recruitment of older adults, men, and Black patients is decreasing over time. **Conclusions:** There is a consistent under-representation of older adults in industry-sponsored, and of Black and Hispanic patients in both industry-sponsored and NIH-sponsored clinical trials. The under-representation of Black patients is likely to be greater in industry-sponsored trials, which has worsened over the last three decades. Research Sponsor: None.

6560 **Poster Session**

CONSENT: Randomized controlled trial of enhanced informed consent compared to standard informed consent to improve patient understanding of early phase oncology clinical trials.

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Background: Early phase oncology clinical trials have become increasingly complicated in terms of patient selection and trial procedures. Informed consent has been contentious due to potential ethical issues associated with performing experimental research on patients with advanced cancer who lack standard treatment options. Prior research has shown significant gaps in patient understanding regarding the nature and intent of these trials. CONSENT aimed to test whether enhanced informed consent can improve clinical trial comprehension. **Methods:** We randomized patients eligible to participate in one of four investigator-initiated early phase oncology clinical trials at the Royal Marsden Drug Development Unit to either a control arm or an experimental arm, stratified by age and educational level. The control arm received the full-length trial PIS, followed by electronic or paper administration of the Quality of Informed Consent Questionnaire Parts A (QuIC-A). The experimental arm received the full-length trial PIS, exposure to a two-page study specific aid and 10 online educational videos (both co-designed with patients and clinicians), followed by administration of the QuIC-A. The primary endpoint was the difference in the QuIC-A score between the control and experimental arm. The accrual target was at least 17 evaluable patients per arm to detect an 8-point difference (80% power, alpha 0.05). **Results:** 23 patients were accrued to the control arm (17 evaluable) and 22 patients (18 evaluable) were accrued to the experimental arm. Patients were evaluable if they had completed the QuIC-A. 38% of the participants were over the age of 65, 91% identified as White, 56% had completed a university degree and 97% spoke English at home. We did not observe a significant improvement in the primary endpoint in evaluable patients – control (QuIC-A - 76.5/100) vs experimental arm (QuIC-A - 77.4/100), p value = 0.39 (one sided, two sample t-test). 20 participants provided feedback on the enhanced consent materials via a study questionnaire –75% found both the 2-page study aid and the videos not at all distressing or uncomfortable and 85% found them either quite useful or very useful. **Conclusions:** This is the first prospective randomized trial evaluating the impact of communication interventions on informed consent in advanced cancer patients considering early phase oncology clinical trials. The co-designed interventions were deliverable online and were acceptable and useful for patients. We did not demonstrate an improvement in the primary endpoint with a high QuIC-A score observed in the control arm- this could be explained by the study population which was highly educated, White and spoke English at home. Future studies should focus on groups with lower literacy and from culturally and linguistically diverse backgrounds. Clinical trial information: NCT04407676. Research Sponsor: Royal Marsden Hospital and Institute for Cancer Research.

6561 **Poster Session**

The patient experience of prior authorization for cancer care: Anxiety, delays, and the erosion of trust.

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Background: Prior authorization (PA) requires healthcare providers to obtain pre-approval from insurance for medical care. While PA is intended to promote evidence-based standards and reduce unnecessary care, it requires clinicians and patients to navigate an often-complex approval process. Delays or denied care can be particularly problematic for patients with cancer and their experience with PA remains unexplored. **Methods:** Social media recruitment enrolled adult cancer patients with a self-reported personal experience with PA to an anonymous online survey of investigator-designed questions on their experience. Descriptive statistics and univariate tests characterized survey responses, and multivariable analysis, controlling for age, diagnosis, race/ethnicity, and education, assessed associations with healthcare and insurance trust and delays in care. **Results:** 178 patients completed the survey; they were mostly women (90%), non-Hispanic white (84%), college graduates (81%), young [18-39 (42%), 40-54 years old (34%)] with private insurance (86%). PA was most frequently required for imaging (71%), IV chemotherapy (48%), surgery (47%), radiation (34%). Most care was ultimately given as recommended (58%); however, 20% of respondents didn't receive recommended care due to delays or denials, and 9% received recommended care but paid out-of-pocket. PA delayed 69% of care, with 51% of patients noting a delay $\geq$2 weeks. Delays did not vary by demographic, clinical, insurance, or treatment factors (all $p > .05$). 67% of patients had to personally get involved in the PA process by either calling their insurance (53%) or filing an appeal (25%); 20% of patients and/or their caregivers spent $\geq$11 hours dealing with PA issues. Overall PA experience was rated as "bad" (40%) or "horrible" (32%) for most respondents. Self-reported PA-related anxiety was significantly higher than self-reported baseline anxiety (mean = 74 vs mean = 37, 0-100 scale, $t = 16.6$, $p < .001$) and was significantly correlated with time spent on PA ($\rho = .16$, $p = .04$) and overall PA experience ($\rho = .34$, $p < .001$). While 18% felt PA made them trust their cancer team less, 89% said it made them trust their insurance company less, and 83% said it made them trust the healthcare system less. Patient involvement in the PA process (vs. healthcare team handling) was associated with higher-than-expected trust in their cancer team ($\chi^2 = 19.6$, $p < .001$), and increased odds of distrusting their insurance company ($\beta = 5.7$, 95% CI: 1.8,17.6) and distrusting the healthcare system ($\beta = 3.2$, 95% CI: 1.3,7.9). Having to file appeal was associated with 2.9 increased odds (95% CI: 1.2,7.2) of experiencing a delay in care. **Conclusions:** PA practices may substantially delay care for patients with cancer increasing anxiety and eroding trust in healthcare. Streamlining the PA process could both allow optimal quality of care and improve the patient experience with cancer care. Research Sponsor: Memorial Sloan Kettering Cancer Center; U.S. National Institutes of Health.

6562 **Poster Session**

Survival analysis of patients treated at oncology practices with more aggressive end-of-life practice patterns.

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Background: Despite national focus on measuring and reducing end-of-life (EOL) systemic treatment among cancer patients, recent studies show a consistently high use of systemic anticancer therapy (SACT) at the EOL, as well as a shift to more targeted therapies. A criticism of measures that focus on deceased populations is that they do not account for patients who received treatment at the same time in their disease trajectory and had a positive response to therapy. We sought to explore whether being treated at an oncologically aggressive (OA) practice (defined as higher practice-level EOL SACT treatment rates), was associated with a survival benefit among patients in six common cancer types. **Methods:** This survival analysis used the nationwide Flatiron Health electronic health record (EHR)-derived de-identified database. We included all adult patients with a confirmed diagnosis of metastatic disease in breast (mBC), colorectal (mCRC), renal cell carcinoma (mRCC) or pancreatic cancer (mPanc), or advanced disease in non-small cell lung (aNSCLC), or bladder cancer (aUC), between 2015 and 2019. The primary exposures were the practice-level risk-standardized 30-day EOL SACT rates calculated among decedents. The primary outcome was real-world overall survival (rwOS) among all patients. Adjusted hazard ratios (aHR) for each quintile of increasing OA EOL SACT rates (Q2-Q5) were estimated using disease-specific Cox proportional hazard models (reference: Q1), adjusting for patient and practice-level factors. Bonferroni correction was applied to account for multiple comparisons. **Results:** A total of 78,446 patients from 144 practices were included in the analysis with most patients seen at less OA practices (Q1-Q2). Patients seen at most OA practices (Q5) were less likely to be <65 (32.5% vs 38.9% in Q1), Black (6.3% vs 12.2%), have Medicare (5.9% vs 10.7%) or Medicaid (1.5% vs 4.1%). After adjusting for covariates, there was no statistically significant difference in rwOS between patients treated at the most (Q5) and the least OA practices (Q1; table). However, there was variation among the moderately OA practices. Patients with mPanc seen at moderately OA (Q2-Q4) had 12% to 19% lower hazards of deaths (aHR range 0.81-0.88), compared to those at the least OA practices (Q1), but these associations were not statistically significant (Bonferroni corrected p-values >0.05). **Conclusions:** When using rates of SACT at EOL to define OA practices, patients treated at these practices do not have improved survival. Research Sponsor: This study was sponsored by Flatiron Health Inc, which is an independent subsidiary of the Roche group.

aHRs for most OA practice quintile (Q5) compared with least OA practice quintile (Q1) by disease.

Disease	aHR (95% confidence interval)	p-value
mBC (N = 11,627)	0.93 (0.76 - 1.15)	0.501
mCRC (N = 15,786)	0.89 (0.72 - 1.09)	0.257
mRCC (N = 4,617)	0.97 (0.70 - 1.34)	0.845
mPanc (N = 7,349)	0.86 (0.71 - 1.05)	0.135
aNSCLC (N = 34,163)	0.94 (0.87 - 1.02)	0.119
aUC (N = 4,792)	0.94 (0.69 - 1.28)	0.703

6564 **Poster Session**

Use of direct oral anticoagulants (DOACs) in oncology: A phase IV study on impact of edoxaban treatment in Italian patients with cancer with venous thromboembolism during antineoplastic therapy (EDOI trial, GOIRC 05-2018).

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Background: The EDOI Study (EUDRACT 2018-003833-14) was designed to evaluate venous thromboembolism (VTE), a common complication of cancer and cancer therapy. VTE contributes to mortality and morbidity, and may interfere with therapy. When drafting the protocol, the standard treatment for VTE consisted of low-molecular weight heparin followed by vitamin K antagonists. DOACs are as effective as vitamin K antagonists in the treatment of VTE. Edoxaban has been confirmed to be effective and safe in the treatment of VTE. Adverse events (AEs) associated with DOACs can delay or interfere with chemotherapy; to date, data regarding the impact of Edoxaban treatment on cancer treatment AEs are scanty. **Methods:** In this multicentric, phase IV study, patients receiving an antineoplastic treatment (and candidates for at least 3 additional months of treatment) and diagnosed with VTE, received Edoxaban as per clinical practice. Patients received between 6 and 12 months of Edoxaban and were evaluated at baseline and after 1, 3 and 6 months. Primary endpoint was the impact of Edoxaban-related AEs on antineoplastic therapy, defined as delays/interruptions/reductions due to adverse drug reactions (ADR) related to Edoxaban (bleeding, hepatobiliary toxicity, renal toxicity, anemia, hypersensitivity reactions). As secondary endpoint, we assessed patient-reported outcomes (PROs) during treatment with Edoxaban (health-related quality of life: FACT-G, expectations and satisfaction with anticoagulant treatment: PACT-Q2 and ACTS). For each tool, mean scores at each time point were calculated. **Results:** One hundred and fifty patients were enrolled, 147 patients were evaluable. The Incidence density rate of antineoplastic therapy delay/interruption/reduction due to ADR related to Edoxaban was 0,8% per person-month (90% CI: [0,4; 1,5%] and 95% CI: [0,4; 1,6%]). For all the patient-reported outcomes, mean scores were maintained at different time points. **Conclusions:** The results of the study clearly show that the edoxaban treatment is well tolerated and has no relevant impact on the delivery of cancer treatments. Results in terms of quality of life and patients' satisfaction with anticoagulant treatment are reassuring. Clinical trial information: EUDRACT 2018-003833-14. Research Sponsor: GOIRC.

PROs results: Compliance and mean scores at different time-points.

	Baseline	1 month	3 months	6 months
Expected questionnaires	147	129	103	73
Completed questionnaires (FACT-G)*	138 (93.9%)	109 (84.5%)	90 (87.4%)	59 (80.8%)
FACT-G total score	66.44	69.59	69.06	69.92
PACT-Q2 convenience score	79.44	85.48	85.60	84.70
PACT-Q2 satisfaction score	60.05	64.00	66.95	65.64
ACTS Burdens scale	52.36	54.71	55.15	54.62
ACTS Benefits scale	10.05	9.99	9.82	10.16

*Compliance was slightly different among questionnaires.

6565 **Poster Session**

The IMPACT of an interdisciplinary goals-of-care program on readmission rates at a comprehensive care center.

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Background: Unplanned readmissions are associated with substantial distress for patients and their families. We hypothesized that goals-of-care (GOC) discussions, by improving goal-concordant care, may reduce unplanned readmissions. However, only a handful of studies have specifically examined this question. We assessed the implementation of a system-wide multicomponent interdisciplinary GOC (myGOC) program on the 30-day unplanned readmission rate and other hospital outcomes for medical patients at our comprehensive cancer center. **Methods:** In this retrospective cohort study, we compared the 30-day unplanned readmission rates in consecutive medical patients during the pre-implementation period from May 1, 2019 to December 31, 2019 and the post-implementation period from May 1, 2020 to December 31, 2020. The primary outcome was the 30-day unplanned readmission rate as defined by Vizient. Secondary outcomes included 7-day unplanned readmission rates, inpatient do-not-resuscitate (DNR) orders and supportive care consults. A multi-variate analysis model was used to examine the association between 30-day unplanned readmission rates and the implementation of the myGOC program adjusting for age, sex, race, index hospitalization type, and Sequential Organ Failure Assessment (SOFA) score. **Results:** This study included 7028 and 5982 unique medical patients during the pre- and post-implementation period, respectively. The 30-day unplanned readmission rates decreased from 13.7% before to 12.0% after implementation of the myGOC program. After adjusting for covariates, the myGOC implementation remained significantly associated with a reduction in 30-day unplanned readmission rates (OR [95% CI] 0.85 [0.77, 0.95], p=0.003). Other factors significantly associated with a decreased likelihood of a 30-day unplanned readmission were hematologic malignancies (vs. solid: 0.71 [0.64, 0.79]), White race (vs. Hispanic: 0.86 [0.75, 0.98]), an inpatient DNR order (0.30 [0.25, 0.37], an ICU admission (0.58 [0.48, 0.71], and an emergent admission (vs. elective: 0.86 [0.76, 0.99]). We also observed a significant decrease in 7-day unplanned readmission rates (0.75 [0.64, 0.89], p=0.0009), an increase in inpatient DNR orders (1.48 [1.35, 1.63], $p<0.0001$) and an increase in supportive care consults (1.22 [1.13, 1.31], $p<0.0001$) post-implementation. **Conclusions:** Implementation of a system-wide multicomponent GOC intervention was associated with a significant reduction in 30-day unplanned readmission rates after accounting for other key clinical factors. Research Sponsor: U.S. National Institutes of Health.

6566 **Poster Session**

Trends of using immune checkpoint inhibitors near end of life in limited resources setting: Experience of single cancer center in the MENA region.

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Background: Immune checkpoint inhibitors (ICIs) are standard of care nowadays in the treatment of many solid tumors as single agent or in combination. Recent literature suggested increased use of ICI near end of life; our aim was to find the characteristics of the patients who received ICI 30 days or less before their death. **Methods:** Data of patients with advanced solid tumors who have (ICI) therapy and died with disease were retrospectively retrieved. Patients were categorized into those dying within 30 days of the last dose of ICI and those receiving the last dose of ICI more than 30 days before death. Variables of potential interest were compared between the two groups by the Chi-square and independent sample *t*-tests as appropriate. **Results:** A total of 411 patients were included in this analysis; 135 (33%) received the last dose of ICI within 30 days of death and 276 (67%) received their last dose more than 30 days before death. Major cancer types included: lung (n=214; 52%), kidney (n=61; 15%), melanoma (n=44; 11%), head and neck (n=41; 10%), and others (n=14; 3%). Patients' characteristics: median age = 58, majority were males (310; 75%), 105 (26%) had ECOG PS $\geq$3, and 147 (36%) had brain metastasis. Patients who received the last dose of ICI within 30 days of death had more frequent ICU admissions (50 (37%) vs. 60 (22%), p=0.001, and were less likely to die under the care of the hospice care service (22 patients (16%) vs. 84 (31%), p=0.001. In addition, patients who received the last dose of ICI within 30 days of death were more likely to have a full code status (89 (66%) vs. 147 (53%), p=0.015, and have received a lower number of doses of ICI treatments (mean number of doses: 4.2 vs. 6.5 doses, p=0.001). We did not observe any significant difference between the two groups regarding type of cancer, age, gender, ECOG PS, presence of brain metastasis, number of hospital admissions, dying inside hospital, and number of emergency room visits. **Conclusions:** Immune checkpoint inhibitors may be overused near end of life which leads to minimal clinical benefits, less likelihood of dying under hospice care, and utilization of ICU resources. Research Sponsor: None.

6567 **Poster Session**

Reducing infusion center wait times in a resource-limited setting.

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Background: Time toxicity is increasingly recognized as an important factor in quality of life in cancer patients, and this effect may be amplified in under-resourced oncology settings. In the safety-net oncology center at Parkland Health (PH), wait time from infusion appointment check-in to treatment start was 147 minutes in June 2022, which led to significant patient frustration, delays in care, and staff dissatisfaction. We aimed to decrease wait time by 20% by December 2022. **Methods:** Baseline wait time data for patients getting infusions in the oncology infusion center was collected daily from the electronic medical record (EMR) time stamps of check in and infusion start (first IV medication given), and the average time was calculated. A value stream map detailing the steps required to start infusion with time stamps was produced. Stakeholders were queried to identify causes of delay, an Ishikawa diagram was constructed, and a priority matrix was developed to determine the most impactful interventions. The first PDSA cycle (July-Oct 2023) intervention consisted of working group formation and implementation of separate infusion pathway for patients getting injections ("fast track"). The second PDSA cycle (Nov-Dec 2023) intervention was rescheduling infusion-only patients to the least congested times of the day to relieve the bottleneck that occurred in the late mornings for patients with labs or provider visit prior to infusion. Patients and infusion center providers were surveyed about their perception of wait times. **Results:** Average wait times decreased from 147 minutes to 131 minutes during first PDSA cycle, a 10.8% improvement from baseline. From Nov-Dec 2023 during second PDSA cycle, wait time improved to 127 minutes, a 15.7% improvement from baseline. The average daily number of infusions and injections increased from 106/day baseline to 115/day by Dec 2023; an increase of 8.5%. Qualitative surveys of patients and infusion providers endorsed increased satisfaction with infusion process. **Conclusions:** Using established quality improvement methods, we improved average wait times for Parkland Health oncology infusion patients by 15.7% over a 6 month period. While we did not meet our goal, we increased daily capacity to treat patients by 8.5% while improving overall infusion wait time. We also improved perceptions of quality of care. Research Sponsor: Niarchos Foundation.

6568 **Poster Session**

The effects of social determinants of health on colorectal cancer screening.

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Background: Colorectal cancer is the 3rd leading cause of cancer death in the United States yet has consistently lagged in screening rates compared to other cancers. While patient-reported barriers have been previously described, few studies have analyzed how patients' social needs affect screening rates. **Methods:** This cross-sectional study includes 3974 Kaiser Permanente (KP) patients ages 50-75 years who completed the 2020 KP National Social Needs Survey. Survey respondents were from the seven KP regions of Southern California, Northern California, Colorado, Washington, Northwest, Georgia, and Hawaii. Five Social Needs categories were assessed: Financial Strain, Housing Instability, Transportation Issues, Social Isolation, and Food Insecurity. Being up to date on CRC screening was determined from patients' KP electronic health records, defined as meeting HEDIS criteria for screening. Multivariate analyses compared the level of social need to the respondents' completion of colorectal screening between the years of 2019-2021, adjusting for age, sex, race/ethnicity, diagnostic category group (DxCG), neighborhood deprivation index (NDI), and insurance type. **Results:** Among the 3974 survey respondents, 92.2% were up to date on their colorectal cancer screening. Not being up to date on CRC screening was significantly associated with having any social need and having severe needs in four of the five social need domains adjusted for sociodemographic and health status (Table). Patients were less likely to be screened if they had severe financial strain (OR 0.54, 95% CI 0.40-0.73), severe social isolation (OR 0.52, 95%CI 0.38-0.71), severe transportation issues (OR 0.33, 95% CI 0.18-0.61), and severe food insecurity (OR 0.41, 95% CI 0.27-0.62). No significant association between screening status and the domain of severe housing instability were found (OR 0.74, 95% CI 0.52-1.06). **Conclusions:** Respondents with financial strain, social isolation, food insecurity, and transportation issues had lower odds of being up to date with colorectal cancer screening. Future efforts aimed to improve colorectal cancer screening rates should assess patients' social needs and target ways to address these potential barriers to screening. Research Sponsor: Kaiser Permanente Bernard J. Tyson School of Medicine.

Odds of colorectal cancer screening by social needs.

Parameter	Adjusted Odds Ratio[1]	95% CI	
Severe Financial Strain (Yes vs No)	0.54	0.40	0.73
Severe Social Isolation (Yes vs No)	0.52	0.38	0.71
Severe Food Insecurity (Yes vs No)	0.41	0.27	0.62
Severe Housing Instability (Yes vs No)	0.74	0.52	1.06
Severe Transportation Issue (Yes vs No)	0.33	0.18	0.61
Any Severe Social Need (Yes vs No)	0.54	0.42	0.70

[1] Receipt of colon cancer screening adjusted for age, neighborhood deprivation index, sex, DxCG risk score, race/ethnicity, primary spoken language, insurance type.

6569 **Poster Session**

Profile of toxicities and quality of life in long-term survivors treated with immunotherapy: A prospective cross sectional trial.

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Background: Long-term cancer survivors (LTS) patients (pts) treated with immunotherapy (IT) represent a relatively new population whose characteristics, such as long-term toxicities, quality of life (QoL), and financial toxicities, need to be elucidated in a real-world setting. The aim of this study is to evaluate long-term toxicities in patients free of disease progression and treated with IT. **Methods:** This is a cross-sectional, multicentric study, involving ten Italian centres. Pts should have started IT (as monotherapy or combination, either in curative or adjuvant setting) more than 2 years before accrual and they needed to be progression free at last follow up (fup). Subjects who discontinued IT for disease progression or who started any subsequent line of systemic treatment were excluded. We retrieved baseline demographic and clinical characteristics of the pts, as well as haematological and biochemical exams at the start of IT (baseline) and at the last fup. We also assessed the patient's toxicities (according to CTCAE v5.0) at last fup and we submitted to each patient three questionnaires: PRO-CTCAE (selection of questions), EORTC QLQ C30, and FITALY (for financial toxicities), which were analysed according to subdomains. **Results:** We enrolled 141 LTS pts treated with IT from 2013 to 2022. Median age was 69 years (35-88), most were male (72%), and still receiving IT at time of last fup (72%). Primary tumour was in lung (43%), genito-urinary tract (26%), or melanoma (14%). IT included pembrolizumab and nivolumab in 40% and 32% of cases, respectively. The median global health status of QoL was 83 (IQR 25). Any toxicities $>$ G2 negatively impacted on individual functional scales (physical, p=0.02; role, p= 0.06; and social p=0.08). A higher baseline Charlson Comorbidity Index was associated with worse global health status (p=0.02) at last fup. Most frequent low grade adverse events were fatigue, dyspnoea, and insomnia; younger age ($<$ 65 years) was associated with higher pain (p=0.04). PRO-CTCAE questionnaires showed that the prevalent complained symptoms were rheumatological and cutaneous, regardless of tumor site. The most affected domain of financial toxicities was financial stress, including costs for out of pocket medications and transports. Pts with melanoma (p=0.01), with skin toxicities (p=0.04), and younger than 65 years (p=0.01) were at higher risk of financial toxicities (global score). **Conclusions:** Overall QoL is well preserved in LTS treated with IT. At long term fup, the pts complained mostly about rheumatological and skin adverse events. Financial stress due to out of pocket costs was the most affected financial toxicity domain. Baseline comorbidities predicted a worse long-term global health status, while young age, skin toxicities and melanoma predicted higher financial toxicities. Research Sponsor: ASCAPE Grant.

6570 **Poster Session**

Multimodal interventions targeting identified barriers to improve lung cancer screening in northeast Georgia.

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Background: Lung cancer is the leading cause of cancer deaths with over 50% of patients diagnosed at an advanced stage. Lung cancer screening (LCS) guidelines were recently updated in 2021, which expanded the age group and reduced the pack years, and thereby increased eligibility. However, the underutilization of low dose computed tomography (LDCT) scans is seen nationwide. In 2015, the National Health Interview Survey found that only 3.9% of eligible adults underwent LCS. The barriers for LCS identified in national literature included failure of electronic medical records (EMR) to notify providers of eligible patients, lack of insurance coverage, patient refusal, and lack of patient and provider awareness. This quality improvement project was performed to improve LCS in primary care clinics (graduate medical education [GME] and non-GME) at a tertiary medical center in northeast Georgia by addressing these barriers. **Methods:** In GME clinics, the goal was to double LDCT scans from 14 to 28 monthly. In non-GME clinics, the goal was to increase LDCT scans by at least 50% from 28 to 42 weekly. LDCT scans performed between January 1st to May 31st 2022 was used as baseline data. The interventions spanned over six months, from June 1st to November 30th 2022. Multimodal interventions were used to target various barriers. Accurate tobacco history in the EMR was improved by participating in the nationwide Just Ask Campaign. Flyers posted in clinics provided information on current guidelines and a QR code for patients to determine their LCS eligibility. Provider reference guides highlighted LCS guidelines and billing codes. Community events and social media were used to spread LCS awareness. **Results:** During the implementation phase, the average monthly LDCT scans increased to 23 scans in GME clinics and 40 scans weekly in non-GME clinics. In GME clinics, the goal of 28 scans monthly was achieved in one out of six months. In non-GME clinics, the goal of 42 scans weekly was surpassed in four out of six months. The Long-Range Acoustic Device (L-RAD) scoring system helped diagnose three cancers in the GME clinics and about one cancer for every 10 L-RAD4 in non-GME clinics. The baseline period LDCT scans of 78 (GME) and 656 (non-GME) increased to 177 (GME) and 1109 (non-GME) during the intervention period. **Conclusions:** This multimodal approach in addressing known barriers to increase LCS across primary care clinics in a single healthcare system is feasible and was associated with short-term improvements. Although the targets were not met every month, there was a notable improvement during the intervention period. A major limitation was the inability to determine which intervention had the greatest impact. A newly identified barrier was the lack of follow up scans being ordered by providers. This project demonstrates the potential to increase LCS using a multimodal approach, which can be implemented in similar healthcare systems. Research Sponsor: None.

6571 **Poster Session**

Just ASK: A quality improvement project to enhance smoking assessment and treatment.

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Background: Persistent smoking after cancer diagnosis causes adverse clinical outcomes. ASCO and other organizations view smoking assessment and treatment as indicators of high-quality cancer care. Yet, adoption of clinical practice guidelines like the 3As (Ask, Advise and Assist) for smoking assessment and treatment has been slow and inconsistent in cancer care settings. **Methods:** Led by the American College of Surgeons Cancer Programs' Commission on Cancer (CoC) and National Accreditation Program for Breast Centers (NAPBC), the "Just ASK" national quality improvement project focuses on enhancing smoking assessment and treatment in cancer care settings. All CoC/NAPBC programs (n~2000) were invited to participate, which consisted of educational webinars, online resources, and 3 online surveys (baseline, 6- and 12-month) collecting information on smoking assessment and treatment practices, plus other variables (e.g., organizational priority, implementation barriers). Program participation was incentivized by fulfillment of accreditation standards. **Results:** In total, 776 programs (731 CoC, 45 NAPBC), participated. At baseline, most programs strongly endorsed the importance of addressing smoking within cancer care and the majority of programs reported routinely assessing smoking (90%) and advising all patients reporting current smoking to quit (71%). However, routine delivery of evidence-based smoking cessation assistance (e.g., quitline referral, cessation medications, counseling services) was low (all $<$ 30%). Program retention was excellent (91%). As shown in the table, the 12-month follow-up revealed marked improvements in evidence-based Ask, Advise and Assist, practices. **Conclusions:** At enrollment, the importance of addressing smoking was evident and high rates of smoking assessment were reported. At 12-month follow-up, marked improvement was reported in all quality indicators of the 3As. These findings guided the sharing of strategies for improving patient assessment, clinical workflow and documentation. Suboptimal delivery of smoking cessation assistance persisted despite overall improvements, which highlight persistent challenges and opportunities for implementing smoking assessment and treatment in cancer care settings. Research Sponsor: U.S. National Institutes of Health.

Assessment and Treatment Practices	Baseline (n=776) Always or Usually	12-month follow up (n=703) Always or Usually
Ask patients about smoking	696 (90%)	690 (98%)
Advise patients to quit smoking	553 (71%)	588 (84%)
Assist patients in quitting	323 (42%)	424 (60%)
Provide self-help information	209 (27%)	395 (56%)
Refer patients to Quitline	219 (28%)	367 (52%)
Refer patients to tobacco treatment specialist in cancer program	204 (26%)	289 (41%)
Provide individual counseling in person	141 (18%)	190 (27%)
Prescribe FDA approved cessation medications	136 (18%)	179 (25%)

6572 **Poster Session**

Use of germline testing in patients with prostate, pancreatic, or ovarian cancer in Washington (WA) state.

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Background: Germline genetic mutations are seen in approximately 10-15% of patients with prostate, pancreatic, and ovarian cancer. While universal germline testing is recommended for patients with these cancers to inform both familial risk and therapeutic approach, underutilization of germline testing has been reported. We investigated the rates of and factors associated with germline testing in a population-based sample of patients with prostate, pancreatic, and ovarian cancer in WA state. **Methods:** We linked Washington state cancer registry records from 2017-2019 with claims records for two large commercial insurers, Medicare, and Medicaid. Patients with prostate (metastatic, regional node-positive, or high-risk localized), pancreatic, and ovarian (including fallopian tube and peritoneum) cancer who were diagnosed in 2017-2019 were identified. Using claims from this database, we identified patients who received germline testing in the first two years of diagnosis. We excluded those who were not continuously enrolled in a health plan during the testing period of interest or died within 3 months of diagnosis. We used a multivariate logistic regression model to investigate factors associated with germline testing. **Results:** Among 2,077 patients, 429 (20.7%) received germline testing. Testing rates were 6.3% (53 of 842 patients) in prostate cancer, 15.4% (118 of 765 patients) in pancreas cancer, and to 54.9% (258 of 470 patients) in ovarian cancer; median time to testing for prostate, pancreas, and ovarian cancer was 162, 133, and 64 days respectively. Testing rates were higher in later years, in patients with more advanced stage cancers and lower in Asian patients and patients with more comorbid conditions. **Conclusions:** Despite guideline recommendations, germline testing rates are low among cancer patients in WA state, with the lowest rates in prostate cancer patients and in Asian and higher comorbidity populations. Underutilization of germline testing may not only adversely affect treatment, but also represents a missed opportunity for testing of high-risk families. Further studies should identify and address barriers to germline testing in high-risk populations. Research Sponsor: Fred Hutchinson Cancer Center.

Factor [Only significant factors shown]	Odds Ratio	95% CI Lower	95% CI Upper	p-value
Asian (ref = White)	0.50	0.28	0.90	0.02
Dx year 2019 (ref = 2017)	1.77	1.29	2.44	0.00
Pancreas (ref = Ovary)	0.15	0.11	0.20	<.0001
Prostate (ref = Ovary)	0.04	0.02	0.05	<.0001
AJCC Stage 2 (ref = 0 and 1)	2.53	1.36	4.71	0.00
AJCC Stage 3 (ref = 0 and 1)	2.63	1.61	4.30	0.00
AJCC Stage 4 (ref = 0 and 1)	3.35	2.04	5.52	<.0001
Comorbidity Score 2+ (ref = 0)	0.56	0.40	0.78	0.00

6573 **Poster Session**

Reporting of patient reported outcomes in randomized clinical trials (RCTs) in non-small cell lung cancer (NSCLC) patients (pts).

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Background: A patient-centric approach to clinical trials has become necessary, with regulators emphasizing the importance of pts' experience. PRO is of utmost relevance for pts with cancers such as NSCLC, that are likely to be highly symptomatic and/or with an unfavorable prognosis. **Methods:** To evaluate the rate at which PRO included in clinical trials are made publicly available when trial results are published, we searched Citeline Trialtrove, a registry of clinical trials, for NSCLC phase 3 RCTs, recruiting during 2017-2022, with PRO listed - regardless of publication type. We excluded supportive care, radiotherapy, and unpublished trials. We identified publications associated with the trial, and extracted various parameters, including if PRO outcome was published. **Results:** Of 122 NSCLC RCTs identified, 66 listed at least 1 PRO. Trials were reported as full-text (43), abstract (9), 1 only in a trials registry; 13 not published. Fifty-three trials were included, all had PRO as a secondary endpoint. The sponsor was industry in the majority of the trials. Most included stage III/IV NSCLC pts, and $1^{st}/2^{nd}$ line or maintenance. 24 PRO tools were used, mainly EORTC QLQ LC13 (35 trials), EORTC QLQ C30 (34), EQ-5D-5L (14), LCSS (8), EQ-5D-3L (6). Seven trials listed 1 tool, 26 listed 2, 18 listed >3. PRO was reported in 36 (68%) of the published trials. In the subgroup of trials with disease control (DC) benefit and no overall survival (OS) benefit, PRO was reported in 15/21 (71%) trials. PRO benefit was shown in 9 of them. Of 43/53 trials published as full-text, 31 (72%) had PRO reported. A benefit in at least 1 PRO tool was reported in 21 studies, 9 did not show a PRO benefit; in 5 trials, only descriptive and no comparative analysis of PRO was reported. Of the 21 trials with PRO benefit, 19 had a DC benefit and 10 had also OS benefit. PRO was reported together with the first reporting of other outcomes in 18 (50%) trials, and after 7-32 months after the initial one in 18 trials. **Conclusions:** Of 122 RCTs only 66 had at least 1 planned PRO, and only 35 had it published. Even where full-text was available or no OS benefit shown, about 1/3 of the trials did not report PRO. Characteristics as disease stage, therapy line, sponsor, and primary endpoint did not differ between all included trials and those reporting PRO. The reporting rate increased compared to our previous report yet it is not satisfactory. The importance of quality of life and pts centric outcomes, and the great efforts needed from pts and operators to collect the data, should translate into routine, timely and appropriate reporting of PRO to allow a thorough assessment of treatment effect. Research Sponsor: None.

