11000 Oral Abstract Session

Shareable artificial intelligence to extract cancer outcomes from electronic health records.

Kenneth L. Kehl, Justin Jee, Karl Pichotta, Pavel Trukhanov, Christopher Fong, Michele Waters, Chelsea Nichols, Ethan Cerami, Deb Schrag, Nikolaus Schultz; Division of Population Sciences, Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA; Memorial Sloan Kettering Cancer Center, New York, NY; Dana-Farber Cancer Institute, Boston, MA

Background: Clinical outcomes such as response, progression, and metastasis represent crucial data for observational cancer research, but outside of clinical trials, such outcomes are usually recorded only in unstructured notes in electronic health records (EHRs). Manual EHR annotation is too resource-intensive to scale to large datasets. Individual cancer centers have trained artificial intelligence natural language processing (AI/NLP) models to extract outcomes from their EHRs. However, due to concerns that models trained on protected health information (PHI) might encode private data, such models usually cannot be exported to other centers. **Methods:** EHR data from Dana-Farber Cancer Institute (DFCI) and Memorial-Sloan Kettering (MSK) collected through the AACR Project GENIE Biopharma Collaborative were used to train and evaluate Bidirectional Encoder Representations from Transformers (BERT)-based NLP models to extract outcomes from imaging reports and oncologist notes annotated with the Pathology, Radiology/Imaging, Signs/Symptoms, Medical oncologist, and bioMarkers (PRISSMM) framework. Document-level outcomes included the presence of active cancer; response; progression; and metastatic sites. 'Teacher' models trained on DFCI EHR data were used to label imaging reports and discharge summaries from the public MIMIC-IV dataset. 'Student' models trained to use MIMIC documents to predict teacher labels were transferred to MSK for evaluation. **Results:** Teacher models were trained at DFCI on 30,332 imaging reports for 2609 patients and 32,173 oncologist notes for 2917 patients with non-small cell lung, colorectal, breast, prostate, pancreatic, or urothelial cancer. The models were used to label 217,642 imaging reports and 141,377 discharge summaries from MIMIC for student model training. These DFCI-trained student models were evaluated at MSK, demonstrating high discrimination (AUROC $>$ 0.90) across outcomes. **Conclusions:** This privacy-preserving "teacher-student" AI/NLP framework could expedite linkage of genomic data to clinical outcomes across institutions, accelerating precision cancer research. Research Sponsor: American Association for Cancer Research; Doris Duke Charitable Foundation; 2020080; National Cancer Institute; R00CA245899.

AUROCs of outcome extraction AI models trained at DFCI.

	Imaging Reports			Oncologist Notes		
Model evaluation center	DFCI	DFCI	MSK	DFCI	DFCI	MSK
Model type	PHI-trained teacher model	MIMIC- trained student model	MIMIC-trained student model	PHI-trained teacher model	MIMIC- trained student model	MIMIC-trained student model
Outcome						
Any cancer	0.97	0.97	0.99	0.95	0.95	0.96
Progression	0.97	0.98	0.95	0.97	0.95	0.91
Response	0.96	0.95	0.96	0.96	0.95	0.94
Brain metastasis	0.99	0.99	0.99			
Bone metastasis	0.99	0.99	0.99			
Adrenal metastasis	0.99	0.99	0.99			
Liver metastasis	0.99	0.99	0.99			
Lung metastasis	0.98	0.97	0.98			
Nodal metastasis	0.97	0.97	0.96			
Peritoneal metastasis	0.99	0.99	0.97			

11001 Oral Abstract Session

Efficacy of eSyM: Acute care utilization among patients with cancer who do versus do not report ePROs.

Michael J. Hassett, Hajime Uno, Angela Tramontano, Christine Cronin, Jessica J Bian, Don S. Dizon, Hannah W. Hazard-Jenkins, Raymond U. Osarogiagbon, Sandra L. Wong, Deb Schrag; Dana-Farber Cancer Institute, Boston, MA; MaineHealth Cancer Care, South Portland, ME; Lifespan Cancer Institute, Rhode Island Hospital, Providence, RI; WVU Cancer Institute, West Virginia University, Morgantown, WV; Baptist Cancer Center, Multidisciplinary Thoracic Oncology Program, Memphis, TN; Dartmouth-Hitchcock Medical Center, Lebanon, NH; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Patients (pts) receiving cancer treatment frequently experience burdensome symptoms that compromise outcomes and necessitate acute care. Prior clinical trials have demonstrated that electronic patient-reported outcome (ePRO)-based symptom management programs improve outcomes in controlled settings. Deploying these programs in routine care settings remains challenging. With funding from the Cancer Moonshot IMPACT Consortium, we created eSyM – an ePRO-based, EHR-integrated symptom management program – to facilitate the widespread adoption of active symptom management efforts. **Methods:** eSyM was deployed across six health systems from September 2019-August 2022 via a modified stepped-wedge cluster randomized pragmatic trial. Pts starting chemotherapy (CHEM) or undergoing surgery (SURG) for a suspected or confirmed thoracic, gastrointestinal, or gynecologic cancer were prompted to complete symptom questionnaires regularly; those reporting symptoms were offered additional supports. To assess eSyM efficacy, we studied pts who were eligible to use the program – comparing those who completed at least one symptom questionnaire to those who did not. Outcomes included emergency department (ED) visits and inpatient encounters (INPT) at 30 and 90-days. Odds ratios with 95% CIs were derived after adjusting to account for the propensity to report ePROs as a function of age, sex, race/ethnicity, employment, marital status, poverty, rurality, insurance, comorbidity, cancer, treatment goal, institution, and calendar time. **Results:** Among eSyM-eligible pts, 51% (N = 10,454/20,471) completed at least one symptom questionnaire (median 4 reports/patient) – 47% (3815/8187) for CHEM and 54% (6639/12,293) for SURG. Comparing symptom reporters to non-reporters, the proportion of CHEM+SURG pts experiencing an ED event was 5.3% vs. 7.1% at 30 days and 10.0% vs. 12.9% at 90 days; and the proportion experiencing an INPT event was 6.7% vs. 11.3% at 30 days and 14.0% vs. 19.5% at 90 days ($p< 0.001$ for all). Adjusted ORs appear in the. **Conclusions:** After accounting for propensity to report symptoms, completing at least one symptom questionnaire was associated with lower odds of experiencing an ED or INPT encounter among CHEM and SURG pts across six diverse health systems. eSyM engagement reduced acute care utilization. This EHR-integrated symptom management solution is broadly available to health systems that use Epic. Clinical trial information: NCT03850912. Research Sponsor: National Cancer Instiute; 1UM1CA233080-01.

Adjusted ORs – symptom reporters vs. non-reporters (95% CI; *P* value).

Outcome	Days	CHEM + SURG	CHEM Only	SURG Only
ED	30	0.859 (0.793-0.932; p < 0.001)	0.833 (0.740-0.938; p = 0.003)	0.881 (0.789-0.984; p = 0.024)
	90	0.907 (0.853-0.963; p = 0.002)	0.905 (0.829-0.988; p = 0.027)	0.905 (0.832-0.985; p = 0.021)
INPT	30	0.653 (0.609-0.700; p < 0.001)	0.648 (0.584-0.718; p < 0.001)	0.656 (0.598-0.721; p < 0.001)
	90	0.780 (0.740-0.822; p < 0.001)	0.813 (0.755-0.876; p < 0.001)	0.742 (0.689-0.800; p < 0.001)

11002 Oral Abstract Session

An AI-assisted navigation approach for patients with radiographic suspicion of new pancreas cancer.

Kristen M. John, Joseph Tenner, Rolando Croocks, Cristina Valente, Bernadette Bingham, Amber N Habowski, Tara McEvoy, Tiffany Zavadsky, Kristen Beyer, Rita Mercieca, Sandeep Nadella, Anthony Carvino, Matthew Barish, Daniel King; Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY; Northwell Health Cancer Institute, New Hyde Park, NY; Northwell Health, New Hyde Park, NY; Cold Spring Harbor Laboratory, Cold Spring Harbor, NY; Division of Surgery, Northwell Health Cancer Institute, New Hyde Park, NY; Northwell Health Cancer Institute, Lake Success, NY

Background: The traditional cancer care paradigm relies on passive referral streams, resulting in suboptimal care delivery. Here, we assessed the results of an AI-assisted navigation approach to proactively coordinate specialty cancer care services for patients with radiographically suspected pancreas cancer. **Methods:** A natural language processing (NLP) classifier was trained to identify radiology reports suspicious for pancreas cancer from imaging reports generated within Northwell Health. The daily workflow consists of the following: the NLP flags reports with suspicion of pancreas cancer, a coordinator validates the finding, a GI oncologist and navigator coordinates specialty oncology and tumor board referral, and a clinical research coordinator pre-screens for research studies. Patients determined to be hospice-bound or with non-PDAC malignancy are excluded. Care delivery metrics were compared by Mann-Whitney U tests. **Results:** Prior to implementation, patients with new suspicion of pancreas cancer at our institution experienced a mean of 22 days to biopsy, 32 days to oncology visit, and 56 days to treatment initiation from radiology report with 17% referred to pancreatic multidisciplinary clinic (PMDC). Per monthly average, 1.8 patients were approached for biospecimen studies, 1.5 were consented, and 0.9 were enrolled. In the month following implementation of the AI-assisted navigation pilot, reports from 1666 patients were flagged, resulting in 38 patients with new suspicion of pancreas cancer identified (Table). Of these, 53% underwent biopsy, 50% were seen by an outpatient oncologist, 29% were referred to PMDC, and 42% received treatment at our institution. From date of radiology report, these patients underwent biopsy at a mean of 7 days ($p<0.01$), outpatient oncology visit at 15 days ($p=0.285$), and treatment initiation at 34 days ($p=0.3479$). A monthly average of 4 patients were approached for biospecimen studies, 4 were consented, and 3.2 were enrolled. **Conclusions:** An AI-guided navigation workflow identified patients earlier in the diagnostic timeline; reduced time to biopsy, follow-up, and treatment initiation; increased patient referrals to PMDC; and tripled participation in biospecimen studies at our institution. Research Sponsor: None.

Demographics of patients identified through AI-guided workflow (n=38).

Age		**69 +/- 12**
Gender	Male	55%
Race	Asian	16%
	Black	24%
	White	47%
	Other	13%
Scan type	CT	87%
	MRI	13%
Scan setting	Inpatient	89%
	Outpatient	11%

11003 Oral Abstract Session

Prescription drug monitoring program mandates and opioid prescriptions received by patients dying of cancer.

Yuhua Bao, Hao Zhang, Laura C Pinheiro, Allison Ju-Chen Hu, Russell K. Portenoy, Eduardo Bruera, M. Carrington Reid, Rulla M. Tamimi, Fang Zhang, Judith A. Paice, William E. Rosa; Weill Cornell Medicine, New York, NY; University of Alabama at Birmingham, Birmingham, AL; Albert Einstein College of Medicine, New York, NY; The University of Texas MD Anderson Cancer Center, Houston, TX; Harvard Pilgrim Health Care Institute, Boston, MA; Northwestern University Feinberg School of Medicine, Chicago, IL; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Strong consensus supports opioid analgesics as first-line pain management for patients with poor prognosis cancer approaching the end of life (EoL). State legislations that mandate prescriber access of Prescription Drug Monitoring Programs (PDMPs) when prescribing opioids intend to mitigate unsafe opioid prescriptions but may have unintended consequences in restricting access to opioids for patients dying from cancer. This study seeks to assess associations between state implementation of comprehensive PDMP mandates – applicable to all prescribers and all clinical settings and not allowing prescriber discretion – with opioid prescriptions received by patients dying of cancer. **Methods:** We used SEER cancer registry linked with Medicare fee-for-service claims to identify 184,123 Medicare beneficiaries 66 years or older who died of cancer in 2011-2019 in one of 10 SEER states with an operating PDMP by the beginning of 2011. We measured opioid prescriptions dispensed to patients near the EoL, defined as 30 days prior to death or hospice admission. We exploited staggered implementation of comprehensive PDMP mandates and assessed the association of such implementation with opioid prescriptions dispensed to patients near the EoL. We estimated logistic regressions for dichotomous outcomes and Generalized Linear Models for continuous outcomes. **Results:** Implementation of comprehensive PDMP mandates was associated with a reduction in the rate of 1 or more opioid days near the EoL from 47.2% to 45.2% (difference, 0.02 [95% CI, -0.027, -0.012]), a reduction in the rate of 1 or more long-acting opioid days from 15.8% to 14.7% (difference, 0.011 [95% CI, -0.016, -0.006]), and a reduction of 130.8 (95% CI, -161.5, -100.2) in total morphine milligram equivalents (MMEs) and of 135.6 (95% CI, -215.1, -56.1) in MMEs from long-acting opioids among patients who received 1 or more days of opioids/long-acting opioids. **Conclusions:** Comprehensive PDMP mandates were associated with 4-9% reduction in opioid prescriptions dispensed to patients at the EOL. Specific strategies are needed to effectively exempt patients with active cancer from such mandates. Research Sponsor: National Cancer Institute; R01 CA267996; The American Cancer Society; RSGI-22-130-01-HOPS.

Outcome	Sample Mean	Predicted, no Policy*	Predicted, with Policy	Difference	95% CI	Relative Change (%)	p-value
1 or more opioid day	0.467	0.472	0.452	-0.020	(-0.027, -0.012)	-4.2%	< 0.001
Days covered by opioids	17.5	17.6	17.1	-0.5	(-0.8, -0.2)	-2.8%	0.001
Total MMEs	1511.0	1538.8	1408.0	-130.8	(-161.5, -100.2)	-8.5%	< 0.001
Daily MMEs	73.3	74.1	70.2	-3.9	(-5.1, -2.7)	-5.3%	< 0.001
1 or more LA opioid day	0.156	0.158	0.147	-0.011	(-0.016, -0.006)	-7.0%	< 0.001
Days covered by LA opioids	20.1	20.2	19.8	-0.5	(-0.9, 0.0)	-2.5%	0.030
Total MMEs from LA opioids	2143.5	2170.9	2035.2	-135.6	(-215.1, -56.1)	-6.2%	0.001
Daily MMEs from LA opioids	93.6	94.3	90.5	-3.9	(-6.3, -1.4)	-4.1%	0.002

*Policy is comprehensive PDMP mandates; LA- Long-acting.

11004 Oral Abstract Session

Payor denial after prior authorization request for long-acting pain medication: Provider and patient perspectives.

Fumiko Chino, Sonia Persaud, Sankeerth Jinna, Lauren Victoria Ghazal, Talya Salz, Bridgette Thom; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY; University of Rochester, Rochester, NY; School of Social Work, The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: For patients with cancer, uncontrolled pain can reduce quality of life, lead to treatment breaks, and result in worse cancer outcomes. Guideline-concordant treatment for chronic, severe pain can include long-acting opioid formulations. Pain medications, however, often face prior authorization (PA), which requires providers to obtain payor pre-approval and may result in delayed or denied care. This analysis characterizes PA-related denials for pain medications for patients with cancer. **Methods:** At an urban comprehensive cancer center, we identified all PA requests for outpatient long-acting opioid (i.e., buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, tapentadol) prescriptions from 2023 and described frequency of PA approvals and denials. For denials, chart review 2 weeks post-PA was conducted of provider notes and patient communications with results summarized qualitatively. **Results:** 1752 new long-acting opioids prescriptions for 982 unique patients required PA. Of those, 1567 (89.4%) were approved after PA process, 99 (5.6%) were denied, 81 (4.6%) were cancelled after PA initiation, and 6 (0.3%) were unresolved. Most were prescribed by pain specialists including supportive care (n = 699, 40.0%) and anesthesia/pain medicine (n = 444, 25.3%) with most common indication: "Neoplasm related pain (chronic)" (61.1%). Oxycodone was the most common long-acting opioid requiring PA (n = 551, 31.4% of prescriptions), followed by fentanyl (n = 501, 28.6%), hydromorphone (n = 205, 11.7%), and methadone (n = 137, 7.8%). Long-acting morphine was denied most frequently (16.3% of n = 129 PA requests denied), followed by buprenorphine (12.1% of n = 33), and hydromorphone (7.3%). Fentanyl was denied the least (2.8%). The 99 denials affected 62 unique patients, including a patient with 7 denials. Chart review (n = 62) of the 2 weeks post-denial revealed a median of 2 (range 0-8) provider notes mentioning pain or PA barriers and median of 1 (range 0-5) patient calls or messages about the same. 22.6% (n = 14) patients ended up in the ER or admitted to the hospital for pain crisis or failure to thrive. Providers documented poor pain control, weight loss, need to "try and fail" other medications, and noted 11.3% (n = 7) patients ending up paying out of pocket for their medications. Patient messages document uncontrolled pain and unmanageable side effects with some literally begging for relief; one patient spoke of their fear of "dying in pain". **Conclusions:** The vast majority of PA requests for long-acting pain medication result in approvals, suggesting that the process -which can delay essential pain management- is largely unnecessary. For the 1 in 20 requests that were denied, provider and patient concerns highlight the negative impact of uncontrolled pain. An improved, transparent PA process is essential for adequately treating chronic, cancer-related pain. Research Sponsor: NCI Cancer Center Support Grant; Memorial Sloan Kettering Cancer Center.

11005 Oral Abstract Session

High deductible health plans and survival among cancer survivors.

Justin Michael Barnes, Patricia Mae Garcia Santos, September Wallingford, Arjun Gupta, Meera Vimala Ragavan, Fumiko Chino; Department of Radiation Oncology, Washington University School of Medicine in St. Louis, St. Louis, MO; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Costs of Care, Boston, MA; University of Minnesota Masonic Cancer Center, Minneapolis, MN; University of California, San Francisco, San Francisco, CA

Background: High deductible health plans (HDHP) enable lower premiums at the expense of potentially high out-of-pocket costs. They are associated with more advanced cancer stage diagnoses and delayed or forgone care among cancer survivors. However, it is unknown how HDHPs are associated with survival among cancer survivors. **Methods:** Individuals ages 18-84 years with non-Medicaid insurance were identified from the 2011-2018 National Health Interview Survey (NHIS) with linked mortality files from the National Death Index. HDHP status was defined by the NHIS as a yearly deductible ≥$1200-1350 for an individual or ≥2400-$2700 for a family (values depend on survey year with increases over time). Cox proportional hazards models using age as the time scale were utilized to determine: 1) association of HDHP status with overall survival (OS) and cancer survival (CS; i.e., freedom from cancer death) among cancer survivors, and 2) how associations differed for survivors compared to those without a cancer history. Models accounted for the NHIS survey design and survey weights and were adjusted for insurance status, marital status, sex, comorbidities, education, income, national region, and cancer site and time since cancer diagnosis (if applicable). Sensitivity analyses adjusting for age at cancer diagnosis were performed using time since diagnosis as the time scale. **Results:** A total of 147,254 respondents were identified, 5.9% of whom were cancer survivors. 25.6% of survivors and 28.5% of individuals without a cancer history reported being insured by a HDHP at the time of NHIS participation. HDHP status was associated with worse OS (HR: 1.46, 95% CI = 1.19 - 1.79) and CS (HR: 1.34, 95% CI = 1.01 - 1.77) among cancer survivors overall in the adjusted model. HDHP status was additionally associated with worse OS among the following subgroups of cancer survivors: non-Hispanic White (HR: 1.45, 95% CI = 1.16 - 1.82), income > 400% federal poverty level (HR: 1.65, 95% CI = 1.16 - 2.36), college (HR: 1.47, 95% CI = 1.07 – 2.00) or high school (HR: 1.59, 95% CI = 1.19 - 2.12) education, and multiple cancers (HR: 1.58, 95% CI = 1.06 - 2.36), without clear patterns by sex, comorbidities, insurance, and cancer site. Sensitivity analyses provided similar results. In contrast, among adults without a history of cancer at the time of NHIS participation, HDHP status was not significantly associated with OS (HR: 1.08, 0.96 - 1.21; Pinteraction < .01) or CS (HR: 0.90, 95% CI = 0.70 - 1.14; Pinteraction < .01). **Conclusions:** This nationwide population-based analysis suggests that HDHPs are associated with both worse overall survival and cancer survival among cancer survivors but are not associated with survival in adults without a history of cancer. HDHPs may financially disincentivize cancer survivors from utilizing necessary medical care to optimize survivorship thereby compromising mortality and cure. Policy changes to limit the proliferation of these plans may improve cancer outcomes. Research Sponsor: None.

11006 Oral Abstract Session

Implementing financial toxicity and health-related social risks screening and referral.

Bridgette Thom, Emeline Mariam Aviki, Fumiko Chino; School of Social Work, The University of North Carolina at Chapel Hill, Chapel Hill, NC; NYU Langone Health, Mineola, NY; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Financial toxicity (FT), or cancer-related economic hardship, is associated with delayed/skipped care, reduced quality of life, and worse mortality. Screening for FT and health-related social risks (HRSR) as part of assessment for social determinates of health is currently being integrated into clinical care, but there is limited research on outcomes after patients screen positive for FT or HRSR. **Methods:** We conducted FT and HRSR screening for patients receiving treatment for breast, gynecologic, gastrointestinal, or thoracic cancer at an urban comprehensive cancer center. Screening included the 11-item Comprehensive Score for Financial Toxicity (COST) tool (scored 0-44, lower scores = worse FT) and a HRSR checklist to identify food, housing, medicine, and transportation insecurity. A COST score ≤20 or any endorsed HRSR was considered a positive screen, and financial/assistance counseling referral was offered. Multivariable logistic regression assessed associations of accepting referral, after controlling for demographic and clinical characteristics. Data were collected 09/2022-08/2023. **Results:** 28,606 patients completed screening, of which 32% (n = 9106) screened positive. Median COST was 16.0. Identified HRSR were: 23% food, 25% housing, 21% medicine, and 24% transportation insecurity. Of positive screens, 51% (n = 4683) requested some form of financial counseling. Associations with accepted referral include: higher FT (β = 1.15, 95% CI: 1.13, 1.16), younger age (β = 1.01, 95% CI: 1.008, 1.02), more essential needs (β = 1.19, 95% CI: 1.13, 1.25), non-White race/ethnicity (β = 1.70, 95% CI: 1.49, 1.93), and stage 3 (β = 1.29, 95% CI: 1.08, 1.53) or stage 4 (β = 1.26, 95% CI: 1.07, 1.49) diagnoses (vs. stage 0/1). Needs of patients who requested counseling included concerns relating to out-of-pocket expenses (68%), non-medical expenses (39%), health insurance coverage (23%), and paying for prescription medication (18%; not mutually exclusive). Of financial counseling sessions with available dispositions (n = 2336/4683, 50%), outcomes (not mutually exclusive) included general counseling (29%), referral to specific assistance programs (e.g., copay assistance, reduced cost care program; 15%), and insurance navigation (15%). One-third of patients requesting counseling did not respond to contact attempts; 21% reported no longer being interested in counseling upon contact. **Conclusions:** Screening for FT and HRSR was feasible, and one-third of patients were identified as at risk for FT or having an unmet essential need. Patients known to have worse FT outcomes (those with later-stage disease, younger age, higher FT, minoritized groups) were more likely to accept financial counseling; however, only one-half of those at risk accepted help. Future work will focus on improving workflows to ensure assistance meets patient needs, including addressing patient stigma around requesting help. Research Sponsor: None.

11007 Oral Abstract Session

Early integrated rehabilitation and vocational rehabilitation in 435 patients with breast cancer: A comparison between the intervention group and control group in a prospective study.

Nikola Besic, Mateja Kurir Borovcic, Zlatka Mavric, Anamarija Mozetic, Tina Zagar, Vesna Homar, Nena Kopcavar Gucek, Andreja Cirila Skufca Smrdel, Nada Rotovnik Kozjek, Vedran Hadzic, Natasa Kos, Bojan Pelhan, Marko Sremec, Tina Rozman, Simona Borstnar; Institute of Oncology Ljubljana, Ljubljana, Slovenia; Community Health Centre Vrhnika, Vrhnika, Slovenia; Community Health Centre Ljubljana, Ljubljana, Slovenia; Faculty of Sport, Ljubljana, Slovenia; University Medical Center Ljubljana, Ljubljana, Slovenia; University Rehabilitation Institute Republic of Slovenia, Ljubljana, Slovenia

Background: Return to work is beneficial both for breast cancer (BC) patients and for society. This study explored the impact of early integrated and vocational rehabilitation on sick leave and disability one year after the start of cancer treatment in BC patients. **Methods:** The subjects of our prospective study were 435 employed female BC patients (26-65 (mean 52) years of age), who participated in the pilot study on the individualized integrated rehabilitation in 2019-2022 and were followed for at least one year. There were 211 patients in the control group and 224 in the intervention group. The patients completed three questionnaires (EORTC QLQ - C30, B23, and NCCN): before, half and one year after the start of cancer treatment. The control group received the standard rehabilitation programme, offered to all BC patients before the start of the study. The multidisciplinary rehabilitation team reviewed the documentation of the patients from the intervention group before, half and one year after the start of treatment and recommended appropriate interventions according to the patient's needs in compliance with the institute's new clinical pathway (psychologist, general practitioner, nutritional treatment, physical rehabilitation, kinesiologist-guided online exercises, gynaecologist, analgesia, vocational rehabilitation). Data on the patients' demographics and needs reported in questionnaires, the extent of the disease and cancer treatment were collected. These data and the frequency of sick leave and disability retirement one year after the start of treatment in both groups of patients were analysed using the chi-square and ANOVA test. **Results:** The patients from the intervention group had 50 calendar days shorter sick leave compared to the control group ($p = 0.002$). Patients without metastatic disease from the intervention group had 52 calendar days shorter sick leave compared to the control group ($p = 0.002$). The intervention group treated with chemotherapy had 43 calendar days shorter sick leave compared to the control group ($p = 0.029$). The difference in sick leave of the group of patients who did not receive chemotherapy was statistically borderline significant (50 calendar days, $p = 0.053$). The patients in the intervention group had a better work ability ($p < 0.001$) and less disability ($p < 0.001$) than the patients in the control group one year after the start of treatment. **Conclusions:** One year after the beginning of cancer treatment, patients from the intervention group had shorter sick leave, better work ability, and a lower proportion of disability compared to the control group. Research Sponsor: The public agency for scientific research and innovation activities of the Republic of Slovenia and The Ministry of Health of the Republic of Slovenia; V3-1906, P3-0289.

11008 Oral Abstract Session

State mandatory paid medical leave policies and cancer stage at diagnosis in US adults.

Abigail Kohut-Jackson, Justin Michael Barnes, Fumiko Chino, Zhiyuan Zheng, Xuesong Han, Kimberly J. Johnson, Robin Yabroff, Kenton J Johnston; Saint Louis University School of Medicine, St. Louis, MO; Department of Radiation Oncology, Washington University School of Medicine in St. Louis, St. Louis, MO; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; American Cancer Society, Atlanta, GA; Washington University, St. Louis, MO; Department of Surveillance and Health Equity Science, American Cancer Society, Kennesaw, GA; Washington University in St. Louis, St. Louis, MO

Background: Since 2012, several states implemented mandatory paid medical leave policies. Mandatory paid medical leave may alleviate time and financial burdens, enabling patients to undergo screening and/or timely diagnostic workup for new cancer-related symptoms. These policies have been associated with increased cancer screening. We investigated whether state mandatory paid medical leave policies were associated with stage at cancer diagnosis. **Methods:** Adults ages 18-64 years diagnosed with cancer from 2010-2019 were identified from the Surveillance, Epidemiology, and End Results program. Differences-in-differences (DID) analyses using the updated method of accounting for heterogeneity in policy enactment compared proportions of stage I and IV cancer diagnoses from pre- to post-policy implementation in states with vs. without paid medical leave policies. Analyses adjusted for age, sex, race, ethnicity, rurality, cancer site, county-level income, and time-varying state Medicaid eligibility levels. Since some cities enacted city-wide policies prior to state-wide implementation, cases from affected states between the time of city and state policy enactment were excluded. Sensitivity analyses were conducted excluding counties with cities that enacted paid leave policies. The plausibility of the parallel trends assumption was assessed by comparing stage at diagnosis between state groups in the pre-policy period and was satisfied for all reported results. **Results:** A total of 1,052,307 adults with cancer were identified. 39.8% and 19.7% of patients were diagnosed with stage I and IV cancers, respectively. In adjusted DID analyses, there was a 1.34 percentage point (PP) increase in stage I diagnoses and a 2.05 PP decrease in stage IV diagnoses associated with mandatory paid medical leave policy implementation (Table). Results were similar in sensitivity analyses. In subgroup analyses, policy-associated stage shifts were seen in males, Hodgkin lymphoma, and liver and lung cancers, with less clear patterns for cervix and pancreas cancers. **Conclusions:** State mandatory paid medical leave was associated with increased early-stage cancer diagnoses and decreased late-stage diagnoses. Paid leave policies may promote earlier detection of non-screenable cancers by enabling employees to promptly seek care for new cancer-related symptoms. Policies that improve opportunities to seek medical care may facilitate earlier cancer detection and ultimately contribute to better patient outcomes. Research Sponsor: None.

DID estimates.

		Stage I		Stage IV	
Subgroup		**Estimate**	**95% CI**	**Estimate**	**95% CI**
Overall		1.34	0.6, 2.09	-2.05	-2.81, -1.29
Sex	M	3.22	1.94, 4.5	-3.96	-5.65, -2.27
	F	0.09	-0.8, 0.98	-0.56	-2.54, 1.41
Cancer type	Cervix	1.42	-5.28, 8.11	-6.86	-10.2, -3.5
	Hodgkin Lymphoma	7.93	1.35, 14.5	-2.59	-4.25, -0.93
	Liver	17.3	12.3, 22.3	-7.94	-13.5, -2.39
	Lung	5.39	1.98, 8.81	-9.29	-17.3, -1.3
	Pancreas	2.13	0.21, 4.05	-8.95	-18.7, 0.79

11009 Rapid Oral Abstract Session

NSQIP audit of enhanced recovery after surgery protocols for radical cystectomy.

John Pfail, Rachel Passarelli, Alain Kaldany, Kevin J. Chua, Benjamin Lichtbroun, Arnav Srivastava, David Golombos, Thomas L Jang, Vignesh T. Packiam, Saum Ghodoussipour; Section of Urologic Oncology, Rutgers Cancer Institute of New Jersey and Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ; Section of Urologic Oncology, Rutgers Cancer Institute of New Jersey, New Brunswick, NJ; University of Michigan, Ann Arbor, MI

Background: Utilization of enhanced recovery after surgery (ERAS) protocols for radical cystectomy (RC) has been associated with improved postoperative recovery and shorter hospital stays. The multiple components within ERAS leads itself to heterogenous implementation across different institutions. We aimed to assess the impact of increasing compliance to ERAS components on postoperative outcomes in patients who underwent RC. **Methods:** The National Surgical Quality Improvement Program database included 3,708 patients who underwent RC from 2019 to 2021. ERAS components of interest included regional anesthesia block, no bowel prep, no prolonged NGT or NPO status, VTE prophylaxis with mechanical and pharmacologic means, and antibiotic duration < 24 hours. Baseline characteristics and complications were stratified by number of ERAS components utilized (≤ 3, 4, or 5). Statistical endpoints included thirty-day complications, length of stay (LOS), and readmissions. Optimal RC outcome was defined as absence of any postoperative complication, reoperation, prolonged LOS (75th percentile, 8 days) with no readmission. Multivariable analyses with Bonferroni correction were performed to assess the association between ERAS compliance and outcomes. **Results:** Of the 3,708 patients who underwent RC with ERAS components utilized, 1,506 (41%) received ≤ 3 interventions, 1454 (39%) received 4, and 748 (20%) received 5. Baseline characteristics were relatively similar across the three groups. On multivariable analysis adjusted for multiple hypothesis testing, when compared to patients who received ≤ 3 interventions, patients who received 4 and 5 interventions had lower rates of any complication (OR 0.71; 99% CI [0.58 - 0.88], OR 0.74 [0.57 - 0.95], respectively), and shorter LOS (β -1.32 [-1.69, -0.95], β -1.74 [-2.19, -1.28], respectively). Moreover, patients with increased ERAS compliance experienced increased odds of an optimal outcome (OR 1.68 [1.38 – 2.05], OR 1.97 [1.55 – 2.51], respectively). **Conclusions:** Greater adherence to ERAS protocol interventions yielded superior post-operative outcomes for patients who underwent RC. This large-scale analysis supports that ERAS protocols are beneficial in a dose-dependent fashion and should be utilized. Research Sponsor: National Cancer Institute; P30CA072720.

Multivariable regression analyses for each postoperative outcome. Covariates included: age, year of surgery, diversion, approach, ASA, BMI, prior pelvic radiation, prior pelvic surgery, number of lymph nodes collected, operative time, and AJCC stage.

	4 Interventions	5 Interventions
Variable	OR (99% CI)	OR (99% CI)
Any Complication	0.71 (0.58, 0.88)	0.74 (0.57, 0.95)
High Grade Complication	0.81 (0.63, 1.04)	0.62 (0.44, 0.87)
LOS (β)	-1.32 (-1.69, -0.95)	-1.74 (-2.19, -1.23)
Optimal Outcome	1.68 (1.38, 2.05)	1.97 (1.55, 2.51)
Readmission	0.95 (0.75, 1.21)	0.81 (0.6, 1.09)

Reference: 3 Interventions.

11010 Rapid Oral Abstract Session

Beyond the binary: A transformative implementation science initiative to improve LGBTQ+ cancer care.

Shail Maingi, Matthew B. Schabath, Ilona Dewald, Janet Storey, Samuel Dooyema, Jeffrey D. Carter, Cherilyn Heggen, Kelly E. McKinnon; Dana-Farber Cancer Institute, South Weymouth, MA; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; PRIME Education, LLC, New York, NY

Background: Patient, provider, and system-level barriers contribute to significant disparities in care of LGBTQ+ persons, including delays in screening and diagnosis, and poorer outcomes. This implementation science initiative was designed to identify and address root causes of disparities in care for LGBTQ+ patients (pts) and drive sustainable change to improve health equity in LGBTQ+ cancer care. **Methods:** In 2023, a steering committee of 3 expert oncologists and 5 LGBTQ+ cancer pts convened to develop survey instruments and a point-of-care LGBTQ+ Cancer Care Toolkit. Next, LGBTQ+ pts with cancer (N = 817) and oncology providers (OPs) from 2 academic and 5 community-based practices (N = 115) completed surveys to reveal alignments and discordances in beliefs, perceptions, and practices regarding cancer care. OPs participated in audit-feedback (AF) sessions to critically assess system-specific practice gaps, prioritize areas for improvement, and develop action plans for improving LGBTQ+ cancer care. **Results:** Provider-reported top challenges in care included: *unsure how sexual orientation/gender identity (SOGI) affect treatment considerations (35%)*, *unsure how to discuss SOGI (30%),*and *systemic barriers that limit inclusion (29%)*. While most providers (84%) were at least moderately comfortable treating LGBTQ+ pts, these data suggest they overestimated the level of comfort of their pts. For example, only 24% of pts reported feeling safe disclosing their LGBTQ+ identity, while 65% of providers thought pts felt safe. Additionally, while most providers (73%) thought it was important to know a pt's gender identity, only 46% thought it was important to know sexual orientation, and only 3% of providers reported routinely discussing SOGI with new pts. Patients and providers were not concordant in several other key areas, including the experience of pts' partners, measures of inclusivity, and supportive care services offered, such as fertility preservation. Survey data also revealed systemic barriers to equitable care, such as EMR documentation of SOGI. In AF sessions, teams reviewed survey outcomes, and developed action plans for improvement, including integrating the toolkit, updating EMR documentation, developing LGBTQ+ education, and adopting measures of inclusivity. Notably, following the intervention, there were considerable gains in provider confidence and knowledge, and ~70% of providers committed to discussing SOGI with their pts at first introduction. **Conclusions:** Through this QI initiative, teams identified patient-, provider-, and systemic-level barriers that affect LGBTQ+ cancer care in their own practices and implemented action plans to address key challenges. The sustainable changes implemented in this QI initiative represent key opportunities for improvement that can be implemented in clinics across the country to improve equitable LGBTQ+ cancer care. Research Sponsor: Bristol Myers Squibb; Gilead Sciences, Inc; Lilly USA LLC; Merck Sharp & Dohme LLC; Pfizer Inc.

11011 Rapid Oral Abstract Session

Improving delivery of smoking cessation assistance for patients with cancer: Results of the Beyond ASK quality improvement.

Timothy W. Mullett, Jessica L Burris, Eileen M Reilly, Rachel C Shelton, Graham W. Warren, Jamie S. Ostroff; Department of Surgery, University of Kentucky College of Medicine, Lexington, KY; University of Kentucky, Lexington, KY; American College of Surgeons, Chicago, IL; Mailman School of Public Health, Columbia University, New York, NY; Medical University of South Carolina, Charleston, SC; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Smoking by cancer patients and survivors causes adverse health outcomes, and quitting smoking after a cancer diagnosis can improve survival. However, assistance with smoking cessation is not regularly provided to cancer patients. Reported are results of the national 2023 Beyond ASK quality improvement initiative to increase and sustain delivery of smoking cessation assistance across participating sites. **Methods:** In 2023, American College of Surgeons Commission on Cancer (CoC) accredited sites were invited to participate in the Beyond ASK quality improvement initiative to increase evidence-based smoking cessation assistance delivery to cancer patients who report current smoking. Participating sites were required to monitor and periodically report on provider performance (e.g., assist rate = number of patients assisted with smoking cessation / number of patients who smoke), resource utilization, barriers, and facilitators. Educational resources, webinars, toolkits, and online data collection were facilitated by CoC. **Results:** Among 306 participating programs who completed the Beyond ASK initiative (94% of baseline programs), high rates of asking patients about and documenting smoking status were maintained at 88-92% from the baseline to final survey. During the 12-month project period, overall rates of assisting with smoking cessation increased from 53% to 67%. Referral to state quitlines increased from 31% to 49%, and referral to 'in house' smoking cessation programs increased from 15% to 28%. Rates of providing brief in office counseling more than tripled from 20% at baseline to 66% at final. The most frequently reported components that contributed to programs' success were educational webinars (30.6%), structured data collection (28.2%), and smoking cessation toolkit (21.2%). The leading logistical barriers were extracting clinical data from the EHR and making changes to the clinical workflow, reported by 36.5% and 28.2% of respondents, respectively. Overall, 95.3% of respondents "agreed" or "strongly agreed" that identifying patients who smoke and assisting patients with cessation was sustainable. **Conclusions:** Increasing smoking cessation assistance through a national accreditation organization is feasible with substantial improvements in assisting patients. Results support delivery of smoking cessation as an achievable national quality component of cancer care. Research Sponsor: University of Wisconsin Center for Tobacco Research and Intervention.

11012 Rapid Oral Abstract Session

Impact of trial eligibility criteria on enrollment to KRAS^{G12C} inhibitor trials in patients with non-small cell lung cancer.

Michael S. May, Margaux Wooster, Benjamin May, Catherine A. Shu, Brian S. Henick, Mark Stoopler, Stephanie Smith-Marrone, Anjali Saqi, Mahesh M. Mansukhani, Gregory J. Riely, Dawn L. Hershman, Benjamin Herzberg; Columbia University Medical Center, New York, NY; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY; Columbia University Irving Medical Center, New York, NY; NYP/Columbia, Bronxville, NY; Columbia University, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Clinical trials of novel therapies should enroll a population that reflects patients (pts) who might receive the drug upon FDA approval. In 2017 ASCO proposed modifications to common eligibility criteria (EC) to increase the generalizability of trial findings. Despite this, barriers to trial enrollment in the recent era of molecularly-targeted therapies are not well-characterized. We examined a cohort of non-small cell lung cancer (NSCLC) pts with KRAS G12C mutations to determine whether EC for trials of KRAS G12C inhibitors allowed enrollment of patients seen as part of routine care at an academic medical center. **Methods:** We extracted EC for Phase I-III trials among six KRAS G12C inhibitors: sotorasib, adagrasib, LY3537982 , divarasib, JDQ443 and RMC-6291. We retrospectively reviewed pts with NSCLC and G12C mutations detected on universal, NGS-based testing of NSCLCs at Columbia University Irving Medical Center (CUIMC) from 2020 to 2023. We defined dates of disease progression and evaluated pts for clinical trial eligibility for each line of treatment. Pts were deemed trial-eligible if they met all EC, borderline if they had 1 laboratory value $<$ 20% from cutoff, or ineligible. The association between baseline factors including self-reported race, sex, and age with rates of eligibility were evaluated with chi-squared tests. **Results:** EC criteria for 14 trials were characterized. EC were similar across trials regardless of agent or phase and did not substantially change over time; 1 Phase III trial had expanded EC from the Phase I/II trials. Of 1172 patients with NSCLC, we identified 185 pts with G12C mutations (15%), including 69 pts with advanced or metastatic disease. Of these, 19% (13/69) would have been eligible for any G12C trial, 15% (10/69) were borderline, and 67% (46/69) were ineligible. 9% (6) would have qualified for only 1 of the trials. The most common reasons for ineligibility were poor performance status (54% [30/56]), excluded comorbidities (25% [14/56]), and renal dysfunction (27% [15/56]). Among patients who received therapy after FDA accelerated approval (N = 22), only 23% (5) would have been eligible for the related Phase III trial. **Conclusions:** Our findings suggest that most patients with KRAS G12C mutations would not have been eligible for relevant trials, including $>$ 75% of patients who received KRAS G12C inhibitors off-trial after accelerated FDA approval. EC did not expand after early phase trials demonstrated evidence of safety. These data should guide sponsor and FDA considerations in the development of trial protocols for targeted therapies, as fewer barriers to trial participation would enable trials to be completed more quickly and would improve the generalizability of trial results. Research Sponsor: National Cancer Institute; T32CA203703-08.

11013 Rapid Oral Abstract Session

5-year multicenter analysis of clinical trial participation and total cost of care for older adults with cancer.