		All N (%)	PRO reported N (%)
		53	36
Stage III/IV		47 (89)	32 (89)
$1^{st}/2^{nd}$ line or maintenance		37 (70)	26 (72)
Sponsor	Industry	45 (85)	30 (84)
	Industry-academic	3 (6)	3 (8)
	Academic	5 (9)	3 (8)
Primary endpoint	OS	28 (53)	19 (53)
	DC - OS	12 (23)	7 (19)
	DC	36 (68)	24 (67)

6574 **Poster Session**

Incidence of infusion related reactions of daratumumab-hyaluronidase-fihj: Pre-post intervention study of premedication omission.

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Background: Daratumumab-hyaluronidase-fihj subcutaneous (Dara-SQ) is utilized frequently in the treatment of newly diagnosed and relapsed/refractory multiple myeloma (MM). Initially approved as an intravenous formulation, daratumumab (Dara-IV) showed significant infusion related reactions (IRRs), requiring premedication (acetaminophen, diphenhydramine, dexamethasone, and some add montelukast) prior to each dose. Dara-SQ was shown to be noninferior to Dara-IV with significantly fewer IRRs. Despite the reduced IRR risk, indefinite premedication is also recommended in the package insert for Dara-SQ. Given that IRRs are rare after the first dose of Dara-SQ and premedication extends the time for patients in an infusion center, we investigated whether premedication may be safely omitted after the first cycle. **Methods:** This pre-post interventional quality improvement study included all patients aged 18 years or older diagnosed with MM or amyloidosis that received at least one dose of Dara-SQ between July 1st, 2020 – December 31st, 2022. Omission of premedication (excluding dexamethasone) after four doses of Dara-SQ was introduced June 1st, 2022. The pre-interventional arm followed standard of care with premedication continued (Arm 1) and post-interventional arm included patients with premedication omitted after fourth dose (Arm 2). Patient demographics, prior therapy, Dara-IV exposure, and premedication usage were collected to evaluate the primary endpoint: incidence of IRR after premedication omission. Secondary analysis included any IRR prior to intervention, timing of reaction, reaction management, and post-reaction management. **Results:** A total of 102 patients (63 in Arm 1 and 39 in Arm 2) were included in the study, with a median age of 69 (38-86) years old; 52% African American and 54% male. IRR prior to fourth dose occurred in 1.6% (1/63) for Arm 1 vs. 5.1% (2/39) for Arm 2 [p= 0.6], Dara-IV exposure was 52.4% (33/63) in Arm 1 vs. 10.2% (4/39) in Arm 2 [p= 0.02], and indication was newly diagnosed MM in 21% (13/63) of Arm 1 vs. 41% (16/39) of Arm 2 [p= 0.03]. For the primary objective, there were zero reactions in both arms. All three reactions prior to fourth dose occurred after the first dose of Dara-SQ, with a median time to reaction of 4.8 hours. These were all grade 2 per CTCAE v5.0, with all patients discharged home after reaction, and all patients received subsequent Dara-SQ without issues. For the two reactions prior to fourth dose in Arm 2, premedication was omitted after 6 doses in one patient and 8 doses in the other with no further issues on subsequent doses. Estimated therapy time saved was 194 hours, with an estimated savings of $145,500 thus far. **Conclusions:** IRRs to Dara-SQ occur early, are rare, and mild in course. Omitting premedication after a minimum of four Dara-SQ doses is safe and carries substantial time savings for patients and infusion centers. Research Sponsor: None.

6575 **Poster Session**

Machine learning and postoperative complications: Determining risk before surgery in patients with cancer.

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Background: In patients with advanced cancer who need unplanned surgery, shared decision making is complex. Surgical risk assessment with high accuracy and in real time may help improve prediction of postoperative outcomes. We previously trained and tested an explainable machine learning model (MLM) to estimate postoperative Clavien-Dindo grade 3 or higher (CD 3+) complication risk in cancer inpatients undergoing unplanned surgery. In this prospective validation study, we report the performance of the MLM Surgical Risk Score (SRS) in the prediction of postoperative outcomes as well as determine association of the risk score with hospital length of stay and mortality. **Methods:** A MLM SRS for cancer inpatients requiring an unplanned, same-hospitalization major surgery was generated using real-time patient specific EHR data. The SRS was integrated into surgeon preoperative workflow. Postoperative outcomes including complications, length of hospital stay, and 30-day mortality were reported. The SRS was dichotomized as high or low based on prior validation threshold for postoperative CD3+ complication development. Model performance was assessed with area under receiver operating characteristic (AUROC) and area under precision-recall curves (AUPRC). Differences in outcomes between high and low-risk SRS groups were studied using Mann-Whitney U test and Fisher's exact test. **Results:** During the study period, 135 cancer inpatients were assessed by surgeons for 166 major unplanned operations. Of the 166 operations, 126 were completed and 40 were cancelled. The SRS was high in 81 (49%) and low in 85 (51%). The most common cancer diagnosis was colorectal (n=39, 28.8%). Operations performed with the highest frequencies were for enteral access (e.g.gastrostomy) followed by exploratory laparotomy and enterectomy. CD 3+ complications were identified in 31% of the completed operations (n=39/126) and included death (n = 10); abscess (n=4); postoperative hemorrhage (n=3); and anastomotic leak (n=2)**.** The SRS predicted CD 3+ complications with a precision of47% and recall of 73%, resulting in an AUROC of 0.75 and AUPRC of 0.58. When comparing patients with high-risk to low-risk SRS, median overall LOS was 10 vs 7 days (p=0.013), median LOS after operation was 9 vs 6 days (p=0.003), 30-day mortality was 19.0% vs 5.3% (p=0.015), and 30-day postoperative mortality was 13.2% vs 3.3% (p=0.04). **Conclusions:** In this prospective study, preoperative SRS generated from a trained MLM on real-time EHR data demonstrated an excellent ability to predict individual risk of postoperative complications. In addition, patients with high SRS have longer postoperative LOS and increased mortality. By improving discrimination of risk of postoperative complications and informing on treatment outcomes, integration of the MLM SRS into the consenting process may enable better informed decision making in cancer inpatients. Research Sponsor: None.

6576 **Poster Session**

Data driven insights from multiple OCM practices to optimize care for managing high-risk cancer patients across multiple cancer types.

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Background: Medicare's Oncology Care Model (OCM) aims to improve the quality and coordination of care for cancer patients. Previously, Integra Connect (IC) developed machine learning (ML) based risk prediction models called Integra Predict (IP) for In-Patient Admissions, Emergency Department Visits and End-of-Life in active chemotherapy patients within the next six months. The patients were risk-stratified with the purpose of optimizing clinical resources utilization. Our objective is to demonstrate the insights derived from an updated IP version applied to OCM patients from three IC network practices: P_1 (a multi-state network of community oncology practices), P_2 (a single site community oncology practice) and P_3 (a regional network of oncology practices connected to academic medical institution). **Methods:** For training the ML models, 90,417 OCM reconciliation episodes from PP4–PP8 (Jan. 2018-June 2020) from 10 distinct IC practices were used. The models comprise 37 features: 12 adverse events (within last 6 month of episode start date), 7 comorbidities (in the past irrespective of lookback period), 7 latest vital sign measurements recorded within 30 days of date of prediction, 11 demographic and other clinical attributes. Based on LogLoss, 54 ML experiments were performed leading to three best algorithms to predict the risk for In-Patient Admissions, Emergency Department Visits and End of Life. To generalize our ML approach, we leveraged an additional holdout dataset in periods PP9 and PP10 (July 2020 - June 2021) pertaining to practices P_1, P_2 and P_3 with 6378, 973 and 5921 episodes, respectively. Matthew Correlation Coefficient (MCC) was chosen as the metric to test the generalizability of the models. For each model, the variance of MCC was then computed. To uncover secondary factors influencing clinical care, top-3 frequently reported adverse events and top-5 comorbidities were determined. **Results:** For each ML model, the variance of MCC applied to the holdout dataset was low (order of 10^{-4}). Types of cancers reported differed within P_1, P_2 and P_3. However, across these practices, irrespective of the cancer type, the most frequently reported adverse events (pain, anemia, and cachexia) and comorbidities (cardiovascular disease, chronic pulmonary disease, dyspnea at rest, dorsopathies and renal disease or failure) observed were the same. **Conclusions:** Low variance in MCC implies ML models are applicable to different types of community oncology practices. A care coordination program for high-risk cancer patients involving the monitoring of pain, cachexia and anemia can lead to optimal utilization of clinical resources within these practices. Program expansion involving optimal management of comorbidities such as cardiovascular disease, chronic pulmonary disease, diabetes, dyspnea at rest and renal disease or failure may yield additional benefits. Research Sponsor: Employer (Integra Connect) sponsored.

6577 **Poster Session**

Palliative care consultation and end-of-life outcomes in a retrospective cohort of patients treated with immune checkpoint inhibitors.

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Background: Immune checkpoint inhibitors (ICI) can prolong survival for various cancers and are generally available as treatment options for most patients because of their favorable adverse effect profile. Although ICIs provide treatment for many patients who would otherwise be out of options, their variable and often delayed efficacy may postpone the de-escalation of care at the end of life. Palliative Care consultation (PCC) is well-established among patients receiving cytotoxic chemotherapy, but its effectiveness is less certain among patients receiving newer treatment modalities. We aimed to test the association of PCC with end-of-life (EOL) outcomes among patients treated with an ICI for any type of cancer. **Methods:** We created a retrospective registry of all patients who received at least one dose of ICI for any indication between 2/1/2011 and 4/7/2022 at a comprehensive cancer center and its outreach clinics. The investigators created a secure, cloud-based registry (REDCap), validated it with data quality rules, and resolved all discrepancies; clinical research specialists at Vasta Global captured most of the data. We used the chi-square test to compare categorical variables, defined statistical significance as $p < 0.05$, and used SAS version 9.4 for analyses. The study had institutional IRB approval. **Results:** The cohort consisted of 3,142 patients with lung cancer (45%) as the most common cancer type, followed by melanoma (14%) and head and neck squamous cell carcinoma (9%). ICI was most often given in the first line setting (46%) with good baseline performance status (ECOG 0-1, 50%). 915 (29%) patients had PCC, which was associated with a higher rate of code status de-escalation from "Full Code" at any point before death (92% vs. 87%, p 0.007). There was no association between PCC and either the initiation of ICI within 30 days of death (7% vs. 5%, p .0172) or any dose of ICI within 14 days of death (5% vs. 6%, p 0.33). Among patients with a confirmed location of death (1013, 32%), PCC was associated with a similar rate of death in the hospital at any level of care (30% vs. 28%, p 0.51). **Conclusions:** PCC was associated with code status de-escalation before death but similar risks of late ICI dosing or inpatient status at the time of death. Further studies are needed to risk-stratify patients starting ICI to identify the subgroups that would benefit the most from PCC. Research Sponsor: U.S. National Institutes of Health.

6578 **Poster Session**

Mortality among oncology patients with multiple unplanned hospital admissions.

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Background: Previous work has shown that patients with solid tumors with an unplanned hospital admission have a median overall survival of approximately six months, and readmission rates are high within this patient population, especially near the end of life. However, the relationship between multiple unplanned hospital admissions and survival and whether patient characteristics are associated with differences in survival have not been studied in this patient population. **Methods:** We recorded all hospital admissions to an inpatient oncology unit for patients with solid tumors from October 1, 2021, through September 30, 2022 and categorized admissions as planned (chemotherapy administration or desensitization) or unplanned. For all unplanned admissions we reviewed the electronic health record for unplanned admissions in the previous six months. For patients with one or more prior unplanned admission, we captured demographics, admitting diagnosis, discharge disposition, and vital status including date of death. We examined median overall survival for patients with two unplanned hospital admissions within six months, median survival for patients with three or more unplanned hospital admissions within six months and 90-day survival in patients with two or more unplanned admission. We also used multivariate Cox proportional hazards models to evaluate whether patient demographics, cancer type, and hospital length of stay were associated with differences in survival. **Results:** There were 1,561 unplanned admissions during the period of analysis. Of these admissions, 692 (44%) were preceded by at least one unplanned admission within the prior six months. A total of 400 patients had two or more admissions. Forty-five percent of readmitted patients had a diagnosis of gastrointestinal malignancy. Median overall survival for patients after a second unplanned admission was 76 days (95% CI 60 - 110), and median overall survival after a third unplanned admission was 50 days (95% CI 35 - 99). Median overall survival was 49 days (95% CI 39 - 67) for readmitted patients with a length of stay of at least seven days. Ninety-day survival was 45% (95% CI 39 – 51) among patients with two admissions and 34% (95% CI 26 – 43) among patients with three or more admissions. In multivariable models, longer length of stay was associated with decreased survival (HR 1.03, 95% CI 1.01-1.05). Age and sex were not associated with differences in survival, and overall survival was similar across all disease groups except head and neck, which was associated with improved survival (HR 0.42, 95% CI 0.21-0.85). **Conclusions:** Patients with solid tumors with multiple unplanned hospital admissions in less than six months represent a distinct population with exceptionally poor outcomes, regardless of the primary tumor site and patient demographics. This easily identifiable population may benefit from targeted interventions to improve the quality of end-of-life care. Research Sponsor: U.S. National Institutes of Health.

6579 **Poster Session**

Use of statistical process control charts to identify impactful implementation strategies for an ePRO-based symptom management program across the SIMPRO Consortium.

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Background: Collecting electronic patient reported outcomes (ePROs) reduces the burden of cancer and prevents acute care hospitalizations. However, broad implementation in the routine care setting remains challenging, partly because the optimal implementation strategies – actions that are most likely to encourage adoption and use – are not known. Since 2019, the SIMPRO Consortium has deployed an ePRO-based symptom management program (eSyM) across 6 community-based cancer centers. **Methods:** We used statistical process control (SPC) charts to identify variation due to special versus common causes (random variation) for one key performance indicator (KPI) – the weekly ePROs response rate. All 6 SIMPRO sites contributed data for this analysis: 3 for chemotherapy patients and 3 for surgery patients. Sites had to have at least 18 months of KPI data; information from the first 4 months after eSyM rollout were excluded to account for program ramp-up. The KPI was calculated as the number of patients who submitted an ePRO questionnaire divided by the number eligible to submit a questionnaire each week. The upper and lower confidence limits were set at +/- 2 sigma to allow for 95% of observations to fall within the limits. Three rules were applied to identify special cause variation: 1) astronomical points (outside sigma limits), 2) shifts (8 or more points above or below a center line), and 3) trends (6 or more points consecutively ascending or descending). Implementation strategies that mapped to special cause variations were selected as those most likely to impact the KPI. **Results:** Across the 6 sites that deployed eSyM, the mean KPI performance ranged from 19.7%-35.7%. SPC charts detected multiple special cause variations in the KPI at all 6 sites, though the patterns varied by site. All sites demonstrated positive and negative astronomical variations as well as positive and negative shifts. Three sites demonstrated negative trends; no sites demonstrated positive trends. Direct patient outreach was the implementation strategy most frequently associated with special cause variation, followed by changes in promoting the ePRO program to clinical staff. Positive changes were associated with strategy initiation; negative changes were associated with strategy discontinuation. **Conclusions:** Applying SPC charts to a KPI from the eSyM deployment highlighted the effect of personal communication with patients and providers, suggesting that these implementation strategies could offer value to other sites deploying eSyM. The absence of positive trends early in eSyM program deployment underscores the need to identify better implementation strategies and allocate more resources to foster program adoption and sustainability. Applying SPCs to other KPIs, such as symptom severity and healthcare utilization, could improve eSyM deployment and impact. Research Sponsor: U.S. National Institutes of Health.

6580 **Poster Session**

The association between systemic anticancer therapy (SACT) at the end of life (EOL) and acute care use among patients treated at oncology practices participating in the Oncology Care Model (OCM).

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Background: Receipt of chemotherapy near EOL has been shown to harm patient and caregiver experience, increase hospitalizations, intensive care unit (ICU) and emergency department (ED) use and drive-up costs. As rates of chemotherapy at EOL have declined, we have seen increases in the rates of immunotherapy at EOL. It is unknown whether use of EOL immunotherapy is associated with the same pattern of higher downstream acute care use and cost. Using data from OCM, a Centers for Medicare and Medicaid Services (CMS) alternative payment model, we evaluated the relationship between SACT type and acute care utilization within 30 days of death. **Methods:** Using anonymized Integra Connect data for OCM episode claims attributed to 8 multi-site OCM practices between July 2016 and December 2021, we stratified patients by SACT type received within 30 days of death (immunotherapy (IO), chemotherapy (CT), or none) and used chi-square tests to compare the proportion of decedents who had inpatient admission, ICU stay, ED visits without inpatient admission, and hospice use within 30 days of death. **Results:** Among 14,169 OCM decedents, 2,227 (15.7%) received IO within 30 days of death, 6,627 (46.8%) received CT and 5,315 (37.5%) received no SACT (table). Patients who received no SACT at EOL were significantly more likely to start hospice within 30 days of death (76%) and to be in hospice for $\geq$3 days prior to death (61%) compared with IO (65% and 40%) and CT patients (59% and 37%) respectively (all p-values$<$0.05). Patients who received IO or CT were significantly more likely to have an inpatient stay within 30 days of death (66% and 68% respectively) compared with patients who received no SACT at EOL (58%, p-values $<$0.001). No difference in ED visits within 30 days of death between IO (18%), CT (20%), and no SACT (19%) p $<$ 0.270. **Conclusions:** Patients who received chemotherapy or IO therapy within 30 days of death had higher proportion of inpatient admissions, ICU stay and lower rates of hospice than patients who received no SACT at the EOL. Patients who did not have any SACT at EOL were more likely to utilize hospice services and for a longer time. Further research should explore whether these findings are generalizable to patients outside of OCM and the magnitude of costs associated with these acute care metrics. Research Sponsor: None.

Acute care and hospice utilization within 30 days of death by SACT treatment within 30 days.

	IO 2,227		CHEMO 6,627		NO SACT 5,315		
	N	%	N	%	N	%	p-value
ICU	**869**	39.0	**2700**	40.7	**1667**	31.4	$<$ 0.01
Inpatient	**1475**	66.2	**4538**	68.5	**3065**	57.7	$<$ 0.01
ED	**408**	18.3	**1310**	19.7	**1009**	19.0	0.270
Hospice started	**1444**	64.8	**3895**	58.8	**4033**	75.9	$<$ 0.01
Hospice for ≥ 3 days	**898**	40.3	**2487**	37.4	**3228**	60.7	$<$ 0.01

6581 **Poster Session**

Real-world program-based lung cancer care.

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Background: Low dose CT screening (LDCT) and lung nodule programs (LNP) promote early lung cancer detection, improve survival; Multidisciplinary Care Programs (MDC) promote guideline-concordance. The impact of such program-based care on 'real-world' population-level lung cancer survival and mortality is uncertain. We evaluated program-based lung cancer care versus care outside structured programs in a large community healthcare system. **Methods:** We linked prospective observational databases for LDCT, LNP and MDC with the Tumor Registry of Baptist Cancer Center facilities across Mississippi, Arkansas and Tennessee, categorizing all lung cancer patients between 2011 and 2021, according to program- (LDCT, LNP, MDC) versus non-program-based care. We compared stage distribution, care patterns, survival and mortality by standard statistical methods. **Results:** Of 12,089 patients, 250 (2%), 1236 (10%), 1045 (7%) and 9558 (79%) were diagnosed through the LDCT, LNP, MDC or no program, respectively; non-program-based care sequentially diminished from 96% in 2011 to 67% in 2021, diagnosis through LDCT increased from 0.3% to 7%, LNP from 0.9% to 21%; and MDC alone decreased from a high of 13% in 2015 to 5% in 2021. Black persons, 28% of the whole cohort, were 13% of LDCT, 25% of LNP, 31% of MDC, and 28% of non-program-based care recipients ($p = 0.0005$). Median (IQR) tumor size was 20mm (13 – 34), 25mm (17 – 44), 35mm (20 – 55) and 35mm (20 – 55), respectively ($p < 0.0001$); 40-46% of patients across programs had adenocarcinoma; clinical stage was I or II in 58%, 48%, 38% and 29% and IV in 16%, 27%, 31% and 42% in the respective programs ($p < 0.0001$). 2609 patients (21.6%) had surgery, including 49.2%, 37.7%, 36.1% and 17.2% in LDCT, LNP, MDC and non-program-based care respectively, among whom aggregate pathologic stage was I in 76%, 71%, 54% and 60% ($p = 0.0005$). Surgery was the sole treatment modality in 27.6%, 21.5%, 12.9% and 10.6%, respectively ($p < 0.0001$). Despite higher proportions with more advanced pathologic stage, 30.8% of recipients of non-program-based care received adjuvant therapy, compared to 42% among recipients of program-based care, including 39.0%, 37.1% and 49.3% in LDCT, LNP and MDC, respectively ($p < 0.0001$); 8.7% of patients in programs received no treatment, compared to 20.1% of non-program-based care. Aggregate 5-year overall survival rates were 60% (95% CI: 52% - 69%), 45% (95% CI: 42% - 49%), 30% (95% CI: 27% - 33%), and 18% (95% CI: 17% - 19%), respectively ($p < 0.0001$). Adjusting for age, sex, race, patient-level rurality and histology, with non-program-based care as reference, the aHR were 0.3 (95% CI: 0.234 – 0.373), 0.51 (95% CI: 0.464 – 0.556, and 0.66(95% CI: 0.607 – 0.712). Results were consistent even without patients who received no treatment. **Conclusions:** Program-based care was associated with more favorable lung cancer characteristics, better quality of care and survival. Disseminating program-based care should be explored as a matter of urgent public policy. Research Sponsor: Baptist Memorial Health Care Foundation for initial funding support: Grant # 15BD03.

6582 **Poster Session**

Proportion of patients in phase I solid tumor oncology trials receiving treatments that are clinically efficacious.

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Background: Phase I trials are frequently regarded as possessing therapeutic intent by patients, oncologists, and governing medical bodies alike. While obtaining initial observations of clinical activity of investigational agents is an aim of phase I trials, such estimates utilize surrogate measures, such as objective response rate, which are difficult to conceptualize and less meaningful to a vulnerable patient population compared to clinical endpoints. Furthermore, phase I studies lack a comparator arm. To date, there are no published estimates of the probability a phase I solid tumor participant receives a treatment at a dose that has greater clinical efficacy than the standard of care for their disease setting. Such data is required to enable fully informed decisions around consent. **Methods:** A random sample of 1000 phase I solid tumor oncology trials conducted world-wide, initiated between 2007 and 2012, and enrolling 29,953 patients was obtained from 2223 eligible trials on ClinicalTrials.gov. ClinicalTrials.-gov, PubMed, Embase, Medline, and ASCO reports were queried between December 1, 2022 and February 1, 2023 for randomized, controlled phase III trials testing the same regimen and indication as that used in each phase I trial. Phase III trials were considered positive if they demonstrated statistically significant superiority over an acceptable standard of care at the time of enrolment of the corresponding phase I trial with respect to overall survival, health related quality of life, or a validated surrogate for these clinical endpoints. All statistical tests were 2-sided. **Results:** A total of 0.82% (245) phase I trial patients received a treatment at a dose that was subsequently demonstrated in a randomized, controlled phase III trial to have statistically superior clinical efficacy over an acceptable standard of care at the time of phase I trial enrolment for the same disease setting. The mean objective response rate for both published and unpublished sampled phase I trials in the advanced or metastatic setting was 4.2%. Meta-regression showed a statistically significantly greater proportion of patients receiving a clinically efficacious therapy in biomarker trials (rate ratio = 3.78., 95% CI = 1.15 – 10.24, P = 0.02) and trials with an expansion cohort (rate ratio = 3.12, 95% CI = 1.05 – 8.89, P = 0.03). Proportions were statistically significantly lower for first in class treatments (rate ratio = 0.21, 95% CI = 0.03 – 0.76, P = 0.03). **Conclusions:** One in 122 patients in phase I solid tumor trials received a treatment that subsequently demonstrated superior clinical efficacy over the standard of care at the time of phase I trial enrolment. Considering published estimates of serious adverse events rates of 10-19%, this reveals low therapeutic value for phase I trial participation. Research Sponsor: None.

6583 **Poster Session**

The association of HIV and other risk factors with triple-negative breast cancer in South African women.

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Background: Breast cancer (BC) mortality in South Africa (SA) is double that of the United States. The aggressive triple-negative breast cancer (TNBC) subtype comprises 20.9% of BC cases among Black women in Southern Africa. SA has the second highest HIV prevalence worldwide, but if and how HIV affects the risk of developing TNBC is not well understood. **Methods:** Using the South African Breast Cancer and HIV Outcomes (SABCHO) prospective cohort of newly diagnosed BC patients from six public hospitals in SA, we evaluated the association of HIV with risk of TNBC relative to other BC subtypes. We developed multivariable logistic regression models to test for this association while adjusting for key demographic and reproductive risk factors. **Results:** Of 3,883 women with BC, 16.4% had TNBC and 23.0% were HIV-positive. The overall median age of BC diagnosis was 55 years. Among HIV positive patients, the median age of BC diagnosis was 45 years, without a difference between TNBC and non-TNBC cases ($p = 0.244$). Only 7.2% of women were nulliparous (4.6% in TNBC and 7.6% in non-TNBC subgroups). Of women who had at least 1 full-term pregnancy, 11.2% did not breastfeed, without a difference between TNBC and non-TNBC cases ($p = 0.292$). In our final multivariable logistic regression model, HIV-positive status was associated with increased risk of TNBC relative to non-TNBC (OR: 1.40; 95% CI: 1.12-1.74, compared to HIV-negative with BC). Parity without breastfeeding was also associated with increased risk of TNBC relative to non-TNBC (OR: 1.72; 95% CI: 1.07-2.84, compared to nulliparous with BC). HIV status and the combined parity/breastfeeding variable had no statistically significant interaction. In exploratory analyses, measures of HIV control at time of BC diagnosis were not associated with BC subtype. **Conclusions:** In this large prospective case-only study conducted in SA, we found that women living with HIV were more likely than HIV-negative women to have TNBC (relative to other BC subtypes), regardless of the extent of HIV control. Whether this relationship is mediated by immune mechanisms or other factors should be the focus of future research. Our findings highlight the importance of rigorous BC screening and early detection among HIV-positive women given their increased relative risk of developing TNBC. Research Sponsor: U.S. National Institutes of Health; Conquer Cancer Foundation of the American Society of Clinical Oncology.

Multivariable logistic regression model for SABCHO cohort adjusting for demographic and reproductive factors (TNBC vs non-TNBC).

Factor	Exposed Category	Multivariable Model[i] Odds Ratios (95% CIs)
Ethnicity	Black	1.21 (0.93-1.60)
Wealth Index		0.99 (0.93-1.07)
HIV Status	Positive	**1.40 (1.12-1.74)**
Age of Menarche	≥15 years	1.06 (0.88-1.29)
Parity and Breastfeeding	Parous, no breastfeeding	**1.72 (1.07-2.84)**
	Parous, breastfeeding	1.51 (1.00-2.35)
Ever on Contraceptive	Yes	1.14 (0.92-1.41)

*Bolded odds ratio indicates p-value < 0.05; [i]Model adjusted for age.

Breast cancer staging for patients with "low risk" disease: Are they all the same?

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Background: Studies have shown that a low (<11) Oncotype DX recurrence score (RS) is associated with better survival outcomes. RS is currently included in the AJCC prognostic staging criteria. Not all patients with a low RS are downstaged. It has been suggested that a low RS should further downstage patients regardless of other disease factors. We explored survival outcomes for patients with a low RS to assess if additional patients should be downstaged. **Methods:** Using the National Cancer Database, female patients ages 18-75 with invasive unilateral pT1-3, pN0-1, M0 hormone receptor positive (ER+ and/or PR+), HER2- breast cancer and a RS <11, diagnosed 2010-2018 were identified. Patients who received neoadjuvant treatment were excluded. Patients were grouped based on the AJCC 8th edition prognostic stage (IA, IB, IIA, IIB, IIIA). Variables were summarized, and unadjusted overall survival (OS) was estimated using the Kaplan-Meier method. Cox proportional hazards models were used to estimate the association of stage with OS after adjustment for available covariates. **Results:** Of the 54,961 patients with a RS <11, median follow-up was 57.7 months (95% CI 57.3-58.1), and median age was 61yo (IQR 52-67). Most tumors were grade 1 (37.6%) or 2 (56.9%) with ductal histology (75.3%). The median tumor size was 1.5 cm (IQR 1-2), and most were pN0 (83.3%). Although most patients with a RS <11 were stage IA (94.2%), some had a higher stage assignment (5.1% stage IB, 0.6% IIA, 0.1% IIB, <0.01% IIIA). Most patients (93.4%) received endocrine therapy (ET), and few (3%) received chemotherapy. Patients treated with chemotherapy more often had younger age, lobular histology, higher grade, larger tumor size, and/or pN+ disease (all p<0.001). Unadjusted OS was reduced with higher stage (log-rank p<0.001), and this remained true when limited to only those who received ET without chemotherapy (log-rank p<0.001). After adjustment for relevant covariates including treatment, higher stage remained associated with worse OS [stage IA: ref; IB: HR 1.66 (95% CI 1.34-2.05); IIA: HR 2.29 (95% CI 1.44-3.65); IIB: HR 2.48 (95% CI 1.03-5.95); overall p<0.001]. **Conclusions:** For patients with a low RS, survival outcomes vary with current AJCC prognostic disease stage, suggesting that not all patients with a RS <11 should be downstaged based on RS alone. Anatomic and other non-genomic factors remain relevant when assessing prognosis. Research Sponsor: Duke University Medical Center; U.S. National Institutes of Health.

OS rates (95% CI) by AJCC prognostic stage among those with RS <11, treated with surgery and endocrine therapy without chemotherapy (RS <11).

AJCC Prognostic Stage	N	1yr OS	3yr OS	5yr OS
IA	47092	0.998 (0.998-0.999)	0.990 (0.989-0.991)	0.975 (0.974-0.977)
IB	2218	0.998 (0.995-0.999)	0.980 (0.973-0.985)	0.949 (0.937-0.960)
IIA	246	0.992 (0.967-0.998)	0.963 (0.926-0.981)	0.907 (0.851-0.943)
IIB	38	1.000 (1.000-1.000)	0.939 (0.777-0.985)	0.895 (0.700-0.966)
IIIA	5	1.000 (1.000-1.000)	1.000 (1.000-1.000)	1.000 (1.000-1.000)

6585 **Poster Session**

Trends in the use of maintenance therapy in ovarian cancer.

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Background: Emerging maintenance therapies in advanced ovarian cancer (OC) remain of high interest since 70% of patients (pts) will relapse and ultimately succumb to OC. This study analyzes nonclinical factors associated with maintenance therapy (MT) in OC. We define MT in OC as the use of polyADP-ribose polymerase inhibitors (PARPi) and/or bevacizumab (bev) following platinum-based chemotherapy. **Methods:** We used data from Optum's de-identified Clinformatics Data Mart Database F to conduct an analysis of OC pts with Medicare or commercial health insurance. Pts were included if they had 1 inpatient or 2 outpatient diagnosis codes for OC from 01/2017 to 12/2020 and received platinum-based chemotherapy after diagnosis. Pts were excluded if they did not have continuous coverage from diagnosis until 6 months after completion of platinum-based chemotherapy or death. MT was identified by insurance claims for PARPi or bev received within 6 months after completion of platinum-based chemotherapy. Descriptive statistics were used to summarize patient characteristics. Multivariable logistic regression was used to evaluate associations between pts' nonclinical characteristics and MT use. Trends in MT use were reviewed by year. Subgroup analysis comparing trends in PARPi use to bev use was also performed. The median time from last chemotherapy until initiation of MT was 22 days. **Results:** 5,652 pts were included in the study with a median age of 70 years. The majority were white (70.7%), Medicare-insured (71.8%), and treated in the South (42.8%). 33.6% of pts received MT and 66.4% of pts received neither PARPi nor bev. More pts received bev alone (19.6%) compared to PARPi alone (10.3%) or combination MT (3.7%). Olaparib was the most commonly prescribed PARPi. After adjusting for insurance type, both PARPi and bev use increased significantly over time from 2017 to 2021. Pts with more comorbidity burdens (i.e. higher Elixhauser comorbidity index) were more likely to receive MT compared to pts with less comorbidity [OR (95% CI): 1.44 (1.26-1.65)]. MT use was significantly associated with treatment in the South compared to the Northeast [1.22(1.01-1.46)] and younger age, pts $>$ 76 years were less likely to use MT compared to pts $<$ 56 years old [0.78 (0.62-0.98)]. In the subgroup analysis, PARPi use was significantly associated with age, race and region compared with no MT use, while bev use was not associated with these factors. **Conclusions:** Age, comorbidity status, and geographic location of treatment were associated with MT use. The increasing use of MT over time is consistent with published data since both agents have demonstrated a progression free survival advantage and have tolerable toxicity profiles. With increasing focus on MT in OC, a better understanding of nonclinical factors associated with MT use is imperative to eliminating potential disparities in OC outcomes. Research Sponsor: This work was supported by the T32 Training Grant CA101642.

6586 **Poster Session**

Survival of patients with solid tumors and sepsis admitted to intensive care in a tertiary oncology center: A retrospective analysis.

Sam Smith, Luke Edwards, Timothy Wigmore, Shaman Jhanji, David Antcliffe, Kate Tatham; Imperial College London, London, United Kingdom; The Royal Marsden NHS Foundation Trust, London, United Kingdom

Background: Sepsis is a life threatening organ dysfunction caused by a dysregulated host response to infection. Patients with cancer are at high risk of developing sepsis and requiring admission to the intensive care unit (ICU). Patients with cancer and sepsis have been found to have worse survival than non-cancer patients, with 90 day survival for cancer patients ranging from 28% to 72%. Survival differs between studies due to multiple factors including variably mixed haemato-oncology and solid tumor cohorts and varying definitions of sepsis. Our objectives were to accurately assess short, medium and long term survival of patients admitted to ICU with a solid tumor and sepsis and to identify the best predictors of 90 day survival at admission. **Methods:** We conducted a retrospective cohort survival analysis. We identified adults (aged 18 years and over) admitted to ICU with sepsis and a solid tumor between 1st January 2011 and 31st December 2020 at a tertiary oncology center with hospitals at two sites (London and Surrey, United Kingdom). We defined sepsis using the Sepsis-3 definition. The primary outcome was 90 day survival, but we also calculated 30 day, 180 day, 1 year and 5 year survival. Survival was calculated excluding patients lost to follow up. Univariate and multivariate analyses were undertaken to identify factors that differed between survivors and non-survivors at day 90. We used the parametric accelerated failure time model for multivariate analysis to generate time ratios (TR). **Results:** 625 patients were identified, with 131 patients lost to follow up by 5 years. The median age was 64 years (Interquartile Range 54-71) and 56% were male. 84.8% (530/625) survived to ICU discharge. The 30, 90 and 180 day survival rates were 72% (439/610), 59.5% (353/593) and 51.7% (300/580) respectively. 1 year survival was 38.7% (221/571) and 5 year survival 8.1% (40/494). Multivariate analysis identified the presence of localized (TR 7.85, 95% CI 4.00 -15.41) or regionalized disease (TR 4.71, 95% CI 2.74-8.08) compared to distant metastatic disease, surgery on the day of admission (TR 6.78, 95% CI 3.24-14.19), lactate (TR 0.80, 95% CI 0.74-0.87), SOFA score (TR 0.84, 95% CI 0.79-0.89), previous radiotherapy (TR 0.53, 95% CI 0.32-0.88), previous medical cancer treatment (TR 0.67, 95% CI 0.42-1.07), bacteremia (TR 2.14, 95% CI 1.25-3.64) and albumin (TR 1.06, 95% CI 1.02-1.10) as independent predictors of 90 day survival. **Conclusions:** This study of solid tumor patients admitted to ICU is one of the largest to date with the longest follow up period, providing up to date survival data to inform clinicians and patients. Patients with solid tumors and sepsis admitted to ICU have short and medium term survival rates comparable to non-cancer populations and therefore the presence of cancer should not prevent ICU admission. Prior oncological therapies may affect survival in patients admitted to ICU with sepsis. Research Sponsor: None.

6587 **Poster Session**

Real-world analysis of cardiac, gastrointestinal, and hematologic toxicities between commonly used antiemetics in everyday oncology clinical practice.

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Background: Antiemetics are highly effective in chemotherapy-induced nausea and vomiting. We utilized Food and Drug Administration Adverse Event Reporting System (FAERS) database to evaluate adverse events (AEs) caused by selected antiemetics commonly used in outpatient oncology practice. **Methods:** We analyzed the FAERS database to assess the cardiac, gastrointestinal (GI), and hematologic AEs for metoclopramide, olanzapine, ondansetron, and promethazine from 2013 through 2022. The disproportionality signal was analyzed by calculating Reporting Odds Ratio (ROR) with a 95% confidence interval (CI)—considered significant when the lower limit of 95% CI was > 1. **Results:** A total of 20,302 AEs were identified, out of which 8,135 (40.1%) were cardiac—arrhythmia and QTc prolongation; 8,656 (42.5%) were GI—nausea/vomiting, constipation/diarrhea, abdominal pain/discomfort, and dyspepsia; and 3,511 (17.3%) were hematologic—leukopenia, thrombocytopenia, anemia, and pancytopenia. Compared to other antiemetics, promethazine and olanzapine had higher cardiac and hematologic AEs, respectively, whereas metoclopramide, followed by ondansetron had higher GI AEs (Table). **Conclusions:** Antiemetics are readily available and effective, yet the preference for a particular drug or drug combination varies. Our study highlights selected antiemetics AEs in order to help individualize treatment for this often challenging and frequently encountered entity. Research Sponsor: None.

	Metoclopramide	Olanzapine	Ondansetron	Promethazine
Cardiac	-	-	-	-
-Arrhythmia	554 (5.7%)	2,593	1,672	883
-QTc Prolongation	307 (3.2%)	(6.5%)	(13.8%)	(26.6%)
		1,179	778 (6.4%)	169 (5.1%)
		(2.9%)		
Total Cardiac AEs, no.	861 (8.9%)	3,772	2,450	1,052
(%)	0.27 (0.25-	(9.4%)	(20.2%)	(31.7%)
ROR (95% CI)	0.30)	0.43 (0.41-	0.32 (0.30-	**1.65 (1.49-**
		0.46)	0.34)	**1.84)***
GI	-	-	-	-
-Nausea, and Vomit-	977 (10.1%)	1,383	1,446	216 (6.5%)
ing	546 (5.7%)	(3.5%)	(11.9%)	108 (3.2%)
-Constipation, and		1,091	1,001	
Diarrhea		(2.7%)	(8.3%)	
-Abdominal Pain,	274 (2.8%)	549 (1.4%)	926 (7.6%)	139 (4.2%)
Discomfort,				
and Dyspepsia				
Total GI AEs, no. (%)	1,797 (18.6%)	3,023	3,373	463
ROR (95% CI)	**2.22 (2.05-**	(7.6%)	(27.8%)	(13.9%)
	2.40)*	0.65 (0.53-	**1.56 (1.47-**	0.52 (0.47-
		0.59)	**1.65)***	0.59)
Hematologic	-	-	-	-
-Leukopenia	74 (0.8%)	893 (2.2%)	210 (1.7%)	10 (0.3%)
-Thrombocytopenia	124 (1.3%)	482 (1.2%)	387 (3.2%)	30 (0.9%)
-Anemia	118 (1.2%)	401 (1.0%)	403 (3.3%)	29 (0.9%)
-Pancytopenia	52 (0.5%)	151 (0.4%)	134 (1.1%)	13 (0.4%)
Total Hematologic AEs,	368 (3.8%)	1,927	1,134	82 (2.5%)
no. (%)	0.62 (0.55-	(4.8%)	(9.3%)	0.24 (0.19-
ROR (95% CI)	0.70)	**1.75 (1.66-**	0.95 (0.88-	0.03)
		1.93)*	1.02)	
Overall Reported AEs	9,625	39,939	12,110	3,319

* Asterisk in the table denotes a positive signal.

6588 **Poster Session**

Multicenter, retrospective population-based study on the incidence of medication-related osteonecrosis of the jaw in patients with breast cancer with bone metastases.

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Background: Antiresorptive therapy with bisphosphonates or denosumab is standard care for patients with primary or secondary osseous metastasized breast cancer. The most important toxicity of this class of drugs is medication-related osteonecrosis of the jaw (MRONJ). MRONJ represents a major medical burden and impairs quality of life. Based on recent studies, the risk of MRONJ occurrence ranges from 1% to 3%. The objective of this study was to assess the population-based incidence of MRONJ in breast cancer patients with bone metastases in Tyrol, Austria. **Methods:** This retrospective multicenter study was conducted between 2000 and 2020 at nine centers across Tyrol, Austria, including 8,860 patients with breast cancer. Depending on whether patients with bone metastases received denosumab, bisphosphonates or denosumab following bisphosphonates they were allocated to one of three groups. Data was collected using an electronic case report form (e-CRF) and managed via the web-based database AskiMed. MRONJ incidences with 95% confidence intervals and the differences between the median of cumulative incidences were calculated in patients treated with bisphosphonates and/or denosumab. **Results:** A total of 639 patients had bone metastasis and received antiresorptive therapy. MRONJ was diagnosed in 56 (8.8%) patients. Regarding the 292 (45.7%) patients treated with denosumab alone, the MRONJ incidence was 11.6% (95%CI 8.2%-15.9%). The group of patients treated with only bisphosphonates included 255 (39.9%) patients; their MRONJ incidence was 2.7% (95%CI 1.1%-5.6%). Of the 92 (14.4%) patients receiving both antiresorptive therapies consecutively, the MRONJ incidence was 16.3% (95%CI 9.4%-25.5%). Thus, a total of 49 (12.8%) MRONJ cases were detected in patients using denosumab alone as well as using the combination of denosumab following bisphosphonates. Patients treated with denosumab developed a MRONJ in median 60 months earlier than with bisphosphonates alone or followed by denosumab. The hazard ratio for MRONJ from start of therapy of denosumab compared to bisphosphonates alone or followed by denosumab was 7.9 (3.8-16.2; p-value < 0.0001). **Conclusions:** This study showed a substantially higher MRONJ incidence for denosumab alone or bisphosphonates followed by denosumab in the tyrolean cohort when compared to other recent studies. Future comparative real-world-evidence research provide explicit benefit-harm tradeoffs to inform treatment decision making. Research Sponsor: None.

6589 **Poster Session**

Real-world evidence to inform clinical insights on tissue-agnostic approvals of therapies.

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Background: Many tissue-agnostic (TA) approvals were based on clinical trials with limited patient numbers without covering all tissue types (TT), raising the question of whether these indications were truly tissue agnostic. Real world evidence (RWE) offers an opportunity to investigate TTs not included in clinical trials/studies to answer this question. Herein we investigate the seven TA approvals to date in a large real world database and report clinical outcomes. **Methods:** A total of 186,581 tumors from over 35 TTs tested with comprehensive molecular profiling including NextGen sequencing of DNA and RNA were investigated for TA alterations (TMB-High (≥10 mutations/MB), MSI-H/MMRd, BRAF V600E mutations and NTRK1/2/3/RET fusions) at Caris Life Sciences (Phoenix, AZ). Time-on-treatment (TOT) from RWE was obtained from insurance claims and calculated from treatment start to finish. Kaplan-Meier estimates were calculated for molecularly defined patient cohorts. Significance was determined as p values of <0.05. **Results:** Among all tumors, 21.2% carried at least one TA alteration, 17.2%, 3.4% and 0.6% had 1, 2 or 3 alterations, respectively. TMB-H in 18.7%, MSI-H/dMMR was seen in 3.9%, BRAF V600E in 2.8% of tumors, NTRK1/2/3 and RET fusion seen in 0.16% and 0.23%. TA alterations were most prevalent in BCC (86%) & SCC (82%) of skin, MEL (71%), THCA (51%) and NSCLC (44%) and least in liposarcoma (0), meningioma (0.7%) and GIST (1.4%). Among tumors treated based on TA indications, substantial variability of TOT among TTs was observed (see table). Looking at TTs included (INC) and not included (nINC) in KEYNOTE-158 and other studies for TMB-H and pembro, median TOT for nINC was similar to INC (N=242 vs 2322, 6.1 m vs 6.3 m, p = 0.55). Nevertheless, statistically significant differences in median TOTs were seen across nINC when comparing TMB-H vs. TMB-L (6.1m vs. 2.9m, HR: 0.58 [95% CI: 0.50-0.67], $p<0.001$) and in a subset of 838 MSS tumors (4.9m vs. 2.8m, $p<0.001$). **Conclusions:** RWE data adds substantially to our understanding of the demographics of TA indications and suggests that some TA treatment benefits may be tissue-specific. Recent TA indications will require further accumulation of cases to draw meaningful conclusions regarding whether TA indications are, in fact, tissue agnostic. Research Sponsor: None.

RWE of TA-positive pembro-treated tumors from 11 selected TTs (TMB-H TT group 1 had significantly longer TOT (months) than group 2; MSI-H TT group A had longer TOT than B; b longer than C all $p<0.05$).

	TMB-H N	TOT (CI%)	MSI-H/MMRd N	TOT (CI%)
NSCLC	1556	6.4 (5.8-7) [1]	30	7.5 (2.8-15.1)
UCEC	363	7 (6.1-8.2) [1]	399	6.9 (5.9-8) [B]
MEL	245	6.5 (5.4-7.2)	0	
CRC	237	7.3 (5.6-8.9) [1]	218	7.7 (5.6-9.1)
BLAC	210	5.5 (0.9-6.1) [2]	15	9.8 (3.5-22.4)
CUP	111	5.4 (3.9-7.7)	23	2.5 (0.7-6.4) [C]
CESC	80	5.4 (3.2-8.8)	15	8.8 (2.1-18.4)
STAD	54	8.4 (4.2-10.5)	51	8.6 (3.5-14.9)
SBA	21	12.9 (3.5-17.5)	18	14.3 (8.6-24.5) [A]
NEC	17	3.7 (0.9-5.5) [2]	8	3.7 (0.6-5.6) [C]
SCLC	12	2.4 (0.7-5.8) [2]	0	

6590 **Poster Session**

Site of metastasis (SoM) and its impact on clinical outcomes in 8 cancer cohorts.

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Background: The prognosis of metastatic cancer is in general poor. This can be affected by several factors including age, histology, treatment choices & SoM etc. **Methods:** This retrospective study leverages ConcertAI's deeply curated Patient360 datasets for 8 solid cancers to assess the impact of SoM on the outcomes of patients. For the purpose of this analysis, we focused on the most common SoM (bone, brain, lung & liver). Patients had either a Single SoM (SSM) or Multiple SoM (MSM) and we focused this analysis on patients with SSM. The overall survival (OS) & progression free survival (PFS) from the date of metastasis as well as the time to metastasis (TTM) from initial diagnosis were determined for each cohort. We also computed a consolidated OS & PFS for all patients with MSM. **Results:** 140K patients were included in this study of which 60K patients had a SoM. The distribution of SoM is dependent on the primary cancer type. For example, in breast & prostate cancer, bone metastasis accounts for 50-80 % of the metastatic cohort whereas it is only 8-21% in lung & melanoma. As expected, the overall values of OS/PFS were primarily governed by the primary cancer type (Table), but this analysis provides further interesting insights: 1. Within a cohort, there were significant differences in the prognosis of patients based on the SoM . Brain & liver had a poorer prognosis compared to the other SoM across most cohorts. 2. The relative prognosis for some SoM were dependant on the primary cancer type. For example, there was a very significant difference between the OS/PFS values in the breast cancer cohort when comparing brain vs bone as SoM. However, in the lung cancer cohort, this difference was less pronounced, and the trend was flipped. 3. For some cohorts the SSM for certain sites had a worse prognosis than the MSM. In breast cancer the OS of the brain & liver SoM was worse than the MSM. 4. The TTM is also dependent on the primary cancer and there is a correlation between the average TTM and the OS of the cohort. **Conclusions:** The patterns of cancer metastasis and the absolute and relative prognosis for a particular SoM is dependent on the primary cancer type. Such insights from a large real-world data study can impact clinical decisions regarding the aggressiveness of treatment based on the primary cancer type as well as the metastatic site. Research Sponsor: None.

Metastatic patient counts and outcomes (OS/PFS in years) for 4/8 cancer cohorts.

	SSM	Bone	Lung	Liver	Brain	MSM
Primary Cancer Type (Mets/overall counts)			Count / OS / PFS			
Breast (12346 / 49361)	7110 / 5.17 / 1.5	3695 / 5.33 / 1.65	1372 / 5.84 / 1.6	613 / 3.05 / 0.91	361 / 2.35 / 0.71	5236 / 3.23 / 0.83
NSCLC (26667 / 52814)	15666 / 1.6 / 0.68	3285 / 1.19 / 0.54	5412 / 1.93 / 0.77	938 / 0.99 / 0.49	3797 / 1.54 / 0.68	11001 / 1.1 / 0.46
Melanoma (3220 / 10479)	1702/ 4.61 / 0.76	130 / 2.45 / 0.42	453 / 7.39 / 1.26	120 / 1.67 / 0.38	301 / 1.3 / 0.41	1518 / 2.01 / 0.38
Prostate (7087 / 10679)	5555 / 4.38 / 1.48	4470 / 4.25 / 1.44	137 / 6.13 / 2.46	48 / 3.35 / 1.19	14 / 0.22 / 0.19	1532 / 3.46 / 1.11

Malnutrition risk at diagnosis and influence on survival in patients with solid tumors at a large academic cancer center.

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Background: Malnutrition is common in cancer patients and negatively impacts quality of life, tolerance to anti-cancer therapies and is associated with poor prognosis. It is, however, unclear if patient-reported malnutrition risk at initial diagnosis is related to overall survival (OS) in solid tumor oncology outpatients in the United States. **Methods:** A cohort of 3,562 patients who completed the malnutrition screening tool (MST), a validated assessment of malnutrition risk, at initial diagnosis of any stage solid tumor and had available survival data were analyzed. The primary objective was to evaluate the relationship of high malnutrition risk (≥2 of 5 = high risk for malnutrition, H-MST) to OS and was assessed using Kaplan Meier techniques and Cox proportional hazards models. Unadjusted analyses were performed, and adjusted multivariable analyses evaluated the impact of H-MST on OS controlling for key clinical baseline confounders. **Results:** The median age was 63 years (IQR: 54-71), with 62% females and 81% White. Most common cancer sites were breast (28%), gastrointestinal (GI, 21%), and thoracic (13%) and 80% were non-metastatic. Median follow up was 48.3 months. H-MST was associated with lower OS in the unadjusted model, median OS in months was 32.5 [H-MST] vs not reached in low MST [L-MST] (HR 3.3, 95% CI 2.9-3.7, p = < 0.001). Multivariable analysis confirmed that H-MST remained independently associated with OS when controlling for age, sex, cancer site, stage, BMI, and symptom scores. Landmark OS rates at 50 months were 60% [H-MST] vs. 69% [L-MST] (HR 1.51 95% CI 1.3-1.7, p = < 0.001). Adjusted subgroup analyses by cancer site showed the independent impact of H-MST was relatively similar across groups (Table). **Conclusions:** High malnutrition risk at initial diagnosis was independently associated with shorter survival across a large representative cohort of solid tumor oncology outpatients. The screening occurred before any anti-cancer therapy and it is noteworthy most had non-metastatic disease. These data highlight the need for systematic screening to identify patients at malnutrition risk who need additional assessment early during cancer. Further research on how to optimize allocation of limited nutrition resources for those with high malnutrition risk is needed. Research Sponsor: None.

	Sample Size/ Number of Events	50-month survival rate (High-MST, %)	50-month survival rate (Low-MST, %)	HR (95% CI) High MST vs Low MST	P-Value
Entire Cohort	3562/ 1145	60	69	1.51 (1.33-1.72)	< 0.001
Subgroup					
Non-Upper GI	337/124	54	63	1.56 (1.07, 2.28)	0.021
Upper GI	382/271	20	32	1.61 (1.22, 2.13)	< 0.001
Head & Neck	133/44	63	66	1.15 (0.61, 2.15)	0.665
Thoracic	453/289	24	36	1.45 (1.13, 1.87)	0.004
Gynecologic	334/89	61	77	2.03 (1.30, 3.16)	0.002
Genitourinary	430/119	67	73	1.33 (0.88, 1.99)	0.175
Breast	1011/104	87	90	1.14 (0.64, 2.06)	0.657
Other	482/105	70	79	1.62 (1.04, 2.52)	0.034

6592 **Poster Session**

Real-world behavioral restrictional practices of cancer patients (pts).

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Background: Quality of life (QoL) assessments do not measure pts' ability to maintain normal daily activities during cancer therapy. Misbeliefs might promote avoidance of activities perceived as dangerous, compromising pts QoL. We examined the daily practices of actively treated pts with cancer. **Methods:** A locally validated questionnaire at the Tel-Aviv Sourasky Oncology Division was distributed internationally using the Belong.life social and professional digital health platform. We examined real-world pts reported practices, provided voluntarily and anonymously. The survey consisted of 15 questions, including demographic, clinical, behavioral parameters and sources guiding and supporting pts practices. Independent clinical and demographic variables were analyzed. Statistical analysis was performed, and a multivariate logistic regression was conducted to identify factors predicting restrictive behaviors. **Results:** The study population comprised 1,395 pts receiving active cancer therapy, reporting their outcomes from the Belong digital platform. Most respondents were from the United States (1082, 77.70%) and Israel (223, 16%), over the age of 40 (1309,93.8%),and female (987, 70.75%). Most common tumor types were breast (394,28.24%) and gastrointestinal cancers (199,14.26%). The majority of pts (1,005,72.88%) reported on at least 1 adopted limitation in daily activities, and 305 (21.86%) maintained more than half of these constraints. Daily life restrictions included avoiding sun exposure (779, 57.83%), international travel (417, 33.33%), indoor public places (malls, etc) (431, 33.13%), hair dyeing (271, 22.72%), domestic tourism (284, 21.93%), contact with friends and family (231, 17.69%), children and grandchildren (202, 16.33%), outdoor public spaces (190, 14.62%), and contact with pets (135, 10.41%). Multiple sources were implicated by the pts as guiding their behavior, with the most common being health-care professionals (951, 65.95%), followed by both non-medical authorities and health-care team (320, 22.19%), and non-medical advisors, including internet, pts forums, partners, friends, and family (171, 11.86%) Pts who maintained strict ($\geq$50% of the limitations) and less strict restrictions, demonstrated no significant association between country of origin ($p = 0.118$), and education level ($p = 0.3591$). A significant association was noted between younger age ($p = 0.0014$), female sex ($p = 0.0141$) and primary cancer site ($p < 0.0001$), and the adoption of strict restrictions. **Conclusions:** The majority of pts reported compromised daily activities, which are likely attributed to misconceptions about therapy and disease, deleteriously impacting QoL, therefore, impeding their ability to continue to conduct a complete and meaningful life. These findings require development of tools examining patients' real-daily life activity as an additional endpoint in clinical trials. Research Sponsor: None.

6593 **Poster Session**

Measuring variation in the quality of systemic anti-cancer therapy delivery across hospitals: A national population-based evaluation.

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Background: To date, there has been little systematic assessment of the quality of care associated with systemic anti-cancer therapy (SACT) delivery across national healthcare systems. We evaluated hospital-level toxicity rates during SACT treatment as a means of identifying variation in care quality. **Methods:** All colorectal cancer patients receiving SACT within 106 English National Health Service hospitals between 2016 and 2019 were included. Severe acute toxicity rates were derived from hospital administrative data using a validated coding framework. Variation in hospital-level toxicity rates was assessed separately in the adjuvant and metastatic settings. Toxicity rates were adjusted for age, sex, comorbidity, performance status, tumour site, and TNM staging. **Results:** Of the 8,173 patients receiving SACT in the adjuvant setting, 2,074 (25%) had a toxicity with adjusted hospital-level rates varying from 11% to 49%. Of the 7,683 patients receiving SACT in the metastatic setting, 3,625 (47%) had a toxicity with adjusted hospital-level rates varying from 25% to 67%. Compared to the national mean toxicity rate in the adjuvant cohort, six hospitals were more than 2 standard deviations (2SD) above, and four hospitals were more than 2SD below. Similarly, in the metastatic cohort, six hospitals were more than 2SD above, and seven hospitals were more than 2SD below the national mean toxicity rate. **Conclusions:** There is substantial variation in hospital-level severe acute toxicity rates in both the adjuvant and metastatic settings, despite comprehensive risk-adjustment. Ongoing reporting of this performance indicator can be used to focus further investigation of toxicity rates and stimulate quality improvement initiatives to enhance care. Research Sponsor: None.

6594 **Poster Session**

Tumor lysis syndrome in solid tumors: A retrospective cohort study of the National Inpatient Sample from 2016 to 2019.

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Background: Tumor lysis syndrome (TLS) is a life-threatening oncologic emergency. Patients with a rapidly proliferating tumor or high tumor burden after cytotoxic chemotherapy, predominantly in hematologic malignancies, are at increased risk of TLS. The advancement in therapeutic strategies of oncology in the past few decades has expanded the spectrum of malignancies associated with TLS. A dearth of literature on the incidence of TLS in various solid malignancies exists. Using the National Inpatient Sample (NIS) data, this study aims to highlight the solid malignancies at risk of TLS, highlight the demographic factors, and draw a comparison with that in hematological malignancies. **Methods:** The NIS 2016-2019 dataset was analyzed utilizing univariate and multivariate logistic regression analysis for the predictors of TLS ($P < 0.05$). StataCorp. 2021. Release 17. College Station, TX: StataCorp LLC, BE version with Stata's svy command, and appropriate weights, were used to perform the analysis. The overall fit was analyzed using Receiver Operative Curves (ROC), and sensitivity analysis was analyzed using the e-value package. **Results:** From 2016-2019, a total of 51,385 (48,917-53,853) hospitalizations had an incidence of TLS. We included 16,249 cases of TLS in patients treated for the ten most common malignancies in the US. We found that older age, male sex, and black race were associated with higher odds of TLS. It was reported highest in large hospitals and urban non-teaching hospitals. The regional distribution of the TLS suggests the highest odds in the Western region. The odds of getting TLS were highest among Leukemias and Lymphomas, respectively. Among solid tumors, the odds of getting TLS were highest in uterine cancer patients, followed by lung, breast, pancreatic, and liver cancer among the top five. (Table). **Conclusions:** In this study, we conclude that solid tumors, mainly uterine, followed by lung and breast, have significantly higher odds of TLS, more so in larger or non-teaching hospitals. There is a need to establish specific management guidelines to prevent these TLS cases that will improve the morbidity and mortality associated with TLS and help build more cost-effective treatment regimens. Research Sponsor: None.

Demographic Characteristics	OR of TLS	95% CI	Hematologic Malignancies	OR of TLS	95% CI
Age	1.01	1.006 to 1.009	Leukemias	56	52.59 to 59.84
Female vs. Male Sex	0.61	0.58 to 0.64	Lymphomas	34.16	31.62 to 36.90
Black Race vs. White	1.31	1.22 to 1.41	Solid Malignancies	OR of TLS	95% CI
Asian or pacific Islanders vs. White	1.31	1.15 to 1.48	Uterine cancer	6.82	5.22 to 8.91
Large vs. Small sized hospitals	2.05	1.82 to 2.31	Lung cancer	4.74	4.27 to 5.26
Medium vs. Small sized hospitals	1.39	1.23 to 1.57	Breast cancer	3.39	2.77 to 4.16
Urban non-teaching vs. Rural hospitals	1.66	1.38 to 1.99	Pancreatic cancer	3.21	2.56 to 4.02
Western vs. Northeast region	1.18	1.05 to 1.33	Liver cancer	3.19	2.50 to 4.08

Real-world response endpoints in patients with mNSCLC treated with chemotherapy across real-world datasets.

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Background: Response Evaluation Criteria in Solid Tumors (RECIST) based response rate (RR) is used for efficacy evaluation in clinical trials and relies on imaging data collected at specified timepoints for uniform assessment. In routine clinical practice, the method and timing of response assessment can vary, and imaging data from electronic health records (EHR) and other real world (rw) sources may not be available, making RECIST-based assessment of rw-response rate (rwRR) using rw data (RWD) challenging. Friends of Cancer Research formed a multi-stakeholder partnership to assess available data attributes to measure response across RWD sources to inform development of a consistent method for measurement. **Methods:** The study included seven EHR data partners who identified and analyzed a cohort of 1,380 patients (pts) with metastatic non-small cell lung cancer (mNSCLC) treated with first-line platinum doublet chemotherapy, following a common protocol and statistical analysis plan. The availability and frequency of data components to assess response including raw images, radiology imaging reports, and clinician response assessments from provider notes were assessed. Response endpoints measured included rwRR, rw-duration of response (rwDOR), and the association of rwR with rw-overall survival (rwOS), rw-time to treatment discontinuation (rwTTD), and rw-time to next treatment (rwTTNT). **Results:** The availability of data components varied across RWD sources (Table). Images were not widely accessible, thus response was analyzed using clinician response assessments (median proportion of pts evaluable, 77.5%). Of these assessments, the majority relied on imaging interpretation. The median rwRR was 46% with a median rwDOR of 119 days. The table provides median rwTTD, rwTTNT, and rwOS across data sources. **Conclusions:** The rwRR among pts with mNSCLC calculated using the clinician assessment was relatively consistent across all RWD sources, with consistent trends in time to event endpoints. While variability in the availability of data components to assess response was observed, the demonstrated feasibility of response endpoints based on clinician assessment suggests further exploration may inform drug effectiveness evaluation with RWD. Research Sponsor: Friends of Cancer Research (Non-profit).

Group*	Pts Evaluable for rwR (Pts Ev) by Images	Pts Ev by Radiology Reports	Pts Ev by Clinician Response Assessment	rwRR	Median rwDOR, days (95% CI)	Median rwTTD, days: Responders /Non-Responders (R/NR)	Median rwTTNT, days: R/NR	Median rwOS, days: R/NR
A	3.5%	73%	79.5%	42%	115 (86, 199)	142/69	200/100	375/245
B	0.5%	55%	80.5%	53%	133 (108, 182)	128/84	209/98	464/314
C	40.5%	77%	77.5%	46%	146 (102, 210)	147/63	234/93	832/213
D	0%	0%	74%	40%	100 (74,-)	105/70	140/115	614/414
E	79.5%	79.5%	76%	38%	119 (98, 231)	132/48	235/93	474/184
F	0%	66.5%	69%	52%	182 (147, 287)	99/43	219/109	436/353
G	0%	85.5%	88.3%	49%	105 (7, 672)	112/21	198/61	392/86

*n=200 pts except G: n=180.

6596 **Poster Session**

Molecular testing utilization in patients with advanced non-small cell lung cancer (NSCLC) in Washington (WA) state.

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Background: Therapies targeted at driver mutations (e.g. EGFR, ALK) in NSCLC have contributed to improved patient survival. While current guidelines recommend that all patients diagnosed with stage IV NSCLC undergo molecular testing to determine eligibility for targeted therapies, real-world testing patterns have not been well described. In a retrospective study using cancer registry and insurance claims, we evaluated rates of molecular testing in a population-based sample of NSCLC patients in WA. **Methods:** We linked WA state cancer registry records from 2017-2019 with claims records for Medicare, Medicaid, and two large commercial insurers. Patients diagnosed with stage IV NSCLC who had continuous insurance enrollment for 2 months prior to and 12 months following diagnosis were identified. Using insurance claims data, we identified patients who received any molecular testing (either testing for specific markers or comprehensive molecular profiling). We compared proportions of patients who received and did not receive molecular testing by insurance type, race, ethnicity, gender, and diagnosis (Dx) year. We performed a multivariate regression analysis to determine factors associated with completion of molecular testing. **Results:** 1048 eligible patients were identified. The median age was 70. Patients were predominately insured by Medicare (62.6%) and non-Hispanic white. 90.3% of all patients underwent molecular testing. Molecular testing rates were similar between white and non-white patients (90.4% vs 89.2%, p=0.647). Testing rates were significantly lower among Hispanic patients vs non-Hispanic patients (77.8% vs 90.7%, p=0.018). Testing rates were lowest among Medicaid enrollees (86.4%) compared to Medicare (88.4%), commercial (97.2%) or multiple insurances (94.9%) (p=0.0018). A multivariate analysis demonstrated that patients age ≥65 and Medicaid patients were less likely to receive molecular testing while females were more likely to receive testing; year of Dx did not impact testing rates (Table). **Conclusions:** While the rate of adherence to recommended molecular testing was high in the overall cohort, testing rates were lower in Hispanic patients, older patients, males, and those with Medicaid insurance. Given the therapeutic implications of testing, drivers of these observed disparities warrant further study to ensure equitable access to efficacious treatment. Research Sponsor: Fred Hutchinson Cancer Center.

Multivariate analysis for patients undergoing molecular testing.

	Odds Ratio	95% Confidence Interval
Age ≥ 65 (ref=Age <65)	0.39	(0.18, 0.85)
Female (ref=Male)	1.76	(1.15, 2.69)
Non-White (ref=White)	0.89	(0.49, 1.62)
Hispanic (ref=non-Hispanic)	0.38	(0.16, 0.91)
Medicaid (ref=Commercial)	0.16	(0.04, 0.59)
Medicare (ref=Commercial)	0.34	(0.10, 1.15)
Multiple Insurance (ref=Commercial)	0.74	(0.19, 2.91)
Dx 2018 (ref=2017)	1.20	(0.72, 2.01)
Dx 2019 (ref=2017)	0.96	(0.59, 1.58)

6597 **Poster Session**

Disparities in PI3K/mTOR inhibitor use, toxicities, and outcomes among patients with metastatic breast cancer.