Ishwaria M. Subbiah, Puneeth Indurlal, Naiyar Alam, Hope Ives, Stuart George Staggs, Lalan S. Wilfong; Sarah Cannon Research Institute (SCRI), SCRI Oncology Partners, The US Oncology Network, Nashville, TN; The US Oncology Network, The Woodlands, TX; Texas Oncology, The US Oncology Network, Dallas, TX

Background: Clinical trial access particularly for older adults aged 65 years and above with cancer is impacted by multilevel barriers, including cost concerns to payers in the usual models of cancer care delivery. Alternative models recently studied include the Centers for Medicare and Medicaid Innovation's Oncology Care Model (OCM), a value-based care pilot to enhance quality & reduce costs. Here, we investigated the association between clinical trial participation (CTP) and the total cost of care (TCOC) within this non-traditional model. **Methods:** We identified prospective longitudinal observational cohort of patients cared for in 11 states within 323 clinics in 14 multi-site community practices participating in OCM, in The US Oncology Network and extracted data (episode claims, medical records, episodes) from OCM performance periods (PP) 3-11 between 7/1/17 and 6/30/22. Propensity score matching by PP, age, gender, date of death, cancer type identified the analysis cohort of matched episodes, then stratified by trial participation (CTP vs usual care) to compare TCOC and drug expenditures. **Results:** Over 5 years, 121,717 unique patients (94% of whom were aged 65y+) received 282,604 episodes of cancer care in the community, most common cancers being breast, lung, multiple myeloma. Propensity score matching identified 13,260 matched episodes (6630 usual care, 6630 CTP). The actual expenditure differed by $2,341 per episode between CTP & usual care (CTP $43,890 vs usual care $41,548; $p < 0.0001$), while trial participation had significant savings against the OCM CTP benchmark ($4816 saved per CTP episode), compared to usual care vs its benchmark ($826 saved per usual care episode, $p < 0.0001$). Drug costs per episode did not differ between the two groups (CTP $29,516 vs usual care $30,553; p 0.54). Further breakdown shows that drug spending on anticancer agents (CTP $28,008 vs usual care $29,139) and other drugs including supportive care meds (CTP $1,511 vs usual care $1,414) did not differ significantly. **Conclusions:** Clinical trial participation saw relative cost savings against the benchmark compared to usual care, owing largely to the higher benchmark prices for CTP episodes in OCM's risk-adjusted price prediction model, rather than an absolute cost savings to payers. Drug expenditures remain the largest contributor to total cost of care in this alternative model. The contributors to both drug expenditures as well as the absence of absolute cost savings between the two cohorts represent key areas for further investigation. CMMI Disclaimer: *The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document.* Research Sponsor: None.

11014 Rapid Oral Abstract Session

The toxicity swimmer plot: A novel approach for evaluating patient-level toxicity following immune checkpoint inhibitor (ICI) therapy on the Checkmate 214 trial.

Hollis Viray, Hui Huang, Charlene Mantia, Opeyemi Jegede, Michael B. Atkins, David F. McDermott, Meredith M. Regan; Beth Israel Deaconess Medical Center, Boston, MA; Dana-Farber Cancer Institute, Boston, MA; Georgetown-Lombardi Comprehensive Cancer Center, Washington, DC; Dana-Farber Cancer Institute and International Breast Cancer Study Group Statistical Center, Boston, MA

Background: Treatment with ICIs creates the possibility of prolonged disease control or remission but also creates the possibility of prolonged toxicity even after treatment is discontinued. Treatment-free survival (TFS) with and without toxicity has previously been described as an integral piece of a partitioned survival analysis in advanced renal cell carcinoma (aRCC). Prior analyses have reported further partition of TFS as mean duration of TFS with and without treatment-related adverse events (TRAEs), but this metric fails to provide more granular information regarding individual patients experiencing toxicity during TFS. We present a novel extended swimmer plot that characterizes patient-level toxicity data within TFS using the example of the Checkmate 214 trial to complement analyses of the population average experience. **Methods:** Data were analyzed from the Checkmate 214 trial which randomized 1096 patients with aRCC to receive either first-line (1L) nivolumab plus ipilimumab (n = 550) or sunitinib (n = 546). The minimum follow-up from protocol therapy initiation was 42 months. Patients' overall survival was partitioned into 3 survival states: time on 1L protocol therapy, TFS, and survival after subsequent therapy initiation. With a re-defined time origin relative to cessation of 1L protocol therapy, we generated swimmer plots highlighting the TFS period and documenting each patient's experience with and without grade 2+ and grade 3+ TRAEs during TFS. The swimmer plot was sorted by duration of TFS and duration of TFS with grade 2+ TRAEs in order to illustrate patterns of individuals' experiences. **Results:** The 42-month mean TFS was 7.8 months (with grade 2+ TRAEs: 3.2 months) for patients treated with nivolumab plus ipilimumab and 3.3 months (1.6 months) for patients treated with sunitinib. In the respective treatment groups, TFS with grade 2+ TRAEs was experienced by 32% and 25% of patients and comprised of 13% and 9% of patients for whom it was the entire TFS period. These percentages were consistent regardless of TFS duration. TFS with grade 3+ TRAEs was experienced by 15% and 3% of patients, respectively. For most patients having TFS with TRAEs, the TRAEs persisted from the protocol therapy period, but 7% and 1% of patients in the respective treatment groups had new-onset grade 3+ TRAE during TFS. A swimmer plot will be presented as a visual presentation of this study's results. **Conclusions:** We describe a novel extension of swimmer plots for presenting patient-level information and illustrating patterns in toxicity duration relative to TFS by incorporating individual toxicity data into a swimmer plot of partitioned survival. This approach allows for a more comprehensive understanding of toxicity trends and risk of prolonged toxicity after treatment is discontinued. Research Sponsor: None.

11015 Rapid Oral Abstract Session

Patient-reported fatigue and risk of treatment-related adverse events (AEs) in patients receiving systemic therapy in cancer clinical trials.

Joseph M. Unger, Riha Vaidya, Michael Jordan Fisch, Salene M. W. Jones, Norah Lynn Henry, Dawn L. Hershman; SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Center, Seattle, WA; SWOG Statistics and Data Management Center, Seattle, WA; The University of Texas MD Anderson Cancer Center; Carelon Medical Benefits Management, Houston, TX; Fred Hutchinson Cancer Center, Seattle, WA; University of Michigan Rogel Cancer Center, Ann Arbor, MI; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY

Background: Fatigue in patients with cancer is common and negatively impacts quality of life. Patient-reported outcomes (PROs) assess a patient's direct report of their symptoms and well-being; research has highlighted their potential to predict cancer outcomes. We examined whether fatigue prior to treatment was associated with AEs. **Methods:** We analyzed 18 phase II and III cancer treatment clinical trials with baseline fatigue data conducted by SWOG between 1988-2018. The Common Terminology Criteria for Adverse Events was used. Symptomatic AEs were defined as those aligned with the NCI's PRO-CTCAE; laboratory-based or measurable AEs were designated as objective (hematologic v nonhematologic). Thirteen symptomatic and 14 objective AE categories were examined. Fatigue was derived from multiple scales (e.g., FACT, EORTC QLQ-C30 and PROMIS-Fatigue 7a). Each measure was mapped to a 5-point Likert scale. Binary categories were compared (e.g., $<$ some vs. $>$ = some fatigue). Generalized estimating equations were used with a binomial distribution and logit link, adjusting for age, sex, race, and BMI, with clustering by study. **Results:** We examined N = 8,040 patients receiving systemic therapy. Among 18 trials (prostate, 5; lung, 3; colorectal, 2; lymphoma, 2; breast, 2; bladder, 1; melanoma, 1; ovarian, 1, pancreas, 1), n = 108,059 AEs were examined. Patient fatigue was present at levels of "a little" or greater in 75.8%, "some" or greater in 42.8%, and "quite a lot" or "very much" in 17.7%. Patients with some or greater fatigue were nearly twice as likely to have severe or worse toxicity (OR = 1.92, 95% CI, 1.53-2.40, $p < .001$) or life-threatening toxicity (OR = 1.93, 95% CI, 1.44-2.59, $p < .001$) and nearly threefold more likely to have fatal toxicity (OR = 2.76, 95% CI, 1.37-5.53, p = .004). Similar patterns were seen at a threshold of "quite a lot". A dose response pattern was evident; patients reporting quite a lot/very much compared to no fatigue were $>$ 5 times more likely to experience fatal toxicity (OR = 5.63, p = .002). These patterns were consistent in symptomatic, objective hematologic, and objective non-hematologic AEs. **Conclusions:** Baseline fatigue was highly predictive of subsequent risk of AEs. These findings suggest that in an era of precision medicine, patient-reported fatigue may be an important component of determining toxicity risk and could aid in treatment decision making. Research Sponsor: NIH, NCI, and National Clinical Trials Network grants U10CA180888 and U10CA180819; Hope Foundation for Cancer Research.

Baseline fatigue and risk of treatment-related AEs.

	Severe (Grade >3)		Fatal (Grade 5)	
Fatigue Levels	**OR (95% CI)**	**p-value**	**OR (95% CI)**	**p-value**
Binary				
>some vs. < some	1.92 (1.53-2.40)	< .001	2.76 (1.37-5.53)	.004
>quite a lot vs. < quite a lot	1.99 (1.58-2.51)	< .001	3.16 (1.79-5.57)	< .001
Categorical				
A little vs. none	1.27 (1.05-1.53)	.01	1.69 (0.77-3.72)	.19
Some vs. none	1.92 (1.44-2.55)	< .001	2.63 (0.75-9.19)	.13
Quite a lot/very much vs. none	2.69 (1.99-3.64)	< .001	5.63 (1.92-16.55)	.002

Association of higher baseline stress and pain with clinical outcomes: Secondary analysis from Alliance A011502.

Shipra Gandhi, Karla V. Ballman, Michelle D. Holmes, Kala Visvanathan, Banu Symington, Margaret Carvan, Carol Matyka, Anna Weiss, Eric P. Winer, Wajeeha Razaq, Lisa A. Carey, Ann H. Partridge, Wendy Y. Chen; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Mayo Clinic, Rochester, MN; Channing Laboratory, Brigham and Women's Hospital and Harvard Medical School, Boston, MA; Johns Hopkins Kimmel Cancer Center, Baltimore, MD; Sweetwater Regional Cancer Center, an Affiliate of Huntsman Cancer Institute, Rock Springs, WY; Patient Research Advocate Dana Farber Cancer Institute, Medford, MA; Dana-Farber Cancer Institute, Boston, MA; University of Rochester, Rochester, NY; Yale Cancer Center, New Haven, CT; University of Okahoma Health Sciences Center, Oklahoma City, OK; Lineberger Comprehensive Cancer Center, The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: A011502 is a phase 3 randomized double-blind clinical trial that enrolled high-risk nonmetastatic breast cancer (BC) patients (pts) and randomized pts to aspirin 300 mg daily vs. placebo. There was no significant difference in invasive disease-free survival (iDFS) between the two arms. A secondary objective was to determine the association of inflammation-affiliated factors (stress, depression, poor sleep quality and pain) with iDFS and overall survival (OS). We hypothesized that these baseline factors are associated with worse clinical outcomes. **Methods:** At baseline, 2735, 2720, 2422 and 2610 pts completed Perceived Stress Scale (PSS), Brief Pain Inventory (BPI), Pittsburgh Sleep Quality Index (PSQI) and Center for Epidemiologic Studies Depression Scale Revised (CESD-R) respectively. Stress was categorized with PSS scores: low (0-13), moderate (14-26) or high stress (27-40). Pain was categorized with BPI scores: none/mild (0-3) or moderate/severe (≥4). Sleep quality was categorized with PSQI scores: good (0-5) or poor (> 5).Depression was categorized with CESD-R scores: no depression (0-15) or depression (≥16). Associations between the measures of interest and outcomes were performed with multivariable Cox models controlling for age, body mass index, time since diagnosis, race, ethnicity, hormone receptor status and treatment arm. **Results:** Median follow up was 35 months. The associations from multivariable Cox model are shown in Table 1. Pts who reported high PSS had significantly worse iDFS and (non-significant) worse OS. Moderate/severe average (avg) pain was significantly associated with worse iDFS and OS. Poor sleep quality and depression were associated with worse iDFS and OS but not statistically significant. **Conclusions:** Pts reporting higher stress and pain at baseline had worse outcomes. We acknowledge that both pain and stress may be related to other non-cancer issues (chronic comorbidities). Our study highlights the need for clinical trials to consider including questionnaires to assess pt-reported outcomes. Future studies are warranted to determine if measures to decrease pain and stress would improve BC outcomes. U10CA180821, U10CA180882, UG1CA233196; https://acknowledgments.alliancefound.org. NCT02927249: Clinical trial information: NCT02927249. Research Sponsor: U10CA180821, U10CA180882, UG1CA233196; https://acknowledgments.alliancefound.org.

Association from adjusted Cox model.

		iDFS			OS		
Measurement		**Events**	**HR (95% CI)**	**p**	**Events**	**HR (95% CI)**	**p**
PSS	**Low n = 1617**	144	1.00 (ref)	**0.04**	62	1.00 (ref)	0.07
	Moderate n = 1051	85	0.96 (0.73, 1.26)		40	1.04 (0.69, 1.56)	
	High n = 64	11	2.13 (1.14, 3.96)		6	2.55 (1.09, 5.93)	
Avg BPI	**No/mild n = 2254**	182	1.00 (ref)	**< 0.01**	75	1.00 (ref)	**< 0.01**
	Mod/severe n = 464	59	1.57 (1.16, 2.14)		33	2.09 (1.36, 3.19)	
PSQI	**Good n = 804**	57	1.00 (ref)	0.11	22	1.00 (ref)	0.10
	Poor n = 1615	147	1.29 (0.95, 1.75)		70	1.50 (0.92, 2.43)	
CESD-R	**Not depressed n = 2230**	193	1.00 (ref)	0.14	87	1.00 (ref)	0.42
	Depressed n = 377	41	1.29 (0.92, 1.82)		19	1.23 (0.74, 2.03)	

HR: Hazard Ratio; CI: Confidence Interval.

11017 Rapid Oral Abstract Session

Early palliative care among patients diagnosed with advanced cancers in the US (2010-2019): Trends and contribution of provider variation.

Xin Hu, Youngmin Kwon, Changchuan Jiang, Qinjin Fan, Sylvia Sylvia Shi, Zhiyuan Zheng, Jingxuan Zhao, Joan Warren, Robin Yabroff, Xuesong Han; University of Virginia School of Medicine, Charlottesville, VA; University of Pittsburgh School of Public Health, Pittsburgh, PA; Division of Hematology and Oncology, Department of Internal Medicine, University of Texas Southwestern, Dallas, TX; American Cancer Society, Atlanta, GA; American Cancer Society, Kennesaw, GA; Retired, MD; Department of Surveillance and Health Equity Science, American Cancer Society, Kennesaw, GA

Background: Early integration of palliative care (PC) is recommended for advanced cancers, but evidence of its use and the role of provider practice patterns and organizational characteristics in uptake is limited. This study examined recent trends of early PC among Medicare beneficiaries newly diagnosed with advanced cancers, and provider- and organization-variation in the receipt of early PC. **Methods:** We identified patients aged ≥65.5 years newly diagnosed with advanced stage breast, colorectal, non-small cell lung (NSCL), small cell lung (SCL), pancreas, and prostate cancers in 2010-2019 with ≥6 months survival and continuous fee-for-service coverage from the linked SEER-Medicare data. Early PC was identified by claims with corresponding diagnosis codes or hospice and palliative medicine provider specialty codes within 90 days post-diagnosis or up to first hospice admission date (whichever came earlier). Treating physicians and corresponding organizations (i.e., Tax Identification Number) were assigned based on the plurality of visits within 180 days after diagnosis. We described the percent of patients receiving early PC each year. Generalized linear models with physician- and organization-fixed effects evaluated variation in early PC receipt between and within physicians/organizations. **Results:** Among 103,045 patients treated by 25,736 unique providers and 11,163 organizations, the percent receiving early PC increased from 0.98% in 2010 to 10.64% in 2019. Although statistically significant increases were observed across cancer types, receipt in patients with prostate cancer was relatively lower compared to pancreas, SCL, NSCL, and breast cancers (Table). After adjusting for patients' characteristics, variation in early PC use between treating providers and organizations explained 47.9% and 31.2% of the total variation, respectively. **Conclusions:** Despite considerable growth in early PC receipt, utilization remained low in 2019. The large variation between providers and organizations suggests important modifiable provider behaviors and organizational characteristics in early PC use, which warrant future research. Research Sponsor: None.

Percent of early palliative care receipt among patients with advanced cancers.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Overall	0.98	1.41	2.1	2.59	3.61	4.99	5.62	7.48	9.29	10.24
Breast	1.30	1.04	2.24	1.79	2.34	4.12	4.65	6.13	8.86	9.73
Colorectal	1.15	1.04	2.34	2.17	2.81	4.89	5.46	6.31	8.49	7.94
NSCLC	0.64	1.37	1.89	2.65	3.70	5.48	5.92	7.89	9.97	11.29
SCLC	1.43	1.95	1.87	3.01	5.00	4.52	7.33	10.59	11.26	11.89
Pancreas	1.51	2.48	4.55	4.18	5.92	8.01	7.60	10.54	14.00	17.13
Prostate	1.13	1.25	1.13	2.07	2.62	2.63	3.36	4.74	5.12	5.20
Total N	**10255**	**10327**	**10450**	**10423**	**10438**	**10760**	**10255**	**10174**	**10092**	**9871**

11018 Poster Session

Assessing patient engagement levels in clinical cancer research: Development of a novel evaluation tool and comparison between eastern and western countries.

Laureline Gatellier, Bertrand F. Tombal, Béatrice Serckx, Hadrien Charvat, Keiko Katsui, Yoshiyuki Majima, Jin Higashijima, Kazuyuki Suzuki, Ingrid Klingmann, Kenichi Nakamura, Tomohiro Matsuda; Div of Int'l Health Policy Research, National Cancer Center Japan, Tokyo, Japan; Cliniques Universitaires Saint-Luc, Brussels, Belgium; Independent Consultant/Expert, Louvain-La-Neuve, Belgium; Faculty of International Liberal Arts, Juntendo University, Tokyo, Japan; Japan Agency for Medical Research and Development, Tokyo, Japan; Pancreatic Cancer Action Network, Tokyo, Japan; Chiba University, Chiba-Shi Inage-Ku, Japan; Novartis Pharma K.K., Tokyo, Japan; Efgcp, Wezembeek-Oppem, Belgium; Department of International Clinical Development, National Cancer Center Hospital, Tokyo, Japan; Int'l Health Policy Research, National Cancer Center Japan, Tokyo, Japan

Background: Patient Public Involvement and Engagement (PPIE) is essential in healthcare and cancer research. Currently, there is no objective method to assess at which stage of a clinical trial PPIE is effectively implemented. In this study, we developed a simple method for objectively assessing PPIE with an international scale. **Methods:** A novel, simple scoring method was developed to evaluate the PPIE implementation in cancer research. It follows the EUPATI Patient Engagement Roadmap and assesses PPIE at eight steps: defining research priorities, fundraising, protocol, informed consent, ethical review, investigator meeting, study results reporting, and application. PPIE level was self-rated by investigators on a five-level engagement scale: no engagement, considered, informed, actively involved, and co-creation. It was submitted to 124 Japanese and 203 European principal investigators (PI) of non-commercial sponsor cancer research clinical trials, conducted between January 2018 and December 2022, identified from publicly available databases (EudraCT, UMIN, jRCT). **Results:** The questionnaire was answered by 66 (53.2%) and 45 (22.2%) of the Japanese and European PIs, respectively. Overall, the PPIE implementation was low in both regions, with a "no engagement" rate of 61.7% in Europe and even lower, 78.5%, in Japan. Forty percent of the European PIs actively engaged patients ("actively involved" and "co-creation") in at least one research step, versus only 16.7% of the Japanese PIs. The percentage of PIs answering "no engagement" in all eight steps was 47.0% in Japan and 11.1% in Europe. PPIE was the highest for the informed consent domain, with 73.3% of the European and 20.3% of the Japanese PIs reporting some level of engagement. Similarly, 55.6% of the European and 18.8% of the Japanese PIs involved PPIE in the ethical review domain. PPIE was notably low in the earlier steps of the research. **Conclusions:** Our innovative PPIE scoring method allowed us to objectively assess PPIE in cancer clinical trials and compare its implementation among different countries. This 2018-2022 snapshot revealed low (EU) to very low PPIE (Japan) levels, especially in the research design. Future assessments should help to monitor the enhancement of PPIE in cancer research on an international scale. Research Sponsor: Grant-in-Aid from the Japan Society for the Promotion of Science; 21K10363.

11019 Poster Session

Multi-stakeholder, intentional outreach for improving representative recruitment in Pragmatica–Lung (SWOG S2302).

Daniel R. Carrizosa, Jieling Miao, Karen L. Reckamp, Konstantin H. Dragnev, Paul Joseph Hesketh, Wade Thomas Iams, Brian S. Henick, Cheryl M. Czerlanis, Frank DeSanto, Jamie Sundstrom, Judy Johnson, Lucy Gansauer, Tiffany Groller, Mary Weber Redman, Roy S. Herbst, Jhanelle E. Gray; Atrium Health Wake Forest Baptist Comprehensive Cancer Center - Levine Cancer Institute, Charlotte, NC; SWOG Statistical Center, Fred Hutchinson Cancer Center, Seattle, WA; Cedars-Sinai Medical Center, Los Angeles, CA; Dartmouth Cancer Center, Lebanon, NH; Lahey Hospital and Medical Center, Burlington, MA; Vanderbilt University Medical Center, Nashville, TN; Columbia University Irving Medical Center, New York, NY; Loyola University Medical Center, Maywood, IL; Swog Cancer Research Network, Portland, OR; Cancer Research and Biostatistics (CRAB), Seattle, WA; SWOG Cancer Research Network, Saint Louis, MO; Southwest Oncology Group, Spartanburg, SC; MMG, Rockville, MD; Medical Oncology, Yale School of Medicine and Yale Cancer Center, New Haven, CT; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL

Background: Studies show that <10% of patients with cancer participate in clinical trials. Pragmatica – Lung (SWOG S2302) utilizes a pragmatic approach for a registrational (FDA) trial that allows less data collection and broader eligibility, thus decreasing barriers to diverse enrollment. S2302 aims to improve overall and diverse accrual by using a novel trial design and multilevel community engagement. **Methods:** S2302 is a real-world randomized phase III registrational study comparing pembrolizumab + ramucirumab vs investigator-chosen standard therapy in 2nd line advanced/metastatic NSCLC. A multi-stakeholder recruitment plan was developed to improve diverse accrual (with initial focus on recruiting Black patients). The plan was vetted through SWOG communications and SWOG Lung Committee's Working Group, DEI champion, patient advocate, and community engagement subcommittee. The DEI champion identified sites in the Southeast with high minority accrual in prior trials and completed directed informational visits. An external firm created culturally and linguistically appropriate patient education material, engaged sites with historically high accrual of Black and/or LatinX patients, leveraged advocacy partners to improve community awareness, and monitored enrollment by site. A monthly accrual report with demographic summaries (including age, sex, race, ethnicity) and site enrollment information is generated from SWOG Statistics and Data Management Center to monitor accrual rate and diversity. **Results:** From March through December 2023 (Table), the study accrued 37% of its goal and is enrolling above its target rate of 25 pts/mo averaging 36/mo over the last 5 months. Of enrolled pts, 58% are male, 13% are Black, and 3% are LatinX; from 59 academic, 67 community (13% rural), and 2 VA sites. Comparatively, LungMAP S1800A (the phase II precursor to S2302) accrued 7% Black and 1.5% LatinX pts with an average accrual of 9.2 pts/mo. Through November, the external firm contacted 24 site PIs (63% community-based), whose sites had collectively enrolled 16 pts, for a normalized pre-call rate of 0.1340 pts/mo. After contact and through November, these sites enrolled 23 pts, a rate of 0.3835 pts/mo – a 186% increase. **Conclusions:** The intentional, multi-pronged recruitment plan has exceeded historical overall, Black, and LatinX patient accrual rates. The data highlight novel approaches to trial design, recruitment strategies, and increased internal and external collaboration resulting in improved diversity of clinical trial enrollment and may be a potential toolkit for future trials. Support: NIH/NCI grants U10CA180888 and U10CA180819; and in part by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, and Eli Lilly and Company. Clinical trial information: NCT05633602. Research Sponsor: None.

S2302 accrual as of december 31, 2023 (N=257).	
Race	
White	79%
Black	13%
Asian	4%
Other	3%
Ethnicity	
LatinX	3%
Non-LatinX	95%
Unknown	2%

11020 Poster Session

Data-driven strategies for enhancing diversity in oncology clinical trials: Optimization of eligibility criteria.

Sandra Griffith, Corey M. Benedum, Selen Bozkurt, Ruma Bhagat, Nicole Richie, Bea Lavery, Somnath Sarkar; Flatiron Foundation Medicine Insights Lab, New York, NY; Emory University, Atlanta, GA; Genentech Inc, South San Francisco, CA; Genentech (a member of the Roche Group), South San Francisco, CA

Background: Advancing inclusive clinical research is essential to benefit all patients (pts) and is an expectation, and in some cases a requirement, by regulators. Enabling the inclusion of representative populations should begin at protocol design. However, it is not always clear which changes in eligibility criteria (EC) will have the most impact on representativeness and whether the impact will have similar effect across historically underrepresented populations (HUPs; i.e., pts ≥75 yrs, females, non-Latinx[NL] Black, or Latinx pts). We have defined a novel application of scoring to assess implications of EC on inclusion of HUPs in trials. **Methods:** Using real-world data from the US nationwide Flatiron Health electronic health record-derived de-identified database for aNSCLC as a benchmark (N=50,263), we selected pts who met trial EC and therapy indication criteria for 9 Phase III aNSCLC trials (2012–2018). We quantified representativeness of the eligible cohort via log disparity [LD], a machine learning fairness metric for the odds of selecting a subgroup vs. the rest of the population; 100% represents parity and 80% is sometimes considered a lower bound for representativeness, but higher benchmarks (e.g., 95%) may be more appropriate. We then identified EC drivers of representativeness by removing or modifying EC. **Results:** Across HUP groups, the majority of trials (≥55%) were below parity. Removing creatinine clearance (CrCl) had a consistently positive impact for older pts (median % Δ [range]: +2 [1, 32]) and NL Black pts (+2 [1, 5]), but the direction of impact differed across trials for female and Latinx pts (increase in representativeness for some trials, decrease for others). The impact of removing ECOG Performance Status (PS) varied across HUPs (positive for older pts, neutral or positive for female pts, trial-dependent for Latinx and NL Black pts); e.g., in Keynote010, removing ECOG PS increased LD for older pts (93% to 99%), but decreased LD for Latinx pts (97% to 93%). Across trials, removing hemoglobin, HIV, and Hepatitis B/C had a consistently positive or neutral impact on LD for NH Black pts (e.g., hemoglobin median % Δ [range]: +3 [2, 5]), however, the impact was negative or trial-dependent for Latinx and older pts. LD scores can also guide modification of cutpoints to optimize representativeness; e.g., for Keynote189, lowering the CrCL cutpoint from 50 to to 37 mL/min could be expected to improve representativeness for older patients (LD: 66% to 80%, the lower bound for representativeness). **Conclusions:** It is important to consider the complex nature of diversity when designing trials to ensure that optimizing inclusion of one group of pts does not inadvertently reduce representativeness for another group. These findings support a data-driven approach to modifying EC during protocol design to maximize inclusion of HUPs in concert with a robust operational plan. Research Sponsor: Flatiron Health.

11021 Poster Session

Impact of the COVID-19 pandemic mitigation strategies on cancer treatment trials: A meta-analysis of industry and NCI studies.

Joseph M. Unger, Hillary Andrews, Laura A. Levit, Brittany Avin McKelvey, Mark Stewart, Emily Van Meter Dressler, Keith T. Flaherty, Peter Fredette, Lee Jones, Therica Miller, Adedayo A. Onitilo, Timil Patel, Suanna Steeby Bruinooge, Elizabeth Garrett-Mayer, Caroline Schenkel; SWOG Statistics and Data Management Center/Fred Hutchinson Cancer Research Center, Seattle, WA; Friends of Cancer Research, Washington, DC; ASCO, Alexandria, VA; Wake Forest University School of Medicine, Winston-Salem, NC; Massachusetts General Hospital, Boston, MA; EQRx, Cambridge, MA; Fight Colorectal Cancer, Arlington, VA; Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai, New York, NY; Marshfield Clinic-Weston Center, Marshfield, WI; U.S. Food and Drug Administration, Silver Spring, MD; Children's National Hospital, Washington, DC

Background: ASCO and Friends of Cancer Research established a task force to evaluate trial mitigation strategies allowed by US regulators during the COVID-19 pandemic, including the use of telemedicine and remote monitoring. We report the results of a meta-analysis quantifying the impact of these strategies on quality metrics and the recovery time to pre-COVID levels. **Methods:** We invited 41 sponsors with active US cancer treatment trials from January 2015-May 2022 to contribute deidentified trial-level aggregate data on major protocol deviations (PDs), dropouts, severe or worse toxicity (CTCAE Grade 3-5), and enrollment. We examined outcomes as proportions of participants at-risk during the pre-COVID, initial wave (IW), initial recovery (IR), and secondary recovery (SR) assessment times (Table). Multi-level beta-regression analyses were adjusted for trial phase ("early", phases I, II, or I/II, vs. "late", phase III) with study and sponsor as random effects. Indicator variables were used for post-COVID time periods with pre-COVID as the reference. **Results:** Ten sponsors (9 industry and 1 NCI Cooperative Group) contributed 82 evaluable studies: 63 early and 19 late phase trials. Among the 15,679 participants, enrollment odds decreased 64% in the IW and 45% in the IR but recovered to approximately pre-COVID levels by the SR (Table). Major PDs, dropouts, and severe or worse toxicity all had lower incidence in the IW compared to pre-COVID; these outcomes were also less frequent in IR ($p<.05$ for each), but not in the SR ($p>.05$ for each) compared to pre-COVID. **Conclusions:** Large declines in enrollment rates during the IW rebounded to pre-COVID levels by 2021-2022. We found steep reductions in the rates of reported occurrence of major PDs, dropouts, and severe or worse toxicity during the initial outbreak, which also recovered to pre-COVID levels by 2021-2022. Findings suggest pandemic-related procedural flexibility did not lead to increased reporting of PDs or dropouts and highlight how use of mitigation strategies likely corresponded with the temporary disruption to trial conduct during the pandemic's peak. Sponsors could consider broader adaptation of trial flexibilities moving forward. Research Sponsor: None.

	Pre-COVID (Jan 2017-Feb 2020)	Initial Wave (IW) (Mar-Apr 2020)		Initial Recovery (IR) (May-Dec 2020)		Secondary Recovery (SR) (Jan 2021-Dec 2022)	
Endpoint	%	%[1]	OR (95% CI)	%[1]	OR (95% CI)	%[1]	OR (95% CI)
Mean monthly enrollment[2]	69.0	48.2	0.36 (0.21-0.63)	59.1	0.55 (0.32-0.96)	64.5	0.90 (0.52-1.62)
Major PDs	14.8	8.2	0.37 (0.26-0.52)	11.5	0.65 (0.47-0.90)	12.7	0.72 (0.52-1.00)
Dropouts	37.8	8.3	0.09 (0.06-0.13)	24.7	0.44 (0.32-0.59)	31.2	0.80 (0.58-1.10)
Severe or worse toxicity	35.2	18.4	0.35 (0.26-0.48)	28.0	0.65 (0.49-0.87)	31.3	0.83 (0.61-1.13)

[1]Among trials with both pre-COVID and follow-up data;
[2]Standardized 0-100 as proportion of maximum study-level monthly enrollment across time periods.

11022 Poster Session

Approaches to engaging participants in a national cancer genomics research network.

Norah L. Crossnohere, Anne L.R. Schuster, Shiraz I Mishra, Bethany Kwan, Participant Engagement Subcommittee of the Participant Engagement in Cancer Genomic Sequencing (PE-CGS) Network; The Ohio State University College of Medicine, Columbus, OH; University of New Mexico Comprehensive Cancer Center, Albuquerque, NM; University of Colorado School of Medicine, Aurora, CO

Background: Although patient engagement is thought to improve the relevance and acceptability of research across diverse patient populations, a paucity of studies actively evaluate engagement activities to assess their impact. The NCI's Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network was established to advance cancer genomics for understudied cancers and among underserved populations by engaging patients and survivors as participants in research. We sought to characterize strategies for engaging and evaluating engagement among research centers within PE-CGS, and to describe factors impacting each center's unique engagement strategies and evaluation methods. **Methods:** We used a multimethod approach to document centers' engagement strategies and methods to evaluate engagement.We first completed a document review of centers' study materials including protocols, specific aims, and publicly available information. We then conducted semi-structured key informant interviews with research center members to validate findings from the document review and to identify factors that influenced engagement strategies. The semi-structured interview guide was developed using the Health Equity Implementation Framework to ensure that we accounted for multi-level factors (societal, contextual, and clinical factors) relevant to engagement. Engagement strategies and evaluation methods were collated and analyzed descriptively. Information about factors that influenced their engagement strategies were analyzed using deductive thematic analysis. **Results:** Across the five PE-CGS research centers, we identified 9 engagement strategies including: convening at network meetings (n=5), use of advisory boards (n=5), brochures (n=3), newsletters (n=2), community outreach through advocacy organizations (n=1) and in-person events (n=2), and use of branded websites (n=4), social media (n=3), and health technology apps (n=1). Methods used for evaluating engagement included: surveys (n=4), interviews/focus groups (n=4), informal feedback from participants (n=2), randomized experiments (n=1), and N-of-1 studies (n=1). Multi-level factors that influenced engagement included those related to the language and culture of the patient population, availability of validated measures, timing of interactions with participants within their health journey, and patient burden imposed by the experienced cancer. **Conclusions:** Across a national research network with a priority to advance participant engagement in cancer genomics research, we observed a range of unique engagement strategies and evaluation methods. Notably evaluation approaches were not typically tied to specific engagement strategies, but rather sought to evaluate broader aspects of engagement in the respective research studies, such as their ability to engender inclusivity, collaboration, and trust among participants. Research Sponsor: National Cancer Institute.

11023 Poster Session

Evaluation of the study of control arms in randomized clinical trials of cancer.

Sandeep Kumar Jain, Marjorie Glass Zauderer, Tarsheen Sethi, Martin W. Schoen, Sam Rubinstein, Ryan Huu-Tuan Nguyen, Seema Nagpal, Sanjay Mohan, Sathwik Madireddy, Mark Lythgoe, Wayne Liang, Amit Kulkarni, Shalin Kothari, Talal Hilal, Matthew James Hadfield, Gaurav Goyal, Teja Ganta, Bhagirathbhai R. Dholaria, Alaina J. Brown, Jeremy Lyle Warner; Brown University, Providence, RI; Memorial Sloan Kettering Cancer Center, New York City, NY; Yale University School of Medicine, New Haven, CT; Saint Louis University School of Medicine, St. Louis, MO; UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC; University of Illinois College of Medicine, Chicago, IL; Stanford University, Palo Alto, CA; Vanderbilt-Ingram Cancer Center, Nashville, TN; Imperial College London, London, United Kingdom; Children's Hospital of Atlanta, Atlanta, GA; University of Minnesota, Minneapolis, MN; Yale University, New Haven, CT; Division of Hematology/Oncology, Mayo Clinic, Phoenix, AZ; Rhode Island Hospital, Brown University, Providence, RI; University of Alabama at Birmingham, Birmingham, AL; Icahn School of Medicine at Mount Sinai, New York, NY; Vanderbilt University Medical Center, Nashville, TN

Background: Randomized clinical trials (RCTs) in cancer typically compare experimental to control arm regimens. The choice of an appropriate control (ctrl) arm can have a major impact on the expected success of an RCT. The frequency with which cancer RCTs use control arms based on established dosing and scheduling protocols has not been described. **Methods:** The HemOnc knowledgebase (KB) was used to identify systemic anti-cancer therapy (SACT) regimen variants, defined as regimens with identical components that differ in dosing, scheduling, and/or route. Non-cancer, nonrandomized, and non-SACT studies were excluded. Study publication year was used to define standard variants as those evaluated in the experimental arm of a positive phase 3 RCT >1 year prior to publication as a control arm, regardless of cancer type or context of treatment. Study-variant dyads were evaluated to determine whether the variant was standard. Success rates of RCTs with standard vs non-standard control arms were evaluated with Fisher's exact test. **Results:** 5221 studies were associated with ≥1 named variant in the HemOnc KB, as of 2024-02-06. After exclusions, there were 3511 study-variant dyads (2386 studies; 1714 variants). The 9 most common regimens are shown in the Table. The median (IQR) number of variants per regimen was 2 (1-3); carboplatin & paclitaxel (CP) had the most variants (n=33). Across all control arm study-variant dyads, 2228/3492 (64%) utilized non-standard variants. For example, 60/97 studies (62%) of docetaxel as control used the 75 mg/m2 q3wk variant after it was established in 2000, whereas n=27 others used 19 non-standard variants. Trials that used a standard control arm had a numerically higher success rate, 45% vs 42% (OR 1.10, 95% CI 0.92-1.32). **Conclusions:** Non-standard regimen variants are frequently used in cancer RCTs. Reasons for this could include toxicity, patient convenience, or emerging data from smaller studies that establish comparable efficacy or improved toxicity to standard variants. However, the *a priori* efficacy of non-standard control arms is less rigorously established, and trials with standard control arms might be more successful. Future directions include quantifying the granular differences between standard and non-standard variants and investigating whether certain types of non-standard variation (e.g. fewer cycles, lower doses) associate with trial success rates. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; U24 CA265879.

Regimen	Timeframe[1]	RCTs Using Regimen as Ctrl	Ctrl Arm Variants	Study-Variant Ctrl Arm Dyads	Study-Variant Ctrl arm Dyads Using a Standard Variant, n (%)
Docetaxel	1997-2023	97	21	115	85 (74)
CP	1995-2023	97	33	120	50 (42)
Gemcitabine	1997-2023	72	21	84	24 (29)
Tamoxifen	1978-2022	72	13	103	74 (72)
Paclitaxel	1992-2023	63	15	73	17 (23)
5-FU & Leucovorin	1987-2023	61	30	66	35 (53)
Cisplatin & Gemcitabine	1998-2023	50	26	52	6 (12)
CMF	1973-2019	44	18	52	22 (42)
FEC	1983-2020	42	21	51	25 (49)

[1]Earliest yr of enrollment as a ctrl arm to latest publication yr.

11024 Poster Session

The science of getting published: Key factors influencing publication in pediatric oncology.

Shushan Hovsepyan, Karen Bedirian, Ruzanna Papyan, Julieta Hoveyan, Amalya Sargsyan, Elen Baloyan, Samvel Bardakhchyan, Gevorg Tamamyan; Immune Oncology Research Institute, Yerevan, Armenia; Yeolyan Hematology and Oncology Center, Yerevan, Armenia

Background: Childhood cancer is rare, with an annual global incidence of 400,000 cases. Research articles play a crucial role in disseminating significant advancements in this rare field; however, it often experiences delays. We investigated the key factors influencing the transition from abstracts presented at the American Society of Clinical Oncology (ASCO) Annual Meetings to publication of articles in the pediatric oncology field. **Methods:** We analyzed oral (OA), poster (PA), and publication-only abstracts (PO) presented during pediatric oncology sessions at ASCO Annual Meetings from 2017 to 2023. We cross-referenced abstract titles and authors with PubMed-indexed journals. Each predictor was assessed for its correlation with the publication status using the chi-square test. Additionally, logistic regression was performed to understand the influence of each predictor while controlling for other variables. **Results:** A total of 521 abstracts were identified. Among these, 93 were OA, 270 were PA, and 158 were PO. Of these, 67%, 60%, and 32% were eventually published, respectively. The mean time to publication was 21.3 months for OA, 17.15 months for PA, and 23.4 months for PO. Female authors comprised 56% of the first authors. Funding was provided for 96% of OA, 87.7% of PA, and 63% of PO. Only 7% of all abstracts were from low-middle-income countries (LMICs). A significant correlation was found between the likelihood of publication and the income level of the authors' country of affiliation ($p<0.0001$), the number of authors ($p=0.001$), presentation type ($p<0.0001$), availability of funding ($p<0.0001$), and the number of institutions involved ($p=0.0001$). The gender of the first author was not a significant predictor of publication ($p=0.46$). However, according to the logistic regression model, only the availability of funding and presentation type had a significant impact on the likelihood of publication ($p<0.05$), while the other variables were found to be insignificant. **Conclusions:** Our study underscores the critical role of funding as a driver in the publication process. Researchers from LMICs are less likely to publish, likely due to a lack of funding. Furthermore, we observed a delay in publication, with an average time exceeding a year and a half. These findings emphasize the importance of equitable funding access and enhanced publication processes to improve research dissemination. Research Sponsor: None.

Improving clinical trial performance using adult-learning methods.