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Background: Advances in breast cancer treatment have led to improvements in survival among patients with metastatic breast cancer (MBC). Nevertheless, Black patients and patients with lower socioeconomic status (SES) continue to bear a disproportionate mortality burden. Furthermore, because landmark trials for novel anticancer agents lacked racial diversity, their toxicity profile for minority patients remains uncertain. Our study examines the impact of race and other sociodemographic characteristics in the use and toxicity outcomes of PI3K and mTOR inhibitors (PI3K/mTORi). **Methods:** We conducted a retrospective analysis of EHR-derived data from the Flatiron Health Database (FHD). A dataset was constructed to include patients with hormone receptor-positive, HER2-negative MBC diagnosed between 1/1/2011 and 1/31/2022. Outcomes included PI3K/mTORi use, rates of hyperglycemia and dose reduction, and time on treatment. Multivariable logistic regression was used to evaluate factors associated with use and outcomes. **Results:** A total of 13,388 patients with MBC were included in our analysis, of which 2,620 (19.6%) received PI3K/mTORi (78.3% everolimus, 14.7% alpelisib, 6.9% both agents). Overall, 67.5% of all patients were categorized as White, 9.8% as Black/African-American (Black/AA); 18.9% were >75 years old; 10.1% were treated at an academic site; 4.0% had Medicaid insurance. Insurance through Medicaid was associated with lower use of PI3K/mTORi compared to commercial insurance (15.6% vs 18.8%; OR: 0.76, 95% CI: 0.59-0.99, p=0.04), as was advanced age (10.9% for >75 years old vs 22.9% for <60 years old; OR: 0.68, 95% CI: 0.58-0.80, p<0.001) and poorer performance status at diagnosis (15.1% for ECOG ≥2+ vs 22.9% for ECOG 0; OR: 0.84, CI: 0.72-0.98, p=0.03). Odds of PI3K/mTORi use were almost 50% higher for patients treated at an academic center (OR: 1.46, CI: 1.06-2.05, p=0.02). While Black/AA patient had lower rates of use than White patients (17.4% vs 20.1%), they had similar odds of receiving PI3K/mTORi on multivariable analysis (OR: 1.00, CI: 0.85-1.17, p>0.9). Black/AA patients experienced higher rates of hyperglycemia on PI3K/mTORi than White patients (67.6% vs 52.5%). On multivariable analysis, odds of hyperglycemia were twice as high for Black/AA patients (OR: 2.1, CI: 1.33-3.35, p<0.01). However, rates of dose reductions and time on PI3K/mTORi therapy did not differ significantly among White vs Black/AA patients. **Conclusions:** This analysis of real-world data suggests that lower SES is associated with decreased PI3K/mTORi use. Efforts to improve access to these life-prolonging agents are warranted. Of concern, we also found racial disparities in toxicity outcomes, with Black patients having twice the risk of hyperglycemia. Greater attention to the tolerability of novel agents in diverse populations is warranted. Research Sponsor: American Cancer Society; Breast Cancer Research Foundation.

6598 **Poster Session**

Decomposing racial differences in financial hardship among older cancer survivors.

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Background: Despite Medicare coverage, financial hardship is a prevalent issue among older cancer survivors, particularly among those belonging to a racial/ethnic minority. Sociodemographic, clinical, and area-level factors may mediate this relationship; however, no studies have assessed the extent to which these factors contribute to disparities. **Methods:** Surveys assessing financial hardship after cancer were completed by 721 patients age 65y+ of Black or white race completing primary cancer treatment for breast, prostate, colorectal, prostate cancer or lymphoma at University of Alabama at Birmingham between 2000 and 2019. Financial hardship included material, psychological, and behavioral domains. Material hardship included *ever* 1) borrowing money/going into debt, 2) filed for bankruptcy, 3) worried about paying large medical bills, and 4) made any other financial sacrifices due to cancer. Psychological hardship was measured by asking if participants were *ever* worried about paying large medical bills related to cancer, its treatment or effects of treatment. Behavioral hardship was measured by asking if participants were unable or delayed in obtaining medical care, tests, treatments or prescriptions *in the last 6 months*. Non-linear Blinder-Oaxaca effect decomposition methods evaluated the extent to which individual-level sociodemographic, clinical, and area-level factors contributed to racial disparities in financial hardship. **Results:** Median age at survey was 78 (IQR = 73-82), majority were female (53%) and non-Hispanic White (84%). The most common cancers were breast (34%) and prostate (27%), followed by lung (17%), lymphoma (9%) and colorectal (14%). Ninety percent were diagnosed at an early stage and median time from diagnosis to survey was 8y (IQR = 5-12). There were no significant clinical differences between Black and white patients. Overall, 22% reported any financial hardship; 14% material, 3% behavioral, and 14% psychological. Black, compared to White participants reported significantly ($p < 0.001$) higher rates of overall (39% v 18%), material (29% v 11%), and psychological (27% v 11%) financial hardship. Notably, Black patients had higher rates of being unable to cover cancer-related costs (23% v 7%), worrying about paying large medical bills (27% v 11%), and having to borrow money or go into debt (9% v 3%). Overall, the observed characteristics explained 81% of racial differences in financial hardship among cancer survivors, primarily by differences in income (24%), cancer diagnosis and stage (22%), and area deprivation (15%). **Conclusions:** These results identify primary contributors to racial disparities in financial hardship among older cancer survivors, which can be used to develop interventions aimed at eliminating inferior healthcare outcomes experienced by certain racial groups, inform policy, and allocate resources to those at greatest risk for financial hardship. Research Sponsor: American Cancer Society.

6599 **Poster Session**

Commercial vs. Medicaid insurance and use of high-priced anticancer treatments.

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Background: Financial incentives presented by the larger markups on cancer drugs among commercial payors may result in increased use of high-priced drugs among commercially insured vs. Medicaid insured patients. We evaluated the association between patient insurance type and the likelihood of receiving higher-priced treatments. **Methods:** We linked cancer registry, administrative claims, and demographic data for individuals diagnosed with cancer in North Carolina from 2004-2011, who had either commercial or Medicaid insurance. We selected cancer types with multiple FDA-approved, guideline-recommended chemotherapy options, and large differences in price between the higher-priced and lower-priced options during the study period: advanced colorectal, lung, and head-and-neck cancer (HNC). The primary outcome was receipt of the higher-priced treatment option, and the primary exposure was insurance type: commercial vs. Medicaid. We estimated risk ratios (RR) for the association between insurance type and higher-priced treatment using log binomial models with inverse probability of exposure weights to control confounding by age, county-level poverty prevalence, and selected comorbidities. We assessed for potential modification of the RR by setting (hospital outpatient vs. physician office) and academic designation (NCI-designated comprehensive cancer center vs. other); these were exploratory analyses due to sparse data and subsequently limited confounding control. **Results:** Of 812 patients: 209 (26%) had Medicaid insurance; 311 (38%) had NHC, 263 (32%) colon or rectal cancer, and 238 (29%) lung cancer. The crude risk of higher-priced treatment was 36% (215/603) for commercially insured and 27% (57/209) for Medicaid insured (RR:1.31, 95%CI 1.02-1.67). After weighting the association was attenuated (RR:1.15, 95% CI 0.81-1.65). While limited by imprecision and the potential for uncontrolled confounding, exploratory subgroup analysis suggested that, compared to Medicaid insurance, commercial insurance was associated with numerically higher risk of higher-priced treatment among patients treated by non-NCI designated providers (RR:1.53, 95%CI 1.14-2.04), and within both the physician office (RR:1.36, 95%CI 0.95-1.95) and hospital outpatient (RR:1.08, 95%CI 0.58-2.02) settings, but lower risk of high-priced treatment within NCI cancer centers (RR:0.39, 95%CI 0.22-0.71). **Conclusions:** Individuals with Medicaid vs. commercial insurance access high-priced treatments at a similar proportion after accounting for differences in case mix, morbidity, and SES. However, modification of the association by and academic setting, observed in exploratory subgroup analysis, suggests the possibility that insurance type may affect treatment for some patient groups. This study was limited by focus on a single state and the potential for residual confounding. Research Sponsor: Conquer Cancer Foundation of the American Society of Clinical Oncology; U.S. National Institutes of Health.

6600 **Poster Session**

The evolving landscape of chemotherapy for the treatment of early-stage breast cancer from 2006-2019: Results of a retrospective cohort study.

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Background: Chemotherapy has been a part of the evolving landscape of treatment for women with early-stage breast cancer (EBC). Over the last 20 years, standard treatment has included over 20 different drug combinations recommended by the National Comprehensive Cancer Network (NCCN), with nearly 45 variations on dosing and schedule across drug combinations. Little is known about the real-world landscape of chemotherapy used in EBC and how treatment patterns have changed with the advent of new standards of care. We evaluated chemotherapy patterns for women with EBC in the Optimal Breast Cancer Dosing (OBCD) Study, which uses electronic health record (EHR) data from KPNC (Kaiser Permanente Northern California) and Kaiser Permanente Washington (KPWA). **Methods:** In a cohort of 34,322 women diagnosed and treated for primary stage I-IIIA breast cancer aged 18+ at KPNC and KPWA, we explored patterns of chemotherapy use over time, from 2006 to 2019. We conducted stratified analyses based on receipt of pertuzumab and/or trastuzumab, due to their longer treatment duration. **Results:** Overall, 13,383 (39.0%) women received intravenous chemotherapy, with a decline observed in receipt of chemotherapy over time (40.5% in 2006 vs 35.9% in 2019) (p-trend$<$0.001). Of the women who received chemotherapy, 8.5% received neoadjuvant treatment, increasing from 4.1% in 2006 to 14.5% in 2019 (p-trend$<$0.0001). The average duration of chemotherapy was 5.4 months in 2006, increasing to 6.3 months in 2019 (p-trend$<$0.0001), and the number of chemotherapy infusion visits increased from an average of 10.7 visits in 2006 to an average of 12.5 in 2019 (p-trend$<$0.0001). Of those who received chemotherapy, 26.8% received trastuzumab or pertuzumab, with receipt of trastuzumab/pertuzumab increasing over time (p-trend$<$0.0001). For those receiving trastuzumab/pertuzumab, there was a decrease in treatment duration and average number of chemotherapy administration visits (p-trend$<$0.0001 for both). Conversely, for those not receiving trastuzumab/pertuzumab, there was an increase in the treatment duration and average number of visits (p-trend$<$0.0001 for both). **Conclusions:** While the prevalence of women receiving chemotherapy in our cohort has decreased since 2006, there has been a marked increase in neoadjuvant chemotherapy among those women receiving chemotherapy, as well as an increase in both the duration of chemotherapy treatment and number of associated chemotherapy administration visits, a pattern specifically observed in non-trastuzumab/pertuzumab containing regimens.The change in average duration and number of visits represents a shift in treatment patterns for patients and providers. Understanding trends in breast cancer chemotherapy is useful to inform clinical care and administrative planning for sites delivering chemotherapy for early-stage breast cancer. Research Sponsor: U.S. National Institutes of Health.

6601 **Poster Session**

Integrating the 31-gene expression profile test into clinical decision-making to guide risk-aligned care decisions for patients with stage I-III cutaneous melanoma: NCI-SEER Analysis.

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Background: Cutaneous melanoma (CM) management depends on an estimate of recurrence risk or death. Because of recognized disease risk and drug efficacy, pembrolizumab immunotherapy has been approved for stage IIB-C patients. However, it is a treatment with potential financial and biological toxicities with 16% of patients experiencing severe treatment related adverse events. Improved risk stratification could identify individuals for whom more selective management would be appropriate. In collaboration with the NCI Surveillance, Epidemiology, and End Results (SEER) program, which includes information on patients tested with a 31-gene expression profile (31-GEP) test in an unbiased and unselected manner, we confirm the 31-GEP adds independent prognostic value in patients with stage I-III CM, and investigated whether the 31-GEP could identify stage IIB-C patients who might reasonably avoid adjuvant therapy while also identifying patients with stage I disease who might benefit from more aggressive diagnostic and/or therapeutic intervention. **Methods:** SEER registries linked CM cases diagnosed 2013-2018 to 31-GEP test results provided by Castle Biosciences (9,207 matched) using a registry trusted third party (honest broker), including subsets of stage IIB-IIC (n=775) and stage I (n=5,651) melanoma. The primary endpoint was melanoma-specific survival (MSS). The 31-GEP risk-groups included Class 1A (low), Classes 1B/2A (intermediate), and Class 2B (high). Each was compared using Kaplan-Meier analysis and the log-rank test. **Results:** In the overall cohort, patients with a Class 1A result had a significantly higher 5-year MSS than a Class 1B/2A or Class 2B result (97.4% vs. 93.5% vs. 83.3%, $p<0.001$). In multivariable analysis, a Class 2B result (HR=3.26, $p<0.001$) and positive lymph node status (HR=3.41, $p<0.001$) were the strongest predictors of diminished MSS. In stage IIB-C, 18.8% (146/775) of patients received a Class 1A result with an associated 5-year MSS of 89.1% (vs. Class 2B: 76.6%, p=0.001), despite the absence of pembrolizumab approval for the evaluated SEER population. Alternatively, 4.6% (260/5,651) of patients with stage I disease had a Class 2B result, with an associated 5-year MSS of 92.3% (vs. Class 1A: 98.0%, $p<0.001$). **Conclusions:** The SEER database allowed a non-biased analysis of a large cohort of patients with stage I-III CM who were tested with the 31-GEP. The 31-GEP identifies patients, including those with stage IIB-C disease, with favorable outcomes and could help physicians and patients decide whether to pursue adjuvant therapy. Moreover, the 31-GEP identities high-risk patients, including those with stage I disease, for whom more aggressive follow-up and early intervention should be considered. Research Sponsor: Castle Biosciences, Inc.

6602 **Poster Session**

Evaluating depth of disparities in relation to relative survival rates: Analysis of SEER data.

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Background: Prior studies have identified widening survival disparities between Black vs White patients (pts) in solid tumors with higher 5-year relative survival rates (RSR), a surrogate for higher amenability to treatment (Tehranifar et al., 2009). Given major advancements in treatment for hematologic malignancies leading to higher RSR, we sought to evaluate whether disparities worsened with higher RSR, especially among Black pts compared to White pts, in the modern era of therapy. We hypothesized that racial disparities would be larger in malignancies with higher amenability, as measured by 5-year RSR. **Methods:** We identified first hematologic malignancies among pts ages ≥18 years diagnosed between 2009-2019 in a collection of 17 Surveillance, Epidemiology and End Results (SEER) Program registries. We treated RSR as a continuous variable. Cox proportional-hazards model was used to correlate RSR and race with overall survival (OS) controlling for other pt characteristics. The interaction between RSR and race was included in the model to test if the racial effect on OS differed at various RSR levels. **Results:** We identified 363,340 pts who met inclusion criteria. Median age was 66 years and 55% were male. 82% were White and 10% Black. With a median follow-up of 48 months (mos), median RSR was 68.2% and median OS was 101 mos (95% CI 100-102 mos). Black pts had a lower median RSR than White pts, 63.8% vs 68.9%, and lower median OS, 90 mos (95% CI 87-93 mos) vs 99 mos (95% CI 98-100 mos). On univariable analysis, all variables were statistically significant given the large sample size. On multivariable analysis (MVA), Black pts had a higher risk of death than White pts. The interaction between 5-year RSR and race was highly significant (p=<0.01, not shown in Table), as indicated by slightly increasing hazard ratios (HRs) reflecting Black-White survival differences with increasing RSR level (i.e., as RSR increased, Black pts had slightly worse OS than White pts) (Table). **Conclusions:** We hypothesized that with increasing RSR, Black-White disparities might increase, as all effective therapies which contribute to improved RSR might not be equitably available to all populations. We observed that statistically significant disparities were present across RSR levels and increased only minimally for those with hematologic malignancies with higher RSR. In conclusion, disparities are prevalent in hematologic malignancies despite the degree of amenability to treatment.
Research Sponsor: None.

MVA*	HR (95% CI)	p-value
Age, 5-year older	1.268 (1.265-1.271)	<.01
Male vs Female	1.177 (1.165-1.190)	
Year of Diagnosis, 1-year later	0.978 (0.976-0.980)	
Race, Black vs White at RSR level**		
30	1.247 (1.209-1.285)	
50	1.262 (1.237-1.286)	
70	1.277 (1.251-1.303)	
90	1.292 (1.251-1.334)	
5-year RSR, 10% higher		
White	0.785 (0.781-0.789)	
Black	0.790 (0.783-0.797)	

*Controlled for other pt variables. **Cutpoints used for ease of visualization for the purpose of this chart.

6603 **Poster Session**

Demographic disparities in lung cancer mortality and trends in the United States between 1999 and 2020: A population-based CDC database analysis.

Alexander Didier, Logan Roof, James Stevenson; The University of Toledo College Of Medicine and Life Sciences, Toledo, OH; Cleveland Clinic, Cleveland, OH; Cleveland Clinic Foundation, Cleveland, OH

Background: Lung cancer is the leading cause of cancer-related mortality in the US and is projected to account for 127,070 deaths in 2023. While the lung cancer mortality rate has been decreasing over the last decade, demographic disparities in mortality still exist. We sought to determine the impact of demographic factors on lung cancer mortality and trends in the US. **Methods:** We queried the Centers for Disease Control database for mortality statistics with an underlying cause of death of lung and bronchus cancer (ICD-10 code C34.0.x) between the years 1999 – 2020. Age-adjusted mortality rates (AAMR) were calculated per 100,000 deaths. We assessed the AAMR by demographic variables, including race (Hispanic, Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Asian or Pacific Islander, Non-Hispanic American Indian/Native American), geographic density (Urban, Suburban, Rural), sex, age (25-44, 45-64, 65+ years), and US Census Region. Temporal trends were evaluated using Joinpoint regression software. Average annual percent change (AAPC) was considered statistically significant if $p < 0.05$. **Results:** Between 1999 and 2020, lung cancer led to 3,380,830 deaths. The AAMR decreased by 42% from 55.1 to 31.8 with an associated AAPC of -2.6% ($p < 0.001$). In 1999, men had an AAMR of 76.8, almost twice as high as women, who had an AAMR of 40.2. These differences became less pronounced over time, and in 2020 men had an AAMR of 38.1, while women had an AAMR of 26.9. Between 1999 and 2020, rural populations experienced the highest AAMR at 52.3, and the slowest rate of decrease at -1.7% annually ($p < 0.001$), compared with urban populations who experienced the lowest AAMR of 40.6 and fastest AAPC decrease of -3.1% ($p < 0.001$). Non-Hispanic Black individuals experienced the highest AAMR at 49.8, with an annual decrease of -3.0% ($p < 0.001$), followed by Non-Hispanic White individuals who had an AAMR of 48.5 with an annual decrease of -2.5% ($p < 0.001$). Subgroup analysis demonstrated that Non-Hispanic Black men who resided in rural counties experienced the highest mortality at 60.2, with an associated decrease of -2.9% annually ($p < 0.001$). States in the 90^{th} percentile of mortality included Arkansas and Kentucky; states in the 10^{th} percentile of mortality included Hawaii and Utah. The West experienced the fastest decrease at -3.1% annually ($p < 0.001$), while the Midwest experienced the slowest decrease at -2.0% annually ($p < 0.001$). **Conclusions:** While lung cancer mortality has been decreasing since 1999, not all demographic groups have experienced the same rates of decline, and disparities in outcomes remain prevalent. Vulnerable subgroups may benefit from targeted interventions, such as tailored smoking cessation education and efforts to increase participation in clinical trials. Expansion of screening CT scans and telehealth platforms may also improve access to care for these populations. Research Sponsor: None.

6604 **Poster Session**

Association between severe adverse event management and overall survival in patients treated with immune checkpoint inhibitor with advanced non–small-cell lung cancer.

Jarushka Naidoo, Douglas Buckner Johnson, Charlotte Doran, Yuexi Wang, Yan Zhang, Trong Kim Le, Sari Hopson, Brian Dreyfus, Lincy S. Lal, Charmy Vyas, Shay Goldstein, Zara Izadi; Beaumont RCSI Cancer Center, Dublin, Ireland; Vanderbilt University Medical Center, Nashville, TN; ConcertAI, Cambridge, MA; Bristol Myers Squibb, Princeton, NJ; Bristol-Myers Squibb, Princeton, NJ

Background: The impact of severe adverse event (sAE) management (mgmt) on clinical outcomes in cancer patients (pts) receiving immune checkpoint inhibitor (ICI) therapy has not been fully examined. We aimed to evaluate the association between mgmt of sAEs and overall survival (OS) in pts receiving ICIs for advanced non-small cell lung cancer (aNSCLC). **Methods:** Data were drawn from the ConcertAI Patient360 dataset, a curated EMR-based US oncology database representing 19,000+ NSCLC patients. aNSCLC pts who initiated ICI in the first 3 lines of anti-cancer therapy from 1/1/15 - 8/31/21 with no record of clinical trial enrollment or diagnosis of a second primary cancer were included. sAEs (dermatologic, gastrointestinal, endocrine, hepatic, respiratory, rheumatic, renal, and cardiac) and mgmt actions were curated from unstructured data from ICI initiation through the earliest of: 100 days after ICI discontinuation, start of a non-ICI regimen, end of study period, or death. Cox regression was used to evaluate the association between sAE mgmt actions (as time-varying covariate) and OS adjusting for baseline characteristics including line of therapy. The earliest sAE and mgmt action per patient were examined in OS analysis. **Results:** 3,211 pts were identified (median [IQR] age 67 [13] years, 55.1% male). Median [Q1-Q3] duration of follow-up from ICI initiation was 8.2 [3.3-17.5] months. Most pts had advanced disease at initial diagnosis (82.0%) and started ICI in first line (61.6%). The most common ICI regimens in the first 3 lines were nivolumab (29.5%) and pembrolizumab + carboplatin + pemetrexed (29.1%). 8.6% of pts had at least one sAE, most often diarrhea (3.5%). Median [Q1-Q3] time from ICI initiation to first sAE was 84 [34-211] days. Mgmt actions any time after first sAE included anti-cancer treatment interruptions [dose reduction (4.0%), hold (20.6%), discontinuation (2.2%)], sAE treatment [corticosteroids (71.8%), immunosuppressive drugs (2.5%)], hospital admission [hospitalization (57.4%), emergency department visit (24.6%)], and other/unknown (4.3%). Overall, median [95% CI] OS was 13.6 [12.6-14.6] months. Compared with pts with no sAEs, pts with sAEs whose earliest mgmt action was hospital admission (N=155) or sAE treatment (N=71) had a higher risk of all-cause mortality (adjusted HR [95% CI] 1.61 [1.38-1.88] and 1.53 [1.22-1.91], respectively). Pts with sAEs first managed with anti-cancer treatment interruptions (N=39) had similar risk of all-cause mortality (0.91 [0.66-1.25]) compared with pts with no sAEs. **Conclusions:** Pts with sAEs first managed with hospital admission or sAE treatment had shorter OS than those with no sAEs. No difference was observed for sAEs first managed with anti-cancer treatment interruptions. Findings suggest early treatment interruption for sAEs does not impact OS. Research Sponsor: Bristol-Myers Squibb.

6605 **Poster Session**

Intrathecal drug delivery systems for cancer pain control: Insights on current contemporary practices in the US.

Vasudha Goel, Melissa Ann Geller, Anne Hudson Blaes, Amitabh Gulati; University of Minnesota, Minneapolis, MN; Department of Anesthesiology, Memorial Sloan Kettering Cancer Center, New York, NY

Background: About a third of cancer survivors report moderate to severe pain. Intrathecal drug delivery system (IDDS) is an implantable pain control option for treating intractable chronic pain not responsive to systemic opioid therapy. Studies on the current practices in the US around the utilization of IDDS for cancer pain are lacking. **Methods:** The Nationwide inpatient sample (NIS) dataset is funded by the Agency for healthcare research and quality (AHRQ) for multistate healthcare research & decision-making. Adult patients admitted to hospitals with a primary or secondary cancer diagnosis between 2016-19 were included. Patients undergoing IDDS implantation were identified using the validated International Classification of Diseases, 10th Revision, Procedure Coding System codes (00HU33Z Insertion of infusion device into spinal canal, percutaneous approach and 0JH80VZ Insertion of infusion pump into abdomen subcutaneous tissue and fascia, open). Baseline demographics, hospital characteristics, and type of cancer associated with IDDS implantation were evaluated in the study. **Results:** 22,895 patients underwent IDDS surgery amongst 7.06 million hospitalizations from 2016-19. The IDDS cohort consisted of patients in the 65-79 years age group (40.49%), female sex (50.42%), and Caucasian ethnicity (75.82%). Most IDDS surgeries were performed in large, urban teaching hospitals. **Conclusions:** Despite recommendations supporting IDDS use, a small minority received the treatment with significant racial & socioeconomic disparities in IDDS use. Research Sponsor: None.

	No IDDS 7,042,953	IDDS surgery 22,895	Total population 7,065,848	p-value
Age (Years)				<.0001
18-34	154240 (2.19%)	820 (3.58%)	155060 (2.19%)	
35-49	544645 (7.73%)	2815 (12.3%)	547460 (7.74%)	
50-64	2186090 (31.04%)	8365 (36.54%)	2194455 (31.05%)	
65-79	2959744 (42.02%)	9270 (40.49%)	2969014 (42.02%)	
≥ 80	1198235 (17.01%)	1625 (7.1%)	1199860 (16.98%)	
Gender				<.0001
Male	3636884 (51.64%)	11345 (49.6%)	3648229 (51.63%)	
Female	3403269 (48.32%)	11525 (50.4%)	3414794 (48.33%)	
Race				<.0001
White	4883598 (69.34%)	17360 (75.82%)	4900958 (69.34%)	
Black	931800 (13.23%)	1480(6.46%)	933280 (13.23%)	
Hispanics	576785 (8.19%)	1460 (6.38%)	578245 (8.18%)	
Asian or Pacific Islander	221740 (3.15%)	1205 (5.26%)	222945 (3.16%)	
Native American	31230 (0.44%)	90 (0.39%)	31320 (0.44%)	
Location of Hospital				<.0001
Rural	483944 (6.87%)	1115 (4.87%)	485059 (6.86%)	
Urban	6559009 (93.13%)	21780 (93.13%)	6580789 (93.14%)	
Hospital bed size				<.0001
Small	1190979 (16.91%)	1510 (6.6%)	1192489 (16.88%)	
Medium	1905423 (27.05%)	2535 (11.07%)	1907958 (27.0%)	
Large	3946552 (56.12%)	18850 (82.33%)	3965402 (56.12%)	
Teaching Status				<.0001
Non-Teaching	1759899 (24.99%)	2535 (24.94%)	1762434 (24.94%)	
Teaching	5283054 (75.01%)	20360 (88.93%)	5303414 (75.06%)	

6606 **Poster Session**

The safety of seasonal influenza vaccination among patients prescribed immune checkpoint inhibitors: A self-controlled case series study using administrative data.

Alicia Ann Grima, Jeff C Kwong, Lucie Richard, Jacques Raphael, Nicole Basta, Alex Carignan, Karin Top, Nicholas Brousseau, Phillip S. Blanchette, Maria Sundaram; Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada; ICES, Toronto, ON, Canada; ICES, London, ON, Canada; Department of Oncology, Division of Medical Oncology, London Regional Cancer Program, Schulich School of Medicine and Dentistry, Western University, London, ON, Canada; McGill University, Montreal, QC, Canada; Université de Sherbrooke, Sherbrooke, QC, Canada; Dalhousie University, Halifax, NS, Canada; Université Laval, Quebec City, QC, Canada; Marshfield Clinic Research Institute, Marshfield, WI

Background: Immune checkpoint inhibitor (ICI) therapy for cancer patients carries a risk of severe immune-related adverse events (IRAEs). Since vaccines are immunomodulatory, administering seasonal influenza vaccinations to individuals on ICI therapy may exacerbate this risk. However, these vaccines provide substantial benefit to this at-risk population. As severe IRAEs are rare, previous vaccine safety studies in this population have been underpowered and have shown conflicting results. **Methods:** We used health administration data on adult Ontarians who initiated ICI therapy and received an influenza vaccine between January 1, 2012, and December 31, 2019. We conducted a self-controlled case series study, with a pre-vaccine control period (12-weeks post-ICI initiation to 14 days before vaccine), risk period (42 days post-vaccine), and a post-vaccine control period (until observation end). Each individual contributed a maximum of 2 years of person-time. Emergency department (ED) visit(s) and/or hospitalization for any cause was used as a surrogate measure of severe IRAE frequency. We fitted a fixed effect Poisson regression model incorporating seasonality and time to estimate incidence. **Results:** We identified 1133 patients who received an influenza vaccine on ICI therapy. The majority were aged ≥66 years (72.7%), male (62.8%), and had lung cancer (53.9%). A quarter (25.9%) experienced an ED visit and/or hospitalization during the observation period. The rate of ED visits and/or hospitalization per person-days in the risk and control periods were similar, with an incidence rate ratio of 1.04 (95% CI: 0.75, 1.45). Subgroup and sensitivity analyses revealed similar findings. **Conclusions:** Receipt of a seasonal influenza vaccine was not associated with an increased incidence of ED visit or hospitalization among adults on ICI therapy. The results from this analysis suggest no significant safety concern with administering influenza vaccines to this patient population. Research Sponsor: Canadian Immunization Research Network (CIRN).

6607 **Poster Session**

Development of natural language processing (NLP) models for extracting key features from unstructured notes to create real-world data (RWD) assets for clinical research at scale.

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Background: RWD derived from Electronic Health Records (EHR) has detailed clinical information about patient journeys that can assist in clinical research, trial design, safety assessments etc. However, much of the vital information is locked away in unstructured clinical texts and needs to be converted to structured format to be useful for downstream applications. We demonstrate how this can be achieved at scale with a high degree of accuracy through NLP. **Methods:** NLP models were developed to extract data for 11 clinical variables from unstructured notes of ~98k lung cancer patients and merged with the structured data into a common data model (Table). These models were a combination of domain knowledge, rule-based models, machine learning models, and deep learning models. The increase in fill rate per variable over structured data only was used to quantify the improvement by NLP. The accuracy of the models was assessed against a manually curated dataset comprising of 752 patients. **Results:** The NLP models significantly improved the fill rate of key clinical variables and were able to extract the information from clinical notes with high accuracy (Table). For some variables such as NSCLC/SCLC status, surgery, tumor grade and histology, all or most of the data was extracted via NLP. Metastatic status via NLP included distant metastasis, locally advanced disease and no metastasis whereas in the structured data, only data for distant metastasis was present. In the case of Performance Status (PS), even though a significant number of patients had at least 1 PS recorded in the structured data, NLP significantly increased longitudinal capture, thus increasing the density of this variable per patient. **Conclusions:** NLP models can be developed and used to enrich structured RWD data by extracting information from unstructured documents thus significantly improving the utility of this data for downstream applications. Given the high accuracy of these models and the scale at which they can be run, this can be a good alternative to human curation or can augment human curation enabling the creation of very large-scale datasets for clinical research. Research Sponsor: None.

Performance of NLP models and their contribution to enriching structured RWD.

NLP Field (# of patients = 98676)	Stage at Dx	T Stage at Dx	N Stage at Dx	M Stage at Dx	NSCLC / SCLC	Tumor Histology	Tumor Grade	Metastatic Status	Metastatic Site	Lung Cancer Surgery	PS
# of unique patients in RWD	57065	50139	51897	55035	0	10534	2771	34067	31510	0	70773
# of unique patients in RWD-NLP	83864	66138	66724	66593	88795	94677	56662	92627	47004	22844	82679
% contribution from NLP	32	20.9	22.2	17.4	100	88.9	95	63.2	33	100	58*
Precision/Recall	0.92/ 0.87	0.92/ 0.83	0.89/ 0.85	0.9/ 0.81	0.98/ 0.91	0.87/ 0.88	0.91/ 0.90	0.88/0.87	0.94/0.97	0.87/ 0.67	0.97**

* Calculated based on patients where at least 1 PS value was added by NLP. ** Accuracy.

6608 **Poster Session**

A pragmatic, single-arm clinical trial of a dose-adjustment algorithm for preventing cytopenia-related delays during FOLFOX chemotherapy.