Matthew M. Burke, Carolyn Kubitschek Trees, Mukta Maan, Mark Levonyak, Lindsay Johnson, Nicholas Koeppen, Victoria Barrera, Agnes Nemeth, Sree Reddy, Robert L. Coleman, Paula J. Franson; Department of Clinical Strategy and Solutions, Vaniam Group LLC, Chicago, IL; Vaniam Group LLC, Chicago, IL

Background: Timely and efficient accrual to oncology treatment trials is among the most vital components of clinical research. However, more than 80% of trials fail to reach enrollment targets, compromising outcome interpretation and cost. We hypothesized that a noveland customized application of adult-learning methods would enhance clinical trial screening and randomization. **Methods:** In collaboration with a multinational sponsor, Vaniam Group (VG) introduced a structured set of interventions to sites in 3 global randomized trials. Sites choosing to "opt in" formed the experimental group (EG). EG received tailored interventions: interactive Trial Educational Discussions (iTEDs: 30-min virtual meetings), and/or interactive Trial Acceleration Meetings (iTAMs: 4-hr liveworkshops of 10-30 investigators), and standard study support. Adult-learning techniques including the Socratic Method, case studies, and teach-back were used. Control group (CG) comprised sites receiving only standard study support. Primary endpoints were screening rate (SR) and randomization rate (RdR) compared atbaseline (6 mos prior to intervention) and 6 mos post-intervention (M6). Nonparametric statistical analyses compared between-group (Mann–Whitney U test) and within-group (Wilcoxon Signed-Rank test) differences. **Results:** Trial 1, a phase 3 placebo-controlled adjuvant trial had been open for 45 mos (54% enrolled) prior to intervention. At baseline, SR and RdR were similar between groups ($P>0.05$). At M6, SR increased 100% and RdR increased 37% in the EG; in the CG, SR did not change and RdR decreased 7%. For both endpoints, EG performed better than CG ($P=0.018$, $P=0.014$). Trial 2, a phase 3 neoadjuvant trial had been open for 49 mos (86% enrolled) with a projected 18 mos to completion. At M6, SR increased 3% in the EG, but decreased 39% in the CG. RdR increased 15% in the EG but decreased 33% in the CG. While changes in performance were not significant between groups ($P>0.05$), study met its target enrollment goal with no further delays. Trial 3, a phase 2 recurrence trial was 30% behind enrollment with a projected 51 mos to completion. At M6, increases in SR were recorded in both EG and CG at 116% and 18%, respectively. RdR increased in both EG and CG (90% and 50%, respectively), augmented by protocol amendment. Despite increases in both groups, SR and RdR were significantly enhanced by VG intervention ($P=0.009$ and $P=0.015$). **Conclusions:** Our novel, site-focused intervention strategy structured upon adult-learning methods significantly enhanced clinical trial performance, as measured by SR and RdR. Future work will expand these findings to different trial designs and outcome measures such as endpoint fidelity and cost. Research Sponsor: Department of Clinical Strategy and Solutions, Vaniam Group, LLC.

Trial 1	Mean SR Baseline	Mean SR Month 6	*P* Value	Mean RdR Baseline	Mean RdR Month 6	*P* Value
Control	0.08	0.08	>0.05	0.06862745	0.06372549	> 0.05
Experimental	0.07511737	0.15023474	0.004	0.06338028	0.08685446	> 0.05
***P* Value**	> 0.05	0.018		> 0.05	0.014	

Underrepresentation of Asian Americans, Native Hawaiians, and other Pacific Islanders (AA & NHPI) in cancer clinical trials that led to FDA approvals in 2010-2022.

Ruby Leong, Felice Yang, Jennifer J. Lee, Geetika Srivastava, Suparna B. Wedam, Asma Ali Dilawari, Chaohong Fan, Grace Tran, Sso Lee, Frances Andrada, Clara Lee, Lola A. Fashoyin-Aje, Laleh Amiri-Kordestani, Harpreet Singh, Steven Lemery, Richard Pazdur, Donna Rivera, Jennifer Gao, Tamy Kim; Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, Office of the Commissioner, U.S. Food and Drug Administration, Silver Spring, MD; U.S. Food and Drug Administration, Office of Oncologic Diseases, Silver Spring, MD; Office of Oncologic Diseases, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Center for Devices and Radiological Health, U.S. Food and Drug Administration, Silver Spring, MD; Office of Regulatory Operations, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Office of Therapeutic Biologics and Biosimilars, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, Office of the Commissioner, U.S. Food and Drug Administration; Office of Oncologic Diseases, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Office of Oncologic Diseases, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, U.S. Food and Drug Administration; Office of Oncologic Diseases, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD

Background: About 6% and 0.3% of the total United States (US) population identify as Asian or NHPI alone, respectively. The most commonly diagnosed cancers among AA & NHPI in the US are breast, prostate, lung, thyroid, and colorectal. Liver, gastric, and head and neck cancers occur in higher rates in AA & NHPI vs. non-Hispanic White. Enrollment of Asian & NHPI patients in multiregional cancer clinical trials may provide additional data regarding intrinsic and extrinsic factors (e.g., diet, infections, environmental exposures) impacting the etiology of cancer. We investigated enrollment trends of NHPI and Asian (within and outside of US) patients in cancer clinical trials that led to an FDA approval from 2010-2022. **Methods:** We analyzed data from ~98,000 patients in 171 cancer therapeutic clinical trials that led to FDA approvals for breast, prostate, lung, thyroid, colorectal, liver, gastric, and head and neck cancer indications from 2010-2022. Separate race categories of Asian and Native Hawaiian and other Pacific Islander were used. **Results:** Descriptive statistics of NHPI and Asians within and outside of US enrollment in breast, prostate, lung, thyroid, colorectal, liver, gastric, and head and neck cancer trials that led to an FDA approval from 2010-2022 are summarized in the table. Enrollment of Asian patients in the US was <1% (except for liver cancer) and NHPI patients was <0.2%. **Conclusions:** Although cancer is the leading cause of death for AA & NHPI, AA & NHPI are under-represented in cancer clinical trials, especially when data are further disaggregated into enrollment of NHPI and Asians within and outside of the US. Cancer etiology may vary in Asians in the US vs. Asia due to different intrinsic/extrinsic risk factors, underscoring the importance of enrolling more AA & NHPI into clinical trials to expand the evidence supporting drug approvals in the US and to advance health equity through clinical trial diversity. Research Sponsor: None.

Asian & NHPI patient enrollment in cancer clinical trials that led to FDA approvals (2010-2022).

Cancer Type	# Clinical Trials/Total # Patients	# NHPI Patients* (%)	# Asians Within US (%)	# Asians Outside of US (%)	Top Non-US Locations Enrolling Asian Patients
Breast	37/31755	51 (0.2)	243 (0.8)	6080 (19)	Japan (JPN), South Korea (KOR), China (CHN), Taiwan (TWN), Thailand (THA)
Prostate	18/17921	11 (0.06)	56 (0.3)	2239 (13)	JPN, KOR, CHN, TWN, Canada (CAN)
Lung	74/28728	34 (0.1)	260 (0.9)	7295 (25)	JPN, KOR, CHN, TWN, THA
Thyroid	7/1844`	1 (0.05)	16 (0.9)	247 (13)	KOR, JPN, CHN, TWN, THA
Colorectal	15/8133	2 (0.02)	33 (0.4)	998 (12)	JPN, KOR, TWN, Singapore, CAN
Liver	8/3543	7 (0.2)	90 (2.5)	1757 (50)	KOR, CHN, JPN, TWN, THA
Gastric	8/4413	0	28 (0.6)	1344 (31)	JPN, CHN, KOR, TWN, India
Head and neck	4/1859	0	9 (0.5)	238 (13)	JPN, TWN, THA, Philippines, Malaysia

*NHPI patients enrolled from US, New Zealand, Australia, and Canada (descending).

11027 Poster Session

Current diagnostic guidelines and perpetuation of inequities in ovarian cancer: A National Cancer Database study.

Anna Jo Bodurtha Smith, Emily Gleason, Sneha Kadiyala, Xingmei Wang, Elizabeth A Howell, Anne Marie McCarthy; University of Pennsylvania, Philadelphia, PA; University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

Background: International guidelines use cancer antigen 125 (CA-125) thresholds to recommend which patients with pelvic masses should undergo evaluation by gynecologic oncologists for ovarian cancer and which patients can be observed without intervention. However, CA-125 thresholds were developed from white populations, and CA-125 levels have been shown to be 10-29% lower in healthy Black women than white women. If CA-125 levels also differ among patients with cancer, current guidelines may contribute to missed or delayed ovarian cancer diagnoses among Black women. Our objective was to examine CA-125 levels at cancer diagnosis by patient race and associations of CA-125 elevation with timely treatment. **Methods:** We conducted a retrospective cohort study of patients with ovarian cancer ages 0 to 90+ years diagnosed from 2018-2020 using the National Cancer Database. CA-125 was defined as positive/borderline or negative/normal by each site. We report descriptive CA-125 elevated by patient characteristics. We use multivariate logistic regression models to examine the association of patient characteristics with CA-125 level overall and for epithelial and high-grade serous cancers. We used generalized linearized models to examine the association of CA-125 with days from diagnosis to chemotherapy start for patients with Stage II-IV disease. **Results:** Of 38,707 patients diagnosed with ovarian cancer and with reported CA-125, 13.4% of patients did not have an elevated CA-125 at diagnosis. Patients who identified as Black, Asian, or Hispanic were less likely to have an elevated CA-125 at ovarian cancer diagnosis as were patients with early-stage disease. Among patients with high-grade serous cancer (n=18,151), 8% of Black patients had normal CA-125 at diagnosis compared to 6% of white patients. In multivariate analyses, being Black remained associated with lower odds of elevated CA-125 (OR 0.71, 95%CI 0.63-0.81), after adjustment for menopausal status, comorbidities, and stage. Even among patients with high-grade serous ovarian cancer, being black was associated with lower odds of having an elevated CA-125 (OR 0.78, 95%CI 0.64-0.96). Patients with Stage II-IV ovarian cancer who had a normal CA-125 at diagnosis had 12 days longer on average to chemotherapy initiation compared to patients with elevated CA-125. **Conclusions:** Current thresholds for CA-125 and gynecologic oncology referral likely miss Black patients with ovarian cancer and may delay timely treatment. Work is needed to develop inclusive CA-125 thresholds and guidelines for ovarian cancer diagnosis and not compound disparities. Research Sponsor: Conquer Cancer, the ASCO Foundation.

Post-market study requirements and associations with timely submission and regulatory action for oncology drugs receiving accelerated approval, 2011-2023.

Martin Kurian, William J. Ferrell, Ernesto Ulloa Perez, Rebecca Hubbard, Steven Joffe, Holly Fernandez Lynch, Ronac Mamtani, Ravi Bharat Parikh; University of Pennsylvania, Philadelphia, PA; University of Pennsylvania Perelman School of Medicine, Philadelphia, PA; University of Pennsylvania Perelman School of Medicine, Carey Law School, Philadelphia, PA; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Background: For oncology drugs receiving accelerated approval (AA), the Food and Drug Administration (FDA) enforces Postmarketing Requirements (PMRs) to verify clinical benefit prior to regular approval. Although previous work has characterized the rigor and timeliness of confirmatory studies, the association between specificity and scope of PMR statements and the timeliness of PMR submission and ultimate approval status is not well understood. **Methods:** We identified 161 oncology indications granted AA between January 2011 and July 2023 using FDA's Cancer AA database. We linked indications to 181 corresponding PMR statements using the Drugs@FDA database. We analyzed PMR statement scope and specificity based on the presence or requirement of eight characteristics: target population, comparator (active or placebo-controlled), randomization, multicenter trial, blinding (double-blind or open-label), enrollment target, follow-up duration, and endpoints. We used chi-square and t-tests to analyze associations between PMR characteristics and two primary outcomes: indication approval status (regular vs. withdrawn) and PMR timeliness (on time vs. late). We defined "late" submissions as PMRs submitted or withdrawals occurring after an expected PMR Final Report submission date. Ongoing PMRs were excluded from the timeliness analysis unless expected dates occurred before August 2023. **Results:** Among 181PMR statements, 98% percent specified target population, 81% endpoint (44% overall survival), 63% use of randomization, 54% comparator (40% active; 14% placebo-controlled), 30% follow-up duration 26% enrollment targets, 24% multicenter trial, and 13% double-blinding (and 8% open-label). Among AAs converted to regular approval, 82% of PMRs were submitted on time vs. 24% on-time for withdrawn AAs (p=0.001). Regular approval PMRs were submitted 10.2 months ahead of expected dates, whereas withdrawn AAs were submitted 14.5 months behind expected dates ($p<0.001$). Compared late PMR submissions, on-time PMR submissions had lower enrollment (400 vs. 665, p=0.01), less blinding (19% vs. 40%, p=0.03), more frequent use of a single trial for both AA and PMR (38% vs. 8%, p=0.001), and primary endpoints other than overall or progression-free survival (36% vs. 5%, $p<0.001$). Compared to late PMR submissions, on-time PMR submissions more often followed PMR statements that specified follow-up duration (39% vs. 13%, p=0.006) and non-survival primary endpoints (30% vs. 8%, p=0.01). **Conclusions:** There is marked variability in the contents of PMR statements for oncology AA drugs. Several characteristics of PMRs – including smaller enrollment size, surrogate endpoints, and single trials for AA and PMR – are associated with timely submission. These findings inform the specificity and scope of future FDA PMRs for oncology AA indications. Research Sponsor: Arnold Ventures.

Project Facilitate: An analysis of the increased utilization in the oncology single patient expanded access pathway.

Mitchell Chan, Cameron Wilson, Jessica Boehmer, Tamy Kim, Richard Pazdur; U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, Office of the Commissioner, U.S. Food and Drug Administration, Silver Spring, MD

Background: FDA Oncology Center of Excellence's (OCE) Project Facilitate (PF) was launched in June 2019 in response to perceived barriers providers face when accessing Expanded Access (EA). PF staff provide step-by-step support to oncology healthcare providers requesting use of investigational drugs to treat their patients with cancer. Since launch, PF has received an increased number of oncology single patient EA applications each calendar year. An analysis of single patient investigational new drug applications (IND) received was performed over each calendar year, starting June 1, 2020. **Methods:** Data was extracted from PF's central database between June 1, 2020 and December 31, 2023. Data collected included IND receipt date, granting date, status, application type, indication, drug name, address of requestor, and patient demographics. The starting date of June 1, 2020 was chosen since it was when PF staff officially started performing clinical review of applications. **Results:** Of the 2791 oncology single patient expanded access applications extracted, there were 681 (24.4%) emergency INDs (eIND) and 2110 (75.6%) non-emergency single patient INDs (SPI). Applications received by calendar year increased since June 1, 2020 to December 31, 2020 (397, 14.2%), 2021 (682, 24.4%), 2022 (822, 29.5%), and 2023 (890, 31.9%). The top-3 disease areas requested include high grade glioma (262, 9.4%), multiple myeloma (213, 7.6%), and melanoma (186, 6.7%). The top-3 disease areas requested in pediatric patients $<$ 17 years of age (568, 20.4%) include AML (88, 15.5%), high grade glioma (85, 15%), and ALL (47, 8.3%). Race and ethnicity information was provided in 32 applications containing white/Caucasian (24, 75%), Black or African American (4, 12.5%), Asian (2, 6.25%), and Hispanic or Latino (2, 6.25%). Applications were received from 46 states and 1 US territory, Puerto Rico. The top 3 states requestors resided in were CA (346, 12.4%), NY (317, 11.4%), and TX (276, 9.9%). Although rare, 22 (0.79%) applications were denied or placed on clinical hold most commonly due to curative or established therapies being available. **Conclusions:** Project Facilitate saw a 20.4% increase in oncology single patient expanded access requests received from calendar year 2021 compared to 2022 and an 8.3% increase from 2022 to 2023, equaling a 30.4% increase in 2023 compared to 2021. Research Sponsor: None.

Demographics		Expanded Access Requests, n (%)				
Age (N=2790)	Year	2020*	2021	2022	2023	**TOTAL**
	<2	26 (6.6)	27 (4)	35 (4.3)	18 (2)	106 (3.8)
	2-11	49 (12.3)	103 (15.1)	103 (12.5)	82 (9.2)	337 (12.1)
	12-17	21 (5.3)	25 (3.7)	39 (4.7)	40 (4.5)	125 (4.5)
	18-64	201 (50.6)	329 (48.2)	344 (41.9)	467 (52.5)	1341 (48.1)
	65-74	66 (16.6)	125 (18.3)	191 (23.3)	163 (18.3)	545 (19.5)
	>75	34 (8.6)	73 (10.7)	109 (13.3)	120 (13.5)	336 (12)
Sex (N=2789)	Male	214 (53.9)	376 (55.1)	427 (52)	460 (51.7)	1477 (53)
	Female	183 (46.1)	306 (44.9)	394 (48)	429 (48.3)	1312 (47)

[1]*June 1, 2020 – December 31, 2020.

Mind the gap: Estimating the opportunity lost due to the gap between FDA and EMA cancer drug approvals.

Samantha Gage, Elias Eteshola, Matthew James Hadfield, Dany Hamze, Ali Raza Khaki, Sanjay Mishra, Michael Kevin Rooney, Gabrielle Masse, Talal Hilal, Sandeep Kumar Jain, Sam Rubinstein, Mark Lythgoe, Jeremy Lyle Warner; Lifespan, Providence, RI; Brown University, Providence, RI; Rhode Island Hospital, Brown University, Providence, RI; Stanford University, Stanford, CA; The University of Texas MD Anderson Cancer Center, Houston, TX; Lifespan Cancer Institute, Providence, RI; Mayo Clinic, Phoenix, AZ; UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC; Imperial College London, London, United Kingdom

Background: Drug regulators operate on their own timelines to assess the safety and efficacy of new drugs and/or extensions to existing indications, such that there are delays between regulators. During such a gap, patients in the "early" domain have access to the approved drug, while those in the "late" domain do not, outside of compassionate use. Our study aimed to quantify the "opportunity lost" for new therapies approved by FDA and EMA, assuming patients in the late domain receive standard-of-care (SOC) therapy – which is presumably inferior to the new drug – during the gap. **Methods:** Anticancer drugs approved by both FDA and EMA were identified through the HemOnc knowledgebase. Inclusion criteria included: 1) drugs approved in both domains based on the same randomized clinical trial (RCTs) for the same indication; 2) a primary time-to-event endpoint; and 3) a quantitated median time-to-event for the primary endpoint. For each included trial, the approval gap between FDA and EMA in days and the ratio of approval gap to median control arm time-to-event duration was calculated. A ratio ≥2 implies that, on average, no late domain patients starting treatment in the first half of the gap would be expected to have access to the new drug prior to an event. **Results:** Of 60 eligible RCTs, 59 had calculable median event durations. 25 (42%) had a primary overall survival endpoint; the most common surrogate endpoint was progression-free survival (PFS; 29/59; 49%). The median (interquartile range [IQR]) approval gap was 186 (124-271) days, with FDA being the first approver in 56/59 (95%) cases. The median (IQR) ratio of approval gap to median control arm event duration was 0.63 (0.35-1.11). Drugs with ratio ≥2 (Table) were targeted or immunotherapies; 7/8 (88%) were approved with PFS endpoint; 5/8 (62.5%) were approved for second line or later. **Conclusions:** Our study shows that FDA approves most drugs prior to EMA and a nontrivial number of patients may experience progression or death events while awaiting access to anticancer therapies already approved in another domain. The analysis does not take into consideration scenarios in which the new therapy is inferior to SOC or delays in patient access (due to slow uptake; regulatory barriers [in Europe/UK]; or patient affordability [in US]). Further regulatory collaboration (e.g., Project Orbis) between FDA and EMA could help to reduce and potentially ameliorate this differential in access to new cancer drugs in the future. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; U24 CA265879.

Study	Drug	Cancer Indication	MCBS	Ctrl arm median time to event, d	Approval gap[1], d	Ratio
NOVA	niraparib	Ovary	3	117	234	2.00
NCIC-CTG BR.21	erlotinib	NSCLC	-	141	305	2.16
KEYNOTE-189	pembrolizumab	NSCLC	4	147	482	3.28
KEYNOTE-811	pembrolizumab	Gastric	2	243	840	3.46
EXAM	cabozantinib	Thyroid	3	120	477	3.98
ASCENT	sacituzumab govitecan	Breast	4	51	229	4.49
Study 19	olaparib	Ovary	2	144	975	6.77
METRIC	trametinib	Melanoma	4	45	397	8.82

[1]All drugs except olaparib had FDA approval first.

11031 Poster Session

The oncology care model and initiation of systemic therapy for cancer.

Nancy Lynn Keating, Miranda B. Lam, Mary Beth Landrum, John Michael McWilliams, Alexi A. Wright, Gabriel A. Brooks, Jose Zubizarreta, Benjamin Buzzee, Landon Bruce; Harvard Medical School, Boston, MA; Brigham and Women's Hospital, Boston, MA; Department of Health Care Policy, Harvard Medical School, Boston, MA; Dana-Farber Cancer Institute, Boston, MA; Dartmouth Cancer Center, Lebanon, NH

Background: The CMS Oncology Care Model (OCM) was an episode payment model for patients with cancer receiving systemic therapy (chemotherapy, targeted therapy, immunotherapy, or hormonal therapy) that began in July 2016. Voluntarily participating practices received monthly care coordination payments of $160 per patient per month and were required to deliver enhanced services; they were eligible to share in savings if they achieved quality and spending targets (based on historic spending trended forward; all practices were in one-sided risk arrangements before 2019). Prior research identified savings of $499 per episode (excluding monthly payments) through OCM's first 5 years, but no overall savings after including incentive payments. One concern about an episode payment model triggered by initiation of systemic therapy is that the financial incentives may prompt an increase in the total number of episodes. We assessed if OCM led to an increase in the likelihood of initiating systemic therapy. **Methods:** Using Medicare data, we studied care for beneficiaries enrolled in Parts A, B, and D of fee-for-service Medicare with index cancer diagnoses in 2010 through 2019. We assessed initiation of systemic therapy in the one year after the index diagnosis date. We studied two populations: (1) all patients with an index cancer diagnosis and no cancer diagnosis in the preceding two years, suggesting newly diagnosed or newly progressive cancers (incident cohort) and (2) patients with poor prognosis cancers. We used a difference-in-differences (DiD) analysis to assess systemic therapy initiation among patients with index cancer diagnoses who had office visits to medical oncology practices that were participating in OCM, compared with matched comparison practices (on number of patients attributed, number of physicians, number of medical oncologists, and academic affiliation, favoring matches within Hospital Referral Region), before and after OCM's start in July 2016. Analyses adjusted for patient demographic and clinical variables. **Results:** Among 742,699 beneficiaries in the incident cancer cohort, 61.9% initiated systemic therapy within 1 year of their index diagnosis. Among 777,951 beneficiaries in the poor prognosis cohort, 58.2% initiated systemic therapy within 1 year of their index diagnosis date. OCM was not associated with the likelihood of initiating systemic therapy in the incident cohort (DID:-0.7 percentage point change, 95% CI:-1.9,0.4, P=0.19) or the poor prognosis cohort (DID:-1.0 percentage point change, 95% CI:-2.1,0.1, P=0.07). **Conclusions:** Despite financial incentives of episode payment models that may favor greater use of systemic therapy for patients with cancer, OCM did not increase the likelihood of initiating systemic therapy episodes among patients with newly diagnosed/newly progressive cancers or poor prognosis cancers who visited a medical oncology practice. Research Sponsor: Agency for Health Care Research and Quality.

11032 Poster Session

Examining the financial landscape of cancer: An analysis of debt and bankruptcy among patients in Massachusetts (2010-2019).

Nishant Uppal, Jorge Gomez-Mayorga, Aaron Fleishman, Ashley L. O'Donoghue, Anastasia Bogdanovski, Katharine Esselen, Benjamin James; Brigham and Women's Hospital, Boston, MA; Beth Israel Deaconess Medical Center, Boston, MA; BIDMC, Boston, MA

Background: Financial toxicity is commonly reported by patients following a cancer diagnosis. Prior patient surveys indicate that up to one-third of cancer patients incur medical debt, of which 55% carry balances exceeding $10,000. In addition to debt and bankruptcy, credit scores are an important indicator of socioeconomic well-being following cancer diagnosis, because they affect housing stability, transportation access, and may even be predictive of health. Limited studies quantify incurred debt, bankruptcy rates, or credit scores following a cancer diagnosis compared with patients without a cancer diagnosis. **Methods:** Individuals with a cancer diagnosis in Massachusetts from 2010 to 2019 were identified through the Massachusetts Cancer Registry, and patient-level records on debt, bankruptcy, and other measures of financial well-being were linked using data from a major United States credit bureau. Changes in medical debt, credit score and bankruptcy filings were evaluated over time and compared with a random sampling of individuals residing in Massachusetts over the same time period that did not have a cancer diagnosis and were matched based on demographic factors. **Results:** 99,175 individuals with cancer and 188,875 individuals without cancer were identified, and average annual total debt balances were $758 and $669, respectively, throughout the study period. The highest total debt balances were observed among individuals with thyroid cancer ($913). Average annual medical collection balances were $45 for individuals without cancer and $52 among those with cancer with the highest balances among those with liver cancer ($66). Across the study period, the average annual bankruptcy incidence rate per 100 persons was 7.15 for those without cancer and 6.22 among those with cancer, with the highest incidence rates among those with thyroid cancer (7.34). Although there was a gradual increase in credit score in the control population, survivors of bladder, liver, ovarian, colorectal and lung cancers experienced a decline in credit scores. **Conclusions:** High rates of financial toxicity among individuals with cancer suggest that widespread healthcare and consumer finance reforms have not yet fully alleviated medical debt and bankruptcy in Massachusetts. Further research is needed to understand drivers of financial burden over time among those with cancer. Research Sponsor: None.

11033 Poster Session

Supplemental Nutrition Assistance Program (SNAP) policy changes and mammography use in the United States.

Ali Kazmi, S. M. Qasim Hussaini, Fumiko Chino, Robin Yabroff, Justin Michael Barnes; St. Louis University School of Medicine, St. Louis, MO; University of Alabama at Birmingham, Birmingham, AL; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Department of Surveillance and Health Equity Science, American Cancer Society, Kennesaw, GA; Department of Radiation Oncology, Washington University School of Medicine in St. Louis, St. Louis, MO

Background: The Supplemental Nutrition Assistance Program (SNAP) alleviates food insecurity among low-income households, which has been linked to healthcare access. Several states increased SNAP eligibility by implementing policies that eliminate asset tests and/or broaden income eligibility criteria. This study investigates the associations of SNAP policy changes on mammography use within the past year among low-income females eligible for breast cancer screening. **Methods:** Income-eligible females ages 40-79 years were identified from the 2006-2019 Behavioral Risk Factors Surveillance System. 28 and 22 states adopted SNAP asset test elimination and income increase policies, respectively. Difference-in-differences analyses compared changes in the percentage of mammography within one year from pre- to post-SNAP policy adoption (asset test elimination or income eligibility increase) between states that did and did not adopt policies expanding SNAP eligibility. The samples were limited to females with household income $<$ 130% and $<$200% federal poverty level for analyses of asset test elimination and income eligibility increase policies, respectively, to correspond to typical eligibility criteria. **Results:** A total of 171,684 and 294,647 income-eligible females were included for the asset test elimination and income eligibility increase policy analyses, respectively. Overall, 58.4% reported mammography within 1 year. Adoption of asset test elimination policies was associated with a 2.11 percentage point (95% CI = 0.07 to 4.15, P=0.043) increase in mammography, particularly for non-metropolitan residents (4.14 percentage points, 95% CI = 1.07 to 7.21, P=0.008), those with household income $<$\$25,000 (2.82 percentage points, 95% CI = 0.68 to 4.97, P=0.01), and those residing in states in the South (3.08 percentage points, 95% CI = 0.17 to 5.99, P=0.038) or in states that did not expand Medicaid under the Affordable Care Act (3.35 percentage points, 95% CI = 0.36 to 6.34, P=0.028). There was no significant association between state-level policies broadening SNAP income eligibility and mammography use (-1.07 percentage points, 95% CI = -2.64 to 0.49, P=0.18). **Conclusions:** This nationwide study suggests that policies eliminating the asset test for SNAP eligibility were associated with increased mammography use within one year, with the most pronounced positive impact observed in Southern states, non-expansion states, non-metropolitan areas, and households with the lowest incomes. Findings highlight the role that states policies have to both meet essential needs and promote health among vulnerable populations. Research Sponsor: None.

Caregivers and legal barriers: Navigating care of a family member diagnosed with cancer.

Krista Y. Chen, Amanda L. Blackford, Monica Fawzy Bryant, Joanna F. Doran, S. M. Qasim Hussaini; Johns Hopkins School of Medicine, Baltimore, MD; Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, MD; Triage Cancer, Culver City, CA; University of Alabama at Birmingham, Birmingham, AL

Background: Caregivers of patients with cancer are vital for coordinating care, but the extent to which they encounter social and legal barriers is unknown.We performed a nationwide analysis of a legal navigation program to assess caregiver utilization of services. **Methods:** This is a retrospective analysis of caregivers who used the Triage Cancer Legal & Financial Navigation Program for legal navigation services on behalf of a family member with cancer or for questions regarding caregiver responsibilities. Triage Cancer is a national nonprofit that provides free education on legal and practical issues impacting patients with cancer. We gathered demographic, financial, disease-site, and legal navigation data and implemented Poisson regression models to explore factors associated with each type of primary legal concern that prompted a call for assistance. **Results:** We examined calls from 553 caregivers between 2021-23 for family members with cancer who were 54% male, 44% aged 40-64y, 51% White, 26% employed, 32% on employer-sponsored insurance, and 42% with income <$50k. Most prevalent cancer types were hematologic (23%), CNS (14%), GI (10%), and breast (9%). A majority of caregivers sought assistance with 1 (51%) or 2 (35%) legal barriers. Most common primary issue was health insurance (34% - including issues related to insurance options, navigation, appeals), followed by financial (22% - financial assistance, housing), disability (15% - insurance applications, claim appeals), other (18% - estate planning, wills, advanced directives; life insurance; family law; education; COVID), and employment (10% - time off, working through treatment, returning to work, job loss, job search, unemployment benefits). Compared to reference groups, caregivers of Black patients (RR 2.2) were more likely to call for financial barriers, patients aged 40-64y (RR 3.4) for disability insurance, uninsured individuals (RR 5.6) for health insurance, and those with income between $50-100k (RR 3.1) or patient age 0-39 (RR 5.2) for employment-related difficulties. **Conclusions:** This study highlights the social and legal navigation undertaken by caregivers of patients with cancer. It underscores an urgent need for accessible legal navigation that considers the caregiver alongside the patient as one family unit undergoing care. Research Sponsor: None.

	HEALTH INSURANCE	FINANCIAL	DISABILITY	EMPLOYMENT
White (ref)	-	-	-	-
Black	0.8 (0.3-1.9)	2.2 (1.0-4.7)	0.5 (0.2-1.8)	1.1 (0.2-4.9)
Hispanic	1.7 (0.9-3.1)	0.6 (0.3-1.4)	0.9 (0.4-2.1)	1.4 (0.5-3.8)
65+ (ref)	-	-	-	-
40-64	1.1 (0.5-2.5)	0.7 (0.3-1.8)	3.4 (1.1-10.0)	2.4 (0.6-9.8)
0-39	1.3 (0.6-2.9)	0.5 (0.2-1.3)	2.7 (0.9-8.3)	5.2 (1.3-21.9)
Employer insurance (ref)	-	-	-	-
Uninsured	5.6 (2.0-15.4)	2.1 (0.7-6.1)	0.1 (0.0-1.1)	-[b]
$100k+ (ref)	-	-	-	-
$50-$100k	0.6 (0.3-1.4)	1.7 (0.3-9.2)	1.0 (0.4-2.6)	3.1 (1.1-9.2)

[a]values reported as Relative Risk (95% Confidence Interval).
[b]sample size too small for analysis.

11035 Poster Session

A two-decade trend analysis of in-hospital outcomes and racial/ethnic disparities among hospitalized patients with lung cancer in the United States.

Ted Akhiwu, Jincong Q. Freeman, Joseph Atarere, Ehizogie Edigin, Eugene Omoike, Philip Onyekaoso Kanemo, Olubunmi Akharume, Randi Williams, Mahsa Mohebtash; Department of Medicine, MedStar Union Memorial Hospital, Baltimore, MD; Department of Public Health Sciences, The University of Chicago, Chicago, IL; MedStar Union Memorial Hospital, Baltimore, MD; Department of Dermatology, University of Texas MD Anderson Cancer Center, Houston, TX; School of Medicine, University of Benin, Benin City, Nigeria; Rapides Regional Medical Center, Alexandria, LA; Department of Internal Medicine, MedStar Health, Baltimore, MD; Department of Oncology, Lombardi Cancer Center, Georgetown University, Washington, DC; MedStar Good Samaritan Hospital, Baltimore, MD

Background: Previous research has focused largely on the disease and healthcare cost burden of lung cancer (LC),however, long-term trends of hospitalizations among LC patients (pts) in the US are limited. We aimed to describe longitudinal trends in in-hospital outcomes among hospitalized LC pts, overall and by race/ethnicity. **Methods:** We analyzed data from the National Inpatient Sample database, spanning 1998 to 2020. The study cohort included pts aged ≥18 years with a principal LC diagnosis. We assessed four in-hospital outcomes: 1) hospitalization, 2) mortality, 3) length of stay (LOS), and 4) total hospitalization charges (THCs). THCs were adjusted for inflation using the Medicare Hospital Care Consumer Price Index.To quantify trends, we performed weighted analyses (weighted means or proportions) and calculated *P*-trend using Cochran-Armitage or Jonckheere-Terpstra tests. **Results:** Of 791,100 pts (mean age 68.2 years), 80.4% were White, followed by 11.9% Black, 4.7% Hispanic, and 3.0% Asian or Pacific Islander (API). Among US hospitalized pts in 1998, 0.54% had a principal LC diagnosis, with hospitalization rates having decreased to 0.37% in 2020 (*P*-trend<.001). By race/ethnicity, the LC hospitalization rate for White pts declined from 0.53% in 1998 to 0.39% in 2020; for Black pts, it declined from 0.35% to 0.26%; and for Hispanic pts, it declined from 0.18% to 0.12% (all *P*-trend<.001). In contrast, the hospitalization rate for API pts increased from 0.30% in 1998 to 0.38% in 2020 (*P*-trend<.001). The overall LC-specific in-hospital mortality rate declined drastically from 15.9% in 1998 to 6.2% in 2020 (*P*-trend<.001); a similar pattern was observed across racial/ethnic groups. The LOS reduced from an average of 7.9 days in 1998 to 5.9 days in 2020 (*P*-trend<.001). By race/ethnicity, the LOS for White pts decreased from 7.8 days in 1998 to 5.2 days in 2020; for Black pts, it decreased from 9.0 to 7.0 days; for Hispanic pts, it decreased from 8.8 to 6.7 days; and it declined from 8.7 to 5.9 days in API pts (all *P*-trend<.001). THCs rose significantly from $39,706 in 1998 to $92,734 in 2020 (*P*-trend<.001). In White pts, THCs rose from $39782 to $89,681; from $41,235 to $91,792 in Black pts; from $49,444 to $119,386 in Hispanic pts; and from $52,779 to $112,365 in API pts (all *P*-trend<.001). Moreover, the odds of female pts hospitalized with LC was higher (AOR=1.47, 95% CI=1.40-1.54, *P*<.001) in 2020 compared to 1998. **Conclusions:** In this racially diverse hospitalized LC cohort, LOS, rates of hospitalizations, and mortality rates have declined, while THCs have risen significantly, over the last 20 years. API and female pts bore a heavier burden of hospitalizations. Our findings suggest the need for targeted healthcare interventions or policies to reduce THCs and hospitalization disparities in LC pts. Research Sponsor: Susan G. Komen; TREND21675016; National Institute on Aging; T32AG000243.

Impact of boarding time on in-hospital mortality in patients with cancer presenting to the emergency department.

Patricia A. Brock, Denise Manon Langabeer, Valda D Page, Aiham Qdaisat; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Longer emergency department (ED) boarding times for admitted patients is associated with increased morbidity and mortality.[1] While research over the years has shown an association between boarding time to mortality in a variety of patient demographics, no specific research has been explored in a cancer population. Patients with cancer visit the emergency department frequently and have a high rate of admission compared to other patients.[2] This study evaluates boarding times and mortality rates in patients presenting to an oncologic ED. **Methods:** A retrospective analysis was performed on 183,524 ED visits located at a comprehensive cancer center between March 2016 and December 2022. Eligibility criteria included patients 19 years and older admitted to the hospital excluding direct intensive care unit admission. Boarding time was defined from the time the physician made an order to admit to the hospital to the time of ED departure. Demographics and clinical characteristics were examined using descriptive statistics. Categorical data was analyzed using chi-square test and continuous variables employed the nonparametric Mann–Whitney U test. Boarding time was grouped into quartiles. Univariate and multivariable logistic regression analyses examined clinical factors, including boarding time and in-hospital mortality. **Results:** The eligible number of visits supporting the study equaled 83,629. Overall median boarding time was 2.7 hours (interquartile range: 1.5–5.1 hours) and in-hospital mortality was 5.5% (n=4607). Longer boarding time was significantly associated with in-hospital mortality. Patients with boarding time ≥5.1 hours had 1.19 (95% confidence interval [95%CI]: 1.09-1.30; $P<0.001$) odds of in-hospital mortality when compared to the reference group (boarding time <1.5 hours) when controlling for other risk factors including comorbidities and emergency severity index (ESI) between 1 through 5. Similar results were observed for patients with boarding times of ≥1.5-<2.7 hours and ≥2.7- <5.1 hours with odds ratio of 1.12 (95%CI: 1.02-1.22; $P=0.013$) and 1.11 (95%CI: 1.02-1.21; $P=0.020$), respectively. Higher Charlson comorbidity index and levels 1 and 2 ESI were also associated with poor survival outcome ($P<0.001$ for both). **Conclusions:** This study found an association between boarding time and in-hospital mortality in cancer patients presenting to the ED. Patients with longer boarding times were likely to experience mortality during their hospital admission. High comorbidity score and high-risk ESI were also identified as risk factors for poor survival outcome. These results emphasize the need for improved strategies to expedite the admission process and optimize care for cancer patients in the ED to reduce mortality rates. Further research and interventions targeting reduction in boarding times are warranted to improve outcomes for this vulnerable population. Research Sponsor: None.

11037 Poster Session

Historic redlining, modern neighborhood structures, and mortality in children, adolescents, and young adults with cancer.

Kristine Karvonen, Annie Vu, Katherine Lin, Joseph Gibbons, Jason Mendoza, Eric Jessen Chow, Lena E. Winestone, Scarlett L. Gomez; University of Washington, Seattle, WA; University of California, San Francisco, San Francisco, CA; Department of Epidemiology and Biostatistics, University of California, San Francisco, San Francisco, CA; San Diego State University Department of Biology, San Diego, CA; Fred Hutchinson Cancer Center, Seattle, WA; UCSF Benioff Children's Hospital, San Francisco, CA

Background: Historic redlining, referring to the Home Owners Loan Corporation (HOLC) program's racially biased risk monitoring maps in the 1930's, has indelible impacts on modern day neighborhood characteristics and health outcomes. The impact of redlining, a form of structural racism, on children, adolescents, and young adults with cancer (CAYACs) is unknown. This retrospective cohort study evaluates the association between redlining and mortality in CAYACs. **Methods:** Using the California Cancer Registry, we identified cases <25 years old diagnosed with first primary malignant cancer between 2000-2019. Using merged HOLC maps and U.S. Census data we determined case redlining status (A "Best", B "Still Desirable", C "Declining", D "Hazardous", and N "Not graded") by residence at diagnosis. We defined residents of D neighborhoods redlined-exposed and residents of A or B neighborhoods unexposed or referent. Kaplan Meier methods and multivariable Cox proportional hazard models were applied to calculate overall survival. Additional models accounted for census tract-level neighborhood SES (nSES, a composite measure incorporating seven SES domains), neighborhood racial and ethnic composition (or typology) and racialized economic segregation (via index of concentration at the extremes). **Results:** In total 8,210 cases were HOLC-graded, the median age was 16 years, 46% were female, and 48% had solid tumors. Overall survival at 5 years was inferior for D cases vs. A or B cases (OS 80.2%, 95% CI: 78.5-81.7 vs. OS 88.2, 95% CI: 84.0-91.3). Adjusting for individual clinical characteristics (age, sex, year of diagnosis, and cancer stage), D cases experienced greater mortality (HR 1.32, 95% CI: 1.12-1.55) compared to A or B cases. Additional adjustment for insurance and nSES attenuated the relationship (HR 1.17, 95%CI: 1.00-1.36 and HR 1.07, 95% CI: 0.92-1.24 respectively). Similar patterns were observed in models adjusting for racialized economic segregation (HR 1.07, 95% CI: 0.92-1.24) and typology (HR 1.10, 95% CI: 0.94-1.28) in place of nSES. **Conclusions:** In this population-based study, redlined-exposed CAYACs experienced greater mortality compared to unexposed CAYACs. Adjusting for insurance and contemporary nSES attenuated the association between redlining and mortality. Findings suggest current neighborhood attributes may be downstream manifestations of structural racism with survival implications for CAYACs. Research Sponsor: Greater Bay Area Cancer Registry; American Cancer Society Clinician Scientist Development Grant; ASCO Young Investigator Award.

11038 Poster Session

Characteristics and pregnancy outcomes of pregnant women by cancer diagnosis status.

Usha Periyanayagam, Lyuba Popadic, Francesca Devine, Yuqin Wei; Komodo Health, San Francisco, CA; Komodo Health, New York, NY

Background: Given the broad exclusion of pregnant patients from clinical trials, limited evidence exists on the impact of cancer diagnoses on pregnancy outcomes. This study aimed to describe patient characteristics and end of pregnancy events among women with and without a cancer diagnosis before pregnancy. **Methods:** This retrospective claims study used data from the Komodo Research Dataset between 01/01/2016–08/31/2023 to identify adult women with a known gestation of pregnancy record and end of pregnancy outcome. Eligible members needed to be continuously enrolled in medical and prescription drug plans for both 365 days before (baseline) and after the derived pregnancy start (index date). This pregnancy cohort was then stratified according to cancer status, evidenced by any cancer diagnosis during the baseline period, to allow assessment of pregnancy outcomes. Valid pregnancy outcomes included full or preterm live birth and pregnancy loss such as miscarriage, stillbirth, and elective termination. Only the earliest pregnancy observed for each eligible member was analyzed. **Results:** Among the 1,921,866 pregnant women included in the analyses, only 0.7% (N=12,723) of patients had any cancer diagnosis in the year prior to pregnancy start. Cancer patients were older than non-cancer patients (mean age: 33.8 and 29.2 years, respectively). Commercial medical insurance was more common (67.7% vs. 58.9%) among cancer vs. non-cancer patients and Medicaid enrollment was less common (30.3% vs. 40.6%) upon pregnancy start. The proportion of patients with a live birth was lower among cancer vs. non-cancer patients (59.7% vs. 67.1%), while the proportion with pregnancy loss was higher (31.6% vs. 25.8%). Medicaid enrollment was more common among patients that had a pregnancy loss relative to live birth for both cancer and non-cancer patients (35.5% vs. 27.5% and 45.7% vs. 38.7%, respectively). The proportion of black patients was higher among patients with a pregnancy loss relative to those with live birth in both cohorts (cancer: 11.1% vs. 8.3%; non-cancer: 16.9% vs. 13.7%), while the proportion of white patients was similar for cancer patients with a pregnancy loss vs. live birth (37.4% vs. 37.1%) and the proportion was lower for non-cancer patients (30.4% vs. 34.4%). **Conclusions:** Preliminary findings suggest pregnancy loss was more common among cancer patients than non-cancer patients. Regardless of cancer status, differences in insurance coverage and race were observed for patients with a live birth relative to patients with pregnancy loss. Additional research should be conducted to identify factors driving differences in pregnancy outcomes, such as in care management by race and ethnicity, particularly among the vulnerable population of cancer patients. Research Sponsor: None.

11039 Poster Session

Diet quality and cardiometabolic risk factors among breast cancer survivors in the Pathways Study.

Isaac J. Ergas, Janise M. Roh, Lawrence H. Kushi, Carlos Iribarren, Mai Nguyen-Huynh, Jamal S Rana, Eileen Rillamas-Sun, Cecile Laurent, Valerie S. Lee, Richard Cheng, Heather Greenlee, Marilyn L. Kwan; Division of Research, Kaiser Permanente Northern California, Oakland, CA; Fred Hutchinson Cancer Research Center, Seattle, WA; University of Washington Medical Center, Seattle, WA

Background: Women with breast cancer (BC) have higher risk of developing cardiometabolic conditions compared to women without BC. However, the relationship between healthy eating and onset of cardiometabolic conditions in BC survivors remains unknown. We set out to determine if diet quality at BC diagnosis was related to subsequent development of hypertension, diabetes, and dyslipidemia. **Methods:** This analysis included 3,415 participants from the Pathways Study, a prospective cohort of women diagnosed with invasive BC (stages I-IV) at Kaiser Permanente Northern California (KPNC) between 2005 and 2013. Food frequency questionnaires were administered at or around the time of BC diagnosis and five diet quality indices (DQI) aligned with healthy eating were evaluated: Dietary Approaches to Stop Hypertension (DASH), a healthy plant-based dietary index (hPDI), 2020 Healthy Eating Index (HEI), American Cancer Society nutrition guidelines (ACS), and the alternate Mediterranean Diet (aMED). Incident hypertension, diabetes, and dyslipidemia were ascertained through electronic health records and participants were followed through first indication of these conditions, disenrollment from KPNC, death, or December 31, 2021. Scores were categorized into ascending quartiles of concordance for each DQI, and multivariable adjusted hazard ratios (HR) and 95% confidence intervals (CI) were estimated. **Results:** There were 554 (16.2%) incident cases of hypertension, 362 (10.6%) of diabetes, and 652 (19.1%) of dyslipidemia over 39,263 person-years of follow-up. Participants in the highest compared to lowest HEI quartile had lower risks of hypertension (HR=0.70, 95% CI 0.53-0.92, $P_{trend}<0.01$), diabetes (HR=0.56, 95% CI 0.40-0.77, $P_{trend}<0.001$), and dyslipidemia (HR=0.76, 95% CI 0.59-0.99, $P_{trend}=0.03$). Participants in the highest vs lowest hPDI quartile had lower risks of hypertension (HR=0.74, 95% CI 0.55-0.98, $P_{trend}<0.05$) and diabetes (HR=0.65, 95% CI 0.46-0.93, $P_{trend}=0.02$), but not dyslipidemia. Women in the highest vs lowest DASH and ACS quartiles had lower risks of diabetes (DASH: HR=0.56, 95% CI 0.39-0.79, $P_{trend}<0.001$; ACS:HR=0.57, 95% CI 0.40-0.79, $P_{trend}<0.001$), but not hypertension or dyslipidemia. No statistically significant differences for aMED were observed between those in the highest vs lowest quartiles. Overall, HRs were similar across DQIs for hypertension and diabetes, except for aMED, which slightly attenuated for diabetes. **Conclusions:** Diets concordant with HEI may provide the most overall benefit for preventing cardiometabolic conditions after a BC diagnosis. The benefit of diets aligned with hPDI, DASH, ACS, and aMED appear to vary by cardiometabolic condition. Future analyses will examine how these benefits may be modified by BC treatments. Consuming a healthful diet should be recommended to BC survivors for long-term cardiovascular health. Research Sponsor: National Cancer Institute; R01 CA214057; National Cancer Institute; U01 CA195565.

Comorbid opioid use disorder and resource utilization outcomes in patients with neoplasm-related pain: A population analysis.

Ted Akhiwu, Jincong Q. Freeman, Joseph Atarere, Andrew Ndakotsu, Eugene Omoike, Ehizogie Edigin, Philip Onyekaoso Kanemo, Mounika Gangireddy; Department of Medicine, MedStar Union Memorial Hospital, Baltimore, MD; Department of Public Health Sciences, The University of Chicago, Chicago, IL; MedStar Union Memorial Hospital, Baltimore, MD; School of Medicine, University of Benin, Benin City, Nigeria; Department of Dermatology, University of Texas MD Anderson Cancer Center, Houston, TX; Rapides Regional Medical Center, Alexandria, LA; Lankenau Medical Center, Wynnewood, PA

Background: Neoplasm-related pain (NRP) is one of the most debilitating sequalae of cancer, affecting patients' (pts) quality of life. Its intersection with opioid use disorder (OUD) adds a layer of complexity to patient care in the United States (US). As the prevalence of both conditions continues to increase, understanding the association between OUD and NRP becomes important. This study aimed to shed light on this intricate relationship by examining outcomes in resource utilization among OUD pts with NRP. **Methods:** We analyzed weighted data from the 2016-2020 iterations of the National Inpatient Sample database. We included pts 18 years or older with a principal discharge diagnosis of NRP with or without a secondary diagnosis of OUD. The main outcomes for the study were length of stay (LOS) and total hospitalization charges (THC) adjusted for inflation using the Medicare Hospital Consumer Price Index. Baseline sociodemographic and hospital characteristics as well as comorbidities of patients with and without OUD were compared using $\chi 2$ for categorical variables and Student's t-test for continuous variables. Multivariable Linear regression was used to assess the relationship between comorbid OUD and resource utilization among NRP hospitalizations. Statistical significance was set at $p<0.05$. **Results:** There were 120,359 hospitalizations for NRP between 2016 and 2020. Among patients hospitalized for NRP, 3335 (2.78%) had a secondary diagnosis of OUD. The mean age of NRP pts was 60 years. Compared to patients without OUD, OUD pts were male (50.67% vs 45.47%; p = 0.0086), younger (mean age 56 vs 60 years; $p<0.0001$), more likely to be on Medicaid (37.48% vs 21.00%; $p<0.0001$) and hospitalized in urban hospitals (94.6% vs 91.37%; p = 0.0040). On multivariable linear regression, OUD was associated with an increased LOS by 0.93 days compared to non-OUD patients (95% CI: 0.265 – 1.600; p = 0.006), as well as increased THC by $9248 (95% CI: 1676.00 – 16820.41; p = 0.017) after adjusting for sociodemographic and hospital covariates. **Conclusions:** Our study highlights an increased resource utilization among pts with NRP and comorbid OUD. We surmise this could be due to increased tolerance to and dependence on the effects of opioids requiring more intricate multidisciplinary care in managing their pain. Recognizing this association is important for medical oncologists and other health care providers when managing NRP pts with OUD. Incorporating multimodality pain management early on admission could improve patient outcomes while optimizing healthcare resources. Research Sponsor: Susan G. Komen; TREND21675016; National Institute on Aging; T32AG000243.

11041 Poster Session

The impact of multiple pharmacy use on medication adherence in individuals with colorectal cancer.

Timothy Barnett, Cliff Rutter, Shehla Zaidi, Elisea Avalos-Reyes, Kelly McAuliff, Rashmi Grover, Lucia Feczko, William Cavers, Kjel Andrew Johnson; CVS Health, Lincoln, RI

Background: Colorectal cancer (CRC) is the third most common cancer diagnosed in the US. The pharmacological care of older and often comorbid members with CRC is a growing healthcare issue. Cancer members are prone to the unintended consequences of multiple pharmacy use, as they often receive chemotherapy and symptom-relieving agents, in addition to medications they may be taking for other comorbidities. The purpose of this study was to assess multiple pharmacy use and adherence in a cohort of individuals with CRC. **Methods:** Adult pharmacy benefit manager (PBM) members who had at least 2 fills of either regorafenib, encorafenib, or trifluridine + tipiracil at specialty pharmacies between 1/1/2022 and 12/31/2022 were included. Any fills must have included one of the following diagnosis codes: C18.X, C19.X, C20.X, C21.8, C78.5, C78.6, D37.4, D37.5. Members were excluded if they did not maintain continuous eligibility for the 180 days prior to initiation in the study. Specialty pharmacy type included CVS Specialty, Competitor Specialty and Competitor non-specialty. Multiple pharmacy use was defined as utilizing more than one pharmacy for medication fills. The primary outcome was adherence determined by the medication possession ratio (MPR), defined as the number of days supplied/number of days in the evaluation period; optimal adherence was defined as MPR $\geq$ 0.8. Continuous and categorical variables were assessed with standard statistical tests. Bivariate logistic regression models were constructed for each covariate; significant variables were included in the multivariate model. Odds ratios (OR) and 95% confidence intervals (CI) are presented; p values $<$ 0.05 were significant. **Results:** 891 members met all inclusion criteria; 362 (40.6%) met the definition of multiple pharmacy use. Members were on average 59.6 $\pm$ 11.2 years old and 54.3% were male. No differences in member demographics between specialty pharmacy type were found (all p $>$ 0.05). Adherence was high with 79.5% of members having a MPR $\geq$ 0.8. Members with multiple pharmacy use had significantly lower adherence rates (76.0% vs. 81.9%; p=0.04) and MPRs (mean $\pm$ SD) (1.06 $\pm$ 0.45 vs. 1.15 $\pm$ 0.53; p=0.011). Controlling for specialty pharmacy type, medication used, and gender, multiple pharmacy use was significantly associated with decreased likelihood of optimal adherence compared to single pharmacy use (OR [95% CI]: 0.705 [0.507-0.98]; p= 0.038). Male gender was associated with significantly higher likelihood of optimal adherence (OR [95% CI]: 1.517 [1.093-2.107]; p=0.013). **Conclusions:** In this study of individuals with CRC receiving regorafenib, encorafenib, or trifluridine + tipiracil, utilizing multiple pharmacies for non-CRC medications was associated with a 29.5% decreased likelihood of optimal adherence compared to those who only utilized one pharmacy. Further examinations are warranted that include other modulators of adherence. Research Sponsor: None.

Development and validation of point-of-care mobile solution to guide the diagnosis of malnutrition: A multicenter, prospective cohort study.

Xueyan Zhou, Nan Lin, Xuelei Ma; West China Hospital, Chengdu, China; West China Hospital, Sichuan University, Chengdu, China

Background: Malnutrition has negative effects on patients with chronic diseases, leading to reduced treatment tolerance, increased risk of clinical complications, and even death. This research was aimed to develop a point-of-care program based on facial features to screen malnourished inpatient patients. **Methods:** In this prospective, multicenter, cohort study, we retrieved facial photograph and malnutrition screening scales from 4 different hospitals. We utilized a variety of machine learning models to explore whether the ocular area could serve as an enhanced region for facial recognition nutrition. Last, we utilized a facial area segmentation and weighted approach to retain the information of full-face features using a BP neural network and validated using Delong-test, IDI-test, and NRI-test. Overall, 619 inpatients' facial photographs and their corresponding nutrition screening questionnaires were used to train, validate and test the machine learning model. **Results:** The Pearson correlation analysis showed a significant correlation ($p<0.05$) between the two questionnaires in all groups. The average AUC obtained from the five-fold cross-validation set was 0.886 (CI 0.843-0.930), 0.834 (CI 0.764-0.904), and 0.927 (CI 0.899-0.955) for the Cancer Inpatient Group, Other Inpatient Group, and All Inpatient Group, respectively, with the corresponding AUC obtained from the external validation set being 0.860 (CI 0.817-0.904), 0.843 (CI 0.796-0.889), and 0.887 (CI 0.829-0.944). **Conclusions:** The facial photograph-based point of-care mobile solution can screen malnutrition with good accuracy, showing its potential for screening malnutrition in inpatients in the hospital in different types of diseases. Research Sponsor: None.

Relationship between receipt of combined axillary dissection and nodal irradiation and age.

Sara Myers, Ann H. Partridge, Laura Elizabeth Warren, Rachel Adams Greenup, Elizabeth A. Mittendorf, Tari A. King, Olga Kantor; Brigham and Women's Hospital, Boston, MA; Dana-Farber Cancer Institute, Boston, MA; Yale University, New Haven, CT

Background: Combined axillary lymph node dissection and regional nodal irradiation (ALND+RNI) is the greatest risk factor for breast cancer-related lymphedema (BCRL), a lifelong ailment that negatively impacts quality of life. As disability from BCRL may be particularly profound for adults <45 yo with longer life expectancy, we examined the association of age and other sociodemographics with receipt of ALND+RNI to further our understanding of patients at greatest risk for BCRL. **Methods:** The National Cancer Database (NCDB) was used to examine age-based differences in receipt of ALND+RNI in patients with stage I-III breast cancer treated from 2018-2020. Cohort characteristics were compared by age (<45 yo, 45-64 yo, and 65 yo). Multivariable regression examined the association between age and ALND+RNI adjusting for relevant factors. Sensitivity analyses explored associations between covariates and combined ALND+RNI by age group. **Results:** Of 155,010 patients, 5.4% were <45 yo, 47.2% were 45-64 yo, and 47.4% were 65 yo. Clinical and pathological node (cN, pN) positive disease, and receipt of ALND, RNI, and ALND+RNI were more common in patients <45 yo (Table). Age <45 yo was independently associated with ALND+RNI (<45 yo OR 1.40; 45-64 yo OR 1.26 vs 65, $p<0.001$). Residing in areas with a high proportion of high-school graduates (%HSG), Hispanic ethnicity but not race, and lower income were also associated with ALND+RNI in adjusted analyses (all $p<0.05$). Medicare ($p=0.02$ vs private insurance) was inversely associated with ALND+RNI. Among clinical factors, pN+ was the greatest risk factor for receipt of ALND+RNI (all $p<0.001$ vs pN0). Higher cT, cN1 and cN2 categories, lobular tumors, mastectomy, not receiving endocrine therapy, and having chemotherapy were also associated with ALND+ RNI (all $p<0.05$). Sensitivity analyses showed that while sociodemographics influenced receipt of ALND+RNI for women 45 yos, only clinical factors were significant for ALND+RNI for <45 yo. Among 45-64 yo, high %HSG ($p<0.001$) and low household incomes ($p<0.01$) were associated with ALND+RNI. In the 65 yo cohort, high %HSG ($p=0.028$), and Asian race ($p=0.011$) were more likely to receive ALND+RNI while Medicare patients were less likely to have ALND+RNI ($p=0.012$). **Conclusions:** Our findings suggests that clinical factors predominate in axillary treatment decisions for younger patients; while sociodemographic factors are more prominent for those 45 yo. Given their higher odds of receiving ALND+RNI, BCRL screening may be especially important in patients <45 yo. Further studies are needed to understand the interplay between age and sociodemographics on receipt of ALND+RNI. Research Sponsor: None.

Cohort characteristics by age.

Characteristic*	<45 yo N=8295	45-64 yo N=73280	65 yo N=73435
Clinically N+	9.0%	6.6%	5.5%
Pathologically N+	29.7%	23%	18.8%
ALND	23.5%	18.2%	15.2%
RNI	20.5%	16.9%	12.1%
ALND + RNI	9.0%	6.3%	4.1%

*All p-values<0.001.

11045 Poster Session

Electronic patient-reported outcome measures (E-Proms): Results of the H2020 CAPABLE project for patients with metastatic renal cell cancer (mRCC).

Laura D. Locati, Mimma Rizzo, Paola Gabanelli, Silvana Quaglini, Valentina Tibollo, Alberto Malovini, Silvia Panzarasa, Matteo Terzaghi, Giordano Lanzola, Andrea Premoli, Sara Demurtas, Lucia Sacchi; Dept. of Internal Medicine and Therapeutics, University of Pavia, Pavia, Italy; Division of Medical Oncology, AOU Consorziale Policlinico di Bari, Bari, Italy; Istituti Clinici Scientifici Maugeri IRCCS, Pavia, Italy; Dept of Electrical, Computer and Biomedical Engineering, University of Pavia, Pavia, Italy

Background: E-Proms were shown to benefit both survival and quality of life (QoL) of cancer patients. So far, E-Proms have been mostly implemented as the electronic version of validated, paper-based questionnaires typically administered at follow-up visits. Benefits of telemedicine systems that put symptom reporting within a wider framework embracing a holistic view of a patient's wellbeing are still under-investigated. **Methods:** Thirty mRCC patients were enrolled in the CAPABLE project intervention cohort during 2023. They were provided with the CAPABLE smartphone app, and with a smartwatch able to monitor vital parameters, physical activity, and sleep. The app acts as a virtual coach, allowing patients to enter any symptom they experience through an interface inspired by both CTACE and proCTCAE. Immediate feedback on whether to contact or not a doctor is generated according to the symptom severity. Patient's data are matched with the ESMO guidelines for toxicity management, a selection of which was computerized within CAPABLE, and any generated recommendation is shown to the patient. The app manages the symptom follow up, periodically prompting the patient to report any change, and it also promotes activities aimed at improving patients' education, mental wellbeing and lifestyle. All the entered data may be visualized by doctors at the hospital. The CAPABLE cohort was compared with a control cohort of 77 mRCC patients, enrolled in 2021/2022, who underwent standard care. All patients filled in a set of questionnaires measuring QoL, satisfaction, nutritional and psychological status at enrollment (T0), after 3 months (T1) and after 6 months (T2). A focus group with the CAPABLE cohort was held close to the end of the study. In this report the primary outcome, i.e. EORTC QLQ-C30 score for QoL, is discussed, together with qualitative results from the focus group. **Results:** The analysis shows an increase in the average QoL for the CAPABLE cohort (80.7 vs 84.9), and a slight decrease in the controls (80 vs 77), with a statistically significant interaction between time and cohort ($p < 0.05$). Considering QLQ-C30 subscales, CAPABLE patients showed less fatigue and improved social and role functioning. As from the focus group, the app was perceived as effective and useful. More connection with the patient's clinical pathway and more personalization according to specific treatments were highlighted as needed improvements. **Conclusions:** This study shows that E-Proms may be effectively included in a comprehensive and engaging system for remote management of mRCC patients. Clinical trial information: NCT06161233. Research Sponsor: EU H2020 programme; 875052.

11046 Poster Session

Examining 1-year mortality risk among patients with malignant melanoma undergoing immune checkpoint inhibitor therapy with a history of cannabis use.

Imtisaal Waris, Rahul Raiker, Nanda Siva, Sanya Goswami, Haig Pakhchanian, Amir Shahzad Kamran; Fairfield Medical Center, Lancaster, OH; West Virginia University School of Medicine, Morgantown, WV; Suny Downstate Health Sciences University, Brooklyn, NY; George Washington University School of Medicine and Health Sciences, Washington, DC; Charleston Area Medical Center (CAMC), Charleston, WV

Background: Cannabis use has become an increased topic of discussion in the United States due to rise in legalization, thereby increasing its accessibility for recreational and medicinal use in diseases like cancer. Immune Checkpoint Inhibitor (ICI) therapy has also recently been increasing in patient with metastatic cancers such as melanoma by targeting PD1 or PD-L1 receptors to manipulate the body's immune response to induce cancer cell death. Cannabis is mediated in part by the CB1 and CB2 receptors in the endocannabinoid system that is present in the natural immune system. Due to the body's immune response to cannabis, it is hypothesized this could interfere with the activity of ICI therapy. However, research examining this is sparse. Therefore, the goal was to assess mortality in malignant melanoma patients with a history of cannabis use who undergo ICI therapy. **Methods:** A retrospective cohort study was performed with TriNetX, a federated database of ~100 million patients across 84 healthcare organizations. Patients >17 years from 2012-2023 were identified based on ICI-therapy initiation within 1 month of malignant melanoma diagnosis. Cohorts were then created by history of those with and without cannabis use disorder. 1:1 propensity score matching was conducted to control for confounding comorbidities and demographics. Unadjusted and adjusted hazard ratios (aHR) with 95% CI were calculated for 1-year mortality after therapy initiation. HR's were estimated using the Cox proportional hazard model. Survival curves were compared using the log-rank test. **Results:** A total 14589 melanoma patients who underwent ICI therapy were identified, of which 2.3% had documented cannabis use disorder. Prior to matching, melanoma patients with cannabis history had a statistically significant higher 1-year mortality compared to those with no cannabis history (HR [95%CI] = 1.29 [1.04,1.6], log rank test: p=0.0197). After matching, two balanced cohorts of 344 patients remained and adjusting for confounders revealed that melanoma patients with cannabis history had no significant difference in 1-year mortality risk compared to patients without cannabis history (1.18 [0.87,1.6], log rank test: p=0.293). **Conclusions:** Cannabis use among melanoma patients was shown to not have any meaningful difference in 1-year mortality risk compared to patients without cannabis use history while undergoing ICI-therapy. Additional studies, such as examining cannabis frequency and dosage, is warranted to further examine its effect. Research Sponsor: None.

Association of frailty assessed by a ten-item frailty index (FI-CGA-10) with health-related quality of life in older adults with cancer.

Tomohiro F. Nishijima, Mototsugu Shimokawa, Kirsten A. Nyrop, Kohei Arimizu, Taito Esaki, Masaru Morita, Yasushi Toh, Hyman Muss; Geriatric Oncology Service, NHO Kyushu Cancer Center, Fukuoka, Japan; Department of Biostatistics, Yamaguchi University Graduate School of Medicine, Yamaguchi, Japan; Lineberger Comprehensive Cancer Center, The University of North Carolina at Chapel Hill, Chapel Hill, NC; Geriatric Oncology Service/Medical Oncology, NHO Kyushu Cancer Center, Fukuoka, Japan; Department of Gastrointestinal and Medical Oncology, NHO Kyushu Cancer Center, Fukuoka, Japan; Department of Gastroenterological Surgery, NHO Kyushu Cancer Center, Fukuoka, Japan

Background: A 10-item frailty index based on a comprehensive geriatric assessment (FI-CGA-10) is a recently developed measure of frailty in the geriatric oncology setting [Oncologist, 26, e1751 (2021)]. Our objective was to investigate the association between frailty defined by the FI-CGA-10 and health-related quality of life (HRQOL) in older adults with cancer. **Methods:** This study included 1015 consecutive older adults with cancer who underwent a CGA before cancer treatment decision at a geriatric oncology service in Japan from February 2020 through September 2023. Fitness and frailty level was evaluated using the FI-CGA-10 that assesses 10 domains: cognition, mood, communication, mobility, balance, nutrition, base and instrumental activities of daily living, social support, and comorbidity. Deficits in each domain were scored as 0 (no problem), 0.5 (minor problem), and 1.0 (major problem). FI-CGA-10 scores (range 0-1) were calculated by dividing the sum of the scores for each domain by 10 and then categorized as fit (<0.2), pre-frail (0.2–0.35), and frail (>0.35). HRQOL was measured by the EQ-5D-5L index score and visual analogue scale (VAS) at the CGA consultation. The minimally important difference (MID) values for the EQ-5D-5L Japan-based index and VAS scores are 0.048 and 7, respectively. Associations between EQ-5D-5L and FI-CGA-10 scores were analyzed by Pearson's correlation and linear regression models adjusting for covariates (age, sex, cancer type, and stage). **Results:** Median age was 80 years, 60% were male, and 68% had gastrointestinal cancer. The mean +- SD of the FI-CGA-10 score was 0.35 +- 0.19. The FI-CGA-10 negatively correlated with the EQ-5D-5L index (Pearson's r = -0.69; 95% CI -0.72 to -0.66; P<.001) and VAS (r = -0.47; 95% CI -0.52 to -0.42; P<.001) scores. After adjusting for the covariates, each 0.1 unit increase in FI-CGA-10 score was associated with 0.070 decrease in EQ-5D-5L index (95% CI -0.075 to -0.066; P<.001) and 4.9 decrease in VAS scores (95% CI -5.5 to -4.4; P<.001). Using the three-level classification, 22% of patients (n = 221) were categorized as fit, 38% (n = 384) as pre-frail, and 40% (n =410) as frail. Overall, the fit group had the highest EQ-5D-5L index and VAS scores followed by the pre-frail and frail groups (table). The score differences between the frailty categories were statistically significant and clinically meaningful according to the MID values. **Conclusions:** This study demonstrated that frailty assessed by the FI-CGA-10 cross-sectionally correlated with HRQOL measured by the EQ-5D-5L in older Japanese adults with cancer. The observed association further supports construct validity of the FI-CGA-10 as a CGA-based frailty measure. Research Sponsor: JSPS KAKENHI.

	Fit	Pre-Frail	Frail
EQ-5D-5L index score (95% CI)	0.874 (0.852-0.895)	0.817 (0.801-0.833)	0.603 (0.588-0.619)
EQ-5D-5L VAS score (95% CI)	78.2 (75.8- 80.5)	70.9 (69.2- 72.7)	56.3 (54.6- 58.0)

11048 Poster Session

Geographic distribution and accessibility of clinic trials for advanced-stage pancreatic cancer in the United States: A focus on rural and minority health disparities.

Wade T. Swenson II, Emily Westergard, Abigail P Swenson, Zachary Schroeder; University of North Dakota, Grand Forks, ND; Gundersen Lutheran Health System Inc, La Crosse, WI; Medical College of Wisconsin - Green Bay, De Pere, WI; University of Kansas School of Medicine, Kansas City, KS

Background: Our research delves into the geographical distribution and accessibility of clinical trials for metastatic pancreatic cancer patients in the U.S., spotlighting the challenges faced by rural communities and minority groups. Prior research indicated nearly half of these patients would have to commute over an hour to reach a trial site. [1] Our study provides a refreshed perspective on this issue, offering a more comprehensive analysis. **Methods:** Utilizing the ClinicalTrials.gov portal, we identified active interventional clinical trials for metastatic pancreatic cancer patients as of November 25, 2022. We obtained distinct zip codes linked to these trials and, using 2020 census data, gauged the proportion of the U.S. populace residing within specific distances from these sites. Our analysis encompassed factors like urbanity, ethnicity, and other socio-economic parameters. We also developed illustrative maps to visually represent the U.S. clinical trial accessibility landscape. **Results:** The majority of Americans diagnosed with metastatic pancreatic cancer have clinical trials within their reach. A significant 65.7% of the U.S. populace resides within a 30-mile radius of a relevant clinical trial site. However, a closer look reveals pronounced disparities based on urban-rural demarcations and racial lines, with American Indians facing the most pronounced accessibility challenges. **Conclusions:** Our data underscores the uneven geographical spread of these trials. This skewed distribution poses accessibility hurdles for specific demographics, especially those in rural areas and certain racial groups. Our findings underscore the pressing need for strategic initiatives to rectify these disparities, ensuring clinical trials are within reach for every individual, irrespective of their location or background. Research Sponsor: None.

11049 Poster Session

Clinical applicability of guideline-recommended molecular targets and genome-targeted cancer therapies.

Ariadna Tibau, Thomas J. Hwang, Jerry Avorn, Aaron S. Kesselheim; Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; Brigham and Women's Hospital, Boston, MA; Brigham and Women's Hospital and Harvard Medical School, Boston, MA

Background: Genomic testing has expanded the possibilities of precision medicine, particularly for advanced, treatment-resistant cancer cases. However, the clinical relevance of most genetic alterations remains uncertain, which can lead physicians to overestimate the benefits of tailored therapies. The National Comprehensive Cancer Network (NCCN) guidelines are cancer-specific treatment recommendations that often determine insurance coverage. We assessed the evidence for clinical benefit and actionability of molecular targets for genome-targeted cancer drugs recommended by NCCN. **Methods:** We identified genome-targeted therapies for solid cancers from the most recent NCCN guidelines. Trial design characteristics were obtained from publications supporting the NCCN recommendations. Genome target actionability was assessed with the European Society for Medical Oncology (ESMO) Scale for Clinical Actionability of molecular Targets (ESCAT). This ranges from genome alternation-therapy combinations that lead to improved outcomes (Tier I) to treatments with potential clinical relevance (Tiers II or III) to those with undetermined relevance (Tiers IV to X). Clinical benefit was evaluated using the ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS). Molecular targets at ESCAT Tier I in combination with a given treatment associated with studies demonstrating substantial clinical benefit by ESMO-MCBS (Grades 4-5) were designated as high-benefit, while those linked to studies achieving an ESMO-MCBS Grade of 3 were categorized as promising but unproven. **Results:** We extracted411 recommendations from NCCN supporting 74 genome-targeted drugs targeting 50 driver alterations. Most recommendations (346/411, 84%) referred to clinical trial data, while one-sixth (65/411, 16%) relied on case reports or preclinical studies. Clinical trials were mostly Phase I or Phase II (271/346, 78%), single arm (262/346, 76%), and evaluated overall response rate as the primary endpoint (271/346, 78%). Over half of target recommendations had Tier I target actionability (246/411, 60%), over one-third were Tier II or III (142/411, 35%), and the rest were undetermined (23/411, 6%). Among 267 scorable trials,12% (32/267) demonstrated substantial clinical benefit (ESMO-MCBS Grades 4-5) and 45% (121/267) were Grade 3. When combining both frameworks,12% (32/267) genomic-based cancer treatments were high-benefit and 33% (88/267) were promising-but-unproven. **Conclusions:** About one-eighth of genome-targeted cancer therapies recommended in NCCN guidelines received a high benefit rating, while one-third were identified as having a promising but unproven substantial benefit according to the ESCAT and ESMO-MCBS frameworks. Ensuring NCCN recommendations are aligned with well-documented clinical benefits is crucial for promoting informed, evidence-based genomic-guided treatment decisions. Research Sponsor: Hospital de la Santa Creu i Sant Pau Private Foundation.

11050 Poster Session

Administrative burden of establishing health care coverage for the uninsured and its impact on timely access to care.

Laura Wang, Arthur S Hong, Aman Narayan, Navid Sadeghi, Ethan A Halm; UT Southwestern Medical Center, Dallas, TX; University of Texas Southwestern Medical Center, Dallas, TX; Rutgers-RWJBarnabas Health, New Brunswick, NJ

Background: Although safety net coverage programs like Medicaid exist to fund health care for low-income patients, the administrative burden of the lengthy application limits uptake by eligible individuals. Therefore, many patients do not attempt to enroll until they become ill, which is common among uninsured adults diagnosed with cancer. The literature reports worse cancer outcomes for those with Medicaid, but reasons for this are unclear. The delays in enrollment for patients with uncertain coverage at the time of diagnosis – those in limbo – are understudied and may explain some of this persisting disparity. We estimated the patient and health system burdens for those with uncertain coverage status at the time of cancer diagnosis at Parkland Health, the main provider of cancer treatment for the uninsured in Dallas, Texas. **Methods:** We assembled the electronic health record financial encounter data of patients with an incident cancer diagnosis in the Parkland tumor registry, diagnosed from 2010 – 2022. We defined patients as being "in limbo" if they had self-pay, pending, or missing insurance plans at the date of diagnosis. We also included patients whose coverage verification date occurred after diagnosis date, since coverage programs can apply retroactively for 90 days. We used plan verification dates to identify when limbo status resolved. We used coarsened exact matching to balance across age, race, Spanish-language preference, Charlson, and screenable cancer type, then multivariate regression to compare patients that were in limbo to those that had established coverage before cancer diagnosis. **Results:** We identified 17,468 adults newly diagnosed with cancer, 80% of whom were < age 65, 55% female, 73% Hispanic and/or Black, and 30% Spanish-language preferring. The most common cancer types were GI/colorectal (19%), breast (17%), and lung (9%); 23% were advanced stage at diagnosis and 13% died within 180 days of diagnosis. 52.1% were already enrolled in Medicaid/charity care, but one-third (35%) were in limbo at diagnosis, which lasted for a median 31 days (IQR 13 – 126). Over half (55%) of patients in limbo resolved to Medicaid or charity care. Patients who experienced limbo had a median of 596 financial account notes in the first year after diagnosis, 121 more than the comparison group (95% CI 86.7 - 156.1) and began treatment 10 days later (95% CI 7.7 - 12.7). They also had a median of 1 ED visit in the year after diagnosis, 0.2 more than patients never in limbo (95% CI 0.11 - 0.26). **Conclusions:** The administrative burden of enrolling into coverage programs for the uninsured may impose direct and indirect costs on patients and safety-net health systems and may contribute to worse cancer care outcomes. A more comprehensive accounting of the effects of administrative burdens might suggest ways to redesign coverage enrollment for the uninsured to improve care and reduce costs. Research Sponsor: American Cancer Society; CSDG-20-023-01-CPHPS; Texas Health Resources Clinical Scholars Program; CSDG-20-023-01-CPHPS.

11051 Poster Session

The annual cost of cancer screening in the U.S.

Michael T. Halpern, Benmei Liu, Douglas R. Lowy, Samir Gupta, Jennifer M. Croswell, Paul Doria-Rose; National Cancer Institute, Bethesda, MD; University of California, San Diego School of Medicine, San Diego, CA

Background: Cancer screening can decrease cancer incidence, mortality, and treatment costs. However, the annual cost of screening to the U.S. healthcare system is unknown. **Methods:** We used data from national healthcare surveys and standard costing sources to model the healthcare system cost of breast, cervical, colorectal, lung, and prostate cancer screening in the U.S. in 2021. Models projected the number of individuals in the U.S. eligible for each screening test based on current guidelines/recommendations; the number of eligible individuals screened by insurance status; and the costs associated with screening (in 2021 US dollars). Multiple sensitivity analyses were performed to examine the effects of changing model population parameters and costs on projected outcomes. **Results:** Total 2021 cancer screening costs to the U.S. healthcare system were estimated to be $57 billion; approximately 88% of the costs were attributable to private insurance, 9% to Medicare, and 3% to Medicaid, other government programs, and uninsured individuals. Most screened individuals had private insurance except for lung cancer screening, where a majority of individuals screened had Medicare coverage. Individuals with private insurance accounted for the majority of costs for each screening modality. Screening for colorectal cancer represented approximately two-thirds of the total cost; screening colonoscopy was approximately 60% of the total cost of cancer screening. Breast and cervical cancer screening represented the second and third largest screening costs, 15.4% and 14.7% (respectively) of total screening costs. Facility costs (amounts paid to facilities where testing occurred) were generally larger components of the total estimated costs of screening than were physician costs. Cost estimates were robust to a range of variations in eligible populations and screening costs. **Conclusions:** The $57 billion estimated annual cost for cancer screening in the U.S. in 2021 is similar to the estimated annual cost of cancer treatment in the U.S. in the first 12 months following diagnosis. Screening may have been suboptimal in 2021, with higher screening rates and costs in subsequent years. Identification of cancer screening costs and their drivers is critical to help inform policy and develop programmatic priorities. The model can be used to estimate the increased costs of enhanced access to recommended cancer screening services among underscreened populations, which would provide population-wide benefits. Research Sponsor: None.

11053 Poster Session

Advancing breast cancer care for underserved women: A study of the Pink Ribbon Mammogram Program in Oakland County.

Kim Abbegail Tan Aldecoa, Nikhil Vojjala, Fathima Shehnaz Ayoobkhan, Andrea Briefs-Ferris, Jennifer Orejuela, Annelise Fernandez, Asad Mohammad Jani, Grey Dietz, Myroslava Tsukan, Ryan Clark, Victoria Golston, Ashley Fitts, Brendan Mamon, Danyal Wani, Pearl Imoh, Oluwatosin Cooper, Jasmine Jones, Camelia Arsene, Amy Kirby, Judie R. Goodman; Trinity Health Oakland Hospital/Wayne State University, Pontiac, MI; Trinity Health Oakland Hospital/Wayne State University School of Medicine, Pontiac, MI; Ross University School of Medicine, Bridgetown, Barbados

Background: The Pink Ribbon Mammogram program, a non-profit initiative in Oakland County, Michigan, aims to provide free breast cancer screening (BCS) to underserved and uninsured women, in partnership with Trinity Health Oakland. The program has served approximately 1500 women since 2009. This study aims to highlight the program's effectiveness in providing free BCS and gather participant feedback to address challenges and improve its operational efficiency. The study also aims to evaluate the factors associated with participants' perceptions of BCS using the Revised Champion's Health Belief Model scale (RCHBMS) and open-ended questions. **Methods:** A survey with open- and close-ended items was conducted among 253 women who participated in the program from 2019-2023 via structured telephone interviews. The RCHBMS, a validated tool, was used to measure participants' perceptions of breast cancer susceptibility and screening benefits and barriers using a 5-point Likert scale (1=strongly disagree, 5=strongly agree). SPSS 28 was used for analysis, with a p-value$<$0.05 indicating statistical significance. **Results:** Over the last 5 years, the program has conducted 363 mammograms, 59 ultrasounds, and 2 biopsies, leading to 1 confirmed and treated case of breast cancer. Among 253 individuals with valid contact details, 96 consented to participate in the survey. Participant demographics are as follows: mean age 50 years; 80% Hispanic, 15% White, 5% Black; 76% primarily Spanish-speaking; all are uninsured or with high copay. The main reasons for participating included the benefit of free coverage (32.3%) and reassurance of being breast cancer-free (31.3%). 44% reported no issues in attending their appointments, while 8.4% faced logistical challenges, equally divided between work commitments and transportation issues, which were the main causes for missed appointments. The primary motivation for 81.3% of participants undergoing mammogram screening was early breast cancer detection. Using RCHBMS, the study also revealed a correlation between participants' perceived susceptibility for breast cancer and their attitudes toward mammogram screening. Those who felt more susceptible to breast cancer also perceived greater barriers and lesser benefits to screening ($p<0.05$). Factors such as younger age, disability, and having private insurance with high copay were associated with increased perceived susceptibility to breast cancer ($p<0.05$). **Conclusions:** This study serves as an important evaluation of a community-driven BCS initiative, highlighting its successes and areas for improvement to better serve underserved populations. This program can serve as a model to increase BCS nationwide. Insights into factors influencing screening perceptions among underserved women offer valuable guidance for healthcare providers and policymakers to improve screening outcomes in similar communities. Research Sponsor: None.

11054 Poster Session

Cancer care service use intensity in Medicare Advantage versus traditional Medicare.

Aaron Philip Mitchell, Yamini Kalidindi, Roger Feldman, Caroline Carlin, Ge Song, Jeah Jung; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY; McDermott+ Consulting, New York, NY; University of Minnesota, Minneapolis, MN; George Mason University, Fairfax, VA

Background: Prior studies have found evidence of lower cost of care and preserved care quality among Medicare Advantage (MA) plans vs. traditional Medicare (TM). However, MA performance for patients with serious conditions such as cancer is yet to be explored. MA plans are incentivized to reduce expenditures, and the high financial cost (often with marginal clinical benefit) of chemotherapy might be an opportunity for savings. We compared service use intensity and quality between MA and TM cancer patients receiving systemic therapy. **Methods:** Medicare claims data and MA encounter records (including only MA contracts that had highly complete data), 2015-2019. We included patients with select major cancer types, and measured outcomes during a 6-month chemotherapy episode, defined by the date of systemic therapy initiation after a 1-year washout period. Service use intensity was measured in dollar terms using standardized Medicare prices. Quality measures included treatment-related emergency department (ED) visits and hospitalizations, avoidable ED visits, preventable hospitalizations, and overall survival. To estimate the association between MA enrollment and these outcomes, we used regression models with county-level fixed effects and inverse probability of treatment weighting to balance the MA and TM samples on patient demographics, cancer type, health-risk score, metastatic status, frailty, and area characteristics. We performed separate analyses by cancer type. **Results:** The study sample comprised 96,501 MA and 206,274 TM beneficiaries who had one of seven cancer types: breast cancer, chronic leukemia, colon cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer, and who initiated systemic therapy between 2016 and 2019. Estimated mean overall service use among MA enrollees was $62,599, compared to $71,317 for TM beneficiaries (-$8,718, $p<0.01$). A majority of the overall difference was accounted for by Part B-covered systemic therapy drugs ($20,691 in MA versus $25,723 in TM, difference -$5,032, $p<0.01$). Although MA enrollees received slightly cheaper drugs (-$277 per treatment day, $p<0.01$), the lower cost of systemic therapy was driven largely by a lower number of treatment days occurring per 6-month episode for MA enrollees (-1.06 days, $p<0.01$). MA enrollees had fewer treatment-related ED visits and hospitalizations (-2.5%, $p<0.01$ and -0.7%, $p<0.01$ respectively) but had more avoidable ED visits (+0.5%, $p<0.01$). There was no difference in survival or preventable hospitalizations. Results were similar within individual cancer types. **Conclusions:** MA enrollment is associated with reduced service utilization but not shorter survival among cancer patients receiving systemic therapy. Further research is needed into the mechanisms of these savings to identify areas where care may be delivered more cost-effectively without negatively impacting outcomes. Research Sponsor: National Institute on Aging (NIA); 1R01AG069352-01A1.

Assessing the true cost of cancer screening: Comparing hospital prices to claims remittance data for common cancer screening tests at top-ranked US hospitals.