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Background: Unplanned delays are common during FOLFOX chemotherapy, and cytopenias (neutropenia and/or thrombocytopenia) are the most common cause of delays. We evaluated a novel, provider-driven FOLFOX dose-adjustment algorithm designed to reduce unplanned delays while maintaining chemotherapy dose intensity. **Methods:** We conducted a pragmatic, single-arm clinical trial to evaluate the FOLFOX dose adjustment algorithm (NCT04526886). The algorithm prescribed graded chemotherapy dose reductions without delay on day 1 of cycles 2-6 for patients with an absolute neutrophil count (ANC) of 750 to 1499/microL and/or a platelet count of 50 to 99 K/microL. The algorithm prescribed a delay when ANC was less than 750 or platelet count was less than 50 on day 1 of cycles 2-6. Chemotherapy dose adjustments and delays for reasons other than cytopenias were at the discretion of the treating provider. Patients receiving initial treatment with FOLFOX chemotherapy (with or without concomitant monoclonal antibodies) were eligible. Subjects received standard chemotherapy doses in cycle 1 (bolus 5-FU 400 mg/m2, oxaliplatin 85 mg/m2, and infusional 5-FU 2400 mg/m2/46 hours). Use of granulocyte colony stimulating factor (GCSF) was not permitted, except for patients who had already experienced an unplanned delay. The primary outcome was any unplanned delay prior to completion of day 1 of cycle 6 of chemotherapy (with an interval of $>$18 days between cycles.) We tested whether the incidence of any unplanned delay was less than the historical rate of 43%, using a one-sample test of proportions. Chemotherapy relative dose intensity (RDI) over cycles 1-6 was a key secondary outcome. **Results:** 48 of 54 enrolled subjects were evaluable. The median age was 66, and 50% were female. The most common primary cancer sites were colorectal (n = 31) and gastroesophageal (n = 12). Metastatic cancer was present in 67%, and 35% received a concurrent monoclonal antibody. Sixteen of 48 subjects had any unplanned delay before completing cycle 6 (33%, 95% CI 0.22-0.47, p = 0.08 for comparison with historical proportion of 43%), and 7 subjects had any cytopenia-related delay (15%, CI 0.07-0.27). Twenty-one subjects (44%) had one or more algorithm-driven chemotherapy dose reductions without a delay, and 8 cycles were delivered without delay with an ANC of 750-999 (without GCSF). The mean (median) chemotherapy RDIs were: bolus 5-FU, 65% (67%); oxaliplatin, 85% (90%); and infusional 5-FU, 92% (97%). **Conclusions:** The 33% observed incidence of any unplanned chemotherapy delay was nominally but not significantly lower than the historical rate of 43%. The incidence of any cytopenia-related delay was 15%, lower than the historical rate of $>$30%. Further refinement and evaluation of the FOLFOX dose adjustment algorithm may help to reduce unplanned delays and their attendant disruptions and costs for patients and providers. Clinical trial information: NCT04526886. Research Sponsor: Dartmouth Cancer Center.

6609 **Poster Session**

Assessment of patient reported outcomes (PROs) completion patterns in patients with cancer: Examining real-world data.

Nada Al-Antary, Eric Adjei Boakye, Samantha Tam, Carl Wilson, Laila Poisson, Theresa Zatirka, Michael Ryan, Kelly Hirko, Steven S. Chang, Benjamin Movsas; Henry Ford Health System, Detroit, MI; Henry Ford Health, Detroit, MI; Michigan State University, East Lansing, MI

Background: Use of Patient Reported Outcomes (PROs) in clinical practice plays a major role in improving care, quality of life, hospitalization, emergency room visits and consequently improving overall survival. However, robust information on real-time assessment of PROs in cancer patients is insufficient, as most available data are limited to specific populations enrolled in clinical trials. This thereby increases disparities among minorities of race, age, and socioeconomic status, creating a barrier between the benefits of PROs and these underserved populations. This study examines the response rates, patterns and characteristics of patients completing PROs in a tertiary cancer center. **Methods:** Patients with a cancer diagnosis and an oncologic provider visit at a tertiary cancer center were offered an opportunity to complete Patient Reported Outcome Measures (PROMs) between August 2020 and July 2022.We used the National Institute of Health's computer adaptive tests Patient-Reported Outcomes Measurement Information System (PROMIS) instruments in pain interference, physical function, fatigue, and depression. Seven days prior to their clinical appointment, patients were assigned the PROMIS instruments in MyChart, then offered in-clinic completion with a tablet at check-in, if not completed online. A decision tree model was employed to assess the factors that may influence patients' PROMs completion (age, gender, race, marital status, insurance, stage, comorbidity score, and provider specialty and location). **Results:** A total of 8,535 patients were offered the PROMIS CAT version 2.0 instrument during the study period. The two most important factors that determine whether a patient completed PROMs in order of importance were provider specialty and patient race. Patients were more likely to complete PROMs if they had a visit with a provider in Radiation Oncology (RC) or Surgery specialty compared with Medicine or Supportive Oncology specialty (40.86% versus 29.68%). Among patients who had a visit with a provider in RC or Surgery specialty, there was a better chance of PROMs completion with White race compared to Black or Other races (45.83% versus 33.69%). Of those who had a visit with a provider in Medicine or Supportive Oncology specialty, there was a better chance of PROMs completion with Other or White races compared to Black race (32.40% versus 22.19%). **Conclusions:** We found that provider specialty and patient race were the most important factors influencing patients' PROMs completion. In order to realize the full benefit of PROs in patient care, multilevel interventions can be employed to increase patient-provider utilization of PROs. Moreover, efforts should focus on a patient-centered design to address patient and provider barriers impeding PROs accessibility and completion. Research Sponsor: None.

6610 **Poster Session**

Molecular diagnostic classification for cancers of unknown primary (CUP): Post-testing diagnosis and treatment impact analysis from real-world claims data.

Zachary Rivers, Ryan W Huey, Rotem Ben-Shachar, Anjali Narayan Avadhani, Timothy J. Taxter, Kyle A. Beauchamp, Adam J Hockenberry, Halla Nimeiri, Joelle Allam, Aparna Kalyan, Kanwal Pratap Singh Raghav, Michael Sangmin Lee; Tempus Labs, Inc., Chicago, IL; University of Texas MD Anderson Cancer Center, Houston, TX; Tempus Labs, Inc., Redwood City, CA; Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL; MD Anderson Cancer Center, Houston, TX

Background: Next-generation sequencing-based molecular diagnostic classifiers can help identify the tissue of origin for CUP, and enable the selection of site-specific therapies (as opposed to empiric chemotherapy) for this vulnerable population with high unmet need. NCCN guidelines do not endorse the use of tissue of origin classifiers as standard of care for CUP patients due to limited clinical evidence. Here, we linked results of a commercial molecular diagnostic classifier with claims data to understand how this test impacted patient care. **Methods:** We assessed de-identified claims data from the Komodo Healthcare Map (a database including provider visits, laboratory tests, procedures, imaging, and prescriptions) linked to the Tempus Tumor Origin (TO) test—a machine learning classifier that uses RNA-seq data to classify tumors into one of 68 histological subtypes. Eligible patients had pathologist-confirmed CUP and were classified as one of 9 subtypes (each having n>10). Impact was determined by identifying either one or more new diagnostic codes or new subtype-related medication claims following TO testing. **Results:** We analyzed data from 490 patients: 483 for the diagnosis analysis and 213 for the medication analysis (206 patients appear in both, due to differences in timing of diagnosis vs. medication claims). We found that post-TO testing, 49.9% (n=241) of patients had a diagnostic code change, 63.8% (n=136) had a treatment change, and 41% (n=85) had both. In total, 59.6% (n=292) of patients were impacted by the use of this classifier, with variation according to predicted subtype (Table). Cancer types with specific treatment options were more likely to have changes in diagnostic code or treatment. For CUP predicted as lung adenocarcinomas, 85% of the cases had a new subtype-aligned medication, and 78% were specifically placed on immunotherapy (IO) compared with 24% of overall patients. **Conclusions:** Using real-world claims data, we show that molecular diagnostic testing utilizing Tempus TO impacted care for a majority of CUP patients. This cohort will be followed to identify how TO testing decisions impact outcomes. Research Sponsor: Tempus Labs.

Cancer Type	Diagnosis Impact	Medication Impact	IO Impact	Total
Breast	15/24 (63%)	10/16 (63%)	3/16 (19%)	16/25 (64%)
Cholangiocarcinoma	57/107 (53%)	26/52 (50%)	4/52 (8%)	69/108 (64%)
Colorectal	16/50 (32%)	17/26 (65%)	0/26 (0%)	25/54 (46%)
Female Reproductive Tract	25/47 (53%)	19/27 (70%)	4/27 (15%)	32/48 (67%)
Gastroesophageal	13/37 (35%)	9/13 (69%)	3/13 (23%)	19/37 (51%)
Lung Adenocarcinoma	61/96 (64%)	23/27 (85%)	21/27 (78%)	67/96 (70%)
Lung Squamous Cell	19/34 (56%)	7/13 (54%)	6/13 (46%)	21/34 (62%)
Pancreatic	19/55 (35%)	15/25 (60%)	3/25 (12%)	25/55 (45%)
Urothelial	16/33 (48%)	10/14 (71%)	8/14 (57%)	18/33 (55%)

6611 **Poster Session**

Using real-world evidence (RWE) in regulatory decision making: A study of 6 oncology approvals with RWE included in the product label.

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Background: The 21st Century Cures Act in 2016 enhanced the FDA's ability to include the use of real-world data (RWD) and consideration of RWE in the development and approval of new medical products. Currently, limited assessments of the use of RWE in FDA approved oncology product reviews exist in the literature. This study was conducted to determine how RWE was used in FDA decisions for oncology drug approvals between 2015 and 2022. **Methods:** A systematic review of FDA submission documents and product labels available on the FDA website from 2020 to 2022, in addition to an exhaustive manual search of grey literature and the results of a targeted literature search from 2015 to 2019 were used to identify RWE that were included in FDA submission documents and in approved product labels. **Results:** In total, 124 oncology product evaluations were reviewed in the 2020 to 2022 literature search. Twenty-nine oncology product NDAs and BLAs included RWE to support efficacy, safety, or indication, of which the majority (n=26) ultimately had RWE accepted as evidence by the FDA for the submission. In these cases, RWE was used to add context (n=16), to support the indication or safety (n=7), to provide substantial basis for indication or safety (n=2), as a statistical comparison (n=2), or for informational purposes only (n=1). Feedback from the FDA reviewers for reasons RWE studies were not considered during product approval reviews included methodology issues, sample size concerns, and omission of patient level data. Ultimately, across the 2015 to 2019 targeted literature review and the 2020 to 2022 FDA submission document review, 6 oncology product labels incorporated RWE: palbociclib, uridine triacetate, lutetium Lu 177 DOTATATE, bevacizumab-adcd, naxitamab-gqgk, and decitabine/cedazuridine. RWE was used to support the initial indication for the majority of products (n=5) and also supported label expansion (n=1). RWE was incorporated in the product label post-marketing experience section (n=3), the clinical studies section (n=2), and the warnings/precautions section (n=1). **Conclusions:** These results suggest that RWE has become an important part of regulatory decision-making for oncology drug approval. Twenty-six of 29 RWE studies were accepted as evidence for the submission. For the 6 oncology products that include RWE in the product label, RWE was most frequently used to support the initial indication and was included in the postmarketing experience section. These examples show consistent use of RWE since the approval of the 21st Century Cares Act and provide evidence of a promising new direction with the creation of the FDA guideline/program for RWE. Research Sponsor: Bayer.

6612 **Poster Session**

Patient reported outcomes (PROs) collection modalities among patients diagnosed with cancer: Online vs in-person.

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Background: Patient reported outcomes (PRO) can be valuable clinical tools to embed the voice of patients into the clinical assessment. PROs provide important metrics to guide treatment decision making, improve quality of life, reduce acute care, and extend survival in cancer patients. Different modalities for collecting patient reported outcome measures (PROMs) exist (e.g., electronic, paper, telephone); yet little is known about factors associated with PROMs completion modality. More information on PROMs completion modality may determine addressable barriers. We sought to determine whether patients' sociodemographic and clinical factors differed by completion modality. **Methods:** Beginning in 2021 all patients diagnosed with cancer who had a visit with an oncologic provider at a tertiary cancer center were assigned the National Institute of Health's computer adaptive tests Patient-Reported Outcomes Measurement Information System (PROMIS) instruments in pain interference, physical function, fatigue, and depression through the MyChart patient portal 7 days prior to the visit. If this was not completed at the time of the visit, it was available for completion on a tablet during check-in. The outcome variable was completion modality defined as the method a patient used to complete their PROMs (MyChart vs. In-Person). Multivariable logistic regression model was used to estimate the association between patients' sociodemographic and clinical factors (age, sex, race/ethnicity, marital status, insurance type, stage, provider specialty) and completion modality. **Results:** A total of 2915 patients completed PROMs, of which 54% completed using MyChart and 46% completed in-person. The average age of patients was 59.6 (SD=12.4) years, most were females (63.1%), White (69.4%) and married (59.2%). Compared to male patients, females were less likely to complete PROMs in-person (aOR=0.80, 0.67–0.95). However, patients were more likely to complete PROMs in-person if they were of Black race (aOR=1.85, 1.52–2.24) or Other race (aOR=1.48, 1.12–1.96) vs. White; single (aOR=1.30, 1.05–1.62) vs. married; or have Medicaid/other insurance (aOR=1.52, 1.15–2.01) vs. private insurance. Patients who had visits with a radiation oncology provider (aOR=1.50, 1.20–1.86) or surgical oncology provider (aOR=1.32, 1.07–1.62) were more likely to complete PROMs in-person compared to those who had visits with a medical oncology provider. **Conclusions:** Almost half of the patients completed PROMs in-person during check-in, which was unexpected in the context of trends toward mobile-based patient engagement. Patients in underserved populations were the most likely to complete PROMs in-person. Although offering PROMs remotely may be more efficient and allow monitoring between visits, offering an in-person option helps to capture PROs from underserved populations. Research Sponsor: None.

6613 **Poster Session**

An assessment of the provider financial risk impacts of adoption of biosimilars in the Medicare Oncology Care Model.

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Background: In 2016, Medicare launched the Oncology Care Model (OCM)—a Value-Based Payment (VBP) initiative providing per-beneficiary prospective payment to providers, and performance-based financial incentives/risks based on cost of care in 6-month 'episodes' vs. risk-adjusted benchmarks for cancer patients receiving chemotherapy. Oncology biosimilars may play an important role in managing financial risk in the OCM and other VBP models, but the real-world impact remains uncertain. The objective of this study was to quantify the impact of biosimilar adoption on oncology provider financial risk under the OCM using real-world data. **Methods:** We estimated the impact of biosimilar adoption on provider financial risk from 2019 to 2021 by modeling the methods (episode framing, pricing, & risk adjustment) of the OCM. Cancer episodes were identified from the 5% Medicare Limited Data Set (LDS). The study sample consisted of cancer treatment episodes with use of any of the following agents or their biosimilars: bevacizumab, rituximab, trastuzumab, epoetin alfa, filgrastim, and pegfilgrastim. Financial risk was defined as the difference in observed total cost of care vs. OCM target episode cost. The primary outcome was the difference in financial risk (expressed in nominal $USD) under observed use of reference and/or biosimilars vs. hypothetical use of 100% reference agent. **Results:** The study sample included 8851 6-month episodes initiating between 1/2019 and 6/2021. Biosimilar adoption resulted in a mean cost *reduction* of $1,020 per episode vs. hypothetical 100% use of reference agents. Biosimilar use increased markedly over the study horizon–with 24% of episodes with a biosimilar in Half (H)1 2019, increasing to 65% by H1 2021, and driven by increased use of antineoplastic (1% to 36%) vs. supportive care biosimilar agents (23% to 34%). Mean financial risk reduction grew with the rapid adoption of biosimilars over this period. The average risk reduction in episodes initiating in H1 2021 was about 10 times larger than that seen in episodes initiating in the H1 2019 ($2060 vs $201, *See Table*). Observed mean cost was below the OCM target cost ($48808) in H1 2021 but exceeded the target cost in all other periods (range: +$1451 to +$4966). **Conclusions:** From 2019 to 2021, rapid adoption of biosimilars in Medicare fee-for-service beneficiaries included in the LDS led to substantial cost savings and reduction in risk for cancer episodes evaluated under the OCM methods. Broad adoption of biosimilars is a key strategy that providers in oncology VBP models will need to consider to manage financial risk. Research Sponsor: Pfizer.

Time Period	Observed Episodes	Observed Cost Per Episode	Cost Per Episode with 100% Reference Agent	Reduction in Financial Risk with Biosimilar Use
H1 2019	1985	$53241	$53443	-$201
H2 2019	1779	$53278	$53661	-$383
H1 2020	1760	$49118	$50084	-$966
H2 2020	1606	$49727	$51423	-$1696
H1 2021	1721	$48587	$50648	-$2060

6614 **Poster Session**

An application of extrapolating clinical data from single-arm trials to assess comparative effectiveness.

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Background: Single arm studies pose some challenges to determining comparative effectiveness of treatments. Such is the case with the tumor agnostic tropomyosin receptor kinase (TRK) inhibitors, larotrectinib and entrectinib. Larotrectinib and entrectinib are indicated for treatment of advanced cancer in patients (pts) with *NTRK* gene fusions. Lacking head-to-head trials, modeling methods are useful to estimate relative benefit. A direct naïve comparison, where single arms from separate trials are compared, can be used. Here, we estimate and compare long term benefit for pts receiving larotrectinib or entrectinib for *NTRK* gene fusion-positive non-small cell lung cancer (NSCLC) and colorectal cancer (CRC) by extrapolating survival curves to generate expected life-years (LYs) and quality-adjusted life-years (QALYs). **Methods:** We used partitioned survival methods to forecast comparative effectiveness. Larotrectinib survival data were derived from an updated July 2021 analysis of 21 adults (≥18 years of age) with NSCLC and 15 pts with CRC (NCT02122913, NCT02637687, and NCT02576431). Survival data for entrectinib were derived from published literature. Extrapolation of results were necessary to estimate long-term outcomes since the mean follow-up was less than three years. Progression free survival and overall survival for both treatments were estimated using several parametric survival distributions (Exponential, Weibull, Log-logistic, and Log-normal), then selecting based on AIC and clinical plausibility. QALYs were estimated by adjusting the time spent in the pre progression and post progression health states by utility values from the literature. A discount rate of 3% was applied to LYs and QALYs. Model uncertainty was evaluated using one-way and probabilistic sensitivity analyses. **Results:** In the larotrectinib trials, response rates were 86% and 33% in NSCLC and CRC, respectively. Exponential curves were fit for both treatments. In the entrectinib trials, response rates were 70% in NSCLC and 29% in CRC. The larotrectinib model estimated 7.3 LYs (95% Credible Interval [CrI]: 3.3, 11.4) and 4.3 QALYs (95% CrI: 2.2, 6.5) in NSCLC and 1.7 LYs (95% CrI: 0.8, 3.2) and 1.3 QALYs (95% CrI: 0.7, 2.3) in CRC. The entrectinib model estimated 2.7 LYs (95% CrI: 1.7, 4.2) and 1.6 QALYs (95% CrI: 1.1, 2.3) in NSCLC and 0.5 LYs (95% CrI: 0.2, 1.6) and 0.4 QALYs (95% CrI: 0.1, 1.1). Compared to entrectinib, larotrectinib produced additional gains of 4.7 LYs and 2.7 QALYs in NSCLC and 1.1 LYs and 0.9 QALYs in CRC. Limitations include non-matched baseline differences in the trial populations. **Conclusions:** In the absence of head-to-head trials, comparative effectiveness can be assessed by extrapolating from single armed studies indicated for the same patient population. Larotrectinib improved survival and quality adjusted survival vs entrectinib. Additional studies are needed to confirm these findings. Research Sponsor: Bayer US LLC.

6615 **Poster Session**

Racial disparities in survival and stage at diagnosis among adolescent and young adult patients with cancer.

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Background: Adolescent and young adult (AYA) patients (15-39 years) are an underrecognized population with high risk of select malignancies. Compared to pediatric and adult patients, AYA patients have not achieved improvements in cancer survival. No studies have evaluated overall survival (OS) and stage at diagnosis among all 5 federally recognized races in the US. Here we aim to investigate OS and stage at diagnosis among AYA patients by race. **Methods:** A retrospective cohort study of AYA patients diagnosed between 2004-2017 was conducted with the National Cancer Database. Patients with the 10 deadliest AYA cancers with at least 6 months of follow-up were included. Primary endpoints were OS (time from diagnosis to death) and late stage at diagnosis (stage III/IV or Grade III/IV for central nervous system [CNS] cancer). Kaplan-Meier estimates and log-rank tests assessed OS. OS and late stage were evaluated by race using multivariable Cox proportional hazard (adjusted hazard ratio [aHR]) and logistic (adjusted odds ratio [aOR]) regressions, respectively, with 95% confidence intervals (95% CI). All regressions were adjusted for sociodemographic and cancer characteristics. **Results:** 291,899 AYA patients were included: 64% female, 65% stage I/II, and 62 month median follow-up. Cancer sites included 27% breast, 16% lymphoma, 13% melanoma, 11% testis, 9% CNS, 7% colorectal, 7% cervix, 5% sarcoma, 3% ovary, and 2% lung. Race included 82.3% Non-Hispanic White (NHW), 14.0% Black, 2.9% Asian, 0.5% American Indian and Alaska Native (AIAN), and 0.3% Native Hawaiian and other Pacific Islander (NHPI). OS differed for all cancers by race ($p<.0001$), except for lung (p=.008), CNS (p=.32), and ovary (p=.28). OS was significantly inferior for NHPI, Black, and AIAN but superior for Asian, versus NHW (Table). NHPI had inferior OS (aHR, 95%CI) for melanoma (4.5, 2.0-10.0), colorectal (1.8, 1.3-2.4), lymphoma (1.7, 1.1-2.1), and cervix (1.6, .1-2.4) cancers. Black patients had inferior OS for melanoma (1.6, 1.2-2.2), lymphoma (1.5, 1.4-1.6), and breast (1.4, 1.3-1.4) cancers. Asian patients had superior OS for breast (0.7, 0.7-0.8) and lung (0.7, 0.6-0.9) but inferior survival for testis (1.9, 1.3-2.9) cancers. AIAN patients had inferior OS for colorectal (1.4, 1.0-1.9). Late stage at diagnosis was higher for NHPI, Black, and Asian patients, compared to NHW patients (Table). **Conclusions:** Both NHPI and Black AYA patients with cancer have higher risk of death and late stage disease at diagnosis, compared to NHW patients. Our data reveal racial disparities among Indigenous AYA patients masked by prior data omission. Research Sponsor: Stanford Cancer Institute – Women Cancer Center's Innovation Award; Stanford Cancer Institute – SCI Fellowship Award; Stanford Cancer Institute - Cancer Innovation Award.

Race	aHR	95%CI	P	aOR	95%CI	P
White	1.00	Ref		1.00	Ref	
AIAN	1.15	(1.02-1.30)	**0.021**	1.09	(0.96-1.22)	0.177
Asian	0.90	(0.85-0.95)	**<0.001**	1.20	(1.14-1.26)	**<0.001**
Black	1.22	(1.19-1.26)	**<0.001**	1.40	(1.36-1.43)	**<0.001**
NHPI	1.25	(1.09-1.44)	**0.002**	1.34	(1.16-1.55)	**<0.001**

6616 **Poster Session**

Real world utilization and disparities in outcome in the use of novel anti-androgen agents for metastatic prostate cancer.

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Background: Despite advances in treatment, disparities exist in prostate cancer treatment and utilization of treatment resources based on several factors including race and socioeconomic status. As evidence-based guidelines increasingly define novel androgen receptor inhibitors (ARIs) as the standard of care, it is important to understand how the utilization of ARIs impacts the outcome. In this study, we investigated the relationship between the utilization of the two most commonly used ARIs, Abiraterone and Enzalutamide, and survival among patients with metastatic prostate cancer. **Methods:** We conducted a retrospective analysis of patients in the Surveillance, Epidemiology, and End Results (SEER)-Medicare database from January 1st, 2013 to December 31, 2017. All patients aged 18 years and above with metastatic prostate cancer were included. The objective of these study was to determine the utilization of ARIs in different groups (age, race, location, income status and marital status) and investigate the impact of these variables on the survival. Kaplan-Meir survival curves were used for the survival analysis. Patients were stratified by: who received an ARI alone or in combination vs. who did not. Log-rank tests were used to compare the stratified survival probability curves by groups. A multivariate proportional hazards model was used to compare the instantaneous risk of death in metastatic prostate cancer between patients based on selected covariates. All hypothesis tests were two-tailed with a p-value < 0.05 considered statistically significant. **Results:** A total of 5889 patients with metastatic prostate cancer were included in the analysis. The median age was 73 years; 39% of patients received an ARI alone or in combination with other agents. Among the patients who received ARIs, 77 %, 15% and 8% were white, black and of other races, respectively. Use of ARIs were more in urban locations (98.1% vs. 1.9% at rural locations) and in patients with higher and mid-level incomes (73.0% vs. 22.7% in low-income group). While survivals were inferior in all subgroups of patients who did not receive ARIs, survivals was better in white race (vs. black and others) as well as in younger age group who received ARIs. However, in the latter group, there was no statistical difference in survival in rural vs. urban locations and low income vs. high and mid-income groups. **Conclusions:** Our study shows that 39% of patients with metastatic prostate cancer in the SEER Medicare population utilized an ARI.There was a significant underutilization of ARIs in non-white, rural locations and low-income subgroup. White race and younger age populations were associated with better survival irrespective of use of ARIs. Among patients who did not receive ARIs, survivals were inferior in rural (vs. urban) and low-income (vs. high and mid-income) patients, but survivals were equivalent in these subgroups who received ARIs. Research Sponsor: External research grant to Dr. Asit Paul by Hyde Family.

6617 **Poster Session**

Effects of concomitant gut-microbiome altering medications on immune checkpoint inhibitors therapy: A retrospective study.

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Background: In cancer patients, gut microbiota influences the antitumor immune response, efficacy, and safety of immune checkpoint inhibitors (ICIs). Antibiotics (ATBs), proton pump inhibitors (PPIs), and corticosteroids can alter the distribution of gut microbiota, resulting in dysbiosis, which can potentially reduce the efficacy of ICIs and may contribute to increased incidence of immune-related adverse effects (irAEs). **Methods:** We conducted a retrospective observational study to investigate the influence of concurrent medicines on patients receiving ICIs at the University of Vermont Cancer Center. We examined the medical records of people who received ICIs alone or in combination with chemotherapy or targeted therapy as a first-line therapy between January 2017 and June 2022. Patients who got ATBs, PPIs, and corticosteroids (>10 mg prednisone) one month before commencing ICIs and during the first six months of treatment were compared to those who did not. We looked at the relative risk for overall survival and the occurrence of irAEs in both cohorts. **Results:** We identified 266 patients, of which 99 (37%) have died. The mean age was 64 years, 55% were male, and 97% of the patients were White. Lung cancer was the most commonly identified malignancy at 36%, and 55% of the cancers were stage IV. The median ECOG was 1, and the median Charlson morbidity index was 6. Of the total cohort, 62% received antibiotics, 67% received steroids, 45% received PPIs, 31% received two of the three, and 27% received all three. The relative risk (RR) of death in the cohort which received antibiotics was 1.53 (p = 0.02), the cohort which received steroids was 1.73 (p = 0.006), and the cohort that received PPIs was 1.61 (p = 0.006). For the group that received two or all three medications, the RR was 2.18 (p = 0.003). Regarding irAEs, the group that received steroids had a RR of 2.13 (p = 0.07); however, most of these patients likely received steroids for an irAE. Antibiotics and PPIs were not associated with a higher risk of irAEs. One of the significant limitations of our study is the small sample size and the retrospective data collection. Data is also confounded because it includes patients who have received ICIs in combination with chemotherapy or other agents. **Conclusions:** Our study suggests that patients who received any of the gut microbiome-modifying medications before starting and within the early phase of ICIs treatments are at higher risk of mortality, likely owing to the poor efficacy of ICIs or possibly because these patients are sicker at baseline. However, we must be judicious with using such medications when patients undergo treatment with ICIs. Large prospective studies looking at this association are needed to understand the risk and potential outcomes. Research Sponsor: None.

Medications	RR for death	P-value
Antibiotics	1.53	0.02
Steroids	1.73	0.006
PPIs	1.61	0.006
Two or more	2.18	0.003

6618 **Poster Session**

An indirect comparison of elranatamab's (ELRA) objective response rate (ORR) from MagnetisMM-3 (MM-3) vs real-world external control arms in triple-class refractory (TCR) multiple myeloma (MM).

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Background: ELRA is a BCMAxCD3 bispecific antibody being investigated for the treatment of R/R MM. The phase 2 MM-3 trial was single-armed; the aim of this study (NCT05565391) was to contextualize the efficacy data from MM-3 with two real-world (RW) external control arms. **Methods:** A retrospective cohort study was conducted to indirectly compare the efficacy observed in MM-3 Cohort A (BCMA-naïve; N=123) from the 9-month data cut with two US-based oncology electronic health record databases, Flatiron Health (FH) and COTA, as external controls. MM-3 inclusion (eg, prior MM diagnosis, ECOG≤2, refractory to ≥1 PI, ≥1 IMiD, and ≥1 anti-CD38) and exclusion (I/E) criteria (eg, plasma cell leukemia, smoldering MM) were applied to each RW database to obtain comparable patient populations across sources. After imposing MM-3 I/E criteria, comparisons between data sources on ORR were conducted by estimating rate ratios (RRs) using log-binomial regression models (unweighted analysis). RRs were also estimated using both inverse probability treatment weighting (IPTW) and augmented IPTW (doubly robust) analyses to account for key covariates (eg, age, comorbidities, ECOG, ISS, prior lines/refractoriness, cytogenetic risk, extramedullary disease, lab values). **Results:** The 123 patients from MM-3 Cohort A were compared with the 152 and 233 patients identified from the FH and COTA databases, respectively. Treatment regimens in the RWD sources included various combinations of PIs, IMiDs, and mAbs, among other agents (eg, selinexor). Across unweighted, IPTW, and doubly robust analyses, the ORR for ELRA was significantly higher than treatments used for TCR MM patients from RWD sources (Table; all p<.05). **Conclusions:** Among TCR MM patients who resemble those of the MM-3 trial, ELRA showed improved ORR compared with treatments currently used in clinical practice. Research Sponsor: Pfizer.

ORR comparison between elranatamab in MM-3 cohort A and RWD external control arms.

	MM-3 Cohort A	FH	P	MM-3 Cohort A	COTA	p
N	123	152		123	233	
Unweighted analysis						
ORR % (95% CI)	61.0 (51.8-69.6)	30.3 (23.1-38.2)	-	61.0 (51.8-69.6)	31.3 (25.4-37.7)	-
RR (95% CI)	2.01 (1.52-2.67)		<.0001	1.95 (1.54-2.47)		<.0001
	MM-3 Cohort A	**FH**		**MM-3 Cohort A**	**COTA**	
N	122*	149*		123	213*	
IPTW analysis						
ORR % (95% CI)	56.0 (41.1-76.2)	31.3 (19.4-50.4)	-	75.7 (65.6-87.4)	34.2 (27.2-43.0)	-
RR (95% CI)	1.79 (1.01-3.15)		.0447	2.22 (1.69-2.90)		<.0001
Doubly robust analysis						
ORR % (95% CI)	61.7 (54.5-68.9%)	27.6 (20.0-35.2%)	-	63.5 (55.2-71.9)	33.7 (27.5-39.8)	-
RR (95% CI)	2.24 (1.68-2.97)		<.0001	1.89 (1.53-2.35)		<.0001

FH, Flatiron Health; CI, confidence interval; ORR, objective response rate; RR, rate ratio.*Some patients were excluded from the IPTW and doubly robust analyses due to missing values for variables used in the propensity score model.

6619 **Poster Session**

Real-world outcomes of patients (pts) with malignant solid tumors treated with immune checkpoint inhibitors (ICI) in relation to smoking status: The SAKK 80/19 SMOKER study.

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Background: ICIs are the standard of care for the treatment of different advanced solid organ tumors. Especially in advanced non-small-cell lung cancer, never-smokers were shown to have an inferior outcome when compared to ex-smokers/smokers, suggesting that the smoking status could be a predictive marker for survival benefits under ICI treatment. **Methods:** Pts within the Swiss Alpine Tumor Immunology Registry (AlpineTIR) treated with an ICI were differentiated by their smoking status (ex-smokers/smokers versus never-smokers). Overall survival (OS) and progression-free survival (PFS) from the start of the first ICI treatment were analyzed by smoking status. Further, subgroup analyses for OS and PFS were done for the most common disease entities. **Results:** A total of 702 pts were included, from which 455 pts (65%) were ex-smokers/smokers, 213 pts (30%) were never smokers, and 34 pts (5%) had an unknown smoking status. The median follow-up time from the administration of the first ICI to the statistical analysis was 2.7 years (95% CI: 2.3 to 3.2 years). The most frequent tumors were lung cancer (50%), melanoma (13%), renal cell cancer (7%), bladder cancer (6%), and others (24%). Across all indications, the median OS was 1.7 years (95% CI: 1.4 to 2.6 years) for never-smokers (n = 213) and 1.5 years (95% CI: 1.2 to 1.8 years) for smokers (n = 455) (HR: 1.10, 95% CI: 0.89 - 1.37). The median PFS was 6.3 months (95% CI: 4.4 to 8.3 months) for non-smokers and 6.2 months (95% CI: 5.2 to 7.0 months) for smokers (HR: 1.05, 95% CI: 0.87 - 1.27). In lung cancer pts, the median OS was 1.4 years (95% CI: 0.8 to 2.8 years) for never-smokers (n = 43) and 1.4 years (95% CI: 1.2 to 1.7 years) for smokers (n = 302) (HR: 1.02, 95% CI: 0.68 - 1.51). In melanoma pts, the median OS was 3.4 years (95% CI: 1.8 to not reached (NR) years) for never-smokers (n = 54) and 1.7 years (95% CI: 0.8 to NR years) for smokers (n = 34) (HR: 1.35, 95% CI: 0.72 - 2.53). In renal cell cancer pts, the median OS was 1.5 years (95% CI: 1.0 to 3.6 years) for never-smokers (n = 28) and 3.5 years (95% CI: 0.6 to NR years) for smokers (n= 17) (HR: 0.74, 95% CI: 0.31 - 1.78). In bladder cancer pts, the median OS was 1.8 years (95% CI: 0.6 to NR years) for never-smokers (n = 17) and 1.4 years (95% CI: 0.5 to NR years) for smokers (n = 26) (HR: 0.88, 95% CI: 0.39 - 1.99). **Conclusions:** No survival difference between smokers and non-smokers with metastatic solid organ tumors treated with ICIs could be detected. Interestingly, even in the subgroup of lung cancer pts, no difference was seen. Based on these data, the smoking status should not guide ICI treatment decisions. Research Sponsor: Swiss Cancer Foundation.