Mason Alford, Austin Triana, Katherine Baker, Yash Trivedi, Samyukta Mullangi, Larry Van Horn; Vanderbilt University School of Medicine, Nashville, TN; Vanderbilt University Medical Center, Nashville, TN; Vanderbilt-Ingram Cancer Center, Nashville, TN; Tennessee Oncology, Nashville, TN; Owen Graduate School of Management, Nashville, TN

Background: Patients in the United States often lack information about the price of common cancer screening services across hospitals and payers. Recent legislation in the US, including the 2021 Hospital Price Transparency Final Rule and the No Surprises Act of 2022, require hospitals to post payer-specific negotiated prices for all services, creating a unique opportunity to understand variation in hospital pricing. While there has been much study regarding the wide variations in prices for healthcare screening services, little is known about the relationship between the prices for screening made publicly available by hospitals and the actual claims remittance recorded for those same services. **Methods:** We extracted payer-specific prices for four common cancer screening tests among 20 top-ranked US hospitals: colonoscopy, low-dose helical computed tomography (CT) scan, mammography, and prostate-specific antigen (PSA). Additionally, we extracted the cash prices published by these same hospitals and determined the median cash price for each screening service. To evaluate price variation for these screening tests, we determined the median and inter-quartile range (IQR) across all payers for these 20 hospitals. We compared this hospital pricing data to the 835 claims remittance data from December 1, 2021 to January 15, 2022. **Results:** Across 20 top US hospitals, the median hospital price for colonoscopy was $1597 (IQR $1780) and median claims price was $806 (IQR $788). The median hospital price for low-dose CT was $315 (IQR $472) and median claims price was $126 (IQR $83). The median hospital price for mammogram was $300 (IQR $351) and median claims price was $72 (IQR $83). The median hospital price for PSA was $85 (IQR $113) and median claims price was $29 (IQR $10). For all four screening tests, the median cash price was greater than the median negotiated price by an average of 27%. **Conclusions:** For common cancer screening tests, the distribution of hospital prices is wider than the actual prices reflected in claims data for the same screening services. Median cash prices published by hospitals were greater than the median negotiated rates for all cancer screening services, consistent with trends observed among large academic centers in metropolitan areas. Policies that improve precision in price estimates may help improve adherence in the United States for uninsured patients by providing more accurate information about prices for common cancer screening services. Research Sponsor: None.

	Median Negotiated Price (Hospital)	Q1-Q3 (Hospital)	Median Price (Claims)	Q1-Q3 (Claims)	Ratio of IQR (Claims) to IQR (Hospital)	Median Cash Price (Hospital)
Colonoscopy	$1597	$962-2742	$806	$633-1421	0.44	$1993
Low-Dose CT	$315	$132-604	$135	$99-182	0.18	$459
Mammogram	$300	$140-491	$72	$47-130	0.24	$355
PSA	$85	$20-133	$29	$23-32	0.07	$102

11056 Poster Session

Financial toxicity during pediatric cancer therapy: A qualitative analysis.

Timothy James Daeeun Ohlsen, Malika R Hale, Anika J Larson, Salene M. W. Jones, Fred Wilkinson, Linda K Ko, Eric Jessen Chow, Arti D Desai; University of Washington, Seattle, WA; Seattle Children's Hospital, Seattle, WA; Fred Hutchinson Cancer Center, Seattle, WA

Background: Childhood cancer treatment may often result in adverse financial consequences—also termed financial toxicity (FT)—for patients and families. Limited research has specifically examined mechanisms and drivers of FT salient to pediatric oncology. **Methods:** Using a phenomenological approach, we conducted in-depth interviews with a purposive sample of English- and Spanish-speaking parents of children receiving treatment for cancer at our institution. Parents were interviewed 6-18 months after a first cancer diagnosis, a period chosen to balance accumulation of financial challenges after treatment initiation with minimal recall bias. Interviews were coded by 3 investigators using an inductive, open-ended approach. We performed thematic analysis of interview transcripts focused on elucidating the main components of FT and relationships between them, identifying ameliorating and exacerbating factors, and exploring the impact of FT on patient and family well-being. We organized relationships between themes into a conceptual framework. **Results:** We interviewed 21 parents (86% mothers, 59% >40 years old, 33% non-Hispanic White, 47% college-educated, 42% of those reporting had a household income of $50-100k, equal proportions above/below this). We identified 5 themes. Four themes pertained to primary elements of FT: (1) increased out-of-pocket spending, often related to additional caregiving and household coordination needs; (2) reduced income, primarily from employment changes inadequately covered by paid leave; (3) new material hardship, with families unable to afford costs of living when previously able to do so; and (4) elevated psychological distress regarding finances. We also identified an additional theme pertaining to response behaviors directed at managing FT, effects of which could be positive ("adaptive behaviors"), negative ("maladaptive behaviors"), or mixed. Response behaviors included reducing discretionary spending, selling off assets, skipping meals, requesting money from strangers, and rummaging through discarded items. Several exacerbating and ameliorating factors pertinent to the development of FT emerged, including household location, composition, wealth, employment flexibility, resource provision, and duration and severity of treatment. Parents provided perspectives regarding policies or interventions to mitigate FT, such as toolkits to better connect families with financial resources and extended paid family leave. **Conclusions:** Families of children with cancer face a wide range of financial toxicity throughout treatment, and many of these experiences differ considerably from those of adult patients. Many families reported substantial impact and unmet needs. These findings will help inform the design of quantitative measures specific to pediatric cancer and identify unique targets for intervention development and policy change for children with cancer. Research Sponsor: Conquer Cancer, the ASCO Foundation; Rally Foundation for Childhood Cancer Research.

11057 Poster Session

Overlapping and non-overlapping indications for checkpoint inhibitors in the US.

Jeddeo Paul, Aaron Philip Mitchell, Aaron S Kesselheim, Benjamin N Rome; Brigham and Women's Hospital, Boston, MA; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Since the first checkpoint inhibitor was approved in 2014, this class of cancer drug has revolutionized the treatment of several malignancies. As of January 2024, 11 checkpoint inhibitors have been approved by the US Food and Drug Administration (FDA), each with its own particular indications. We assessed the overlap of approved indications, which has implications for competition and price negotiation by payers. **Methods:** In this cross-sectional study, we evaluated the FDA-approved indications for 11 checkpoint inhibitors as of January 2024. Indications were defined by cancer tissue type (or mutation status for non-tumor-type indications), stage, and line of treatment (first-line, second-line, third-line, or fourth-or-greater-line). Non-overlapping indications were defined as those with only a single drug approved; for overlapping indications, we tabulated the number of approved drugs. **Results:** The 11 FDA-approved checkpoint inhibitors were associated with 43 distinct indications, ranging from 2 (retifanlimab, toripalimab, and tremelimumab) to 35 (pembrolizumab) indications per drug. Fifteen (43%) indications were non-overlapping. Pembrolizumab had 11 non-overlapping indications (e.g., certain breast, cervical, and urothelial cancers); all other drugs had between 0 and 2 non-overlapping indications (Table). Among the 28 overlapping indications, 15 (54%) had approvals for 2 drugs, 9 (32%) had approvals for 3 drugs, 3 (11%) had approvals for 4 drugs, and 1 (3%; non-small cell lung cancer) had approvals for 7 of the 11 drugs. **Conclusions:** Checkpoint inhibitors are FDA-approved for a total of 43 different indications, but most indications were included on the labeling of 3 or fewer drugs in this class. Over 1 in 3 indications had only 1 approved drug, most commonly pembrolizumab. This limited overlap of indications suggests that manufacturers may avoid seeking approval for indications that already have multiple approved drugs of the same class, which may decrease competition and lead to sustained high drug prices. To provide patients with better information about the checkpoint inhibitor most appropriate for their cancer, the NIH could fund, and the FDA could encourage, more direct comparative effectiveness trials. Research Sponsor: None.

Checkpoint Inhibitor	Date of First FDA Approval	# of Total Indications	# of Mon-overlapping Indications	# of Indications Overlapping with >3 Other Drugs
Ipilimumab (Yervoy)	Mar 2011	8	0	4
Pembrolizumab (Keytruda)	Sep 2014	35	11	4
Nivolumab (Opdivo)	Dec 2014	18	2	4
Atezolizumab (Tecentriq)	May 2016	7	1	2
Avelumab (Bavencio)	Mar 2017	4	0	1
Durvalumab (Imfinzi)	May 2017	5	0	1
Cemiplimab (Libtayo)	Sep 2018	4	1	1
Tremelimumab (Imjudo)	Oct 2022	2	0	1
Retifanlimab (Zynyz)	Mar 2023	2	0	0
Dostarlimab (Jemperli)	Jul 2023	4	0	1
Toripalimab (Loqtorzi)	Oct 2023	2	0	0

11058 Poster Session

Association of characteristics of cancer, patient, and county with telemedicine services use: Impact of the waiver of reimbursement restrictions on telemedicine.

Hyo Jung Tak, Andrew M Goldsweig, Min Sok Lee, Dana Verhoeven, Ronnie D Horner; University of Nebraska Medical Center, Omaha, NE; Baystate Medical Center and University of Massachusetts-Baystate, Springfield, MA; University of Chicago, Chicago, IL

Background: Telemedicine services have great potential to improve access to care of cancer patients who are vulnerable in health status and may experience financial hardship due to the cost of their care. However, very little is known about how the Centers for Medicare and Medicaid Services' waiver of reimbursement restrictions on telemedicine and characteristics of cancer affected their use of telemedicine services. We examined the changes in frequency of telemedicine use before and after the waiver and, after the waiver, the determinants of telemedicine use across medical provider types. **Methods:** We used the 5% Surveillance, Epidemiology and End Results registry file linked to Medicare data among patients who had a newly diagnosed cancer in 2019 and were enrolled in Medicare Parts A and B during 2019-2020, and Area Health Resources File. Our outcomes were binary variables of telemedicine services use in outpatient (OP), office-based clinics (OB), and emergency department (ED), respectively, and for detailed provider types in OB. Primary independent variables included the ten most frequently observed cancer sites (reference: all other sites), sequence of cancer, stage of diagnosis, and quarter of diagnosis in 2019. Analysis was by a multilevel mixed effects logistic regression model, adjusting characteristics of cancer, patient and county. **Results:** Among eligible patients (n = 14,226), telemedicine services use for all provider types increased from 4.3% in pre-waiver period to 40.3% (5.2% in OP, 39.3% in OB, and 0.2% in ED) in post-waiver period. Telemedicine services use varied by primary cancer site, but was higher for those with a cancer recurrence (odds ratio [OR] 1.36, 95% confidence interval [CI] 1.16-1.60) and advanced cancer stage (OR 1.24, 95% CI 1.03-1.48). For visits to oncologists, cancer characteristics such as recurrence (OR 1.67, 95% CI 1.34-2.08), advanced stage (OR 5.52, 95% CI 4.12-7.40) and diagnosis in the last quarter in 2019 (OR 1.39, 95% CI 1.20-1.61) were associated with greater use of telemedicine. Patients of older age and minority race/ethnicity and in non-Northeast regions were less likely to use telemedicine, while women, patients with dual eligibility for Medicaid, and those living in a county with high median household income and high availability of hospital beds were more likely to use telemedicine. **Conclusions:** Cancer patients used telemedicine services more frequently after the waiver and their cancer characteristics were most strongly associated with that use, implying their greater need for, and benefit from, telemedicine. Disparities in telemedicine use related to individual and county-level socio-demographics and medical supply suggest health policy changes to improve equitable access to telemedicine and efficient cancer care planning. Research Sponsor: National Cancer Institute/ U.S. National Institutes of Health.

Opioid prescribing trends and pain scores among adult patients with cancer in a large health system.

Laura Van Metre Baum, Pamela R. Soulos, Madhav KC, Molly Jeffery, Kathryn Jean Ruddy, Catherine C. Lerro, Hana Lee, David J. Graham, Mark Liberatore, Donna Rivera, Michael Leapman, Vikram Jairam, Michaela Ann Dinan, Cary Philip Gross, Henry Soo-Min Park; Yale School of Medicine, Department of Medicine, New Haven, CT; Yale School of Medicine, New Haven, CT; Cancer Outcomes, Public Policy and Effectiveness Research (COPPER) Center, Yale School of Medicine, New Haven, CT; Mayo Clinic, Rochester, MN; Oncology Center of Excellence, U.S. Food and Drug Administration, Silver Spring, MD; U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, Office of the Commissioner, U.S. Food and Drug Administration, Silver Spring, MD; Department of Urology, Yale School of Medicine, New Haven, CT; Yale Cancer Center, New Haven, CT; Yale Cancer Outcomes, Public Policy and Effectiveness Research Center, New Haven, CT; Department of Therapeutic Radiology, Yale School of Medicine, New Haven, CT

Background: Some opioid stewardship policies could negatively affect patients with cancer pain. However, patients with cancer are also at risk for opioid related harms, especially with persistent use. We assessed opioid prescribing trends in the context of cancer treatment and patient reported pain in a large health system in Connecticut. **Methods:** We conducted a retrospective cohort study of opioid-naïve adult patients with solid tumor malignancies diagnosed from 2016 through 2020 within the Yale New Haven Health System. We identified new (≥1 opioid prescription in 0-6 months following diagnosis) and additional (0-6 and 6-9 months) opioid prescriptions. The analysis evaluated all eligible patients as well as two clinical cohorts: patients treated surgically and patients with metastatic cancer. For patients with metastatic cancer and a documented pain score in the electronic health record flowsheet data, we further stratified by any (any score≥1) or no (all scores=0) pain in the 6 months since diagnosis and prior to first opioid, if given. For these patients, we noted therapeutic class of the first opioid. We used a logistic model adjusted for patient demographics to calculate predicted probability of opioid prescription and change over time. **Results:** A total of 10,868 patients met study criteria. Overall, we observed a decline in new opioid prescribing from 69.0% to 62.7% (p<.001) (Table). Additional opioid use also declined from 23.4% to 20.2% (p=.02). In the surgery cohort, new opioid prescribing fell from 95.7% to 88.2% (p<.001), while additional opioid use was stable over time (approximately 12%). For patients with metastatic cancer with any documented pain, new opioid prescribing was stable over time (approximately 56%). For those with documented pain scores=0, new opioid prescribing declined from 59.7% to 34.2% (p<.001). In these patients, the class listed on the first opioid prescription was analgesia in 86.6% and cough in 13.4%. **Conclusions:** Overall, and in patients treated with oncological surgeries, our study in a single large US health system suggests a modest, gradual decline in opioid prescribing for patients with cancer over time. On the other hand, among patients with metastatic cancer, opioid prescribing remained stable for those with documented pain and declined steeply for those without documented pain. Research Sponsor: Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS); U01FD005938.

Change in predicted probability of new opioid prescription.

Strata (N)	Predicted Probability (95%CI)		Relative Change (95%CI)	P-value for comparison of relative change
	2016	**2020**		
Overall (10868)	69.0 (67.3, 70.8)	62.7 (60.8, 64.6)	**-9.2 (-12.6, -5.7)**	n/a
Surgery (4540)	95.7 (94.5, 97.0)	88.2 (85.9, 90.6)	**-7.8 (-10.5, -5.1)**	0.97
Metastatic (2242)	65.0 (60.2, 69.7)	60.0 (55.4, 64.7)	-7.5 (-17.5, 2.3)	
Metastatic – No Pain (687)	59.7 (51.1, 68.4)	34.2 (25.9, 42.5)	**-42.8 (-58.9, -26.6)**	**<.001**
Metastatic – Any Pain (1127)	55.6 (48.4, 62.7)	56.5 (49.6, 63.5)	1.7 (-16.4, 19.9)	

In search of strategies to mitigate financial toxicity in survivorship care: A survey of 347 head and neck cancer survivors.

Ya-Chen Tina Shih, Eden Brauer, Patricia A. Ganz; School of Medicine, University of California, Los Angeles, Los Angeles, CA; University of California, Los Angeles, Los Angeles, CA; Schools of Medicine and Public Health, University of California, Los Angeles, Los Angeles, CA

Background: High costs of cancer treatment exert substantial financial toxicity for patients undergoing treatment. Growing literature suggests lasting financial toxicity (FT) after treatment completion. This calls for the development and integration of mitigating strategies in survivorship care to reduce FT; thereby improving the overall well-being of survivors. **Methods:** Cross-sectional survey data from 347 head and neck cancer survivors were analyzed to explore the relationship between FT and potential targets for intervention. We measured FT using the COmprehensive Score for financial Toxicity (COST, v1), and defined severe, moderate, and mild-to-no FT as having COST score ≤13, 14 to 25, and ≥26, respectively. The survey also collected information on demographics, quality of life, work and activity impairment, and cancer care coordination (CCC) communication and navigation subscales. We conducted logistic regression to examine which COST item is most predictive of severe FT, and mediation analysis using structural equation model to explore potential targets for interventions to reduce FT. **Results:** The average age of respondents was 65.5 yrs (SD=11.3). 334 completed COST; 6.3%, 22.2% reported severe and moderate FT, respectively. Study cohort included 20% diagnosed within 2 yrs, 45% 3-4 yrs and 35% ≥5 yrs; the proportion of patients reporting severe FT did not decrease by year since diagnosis (6%, 5.3%, and 7.7%, respectively, P=0.73). Of the 11 items in COST, financial stress was most predictive of severe FT. Survivors who rated financial stress as "very much" or "quite a bit" were 92.8 (P=0.02) times more likely to have severe FT. Higher financial stress was significantly associated with being < age 65, having higher comorbidity score, lower CCC-navigation score, higher activity impairment; navigation and activity impairment are potentially actionable. None of these four variables were statistically significantly associated with severe FT. Mediation analysis showed financial stress has strong mediation effect on severe FT, and survivors with low CCC-navigation scores and high activity impairment were 3.2 times (95% CI: 1.3 – 7.8; P=0.01) and 2.5 (95% CI: 1.1 – 5.2; P=0.02) more likely, respectively, to report high financial stress. Survivors with high financial stress were significantly more likely to be interested or very interested in receiving resources covering financial issues compared to those without (63.4% vs 17.8%, P<0.01). **Conclusions:** Survivorship care that incorporates interventions designed to improve coordination and navigation and decrease activity impairment can potentially mitigate FT for cancer survivors through reducing their financial stress. The Centers for Medicare and Medicaid Services began paying for navigation services in 2024, opening the opportunity to integrate these interventions into covered navigation services. Research Sponsor: None.

11061 Poster Session

Prospective iterative data visualization (DV) study to enhance health literacy in prostate cancer (PC).

Daniel Eidelberg Spratt, Patrick Bingham, John Randall Eckardt, Shelby Moneer, Matthew Pagano, Kirsten York; University Hospitals Seidman Cancer Center, Case Western Reserve University School of Medicine, Cleveland, OH; ZERO Prostate Cancer, Alexandria, VA; Janssen Global Medical Affairs, Raritan, NJ; buzzback, New York, NY; ENTRADA, New York, NY

Background: Methods used to visualize and present comparative effectiveness research (CER) impact patient (pt) and caregiver (CG) understanding and ultimately treatment decisions. Evidence-based approaches to optimize DV and comprehension in PC are lacking. We studied the presentation and DV of CER with key stakeholders aiming to overcome health disparity/inequity barriers related to understanding of CER DV. **Methods:** A panel representing pt and advocate, industry, and health care provider viewpoints provided qualitative feedback on multiple CER DV methods and generated a survey for US PC pts and CGs. Respondents were identified by a market research agency (buzzback, n=192) or a pt advocacy group (ZERO Prostate Cancer, n=58). Respondents first reported on comfort with and understanding of scientific data on PC using a Likert scale, then evaluated a randomly assigned graphic (1 of 2 versions each depicting the same information) for each of 4 topics. For efficacy and prostate-specific antigen (PSA) data, figures showed superiority of treatment over placebo; for safety, figures positively or negatively represented outcomes. For quality of life (QoL), overall QoL and specific QoL domains were illustrated. For each graphic, respondents first suggested their own key takeaway, then selected the best from 4 options, and reason for selection. Graphics were then assessed side by side with better key takeaway selected to create an overall story. **Results:** Respondents (pts, n=199; CGs, n=51) enrolled between Aug and Sep 2023; 54% were non-White; 52% had an annual income <$75,000/yr; 45% had no college degree. Some respondents reported being uncomfortable/neutral toward PC scientific data (26%) or found data difficult to understand (35%) or overwhelming (29%). >70% identified correct takeaways for Efficacy and PSA. Figures with numerical data showing a difference between treatment groups (Efficacy, PSA) more effectively communicated key takeaways than those without (Safety, QoL). Figures representing pts without toxicity (positive reporting) versus pts with toxicity (negative reporting) were better understood (62% vs 37%) and communicated (67% vs 33%). Respondents (~55-60%) chose the correct key takeaway for QoL figures, not containing quantitative data, and were divided as to which version best communicated the key takeaway. There were no consistent, robust patterns of differences in accuracy of interpretation based on respondent characteristics, especially for top performing Efficacy and PSA graphics. **Conclusions:** This is one of the first prospective multistakeholder studies in PC to explore comprehension and preferences from a diverse group of pts and CGs. Figures showing a difference between treatments were more accurately interpreted than those conveying parity. We provide a benchmark for best practices for CER DV for pts and CGs to assist in their education and optimize shared decision-making. Research Sponsor: Janssen.

11062 Poster Session

National survey of patient perspectives on medication costs among co-pay assistance recipients with cancer.

Anh B. Lam, Ryan David Nipp, Jill S. Hasler, Bonnie Y. Hu, Gregory J. Zahner, Sarina Robbins, Stephanie B. Wheeler, Erin K. Tagai, Suzanne M. Miller, Jeffrey M. Peppercorn; University of Oklahoma Health Sciences Center, Oklahoma City, OK; University of Oklahoma, Oklahoma City, OK; Fox Chase Cancer Center, Philadelphia, PA; Massachusetts General Hospital, Boston, MA; HealthWell Foundation, Washington, DC; The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: Individuals with cancer may seek assistance from co-pay assistance programs (CAPs) to help with high medication costs. However, little is known about these individuals' perspectives on medication costs and their associations with other patient-reported outcomes (PROs). **Methods:** From 10-11/2022, we conducted a national, cross-sectional survey of CAP recipients with cancer, which asked about patient perspectives on medication costs (knowing monthly spending on medications, belief that health insurance would prevent high medication costs, and inability to afford care even with help paying for medications). We fit logistic regression models to describe associations between patient characteristics, including patient demographics and PROs (depression/anxiety symptoms [PHQ-4], financial toxicity [COST tool, score <14 indicates high financial toxicity], and health literacy [Brief Health Literacy Screener]), with patient perspectives. **Results:** Among 1,108 survey participants (median age=72 [range 41-92], 60% male sex), the most common cancer types were multiple myeloma (54%) and prostate cancer (13%). The majority of participants reported knowing their monthly spending on medications (75%); most believed their health insurance would prevent them from high medication costs (67%); under half reported an inability to afford care even with help paying for medications (41%). Factors associated with lower odds of knowing monthly medication spending included Black race (OR=0.45, P=.005), having Medicare Advantage (OR=0.73, P=.036), lack of supplemental insurance (OR=0.68, P=.011), more comorbidities (OR=0.52, P=.002), depression symptoms (OR=0.61, P=.013), and low health literacy (OR=0.43, P<.001). Factors associated with believing that health insurance would prevent high medication costs were depression symptoms (OR=1.54, P=.02), anxiety symptoms (OR=1.40, P=.045), and financial toxicity (OR=2.24, P<.001). Factors associated with reporting an inability to afford care even with help paying for medications included Hispanic ethnicity (OR=2.55, P=.024), more comorbidities (OR=1.84, P=.003), depression symptoms (OR=3.16, P<.001), anxiety symptoms (OR=3.60, P<.001), and financial toxicity (OR=7.83, P<.001). **Conclusions:** In this large sample of CAP recipients with cancer, most reported knowing their monthly medication spending, believing health insurance would prevent high medication costs, and feeling able to afford care with help paying for medications. We identified patient characteristics associated with these perspectives and found correlations between depression/anxiety symptoms, financial toxicity, and low health literacy with greater concerns regarding medication costs. Efforts to mitigate financial toxicity by reducing adverse effects of medication costs in oncology should consider patients' perspectives and their impact on PROs. Research Sponsor: None.

11063 Poster Session

Oral cancer drug repositories: Challenges and solutions.

Medha Sharath, Scott F. Huntington, Stephanie Halene, Osama Abdelghany; Bangalore Medical College And Research Institute, Bengaluru, India; Yale University, New Haven, CT; Yale School of Medicine, New Haven, CT; Yale-New Haven Hospital, New Haven, CT

Background: Frequent drug shortages and high out-of-pocket costs due to inadequate and unaffordable insurance coverage hinder access to oral chemotherapy. Amidst this, oral cancer drugs estimated a mean of $4290/patient are wasted due to dose modification, discontinuation or death[Lam M. et al, JAMA Oncol. 2023;9(9):1238-1244]. To combat this discrepancy, multiple states have passed laws establishing drug repositories that collect unused oral cancer medications and redistribute them to patients in need. ASCO has also endorsed these programs, even advocating for open distribution systems allowing donations from individuals. **Methods:** We analysed statewise cancer drug repositories(source:National Conference of State Legislatures) and communicated with representatives from programs including SIRUM, RemediChain and I-DROP Coalition. We used a mixed methods approach to examine the breadth and functioning of these programs. **Results:** 28 out of the 44 states with laws establishing prescription drug repositories operate state-run drug recycling programs (Updated September 2023). However, only 14 states (California, Florida, Iowa, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Tennessee, Utah, Washington and Wisconsin) have provisions for donation of cancer medications, or for creation of separate cancer drug repositories. Other nonprofits like RemediChain and SIRUM function at a national level, covering 47 states and Washington D.C. between them. Conversations with 3 such programs revealed multiple obstacles that limit the effectiveness of drug recycling. All 3 programs reported inadequate donations, ranging from 2-3 donations/month in a state level program (I-DROP) to 1-10 donations/day in a larger national level program (RemediChain). 3/3 programs received more donations of unused pills from patients or their families than from pharmacies/health facilities. All 3 surveyed programs reported limited and inconsistent supply of donated drugs; expiration of drugs before re-distribution; lack of demand for specialty drugs and unavailability of common oncology drugs that patients request since these drugs are less likely to go unused. All surveyed programs mentioned struggling with funding and staffing. Notably, all 3 repositories stressed that informing patients about recycling options right at the beginning of treatment was crucial to improve donation rates; and that expanding repository donor and recipient coverage could increase the chances of successfully redistributing drugs. **Conclusions:** Improving awareness amongst providers and patients, campaigning for federal funding and increasing the scale of coverage by expanding repository programs to all states and allowing interstate transfer of drugs could address current challenges to drug recycling. This would limit wastage of expensive medication while reducing financial burden on patients and improving access to life saving treatment. Research Sponsor: None.

System-level variation in evidence-based multidisciplinary cancer care delivery.

Kelsey B. Montgomery, Joseph Cotler, Joshua S. Richman, Smita Bhatia, Kristy Kummerow Broman; Department of Surgery, University of Alabama at Birmingham, Birmingham, AL; American College of Surgeons, Chicago, IL; Institute for Cancer Outcomes and Survivorship, University of Alabama at Birmingham, Birmingham, AL

Background: Widespread health system integration of hospitals continues to reshape the landscape of U.S. healthcare delivery. While complex cancer care has become centralized to high-volume centers, care for common cancers happens across the spectrum of hospital sizes, with known variation in receipt of evidence-based practice (EBP) based on system affiliation. Strategies are needed to evaluate system performance in order to identify system characteristics and processes that contribute to high-quality cancer care. **Methods:** Using a novel data linkage between the National Cancer Database and AHRQ Compendium of U.S. Health Systems, adult patients treated for breast, colon, melanoma, and thyroid cancers between 2010 and 2020 at Commission on Cancer (CoC) hospitals were identified. Systems were categorized based on number of CoC hospitals (small, 2-3; medium, 4-9; large, 10+). Eight EBP measures were developed using national multidisciplinary guidelines, and measure-specific cohorts were extracted to calculate system-level EBP performance and within-system variation using mixed effects multivariable logistic regression models. Systems were then ranked across all measures for performance and variation, and average rankings were compared by system size. **Results:** 3,052,453 patients with breast (60.0%), colon (17.0%), melanoma (14.0%), and thyroid (9.0%) cancers were treated at 866 CoC hospitals in 368 health systems. The 8-measure analytic cohort had 104 systems, most of which were small systems (n=74, 71.2%). Large systems (n=9, 8.7%) had worse average performance rankings compared to medium or small systems, though this was not statistically significant (p=0.1) (Table). A significant increase in within-system variation (as measured by average ranking of variability across EBP measures) was seen with increasing system size ($p<0.001$). **Conclusions:** Significant variation in EBP performance for common cancers was noted based on health system size in this large, contemporary cohort, with greater within-system variation as system size increased. Future work will identify modifiable system characteristics associated with performance that could aid system leaders and policy makers to design, measure, and incentivize systems that employ effective cancer care delivery strategies. System rankings from 1 to 104 (best to worst), averaged over all measures; data presented as median (IQR). Research Sponsor: Agency for Healthcare Research and Quality; T32HS013852; National Cancer Institute/U.S. National Institutes of Health; 1K08CA283001.

System-level characteristics and EBP performance by system size category.

Characteristic	Overall, N=104	Large Systems, N=9	Medium Systems, N=21	Small Systems, N=74	p-value
System EBP Performance Average Rank	50.8 (39.7, 61.4)	65.1 (50.4, 69.4)	52.8 (42.3, 58.4)	47.2 (39.0, 56.7)	0.1
Within-System Variation Average Rank	49.3 (40.0, 57.9)	64.5 (56.6, 65.4)	54.4 (49.3, 60.8)	46.1 (36.0, 53.2)	<0.001
Number of Hospitals per System	3.0 (2.0, 5.0)	12 (11.0, 15.0)	6 (5.0, 7.0)	2.5 (2.0, 3.0)	<0.001

11065 Poster Session

Trends in pharmaceutical industry payments to US cancer centers, 2014-2021.

Aaron Philip Mitchell, Nirjhar Chakraborty, Meredith Brown, Sonia Persaud, Grace B Gallagher, Niti U. Trivedi, Peter Brian Bach; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY; US Digital Corps, US General Services Administration, Washington, DC, DC; DELFI Diagnostics, Baltimore, MD; Delfi Diagnostics, Baltimore, MD

Background: US National Cancer Institute-designated comprehensive cancer centers (NCICCCs) receive federal funding to support their public missions. However, these institutions also receive substantial funds (both research and non-research) from the pharmaceutical companies, which have private, for-profit goals. The amount of industry money received by NCICCCs, with respect to their federal funding, is poorly understood. The goal of this study was to examine trends in industry payments to US cancer centers. **Methods:** NCICCCs were identified (N=51). Industry payments to each NCICCC from 2014-2021 were obtained from Open Payments, and NIH grant funding from NIH RePORT. Given our interest in NCICCCs, we focused on the subset of industry payments (those designated as being related to a cancer drug, both research and non-research) and NIH grant funding (grants awarded by the NCI specifically, as opposed to other institutes) that were likely to be cancer-related (we also measured overall industry payments and overall NIH funding). In order to capture both industry payments and grant funding broadly, we manually identified teaching hospitals and research universities affiliated with each NCICCC and included payments and grants to these as well. All amounts were inflation-adjusted to 2021 dollars. **Results:** Oncology-related industry payments increased from $320 million in 2014 to $896 million in 2021. NCI funding increased slightly during the same period, from $2,481 million to $2,691 million. Overall industry payments increased from $1,811 million in 2014 to $3,015 million in 2019 (exceeding NCI funding in that year), though overall industry payments subsequently declined to $1,977 million in 2021. Non-research (as opposed to research) payments were the minority of industry payments; the year with the greatest proportion of non-research payments was 2019, at 39%. NCI funding exceeded oncology-related industry payments at all NCICCCs except for two: City of Hope ($1,137 million oncology-related industry payments vs. $311 million in NCI funding) and MD Anderson ($1,040 million vs. $1,001 million). **Conclusions:** Oncology-related industry payments to NCICCCs has increased substantially more than NCI funding in recent years. Although most industry payments are research-related, a substantial portion are not. A small number of NCICCCs receive comparable or greater amounts of money from industry than they receive in grant funding from the NCI. These trends raise concerns regarding the influence of industry payments and the ability of these institutions to maintain their public missions. Research Sponsor: National Cancer Institute; R37CA264563; National Cancer Institute; P30CA008748.

11066 Poster Session

Accelerating cancer research trial startup in the community setting: A quality-improvement study.

Jason Joseph Claes, James F. Maher, Wayne Thompson, Lisa Benoit, Billie Cook, Patrick Newbury, Alyssa Adams, Melinda O'Connor, Emma Ohlhaut, Chelsea Wirthlin; TriHealth Cancer Institute, Cincinnati, OH; Trihealth Cancer Institute, Cincinnati, OH; TriHealth Cancer Institute - Montgomery, Montgomery, OH

Background: There is a large variation in activation times for cancer clinical trials, delaying the opportunity for patients to benefit from cutting edge treatments. Academic medical centers typically take longer to activate a clinical trial as compared to community settings. Some academic medical centers have adopted quality improvement processes to reduce clinical trial start-up time. Our center, TriHealth Cancer & Blood Institute (TCBI) in the SW Ohio community has also adopted quality improvement processes to further reduce startup time within our oncology research group. **Methods:** This study encompassed July 2022-June 2023, with baseline data drawn from January 2021 to December 2021 prior to the study period which revealed a mean clinical trial start-up time of 116 days. The research group used a swim-lane process to define the typical process & stakeholders for clinical activation time at our institution prior to the study time. Our group identified three major areas with significant lag-time - contracts, budgets, & IRB/ICF - with the overarching root cause for delays due to lack of organizational process & expertise in these major areas. Using Plan-Do-Study-Act (PDSA), we instituted interventions, which included utilizing a central IRB, identifying a responsible member with extensive research budgeting to review research study budgets, & identified a responsible member with extensive contracts review & negotiations working with Central Legal throughout the contracts negotiation process with sponsor(s). **Results:** During this 12-month study time, our center demonstrated a 44% reduction in trial start up time (141 days to 79 days), while at the same time doubling the number of active trials. This process change resulted in sustainability that carried into 2023, further reducing start-up time to 70 days. In 2021, we opened 6 studies and after adoption of these process improvements (2022) we doubled the number of studies by 117%, while opening 67% more in 2023 than in 2021. The ability to open more studies has allowed us to shift patient enrollment to more investigational trials while increasing treatment enrollment from 2022 to 2023 by 24%. Through process improvement, more treatment studies are open & available for our community. **Conclusions:** By implementing interventions to streamline clinical trial activation time, our center was able to significantly & sustainably reduce the time required to start a clinical trial in our community health system in a 12-month period, resulting in our ability to initiate more clinical trials. As a result, more treatment trial patients were able to be enrolled in these clinical trials at TCBI, with the hope of improved outcomes. We anticipate that further adoption of just-in-time studies may help to decrease this activation time further. Research Sponsor: None.

Calendar Year	# of Studies	Days	% Reduction
***2021**	6	141	0%
2022	13	79	44%
2023	10	70	50%

*Prior to process improvement.

11067 Poster Session

Inpatient burden and clinical outcomes of cytokine release syndrome in patients with cancer: A National Inpatient Sample study.

Sarah Makhani, Waqas Azhar, Ejaz Shah, Mohammad Junaid Hussain, Ruchika Goel; NYU Grossman School of Medicine, New York, NY; Southern Illinois University School of Medicine, Springfield, IL

Background: Cytokine release syndrome (CRS) is a potentially life-threatening complication commonly seen in patients receiving chimeric antigen receptor (CAR)-T cell therapy, allogeneic stem cell transplant, or immunotherapies. This study aims to evaluate the inpatient burden outcomes of CRS leading to hospitalization in patients diagnosed with cancer. **Methods:** Hospitalizations for cytokine release syndrome (CRS) were identified using ICD-10 coding from the 2020 National Inpatient Sample (NIS), the largest all-payer inpatient database in the US. Only CRS patients with a co-diagnosis of cancer (identified using the Clinical Classification Software (CCS) coding) were included in this study. The underlying severity of illness index was used to verify CRS grading. Sampling weights were applied to generate nationally representative estimates. **Results:** In 2020, there were 4,765 hospitalizations coded with CRS. 27.2% of these admissions had a co-diagnosis of cancer (n=1,295) and were included in the final analysis. The top co-diagnoses in the patients with CRS without cancer were COVID-19 infection and sepsis. Hematologic malignancies had the highest incidence amongst cancer types (75.7%), the distribution was as follows: 29.6% with diffuse large B-cell lymphoma, 19.9% with acute lymphoblastic leukemia, 12.8% with multiple myeloma, 12.2% with acute myeloid leukemia, and 7.7% with mantle cell lymphoma. The most common procedures in oncology patients hospitalized with CRS were CAR-T cell therapy (29.3%), chemotherapy (28.6%), stem cell transplant (8.5%), or Blinatumomab bispecific antibody (5.4%). 11.4% of patients with CRS received tocilizumab. Of those that received tocilizumab, 10% were CRS grade 2, 56.7% were grade 3, 33.3% were grade 4. 51.7% of tocilizumab was given in the first 48 hours of admission. A minority of CRS patients required critical care interventions: 12.0% requiring intubation, 5.8% requiring vasopressor support, and 2.7% received dialysis. Overall, 10.4% of all oncology admissions with CRS resulted in death during hospitalization (n=135). Of these deaths, 92.6% were in the extreme severity of illness and 63.0% were CRS grade 4. Those with CRS who died during hospitalization had a significantly longer length of stay (24.6 vs 13.6 days, $p<0.001$). The overall median hospital charges of a CRS-related admission were $531,692. **Conclusions:** This study represents the inpatient burden of CRS-related admissions in patients diagnosed with cancer. CRS admissions are commonly seen in patients with hematologic malignancies, those undergoing CAR-T cell or immunotherapies (bispecific antibodies). CRS poses a significant healthcare burden, with average hospital charges being greater than 0.5 million US dollars per admission. About 1 in 10 patients with CRS died during hospitalization with higher mortality likely with severe CRS grades and longer length of stay. Research Sponsor: None.

Health-related quality of life (HRQoL) and symptoms in LIBRETTO-431 patients with *RET* fusion-positive advanced non-small-cell lung cancer (NSCLC).

Caicun Zhou, Silvia Novello, Pilar Garrido, Christophe Alfons Dooms, Jorge Arturo Alatorre Alexander, Niels Reinmuth, Adrienne M. Gilligan, Nalin Payakachat, Kim Cocks, Gill Worthy, Koichi Goto; Shanghai Pulmonary Hospital, Shanghai, China; Department of Oncology, AOU San Luigi, Orbassano, University of Torino, Torino, Italy; Medical Oncology Department, Hospital Ramón y Cajal, Universidad de Alcalá, Madrid, Spain; Department of Respiratory Diseases, University Hospitals KU Leuven, Leuven, Belgium; Health Pharma Professional Research, Mexico City, Mexico; Asklepios Lung Clinic, member of the German Center for Lung Research (DZL), Munich-Gauting, Germany; Eli Lilly and Company, Indianapolis, IN; Adelphi Values, Bollington, United Kingdom; Adelphi Mill, Bollington, Cheshire, United Kingdom; Department of Thoracic Oncology, National Cancer Center Hospital East, Kashiwa, Japan

Background: LIBRETTO-431 (NCT04194944), a randomized phase 3 trial, compared first-line selpercatinib to platinum-based chemotherapy +/- pembrolizumab (pembro). Selpercatinib, a highly selective and potent CNS penetrant *RET* inhibitor, is approved for the treatment of advanced *RET* fusion+ NSCLC. This analysis reported NSCLC symptoms and HRQoL from LIBRETTO-431. **Methods:** This analysis used data (cut-off date: May 01, 2023) from the intent-to-treat (ITT) pembro subpopulation [selpercatinib (n=129); chemotherapy + pembro (control, n=83)] to assess time to confirmed deterioration (TTCD) of NSCLC symptoms (cough, dyspnea, pain, fatigue, poor appetite using NSCLC-Symptom Assessment Questionnaire [SAQ]). TTCD of NSCLC symptoms were defined as time from randomization to the first score that met the pre-specified meaningful within-patient change thresholds, confirmed at next assessment. TTCD was compared between treatment arms using log-rank test and Cox proportional hazards model. Changes of NSCLC-SAQ total score (meaningful important difference [MID] ≥2 points) and HRQoL (using EORTC QLQ-C30 Physical Function (MID ≥6 points) and Global Health Status (GHS)/QoL (MID ≥5 points)) up to 1 year were evaluated and compared between the arms using a growth curve model and mixed model for repeated measures. **Results:** Selpercatinib significantly ($p < .05$) delayed TTCD of all individual symptoms with hazard ratio ranging from 0.41 (cough and pain) to 0.57 (dyspnea), compared to control (Table). Selpercatinib also showed a significant and clinically meaningful difference in the mean NSCLC-SAQ total score (difference = -2.0, $p < .001$) and physical function (difference = 8.1, $p = .003$) at 1 year, compared to control. GHS/QoL was improved in both arms with no difference in the mean scores between the arms at 1 year. **Conclusions:** Selpercatinib significantly delayed TTCD of NSCLC symptoms and improved physical function compared to control in this patient population after 1 year of treatment. The findings were consistent with the favorable efficacy of selpercatinib compared with platinum-based chemotherapy + pembro and further support 1L use of selpercatinib in this population. Research Sponsor: Eli Lilly and Company.

Results of TTCD of NSCLC-SAQ symptoms.

NSCLC-SAQ symptom	Median Time (months) (95% CI)		Hazard Ratio (95% CI)	p-value
	Selpercatinib	Control*		
Cough	NE	NE	0.41 (0.21, 0.81)	0.008
Pain	NE	8.8 (1.0, NE)	0.41 (0.21, 0.81)	0.011
Dyspnea	14.0 (4.9, NE)	2.6 (1.3, 7.0)	0.57 (0.36, 0.91)	0.015
Fatigue	14.0 (2.9, NE)	0.8 (0.4, 2.9)	0.54 (0.35, 0.84)	0.005
Poor appetite	16.4 (7.9, NE)	2.3 (1.0, 5.8)	0.45 (0.28, 0.72)	<0.001

*chemotherapy + pembro; CI, confidence interval; NE, not estimable.

11070 Poster Session

Trends in NCCN enforcement of financial conflict of interest policies for guidelines panelists.

Dedipya Bhamidipati, Niloufar Saririan, Pranam Dey, Sonia Persaud, Nirjhar Chakraborty, Sara Tabatabai, Grace B Gallagher, Niti U. Trivedi, Aaron Philip Mitchell; Department of Internal Medicine, Brooklyn, NY; University of Florida, Gainesville, FL; Yale University School of Medicine, New Haven, CT; Memorial Sloan Kettering Cancer Center, New York, NY; Delfi Diagnostics, Baltimore, MD; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Financial conflict of interest (FCOI) among authors of clinical practice guidelines is a potential concern for the independence and integrity of guideline recommendations. The National Comprehensive Cancer Network (NCCN) Guidelines policy stipulates limits on physician-industry FCOI among its panelists (<$50,000 overall and <$20,000 from each individual company, annually). Those in violation will be asked to resign. However, COI policies reliant on physician self-report may be difficult to enforce. The increased transparency of FCOI resulting from Open Payments – and the ensuing attention in 2016 on high levels of FCOI among guideline-writing bodies including the NCCN – may have enabled and motivated increased enforcement of existing FCOI policy. We describe trends in FCOI among NCCN Guidelines panelists and in enforcement when violations occur. **Methods:** We manually extracted NCCN Guidelines panelist names and terms of service for the 20 most prevalent cancers, 2013-22. We manually linked each physician to their Open Payments records, a federal archive of financial transactions from industry to physicians. For each panelist, we included only the categories of industry payments deemed relevant by the NCCN COI policy: ownership payments and some General Payments categories (eg., speaking fees, consulting) but not others (eg., free meals). We measured payments during each full calendar year of service. If a panelist received payments above NCCN limits ("violation"), we assessed whether their term of service continued for at least 1 additional full calendar year ("retained"), inferring that panelists who were retained had not been asked to resign as stipulated. We assessed whether retention post-violation was less likely after 2016. **Results:** There were 978 eligible physician-guideline pairs. Mean industry payments increased from $6175 in 2014 to $9169 in 2019, then declined to $6492 in 2021 following the COVID-19 pandemic. There were 143 panelist-years in violation of NCCN FCOI limits. Violations occurred among 99 unique panelists; 32 panelists had multiple observed violations. Across the full study period, panelists with a violation were less likely to be retained versus those without a violation (OR 0.21, 95% CI 0.15-0.31). However, likelihood of post-violation retention was lower after 2016 compared to before. 81% were retained during 2014-15 (versus 89% for those without violation, OR 0.55, 95% CI 0.26-1.31) compared to 47% during 2017-20 (versus 89% without violation, OR 0.10, 95% CI 0.06-0.17). **Conclusions:** Lower retention among panelists receiving excessive industry payments is consistent with NCCN enforcement of its COI policy. Lower post-violation retention after 2016 is consistent with stricter enforcement following that year. However, even in 2017-20, in 47% of violations, the panelist continued to serve, suggesting that enforcement remains incomplete. Research Sponsor: None.

11071 Poster Session

Healthcare spending after a cancer diagnosis among working-aged adults.

Helen M. Parsons, Marcelo C Perraillon, Roxanne Clark, Cathy J Bradley, Samuel Greenwald, Jingxuan Zhao, Robin Yabroff; University of Minnesota, Minneapolis, MN; University of Colorado Cancer Center, Aurora, CO; Colorado School of Public Health, University of Colorado Anschutz Medical Campus, Aurora, CO; American Cancer Society, Atlanta, GA; Department of Surveillance and Health Equity Science, American Cancer Society, Kennesaw, GA

Background: The cost of cancer care has increased dramatically over the past decades, increasing the financial burden on patients. However, current estimates of healthcare spending and out-of-pocket burden rely heavily on data from older populations, which may not reflect contemporary treatment patterns in working-aged adults given the rise in use of novel therapies and increased incidence at younger ages. **Methods:** We used the 2012-2021 Colorado Central Cancer Registry linked to the All-Payer Claims Database to identify adults aged 22-63 newly diagnosed with cancer. We examined median health plan payments and out-of-pocket spending across the most common insurance and cancer types in six months after diagnosis. **Results:** Among 20,460 individuals newly diagnosed with cancer, the median total spending in the six months after diagnosis was $60,123 for those insured by private fee-for-service (FFS) plans and $26,326 for those insured by Medicaid. The majority of spending was for medical care. Among individuals insured by private FFS plans, those with lymphoma had the highest total median spending at $125,892, followed by lung ($99,823), breast ($87,121), leukemia ($86,776), and colorectal cancer ($76,273). Although total spending was markedly lower among those insured by Medicaid, individuals with leukemia ($52,591) and lymphoma ($46,787) experienced the highest median spending. Out-of-pocket spending was substantially higher for the privately insured ($3,751 or approximately $625/month) across all cancer types, and highest for lymphomas ($4,262), breast ($4,706) and colorectal ($4,216) cancers. **Conclusions:** Total healthcare spending after a cancer diagnosis is significant in the working-aged population and creates a substantial out-of-pocket burden, even among those privately insured. Research Sponsor: Leukemia and Lymphoma Society.

Median spending in the 6 months after diagnosis (in 2021 dollars).

Cancer Type	**Private FFS** Medical Care Plan Payments	**Private FFS** Pharmacy Plan Payments	**Private FFS** Out-of-Pocket Spending	**Private FFS** Total Spending	**Medicaid** Medical Care Plan Payments	**Medicaid** Pharmacy Plan Payments	**Medicaid** Out-of-Pocket Spending	**Medicaid** Total Spending
Overall	51,407	251	3,751	60,123	23,033	625	12	26,326
Lymphomas	120,799	343	4,262	125,892	43,890	705	15	46,787
Breast	79,036	224	4,706	87,121	30,334	443	16	32,680
Lung	73,373	871	3,938	99,823	30,835	1,270	16	34,428
Colorectal	67,257	268	4,216	76,273	24,523	547	10	27,171
Leukemias	46,321	3,310	2,679	86,776	30,909	6,317	18	52,591
Prostate	22,548	96	3,203	28,590	11,218	376	9	12,835
Other	35,516	269	3,289	41,766	18,243	595	11	20,882

11072 Poster Session

Disrupting how we recruit to cancer clinical trials.

Nina A. Bickell, Benjamin May, Ihor Havrylchuk, Jimmy John, Sylvia Lin, Radhi Yagnik, Ariana Tao, Grace C. Hillyer, Bruce Rapkin, Nicholas Tatonetti; Icahn School of Medicine at Mount Sinai, New York, NY; Columbia University Medical Center, New York, NY; Montefiore Einstein Cancer Center, Bronx, NY; Albert Einstein College of Medicine, Bronx, NY; Department of Biostatistics, Columbia University, Mailman School of Public Health, New York, NY; Montefiore Medical Center, Albert Einstein College of Medicine, Department of Oncology, Bronx, NY; Columbia University Irving Medical Center, New York, NY

Background: Traditional methods to identify eligible patients for cancer clinical trials rely heavily on manual review, a time-consuming bottle neck limiting access to novel treatments, particularly for underserved populations. This study presents an automated informatics platform designed to simplify and streamline patient identification and trial matching. **Methods:** Our platform leverages three tools: 1. Parser:Extracts and categorizes trial data based on cancer type, stage, and receptor status from the National Cancer Institute's ClinicalTrials.gov database, storing it in a structured JSON format; 2. Screener: Utilizes Epic Clarity electronic health record data to identify upcoming patients approaching treatment decision points, times when clinical trials are more relevant. Patients are classified as "newly diagnosed" or "potentially progressed" based on progress notes and imaging reports. Eligibility criteria, including stage and receptor status, are assessed using regular expressions; 3. Matcher: Pairs eligible patients with relevant trials based on compatible cancer stage and receptor status. One Cancer Center (CC) is prospectively using the platform to identify patients. The 2nd CC is refining the code using retrospective data. Accuracy was measured comparing automated to manual review by experienced trained abstractors. **Results:** Implementation across two cancer centers yielded: 1. Reduced manual review burden: Between June 2023 – Jan 2024, of 674 breast cancer patients seen at CC #1, 371 were new patients (N=371) and thus, at a treatment decision point; 3 did not undergo imaging. Of the 300 established patients undergoing imaging studies, the algorithm identified 50/300 (17%) scans as "positive," and 61 (20%) with mixed disease progression/regression, requiring manual review and trial matching. 189 scans were read as "negative": 96% True Negatives; 4% were False Negatives. Automated screening reduced manual review from 300 to 111 patients, significantly alleviating workload on healthcare personnel. 2. Variable staging accuracy: While receptor status classification proved effective, stage accuracy varied between centers, highlighting a need for further refinement in this area. 3. Accurate receptor status classification: The system achieved high accuracy in demonstrating reliable assessment of this vital factor. **Conclusions:** This automated informatics platform demonstrates significant potential to streamline case identification for cancer clinical trials and thus, foster broader access to novel therapies. Its adaptability makes it suitable for implementation across diverse healthcare settings, empowering wider participation in advancements in cancer care. Ongoing efforts to refine the staging module are underway. Clinical trial information: NCT05146297. Research Sponsor: None.

Cancer Center	Patients with Upcoming Appt	Stage accuracy	Receptor Status Accuracy
1	**862**(Apr 2023-Jan 2024)	**70%**	**77%**
2	**252**(Sept-Dec 2023)	**48%**	**85%**

11073 Poster Session

Cost trends in standard-of-care cancer treatments, 2017-2021.

Judy J. Wang, Sonia Persaud, Sara Tabatabai, Nirjhar Chakraborty, Pranam Dey, Niti U. Trivedi, Aaron Philip Mitchell; New York Presbyterian/Weill Cornell Medical Center, New York City, NY; Memorial Sloan Kettering Cancer Center, New York, NY; University of Chicago, Harris School of Public Policy, Chicago, IL; Yale University School of Medicine, New Haven, CT; DELFI Diagnostics, Baltimore, MD; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Financial burden of cancer care in the United States is substantial. Prior studies have explored price trends at the level of individual cancer drugs but not that of clinical indications, which can be impacted not only by changes in drug prices but also changes in standard-of-care. This study evaluates temporal trends in the cost of providing the contemporary best guideline-concordant therapy for each cancer indication. **Methods:** We analyzed trends in the cost of the standard-of-care treatments for the 20 most prevalent cancer types, using NCCN Guidelines to identify the standard-of-care (SOC) treatment for each indication. Our primary comparison of interest was the cost of providing the SOC treatment regimen for each indication in 2021 vs. 2017. All solid tumor treatment indications present in the NCCN Guidelines at both study time points, 7/1/2017 and 7/1/2021, were included. Indications that involved radiotherapy or stem cell transplant among the treatment options were excluded. Costs of all recommended treatment options for each included indication were calculated using Medicare reimbursement rates. We included costs of the antineoplastic agents themselves as well as necessary supportive medications. Costs were inflation-adjusted to 2021 USD. We identified the SOC treatment for every indication at both time points by referring to NCCN Evidence Blocks and identifying the regimen(s) with the highest scores (prioritizing Efficacy, then Safety, then Quality, then Consistency, in that order). If multiple SOC treatments for a single indication had identical scores, we chose the least-costly treatment. **Results:** 83 clinical indications across 16 solid tumor cancer types (bladder, brain, breast, colon, kidney, liver, lung, melanoma, oropharyngeal, ovary, pancreas, prostate, rectal, soft tissue, stomach, and uterus) were included. Median SOC cost was $8,364 (IQR = $3,838, $15,783) in 2017, compared to a median of $4,290 (IQR = $1,438, $14,947) in 2021. 57 indications (68.7%) had lower SOC costs in 2021 vs 2017, with median change of -$935 (IQR = -$4,432, +$452), representing a 31% decrease (IQR = -50%, 8%). Gastric cancer perioperative chemotherapy had the biggest absolute cost decrease at $65,612 (-90%), while extensive stage small cell lung cancer had the biggest absolute increase at $37,213 (706%). 45 indications (54.2%) had the same SOC regimen across this study period, of which 75.6% saw price drops. Of the 38 indications with new SOCs, 60.5% had lower costs. **Conclusions:** Majority of the best SOC treatments decreased in cost over a 4 year period. Although introduction of newly approved drugs can cause large price increases for some indications, more commonly the financial cost of delivering the standard-of-care treatment for a given cancer trended down due to slower-than-inflation price increases and new generic entrants. Research Sponsor: None.

11074 Poster Session

Risk prediction model for acute care use among patients with advanced cancer on clinical trials.

Dawn L. Hershman, Cathee Till, Riha Vaidya, Michael Leo LeBlanc, Joseph M. Unger; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY; Fred Hutchinson Cancer Research Center, Seattle, WA; SWOG Statistics and Data Management Center/Fred Hutchinson Cancer Research Center, Seattle, WA

Background: Reducing acute care use is an important strategy for improving value. Patients with advanced cancer are at high risk for unplanned Emergency Room visits (ER_visit) and hospital stays (HS). Identifying patients at highest risk could inform personalized risk-based intervention strategies and resource allocation. **Methods:** The data were from the SWOG Cancer Research Network. We linked data from trials in advanced cancer to Medicare claims data. The primary endpoint was the occurrence of any HS or ER_visit within 1 year after enrollment. Patients were required to have had continuous Medicare parts A and B claims from registration to 12 months after registration or death to detect all utilization outcomes. We examined sociodemographic (age, sex, race, ethnicity, insurance status), geographic (rural or urban, area-level deprivation), clinical (prognostic risk, performance status), treatment characteristics (line of therapy, therapy type), and individual comorbidity factors to establish a predictive risk model. Twenty-six factors were evaluated. A training/test approach was used. First, a 60% random sample training set of patients was generated. Best subset selection was used to identify candidate variables that minimized mean squared error using 5-fold cross validation repeated 10 times. Candidate variables were examined in multivariable logistic regression, with factors with $p<.05$ retained. A risk model was built by summing adverse factors and creating high vs low- risk groups by splitting at the median and into quartiles. The derived model is reported. **Results:** Among N=1397 total patients from 6 trials (lung, 3; prostate, 2; pancreas, 1), 839 (60%) comprised the training set. In these, 32.9% were 75+ years, 21.3% were female, and 7.7% were Black. The overall proportion of patients with >1 hospitalization/ER visit was 67.5%. In the training set, adverse risk factors were first line treatment (vs. subsequent), high (vs. low) prognostic risk, coronary artery disease (yes vs. no), hypertension (yes vs. no), and liver disease (yes vs. no). Patients with >2 factors (high risk; n=487, 58.0%) vs. 0/1 risk factor (low risk; n=352, 42.0%), were more likely to experience hospitalization/ER visit (80.3% vs. 49.7%, $p<.001$), corresponding to a >4-fold increase in risk (OR=4.12, 95% CI, 3.03-5.59, $p<.001$). Quartile-level proportions were 38.8%, 55.4%, 76.8%, and 84.0%, respectively, with an eight-fold increased risk for those in the highest vs. lowest quartiles (Q4 vs. Q1, OR=8.25, 95% CI, 4.98-13.65, $p<.001$). Validation of the derived risk model in an independent set of 558 patients (40%) is planned. **Conclusions:** A limited set of 5 comorbid conditions, clinical and treatment variables predicted a 4-fold increased risk of HS and ER_visits in cancer patients with advanced disease. Personalized targeted interventions aimed at preventing acute care use could decrease the cost and improve the quality of cancer care. Research Sponsor: National Cancer Institute; UG1CA189974; THe Hope Foundation for Cancer Research.

11075 Poster Session

Trends in prices of checkpoint inhibitors in the US, 2016-2023.

Jeddeo Paul, Aaron Philip Mitchell, Aaron S Kesselheim, Benjamin N Rome; Brigham and Women's Hospital, Boston, MA; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Checkpoint inhibitors have revolutionized the treatment of several cancers since the first Food and Drug Administration (FDA) approval in 2014. Yet the cost of these drugs remains high, with implications for patient access and healthcare sustainability. We assessed pricing trends for drugs targeting program death-ligand 1 (PD-L1) or programmed cell death protein 1 (PD-1) from 2016-2023. **Methods:** This study included 6 PD-L1 or PD-1 inhibitors approved through 2019. Quarterly Medicare Part B spending limits, which are based on the average sales prices of drugs from manufacturers to wholesalers or direct purchasers, were collected from public files. To directly compare drugs, prices were converted to prices per month (28 days), based on the FDA-labeled dosage and frequency for metastatic non-small cell lung cancer (NSCLC), a common cancer for which each drug was approved. Prices were adjusted to 2023 dollars using the consumer price index for all urban consumers. **Results:** In 2016, monthly prices for pembrolizumab ($15,604) and nivolumab ($15,814) were similar. Prices for these 2 drugs and avelumab, approved in 2017, remained within 5% of each other throughout the study period. Three other drugs (cemiplimab, atezolizumab, and durvalumab) were approved from 2016-2018 and had prices 3%-20% lower than the other 3 drugs (Table). Inflation-adjusted prices for all drugs remained stable from 2016-2019 and decreased from 2020-2023, corresponding with a period of higher inflation. In 2023, monthly prices for the 6 drugs ranged from $11,961 (durvalumab) to $15,043 (pembrolizumab). From 2016-2023, inflation-adjusted prices decreased, by an average of 0.7% (pembrolizumab) to 4.8% (cemiplimab) per year. **Conclusions:** Although the FDA approved 6 mechanistically similar PD-1 or PD-L1 inhibitors from 2014-2018, prices remained generally unchanged during those years and through 2023, with slight declines in real prices attributable to post-COVID consumer inflation. Competition among these brand-name cancer drugs did not meaningfully affect prices. Regulators should investigate why price competition has not emerged, and policymakers should grant more opportunities to negotiate lower prices for patients and the health care system, as is being rolled out this year in Medicare following passage of the Inflation Reduction Act. Research Sponsor: None.

Prices for approved PD-1 or PD-L1 inhibitors, 2016 through 2023.

Checkpoint Inhibitor	2016 Q1	2019 Q4*	2023 Q4	Average percentage change in price per year**
Pembrolizumab	$15,825	$15,746	$15,043	-0.7%
Nivolumab	$15,814	$15,956	$14,604	-1.0%
Cemiplimab		$15,313	$12,563	-4.8%
Atezolizumab		$14,731	$13,219	-2.2%
Avelumab		$15,871	$14,543	-1.4%
Durvalumab		$13,385	$11,961	-2.4%

*First quarter that prices for all drugs were available.
**Based on compound annual growth rate between first price and last price in the study period.

11076 Poster Session

Effect of multi-cancer early detection screening on late-stage cancers: A modeling study.

Jagpreet Chhatwal, Jade Xiao, Selin Merdan, Andrew ElHabr, Christopher Tyson, Xiting Cao, Sana Raoof, A. Mark Fendrick, Burak Burak Ozbay, Paul J. Limburg, Tomasz M. Beer, Ashish Deshmukh, Andrew Briggs; Massachusetts General Hospital, Harvard Medical School, Boston, MA; Value Analytics Labs, LLC, Boston, MA; Exact Sciences Corporation, Madison, WI; Memorial Sloan Kettering Cancer Center, New York, NY; School of Public Health, University of Michigan, Ann Arbor, MI; Medical University of South Carolina, Charleston, SC; London School of Hygiene & Tropical Medicine, London, United Kingdom

Background: Emerging blood-based multi-cancer early detection (MCED) tests can revolutionize early cancer detection. We evaluated the potential impact of MCED screening in reducing risk of late-stage diagnosis of 12 specific cancers which represent 70% of all cancer incidence in the US. **Methods:** We developed Simulation Model for MCED (SiMCED), a microsimulation model of 12 solid tumor cancer types: breast, colorectal, endometrial, esophageal, gastric, kidney, liver, lung, ovarian, pancreatic, prostate, and urinary bladder. Transitions between cancer stages (I-IV) were driven by cancer type- and stage-specific dwell times, which were synthesized from published literature and empirical estimates. MCED test sensitivity was derived from the PRE-ASCEND study on average-risk American adults. The model was calibrated to reproduce yearly observed cancer incidence diagnosed symptomatically or through screening as captured in the Surveillance, Epidemiology, and End Results (SEER) database, while accounting for unobserved cancer incidence by age, sex, and cancer type and stage. Using a 50-year time horizon, we simulated 100,000 individuals aged 50 to 84 years. Diagnosis of cancer could arise from usual care (UC) or annual MCED screening. **Results:** Over the 50-year horizon, MCED screening of 100,000 individuals resulted in 1,323 fewer Stage IV (24%) diagnoses relative to UC, with 38% of Stage IV reductions attributed to non-screening-detectable cancer types (i.e., those without recommended screening guidelines). The table displays absolute and percentage reductions in Stage IV diagnoses for the 8 cancer types with the highest absolute reduction in Stage IV diagnoses. The percentage of Stage IV reduction was 21% for screening-detectable cancers and 29% for non-screening-detectable cancers. **Conclusions:** Our study suggests that MCED screening could be effective for reducing the incidence of Stage IV cancer, which is associated with the worst survival and quality of life. Of note, MCED has the potential to reduce Stage IV cancer incidence for cancers without recommended screening guidelines. However, the real-world impact of MCED tests and their cost-effectiveness require further investigation. Research Sponsor: Exact Sciences.

Cancer Type	UC: Stage IV N	UC+MCED: Stage IV N	Reduction: Stage IV N (%)
Lung	2,364	1,914	450 (19%)
Colorectal	651	391	260 (40%)
Pancreatic	639	479	160 (25%)
Gastric	222	124	98 (44%)
Breast	302	205	97 (32%)
Liver	169	88	81 (48%)
Esophageal	121	73	48 (40%)
Ovarian	146	101	45 (31%)
Total	5,603	4,280	1,323 (24%)

11077 Poster Session

Impact of race and ethnicity on financial toxicity in patients with genitourinary cancers.

Atulya Aman Khosla, Nitya Batra, Mohammad Arfat Ganiyani, Shreyas S Bellur, Ahmad Ozair, Karan Jatwani, Rohit Singh, Mukesh Roy, Muni Rubens, Anshul Saxena, Rohan Garje, Ishmael A. Jaiyesimi, Ulka N. Vaishampayan; Corewell Health William Beaumont University Hospital, Royal Oak, MI; Miami Cancer Institute, Baptist Health South Florida, Miami, FL; Roswell Park Comprehensive Cancer Center, Buffalo, NY; University of Vermont Medical Center, Burlington, VT; Division of Hematology/Oncology, University of Michigan, Ann Arbor, MI

Background: Genitourinary (GU) cancers contribute substantially to the cost of healthcare in the United States (US). While advancements in cancer treatment have improved patient outcomes, disparities in healthcare costs persist, exacerbating the financial burden on vulnerable populations. We sought to investigate the disparities in costs of inpatient hospitalizations among patients with GU cancers in the US. **Methods:** Eligible adult GU cases from the Medical Expenditure Panel Survey (2019–2021) were included in this study. ICD-10 CM codes were utilized to identify renal cell, prostate, urothelial, testicular, and penile cancers. In addition to the total hospital inpatient (IP) facility expenditure, questions about ability to pay for healthcare were included in the analysis after accounting for the complex survey design and sampling weights. **Results:** The study included a weighted sample size of 9,061,181 (wt*SE* = 538,502) GU cases in the US between 2019 and 2021. The mean (95% CI) age of the sample was 71.6 (70.7, 72.5) years. The sample consisted of 7.9% Hispanics, 74.8% non-Hispanic White (NHW), 13.8% non-Hispanic Black (NHB), and 3.5% Asian or other races (NHA). In 2021, NHB participants reported the lowest annual family income of $51742 (18932, 106185), followed by Hispanics with $65233 (24314, 95859), and NHW with 82035 (36298, 158863). A greater proportion of the elderly NHW population was insured compared to NHB and Hispanics (44.9% vs. 32.5% vs. 19.5%), respectively. Of note, NHB patients had worse self-perceived physical and mental health compared to NHW and Hispanics, with 18.1% reporting fair or poor physical and mental health (vs. 8.1% and 14.3%, respectively). NHB participants reported higher rates of familial financial hardship (2019: 10.2% vs. 3.6%; 2020: 6.2% vs. 3.5%; 2021: 7.1% vs. 3.3%) or not being able to afford medical care (2019: 7.2% vs. 2.1%; 2020: 2.5% vs. 0.6%; 2021: 1.9% vs. 1.7%) when compared to NHW. Overall, mean total hospital IP facility expenses were: Hispanics = $2873.30 (1434.49, 4312.12); NHW = $4213.81 (3241.05, 5186.56); and NHB = $5199.99 (2842.93, 7557.05). After accounting for sample weights, gender, family income, age, insurance status, and survey year, Poisson regression analysis showed significant differences between different racial groups. Hispanics were less likely (?=-0.48; $p<0.0001$), while NHB (?=0.152; $p<0.0001$) and NHA (?=0.48; $p<0.0001$) were more likely to spend for an IP hospitalization when compared to NHW (ref.). **Conclusions:** Our data revealed racial disparities in the costs of inpatient hospitalizations, highlighting potential financial toxicity among patients with GU cancers. Additional investigation is warranted to elucidate factors contributing to these inequities, aiming to optimize cancer management and alleviate financial burdens. Addressing these disparities is crucial to prioritize equitable healthcare access and promote systemic change. Research Sponsor: None.

Clinicians' perspectives on the Telehealth Serious Illness Care Program for older adults with myeloid malignancies.

Marissa LoCastro, Ying Wang, Tristan Yu, Soroush Mortaz, Jason Mendler, Sally Norton, Rachelle Bernacki, Thomas Carroll, Heidi D. Klepin, Lucy Wedow, Sean Goonan, Hannah Erdos, Brenda Bagnato, Jane Liesveld, Eric Huselton, Benzi Kluger, Kah Poh Loh; University of Rochester School of Medicine & Dentistry, Rochester, NY; University of Rocheser Medical Center, Rochester, NY; University of Rochester, Rochester, NY; University of Rochester Medical Center, Rochester, NY; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY; Dana-Farber Cancer Institute/Mass General Brigham, Boston, MA; Wake Forest Baptist Medical Center, Winston Salem, NC

Background: Serious illness conversations (SICs) may help patients avoid unwanted treatments at end-of-life (EOL). Nonetheless, SICs happen infrequently, often due to lack of time and fear of taking away hope. We previously piloted the telehealth Serious Illness Care Program (SICP), a systematic method to promote SICs, for older adults with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). The aim of this analysis was to understand the experience of the telehealth SICP from the clinician perspective. **Methods:** We piloted the telehealth SICP in a single-arm study of 20 older adults (>=60 years old) with AML/MDS. Eligible clinicians (oncologists and advanced practitioners) cared for >=1 older adult with AML/MDS in the last year. Consented clinicians were scheduled for a 2.5- to 3-hour virtual training session to learn how to use the Serious Illness Conversation Guide (SICG). The SICG is a script to elicit patient values and care preferences. After training, clinicians were scheduled for telehealth SICP visits with eligible patients and available caregivers. At the end of the study, clinicians completed an audio-recorded interview to discuss their experience. Qualitative analysis of the interviews was undertaken using MAXQDA software (VERBI Software GmBH). Quantitative measures included: 1) Clinician confidence in having SICs (before first study visit and end of study) and 2) Clinician acceptability (end of study). Clinician confidence was measured using a 22-item survey (range 1-7, higher score better). Acceptability was measured using a 11-item survey (5-point Likert scale). **Results:** Mean age of clinicians was 42 years [N=10, Standard Deviation (SD) 12.7]. The majority were White (90%), non-Hispanic (100%), and female (60%). Mean number of patients per clinician was 1.9 (SD 1.4, range 0-4). Three qualitative categories emerged: 1) The telehealth SICP deepened relationships and renewed trust, 2) Each telehealth SICP visit felt unique and personal in a positive way, and 3) Uninterrupted, unrushed time is preferred to optimize the experience of visits. Quantitative data revealed a statistically significant increase in clinician confidence overall, with a mean increase of 0.5 (SD 0.6, p=0.03). The largest increase in confidence was in helping families with reconciliation and saying good-bye [+1.4 (SD 1.5), p=0.04]. The majority of clinicians agreed that the format was simple (6/7, 86%) and easy to use (6/7, 86%). Clinicians felt they gained useful information from asking about the patient's goals (6/7, 86%) and that the telehealth SICP was effective in understanding their patient's values about EOL care (7/7, 100.0%). **Conclusions:** Clinicians felt the telehealth SICP deepened their relationships with patients and increased their confidence in having SICs. The majority of clinicians found it to be a simple and easy way to understand patient values about their care. Clinical trial information: NCT04745676. Research Sponsor: National Center for Advancing Translational Sciences of the National Institutes of Health; TL1 TR002000 to ML; National Cancer Institute; UG1CA189961; K99CA237744l and R00CA237744 to KPL; National Institute of Aging at the National Institutes of Health; R03AG073985 to KPL; R33AG059206 to HDK; K02AG062745 to BMK; Conquer Cancer, the ASCO Foundation; Conquer Cancer and Walther Cancer Foundation Career Development Award to KPL; Wilmot Cancer Institute; Wilmot Research Fellowship Award to KPL.

11079 Poster Session

Characterizing the authorship of phase 3 randomized clinical trials in oncology, 1960-2023.

Jeremy Lyle Warner, Brianna R. Bakow, Alaina J. Brown, Jennifer Hsing Choe, Elaine Fan, Teja Ganta, Michael Glover, Matthew James Hadfield, C. Beau Hilton, Ali Raza Khaki, Shalin Kothari, Mark Lythgoe, Seema Nagpal, Ryan Huu-Tuan Nguyen, David H Noyd, Irbaz Bin Riaz, Michael Kevin Rooney, Tarsheen Kaur Sethi, Eric Kumar Singhi, Sam Rubinstein; Brown University/Legorreta Cancer Center, Providence, RI; Dana-Farber Cancer Institute, Boston, MA; Vanderbilt University Medical Center, Nashville, TN; Vanderbilt-Ingram Cancer Center, Nashville, TN; University of Kansas Medical Center, Wichita, KS; Icahn School of Medicine at Mount Sinai, New York, NY; Stanford University Medical Center, Stanford, CA; Rhode Island Hospital, Brown University, Providence, RI; Vanderbilt University Medical Center, Hendersonville, TN; Stanford University, Stanford, CA; Yale University, New Haven, CT; Imperial College London, London, United Kingdom; Stanford University, Palo Alto, CA; University of Illinois College of Medicine, Chicago, IL; University of Washington, Seattle, WA; Mayo Clinic, Scottsdale, AZ; The University of Texas MD Anderson Cancer Center, Houston, TX; UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC

Background: Phase 3 randomized clinical trials (RCTs) inform the standard of care in cancer treatment yet have a mixed track record of success. In this study, we sought to 1) determine the overall success rate of phase 3 RCTs; 2) assess whether authorship patterns differ between successful (positive) and unsuccessful (negative) trials; and 3) explore if individual authors have distinct track records of success. **Methods:** The HemOnc knowledgebase (KB) was queried for initial publications of phase 3 RCTs of systemic anticancer therapy; those without primary outcome described were excluded. RCTs were labeled positive if the primary endpoint was met per HemOnc standard criteria (P value $\leq$ 0.05 or hazard ratio upper bound $\leq$ 1 for any experimental arm[s]) and negative if they did not meet these criteria or if the experimental arm was statistically inferior. Trial metadata and author information were extracted from the HemOnc KB. Author positive publication rate (PPR) was defined as % of publications reporting a positive result divided by total number of eligible publications. Prolific authors were defined as those with 6+ eligible publications. Author count for manuscripts reporting positive vs negative results was evaluated with the Mann-Whitney U test; other statistics were descriptive. **Results:** 3328 studies met criteria as of February 5, 2024; these were associated with 3305 initial publications between 1960-2023, involving 25,412 unique authors. 1474 (44.3%) of the studies were positive. Publications reporting positive trial results had, on average, 3 more authors, median (interquartile range) of 18 (12-23) vs 15 (11-20), $p<0.0001$. The mean ($\pm$SD) PPR for n=1967 prolific authors was 47.7% ($\pm$22.3%). The PPR was not related to individual author output; mean PPR for non-prolific authors was 48.0% (SD not reported). Differences in PPR were apparent by the disease under study and the years of publication (Table). Among the 46 prolific authors who had a PPR 2+ SD above the mean, 26 (55%) were from China followed by Italy with 3 (6%). **Conclusions:** Despite known positive publication bias, the success rate of published phase 3 RCTs remains $<$50%. Publications reporting positive results had significantly more authors; this finding requires further study including adjustment for trial sample size. Significant variation in PPR amongst fields could be due to watershed therapeutic advances, differential selection of primary endpoints, and/or selective reporting of results. Finally, a signal for geographic association of outlier PPRs suggests the need for further investigation. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; U24 CA265879.

Condition	Authors	Mean PPR%	Condition	Authors	Mean PPR%
Neuro-onc	891	33.3	Head & Neck	1428	49.2
Sarcoma	859	36.6	Lymphoid	3434	51.4
GYN	1839	43.1	Myeloma	1656	62.0
Derm	1026	43.5			
GI	5481	45.0	**Year of pub.**	**Authors**	**Mean PPR%**
Thoracic	3940	45.0	1960-93	2208	43.7
GU	2543	47.4	1994-2008	7847	41.1
Breast	4451	48.1	2009-18	13,235	44.5
Myeloid	2325	49.0	2019-23	9689	58.0

Access barriers and cost of varenicline for smoking cessation: A national comparative analysis of Medicare standalone part D and Medicare Advantage plan.

Changchuan Jiang, Qian Wang, Arthur S Hong, Megan A Mullins, Jiazhang Xing, Tianci Wang, Xin Hu, Ryan David Nipp, Robin Yabroff, Joshua Liao, Xuesong Han, Ya-Chen Tina Shih; Division of Hematology and Oncology, Department of Internal Medicine, University of Texas Southwestern, Dallas, TX; University Hospitals Seidman Cancer Center and Case Western Reserve University, Cleveland, OH; University of Texas Southwestern Medical Center, Dallas, TX; Peking Union Medical College Hospital, Beijing, China; Texas Christian Univerisity, Fort-Worth, TX; University of Virginia School of Medicine, Charlottesville, VA; University of Oklahoma, Oklahoma City, OK; Department of Surveillance and Health Equity Science, American Cancer Society, Kennesaw, GA; UT Southwestern Medical Center, Dallas, TX; American Cancer Society, Atlanta, GA; School of Medicine, University of California, Los Angeles, Los Angeles, CA

Background: Smoking cessation is a critical part of cancer prevention and control. Oral varenicline is the most cost-effective medication for smoking cessation, yet seniors enrolled in Medicare Part D Prescription Drug Plans (PDPs) can potentially face costs and access barriers to varenicline in the forms of prior authorization and quantity limits. Although over half of Medicare beneficiaries are now insured and receiving drug benefits through Medicare Advantage, it remains unclear how costs and access barriers compare between PDPs and MA drug plans (MADPs). This study compared plan-level costs and prevalence of prior authorization and quantity limit policies between PDPs and MADPs for oral varenicline. **Methods:** We used 2023 Q3 MA and PDP data from the Center for Medicare and Medicaid Services, excluding employer-sponsored and Supplemental Need Plans (including dual-eligible plans) and plans with <10 enrollees. We focused on two generic varenicline forms: 0.5mg and 1mg tablets. To compare medication quantities, we calculated the plan-level median (IQR) cost for 30-day supply, based on the average unit cost. Price benchmarks were defined based on average wholesale acquisition cost (WAC) from Micromedex Red Book. T-test and Chi-squared tests were used to compare costs and prevalence of prior authorization and quantity limits. **Results:** Across 3512 MADPs and 813 PDPs, median costs for a 30-day supply of varenicline were similar (0.5mg tab: $375.32 vs. $376.87, p=0.64; 1mg: $371.88 vs. $376.87, p=0.49, respectively). Median costs for both PDPs and MAPDs were higher than benchmarks; p<0.01 for all). For both varenicline dosages, MAPDs had higher rates of prior authorization (27.1% vs 16.2%, p<0.01) and quantity limits (48.0% vs 30.4%, p<0.01) than PDPs. **Conclusions:** Varenicline prices in both PDPs and MAPDs were much higher than benchmarks. Compared to PDPs, MAPDs used more prior authorization and quantity limit to control cost. This can create access barriers to this cost-effective medication, burdening patients, physicians, health systems, and pharmacies. Research Sponsor: University of Texas Southwestern Medical Center.

Varenicline	2023Q3	PA%	QL%	Median Cost (IQR) for 30 days supply (USD)	Benchmark WAC
0.5mg	**MAPD**	**27.1**	**48.0**	**375.32 (308.32-379.64)**	**328.92**
	PDP	**16.2**	**30.4**	**376.87 (364.66-386.33)**	
1mg	**MAPD**	**27.1**	**48.0**	**371.88 (323.77-405.63)**	**317.97**
	PDP	**16.2**	**30.4**	**376.87 (356.53-379.64)**	

Notes: MADPs=Medicare Advantage Drug Plans. PDPs=Prescription Drug Plans. PA=prior authorization. QL=quantity limit.

11081 Poster Session

Performance of a trained large language model to provide clinical trial recommendation in a head and neck cancer population.

Tony Hung, Gilad Kuperman, Eric Jeffrey Sherman, Alan Loh Ho, Winston Wong, Anuja Kriplani, Lara Dunn, James Vincent Fetten, Loren S. Michel, Shrujal S. Baxi, Chunhua Weng, David G. Pfister, Jun J. Mao; Memorial Sloan Kettering Cancer Center, New York, NY; Columbia University, New York, NY; Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Chatbots based on large language model (LLM) have demonstrated ability to answer oncology exam questions; however, leveraging LLM in medical-decision support have not yet demonstrated suitable performance in oncology practice. We evaluated the performance of a trained a LLM, GPT-4, to recommend appropriate clinical trials for a head & neck (HN) cancer population. **Methods:** In 2022, we developed an artificial intelligence powered clinical trial management mobile app, LookUpTrials, and demonstrated promising user engagement among oncologists. Using LookUpTrials database, we applied direct preference optimization to train GPT-4 as an in-app assistant to LookUpTrials. From Nov 7 to Dec 19, 2023, we collected consecutive, new patient cases and their respective clinical trial recommendations from oncologists in the HN medical oncology service at Memorial Sloan Kettering Cancer Center. Cases were categorized by diagnosis, cancer stage, treatment setting, and physician recommendation on clinical trials. Trained GPT-4 is prompted using a semi-structured template: "Given patient with a <diagnosis>, <cancer stage>, <treatment setting>, what are possible clinical trials?" Physician recommendations were compared with trained GPT-4 responses. We analyzed the performance of GPT-4 based on its response precision (positive predictive value), recall (sensitivity), and F1 score (harmonic mean of precision and recall). **Results:** We analyzed 178 patient cases, mean age 65.6 (SD 13.9), primarily male (75%) with local/locally advanced (68%) HN (61%), thyroid (16%), skin (9%), or salivary (8%) cancers. Majority were treated in the definitive setting with combined modality therapy (42%) and modest proportion were treated under clinical trials (10%). Overall, trained GPT-4 achieved a moderate performance matching physician clinical trial recommendations with 63% precision and 100% recall (F1 score 0.77), narrowing a total list of 56 HN clinical trials to a range of 0-4 relevant trials per patient case (mean 1, SD 1.2). Comparatively, performance of our trained GPT-4 exceeded historic performance of untrained LLMs to provide oncology treatment recommendation by 4-20 folds (F1 score 0.04 - 0.19). **Conclusions:** This proof-of-concept study demonstrated that trained LLM can achieve moderate performance in matching physician clinical trial recommendation in HN oncology. Our results suggest the potential of embedding trained LLM into oncology workflow to aid clinical trial search and accelerate clinical trial accrual. Future research is needed to optimize precision of trained LLM and to assess whether trained LLM may be a scalable solution to enhance the diversity and equity of clinical trial participation. Research Sponsor: emorial Sloan Kettering Cancer Center (MSK) Support Grant (P30-CA008748).

Cost-effectiveness of a circulating tumor fraction molecular biomarker for treatment response monitoring.

Zachary Rivers, Charu Aggarwal, Marc Ryan Matrana, Josephine Louella Feliciano, Akash Mitra, Halla Nimeiri, Rotem Ben-Shachar, Cathy Eng, Sheetal Mehta Kircher; Tempus AI, Chicago, IL; Perelman School of Medicine at the University of Pennsylvania, Abramson Cancer Center, Philadelphia, PA; Ochsner Health Center, New Orleans, LA; Johns Hopkins University, Baltimore, MD; Vanderbilt-Ingram Cancer Center, Nashville, TN; Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL

Background: Clinical validation studies have demonstrated that molecular biomarkers quantifying ctDNA changes in circulating tumor fraction (TF) predict survival outcomes and may be used for treatment response monitoring (TRM). While clinical utility studies to determine the impact on outcomes of molecular biomarker-driven treatment decisions versus standard of care imaging are ongoing, cost-effectiveness has not been evaluated. Here we evaluate the cost-effectiveness of a molecular biomarker, Tempus xM, used for TRM. **Methods:** xM quantifies changes in TF from baseline and on-treatment liquid biopsies. We use a patient-level Markov simulation to compare xM-guided treatment (intervention) to diagnostic imaging-guided treatment (control) over 24 weeks of therapy. In both arms xM and imaging is assessed at 12 weeks and treatment decisions are made based on xM (intervention) or diagnostic imaging (control). Imaging and xM concordance (Table) was based on a retrospective, real-world (RW) study of 51 patients tested with xM that received rw-imaging that evaluated the association of xM with rw-outcomes in advanced pan-cancer patients treated with immune checkpoint inhibitors (ICIs) +/- chemotherapy (CT). We assume non-responders discontinue ICIs and switch to CT and responders remain on ICIs. Appropriate (inappropriate) therapy was defined as treatment decisions concordant (discordant) with xM results. Costs were calculated from Medicare's perspective in 2023 USD. Control patients do not accrue the cost of xM. Sensitivity analyses were conducted. **Results:** Intervention patients saved $4,400 ($63,424 vs. $67,824 in controls) by preventing use of ineffective therapy (4.3 weeks avoided vs 0.2 weeks in controls), a savings of $1076 per week of ineffective therapy avoided. In all sensitivity analyses, xM-guided therapy remained cost effective (Table). The timing of therapy intervention and the cost of therapy had the largest impact on savings. **Conclusions:** This model demonstrates that xM-guided treatment is cost-saving compared to imaging alone during 24 weeks of treatment. Future work will incorporate variable clinical uptake and long-term outcomes by expanding the time horizon and including treatment discontinuation due to toxicities and mortality. Research Sponsor: Tempus AI.