6620 **Poster Session**

The impact of using Elsevier ClinicalPath oncology treatment pathways on survival and cost of care.

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Background: Cone Health is a 921 bed hospital system in North Carolina with a comprehensive cancer center. Our aim was to determine the value of using Elsevier's ClinicalPath oncology pathways on short-term survival and cost of care from the patient and health system perspectives. Cancer treatment has become more complex as it progresses more toward precision medicine modalities. As such, clinical decision support tools, such as ClinicalPath, have gained traction. Health systems struggle to survive after the COVID pandemic, with residual financial impacts lingering into 2023. It is more important than ever before that health systems focus on value where the patient benefits and financial sustainability are improved. **Methods:** We used a retrospective cohort study design with matching. Exposure was the use of the ClinicalPath decision support tool in Epic (exposed) versus no use of the tool (not exposed). We matched on cancer body site, AJCC clinical stage, the goal of treatment, Elixhauser comorbidity score, and year of a cancer diagnosis. We were able to match 509 exposed to 509 unexposed. Our primary outcomes were 12-month survival from the time of the first treatment and contribution margin. We used a log-rank calculation based on our hazard ratios (Freedman method) to determine the sample size required for each group, assuming a power of 80%. We used a Weibull parametric model to assess 12-month survival with additional covariates. An OLS model was used to evaluate the contribution margin. **Results:** Results demonstrate that when ClinicalPath is used to guide treatment, patients are half as likely to die within 12 months from treatment compared to the unexposed (HR 0.50; 95% CI 0.37-0.68). The OLS contribution model found, on average, that margin has an associated 74.0% (0.74; 95% CI 0.58-0.90) increase when ClinicalPath is used to guide treatment compared to the unexposed. This equates to a crude increase in contribution margin for cancer treatment of $58,362, on average per case, when ClinicalPath is used. Variable direct costs are higher when using ClinicalPath. This means, on average, it costs more to treat patients on pathway using best available evidence. Still, they have better short-term survival and payers are covering the additional costs given the increase in contribution margin for our system. **Conclusions:** Short-term recurrence free survival is significantly improved when providers utilize ClinicalPath compared to not using the tool consistent with the primary aim of the CDS solution. Newer, more efficacious treatments may have higher initial costs, as expected. Still, the effectiveness of these treatments on survival in the real-world setting is born out in the current study. The higher initial direct costs are counterbalanced by a higher contribution margin per patient providing evidence that improved outcomes in cancer therapy can also provide a positive ROI for provider organizations. Research Sponsor: None.

6621 **Poster Session**

Rates of emergency department visits and acute-care hospital admissions after starting chemotherapy or having surgery across six community-based cancer centers.

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Background: Cancer patients who start chemotherapy or have surgery are at risk for serious adverse events, which can include emergency department visits (EDV) and acute-care hospital admissions (ADM). These events are relevant to patients, clinicians, health systems, and policy makers. Few studies have described the frequency and predictors of EDVs and ADMs in the routine care setting. We sought to address this knowledge gap, and to describe the impact of the COVID pandemic on these events, using data from the SIMPRO consortium of six US-based health systems. **Methods:** In 2019, SIMPRO started a phased deployment of an electronic health record-integrated symptom management program (eSyM) as part of the routine care provided to patients with a suspected or confirmed gastrointestinal, thoracic, and gynecologic malignancy. eSyM prompts patients to complete symptom questionnaires and provides symptom management resources for 180 days after starting chemotherapy and 60 days following surgery. This analysis includes all patients, whether they used eSyM resources or not. Outcomes, which were measured using EHR-based encounter data, included the rates of EDVs and ADMs at 30 and 90-days after starting chemotherapy or following discharge from surgery. To account for potential confounding, we used multivariable logistic regression for the 30-day outcomes and Cox regression for the 90-day outcomes. **Results:** From September 2019-December 2022, 8664 patients started chemotherapy and 11,578 had surgery, with 3075 and 2587 patients, respectively, experiencing at least one outcome event (Table). 90-day outcomes varied significantly across health systems for chemotherapy (EDV 2-21%, ADM 5-28%) and surgery (EDV 7-14%, ADM 9-18%) patients. In multivariable analyses, patients who reported an employment status of disabled were more likely to report an EDV (OR 1.73-1.96) and an ADM (ORs 1.52-1.96). Widowed status was associated with greater odds of having an ADM (ORs 1.29-1.30), but not an EDV. Cox regression found chemotherapy recipients experienced lower hazards of an EDV, but not an ADM, during 2020 (coinciding with the start of the COVID pandemic). For surgery patients, there was no significant association between calendar year and EDVs or ADMs. [$p<0.001$ for all reported values]. **Conclusions:** A meaningful proportion of patients who started chemotherapy or had surgery for a suspected or confirmed malignancy in the routine-care setting had an EDV or ADM within 90 days. Most events occurred within 30 days. Further work is required to ascertain how many of these encounters are avoidable and what structural or procedural interventions could improve outcomes. Clinical trial information: NCT03850912. Research Sponsor: U.S. National Institutes of Health.

		Chemotherapy Patients (N=8664)	Surgery Patients (N=11,578)
		Percent	Percent
Age	(median)	(67)	(63)
Sex	Female	54	69
Race	Non-white	21	10
EDVs	30 days	7.3	5.4
	90 days	13.9	9.5
ADMs	30 days	10.6	8.0
	90 days	21.6	12.9

6622 **Poster Session**

Improved outcomes from reflex comprehensive genomic profiling-guided precision therapeutic selection across a major US healthcare system.

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Background: An ever-increasing number of biomarker-guided therapies, some with pan-cancer indications have expanded the oncologist's toolbox for fighting advanced cancer. Despite this, not all advanced cancer patients receive tumor genomic testing, or are tested for a limited number of targets. Still others are tested too late in their care journey to benefit from precision therapy. To assess the impact of removing testing barriers, we developed a reflex testing protocol where comprehensive genomic profiling (CGP) was routinely ordered by pathologists at time of diagnosis for advanced cancer patients. **Methods:** Reflex CGP testing was primarily initiated by the pathologist at the time of advanced cancer diagnosis. Testing was performed between 2019 and 2021 via CGP using the ProvSeq 523 lab-developed test, and testing was performed at no cost to the patient. Post-CGP, stage 4 patients were followed for $\geq$ 12 months. We assessed time to therapy, therapy selection, and overall survival (OS). Therapies were stratified by presence of biomarkers associated with approved targeted therapies (TT), presence of biomarkers for immunotherapies (IO), and/or therapies that were guideline based (GB) and not associated with a specific biomarker. As much key patient information is only consistently available in free-text medical charts, we implemented a novel natural-language processing (NLP) approach based on deep learning and large language models to accelerate abstraction. **Results:** A cohort of 1,423 advanced cancer patients met the study criteria. The median age was 66 years, 53% were female, and 82% white. The 3 most tested tumor types were 22% non-small cell lung cancer, 16% colorectal cancer, and 12% breast. Overall, 49% (N=704) of patients had a biomarker result considered actionable for an approved TT or IO. Median (IQR) time-to-treatment initiation post-CGP was 19 (2-70) days. In patients with no actionable TT or IO biomarkers (N=719), 63% were treated with chemotherapy-based regimens, 11% with GB, 17% with unmatched TT, and 8% with unmatched IO. Of patients who had only an actionable TT biomarker (N=287), 18% received matched TT and 13% received GB. 36% of patients with only an actionable IO biomarker (N=317) received matched IO monotherapy. 48% of patients with both actionable TT and IO biomarkers (N=100) received matched TT or IO monotherapy, and 5% received GB. Across all tumor types, patients receiving a TT had better OS compared to patients receiving chemotherapy with 12 months OS (%) of 70.1 (95% CI=64.4 - 76.3) for TT-treated patients, compared to 62.9 (95% CI=58.8 - 67.3) for chemotherapy only. **Conclusions:** CGP-guided precision therapy use is associated with significantly higher survival in a reflex testing population. A reflex protocol can overcome key barriers to the use and timing of genomic testing to improve access to these life-extending treatment modalities. Research Sponsor: Illumina; Providence Foundation of Oregon.

6623 **Poster Session**

Financial toxicity, quality of life, symptom burden, and access to resources in early-phase clinical trial (EP-CT) participants.

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Background: EP-CTs are an important therapeutic option for patients, and financial toxicity represents an increasing concern in oncology. Little is known about the financial toxicity of EP-CT participants. We sought to describe financial toxicity in EP-CT participants and assess associations of this factor with patient characteristics, quality of life (QOL), symptom burden, and access to resources. **Methods:** We prospectively enrolled consecutive adults participating in EP-CTs at Massachusetts General Hospital from 04/2021 – 01/2023. Participants completed surveys prior to treatment initiation that assessed financial toxicity (Comprehensive Score for Financial Toxicity [COST tool], higher scores indicate greater financial wellbeing). We adapted a financial toxicity grading scale proposed by the creators of the COST tool to define levels: low (COST $\geq$26) and high (COST 0–25). We surveyed QOL (Functional Assessment of Cancer Therapy-General) and symptom burden (psychological: Patient Health Questionnaire-4 [PHQ4]; physical: Edmonton Symptom Assessment System [ESAS]). Patients were asked their concerns regarding access to resources. We explored associations of financial toxicity with patient characteristics, QOL, symptom burden, and access to resources. **Results:** Of 221 eligible patients, we enrolled 196 (median age = 62.3 years [range 31.8-88.6], 57.1% female). Most common tumors were gastrointestinal (33.2%) and breast (20.4%); most (93.7%) had metastatic disease. Patients had an average COST score of 28.4 (SD 9.0), with 33.7% reporting high financial toxicity. Patients with high financial toxicity were more likely to be <65 years (70.0% vs 47.7%, p=0.003), unemployed (44.6% vs 17.7%, p<0.001), lack a college degree (52.3% vs 25.6%, p<0.001), and have income <$60,000 (60.6% vs 25.4%, p<0.001) compared to those with low financial toxicity. Compared to those with low toxicity, patients with high financial toxicity also had lower QOL scores (69.9 vs 77.3, p<0.001) and increased psychological (1.3 vs 0.9, p=0.02) and physical (19.3 vs 15.9, p=0.091) symptom burden, although increased physical symptoms did not reach statistical significance. Those with high financial toxicity were more likely to report concerns regarding access to several resources (housing [10.6% vs 2.3%, p=0.033], bill paying [31.8% vs 3.8% 3.8%, p<0.001], food [9.0% vs 0.7%, p<0.006], employment [21.2% vs 1.5%, p<0.001]; there was no significant difference in transportation [22.7% vs 16.1%, p=0.261]). **Conclusions:** We found that one third of EP-CT participants report high financial toxicity and identified factors associated with higher toxicity. We demonstrated novel associations between high financial toxicity and lower QOL, greater depression, and increased concerns regarding access to resources. Findings highlight the need to address financial toxicity among this population. Research Sponsor: None.

6624 **Poster Session**

Evaluation of cachexia and outcomes in patients with aggressive B-cell non-Hodgkin lymphoma.

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Background: Cancer cachexia is a muscle wasting syndrome characterized by anorexia, asthenia, and weight loss. Cachexia rates are as high as 35% for aggressive B-cell Non-Hodgkin Lymphomas (B-NHL), and is considered an independent factor in cancer outcomes compared to other disease burden markers. However, there remains no set protocol to identify hematologic cancer patients at risk for cachexia, and current imaging-based measures for muscle wasting can be costly and burdensome. Weight loss grading scale (WLGS) is a newly validated method to assess cachexia in solid tumor cancers but not hematologic malignancies. This study evaluates the relationship between WLGS and cancer treatment outcomes in B-NHL patients. **Methods:** This was a retrospective cohort study of adult patients with aggressive B-NHL treated between 2005-2020. WLGS grade was used as a cachexia marker to analyze its effect on outcomes. WLGS combines weight loss (since diagnosis) with a patient's BMI at that same time. A grade of 0 indicates no cachexia, and a grade of 4 indicates severe cachexia. Data for WLGS grade was captured for patients at 3- and 12-months post-treatment induction. Survival curve analyses assessed disability-free survival (DFS) (time from induction therapy to a patient requiring rehabilitative, home health, or skilled nursing services), progression-free survival (PFS), and overall survival (OS) outcomes. **Results:** Our cohort included 258 B-NHL patients. Within our study population, 45% were female, with an average age of 57 at diagnosis. B-NHL patients with higher WLGS, defined as a grade >2, composed 22% and 18% of patients at 3- and 12-months post-induction therapy, respectively. Patients with elevated WLGS were found to have significantly higher progression rates compared to lower WLGS grade individuals at 3 months (HR=1.8, p=0.049) and 12 months (HR=2.4, p=0.014) post-induction therapy. Furthermore, higher WLGS patients had significantly greater rates of disability compared with lower WLGS patients at 3 months (HR=1.7, p=0.013) and 12 months (HR=1.7 p=0.025) post-induction therapy. Finally, patients with a WLGS of 4 at 12 months post-induction therapy demonstrated significantly lower OS (HR=323, $P<0.0001$) than all other patients. **Conclusions:** In conclusion, WLGS, a new marker for cachexia, is highly correlated with morbidity and mortality outcomes in B-NHL patients. Specifically, PFS and DFS were significantly lower in groups with higher WLGS grades, and OS was significantly lower for individuals with a WLGS of 4. Weight and BMI, the two metrics used to calculate the WLGS score, require minimal time and resources to assess. Thus, regularly tracking weight can be an adjuvant screening to imaging and biomarker testing to identify patients at increased risk for disease progression or disability. The accessibility of WLGS tracking would further benefit disease tracking in resource-scarce areas and simplify disease assessment. Research Sponsor: None.

6625 **Poster Session**

Efficacy-effectiveness gap with immune checkpoint inhibitors in solid cancers: A population based cohort study.

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Background: Immune checkpoint inhibitors (ICIs) have been central in oncology drug development in the last decade often demonstrating large improvements in overall survival (OS) in pivotal randomized controlled trials (RCTs). Patient selection and/or care may be less stringent in the real world but ascertaining that benefits are translated satisfactorily from pivotal RCTs into the real world is crucial, as patients often base their treatment decisions on outcomes quoted to them from pivotal RCTs. **Methods:** After necessary ethics approvals, we collected relevant data on all consecutive patients with advanced solid cancers treated with ICIs in the province of Manitoba, Canada from inception to June 30, 2022 using pharmacy database and cancer registry. Eight most frequent ICI indications are included here. Survival probabilities were plotted using Kaplan-Meier Method, and descriptive statistics used to report relationship between variables. To put outcomes into perspective, we report real world data alongside that of pivotal RCTs used to support approvals of respective ICIs by Health Canada and the US FDA. **Results:** Eight ICI indications included 992 patients followed for a median of 40 months (range: 21-86 months). Patients required to meet precise provincial formulary criteria to receive ICIs, adopted mostly from the inclusion criteria of the corresponding pivotal RCTs. Median OS was shorter in the real world population not only compared to the experimental arms of the respective pivotal RCTs [by a median of 16 months (range: 3 - 38 months)] but also compared to their control arms [by a median of 3 months (range 3 to 32 months)]. This translated into an average of 51.1% (standard deviation: 20.1) compromise in median OS with ICIs in the real world compared to that observed in respective pivotal RCTs. **Conclusions:** Treatment with ICIs within high standards of practice in a Canadian province overall offered less than half the median OS observed in pivotal RCTs supporting their approvals. Current ICI treatment decisions by patients (and physicians) may therefore be based on highly inaccurate expectations. Our results should inspire rigorous phase IV clinical studies to identify pertinent real-world variables affecting outcomes including treatment related morbidity and mortality, with an ultimate aim to narrow the alarming efficacy-effectiveness gap. Research Sponsor: None.

		Pivotal RCT Outcomes (months)			Real World Outcomes		
ICI	Indication	Median F/U	Median OS (Experimental Arm)	Median OS (Control Arm)	Number of Patients	Median F/U (months)	Median OS (months)
Pembrolizumab	Melanoma	57.7	32.7	15.9	89	53	21.1
Pembrolizumab	NSCLC	25.3	30	14.2	327	32.2	11.2
Pembrolizumab	RCC	42.8	45.7	40	96	21	8
Nivolumab	NSCLC	40.3	12.9	9.8	153	49.1	6.6
Nivolumab	RCC	72	25.8	19.7	87	47	11.8
Ipilimumab	Melanoma	60	15	6.6	81	86.3	12.1
Ipilimumab + Nivolumab	RCC	67.7	55.7	38.4	54	32.2	18
Durvalumab	NSCLC	34.2	47.5	29.1	105	28.1	29.6

Electronic health record (EHR)-based machine learning (ML) to predict disease recurrence after surgical resection of early-stage non-small cell lung cancer (eNSCLC).

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Background: Surgical resection (SR) is a guideline-recommended definitive therapy for patients (pts) with eNSCLC. However, 30–50% pts develop disease recurrence (DR) within the first 5 years (yrs) after surgery. ML applied to routinely collected EHR data could facilitate timely identification of pts at risk of DR who would benefit from enhanced surveillance or initial treatment (Tx) intensification. **Methods:** eNSCLC pts with stage IB-IIIA at the time of SR between Jan 2010 – February 2022 were identified from ConcertAI Patient360 oncology database comprising structured and curated records from US-based EHR. DR was defined as the human-curated earliest advanced/metastatic diagnosis date from SR. Gradient boosting (GB), random forest (RF), and logistic regression (LR) algorithms with 6-fold nested cross-validation were trained and compared to predict the risk of DR or death at 2 yrs from SR. Pts who did not experience DR and were lost to follow-up within 2 yrs from SR were removed. Feature importance was defined using Shapley Additive Explanation (SHAP)-derived odds ratios (OR). Due to low prevalence of DR at 2 yrs, AUPRC was used as performance metric. Pts in the 1^{st} and 4^{th} quartiles of predicted probabilities from XGB model were defined as low-risk vs. high-risk groups. **Results:** Among 3597 pts, median age was 68.3 yrs (IQR 12.5), 51.8% were female, and 8.6% were Black. 24.4% developed DR within 2 yrs. GB, RF, and LR models had similar ability to predict DR at 2 yrs with mean hold-out set AUPRC of 0.33. In GB model, DR prevalence at 2 yrs was 34% in the high-risk vs. 18% in the low-risk group in hold-out set. N0 stage, T stage < 3, receipt of adjuvant immune checkpoint inhibitor (ICI), and presence of EGFR mutations were protective against DR at 2 yrs, while history of anemia and congestive heart failure (CHF) were risk factors (Table). SHAP revealed a N stage-by-adjuvant therapy and a N stage-by-CHF interaction: benefit from adjuvant chemotherapy (CT) was limited to higher N stages, while adjuvant ICI was beneficial for all N stages. CHF was a risk factor for lower N stages but not for higher N stages. **Conclusions:** ML applied to structured and unstructuredEHRs identified predictors of risk of DR at 2 yrs after surgery in eNSCLC and may identify high-risk pts who would benefit from enhanced surveillance plans and Tx intensification in the eNSCLC setting. The model indicated favorable outcome from adjuvant targeted therapies in EGFR mutated pts. Research Sponsor: ConcertAI.

Feature importance (Mean OR, 95% CI).	
Adjuvant ICI	0.78 (0.66, 0.92)
N-stage (0 vs >0)	0.80 (0.74, 0.92)
T-stage (< 3 vs ≥ 3)	0.84 (0.79, 0.88)
History of anemia	1.30 (1.18, 1.56)
History of CHF	1.16 (1.06, 1.28)
EGFR exon 19 deletions or L858R	0.94 (0.89, 0.97)
Interactions	**% DR at 2 yrs**
N-stage-by-CHF	N=0: (CHF = 33.7, no CHF = 20.4); N>0: (32.6, 31.1)
N-stage-by-adjuvant CT	N=0: (CT = 20.1, no CT = 21.4); N>0: (27.8, 33.9)

6627 **Poster Session**

Endoscopist volume and the quality of colonoscopy of the Korean National Cancer Screening Program.

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Background: The Korean government established the National Cancer Screening Program (KNCSP). The KNCSP has provided annual faecal immunochemical test (FIT) for adults aged 50 years or older, and colonoscopy or a double-contrast barium enema test to those with positive results from the FIT. High-quality screening colonoscopy is mandatory to achieve maximum possible CRC prevention. The case volume has been shown to correlate with outcomes in surgical specialties. In contrast, relevant data on colonoscopy is limited. This study aimed to assess the quality indicators of organized CRC screening according to annual colonoscopy volume using KNCSP data. **Methods:** We used the KNCSP data from 2018 to 2020, which accounted for 378,354 colonoscopy examinations. We used cancer registration data of an extended health insurance program using ICD-11 codes (C18-20). A total of 12,109 CRC patients were registered within 1 year of the date of colonoscopy. We calculated the annual number of colonoscopy examinations by an individual endoscopist. We excluded endoscopists who had a very low or high number of examinations with the highest 1% or lowest 1% as outliers. The final number of endoscopists was 16,552 and colonoscopy examinations were 331,231 during 2018–2020. The annual colonoscopy volume by individual endoscopists was divided into four groups (2–12, 13–24, 25–36, and 37 or more examinations). Multiple linear regression analysis was performed to confirm the association between test accuracy indicators and colonoscopy frequency using a generalized linear model (GLM). We calculated the estimates of the rates for each indicator by adjusting the year. **Results:** The positive and false positive rates, sensitivity, specificity, and positive predictive value were 4.09%, 1.07%, 83.53%, 98.93%, and 74.68%, respectively. The cancer detection and interval cancer rates were 30.53‰ and 6.29‰, respectively. Quality indicators were related to the annual colonoscopy volume of the endoscopist. Endoscopists with a higher annual colonoscopy volume were more likely to have higher sensitivity, specificity, and positive predictive value than those with a lower annual colonoscopy volume. Endoscopists with higher annual colonoscopy volumes were more likely to have lower positive rates, cancer detection rates, false positive rates, and interval cancers rate than those with lower annual colonoscopy volumes. **Conclusions:** This study found that the annual volume of colonoscopy examinations was associated with better colonoscopy quality in an organized CRC screening program. A high colonoscopy load could be a sign of substantial experience and lead to better outcomes, as has been shown for surgery. The relationship between quality indicators and case volume is logical and plausible; therefore, more research is required to determine the number of cases that need to be performed in a year to adequately maintain high colonoscopy quality. Research Sponsor: National Cancer Center Korea.

6628 **Poster Session**

An ehealth intervention during radical radiotherapy: Patient-Reported Outcome Side effects (PROSE) study—An emerging approach from sub-Saharan Africa.

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Background: PROSE is an electronic patient-reported outcome tool for real-time, remote monitoring of treatment related side-effects. It enables a two way communication between the patient and clinicians. Remote monitoring of treatment related toxicities can eliminate underreporting of side effects (SE), facilitate timely symptom assessment, and improve management of SE. These will thereby reduce morbidity and hospitalization and improve treatment outcomes and quality of life of affected patients. The overarching goal of the study is to enhance the efficiency of the conventional weekly SE clinic using an emerging technology and thereby create evidence for a personalized digital health interventions for cancer patients in Africa. **Methods:** A prospective study among adult cancer patients receiving radical radiotherapy for head and neck, pelvic, and breast cancers at NSIA-LUTH Cancer Centre in Nigeria between March and October 2022. Eligible ($\geq$18 years, KPS$\geq$75%) and consenting participants were trained on to report their SE daily and receive remote clinical advice on prosecare.com. The PROSE tool was built as an adapted version of the Patient Reported Outcome version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). The study participants were monitored throughout their radiotherapy sessions and two weeks thereafter. The cancer care team can review the Patients Reported Outcome (PRO) data through a dedicated log-in portal during the SE clinic. Participants scored their SE daily and EORTC QLQ-30 quality of life surveys were administered thrice during the study and 2 weeks thereafter. SE reports were chosen according to the site of disease; 12 items for head and neck tumors, 9 items for breast tumors, 14 items for female pelvic and 18 items for male pelvic tumors. Patient's PROSE tool application utilization was defined as $>$50% daily reporting during study period. **Results:** A total of 137 participants were screened, of which 120 met the eligibility criteria. Of the 120 patients eligible, 23 had technical issues with the use of the PROSE tool application and 1 died during the study; thus, 96 participants data were analyzed. More than 40,000 SE reports were generated during the study. SE with highest symptom burden include urinary frequency in male pelvic cancers (n=17), radiation dermatitis in breast cancer (n=40), diarrhea in female pelvic cancer (n=19) and xerostomia in head/neck cancers (n=20). The app utilization rate was 58%. **Conclusions:** There was a moderate utilization (58%) of the PROSE tool application. The PROSE pilot study demonstrated the potential utility of the PROSE application as a promising tool and data resource that offers a great opportunity to improve cancer care and the development of predictive clinical algorithms by engaging patients in their own care and increased SE reporting of acute radiation toxicities. Research Sponsor: Conquer Cancer Foundation of the American Society of Clinical Oncology.

6629 **Poster Session**

Real-world study of treatment patterns and clinical outcomes in patients with metastatic non-small cell lung cancer (mNSCLC) post-approval of immunotherapy in the community oncology setting.

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Background: Clinical outcomes in patients with mNSCLC have improved post-approval of immunotherapy (IO). However, limited real-world data exists describing the evolution of treatment patterns and impact on outcomes in later lines of therapy (LOT). Here we describe the treatment landscape and outcomes of patients with mNSCLC without driver mutations within community oncology settings. **Methods:** This retrospective observational study included adult patients with mNSCLC who initiated first LOT (LOT1) for mNSCLC in the US Oncology Network from 1/1/2015 to 12/31/2020 (followed through 3/31/2022), using structured electronic health records. Patients who initiated LOT1 with a targeted therapy or EGFR/ALK/ROS1 inhibitor during any LOT were excluded. Second, third, and fourth LOT (LOT2, LOT3, LOT4) were assigned using start and stop dates. Treatment patterns up to LOT4 were summarized descriptively by period of treatment initiation (early-IO period: 2015–2017; post-IO period: 2018–2020). Overall survival (OS) and time to next treatment (TTNT) were assessed by LOT using Kaplan-Meier analysis. **Results:** Overall, 11,035 patients met study criteria, of which 3,835 (35%) patients initiated LOT2, 1,264 (11%) patients initiated LOT3, and 393 (4%) patients initiated LOT4 between 2015 and 2020, respectively. From 2015–2017 to 2018–2020, pembrolizumab plus platinum chemotherapy with pemetrexed or paclitaxel as LOT1 increased from 3% (n = 176) to 42% (n = 2,448), and pembrolizumab monotherapy increased from 9% (n = 465) to 26% (n = 1,518). In patients who initiated LOT2, IO followed by docetaxel ± ramucirumab increased from 1% (n = 15) to 15% (n = 295), whereas this sequence from LOT2 to LOT3 was used in 23% (n = 111) from 2015–2017 and 20% (n = 159) from 2018–2020. Median (95% CI) OS was 13.3 (12.6, 14.0) months vs. 14.7 (13.8, 15.3) months from initiation of LOT1 in 2015–2017 vs. 2018–2020, respectively (P = 0.187). Clinical outcomes by LOT and period of treatment initiation are presented as median (95% CI) in the table below. **Conclusions:** Understanding evolving treatment patterns in the community oncology setting is important for uncovering opportunities for mNSCLC treatment optimization. This descriptive study reveals the increasing use of mono- and combination IO followed by docetaxel ± ramucirumab in the community setting. Additionally, longer OS was noted in the post-IO period, suggesting possible extended benefits from earlier LOT. Research Sponsor: Mirati Therapeutics.

		2015-2017	2018-2020	Log rank p-value
LOT2	N (%)	1,828 (48%)	2,007 (52%)	-
	OS	10.6 (9.7, 11.4)	12.4 (11.5, 13.6)	0.015
	TTNT	5.3 (4.9, 5.7)	6.2 (5.9, 6.7)	0.006
LOT3	N (%)	477 (38%)	787 (62%)	-
	OS	7.9 (6.9, 9.0)	11.1 (9.3, 13.0)	0.033
	TTNT	4.8 (4.3, 5.3)	5.4 (5.0, 6.0)	0.096
LOT4	N (%)	106 (27%)	287 (73%)	-
	OS	6.0 (4.7, 8.1)	10.1 (8.3, 15.3)	0.016
	TTNT	4.3 (3.0, 5.1)	5.0 (4.4, 5.7)	0.013

6630 **Poster Session**

Evaluation of studies with commonly used real world data sources submitted to ASCO journals: Initial steps toward furthering transparent reporting.

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Background: Real world data (RWD) are used to understand treatment, care, and outcomes of patients with cancer. Reporting guidelines for observational studies, such as RECORD (health), RECORD-PE (treatment) and TRIPOD (prediction), were developed to increase the transparency of studies using RWD. These guidelines are not required for publication in ASCO Journals (JCO- Journal of Clinical Oncology, PO- Precision Oncology, OP- Oncology Practice, CCI- Clinical Cancer Informatics, GO- Global Oncology). Our objective was to describe the use of RWD among studies submitted to ASCO Journals and evaluate the applicability of guidelines and adherence to guidelines. **Methods:** ASCO submission system was used to identify all studies submitted to ASCO Journals between 2018-2022. Based on the abstract, the studies were categorized on whether selected RWD were used: SEER, Medicare, National Cancer Database [NCDB], Flatiron, CancerLinQ, IQVIA, Optum, MarketScan. Through manual review of the published manuscripts, we calculated positive predictive value (PPV) of our algorithm to identify the RWD. We estimated acceptance rate. For each study we evaluated the following: (1) linkages with other RWD; (2) applicability of reporting guidelines RECORD, RECORD-PE, TRIPOD; (3) use of flow diagram (RECORD) or study design figure for treatment and outcome assessment (RECORD-PE). **Results:** The PPV of our search algorithm was 79% (95%CI 73-84) but varied by journal (PPV 73-100; p=0.02). Based on our algorithm, among the 16,133 original reports submitted, 1,156 (7.2%) used one of the RWD sources. Overall acceptance rate among RWD sources was 18%. There was variability in submissions and acceptance rate of RWD by journal. OP and GO most and least frequently received a manuscript with the selected RWD 13% and 1%, respectively. GO accepted 77% of manuscripts that used selected RWD (88% of which were SEER). JCO accepted 3.5% of RWD manuscripts. Medicare, SEER, and NCDB were frequently identified data sources (61%, 31%, and 11%, respectively). SEER was linked to Medicare claims, surveys, or other sources in 77% of studies. The other data sources accounted for $<$5% each, although submission of EHR-linked to claims/registry increased over time (OR 1.26: 95%CI 1.07-1.49). RECORD, RECORD-PE and TRIPOD were applicable to 100%, 10% and 8% of the studies. RECORD-PE and TRIPOD were most applicable to PO/OP/CCI and CCI, respectively. A flow diagram demonstrating selection of participants was present in 31% of the studies. A figure to visualize study design was used in $<$5% of RECORD-PE relevant studies. **Conclusions:** RWD are commonly submitted and published within ASCO Journals. Reporting guidelines are applicable and particularly important when linkages occur. Studies using oncology RWD may benefit from reporting guidelines tailored to the unique qualities of these data sources and populations.
Research Sponsor: None.

6631 **Poster Session**

Racial disparities in hospitalization outcomes among patients with cholangiocarcinoma.

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Background: Studies have reported on the rising incidence and mortality outcomes among patients diagnosed with cholangiocarcinoma (CCA) but racial disparities in outcomes among inpatients have not been explored in this population. We examined the racial disparities in outcomes among adult hospitalized patients with a diagnosis of CCA. **Methods:** Retrospective cohort analyses were conducted using data from the National Inpatient Sample (NIS), 2016-2020. Multivariate logistic and linear regression models were used to examine the association between race/ethnicity and patient disposition, length of stay, elective admissions, and total hospital charges. **Results:** In the adjusted analyses, while Black patients had 14% higher odds (95% Confidence Interval (CI): 1.04–1.25) of being discharged to a facility/home with home health care versus routine discharge when compared to their White counterparts, Hispanics had 14% lower odds (95% CI: 0.79–0.95). Black patients had 39% higher risk (95% CI: 1.19–1.63) of death versus routine discharge relative to the White patients. Compared to White patients, Blacks (AOR: 1.23; 95% CI: 1.13–1.34), Hispanics (AOR: 1.15; 1.06–1.25) and other race/ethnicities (AOR: 1.20; 1.10–1.31) were more likely to have a length of hospital stay greater than 5 days relative to 5 days or less. Hispanics (β: $16,789; 95% CI: $11,480–$22,099) were found to have higher total hospital charges when compared to the White CCA patients. Additionally, Black (AOR: 0.68; 95% CI: 0.60–0.78) and Hispanic patients (AOR: 0.87; 95% CI: 0.77–0.99) were less likely to be admitted electively to the hospital. **Conclusions:** Despite advances made in treatment of patients with CCA, the prognosis remains poor. We report disparities in various hospitalization outcomes among adult patients with a diagnosis of CCA. Health care providers need to be aware that these disparities exist and health policies should be implemented to narrow the gap in existing disparities. Research Sponsor: None.

Racial disparities in hospitalization outcomes among patients with cholangiocarcinoma using the NIS (2016–2020).

	Race/Ethnicity			
	Whites	Blacks	Hispanics	Others
Facility/Home Health Vs Routine [AOR (95% CI)]	Ref	**1.14 (1.04–1.25)**	**0.86 (0.79–0.95)**	**0.89 (0.80–0.99)**
Died Vs Routine [AOR (95% CI)]	Ref	**1.39 (1.19–1.63)**	0.89 (0.75–1.05)	1.06 (0.90–1.26)
Elective admission [AOR (95% CI)]	Ref	**0.68 (0.60–0.78)**	**0.87 (0.77–0.99)**	0.88 (0.78–1.00)
Length of stay >5 days [AOR (95% CI)]	Ref	**1.23 (1.13–1.34)**	**1.15 (1.06–1.25)**	**1.20 (1.10–1.31)**
Total charges [β (95% CI)]	Ref	3914.47 (-35.82–7864.75)	**16789.48 (11480.02–22098.95)**	**14293.19 (9138.74–19447.64)**

NIS – National Inpatient Sample; AOR= Adjusted odds ratio; β=point estimate; Ref=Reference; CI=confidence intervals; models adjusted for age, gender, hospital region, hospital location, Charlson comorbidity index and type of insurance, boldface signifies statistical significance.

6632 **Poster Session**

Cancer survival (SURVCANCER BRAZIL): Analysis of 132,621 cases from 19 hospital-based registries in southernmost Brazilian state comparing public and private insurance.

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Background: Brazilian data for cancer survival are scarce. Therefore, we aimed to describe the 5-year overall survival (OS) of individuals with public and private insurance from Rio Grande do Sul/RS (Brazil) diagnosed with the 17 most incident tumors in the country. **Methods:** Data from 19 of the 27 hospital-based cancer registries from RS were integrated with the Brazilian Information System data. Individuals with confirmed cancer diagnoses between 2005-2017 were included. Passive follow-up time was calculated as the difference between diagnosis and death (from any cause) or censure date. Survival was estimated by Kaplan-Meier method. Comparison between the survival of individuals assisted by public or private insurance was evaluated using hazard ratios (HR) estimated by multivariate Frailty and Cox regression models with adjustments for age, sex, and economic status. **Results:** 5-year OS was higher for patients with private health insurance for 13 of the 17 cancers studied. **Conclusions:** The survival trends among cancer patients assisted by public and private health insurance systems reveal vast differences that may be likely attributable to differences in access to early diagnosis and optimum treatment. We hope our results will help government officials understand that ongoing cancer survival surveillance is an indispensable source of information and a key policy tool for public health decisions. Research Sponsor: In part by Roche; fapergs and researchers.

Cancer	Coverage	5-year Overall Survival	HR adjusted	p-value
Bladder	Private	57.2 (52.5-62.3)	1.08 (0.89-1.31)	0.410
	Public	56.0 (53.7-58.4)		
Brain	Private	35.5 (30.6-41.1)	1.20 (1.01-1.40)	0.034
	Public	30.6 (27.7-33.8)		
Breast	Private	87.2 (86.1-88.3)	1.40 (1.25-1.57)	<0.001
	Public	79.7 (79.1-80.4)		
Colorectal	Private	64.1 (62.0-66.3)	1.43 (1.30-1.57)	<0.001
	Public	52.1 (50.9-53.2)		
Cervix	Private	68.8 (64.0-73.9)	1.24 (1.00-1.53)	0.043
	Public	58.3 (56.6-59.9)		
Larynx	Private	60.7 (55.1-66.9)	1.53 (1.22-1.91)	<0.001
	Public	42.0 (39.6-44.6)		
Leukemia	Private	49.5 (43.0-56.9)	1.20 (0.97-1.48)	0.089
	Public	43.4 (41.0-46.0)		
Lung	Private	30.5 (28.3-32.9)	1.26 (1.17- 1.37)	<0.001
	Public	19.2 (18.2-20.2)		
Lymphoid	Private	73.0 (69.9-76.3)	1.48 (1.24-1.77)	<0.001
	Public	58.2 (56.4-60.0)		
Melanoma	Private	75.7 (72.2-79.3)	1.37 (1.10-1.71)	0.004
	Public	68.5 (66.3-70.7)		
Esophagus	Private	31.9 (26.9-38.0)	1.41 (1.19- 1.67)	<0.001
	Public	21.5 (20.1-23.1)		
Oral Cavity	Private	64.3 (58.1-71.2)	1.66 (1.27- 2.16)	<0.001
	Public	45.5 (42.7-48.5)		
Ovary	Private	56.9 (50.6-64.0)	1.13 (0.86-1.47)	0.360
	Public	54.7 (51.8-57.6)		
Prostate	Private	86.3 (84.9-87.6)	1.42 (1.24-1.61)	<0.001
	Public	77.0 (76.2-77.9)		
Stomach	Private	43.6 (39.5-48.2)	1.60 (1.38-1.84)	<0.001
	Public	27.4 (25.7-29.2)		
Thyroid	Private	97.3 (96.3-98.4)	3.26 (1.84-5.74)	<0.001
	Public	91.2 (89.4-93.1)		
Uterus	Private	69.7 (64.4-75.6)	1.00 (0.77-1.30)	0.990

6633 **Poster Session**

Real-world analysis of commercially insured and Medicare Advantage patients with advanced cancer and rates of molecular testing.

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Background: Guideline-recommended molecular testing has become essential for biomarker-guided clinical decision making, particularly for patients with advanced (adv) disease. Several biomarkers have indications that are tumor type-agnostic (starting with MSI in 2017, NTRK in 2018, TMB in 2020, and RET and BRAF in 2022). Biomarker testing is covered by insurers, both Medicare (covers comprehensive genomic profiling [CGP] and non-CGP panels) and commercial (at least non-CGP). This study aimed to understand utilization of biomarker testing across tumor types. **Methods:** This retrospective analysis used de-identified administrative claims from Optum Labs Data Warehouse. Adult Commercial (COM) and Medicare Advantage (MA) enrollees diagnosed with any 1 of 6 adv cancer types from 1/2018 to 8/2021 were identified; the date of the first claim indicating adv cancer was the index date. Continuous enrollment for 12 months prior to (baseline), and ≥6 months post-index date, unless they died (follow-up) was required. Biomarker testing was captured using Current Procedural Terminology (CPT) codes indicating CGP (> 50 gene panels), non-CGP (at most 5-50 gene panels), or CPT code 81479 (unlisted molecular pathology procedure) during the study period. The primary analysis evaluates testing in the follow-up only, with secondary analyses evaluating testing including the baseline (to account for testing prior to the index date). **Results:** We identified 16,931 breast (BC), 16,838 non-small cell lung (NSCLC), 8,755 colorectal (CRC), 4,244 pancreatic (PC), 2,610 ovarian (OC), and 1,231 gastric (GC) adv cancer patients meeting study criteria. Overall biomarker testing rates in the follow-up period were: 37% NSCLC, 19% BC, 41% CRC, 35% PC, 51% OC, 35% GC. The Table shows testing rates by cancer, insurance type, and panel size during follow-up. Testing rates were lower among MA patients compared to COM patients. Even considering baseline and follow-up periods, overall biomarker testing rates were low, and lower among MA compared to COM : 48% NSCLC (53% COM, 47% MA), 27% BC (34% COM, 22% BC), 56% OC (61% COM, 53% MA),42% PC (53% COM, 38% MA), 47% CRC (56% COM, 42% MA), 41% GC (54% COM, 35% MA). **Conclusions:** Considering guideline recommendations, rates of biomarker testing across tumor types are far from optimal despite insurance coverage for testing. Identification of barriers to biomarker testing and interventions to overcome these are needed to improve adherence to biomarker testing guidelines. Research Sponsor: Illumina.

Biomarker testing in follow-up.

Commercial	NSCLC N=2,800	BC N=6,717	OC N=862	PC N=1,020	CRC N=2,972	GC N=362
Any biomarker test, %	44	22	57	45	49	48
CGP, %	14	5	19	18	15	19
Non-CGP, %	32	11	29	24	29	26
81479, %	15	12	30	18	23	18
Medicare Advantage	**NSCLC N=14,038**	**BC N=10,214**	**OC N=1,748**	**PC N=3,224**	**CRC N=5,783**	**GC N=869**
Any biomarker test, %	36	17	49	32	36	30
CGP, %	12	5	22	13	11	13
Non-CGP, %	23	8	24	16	21	13
81479, %	11	9	22	12	13	10

6634 **Poster Session**

Prognosis and risk of suicide after cancer diagnosis.

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Background: Suicide rates are elevated acutely after cancer diagnosis. We sought to create a unifying theory that explains variations in suicide risk across cancer sites, stages, and demographics. Based on the stress-diathesis model, we hypothesized that suicide risk correlates with cancer prognosis and that the impact of prognosis on suicide risk is greatest for populations with higher baseline risks of suicide. **Methods:** We identified all patients with newly diagnosed cancers from 2000-2019 in the Surveillance, Epidemiology, and End Results (SEER) 17 database, representing 27% of U.S. cancers diagnosed over the past 20 years. Multiple primary-standardized mortality ratios (SMR) were used to determine the relative risk of suicide within the first 6 months compared to the general U.S. population, adjusted for age, sex, race, and year of follow-up. We correlated suicide and 2-year overall survival rates for 20 cancer sites using a weighted linear regression model. **Results:** We identified 9,046 suicides among 6,811,940 persons diagnosed with cancer, 1,610 of which occurred within 6 months of diagnosis. There were 5.3 suicides per 10,000 person-years, compared with an expected rate of 1.7 (SMR 3.1 [95% CI 3.0-3.3]). Suicide risk correlated strongly with prognosis (increased risk of 9.5% per percent survival deficit at 2 years, $R^2 = 0.88$, $P < .0001$). The impact of prognosis on suicide risk was greater for demographic groups with higher baseline risks of suicide. For men, the risk of suicide increased by 3 suicides per 10,0000 person-years ($R^2 = 0.84$, $P < .0001$) versus 0.3 in women ($R^2 = 0.54$, $P < .0001$). The impact of prognosis on suicide risk was also greater for persons age 60+ and for white (versus black) race. **Conclusions:** Poorer prognosis correlates with suicide risk in patients with cancer and has a greater effect on populations with higher baseline rates of suicide. Our model should provide a useful framework for triaging patients that need increased surveillance or urgent psychiatric referral.
Research Sponsor: None.

6635 **Poster Session**

A comparison of the Optum Clinicogenomics Solid Tumor Database and the SEER Population-Based Cancer Registry.

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Background: Real-world data (RWD) and real-world evidence (RWE) are increasingly utilized across a range of research and regulatory applications, including biomarker discovery, risk stratification, external control arms, and post-market surveillance. Two-thirds of FDA approvals in 2021 utilized genomic data and the growing interest in targeted therapies will likely continue this trend. While genomics or any one type of RWD alone yields an incomplete view of the patient journey, Optum's clinicogenomic data links de-identified longitudinal clinical and claims data to next-generation sequencing (NGS) results. Ensuring the value of this data requires identifying and limiting biases and maximizing diversity. **Methods:** To evaluate the robustness and representativeness of Optum's Clinicogenomic Solid Tumor Database, we compared demographic and clinical characteristics to the Surveillance, Epidemiology and End Results (SEER) database across 16 solid tumor types. Variables of interest included age at diagnosis, sex, self-identified race, year of diagnosis, and metastatic status. The Optum data was derived from clinical data that includes 156 million lives and claims data that covers 95 million lives. The solid tumor sub-cohort used for this analysis included 157,164 patients diagnosed between January 1, 2011, and December 31, 2021 with linked broad-panel NGS results. SEER Incidence Data included patients diagnosed between January 1, 2011, and December 31, 2018. Using the Optum data, we also report average continuous enrollment and sequential testing frequency across all solid tumor types. **Results:** The overall distributions of age at diagnosis, sex and race were similar across all cancer types, with a few exceptions. On average, SEER had a larger proportions of patients 80 years and older (15% vs 7.2%, all solid tumors) and of Asian race (7.1% vs 3.2%, all solid tumors). Cancer diagnoses in the Optum data increased year over year corresponding with the increasing availability and uptake of genetic testing in oncology, while the SEER data was equally distributed across all years. The average continuous enrollment for solid tumor patients was 8.1 years in the Optum data, and 13% of patients had sequential testing results from >1 time point. **Conclusions:** Given the increased reliance on RWD and RWE as part of the drug development and regulatory approval processes, ensuring the representativeness of clinicogenomic databases is paramount. This analysis of general patient characteristics across the Optum Clinicogenomics and SEER solid tumor databases found largely similar distributions of key variables. Observed differences between these two representative databases reflect the genetic testing landscape in oncology and provide the opportunity to investigate disparities related to accessing genetic services, corresponding targeted treatment options, and health outcomes. Research Sponsor: Optum.

6636 **Poster Session**

Disparity in regional recruitment across global cancer trials: A meta-analysis.

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Background: Equitable regional enrollment in clinical trials is critical to addressing global inequities in health care outcomes. Therefore, we quantified disparities in regional recruitment in global cancer trials. **Methods:** Phase II/III clinical trials in prostate (PC), breast (BC), colorectal (CRC) and lung cancer (LC), and reporting regional recruitment were identified from Medline. Global regions were defined as North-(NA) and South- America (SA), Europe (EU), Africa (AF), Asia (AS), and Australia (AU). For multi-regional trials, enrollment incidence ratios (EIR) which compare region-wise trial enrollment against global estimates of region-wise specific cancer incidence obtained from Global Burden of Disease 2019 database. Trial-level EIRs were pooled using random-effects meta-analysis. A pooled EIR of $<$ 1.0 indicates underrepresentation of a particular region in clinical trial enrollment compared to the actual burden of the specific cancer in that region. Statistical analyses were conducted in R v4.1.2. **Results:** Of the total 2125 trials identified, 1681 (79.1%) trials with 691,800 participants reported information regarding regional recruitment. Among those, only 1400 (65.9%) trials reported proportions of patients from pre-defined regions. A total of 1231 (57.9%) trials were single-regional recruiting patients from EU (589; 47.8%), NA (329; 26.7%), AS (295; 23.9%), AU (10; 0.8%), AF (4; 0.3%), and SA (4; 0.3%). There was significant underrepresentation of patients from AS (EIR: 0.47; 95% CI: 0.41-0.54) in cancer clinical trials. This was consistent across different cancers: PC (0.49; 0.35-0.71), BC (0.63; 0.43-0.94), CRC (0.63; 0.43-0.94), LC (0.39; 0.30-0.50). Similarly, there is a trend of under-representation of patients from AF (0.67; 0.43-1.04). Consistently, patients from were under-represented in PC (0.43; 0.24-0.77) and LC (0.26; 0.09-0.79) trials. Patients from NA (1.27; 1.08-1.51), EU (1.64; 1.57-1.72), and AU (5.41; 3.90-7.51) were significantly over-represented in multi-regional cancer clinical trials. The results are provided in table. **Conclusions:** There is suboptimal reporting of region-wise enrollment in cancer clinical trials. Representation of Africa and Asia in cancer clinical trials appears to be less than their expected share based on their burden of cancer incidence.
Research Sponsor: None.

	EIR (95% CI)				
Region	Overall	PC	BC	CRC	LC
AF	0.67 (0.43-1.04)	0.43 (0.24-0.77)	0.73 (0.36-1.49)	1.70 (1.16-2.50)	0.26 (0.09-0.79)
AS	0.47 (0.41-0.54)	0.49 (0.35-0.71)	0.63 (0.43-0.94)	0.63 (0.43-0.94)	0.39 (0.30-0.50)
AU	5.41 (3.90-7.51)	5.27 (2.76-10.07)	8.33 (5.36-12.93)	8.33 (5.36-12.93)	5.58 (2.43-12.84)
EU	1.64 (1.57-1.72)	1.26 (1.14-1.39)	1.79 (1.65-1.94)	1.79 (1.65-1.94)	2.00 (1.80-2.22)
SA	1.37 (1.11-1.69)	0.76 (0.56-1.03)	0.99 (0.55-1.77)	0.99 (0.55-1.77)	1.89 (1.32-2.71)
NA	1.27 (1.08-1.51)	1.12 (0.94-1.33)	8.49 (6.09-11.84)	8.49 (6.09-11.84)	0.90 (0.68-1.18)

6637 **Poster Session**

Real world data for venous thromboembolisms (VTEs) in patients with active cancer: Thromboprophylaxis pooled analysis from GMaT and ACT4CAT studies.

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Background: Venous Thromboembolisms (VTEs) lead to many negative consequences for patients with active cancer and are reported up to 20%. They affect anticancer treatment plan, increase morbidity, mortality, economic burden, and escalate psychological drain. Current guidelines recommend pharmacologic prophylaxis for thrombosis in ambulatory cancer patients with Khorana score ≥2. **Methods:** GMaT and ACT4CAT are prospective observational phase IV studies conducted by HeSMO in Greece. The aim was to record the clinical practice for ambulatory patients with active cancer who received thromboprophylaxis and enrolled after signing informed consent. Studies were approved by the bioethics committee. **Results:** 1157 patients from 26 oncology clinics enrolled who received thromboprophylaxis. Tumor types: gastrointestinal 38.5%, lung 24.8%, urological 12.2%, gynecological 6.9%, breast 6.1% and others 11.5%. Treatment lines: 1st 62.5%, 2nd 15.1%, 3rd 4%, adjuvant 9.7% and neoadjuvant 5.9%. Age ≥65 in 55.2%, BMI ≥30 in 17.8% and males 59.9%. High-Risk for Thrombosis Agents (HRTAs) received 82.3%: platinum agents (52.9%), antimetabolites (49.0%) and immunotherapy (10.2%). Notably, 52.7% of anticancer agents had potential drug-drug interactions (DDIs) with Direct Oral Anticoagulants (DOACs). High thrombotic risk factors presented in table. Thromboprophylaxis duration was 5.1±3.3 months with: tinzaparin 91.2%, fondaparinux 4.6%, bemiparin 2.3%, enoxaparin 1.2%, rivaroxaban 0.4% and apixaban 0.3%. Intermediate thromboprophylaxis doses of Low Molecular Weight Heparins (LMWHs) received 62% of patients; 50% in adjuvant setting & 72.6% in metastatic. 32 thrombotic events reported (efficacy: 97.2%, 95%CI: 96.3-98.2%) and 26 grade 1 or minor bleedings (2.2%, 95%CI:1.4-3.1%). Patients receiving intermediate doses of LMWHs had less risk for thrombosis (p=0.0308). **Conclusions:** VTEs prophylaxis in ambulatory patients with active cancer was found safe and effective. Apart from Khorana score, metastasis, HRTAs and DDIs seem to affect clinical decision for thromboprophylaxis mainly with LMWHs and often using intermediate doses irrelevant of clinical setting. Cancer Associated Thrombosis (CAT) is not negligible risk for patients and oncologists appeared to be aware about this. Clinical trial information: NCT03292107, NCT03909399. Research Sponsor: None.

Neoplasm type	Incidence	Female	Age ≥65	BMI ≥30	Smoking	Metastasis	HRTAs	DDIs	Radiotherapy	Comorbidities
Lung	24.8	21.4	56.5	18.5	88.5	82.5	82.9	58.9	34.3	46.1
Pancreatic	21.5	41.6	54.6	11.2	50.2	75.7	96.4	63.1	3.3	35.8
Urological	12.2	10.3	58.9	19.2	71.6	70.1	72.1	44	19.3	53.2
Colorectal	9.5	39.8	58.2	15.5	50.9	81.3	89.1	27.3	15.6	52.3
Stomach	7.4	29.1	60.5	11.6	62.8	74.1	91.8	40.7	10.5	47.6
Gynecological	6.9	100	55	35	30	71.1	87.3	71.3	5.1	46
Breast	6.1	98.5	37.1	20	31.4	67.7	52.9	61.4	45.5	60.6
Head & neck	1.3	30	33.3	33.3	80	63.6	80	60	73.3	53.3
Others	10.3	47.3	56.3	20.2	57.1	59.6	64.4	40.3	27.4	47.9

6638 **Poster Session**

Cost of genetic testing, delayed care, and suboptimal treatment associated with polymerase chain reaction (PCR) versus next-generation sequencing (NGS) testing strategies in metastatic non-small cell lung cancer (mNSCLC).

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Background: NGS testing for genomic alterations has been found to expedite time to appropriate targeted therapy initiation compared to PCR testing in mNSCLC. This study assessed US payers' costs of testing, delayed care, and suboptimal treatment initiation for PCR versus NGS testing in patients with mNSCLC. **Methods:** A decision tree model evaluated testing for guideline-recommended alterations (EGFR, ALK, ROS1, BRAF, KRAS, MET, HER2, RET, NTRK1/2/3) in patients with newly-diagnosed mNSCLC from first test until appropriate therapy initiation using 1) liquid or tissue NGS (60% [90% tissue, 10% liquid] of patients), 2) exclusionary KRAS test followed by sequential PCR tests (5%), 3) sequential PCR tests (5%), or 4) hotspot panel (30%) PCR tests. The proportion of patients testing positive for a targetable alteration and time to appropriate therapy initiation were evaluated. Cost components included genetic testing, testing-related medical services, delayed care (i.e., costs for medical services while waiting for test results), immunotherapy [IO]/chemotherapy [CTX] initiation prior to test results, and suboptimal treatment initiation after test results (i.e., costs of first-line IO/CTX in patients falsely testing negative for an actionable mutation). **Results:** In a modeled cohort of 1 million members (75% commercial, 25% Medicare), an estimated 1,119 patients had mNSCLC and were tested. The proportion of patients testing positive for a targetable alteration was 45.9% for NGS and 39.4% for PCR testing (Table). Total mean per patient costs were lower for NGS ($8,866) than for PCR ($18,252), driven by more rapid treatment with appropriate therapy (2.1 versus 5.2 weeks), resulting in lower delayed care costs and IO/CTX costs prior to test results. **Conclusions:** Results suggest that NGS testing may lead to better patient care and reduced costs to the health system relative to PCR testing. Costs of inappropriate IO/CTX initiation are an important component of increased costs of PCR-based approaches. Research Sponsor: Janssen Scientific Affairs, LLC.

Results	NGS Number tested (N) =671	Sequential N=56	Exclusionary N=56	Hotspot Panel N=336	PCR Approaches Combined* N=447
Proportion testing positive for a targetable alteration	45.9%	37.9%	33.1%	40.7%	39.4%
Proportion initiating suboptimal treatment	0.0%	8.0%	12.8%	5.2%	6.5%
Time to appropriate therapy initiation, weeks	2.1	10.5	10.1	3.5	5.2
Total testing-related costs, per patient	**$8,866**	**$27,939**	**$28,032**	**$15,009**	**$18,252**
Gene testing	$4,022	$4,669	$4,051	$6,091	$5,659
Medical	$1,245	$1,919	$1,806	$1,250	$1,403
Delayed care	$1,301	$6,445	$6,220	$2,155	$3,199
Treatment initiation prior to test results	$2,298	$12,374	$11,901	$3,862	$5,930
Suboptimal treatment initiation after test results	$0	$2,532	$4,053	$1,651	$2,061

*Sum of components differs slightly due to rounding.

6639 **Poster Session**

Oncologists' receipt of pharmaceutical industry payments and use of non-recommended and low-value cancer care services.

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Background: Personal payments from the pharmaceutical industry to US physicians are common and influence physician practice. Prior studies have found that industry payments sway physicians' selection among effective, medically appropriate treatments. However, whether industry payments may be associated with non-recommended and low-value care has not been assessed. The objective of this study was to estimate the association between oncologists' receipt of industry payments and use of non-recommended and/or low-value (NR/LV) interventions. **Methods:** Population-based cohort study using fee-for-service Medicare claims and Open Payments records of industry payments. We identified four NR/LV cancer interventions: 1) denosumab for castrate-sensitive prostate cancer; 2) GCSF for patients at low risk for neutropenic fever; 3) nab-paclitaxel instead of paclitaxel for breast and lung cancer 4) branded drug instead of a generic or biosimilar. Study sample: Medicare beneficiaries with an incident cancer diagnosis (identified by new occurrence of a cancer diagnosis code in proximity to claims for cancer treatment) from 2014-2019. We applied additional requirements as appropriate to identify four sub-cohorts, corresponding to patients at risk for each of the NR/LV treatments, and identified the treating oncologist using claims. The primary exposure was receipt, by a patient's oncologist, of any industry payments for the corresponding NR/LV treatment of interest, within 365 days before the patient's index cancer date. The primary outcome was receipt of the corresponding NR/LV treatment. We fit general linear models controlling for patient characteristics and calendar year. To assess robustness, we also accounted for physician-level fixed effects in separate models. **Results:** Cohort sizes were: denosumab N = 9,799; GCSF N = 271,485; nab-paclitaxel N = 86,394; branded drug N = 13,386. Controlling for patient characteristics and calendar year, industry payment was associated with an increase in the absolute prevalence of denosumab (+17.5% [95%CI:15.3 to 19.7%]), GCSF (+5.8% [95%CI:5.4 to 6.1%]), and nab-paclitaxel (+7.6% [95%CI:7.1 to 8.1%]) use, but lower branded drug use (-4.6 [95%CI:-5.8 to -3.3]). In physician-level fixed effects models, industry payment was associated with increased denosumab (+7.4% [95%CI:2.5 to 12.2%]) and nab-paclitaxel (+1.7% [95%CI:0.9 to 2.5%]) use, but not with GCSF (+0.4% [95%CI:-0.3 to 1.1%]) or branded drugs (+1.2% [95%CI:-5.8 to 8.3%]). **Conclusions:** Recent receipt of industry payments by physicians was associated with increased use of several forms of NR/LV cancer treatment. These findings raise quality-of-care concerns regarding physician-industry financial relationships. Additional work is needed to further explore the causal relationship between payments and non-recommended treatments, and between payments and patient outcomes. Research Sponsor: U.S. National Institutes of Health; NIHCM.

6640 **Poster Session**

Palliative care as a component of high-value and cost-saving care during hospitalization for metastatic cancer.

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Background: Randomized controlled trials have demonstrated that palliative care can improve both quality of life and survival for outpatients with advanced cancer, but there is limited population-based data on the value of inpatient palliative care. We assessed palliative care as a component of high-value care among a nationally representative sample of inpatients with metastatic cancer. We further identified care, patient, and hospital characteristics significantly associated with high costs. **Methods:** This study analyzed hospitalizations of patients ≥18 years with a primary diagnosis of metastatic cancer from the National Inpatient Sample (covering 97% of the U.S. population) from 2010-2019. We utilized multivariable mixed-effects logistic regression to assess medical services (receipt of palliative care, invasive medical ventilation [IMV], systemic therapy), patient demographics, and hospital characteristics that were associated with higher charges billed to insurance and hospital costs. We utilized generalized linear mixed-effects models to determine cost savings associated with provision of palliative care. **Results:** Among 397,691 hospitalizations from 2010 to 2019, the median charge per admission increased by 24.9%, from $44,904 in 2010 to $56,098 in 2019, while the median hospital cost remained stable at $14,300. Receipt of inpatient palliative care was associated with significantly lower charges (Odds Ratio [OR], 0.62; 95% CI, 0.61-0.64; $P < .001$) and costs (OR, 0.59; 95%CI, 0.58-0.61; $P < .001$). Factors associated with high charges were receipt of invasive medical ventilation ($P < .001$) or systemic therapy ($P < .001$), Hispanic patients ($P < .001$), and young age (18-49 years, $P < .001$). For-profit hospitals were more likely to bill higher charges (OR, 5.05; 95% CI, 4.78-5.33, $P < .001$) but less likely to incur high hospital costs (OR, 0.51; 95%CI, 0.48-0.54, $P < .001$) than public hospitals. In adjusted generalized linear mixed effects regression, palliative care provision was associated with a $1,293 (-13.4%, $P < .001$) reduction in costs per hospitalization compared to no palliative care, independent of receipt of invasive care and age. Significant interactions were observed between receipt of palliative care and patient age group (-9.6% for 18-49 years; -14.7% for ≥70 years), receipt of IMV (-6.4% for IMV receipt; -14.0% for no IMV), hospital ownership (-19.6% for for-profit; -10.5% for public), and year of hospitalization (-15.4% for 2010; -8.9% for 2019). **Conclusions:** Inpatient palliative care is associated with reduced hospital costs for patients with metastatic cancer, irrespective of age and receipt of aggressive interventions. Assuming inpatient palliative care receipt increases by 50%, we estimate $4,045,000 in annual national savings. Integration of inpatient palliative care may de-escalate costs incurred through low-value inpatient interventions. Research Sponsor: None.

6641 **Poster Session**

The role of private insurance characteristics in the out-of-pocket costs of patients with multiple myeloma.

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Background: Over the past two decades, the major advances in the treatment of multiple myeloma have improved overall survival considerably. High costs of novel medications and patient out-of-pocket costs were suggested to have a role in treatment disparities but available data on total- and patient-out-of-pocket costs are dated. We examined the costs in privately insured patients with newly diagnosed multiple myeloma in the first year after the diagnosis, based on insurance plan characteristics. **Methods:** This retrospective study used the IBM MarketScan Commercial Database for the years 2011–2019, which consists of medical and prescription medications data from 120+ large employers and 40+ health plans in the US. The primary outcome variables were total- and patient out-of-pocket costs during 1 year after the index diagnosis. **Results:** 5,487 privately insured adults with an index multiple myeloma diagnosis during 2012-2018 were identified. Approximately 41% (n=2,240) of the study population received bortezomib, 38.6% (n=2,117) received lenalidomide, and 5.7% (n=314) received carfilzomib during 1 year after the index diagnosis. The median total cost of care in the first year after multiple myeloma diagnosis increased from $133,938 (interquartile range, $19,770 – $292,501, expressed in 2018 USD) in patients diagnoses in 2012 to $252,559 ($33,089 – $380,662) in patients diagnoses in 2018. The median patient out-of-pocket costs were $3,147 (interquartile range $1,562 - $5,441, 2018 USD) in patients diagnosed in 2012 and $3,711 ($1,756 – $6,466) in patients diagnosed in 2018. Among patients diagnosed in 2018, the median patient out-of-pocket cost was $1,706 ($902 – $2,873) for patients with low out-of-pocket cost plans, $3,428 ($1,794 – $6,371) for those with average out-of-pocket cost plans, and $5,623 ($3,517 - $7,810) for patients with high out-of-pocket cost plans. **Conclusions:** While the total cost of care in the first year after multiple myeloma almost doubled during the study period, the patient out-of-pocket costs remained relatively stable. The protections imposed by the Affordable Care Act are likely key in preventing surges in patient out-of-pocket costs. Additional legislative action could help curb the price increases for multiple myeloma medications. Research Sponsor: Dr. Hamlet Gasoyan received support from the Cancer Intervention and Surveillance Modeling Network's Junior Investigator Career Enhancement Research Award.

Costs during one year after multiple myeloma diagnosis, n=5,409.

Year	2012	2013	2014	2015	2016	2017	2018
Median Out-Of-Pocket Cost (Interquartile Range)	3,147 (1,562 - 5,441)	3,505 (1,708 - 5,565)	2,915 (1,464 - 5,099)	2,884 (1,531 - 5,181)	3,363 (1,576 - 5,618)	3,132 (1,483 - 5,299)	3,711 (1,756 - 6,466)
Median Total Cost (Interquartile Range)	133,938 (19,770 - 292,501)	151,713 (27,392 - 297,279)	126,898 (20,134 - 291,692)	161,508 (19,420 - 333,108)	201,603 (27,291 - 350,144)	175,070 (19,831- 340,040)	252,559 (33,089- 380,662)

Costs pooled from different years were expressed in 2018 US dollars, using the Consumer Price Index.

6642 **Poster Session**

Estimated life-years gained and resultant cost savings from follow-up colonoscopy after a positive multi-target stool DNA (mt-sDNA) test for colorectal cancer screening in commercially insured and Medicare populations.