Parameter	Base Value	Range	Range of Savings per Week of Ineffective Therapy Avoided, USD
xM Sensitivity	0.98	0.96 - 1	$1,087-$1,063
xM specificity	0.99	0.96 - 1	$1,122-$1,061
xM cost	$2,000	$1,000 - $3,000	$1,320-$831
Annual ICI Cost	$180,187	$144,150-$216,224	$763-$1,389
Week of therapy intervention	12	12 - 8	$1,076-$2,863
% of patients that are non-molecular responders and have CR/PR/SD	25.5	20.4 - 30.6	$670-$1,390
% of patients that are molecular responders and have PD	9.8	7.8 - 11.8	$1,342-$832

11083 Poster Session

Options for evaluating communication strategies in treatment and clinical trial discussions.

Monica Arun Patel, Michael C Matthews, Samantha Vuong, Noelle K. LoConte, Jennifer Weiss, Earlise Ward, Narjust Florez, Toby Christopher Campbell; University of Wisconsin, Madison, WI; Dana-Farber Cancer Institute, Boston, MA

Background: Nationally, participation in oncology clinical trials is low, with lack of representation of women and ethnic and racial minorities. Interventions to increase patient enrollment in clinical trials and to ensure equity are necessary to improve cancer care for all patients. Shared decision-making conversations are in physicians' control and are amenable to intervention. However, we must understand the current communication strategies used by medical oncologists in their discussions with patients about high-stakes treatment decisions, including participation in clinical trials. **Methods:** This was an observational qualitative study conducted between Jan 2022 to Feb 2023. We recruited US medical oncologists who routinely treat colon cancer and have access to clinical trials. Oncologists participated in a simulated, recorded telehealth encounter with a standardized patient recently diagnosed with advanced colon cancer and referred for discussion of treatment options, including a possible clinical trial. Oncologists were provided with the same background information on the patient. Four actors, a Black female, Black male, White female, and White male, were trained to represent the same patient with the same values. **Results:** 107 physicians at 42 academic institutions across 27 states were contacted via email, 47 responded (44%). 26 consented, and 21 completed the study. Participants were a median age of 41 (range 31-71 years), 48% female, 29% Asian, 5% Black. Encounter length ranged from 28:25 to 76:12 minutes (average 44:05 min). One to four treatment options were discussed during the encounter, including standard of care (1 or 2 options), clinical trial, and best supportive care. Clinical trials were explicitly discussed in nearly all (20/21) conversations and were introduced as an option 1st (1/20), 2nd (5/20), 3rd (12/20), 4th (2/20). Clinical trial discussion length ranged from 3:34 to 19:40 min (average 8:30 min). Discussions were shorter with Black vs White patient, average time 7:00 vs 10:00 min, respectively ($p = 0.05$), female vs male patient was 9:53 vs 7:34 min, respectively ($p = 0.12$). Recommendations varied from strong recommendation for a clinical trial (9/21), decision deferred to patient (9/21), recommendation for standard of care (3/21). **Conclusions:** The way oncologists discuss treatment options with their patients powerfully influences the outcome of the conversation and potentially the decision to participate in a clinical trial. In our study, fewer than half of academic GI oncologists recommend a trial. There is significant variability in option talk including the order as well as the content, duration, detail, and recommendations. Clinical trial discussions were shorter for Black patients. A structured approach to this complex decision-making conversation may help oncologists communicate treatment options to patients in a more equitable and effective way. Research Sponsor: MSN249878 – UW Carbone Cancer Center Support Grant (CCSG).

11084 Poster Session

Adopting combination machine learning models could reduce hospital length of stay for oncology patients.

Srisairam Achuthan, Shaikh Salamatullah, Jeffrey A. Scott, Karna Sheth, Logan Lantrip, Drew Lilienthal, Joseph Ricca, Scott C. Pepper, Rishov Chatterjee; Integra Connect, West Palm Beach, FL; Integra Connect, Bengaluru, India; Everett Castle, LLC, Hillsboro, OR

Background: Integra Connect previously created in-patient (IP) admission prediction model based on OCM data. One of the challenges for practices in a value-based care (VBC) program is to provide continuous care-coordination during and after an IP admission. Our objective is to show how adopting combination machine learning (ML) models can predict IP length of stay (LOS). Potential benefits include an overall reduction in LOS which could minimize the risk of hospital acquired conditions. **Methods:** ML models were trained on 5 major cancer types (Lung Cancer, Multiple Myeloma, Lymphoma, Small Intestine / Colorectal Cancer, High-risk Breast Cancer') from 7 OCM practices of PP4-PP9 data, excluding surgery IP admission. The top 5 cancer types accounted for ~50% of total in-patient admissions and ~50% of total LOS in days. The IP admissions were divided into 4 major cohorts in terms of LOS in days (1-3: class 1, 4-8: class 2, 9-15: class 3, and more than 15: class 4). To reduce the overall LOS, we adopted two ML models: 1) To classify LOS, a multi-classification model (Model1, an eXtreme Gradient Boosted Trees Classifier) and 2) To predict the LOS for classes 1-3, a regression-based model (Model2, an eXtreme Gradient Boosted Trees Regressor with Early Stopping). Class 4 cohort had a wide range (16- 90+ days) for LOS and therefore was excluded from Model2. The other three cohorts belonged to Q1, IQR, and Q4, respectively. Model1 was trained on 4,280 randomly selected sample IP admissions to balance each class and Model2 was trained on 19,636 IP admissions, both with 102 features. **Results:** The models were tested on PP10-PP11 claims excluding 0 days LOS. Model1 predicted 296 (3,945) IP admissions in class 4 of which 88 were true positives. Assuming at least a 10% reduction in associated total LOS translated to lower LOS of 1-3% for 5 (7) practices. The remaining 3,649 IP admissions were used to predict LOS by Model2. The difference between actual LOS and Predicted LOS was found as 18%-24%. To address model prediction errors, we defined the target LOS to be predicted LOS with an upper bound of at least 10%. This led to reductions of 6% -16% across practices. Finally, combining the results of both ML models we determined that the potential to lower LOS was at least 6% and at most 19%. **Conclusions:** Our ML models identified opportunities to reduce LOS across multiple OCM cancer practices for 5 major cancer types. We also identified a cohort of patients with critical condition (class 4) that is vital for practice transformation initiatives. These identified reduction in LOS for oncology patients provides cost reduction and quality improvement opportunities in VBC programs. In the future, more opportunities to lower LOS will be explored with a re-admission prediction model. Research Sponsor: None.

11085 Poster Session

Association between financial fragility and treatment patterns in multiple myeloma.

Christopher Su, Rahul Banerjee, Li Li, Catherine R. Fedorenko, Andrew Cowan, Scott David Ramsey, Veena Shankaran; Fred Hutchinson Cancer Center, Seattle, WA

Background: Multiple myeloma (MM) drugs are associated with significant out-of-pocket costs. We hypothesize that patients with financial fragility (FF) may receive suboptimal MM treatment, as they might be less likely to be able to access and afford these medications compared to patients in good financial standing. We examined the association between FF and MM treatment by using a novel database that links patient-level credit records to cancer and claims data in Washington (WA) state. **Methods:** We conducted a retrospective analysis of newly diagnosed patients with MM (2012-2020) with Medicare and commercial health insurance, via a database linking WA cancer registry data (including Western WA SEER), health insurance claims, and depersonalized credit reports (TransUnion). All eligible patients received combination therapy with an oral immunomodulatory drug and at least one injectable medication within 6 months of diagnosis. FF was defined as evidence of at least one of the following in credit reporting around diagnosis (50 days before or after): charge-offs, collections, liens, foreclosures, repossessions, and bankruptcy in the last 12 months. Patients were categorized as receiving suboptimal treatment (the composite outcome) if they experienced at least one of the following: delay in time to treatment initiation (>40 days from diagnosis), treatment interruption (gap of >30 days without treatment in the first 6 months), or lack of autologous stem cell transplantation (ASCT, within the first 12 months). We performed chi-squared tests followed by multivariable logistic regressions, adjusting for age, sex, race (white/nonwhite), insurance type, and Area Deprivation Index (dichotomized; 1-5 and 6-10). **Results:** A total of 204 eligible patients (median age 69 years, 60% male, 91% White, and 60% Medicare-insured) met eligibility criteria. Of these, 39 patients (19%) had evidence of FF and 120 patients (59%) met the composite outcome. FF was significantly associated with the composite outcome of suboptimal treatment in bivariate analysis (74% vs. 55%, p=0.03) and adjusted multivariable analysis (OR 2.41 [95% CI: 1.05-5.51], p=0.04). As 182 (89%) patients received ASCT within 12 months in this cohort, we performed a sensitivity analysis by removing ASCT as a component outcome; in this analysis, 108 patients (53%) met the composite outcome. FF was associated with the composite outcome of suboptimal treatment in bivariate analysis (69% vs. 49%, p=0.02) and adjusted multivariable analysis (OR 2.31 [95% CI: 1.05-5.10], p=0.04). **Conclusions:** FF is significantly associated with suboptimal MM treatment patterns, including delay to treatment initiation, treatment interruption, and decreased receipt of ASCT. Larger prospective studies with more diverse demographic representation and incorporation of clinical data are in development to elucidate the mechanisms through which FF leads to suboptimal MM treatment. Research Sponsor: National Cancer Institute; K12-CA-076930.

Use of artificial intelligence (AI) in augmenting prior authorisation process for financial support in hemato-lymphoid malignancies: Joint project of Navya AI and Indian Cancer Society Cancer Cure Fund (ICS-CCF).

Nehal Rishi Khanna, Anant Gokarn, Manju Sengar, Ann Rawat, Usha Thorat; Tata Memorial Centre, Parel, India; Bone Marrow Transplant Unit, Department of Medical Oncology, Tata Memorial Centre, Advance Centre for Treatment, Research and Education in Cancer, Navi Mumbai, India; Tata Memorial Centre, Mumbai, India; Indian Cancer Society, Mumbai, India

Background: Hemato-lymphoid malignancies have a special urgency on time to initiate treatment and prior authorisation has relied on rapid review by domain experts. Since 2011, ICS-CCF has contributed over $32 million to cover the treatment costs of 14,600 underprivileged patients, including hematolymphoid malignancies. A mandate of ICS-CCF for this philanthropic funding is to choose beneficiaries who have a high chance of cure with standard of care. For this, a Due Diligence Team (DDT) of expert oncologists and the Governing Advisory Council (GAC) of ICS-CCF sequentially adjudicate every application. To augment and scale up this process, in Feb 2021, ICS-CCF evaluated and implemented the use of AI for prior-authorizations. Navya AI is a clinically validated AI model that matches clinical data of applicants with available evidence and registry data to predict survival, and generates payor/national guidelines based optimal treatment plans. Since Feb 2021, 80% of applications are adjudicated by Navya AI with a 99% concordance with GAC. **Methods:** This study was planned to assess the impact of Navya AI on the process of prior authorisation in a cohort of adult and pediatric hemato-lymphoid malignancies. All patients evaluated by Navya AI alone or with DDT from February 2021 to July 2023 were analyzed. Adjudication rates reflecting effort and time savings were calculated as the % of patients for whom Navya AI could make a decision on its own without referring to the DDT for review. **Results:** Of the 5775 applications reviewed by Navya AI, 2255(39.04%) were hematolymphoid malignancies. 37.16%(838/2255) of patients were pediatric (Age<=15years) and 62.8%(1417/2255) were adults (Age>15 years). Of these 2255, Navya AI alone adjudicated 73.61%(1660/2255) cases and 25.36%(572/2255) were referred to DDT for adjudication. Analysis was done on 2232 cases excluding the 1.01%(23/2255) reapplication cases. Details in table. **Conclusions:** With AI, only one fourth of beneficiary applications with hematolymphoid malignancies need expert review for prior authorisation. Implementation of AI has potential to save time in the authorization process for philanthropic funding for governmental and non governmental health care schemes. Research Sponsor: None.

Diagnosis	Total Cases	Navya AI Adjudicated	Referred to DDT
Acute Lymphoblastic Leukemia	807	711/807 (88.10%)	96/807 (11.89%)
Non-Hodgkin's Lymphoma	553	412/553 (74.50%)	141/553 (25.49%)
Acute Myeloid Leukemia	303	201/303 (66.33%)	102/303 (33.66%)
Multiple Myeloma	194	72/194 (37.11%)	122/194 (62.88%)
Hodgkin's Lymphoma	181	115/181 (63.53%)	66/181 (36.46%)
Chronic Myeloid Leukemia	177	137/177 (77.40%)	40/177 (22.59%)
Chronic Lymphocytic Leukemia	17	12/17 (70.58%)	5/17 (29.41%)
Total	2232	1660 (74.37%)	572 (25.63%)

11087 Poster Session

Impact of lung biomarker testing on out-of-pocket costs for metastatic non-small cell lung cancer.

Laila A. Gharzai, Sarah Bell, Divya Myadam Gupta, Ruth C. Carlos; Northwestern University, Chicago, IL; University of Michigan, Ann Arbor, MI

Background: Biomarker testing in metastatic non-small lung cancer (NSCLC) is critical for appropriate selection of therapy options. Claims-based datasets offer real-world information on the use and cost of biomarker testing across the United States. **Methods:** We used de-identified administrative claims data from Optum's Clinformatics Data Mart Database (CDM) from 2013 to 2021 to assess for trends in biomarker testing. Eligible patients were adults with two or more lung cancer diagnosis codes and with two or more claims of a secondary malignant neoplasm. Patients were excluded if they had another primary cancer or did not have continuous insurance coverage twelve months prior and six months after diagnosis. We assessed claims-based out-of-pocket (OOP) costs associated with testing and treatment. Descriptive statistics were used to assess biomarker testing rates, and multivariable analyses (MVA) were performed to assess factors associated with testing. **Results:** A total of 4377 patients with metastatic NSCLC were eligible (mean age 60 years (SD: 8.33 years), 49.6% female, 76.7% former smokers). Testing rates within two months of diagnosis increased from 58.15% in 2013 to 69.96% in 2021. On MVA, biomarker testing was associated with younger age, being non-smokers, living in Mountain geographic region, or having point-of-service insurance plans. Biomarker testing was associated with a median OOP cost of $98 (IQR: $43.87-$306.58). Patients who underwent biomarker testing had a median total OOP cost of all services within 6 months of diagnosis of $3560.20 (IQR: $1538.37-$6199.44) compared to $1979.58 (IQR: $725.75-$4003.06) for those who did not undergo biomarker testing. **Conclusions:** Using claims data, we find that 70% of patients with metastatic NSCLC undergo biomarker testing within two months of diagnosis with metastatic disease. Most patients undergo biomarker testing early in their treatment course (0-60 days), suggesting that testing is appropriately being obtained early on in their treatment course, but this testing is associated with substantially higher overall OOP costs to patients. Research Sponsor: None.

11088 Poster Session

Post-acute care facility utilization and outcomes among Medicare beneficiaries undergoing inpatient cancer surgery.

Daniel E Lage, Mary Beth Landrum, Alexander Melamed, Alexi A. Wright, Spencer H Luster, Robert E Wolf, Nancy Lynn Keating; Massachusetts General Hospital, Boston, MA; Harvard Medical School, Boston, MA; Division of Gynecologic Oncology, Department of Obstetrics & Gynecology, Massachusetts General Hospital, Boston, MA; Dana-Farber Cancer Institute, Boston, MA

Background: Patients with cancer using post-acute care facilities have poor outcomes, including delayed return home and increased health care utilization. However, little is known about post-acute care use and outcomes among patients with cancer undergoing surgery. **Methods:** We examined Medicare claims of 100% of fee-for-service Medicare beneficiaries from 2010-2022, to identify patients who underwent inpatient cancer-directed surgery and were thus eligible for a post-acute facility stay. We used billing codes within 3 days of hospital discharge to identify post-acute facility stays, defined as skilled nursing facility (SNF), long-term acute care hospital (LTACH), or inpatient rehabilitation facility (IRF) stays. We used logistic regression to identify patient sociodemographic and clinical factors associated with post-acute care facility use. We also compared hospital readmissions within 30 days and days at home (defined as days not in an acute or post-acute facility) in the 90 days after discharge by setting, using Chi-square and Wilcoxon rank sum tests. **Results:** We studied 1,637,792 Medicare beneficiaries who underwent inpatient cancer surgery from 2010 to 2022. About half (48.9%) were women; median age was 73.0 years. The most common cancer diagnoses were colorectal (28.4%), lung (14.4%), and prostate (12.1%), and 22.7% had a Charlson comorbidity index (CCI) of $\geq$3. Overall, 16.0% of patients were discharged to a post-acute care facility (11.4% SNF, 4.5% LTACH/IRF). Discharge to post-acute care was greater among patients who were aged $\geq$80 vs 65-69 (Adjusted Odds Ratio[AOR] 3.85, 95% Confidence Interval[CI] 3.79,3.90), had CCI $\geq$3 versus 0 (AOR 2.92, 95%CI 2.88,2.95), were dual-eligible (AOR 2.01, 95%CI 1.99,2.04), or had metastatic cancer (AOR 1.26, 95%CI 1.24,1.28). Patients undergoing brain or spinal surgeries for primary or metastatic cancers had highest odds of PAC facility utilization. Compared to those discharged home, patients discharged to post-acute care facilities had a higher 30-day hospital readmission rates (18.6% vs. 9.5%, $p<0.0001$), and fewer days at home in the 90 days after discharge from their index surgical admission (median 68 vs. 90 days, $p<0.0001$). **Conclusions:** Patients with cancer undergoing inpatient surgery who are older, have comorbidities, or have advanced disease have higher rates of post-acute care facility use, and such post-acute care is associated with higher hospital readmissions and fewer post-operative days at home. Further work is needed to improve pre-operative decision-making and optimization as well as to develop supportive care and rehabilitative interventions that can improve post-operative outcomes for patients who need post post-acute care. Research Sponsor: U.S. National Institutes of Health.

11089 Poster Session

Cost-effectiveness of short-course radiotherapy versus long-course chemo-radiation in organ preservation for locally advanced rectal cancer.

Anna Dornisch, Christina Cui, William Yu Luo, Michael Vincent Sherer, James Don Murphy; Department of Radiation Medicine and Applied Sciences, University of California San Diego, La Jolla, CA; Duke Health Systems, Durham, NC; The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: Short-course radiation therapy (SCRT) has previously been found to be cost-effective compared to long-course chemoradiation (LCRT) for patients with locally advanced rectal cancer undergoing operative management. However, non-operative management protocols have recently become a standard treatment option for patients diagnosed with locally advanced rectal cancer achieving a complete clinical response after total neoadjuvant therapy (TNT) as surgery has significant impacts on quality of life. Recent data suggests higher rates of local regrowth and a correspondingly lower rate of organ preservation with SCRT-TNT compared to LCRT-TNT. With this study, we evaluated the cost-effectiveness of SCRT versus LCRT in the setting of non-operative management for locally advanced rectal cancer. **Methods:** We built a microsimulation model to simulate 5-year outcomes for 1 million hypothetical patients aged 65 years with locally advanced rectal cancer treated with TNT including either SCRT or LCRT. Patients achieving a complete clinical response with TNT opted for a non-operative management approach, undergoing surgery only with subsequent local progression. Patients not achieving a complete clinical response went directly to surgery. The model incorporated costs, quality of life (measured by health utility), and probabilities of disease progression and death. We extracted probabilities of disease progression and death and health utilities from published literature. We assessed costs from the healthcare payer perspective. We measured cost-effectiveness with incremental cost-effectiveness ratio (ICER), with ICERs under *$100,000* per quality-adjusted life-year (QALY) considered cost-effective. One way and probabilistic sensitivity analyses were used to test model uncertainty. **Results:** We found that compared to SCRT, LCRT increased overall cost by $10,457 and improved effectiveness by 0.16 QALYs resulting in an ICER of $67,200/QALY. The model was most sensitive to assumptions about risks of local recurrence in the non-operative setting, the health utility of non-operative management, and the costs of LCRT and SCRT. The model was not sensitive to assumptions about costs of diagnostic evaluation (i.e. flexible sigmoidoscopy) and probability of distant recurrence. Probabilistic sensitivity analysis demonstrated that LCRT was cost-effective in 91% of iterations. **Conclusions:** Long-course chemoradiation could represent a cost-effective strategy compared with short-course radiotherapy in the non-operative management of patients with locally advanced rectal cancer. The ongoing ACO/ARO/AIO-18.1 trial testing the hypothesis that LCRT-TNT will increase organ preservation rates relative to SCRT-TNT will help confirm these findings. Research Sponsor: None.

Effects of prehab or rehabilitation on upper extremity disability and quality of life after breast cancer surgery.

Kelley C Wood, Jessica Bertram, Kim Love, Tiffany Kendig, Ashley N Lightner, Stacye Mayo, Lynn DiDonato Canavan, Mackenzi Pergolotti; Select Medical, Mechanicsburg, PA; Baylor Scott and White Health, Grapevine, TX; K. R. Love Quantitative Consulting and Collaboration QCC, Athens, GA; Select Medical, Machanicsburg, PA; Texas Breast Surgeons, Plano, TX

Background: Growing evidence and NAPBC guidelines support the need for physical and/or occupational therapy (PT/OT) to optimize recovery from surgery. Research is needed to better understand the benefits of prehab (PT/OT before surgery and continuing afterward). We performed a retrospective study to understand the effect of participating in prehab or rehab-only on outcomes after surgery. **Methods:** Outpatient medical record data was extracted for cases who attended prehab (n=328) or rehab-only (n=306). Outcomes were upper extremity disability (Quick-DASH) and HRQOL (PROMIS measures of physical functioning, social role functioning, and global health [physical and mental]). Outcome time points included the post-surgery PT/OT assessment (T1, M=4 weeks), and PT/OT re-assessment (T2, M=15 weeks). We used linear mixed-effect models to examine the effect of prehab on T1/T2 outcomes while controlling for covariates (age, PT/OT, payer, and time), and to examine changes in outcomes from T1 to T2 for both groups. **Results:** Attending prehab was associated with better outcomes at T1 (upper extremity disability, $p<.001$; physical functioning, $p<.001$; social role functioning, $p<.001$; and physical health $p<.001$) and T2 (upper extremity disability, $p=.025$; physical functioning, $p=.045$; and social role functioning, $p=.028$; Table). From T1 to T2, each group improved significantly: upper extremity disability (prehab: $M\Delta=8.92$, $p<.001$; rehab-only: $M\Delta=17.65$, $p<.001$), physical functioning (prehab: $M\Delta=1.89$, $p<.001$; rehab-only: $M\Delta=3.51$, $p<.001$), social role functioning (prehab: $M\Delta=1.61$, $p=.009$; rehab-only: $M\Delta=3.66$, $p<.001$), and physical health (prehab: $M\Delta=1.73$, $p<.001$; rehab-only: $M\Delta=3.50$, $p<.001$). There was no significant effect of prehab on mental health and improvement from T1 to T2 was non-significant for both groups ($p>0.05$). **Conclusions:** In this study, attending outpatient prehab PT/OT services was associated with less upper extremity disability and greater HRQOL after breast cancer surgery. After post-surgery PT/OT, prehab and rehab-only cases each improved significantly; and upper extremity disability, physical functioning and social role functioning remained better among prehab cases. Although more research is needed, these findings support the integration of PT/OT in routine care and suggest that early PT/OT may optimize outcomes.
Research Sponsor: None.

Estimated marginal mean score and SE at each timepoint after surgery.

	T1		T2	
Outcome	**Prehab**	**Rehab-only**	**Prehab**	**Rehab-only**
Upper extremity disability	22.71, 2.79	36.26, 2.88	13.79, 2.89	18.61, 3.00
Physical functioning	52.93, 1.12	48.76, 1.12	54.54, 1.17	52.42, 1.18
Social role functioning	44.38, 0.99	41.09, 0.99	46.27, 1.03	44.59, 1.04
Physical health	46.86, 1.01	43.62, 1.01	48.59, 1.05	47.11, 1.05

11091 Poster Session

Multilevel factors associated with delays to neoadjuvant chemotherapy among young adults with operable breast cancer.

Melissa Beauchemin, Margaux Wooster, David DeStephano, Sarah Harkins, Shikun Wang, Jason Dennis Wright, Justine Kahn, Melissa Kate Accordino, Dawn L. Hershman; Columbia University School of Nursing, New York, NY; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY; Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center, New York, NY; Columbia University Medical Center, New York, NY

Background: Breast cancer (BC) rates are increasing in young adults (YAs: age 18-39) and this population may experience unique barriers to treatment initiation. We identified factors associated with treatment initiation delays in a cohort of YAs with operable BC who received neoadjuvant chemotherapy (NACT). **Methods:** Using the National Cancer Database, we identified YAs diagnosed with non-metastatic BC from 2010-2020 who received NACT. We grouped patients by receptor status and clinical stage: 1) Hormone Receptor positive/HER-2 negative (HR+/HER2-) and were lymph node (LN) LN+; 2) HER-2 positive (HER2+) cT2+ or LN+; and 3) triple negative BC (TNBC) cT2+ or LN+. Primary outcome was delayed treatment initiation, defined as > 60 days from diagnosis date to NACT. Multivariable (MV) logistic regression was used to model factors associated with delay and adjusted for sociodemographic, clinical, and facility-level factors. We also examined factors associated with delays by tumor type. **Results:** Of 23,078 included patients, 62% were non-Hispanic White (NHW) and 74% had private insurance. By tumor type, 28% (n=6,350) were ER/PR+, 39% (n=8,921) were HER2+, and 34% (n=7,807) had TNBC. Most patients were treated at academic comprehensive cancer programs (ACCP) or comprehensive community cancer programs (CCCP) (40% and 34%). Treatment delays were observed among 7% of patients (n=1,638) across all tumor types. In MV analysis, non-Hispanic Black (NHB) and Hispanic YAs had 2-fold higher odds of delays compared with NHW YAs. YAs with low-income had higher odds of delays compared with higher income (OR=1.41), and YAs with private insurance had lower odds of delays compared with Medicaid (OR=0.54). YAs treated at any non-ACCP facility were less likely to experience delays. The results were similar for each tumor type. **Conclusions:** While the overall incidence of delays was low, significant racial, ethnic, and institutional-level treatment initiation disparities were observed among YAs receiving NACT for BC. Research Sponsor: U.S. National Institutes of Health; KL2TR001874.

MV models: Delayed treatment initiation (60 days) overall and by tumor type*.

		Tumor type		
Factors	**Overall OR [95% CI)**	**ER/PP+**	**HER2+**	**TNBC**
Race/ethnicity (Ref: NHW)				
NHB	**2.09 [1.79-2.44]**	**1.83 [1.38-2.41]**	**2.54 [1.94-3.31]**	**1.99 [1.51-2.60]**
Hispanic	**2.22 [1.88-2.62]**	**1.90 [1.41-2.55]**	**2.73 [2.06-3.60]**	**2.06 [1.55-2.74]**
Insurance (Ref: Medicaid)				
Private	**0.54 [0.47-0.62]**	**0.54 [0.42-0.69]**	**0.48 [0.38-0.60]**	**0.60 [0.47-0.77]**
Income (Ref: $63,333+)				
<$40,227	**1.41 [1.18-1.67]**	**1.73 [1.28-2.32]**	1.18 [0.87-1.59]	1.38 [1.00-1.88]
Facility type (Ref: ACCP)				
CCCP	**0.71 [0.62-0.82]**	**0.67 [0.52-0.85]**	**0.66 [0.52-0.82]**	0.82 [0.64-1.04]
Community Cancer Programs	**0.74 [0.55-0.98]**	0.89 [0.89-1.39]	0.67 [0.40-1.07]	0.66 [0.36-1.11]
Integrated Network Cancer Programs	**0.66 [0.56-0.78]**	**0.64 [0.47-0.87]**	**0.55 [0.41-0.73]**	0.80 [0.60-1.08]

*MV model adjusted for sociodemographic and clinical factors.

Systemic anti-cancer therapy and cost at end of life: A SEER Medicare analysis.

Kerin B. Adelson, Lee Cheng, Yu-Ting Huang, Jiangong Niu, Hui Zhao, Nico Nortje, Jenny Jing Xiang, Sharon H. Giordano, Maureen Canavan; The University of Texas MD Anderson Cancer Center, Houston, TX; Yale School of Medicine, New Haven, CT

Background: Systemic anticancer therapy (SACT) administered near the end of life (EOL) is associated with higher costs, driven by pharmaceuticals and associated acute care use that occurs when patients continue treatment in lieu of transition to hospice. Since 2015 overall rates of systemic therapy at the EOL have remained stable, while some chemotherapy has been replaced by costly immunotherapy. It is not known whether immunotherapy is associated with the same impact on total cost of care (TCOC) as chemotherapy. We evaluated the relationship between type of SACT vs no SACT within 30 days of death on categories of cost. **Methods:** We identified patients from the SEER-Medicare database diagnosed between 2005 and 2019 with solid tumors (ST) and liquid tumors (LT) who died from 2015-2020. We assessed differences in Medicare cost within 30 days of death by subtype of SACT: combination chemo-immunotherapy (CI), immunotherapy only (IO), chemotherapy only (CO) and no SACT. Dependent variables were TCOC (including all Medicare claims), as well as cost of drugs, hospitalizations, emergency department (ED), and hospice normalized and adjusted for inflation. **Results:** 6.2% (27,317/440,349) of ST decedents and 12.7% (7,544/59,449) LT decedents received SACT at EOL. See table. Among ST patients who received SACT, the mean TCOC was $26,282 (standard deviation (SD) $26,700) and was highest among patients receiving CI, $27,973 (SD: $26,285) vs. $17,642 (SD: $29,798) for patients without SACT (p <.001). Among LT patients who received SACT, the mean TCOC was $26,282 (SD $26,700) and was highest among CI patients $33,632 (SD: $26,283) vs. $24,689 (SD: $39,735) for patients with no SACT (p<.001). We observed higher cost for drugs, hospitalizations (except for LT patients receiving CI vs. no SACT), ED and lower hospice costs for patients receiving each SACT subgroup compared with no SACT. All results except those noted in table were significant (p <.001). **Conclusions:** Receipt of SACT within 30 days of death was associated with significantly higher Medicare costs. Higher TCOC in those who received SACT is only partially explained by drug costs; most acute care costs were also significantly higher among patients who received any type of SACT including CI, IO, CO than among those who did not. Research Sponsor: None.

Mean cost ± SD ($) by SACT type.

	Treatment Type	No SACT	CO	IO	CI
ST	N	413,032	13,628	9,757	3,932
	Drug	0.0±0.0	2,536 ± 4,615	5,865 ± 6,883	7,332 ± 6,150
	Hospitalization	13,166± 28,444	16,172±22,978	14,364±21,757	15,383±24,570
	ED	117 ± 360	181 ± 440	200 ± 484[†]	190 ±465[†]
	hospice	1,860±2454	1,139±1,869	1,202±1,832	921±1,686
LT	N	51,905	4,616	1,654	1,274
	Drug	0.0±0.0	4,476 ± 5,537	9,091 ± 7,050	10,657 ± 7,322
	Hospitalization	19,707±38,371	24,311±33,524	23,366±34,067	19,718±25,065[†]
	ED	118 ± 361	177 ± 457	179 ± 441[†]	160 ± 393[†]
	hospice	1,566±2,275	876±1,571	901±1605	629±1,284

All p-values <.001 for difference between each individual SACT subgroup and No SACT unless.
[†]where p-value >0.05.

11093 Poster Session

Enhancing the patient journey to clinical trial enrollment with navigation to optimize accrual: A pilot study for a pragmatic multicentre, stepped wedge, cluster randomized controlled trial (The CTN Pilot Trial).

Emmanuel Akingbade, Rija Fatima, Megan Delisle, Rhonda Abdel-Nabi, Mahmoud Hossami, Kayla Touma, Renee Nassar, Depen Sharma, Anthony Luginaah, Caroline M. Hamm; University of Windsor, Windsor, ON, Canada; University of Manitoba, Winnipeg, MB, Canada; Clinical Trials Navigator, Wheatley, ON, Canada; Western University, London, ON, Canada; University of Western Ontario, Windsor, ON, Canada

Background: Clinical trials are essential to the advancement of clinical therapies, yet accrual rates remain disappointing. Multiple challenges lead to less than 5% of cancer patients enrolled onto clinical trials. The Clinical Trials Navigator (CTN) program was established to assist patients and health care professionals identify appropriate clinical trials for patients. **Methods:** Between March 2019 to January 2024, a novel navigator-assisted clinical trials search program was offered to Canadian patients. Three non-medical navigators were trained to receive referrals, review medical information, and search five different clinical trial search engines. Eligibility criteria was scrutinized. A second review of the clinical trial list was conducted by two physicians. The final curated list of clinical trials was provided to patients and their oncologist. **Results:** A total of 373 patients were referred to the CTN program during the study period. A unique clinical trial search was performed for each patient yielding a median of only one potentially eligible trial per patient. Clinical trial enrolment occurred in 3.2% of patients in our database which translates to a 19% rate of successful enrolment of those referred to a trial by the CTN. Most patients (78%) were referred to clinical trial sites that conducted more than 100 clinical trials at any time. Compared to the Canadian cancer statistics, lung, lymphoma, pancreatic and brain cancers were overrepresented in referrals to the CTN program while prostate cancer was underrepresented. Type of cancer played a significant role in the likelihood of a successful referral ($p < 0.01$). Lung cancer was the most frequently reported cancer that resulted in referrals and breast cancer showed a lower frequency of referrals. The cancer type, stage and number of lines of prior therapy were not significantly associated with the patient enrollment onto a clinical trial. An increase in survival of referred patients from last analysis from 3.0 months to 5.3 months. **Conclusions:** The CTN program is a successful tool to identify clinical trials for cancer patients and can improve clinical trial accrual, as almost one fifth of patients (19%) who were referred to a clinical trial were enrolled. Ongoing iterative changes to the program to improve these metrics are underway and efforts to improve implementation of the CTN program across Canada are ongoing. Research Sponsor: None.

Disparities in stereotactic radiosurgery practice patterns for treatment of brain metastases: A large national cancer database study.

Kekoa A. Taparra, Jonathan Shih, Manali I. Patel, Erqi L. Pollom; Stanford Cancer Institute, Palo Alto, CA; University of California San Francisco School of Medicine, San Francisco, CA; Division of Oncology, Veterans Affairs Palo Alto Health Care System, Palo Alto, CA

Background: Brain metastases (BM) portend high mortality rates. While whole brain radiation therapy (WBRT) is a commonly used treatment strategy for BM, stereotactic radiosurgery (SRS) has less neurocognitive toxicity with comparable survival. The objective of this study was to compare treatment practice patterns for SRS vs WBRT using a large national hospital database. **Methods:** The National Cancer Database (NCDB) was queried for patients ≥18 years treated with radiotherapy (RT) for a BM diagnosis between 2004-2017 and with known follow-up. 12 cancers were included based on highest prevalence including: breast, colorectal, kidney/bladder, liver, lung, lymphoma, melanoma, oral cavity, pancreas, prostate, and thyroid. Patients were grouped by first course RT modality (SRS vs WBRT) confirmed by fraction number (SRS: 1-5; WBRT: 5-15). Multivariable logistic regression assessed predictors of SRS as adjusted odds ratios (aOR) with 95% confidence intervals (95%CI). Analyses were adjusted for patient and cancer characteristics. **Results:** Of 88,539 patients with BM, 17,734 (18%) received SRS. Median age was 64 years. Most patients were White (84%), diagnosed in 2011-2017 (58%), with a higher income (55%), more education (55%), and Medicare/Medicaid (58%). The most common cancer treated with RT for BM was lung (86%). Patients were less likely to be treated with SRS if they were Hispanic (aOR=0.85; 95%CI=0.76-0.96), lower income (aOR=0.90; 95%CI=0.86-0.95), lower education (aOR=0.87; 95%CI=0.83-0.91), with Medicare/Medicaid (aOR=0.83; 95%CI=0.79-0.87) or no insurance (aOR=0.46; 95%CI=0.41-0.51), at a Midwest hospital (aOR=0.74; 95%CI=0.71-0.78; vs Northeast), and at a community (aOR=0.28; 95%CI=0.25-0.30; vs academic) or comprehensive community cancer program (aOR=0.50; 95%CI=0.47-0.52). Patients were more likely to be treated with SRS if they were older (aOR=1.01; 95% CI=1.01-1.01), diagnosed in 2011-2017 (aOR=2.39; 95%CI=2.30-2.49; vs 2004-2010), lived farther from the hospital (aOR=1.09; 95%CI=1.07-1.11), and received chemotherapy (aOR=1.41; 95%CI=1.35-1.47). SRS was most often used to treat BM from primary colorectal cancer (aOR=1.99; 95%CI=1.65-2.40), endometrial cancer (aOR=1.52; 95%CI=1.08-2.10), kidney/bladder cancer (aOR=3.09; 95%CI=2.68-3.55), and melanoma (aOR=2.74; 95% CI=2.39-3.14), while less often used to treat BM from lymphoma (aOR=0.18; 95%CI=0.11-0.30), vs breast primary cancers. **Conclusions:** In one of the largest BM studies with nearly 90,000 US patients, disparities in SRS treatment patterns were identified. On adjusted analysis, SRS was less likely to be used for patients who were of Hispanic ethnicity, lower income, lower educational attainment, without private insurance, and treated at community centers. The data highlight populations with cancer and BM who may benefit from increased access to SRS. Research Sponsor: Conquer Cancer, the ASCO Foundation; Stanford Cancer Institue; Stanford Cancer Institute.

11095 Poster Session

Implementation and preliminary efficacy of a risk stratification system +/- patient-reported outcomes monitoring for patients with hospital-diagnosed advanced lung cancer.

Emily Miller Ray, Amanda Gentry, Madeleine Ledenyi, Jennifer Elston Elston Lafata, Hanna Kelly Sanoff, Gita N Mody; Division of Oncology, Department of Medicine, The University of North Carolina at Chapel Hill, Chapel Hill, NC; The University of North Carolina at Chapel Hill, Chapel Hill, NC; UNC Eshelman School of Pharmacy and Lineberger Comprehensive Cancer Center, Chapel Hill, NC; Lineberger Comprehensive Cancer Center, The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: Risk stratification systems may improve quality of care for patients with advanced lung cancer (ALC) by identifying those at high risk of rehospitalization and directing them to supportive care. The purpose of this study was to evaluate the implementation and preliminary efficacy of a risk-based system, with/without electronic patient-reported outcome (ePRO) symptom monitoring, to trigger supportive care for patients with hospital-diagnosed ALC. **Methods:** In this single-site, non-randomized, pragmatic study, patients in an academic center with hospital-diagnosed ALC were stratified to low or high risk using an established tool. High-risk patients were referred to two-pronged supportive care: patient navigation and outpatient palliative care. Eligible patients were recruited for 3 months of ePRO symptom monitoring coupled with provider alerts. Healthcare utilization was assessed at 90 days post-discharge. Program feasibility and acceptability were assessed using percent of eligible supportive care referrals made and completed, enrollment rates in ePROs, ePRO completion, and notifications to providers of concerning symptoms. Preliminary efficacy was defined as percentage of concerning ePRO symptoms resulting in new clinical action and 90-day readmissions. **Results:** At the time of interim analysis, 49 patients had been assessed with 48/49 (98%) identified as high risk. Patients had a mean age of 66 years, and were non-Hispanic, 51% male, and 22% Black. Patient navigation referral (92%) and completion (88%) was high. Palliative care referral (89%) and completion (45%) was lower. 14/39 (36%) of eligible patients enrolled in ePRO symptom monitoring, with competing priorities or feeling overwhelmed as the primary reasons for non-participation. Patient-level ePRO completion ranged from 0-100% (mean 53%). Nearly all (97%) concerning symptoms were reported to the clinical team; 27% of these resulted in new clinical action. By 90 days, 16/37 (43%) had hospital readmissions. **Conclusions:** Patient navigation was feasible and acceptable in patients with hospital-diagnosed ALC. However, there are ongoing barriers to implementation of post-hospitalization ePRO symptom monitoring and palliative care. Additional evaluation is needed to understand the barriers and facilitators and to measure the impact of navigation on patient outcomes. Since nearly all patients met high-risk criteria, future programs will eliminate risk stratification and target all patients with hospital-diagnosed ALC. Clinical trial information: NCT05722847. Research Sponsor: Lung Cancer Initiative.

High-risk criteria among patients (n=49).

	n (%)
>1 Charlson comorbidity	38 (77.6)
Prior ED/hospitalization w/in 6 months	31 (63.3)
>8 days hospital stay	29 (59.2)
Black or African American	11 (22.4)
Small cell lung cancer	9 (18.4)
Wheelchair prescribed	2 (4.1)
Hispanic or Latino	0 (0.0)
Did not meet any criteria	1 (2.0)

11096 Poster Session

Evaluating disparities in receptor status, overall survival, and time to hormone therapy among women with breast cancer.