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Background: Although follow up colonoscopy (COL) after a positive stool-based colorectal cancer (CRC) screening test is necessary to complete the CRC screening process, follow-up COL rates remain suboptimal, especially among underserved populations. As of January 2023, federal policies require commercial insurers and Medicare to eliminate out of pocket costs for follow-up COL. To estimate the implications of this policy change, we compared the clinical and fiscal outcomes for a simulated cohort receiving a follow-up COL after a non-invasive CRC test ($0 cost sharing), compared to the same cohort not completing follow-up COL (status quo). **Methods:** Using the validated CRC-AIM model, we simulated a cohort of 6 million average-risk individuals who received mt-sDNA (commercial patients at age 45 and Medicare patients at age 65) and further analyzed only the population with positive mt-sDNA. Life-years gained, CRC incidence, CRC-related mortality and total costs of care (inclusive of CRC screening and treatment) were calculated for a cohort that underwent follow-up COL and compared these outcomes to that same cohort that did not complete follow-up COL. The cost of follow-up COL was assumed to be $1,576 for Medicare and $3,086 for commercially insured patients ($0 out of pocket costs for all). **Results:** Patients undergoing follow-up COL after a positive mt-sDNA experienced more life-years (83 per 1,000 commercially insured patients and 80 per 1,000 Medicare beneficiaries) compared to those who did not undergo follow-up COL. The follow-up COL resulted in reductions in CRC incidence and CRC mortality by 14% and 16% for commercial and 19% and 23% for Medicare beneficiaries, respectively. Compared to those patients with a mt-sDNA positive test result and did not complete follow-up COL, the total cost per patient for those receiving follow-up COL was $3,339 less for commercially insured ($15,690 – no follow up vs. $12,351 – follow up) and $4,382 less for Medicare beneficiaries ($19,337 – no follow up vs. $14,955 – follow up). Total spending for patients receiving follow-up COL was cost-saving when compared to no follow-up as long as the COL costs were less than $6,269 for commercial plans and $5,753 for Medicare. **Conclusions:** Completing a follow-up COL after a positive mt-sDNA screening saves lives, enhances equity, and lowers total expenditures. Thus, health care stakeholders should invest in efforts to identify and reduce barriers that ultimately lead to an increase uptake of this potentially lifesaving and cost-reducing intervention. Research Sponsor: Exact Sciences Corporation.

6643 **Poster Session**

Unnecessary thrombophilia testing reduction: Quality improvement project.

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Background: The American Society of Hematology (ASH) recommends reducing inpatient thrombophilia testing but adherence to these recommendations remains suboptimal. We report the results of a quality improvement (QI) project which aimed to minimize unnecessary testing. **Methods:** We performed retrospective review of records of patients with a new diagnosis of venous thromboembolism (VTE) across 3 hospitals in Central PA from September 2021 to December 2021 to see how many patients underwent thrombophilia workup. Our QI project consisted of education for physicians based on ASH recommendations with lectures, biweekly emails, and educational posters. We then performed a second retrospective review of patients admitted under the same conditions between June 1, 2022, and August 31, 2022, to reevaluate thrombophilia testing rates. The cost of testing was extrapolated from institutional hospital cost reports. Descriptive statistics included reporting the categorical variables as number and percent. The categorical variables were compared between groups with Fisher's exact test or the chi-square test. **Results:** During the first study period, 310 patients had new VTE. Provoking factors were found in 269 patients (86.7%) and 41 patients (13.2%) had unprovoked VTE. Overall, 33 out of 310 patients (10%) underwent thrombophilia workup, with a total of 175 tests performed. Thrombophilia testing rate was significantly higher in the unprovoked group (29.3% vs 7.8%, p = 0.0003). Both groups have equally received inpatient hematology consult (33.83% vs 47.50%, p = 0.0920). Only 16% of thrombophilia tests were recommended by hematology consult while the rest was ordered by the primary team. The cost of all tests ordered outside of hematology recommendation was $34,083 ($344 per person). Of the group that got tested regardless of provoking factors, there was no difference between hospital length of stay (2-12 days vs 3-12 days, p = 0.0665) or anticoagulation choice. During the second study period, 191 patients had new VTE. Provoking factors were found in 157 patients (82.1%) while 34 patients (17.9%) had unprovoked VTE. Overall, 21 out of 191 patients (10.9%) underwent thrombophilia workup, with a total of 78 tests performed. More testing was ordered in the unprovoked group (26.47% vs 7.64%, p = 0.0040). More inpatient hematology consults were performed in the unprovoked group (64.71% vs 40.76%, p = 0.0110). Of the hematology consults, 12 out of 21 patients (57%) had thrombophilia testing recommended by hematologist. The rate of thrombophilia testing ordered outside of hematology consultation has decreased from 84% to 43% after our intervention, resulting in a $16,635 savings for that quarter. **Conclusions:** Our experience confirmed that thrombophilia work up was costly and did not impact quality of care. Despite the relatively low frequency of inpatient workup, eliminating unnecessary testing saved our health system $16,635 in a 3-months period. Research Sponsor: None.

6644 **Poster Session**

Association between targeted cancer drug net health benefit and uptake, patient out-of-pocket spending, and total spending.

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Background: Targeted cancer drugs (TCDs) have revolutionized oncology, but they are widely variable in their clinical benefit and are often accompanied by high patient-out-pocket (OOP) costs. The ASCO Value Framework uses published clinical trial data on survival, toxicity, and potential for symptom palliation to quantify the net health benefit (NHB) of any given cancer drug. We aimed to evaluate the association between NHB and uptake, patient OOP spending, and total spending for eight oral TCDs approved for the first line treatment of an advanced solid tumor based on one or more clinical trials comparing to a non-TCD control arm. **Methods:** We conducted a retrospective cohort study of incident pharmacy claims for oral TCDs prescribed to patients aged 18-64 years between 2012-2020 in the nationwide Health Care Cost Institute de-identified commercial claims dataset. NHB scores were calculated for each TCD of interest using the ASCO Value Framework and categorized as high (>60), medium (40-60), and low (<40) net health benefit. Distributions of incident 28-day TCD supplies were plotted over time by NHB category. The primary outcome was patient OOP spending (patient copay + coinsurance + deductible), whereas the secondary outcome was total spending (patient OOP spending + pharmacy reimbursement). Generalized linear models were used to evaluate the association between each outcome of interest and TCD NHB, adjusted for cancer indication. **Results:** We included 8,524 incident pharmacy claims for eight TCDs with nine indications in breast cancer, non-small cell lung cancer (NSCLC), melanoma, and pancreatic cancer. NHB scores ranged from 7 (erlotinib for pancreatic cancer) to 81 (crizotinib for ALK-rearranged NSCLC), with 1,145 (13%), 6,608 (78%), and 771 (9%) of pharmacy claims falling into low-, medium-, and high-NHB categories, respectively. Medium- and high-NHB TCDs accounted for the majority of incident TCD prescriptions throughout the study period. Median patient OOP spending was $18.78 for the first 28-day TCD supply (IQR $0.00-$87.57), with 45% of patients paying $0 and 8% paying >$1,000 OOP. Patient OOP spending was not significantly associated with TCD NHB category (difference $0.94, 95% CI -$49.99-$51.87 for medium vs low NHB; difference $58.86, 95% CI -$28.04-$145.75 for high vs low NHB). Median total spending was $10,118.79 (IQR $6,365.95-$10,600.37) for an incident 28-day TCD supply. There was a $1,083.56 increase in total spending for each 10-point increase in NHB score (95% CI $1,050.27-$1,116.84, $p < 0.01$ for H0 = $0). **Conclusions:** Although TCDs are widely variable in their NHB, low-NHB TCDs are not prescribed as frequently as medium- and high-NHB TCDs. Total spending on TCDs is high and positively associated with NHB. Commercially insured patients are largely shielded from high OOP spending on TCDs. Research Sponsor: Robert Wood Johnson Foundation.

6645 **Poster Session**

Association of early completion of portable medical orders with inpatient costs at end-of-life for patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

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Background: Patients with hematologic malignancies receive more aggressive care at end-of-life (EOL) compared to patients with solid tumors. Costs of care in patients with hematologic malignancies at EOL are high, particularly in the inpatient setting. We previously found that early completion of portable medical orders [termed medical orders for life sustaining treatment (MOLST) in New York state] is associated with less intense care at EOL for patients with AML and MDS. Thus, we hypothesized that early MOLST completion would also be associated with lower inpatient costs at EOL among patients with AML and MDS. **Methods:** We previously conducted a retrospective study of 358 adults patients with AML or MDS treated at Wilmot Cancer Institute and its affiliated sites who died between January 1, 2014, and December 31, 2019. Of these, 271 patients were eligible for cost analysis. Cost of inpatient care received at the University of Rochester Medical Center (URMC) within the last 30 days of life was obtained from our Finance Decision Support Department. Patients were excluded if inpatient costs at EOL were unavailable. **Results:** Mean age of patients was 69 years (N=271, range 20-95); 84% (n=227) of patients were hospitalized within 30 days of death. One-third (34%, n=93) of patients completed a MOLST early (>30 days prior to death) whereas 66% (n=178) either did not complete a MOLST or completed a MOLST late (less than or equal to 30 days prior to death). Mean and median inpatient cost of care for all patients at EOL was $39,284 and $19,703, respectively. The rate of hospitalization was lower for patients who completed a MOLST early vs late/never (73.1% vs 90.5%, respectively; p=0.0003), although there was no difference in the number of inpatient visits between the two groups (median=1 visit in both groups; p=0.23). In addition, median cost of inpatient care was lower for patients who completed a MOLST early vs late/never ($10,673 vs $23,177, respectively; p<0.0001). After adjusting for age, sex, and diagnosis, there was a trend toward lower EOL costs in patients completing a MOLST early (p=0.07). **Conclusions:** In patients with AML or MDS, early MOLST completion may be associated with lower inpatient costs at EOL. Viewing MOLST completion as a surrogate for a goals-of-care discussion, it follows that interventions aimed to increase the frequency of early goals-of-care discussions, advanced care planning, and MOLST completion are likely to improve quality of care and decrease costs at EOL in these patient populations. Research Sponsor: University of Rochester CTSA award number TL1 TR002000 from the National Center for Advancing Translational Sciences of the National Institutes of Health; Conquer Cancer Foundation of the American Society of Clinical Oncology; U.S. National Institutes of Health; Wilmot Research Fellowship Award.

6646 **Poster Session**

Maxed out: Reaching the annual maximum out-of-pocket limit among insured patients diagnosed with cancer.

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Background: Patients with cancer face potentially high out-of-pocket costs associated with their medical care, which may lead to adverse medical and financial outcomes. Depending on their health insurance plan, patients may have to pay several thousands for medical care costs until they reach the annual maximum out-of-pocket [MOOP] spending limit; after which care costs are covered by insurance. The purpose of this study was to measure the proportion of adult patients who reach their health plan MOOP limit in the year of cancer diagnosis. **Methods:** Electronic health record data from 13,057 patients aged ≥18 years, diagnosed with cancer between Jan. 1, 2016–March 31, 2021 [index cancer], with ≥12 months of continuous health insurance coverage pre-cancer diagnosis were included. The primary outcome was defined as reaching the MOOP limit in the health plan benefit year of index cancer diagnosis (binary, yes/no). We additionally created a secondary outcome using 3 categories: (i) did not reach MOOP; (ii) reached MOOP prior to cancer diagnosis; (iii) reached MOOP after cancer diagnosis. Descriptive statistics were used to assess the distribution of outcomes across patient characteristics including health insurance type (e.g., commercial), high-deductible health plan (HDHP), cancer type, age at diagnosis, and Census-level household income was included. Multivariable logistic regression estimated the association between patient characteristics and the primary outcome. Complete case analyses were performed using Stata 16.1. **Results:** Patients' mean age was 66 years (standard deviation [sd]: 13) and mean Census-level household income was $73,100 (sd: $24,000). Approximately 40% of patients had commercial health insurance and 62% had Medicare; 2% (n=283) had a HDHP. Breast (18%), lung (11%) and prostate (11%) cancers were most common. The mean annual MOOP limit was $3,040 for commercial plans and $2,688 for Medicare plans. Among patients with a commercial plan insurance, 46% reached their MOOP limit including 8% before and 37% after cancer diagnosis. For Medicare patients, 20% reached their MOOP limit, including 3% before and 17% after cancer diagnosis. Patients with a HDHP (adjusted Odds Ratio [aOR]: 2.61, 95% CI: 1.96-3.47), breast cancer (aOR: 2.29, 95% CI: 1.84-2.84), and lung cancer (aOR: 2.71, 95% CI: 2.04-3.61) had significantly greater odds of reaching the MOOP than those with a non-HDHP and other cancers. Household income was also significantly associated (aOR: 0.97, 95% CI:0.95-0.99) with reaching the MOOP. **Conclusions:** A substantial proportion of patients reach the annual MOOP limit during the year of cancer diagnosis, representing a population at high-risk for medical financial hardship. Future longitudinal studies are needed to assess the trajectory of OOP spending and implications on care utilization and health outcomes. Research Sponsor: U.S. National Institutes of Health.

6647 **Poster Session**

National survey of financial burdens and experience among patients with cancer receiving charitable co-pay assistance.

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Background: High healthcare costs can pose a barrier to access and contribute to financial hardship among patients with cancer. Charitable co-pay assistance (CPA) foundations provide financial support to patients facing high out-of-pocket costs, but little is known about the sociodemographic characteristics, financial burdens, views and experience of those receiving assistance. **Methods:** We conducted a national, cross-sectional survey of CPA grant recipients receiving financial assistance from the HealthWell Foundation (charitable CPA foundation) to cover cancer drug costs. The primary outcome of interest was self-reported financial distress (FACIT-COST). Secondary outcomes included measures of out-of-pocket spending, patient perspectives on CPA support, healthcare access and costs, and the impact of financial burden on healthcare utilization. **Results:** Among 1,108 CPA grant recipients, over 20 cancer types were represented, including 30% with solid tumors and 70% hematologic malignancy. Average age of CPA recipients was 72 (range: 41-92), 60% were male, 88% white, 55% college educated, and 67% had annual income $<$ \$60,000. 96% had Medicare (53% Traditional, 43% Advantage, 58% with supplemental insurance), and 66% believed insurance would prevent them from paying high drug costs. However, 54% reported spending $>$ \$500 per month on healthcare, with 39% spending $>$ 10% of household income. Among 17% reporting delays in starting therapy due to cost, 28% reported delay $>$ 4 weeks. Overall, 18% reported skipping medical services due to cost, and 24% believed they would not have received their treatment without CPA. On the COST scale, 56% reported mild financial toxicity (COST 14-25) and 27% moderate/severe (COST $<$ 14) despite CPA. In bivariate analysis, younger age, solid tumor, lower income, female gender, higher anxiety and depression (PHQ4), greater comorbidity, and traditional Medicare were all significantly associated with greater financial distress (lower COST scores, $P < 0.05$ for all). Most (76%) CPA recipients believed that doctors should be aware of costs when making decisions, and 91% supported Medicare negotiating drug prices with manufacturers. With regard to why they required CPA, only 6% attributed it to failure to discuss costs with their doctor, 14% to the healthcare system, 51% to poor insurance coverage, 61% to their financial status, and 82% to high drug costs. Notably, 73% reported a decrease in financial concerns as a result of CPA. **Conclusions:** In this large national sample of CPA grant recipients with cancer, most had Medicare and believed insurance would shield them from high drug costs, yet many reported delays in starting therapy prior to CPA and ongoing financial distress. CPA may play an important role in securing access to therapy but these findings highlight an ongoing need to address financial toxicity and understand potential disparities in access to CPA. Research Sponsor: HealthWell Foundation.

6648 **Poster Session**

A health economic model to assess the impact of prehabilitation on hospital cost savings in gastrointestinal cancer, modelled on English National Health Service tariff.

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Background: Prehabilitation is increasingly being recognised as a high-priority intervention to improve physical and psychological health in cancer patients, prevent treatment-related functional decline and to reduce the incidence and severity of post-surgical complications. The aim of this study is to develop a health economic (HE) model to evaluate the impact of prehabilitation in patients undergoing gastrointestinal cancer surgery. **Methods:** The objective of the HE model is to estimate the impact of prehabilitation on reducing treatment costs. Data was extracted from systematic reviews and meta-analysis on the effects of prehabilitation in gastrointestinal cancer surgery to identify: i) treatment pathway, ii) prehabilitation components (nutrition/exercise/psychological intervention), and iii) effects on three study outcomes (length of hospital stay, reduction of post-operative complications, and reduced Intensive Care Unit (ICU) stay). The modelling study accounts for the number of hospital admissions and unit costs from NHS hospitals, including cost per bed-day from NHS Reference costs 2017-18 and complication costs and ICU cost from NHS Reference National Cost Schedule 2019-20. Double counting has been corrected to account for the compounded effects on length of stay and complications. The HE model considers the average effect of each study outcome and their confidence intervals. This provides a range of potential impact of prehabilitation in terms of cost reduction based on NHS tariff. **Results:** Patient weighted average cost savings from prehabilitation was £785, excluding ICU costs. Breakdown of cost savings include £178.6 from reduced length of hospital stay, £214.8 and £434.5 cost savings originating from reductions in minor and major complications, respectively (excluding ICU complication costs). ICU cost savings from prehabilitation were £1,620. For the NHS, based on 237,000 annual surgical procedures, this amounts up to £186,082,321 in cost savings, from a reduction in complications and 421,840 hospital days, and £52,761,227 from ICU stay. **Conclusions:** In addition to the impact on post-operative complications and hospital stay, this study has demonstrated that prehabilitation results in significant costs savings to healthcare systems. The cost savings are largely from a reduction in the incidence and severity of post-operative complications. The latter contributing to reduced ICU costs. Research Sponsor: None.

6649 **Poster Session**

Value-driven colorectal cancer survivorship through partnership with primary care.

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Background: The risk of recurrence for colorectal cancer (CRC) is low after 5 years (<1.5% per year) hence, surveillance visits, CEA blood tests and annual CT scans are not recommended beyond this period (NCCN guidelines). Importantly, right-siting survivorship care to the community allows primary care providers (PCP) to focus on preventive health beyond cancer. The National University Cancer Institute, Singapore, a tertiary, academic cancer center developed a program to transition CRC survivorship care to the community after 5-years of active surveillance. Patients (Pts) are discharged to the community with a survivorship care plan and followed-up via phone calls. We hypothesize that by transitioning CRC survivors to the community, we can optimize healthcare resources by reducing specialist visits and tests at the cancer center without compromising outcomes. **Methods:** From July 2018, CRC pts beyond 5-years from diagnosis with no evidence of cancer recurrence were eligible for transition. Pts were followed prospectively to determine date of cancer recurrence, issues preventing transition to the community and a phone survey on pt satisfaction was conducted for those who transitioned to primary care. Data on healthcare utilization amongst pts who transitioned vs. pts who remained in tertiary care was collected. Data cutoff was June 2022. Statistical analysis was performed with IBM SPSS Statistics (v28.0). **Results:** Between July 2018 - June 2022, there were 791 CRC pts who were eligible for transition, of which 534 pts (67.5%) had no clinical issues preventing transition and included in this analysis. 54.3% (N= 290) were males and stage distribution of cancers were 14.2%, 34.0%, 47.1% and 4.7% for stages I, II, III and IV, respectively. The mean number of years since diagnosis was 6.88 (range: 5-16 years; SD 2.25). 380 pts (71.2%) were transitioned to the community. There was consistently higher utilization of healthcare resources in the group not transitioned vs. transitioned: mean number of consults (2.86 vs 1.02; $p<0.001$); CEA (1.23 vs 0.31; $p<0.001$); CT scans (0.08 vs 0.05; $p=0.221$) and colonoscopies (0.25 vs 0.16; $p=0.031$). Mean healthcare expenditure (mean gross bill per year) was consistently higher in pts across all categories for the group not transitioned vs. transitioned: consults ($158 vs $56; $p<0.001$); CT scans ($60 vs $39; $p=0.273$); CEA ($26 vs $7; $p<0.001$) and colonoscopies ($208 vs $126; $p=0.018$). Importantly, recurrence rates were low with no difference in both groups (0.8% vs 1.3%; $p=0.629$). 82% of CRC pts were satisfied or very satisfied with follow-up care provided by their PCPs on a subsequent survey. **Conclusions:** We have demonstrated value-driven survivorship care by right-siting CRC survivors into the community. Healthcare resources were optimized with reduction in specialist visits and tests which lead to lower costs while recurrence rates remain low. Pt satisfaction in the community was also high. Research Sponsor: None.

6650 **Poster Session**

Impact on costs and outcomes of multi-gene panel testing for advanced solid malignancies: A cost consequence analysis using linked administrative data.

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Background: To date, economic analyses of tissue-based next generation sequencing genomic profiling (NGS) have required models with multiple assumptions, with little real-world evidence on overall survival (OS), clinical trial enrollment or end-of-life (EOL) quality of care. The OCTANE clinical trial (NCT02906943) is a prospective study evaluating the role of NGS for advanced solid tumors in Ontario, Canada. We performed a cost consequence analysis of OCTANE. **Methods:** We undertook a longitudinal, propensity score-matched retrospective cohort study using linked administrative data. OCTANE patients (pts) at Princess Margaret Cancer Centre from August 2016 until March 2019 undergoing NGS panel testing (555 or 163-gene panels) were matched with contemporary controls from across Ontario not enrolled in OCTANE. Patients were matched according to 19 variables including age, sex, place of residence, tumor site, symptom burden, income quintile, comorbidities and prior lines of systemic therapy. Primary outcomes were mean per capita health care costs (2019 Canadian dollars [CAD]) from the public payer's perspective, OS, clinical trial enrollment and EOL quality metrics. Full 2-year follow-up data was available. Sensitivity analyses considered alternative matched cohort specifications. **Results:** There were 782 OCTANE pts with 782 matched controls. Variables were balanced after matching (standardized difference [std. diff.]<0.10). Most common tumor sites were: Ovary (30.4%), endometrium (15.0%) breast (12.3%) and colon (8.6%). OCTANE pts had higher mean healthcare costs than controls ($79,702 vs. $59,550), mainly due to costs of oncology visits ($33,165 vs. $26,197), outpatient clinic visits ($8,696 vs. $5,114) and emergency visits ($1,723 vs. $1,373) (all $p<0.05$). Publicly funded drug costs were less for OCTANE pts ($20,015 vs. $24,465). Overall, OCTANE enrollment was not associated with improved OS (restricted mean survival time (RMST) [standard error]: 1.50 ($\pm$0.03) vs. 1.44 ($\pm$0.03) years, log-rank $p=0.153$), but OCTANE was associated with longer OS in ovarian cancer (RMST: 1.69 ($\pm$0.05) vs. 1.45 ($\pm$0.06) years, $p=0.011$) and biliary tract tumors (RMST: 1.16 ($\pm$0.13) vs. 0.80 ($\pm$0.11) years, $p=0.02$). Importantly, OCTANE correlated with increased clinical trial enrollment (25.5% vs. 9.5%, $p<0.001$) and better EOL quality due to fewer deaths in hospital (10.2% vs 16.4%, $p=0.003$). Results were robust in sensitivity analysis. **Conclusions:** There was an increase in healthcare costs associated with NGS testing for advanced cancers. The impact on OS was not significant in the overall population, but varied across tumor types. OCTANE was associated with greater trial enrollment, lower publicly funded drug costs and fewer in hospital deaths suggesting important considerations in determining the value of NGS for advanced cancers. Clinical trial information: NCT02906943. Research Sponsor: Ontario Institute for Cancer Research through funding provided by the Government of Ontario (#IA-035 and P.HSR.158) and Canadian Network for Learning Healthcare Systems and Cost-Effective 'Omics Innovation (CLEO) via Genome Canada (G05CHS).

6651 **Poster Session**

The impact of a cancer-specific novel therapy adjustment (NTA) in Medicare value-based care programs: A simulation exercise.

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Background: The Oncology Care Model (OCM) was a value-based care program implemented by the Centers for Medicare & Medicaid Innovation (CMMI) between July 1, 2016, and June 30, 2022, that aimed to provide high-quality care while reducing total cost of care (TCOC). In 2023 CMS plans to implement the Enhancing Oncology Model (EOM), which builds on lessons learned from the OCM. Over 200 novel therapies were approved by the FDA between 2016 and 2022. Novel therapies come with increased cost, leading to concerns that the model could discourage use of novel therapies. CMMI implemented a novel therapy adjustment (NTA) to offset the increased cost of these expensive therapies, when a practice has a higher proportion of novel therapy expenditures. A key change in the EOM is the calculation for NTA at the individual cancer type level compared to full population of episodes in the OCM. We studied the impact of moving from a population-based NTA to a cancer type-based NTA calculation. **Methods:** Claims and performance data from 10 performance periods (PP) in the OCM (PP1 to PP10) for 14 practices in The US Oncology Network were reviewed. Descriptive statistics for the simulation were evaluated to determine changes from population-based NTA to cancer-based NTA. The OCM NTA methodology was deconstructed to apply the NTA at a cancer type level. We performed a simulation exercise by applying cancer specific NTA methodology systematically to the claims and performance data. We then evaluated the impact of NTA on the EOM cancer types. **Results:** 20.95% of the TCOC was attributed to novel therapy expenditures in the OCM for all cancer types (range 0.0% - 49.4%) vs 24.2% (range - 3.5% - 43.7%) of TCOC for the EOM cancer types (high-risk breast, colon, lung, high-risk prostate, myeloma, lymphoma and chronic leukemia) in the same time-frame. 75.5% of the novel therapy expenditures in the OCM came from the 7 EOM cancers. In the OCM only 31.8% of eligible performance periods received a NTA. Had the NTA been applied at the cancer type level, 49.5% of eligible episodes would have received an adjustment. The top cancers with the most novel therapy use as a percentage of TCOC were lung, myeloma and high-risk/castrate-resistant prostate. The NTA for these practices adjusted the benchmark by an average of 0.56% (range -0.21% to 1.1%) over 10 periods. When applied at a cancer type level, NTA increased the adjustment by 3 times to an average of 1.73% (range - 1.16% to 2.11%). **Conclusions:** The NTA applied at a cancer type level would have resulted in more instances where practices would have qualified for a benchmark adjustment. We believe that the EOM approach to NTA applied at a cancer type level is more favorable for participating practices and provides valuable financial protection when incorporating clinically appropriate novel therapy for cancer treatment. We commend CMMI for making improvements to the NTA risk adjustment methodology within the EOM. Research Sponsor: None.

6652 **Poster Session**

Assessment of price variation in colorectal cancer screening procedures at US hospitals.

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Background: Following the 2021 Hospital Price Transparency Final Rule, US hospitals were mandated to publish their insurer-negotiated prices. We identified factors contributing to price variability of colorectal cancer (CRC) screening procedures across the US. **Methods:** We compared prices of colonoscopy, flexible sigmoidoscopy, CT colonography, fecal occult blood test, fecal immunochemical test, and Cologuard across U.S. hospitals using the Turquoise dataset (N = 6,378). Psychiatric, rehabilitation, and pediatric hospitals were excluded. Prices in the top and bottom 1% were also excluded to minimize the effect of outliers. Prices were adjusted by the Medicare Geographic Price Index to account for regional variability. We then compared prices across several subgroups, including National Cancer Institute (NCI) designated hospitals, teaching hospitals, and investor owned hospitals. Significance was assessed using the Kruskal-Wallis test. To quantify price variability across insurance plans within a hospital, we defined the within-center-ratio as the 90^{th} percentile rate at a hospital divided by the 10^{th} percentile rate. To quantify variability across hospitals, the across-center-ratio was defined as the 90^{th} percentile median rate across all hospitals divided by the 10^{th} percentile median rate. **Results:** 1,460 hospitals reported commercial prices for colonoscopy with a median commercial price of $1,867 (IQR: $1,208 - $2,689). For colonoscopy, the within center ratio was 2.5 (IQR: 1.5 – 3.8) and the across-center ratio was 6.2. Prices for other procedures are provided in the table. Compared to non-investor owned hospitals, prices of colonoscopy ($2,082 vs $1,787, $P < 0.001$) and flexible sigmoidoscopy ($2,022 vs $1,289, $P < 0.001$) were significantly higher at investor owned hospitals. Furthermore, across investor classes, hospitals with >5% ownership from private equity firms had the highest median price for both colonoscopy ($2,898), and flexible sigmoidoscopy ($2,697). We did not find significant differences in price by NCI designation, academic teaching center affiliation, overall hospital mortality, overall hospital readmission rate, or urban/rural location. **Conclusions:** CRC screening procedure prices vary significantly both within and across hospitals. Private equity and other investor owned hospitals had significantly higher prices compared to non-investor owned hospitals. Research Sponsor: None.

Code type	Code description	Number of centers	Median commercial price, $ (IQR)	Within center ratio (IQR)	Across center ratio
45378	Colonoscopy	1,460	1,867 (1208 - 2689)	2.5 (1.5 - 3.8)	6.2
45330	Flexible Sigmoidoscopy	1,332	1,473 (823 - 2251)	2.3 (1.4 - 3.9)	15.9
82270	Fecal occult blood test (guaiac)	1,300	16 (7 - 32)	3.2 (1.7 - 6.7)	13.1
82274	Fecal Immuno-chemical test	1,185	41 (25 - 65)	2.5 (1.6 - 4.3)	5.5
74263	CT colonography	644	1,060 (675 - 1621)	1.8 (1.1 - 3.3)	5.8
81528	Cologuard	199	560 (509 - 1074)	1.7 (1 - 2.6)	3.4

TPS6653 **Poster Session**

The FOR ME (Fostering Opportunities in Research through Messaging and Education) study: Developing a culturally sensitive narrative intervention to promote equity in clinical trials.

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Background: Black women are more likely to die from breast cancer than women of any other race/ethnicity. Contributing factors to this inequity include structural and socioeconomic determinants of health, differential access to novel therapies, tumor biology and comorbidities. In 2020, only 7.2% of enrollees in clinical trials that led to approval of 3 novel drugs for breast cancer were Black. Underrepresentation of patients from racial/ethnic minority groups in clinical trials is a contributing factor to health disparities. The first aim of this study is to conduct multiple qualitative methods with multi-level stakeholders to identify barriers, facilitators, and intervention priorities that would assist Black breast cancer patients to make informed decisions about participating in clinical trials. Secondly, we aim to create a culturally sensitive, narrative intervention designed to support decision making and motivate Black breast cancer patients to participate in clinical trials. Aim 3 will pilot a study to determine acceptability of the intervention among patients and assess whether it increases clinical trial participation in a safety net oncology practice. **Methods:** Community-based participatory research approaches are guiding our research methodologies. First, we are conducting interviews and story circles with Black women with breast cancer, community partners and advocates, and oncologists and clinical trials office staff. These interviews will identify themes to inform intervention content. Next, interviews and focus groups will invite feedback on the educational/motivational content of the intervention and will be used to develop a culturally sensitive script and storyboards. A video production company will produce the narrative intervention. Finally, focus groups and interviews with participant cohorts will provide feedback on the completed intervention. Black women diagnosed with breast cancer will view the intervention in an oncology clinic. Using a pretest/posttest design, we will analyze the acceptability of the intervention and its effect on intention to participate in clinical trials. We will then conduct a quasi-experimental study in a safety net oncology practice to determine whether the rate of clinical trial participation among Black breast cancer patients increases following implementation of the intervention as a standard component of new patient education. Recruitment started in July 2022, and currently, 14 of 30 interviews with patients are completed. Aim 1 interviews with patients, oncologists, clinical trial staff, and advocates are expected to finish by April 2023, and results will be presented. Research Sponsor: American Cancer Society.

TPS6654 **Poster Session**

Understanding patient acceptance and compliance of a blood-based colorectal cancer screening test.

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Background: The Covid-19 pandemic has caused a significant disruption in healthcare utilization. The halt and delay of CRC screening have led to a substantial decline in CRC screening rates. The backlog and the slow resuming of CRC screening will have significant consequences. Although COVID-19 created challenges in CRC screening, it also presents an opportunity for potential innovative approaches that may improve patient compliance and screening rates, such as a blood-based CRC screening test which can be done at the point of care without preparation. Adherence to CRC screening is poor among vulnerable populations even before COVID-19, and these populations disproportionately receive health care in safety-net settings, such as federally qualified health centers (FQHCs). Thus, FQHCs play a significant role in improving CRC-related outcomes and ensuring health equity. This study will examine patient compliance with CRC screening by offering another option, a blood-based screening test, after failing to complete a stool-based screening test or colonoscopy in six months at three FQHCs. **Methods:** The study will use a stepped wedge cluster trial design and include an initial period of no exposure. Each FQHC will have a cluster of 10 to 17 primary care clinics. After the initial no-exposure period, two FQHCs will implement a blood-based CRC screening test at their primary care clinics. Another FQHC will follow nine months later. Each FQHC will contribute to exposed and unexposed observations and function as its own control. This study will collect quarterly data to capture the impact, feasibility, and acceptability over time. The primary endpoint will be assessed by calculating the number of participants who, otherwise, will not have participated in the CRC screening. In addition, the effectiveness of the implementation strategies will be assessed since transferring innovations into real-world settings is complex, and practical strategies are critical to accelerating future implementation and assisting decision-making. The study will recruit patients who fail to complete a CRC screening after six months and meet the inclusion criteria: between 45-75 years of age, average risk for CRC, capable of and willing to give informed consent, and willing to provide a blood sample. For eligible patients, a blood-based CRC screening test developed by a CLIA-certified laboratory and made commercially available (Guardant Health, CA) will be offered at no cost. An order will be obtained from the participant's primary care provider before the blood sample is collected. This study plans to enroll up to 2,400 patients over a 3-year period. Patient compliance is a significant barrier to improving CRC screening, and the key to increasing screening participation is patient acceptance of the screening method. A blood-based screening test may offer an alternative for patients who fail to comply with other CRC screening modalities. Clinical trial information: NCT05536713. Research Sponsor: Guardant Health.