Kekoa A. Taparra, Nicole V DeVille, Alex Melendez-Ramos, Javier Blanco-Portillo, Alexander Ioannidis, Manali I. Patel, Erqi L. Pollom, Kathleen C. Horst; Stanford Cancer Institute, Palo Alto, CA; University of Nevada Las Vegas, Las Vegas, NV; Stanford University, Palo Alto, CA; University of California, Santa Cruz, Santa Cruz, CA; Stanford University - School of Medicine, Palo Alto, CA; Stanford University Medical Center, Stanford, CA

Background: Breast cancer receptor status (ER/PR/HER2) is essential to guide treatment decisions. However, national race/ethnicity subtype studies rarely include Indigenous American Indian and Alaska Native (AI/AN) and Native Hawaiian and other Pacific Islander (NHPI) women. This study aims to compare across race/ethnicity: 1) hormone receptor (HR)/HER2 status, 2) Overall Survival (OS) for Triple Positive breast cancer, and 3) Time to Hormone Therapy (THT). **Methods:** A cohort study of women with breast cancer (Stage 1-4), age ≥18 years, diagnosed 2004-2017 was conducted with the National Cancer Database. Race was used as federally defined (White, Black, Asian, AI/AN, and NHPI) with Hispanic ethnicity. Primary endpoints were receptor status, OS, and THT (days from diagnosis to hormone therapy). Kaplan-Meier estimates and log-rank tests assessed OS. Multivariable logistic, Cox Proportional Hazard, and linear regression evaluated the likelihood of HR+/HER2+ (adjusted Odds Ratio [aOR]), death (adjusted Hazard Ratio [aHR]), and THT in days (adjusted β [aβ]), respectively, with 95% confidence intervals (95%CI). The majority non-Hispanic White population served as reference. All regressions were adjusted for sociodemographic and cancer characteristics. All HER2 analyses used a subset of women diagnosed post-2010, given inconsistent testing pre-2010. **Results:** 1,812,911 women were included who mostly had Stage 1 cancer (53%), from metropolitan areas (84%), with private insurance (51%), and a median age of 61 (IQR 51-71) years. Women were 81% White, 11% Black, 5% Hispanic, 2% Asian, 0.3% AI/AN, and 0.2% NHPI. NHPI women had the highest ER+ (84%) and PR+ (75%) cancers, while Asian women had the highest HER2+ (18%). Adjusted for covariates, only NHPI women were significantly more likely to have HR+ cancer (aOR=1.3, 95%CI=1.2-1.5) while Black women were less likely (aOR=0.6, 95%CI=0.6-0.6), compared to White women. Hispanic women were significantly more likely to have Triple Positive cancer (aOR=1.1, 95%CI=1.1-1.2) while Black women were less likely (aOR=0.9, 95%CI=0.9-0.9). Median follow-up was 63 (IQR 36-101) months. Among women with Triple Positive breast cancer, there were significant differences in OS ($p < .0001$) with 7-year survival ranging from 77% for NHPI women to 89% for Asian women. NHPI women had the highest risk of death (aHR=1.5, 95%CI=1.0-2.1), followed by AI/AN (aHR=1.5, 1.05-2.0), and Black (aHR=1.2, 95%CI=1.1-1.2). Adjusted for covariates, among women with HR+ breast cancer, longer THT occurred among Black (aβ=18 days, 95%CI=17-18), Hispanic (aβ=16 days, 95%CI=15-17), and NHPI women (aβ=14 days, 95%CI=9-18). **Conclusions:** NHPI women have higher HR+ rates while Black, Hispanic, and NHPI women with HR+ cancer experience longer times to hormone therapy. This is likely the first US analysis of breast cancer subtypes using federal race/ethnicity standards. Research Sponsor: Conquer Cancer, the ASCO Foundation; Stanford Cancer Institue; Stanford Cancer Institute.

11097 Poster Session

Sociodemographic differences in suicide/intentional self-harm among cancer survivors versus the general United States population.

Jason Semprini, Eric Adjei Boakye, Justin Michael Barnes, David B Goldston, Evan Michael Graboyes, Nosayaba Osazuwa-Peters; University of Iowa College of Public Health, Iowa City, IA; Henry Ford Health System, Detroit, MI; Department of Radiation Oncology, Washington University School of Medicine in St. Louis, St. Louis, MO; Duke University, Durham, NC; Medical University of South Carolina, Charleston, SC; Duke University School of Medicine, Durham, NC

Background: Suicide is a national public health crisis, and one of the leading causes of death in the United States. Worse yet, the suicide mortality rate is at least double among cancer survivors compared to the general population. Suicide rates vary across the population, but it is unclear how sociodemographic factors explain differences in suicide rates among cancer survivors versus the general United States population. **Methods:** We analyzed two sets of population-based data. First, we retrieved suicide/self-harm mortality rates for the general population from the National Vital Statistics System. Next, we accessed cancer case data from the Surveillance, Epidemiology, End Results (SEER) program to estimate number of deaths due to suicide/self-harm among cancer patients, per 100,000 persons, with a 95% confidence interval. All analyses were restricted to contiguous states with full state representation in SEER (CA, CT, GA, ID, IA, KY, LA, NJ, NM, NY, TX, UT). We then compared subgroup differences by sex, race/ethnicity, age, and state. **Results:** In 2020, there were 15,813 deaths in the general population (12.1 suicide/100,000 persons; 95% CI: 11.9, 12.3), and 1,127 among cancer survivors (22.1 suicide/100,000 persons; 95% CI: 22.0, 22.1) due to suicide/intentional self-harm. Among racial/ethnic groups, the largest difference was found in the non-Hispanic White cancer survivors, with 10.4 more suicide/100,000 persons vs. White individuals in the general population. In contrast, two racial minority groups had higher suicide mortality rate in the general population vs. cancer survivors: Non-Hispanic Black individuals (general population = 7.4 suicide/100,000 persons vs cancer survivors = 6.9 suicide/100,000 persons), and Native American Indian (general population = 16.6 suicide/100,000 persons vs. cancer survivors = 11.3 suicide/100,000 persons). Among females, suicide mortality rate was slightly higher by 1.3 suicide/100,000 persons in cancer survivors vs. general population, and much higher among male cancer survivors vs. general population (19.9 suicide/100,000 persons more). For age groups, the lowest difference in suicide mortality between cancer survivors vs. general population was in the 65-84 age group (5.1 more suicide/100,000 persons). Across all other age groups, suicide rates were 11.9 to 14.4 higher in cancer survivors vs. the general population. Across the 12 states in our analysis, the smallest difference was in Iowa (1.9 more suicide/100,000 persons), and the largest difference was in Idaho (27.0 more suicide/100,000 persons). **Conclusions:** In most subgroups, people diagnosed with cancer appear to be at greater risk of death from suicide/intentional self-harm than the general population. As the number of people living with cancer continues to grow, policies increasing the quality of life for cancer patients are warranted. Research Sponsor: None.

11098 Poster Session

Quality of life and testosterone recovery after androgen deprivation therapy in patients with high-risk prostate cancer: Long-term data from a phase III trial.

Abdenour Nabid, Nathalie Carrier, André-Guy Martin, Jean-Paul Bahary, Peter Vavassis, Sylvie Vass, Boris Bahoric, Robert Archambault, Francois Vincent, Redouane Bettahar, Luis Souhami; Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, QC, Canada; CHU de Québec, Québec, QC, Canada; Centre Hospitalier Universitaire de Montréal, Montréal, QC, Canada; Hôpital Maisonneuve-Rosemont de Montréal, Montréal, QC, Canada; Centre de Santé et de Services Sociaux de Chicoutimi, Chicoutimi, QC, Canada; Hôpital Général Juif de Montréal, Montréal, QC, Canada; Centre Intégré de Santé et de Services Sociaux de l'Outaouais, Gatineau, QC, Canada; Centre Intégré Universitaire de Sante et Services Sociaux, Mauricie-Centre-du Quebec, Trois-Rivières, QC, Canada; Centre Hospitalier Universitaire de Rimouski, Rimouski, QC, Canada; McGill University Health Centre, Montréal, QC, Canada

Background: No prospectively collected data exist assessing the impact a hypogonadal status has on quality of life (QoL). Using data from a randomized Phase III trial in high-risk prostate cancer (HRPC) and based on Patient Reported Outcomes (PRO), we compared QoL between patients (pts) with or without testosterone (T) recovery after ADT. **Methods:** From 10/2000 to 01/2008, 630 pts with HRPC were randomised to 36 (310 pts) vs. 18 months (320 pts) of ADT. We assessed QoL by the validated EORTC 30 items regrouped into 9 scales and the PR 25 items into 5 scales. All items and scales scores were linearly transformed to a 0 to100 points scale. T measured at baseline and during follow-ups. T recovery was defined as a return to normal level. PRO measured up to 5 years. We estimated means and standard deviation of items and scales for each group at each time point. We analyzed all items and scales scores with general linear model with repeated measures to evaluate changes between patients who did versus those who did not recover T to a normal level, over time, in both ADT groups. *P*-value <0.01 was considered statistically significant to account for multiple comparisons and a difference in mean scores of ≥ 10 points was considered clinically relevant. **Results:** 494/630 patients were retained for the analysis. 515 had proper T data available (baseline and follow-up) from whom 21 were excluded (no QoL data). With a median follow-up of 13.1 years, the two groups were well-balanced. Over a period of 21 years, 5 982 T measurements were available: 3590 in 314 pts in the and 2392 in the 18- and 36-month cohort, respectively. A total of 256 (51.8%) recovered T to, at least, a pre-castrate level. A significantly higher percentage of pts recovered a normal T level in the 18-month cohort as compared to the 36-month (56.4% vs. 43.9%, p=0.008). Among pts regaining T to a normal level, the median time to recovery was significantly faster for the 18 compared to the 36-month cohort, 3.0 (95% CI: 2.55 to 3.65) vs. 5.00 (4.50 to 5.96) years, $p<0.001$. Considering the unified 55 items, overall adherence to QoL questionnaires (QoLQ) was 83.1% (4554/5480), 88.2% vs. 93.3% at baseline and 61.5% vs 58.3% at 5 years, for 18 vs. 36-month, respectively. Patients recovering T had a significantly better QoL. In 32 out of 55 items and in 10 out of 21 scales ($p<0.01$) in the 18-month and 30 out of 55 items and 10 out of 21 scales the 36-month cohort. Also 9 items and one scale reached clinical relevance in the 18-month cohort and 10 items and one scale in the 36-month cohort. **Conclusions:** In HRPC treated with RT and long-term ADT, T recovery to normal level is associated with major improvements in QoL in several domains. Since a higher proportion of pts recover a normal T level in a much shorter time without apparent detriment in long term outcomes, our results suggest that 18-month may be the most appropriate ADT duration for these pts. Research Sponsor: None.

11099 Poster Session

Association of cancer survivors' experience of care with financial toxicity: Results from a national survey.

Michael T. Halpern, Reegan Kate Knowles, Carla Thamm, Raymond J Chan; National Cancer Institute, Bethesda, MD; Flinders University, Bedford Park, SA, Australia; Queensland University of Technology, Kelvin Grove, QLD, Australia

Background: Financial Toxicity (FT), negative economic impacts resulting from cancer or cancer treatment, can adversely affect quality of life, treatment adherence, and clinical outcomes. Patient experience of care (EoC) captures information from patient's perspectives on interactions with healthcare providers and systems and receipt of medical care services. While EoC is used to evaluate health care system and provider quality, the impacts of EoC on FT are unknown. **Methods:** To examine associations of EoC and FT, we used data from the from the 2016-2017 Experience of Cancer Survivorship Supplement of the Medical Expenditure Panel Survey (MEPS), the most recent years available of this national U.S. household survey. EoC was assessed using patient-reported frequencies (rated "never/sometimes", "usually", or "always") of their health professionals explaining things in a way that was easy to understand; listening carefully; showing respect; and spending enough time with the patient in the past 12 months. FT was based on 9 MEPS items and classified as material FT (borrowing money, making financial sacrifices due to cancer), psychologic FT (worry about paying medical bills or financial stability), and behavioral FT (delaying/forgoing cancer care due to costs). Analyses were performed using multivariable logistic regressions controlling for patient sociodemographic and clinical characteristics and weighted to produce nationally representative estimates and address survey non-response. **Results:** Data included 1068 individuals diagnosed with cancer at age 18 or older; 30% reported material FT, 35% psychologic FT, and 27% behavioral FT. Examining EoC, 64% of respondents indicated their health professionals always explained things; 60% that they always listened; 66% that they always showed respect; and 57% that they always spent enough time with the patient. In multivariable regressions, the odds of psychologic FT were significantly ($p<0.05$) lower among patients reporting their health professionals always (vs. never/sometimes) listened (odds ratio [OR] 0.37, 95% CI 0.19-0.70), showed respect (OR 0.36, 95% CI 0.16-0.81), and spent enough time with the patient (OR 0.47, 95% CI 0.26-0.86). Significant associations with EoC were also found with individual psychologic FT questions from the MEPS on worry about paying bills, financial stability, and keeping job/income. **Conclusions:** Worry/anxiety regarding costs can be a major factor affecting individuals with cancer. Improving patient-provider interactions to enhance patient EoC may help reduce this aspect of FT. Research Sponsor: None.

11100 Poster Session

Risk of significant functional impairment across cancer diagnosis and care continuum.

Ann Marie Flores, Mitisha Shah, Katy Bedjeti, Patricia D. Franklin, John Devin Peipert, Sofia F. Garcia, Nicola Lancki, Kimberly A. Webster, Mary Lillian O'Connor, David Cella; Dept. of Physical Therapy and Human Movement Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL; Dept. of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL; Northwestern University, Chicago, IL; Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL; Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL

Background: The purpose of this paper is to examine the extent of unmet need to address physical and functional (PF) impairment among ambulatory cancer patients who were screened at baseline for PF impairment in the NCI Cancer Moonshot study - Northwestern University Improving the Management of Symptoms during and Following Cancer Treatment (NU IMPACT). We hypothesized that PF impairment, measured using the Patient Reported Outcome Measurement Information System – Physical Function (PROMIS-PF), would be common overall, and more prevalent for patients receiving active treatment (intent to cure or palliative) as compared to those in the post-treatment survivorship phase. We also hypothesized that PF impairment would differ across tumor types, independent of cancer continuum phase. **Methods:** The sample consisted of adults diagnosed with cancer, enrolled and consented in NU IMPACT (n=2,273). We compared PROMIS-PF scores across phases of the cancer continuum. Cancer continuum status was defined by the electronic health record (Epic) Beacon module that classifies patients as receiving active cancer treatment (intent to cure or palliative). Patients not assigned a Beacon status were classified as being in the survivorship group. Tumor type was derived from tumor registry data. A PF score less than or equal to 40 was categorized as moderate-to-severe impairment. We used multivariable logistic regression models to evaluate our hypotheses with a 95% confidence interval. **Results:** Overall, 40% of patients reported moderate-to-severe PF impairment. Patients diagnosed with melanoma reported the least impairment; those with lung cancer were 6.5 times more likely to have moderate-to-severe PF impairment (95% CI: 2.39 - 17.77). Those in non-curative intent treatment were 1.5 times more likely to have PF impairment (95% CI: 1.05 - 2.15) with lower mean PF scores (mean = 43; $p<.001$) as compared to those in curative intent (mean=46) and survivorship (mean=48). One-third of those reporting PF impairment also reported moderate-to-severe levels of pain and/or fatigue. **Conclusions:** PF impairment is present for a large minority of our cohort. Except for patients with lung cancer, PF impairment varied little by tumor type suggesting unmet need across the board. Those in non-curative treatment had more PF impairment than those in post-treatment survivorship providing guidance for targeted and early intervention by cancer rehabilitation. There appears to be a clustering of symptoms that affect human movement. Regular monitoring for PF impairments – in addition to pain and fatigue - may fill a gap in care that should be addressed with appropriate cancer rehabilitation referral and intervention. PROMIS-PF effectively identified variation in physical function. Future studies will explore how timely detection of PF impairment can be used to refer patients for appropriate cancer rehabilitation services and utilization. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; 1UM1CA233035; National Cancer Institute/U.S. National Institutes of Health; 3UM1CA233035-01S1; National Cancer Institute/U.S. National Institutes of Health.

Associations of symptom burden with patient-reported outcomes (PROs) and clinical outcomes among early-phase cancer clinical trial (EP-CT) participants.

Anh B. Lam, Debra Lundquist, Andrea Pelletier, Sienna Durbin, Laura A Petrillo, Rachel Jimenez, Victoria Turbini, Viola Bame, Kaitlyn Lynch, Vaishnavi Reddy Yalala, Nicholas Ollila, Benjamin Malowitz, Casandra McIntyre, Dejan Juric, Ryan David Nipp; University of Oklahoma Health Sciences Center, Oklahoma City, OK; Massachusetts General Hospital, Boston, MA; Brigham and Women's Hospital, Boston, MA; Henri and Belinda Termeer Center for Targeted Therapies, Massachusetts General Hospital, Boston, MA; University of Oklahoma, Oklahoma City, OK

Background: Individuals with cancer often endure a substantial physical and psychological symptom burden. However, little is known about the baseline symptom burden of patients with cancer participating in EP-CTs or the associations of this symptom burden with other PROs and clinical outcomes. **Methods:** We prospectively enrolled adults with cancer participating in EP-CTs at Massachusetts General Hospital from 4/2021-1/2023. Participants completed baseline surveys prior to EP-CT initiation that assessed symptoms (Edmonton Symptom Assessment System [ESAS]), quality of life (QOL; Functional Assessment of Cancer Therapy-General), hope (Herth Hope Index), depression/anxiety symptoms (Patient Health Questionnaire-4 [PHQ-4]), and financial wellbeing (COST tool, higher scores indicate greater financial wellbeing). We used regression models to explore associations of baseline symptom burden with other PROs (QOL, hope, depression/anxiety, financial wellbeing) and clinical outcomes (time on trial, hospitalizations, overall survival). **Results:** Among 205 participants (median age=63.3 [range: 31.8-88.6], 57.1% female), the most common cancer types were gastrointestinal (34.6%), breast (20.0%), and head and neck (10.2%). Based on the ESAS, approximately half of participants reported moderate/severe fatigue (50.2%) and poor wellbeing (49.5%). Under half reported moderate/severe drowsiness (35.7%), pain (25.9%), lack of appetite (25.4%), shortness of breath (20.0%), anxiety (18.0%), depression (15.4%), and nausea (9.2%). Higher baseline ESAS total, physical, and psychological scores were associated with worse QOL, lower hope, greater PHQ-4 depression/anxiety symptoms, and worse financial wellbeing (see Table). Higher baseline ESAS scores were associated with decreased time on trial and worse overall survival. **Conclusions:** In this study of EP-CT participants, we found associations of baseline symptom burden with other important PROs and clinical outcomes. Specifically, higher baseline symptom burden was associated with decreased QOL, lower hope, increased depression/anxiety symptoms, and diminished financial wellbeing as well as greater risk for shorter time on trial and worse survival. Interventions seeking to enhance care delivery and outcomes for EP-CT participants should strive to address the symptom burden of this population. Research Sponsor: None.

Outcomes	ESAS Total		ESAS Physical		ESAS Psychological	
PROs	Beta	P	Beta	P	Beta	P
QOL	-0.55	<0.001	-0.68	<0.001	-1.93	<0.001
Hope	-0.10	<0.001	-0.09	<0.001	-0.53	<0.001
PHQ-4 Depression/ Anxiety	0.06	<0.001	0.06	<0.001	0.39	<0.001
Financial Wellbeing	-0.13	0.003	-0.16	0.009	-0.36	0.032
Clinical Outcomes	HR	P	HR	P	HR	P
Hospitalizations	1.01	0.066	1.02	0.059	1.03	0.290
Time on Trial	1.01	0.069	1.01	0.208	1.04	0.046
Overall Survival	1.02	<0.001	1.03	<0.001	1.04	0.088

11102 Poster Session

Real-world assessment of treatment-related symptoms and associated burden among African American and Caucasian patients receiving chemotherapy in the US.

Aaron Galaznik, Emelly Rusli, Tracy Holt, Mordecai Kramer, Peter Trask; Carevive Systems Inc., Miami, FL; Carevive Systems Inc., North Miami, FL; Parexel, Billerica, MA; Carevive, Brookline, MA; Genentech Inc, South San Francisco, CA

Background: In the treatment of breast cancer, research has identified racial differences in the ability to receive the full dose of prescribed chemotherapy which may be due in part to cancer-treatment symptom burden. In clinical trials, evaluation by race is challenging due to enrollment disparities, with African Americans (AA) accounting for 7% of trial participants, but comprising 12% of the US total population. The objective of this study is to evaluate treatment-related symptoms and treatment burden among patients treated with chemotherapy through an electronic remote symptom monitoring system, and explore whether there were any racial differences. **Methods:** Patients (pts) diagnosed with multiple myeloma, breast, ovarian, or lung cancer in academic cancer practices were enrolled in Carevive's Patient Reported Outcomes Mobile Platform (Carevive PROmpt) between September 2020 and June 2023. A total of 1000 pts received chemotherapy alone or in combination. PRO-CTCAE-derived weekly surveys assessed severity, frequency, and interference for 16 symptoms: anxiety, constipation, cough, decreased appetite, diarrhea, fatigue, general pain, insomnia, mouth/throat sores, muscle pain, nausea, numbness and tingling, rash, sadness, shortness of breath, and vomiting. The GP5 assessed weekly overall burden from treatment. **Results:** The mean age of pts was 60.9 (SD=12.8) years, with 75% female, and 20% AA. At the time of enrollment, fatigue was reported by roughly 48% of AA and Caucasian (C) pts. Muscle pain was noted in 38% of AA pts, followed by general pain (33%), and anxiety (30%), with constipation, decreased appetite, insomnia, nausea, and numbness/tingling occurring in over 20% of pts. A different pattern was observed in C pts, with anxiety occurring in 38%, followed by cough, decreased appetite, general pain, insomnia, muscle pain, nausea, and numbness/tingling present in 20% of pts. The proportion of pts at least "somewhat" bothered by the side effects of treatment were similar (44% AA, 45% C). **Conclusions:** This study enabled evaluation of symptom burden in cancer in a population closer in racial representation to the real world than in clinical trials; with AA representation being three-fold that seen in clinical trials. Consistent with a qualitative study of AA breast cancer pts, fatigue was identified as the most frequent symptom among those treated with chemotherapy either alone or in combination in the real world. Racial differences in the proportions of pts reporting pain (muscle or general) and anxiety suggest that treating physicians should consider these symptoms to ensure they do not interfere with patients' ability to receive full chemotherapy courses. Additionally, the levels of anxiety reported in patients highlights the importance of considering concomitant psycho-oncology treatments in cancer therapy. Research Sponsor: Genentech.

11103 Poster Session

Patient-reported outcomes corresponding to most common symptomatic adverse events in lung cancer clinical trials.

Erica Horodniceanu, Tejaswi Datla, Erin A. Larkins, Harpreet Singh, Paul Gustav Kluetz, Vishal Bhatnagar; Oncology Center of Excellence, U.S. Food and Drug Administration, Silver Spring, MD; Center for Drug Evaluation and Research, Office of Oncologic Diseases, U.S. Food and Drug Administration, Silver Spring, MD; Office of Oncologic Diseases, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; Oncology Center of Excellence, U.S. Food and Drug Administration; Office of Oncologic Diseases, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD

Background: FDA recommends assessing the most relevant expected symptomatic adverse events (AEs) with patient-reported outcomes (PROs) in cancer clinical trials (CTs) to complement traditional safety data. To inform selection of symptomatic AEs, we previously identified the most common (i.e., all-grade, clinician-reported in ≥20% of patients) symptomatic AEs from FDA-approved lung cancer product approvals from 2015 through 2021 based on CT monotherapy experimental arm safety data from US Prescribing Information (USPI). The present research aims to assess whether these CTs included PROs which adequately captured common symptomatic AEs. **Methods:** We assessed 30 CTs that supported lung cancer approvals from 2015 through 2021. We reviewed the study protocol, statistical analysis plan, and/or clinical study report to determine the PRO measures included. We matched symptoms included within PRO measures and items to the most common clinician-reported symptomatic AEs per the USPI to determine the extent to which the PROs and symptomatic AEs corresponded. **Results:** Twenty-three out of 30 (77%) CTs supporting non-small cell lung cancer (NSCLC) approvals included PRO(s). Nineteen included more than one PRO measure. The most frequently used PRO measures were the European Organisation for Research and Treatment of Cancer-Core Questionnaire (EORTC QLQ-C30; n=19), EORTC-Lung Cancer (EORTC QLQ-L13; n=17), EuroQoL 5-Dimension (EQ-5D; n=12), and selected items from the Patient-reported Outcomes version of the Common Terminology Criteria for Adverse Events item library (PRO-CTCAE; n=4). Nearly all (20 of 23) CTs included PRO items corresponding to more than half of the common symptomatic AEs reported. Symptomatic AEs for types of pain corresponded to general pain PRO items (e.g., "musculoskeletal pain" matched to EORTC item for "pain"). However, PRO items for specific types of pain were not often used. While important symptomatic AEs such as fatigue, diarrhea, nausea, and decreased appetite were often assessed by PROs, others including rash and edema were not usually captured. Ultimately, only 4 of 23 (17%) CTs with PROs included items that assessed all symptomatic AEs that occurred in ≥20% of patients. Of the 4 CTs which included an item library, 3 (75%) comprehensively assessed patient-reported symptomatic AEs, compared to 3 of 19 (16%) CTs that did not employ an item library for patient-reported symptom collection. **Conclusions:** Based on USPI safety data and PRO measures from CT monotherapy experimental arms of recently approved NSCLC cancer drugs, we determined that while the majority of CTs include PRO items for some relevant symptomatic AEs, other important expected symptomatic AEs (e.g., edema, rash, specific types of pain) were not measured. Future NSCLC CTs should include PRO items for common expected symptomatic AEs which is feasible using well-established PRO item libraries. Research Sponsor: None.

Impact of clinical response and AEs on health-related quality of life (HRQoL) in patients (pts) with R/R large B-cell lymphoma (LBCL): Pooled data from 4 liso-cabtagene maraleucel (liso-cel) trials.

Patrick Connor Johnson, Jeremy S. Abramson, Ling Shi, Yeran Li, Laurie Eliason, Shien Guo, Fei Fei Liu, Leo I. Gordon; Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA; Evidera PPD, Bethesda, MD; Bristol Myers Squibb, Princeton, NJ; Northwestern University, Feinberg School of Medicine, Robert H. Lurie Comprehensive Cancer Center, Chicago, IL

Background: Four liso-cel clinical trials in R/R LBCL (TRANSCEND NHL 001, PILOT, OUTREACH, and TRANSFORM) demonstrated a favorable clinical profile with high response rates (73%–80%) and positive changes in HRQoL after treatment. This analysis pooled data across 4 trials to assess the impact of clinical response and AEs on HRQoL. **Methods:** The EORTC QLQ-C30 and EQ-5D-5L were used to assess HRQoL repeatedly at prespecified time points up to Day 730. Six clinically relevant domains (EORTC QLQ-C30 global health status/quality of life [GHS/QoL], physical functioning, cognitive functioning, fatigue, pain, and the EQ-5D-5L visual analog scale [VAS]) were analyzed in liso-cel–treated pts pooled across trials with HRQoL scores at baseline and postbaseline visits. Linear mixed-effects regression models examined changes in HRQoL over time, with clinical response status and AEs as time-varying covariates, adjusting for relevant baseline and other time-varying factors. Trends in HRQoL change up to Day 730 over time were examined by cytokine release syndrome (CRS) and neurological events (NE) occurring ≤ 30 days after infusion. **Results:** The analysis included 368 and 372 pts for EORTC QLQ-C30 and EQ-5D-5L VAS, respectively. Achieving a clinical response (CR or PR) was associated with significant HRQoL improvement versus stable disease (SD) or PD in all 6 domains (Table). Meaningful improvement occurred ≤ 30 days after achieving CR or PR for all domains except cognitive functioning, where improvement occurred ≤ 90 days, and was sustained across remaining follow-up visits. CRS and NEs were associated with HRQoL worsening in selected domains; however, pts who experienced CRS or NEs ≤ 30 days after infusion recovered to levels of pts without the AE by Day 60 and maintained thereafter. **Conclusions:** Among liso-cel–treated pts with R/R LBCL, positive clinical response was associated with meaningful and sustained improvement in nearly all HRQoL domains. CRS and NEs may negatively impact certain HRQoL domains but are temporary. As liso-cel has demonstrated high response rates and a manageable safety profile across studies, these findings further support the pt-reported benefits of liso-cel for R/R LBCL. Research Sponsor: This study was funded by BMS. All authors contributed to and approved the abstract; writing and editorial assistance were provided by Nikola Vojtov, PhD, of The Lockwood Group (Stamford, CT, USA), funded by BMS.

Difference (95% CI) in multivariable least squares mean change over time[a].

Domain	CR/PR vs SD/PD	CRS (yes vs no)	NEs (yes vs no)	MID
GHS/QoL	**8.7**(6.7, 10.7)	**−5.1**(−8.1, −2.1)	NS	4
Physical functioning	**7.4** (5.6, 9.3)	**−5.0** (−7.8, −2.2)	−4.3 (−7.8, −0.9)	5
Cognitive functioning	2.2 (0.5, 4.0)	NS	**−7.7** (−10.8, −4.6)	3
Fatigue	**−10.2**(−12.4, −7.9)	**8.5** (5.0, 12.0)	NS	5
Pain	**−9.5** (−11.9, −7.0)	NS	NS	6
EQ-5D-5L VAS	**9.0** (7.3, 10.7)	−2.8 (−5.3, −0.2)	−4.7 (−7.8, −1.7)	7

[a]Bold values denote meaningful differences exceeding minimal important difference (MID) thresholds (Cocks, 2011). NS, nonsignificant results (nominal $P \geq 0.05$).

Relationship between cognitive and emotional domains of prognostic awareness with quality of life and psychological distress in patients with advanced cancer.

Claire Greydanus, Mitchell W. Lavoie, Jennifer S. Temel, Joseph A. Greer, Elyse R. Park, Vicki Jackson, Areej El-Jawahri, Hermioni L. Amonoo; The Warren Alpert Medical School of Brown University, Providence, RI; University of Massachusetts Chan Medical School, Worcester, MA; Massachusetts General Hospital, Harvard Medical School, Boston, MA; Brigham and Women's Hospital, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA

Background: Prognostic awareness, a measure of patients' cognitive and emotional perception of their illness and prognosis, allows individuals to align their medical decision-making with their goals and values. Prior studies have shown mixed findings regarding the relationship between prognostic awareness with better quality of life (QOL) and less psychological distress in patients with advanced cancer. However, studies have not investigated whether it is the cognitive or the emotional aspects of patients' awareness of their prognosis that are associated with QOL and psychological distress in patients with advanced cancer. **Methods:** We conducted a cross-sectional study of patients with metastatic solid malignancies not being treated for curative intent at a single academic center from 11/2019-6/2022. We used the Prognostic Awareness Questionnaire (PAIS) to measure the cognitive (i.e., the capacity to understand one's prognosis characterized by the accurate perception that a cancer is curable or not) and emotional coping with prognosis (i.e., the capacity to emotionally process prognostic uncertainty and terminal prognosis). We used the Functional Assessment of Cancer Therapy-General (FACT-G), Hospital Anxiety and Depression scale (HADS), and the Peace, Equanimity and Acceptance in the Cancer Experience (PEACE) scale to measure, QOL, psychological distress, and acceptance of illness, respectively. We used multivariate regression models controlling for age, gender, and cancer type to assess the relationship between the cognitive and emotional prognostic awareness domains and patient-reported outcomes. **Results:** Overall, 632 participants (age 65 years (SD=11.3), 51% female, 76% married or living with a partner) were enrolled in the study. In multivariate models, higher cognitive understanding of prognosis was not associated with QOL (b=-2.134; p=0.069), psychological distress (i.e., anxiety: b=0.331; p=0.232 and depression; b=0.233; p=0.368), or peaceful acceptance of terminal illness (b=-0.045; p=0.838). However, emotional coping of prognosis was associated with better QOL (b=1.981; $p<0.001$), less anxiety (b=-0.516; $p<0.001$) and depression (b=-0.370; $p<0.001$) symptoms, and more peaceful acceptance of terminal illness (b=0.438; $p<0.001$). **Conclusions:** Patients' emotional coping with their prognosis, rather than their cognitive understanding of their terminal prognosis, was associated with their QOL, psychological distress, and acceptance of their illness. These findings underscore the importance of examining prognostic awareness and its association with patient-reported outcomes by domains. We also highlight the need to develop supportive care interventions to promote effective coping strategies for patients after prognostic disclosure. Research Sponsor: National Cancer Institute; K08CA251654; The Doris Duke Foundation Clinician-Scientist Development Award.

11107 Poster Session

Feasibility and utilization of electronic patient-reported outcome measures for lung cancer in routine clinical care.

Ethan Basch, Huamao Mark Lin, Mary Lynn Cala, Melpomeni Styliadou, Aaron Galaznik, Debra Wujcik, Emelly Rusli, Nicholas C Coombs, Emily R Beamon; The University of North Carolina at Chapel Hill, Chapel Hill, NC; Takeda Development Center Americas, Inc., Lexington, MA; Takeda Pharmaceutical Company Limited, Cambridge, MA; Takeda Pharmaceutical Company Limited, Zurich, Switzerland; Carevive Systems, Inc., Boston, MA; Piedmont Research Strategies, Billings, MT; Piedmont Research Strategies, Greensboro, NC

Background: Prior studies have shown the value of Patient-Reported Outcomes (PRO) in cost burden, quality of life (QoL), and survival in cancer care. To facilitate focus on patient-centricity and value-based care, the International Consortium for Health Outcomes Measurements (ICHOM) and European Health Outcomes Observatory (H2O) developed a Core Outcomes Set (COS) in lung cancer. We explored the feasibility of deploying standardized PRO measures among patients with lung cancer in US clinical practice. Methods: A retrospective database study was conducted, with IRB waiver, using Carevive PROmPT, an electronic PRO (ePRO) remote symptom monitoring platform with weekly surveys comparable in scope to ICHOM/H2O COS, of symptomatic adverse events (PRO-CTCAE), physical function (PROMIS 4A Physical Function), and QoL items (EORTC QLQ-C30 items #29,30). Severe PRO-CTCAE symptom scores triggered care team alerts. From 9/2020 to 5/2023, 207 patients enrolled across 9 US cancer centers. Patients were ≥18 years, with lung cancer, and in current treatment. Patient engagement was measured by survey compliance, follow-up time, and completeness; clinician engagement was measured by platform utilization time, time to alert response, and clinical action taken. **Results:** Participants were 50% female, 86% White, 12% African American, median age 68, 81% NSCLC, and 26% with metastatic disease. Median survey persistence: 8 weeks, with 85% compliance over that time. Of domains assessed, 37 (58%) from Carevive data overlapped with ICHOM/H2O COS, with 19 measured over time. Overlapping domains included 15 clinical outcomes with 60% median completion rate and 22 PRO domains with 98% median completion. Of 19 domains assessed longitudinally, median compliance was 76%. Of patients triggering ≥1 ePRO symptom alert, 87% were within 4 weeks, with 46% requesting call-backs. Median clinician follow-up to alerts was 20 hours, with 69.3% addressed within 48 hours. Clinicians accessed the platform 2-3 times weekly, for median 2 minutes (range: 1-14 minutes) per login for nurses and Advanced Practitioners (AP). 89% of alerts were addressed by nurses and AP. Of alert responses, 66% indicated continuation of treatment, 12% were escalated to the clinical team, and 1% were escalated to hospitalization or ER visit. **Conclusions:** Results support the feasibility of integrating a standard set of multi-domain ePRO measures, comparable to the ICHOM/H2O COS, into routine cancer care, across multiple sites, with consistent patient engagement and provider utilization. One limitation is that clinical and financial impact were not directly assessed. Future research should explore direct clinician feedback, systematic implementation of PRO measures, and impacts on patient outcomes, resource utilization, and health systems. Research Sponsor: Takeda Development Center Americas, Inc.

SPPADE symptom prevalence and severity in a diverse sample of patients living with metastatic cancers.

Deirdre R. Pachman, Kathryn Jean Ruddy, Veronica Grzegorczyk, Kurt Kroenke, Joan M. Griffin, Jennifer Ridgeway, Linda L. Chlan, Cindy Tofthagen, Konstantinos Leventakos, Jacob J. Strand, Jessica Austin, Ashley Wilder Smith, Sandra A. Mitchell, Jeph Herrin, Andrea L. Cheville; Mayo Clinic, Rochester, MN; Indiana University School of Medicine and Regenstrief Institute, Indianapolis, IN; Mayo Clinic Florida, Jacksonville, FL; Mayo Clinic, Scottsdale, AZ; National Cancer Institute, Bethesda, MD; Yale University School of Medicine, New Haven, CT

Background: Advances in cancer treatment have led to a growing population of patients living with metastatic cancer. Symptom burden for these patients is understudied. Our objective is to report the prevalence and severity of SPPADE symptoms (sleep disturbance, pain, physical function impairment, anxiety, depression, and low energy /fatigue) in a large cohort of patients with metastatic cancer. **Methods:** These data are drawn from the Enhanced, EHR-facilitated Cancer Symptom Control (E2C2) stepped wedge pragmatic trial evaluating a symptom management intervention for cancer patients (NCT03892967). This analysis was limited to those identified with metastatic disease using ICD- codes and a natural language processing algorithm prior to or within 30 days of their baseline symptom survey. Symptom severity was measured on a 0-10 scale with scores of 1-3 categorized as "mild", 4-6 as "moderate", and ≥7 as "severe." A SPPADE composite score was calculated by summing six individual symptom scores and is an indicator of total symptom burden. We report descriptive statistics for each symptom by severity category. We also test for differences in SPPADE composite score by race, disability status, employment status, education and cancer type using Kruskal-Wallis tests. **Results:** 12,824 patients with metastatic disease completed a survey between March 2019 and January 2023. Discretized score distributions for the SPPADE symptoms are reported in the Table. The SPPADE composite mean score for the cohort was 17.6 (SD +/- 12.0). Significant differences were found in total symptom burden by sociodemographic and clinical characteristics ($p<0.01$): Higher total symptom burden (Mean [SD])was experienced by individuals who were American Indian/Alaska Native (AI/AN) (23.8[13.5]) or African American (AA) (20.5[14.7]), disabled (24.0[12.8]) or unemployed (21.1[13.0]), and had a high school education (20.0[13.3]) or less than high school education (18.5[12.4]). There were also statistically significant differences ($p<0.01$) in symptom burden across cancer types, with patients with metastatic lung cancer reporting the highest symptom burden (20.0[12.2]) and those with metastatic melanoma reporting the lowest (14.7[11.4]). **Conclusions:** SPPADE symptoms are common in patients with metastatic cancer, especially fatigue, sleep disturbance, and physical function impairment. Symptom burden is especially high in AI/AN, AA, disabled/unemployed, and less educated patients. Further research is needed to tailor symptom interventions among those living with metastatic disease. Research Sponsor: The IMPACT Consortium is a Cancer Moonshot Research Initiative under the authorization of the 2016 United States 21st Century Cures Act. Research reported in this publication was supported by the NCI of the NIH (PI Cheville); UM1CA233033.

SPPADE symptoms in patients with metastatic cancer (N= 12,824).

	Pain	Fatigue	Sleep	Anxiety	Depression	Physical Function
Mean Symptom Score (SD)	2.7 (2.6)	3.8 (2.6)	3.0 (2.7)	2.6 (2.5)	2.4 (2.4)	3.1 (2.6)
None %	28.3	12.6	26.2	26.0	31.2	23.9
Mild %	38.9	37.2	35.7	42.7	40.8	34.1
Moderate %	21.5	31.6	24.9	21.5	20.1	29.5
Severe %	11.3	18.7	13.2	9.8	8.0	12.6

11109 Poster Session

Health-related quality of life (QoL) in randomized phase III trials in oncology: Association between results of QoL, results of primary endpoint and drug approval.

Chiara Paratore, Rocco Schiavone, Clizia Zichi, Andrea Caglio, Teresa Gamba, Sebastiano Bombaci, Giorgio Vellani, Laura Marandino, Francesco Perrone, Massimo Di Maio; Department of Oncology, Ivrea Community Hospital, ASL-TO4, Ivrea (Turin), Italy; Department of Oncology, University of Turin, Città della Salute e della Scienza di Torino, Turin, Italy; Department of Oncology , University of Turin, A.O.Ordine Mauriziano, Turin, Italy; Department of Oncology, University of Turin, AO Ordine Mauriziano, Turin, Italy; Royal Marsden Hospital, Renal and Melanoma Unit, London, United Kingdom; Istituto Nazionale per lo Studio e la Cura dei Tumori, IRCCS Fondazione Pascale, Naples, Italy; Department of Oncology, University of Turin, AOU Città della Salute e della Scienza di Torino, Turin, Italy

Background: scientific community and regulatory agencies have shown a growing interest on QoL, although the inclusion and reporting of QoL analysis in clinical trials is still suboptimal. **Methods:** we previously published a meta-research study of phase III randomized clinical trial (RCT) in patients with solid neoplasms treated with systemic therapy, published from 2012 to 2021 (BMJ Oncology 2023;2:e000021). For the present analysis, we selected the RCT conducted in the advanced setting, integrating the database with results of QoL and of primary endpoints, and with info about regulatory approval. The main outcome was the analysis of correlation of QoL results with study primary endpoint (EP1), namely overall survival (OS) or progression free survival (PFS). Among secondary outcomes, the availability of QoL results was reported for treatments approved by EMA/FDA, with description of time-trends. **Results:** 592phase III RCTpublished from 2012 to 2021 were included: 322 (54.4%) published in 2012-2016 and 270 (45.6%) in 2017-2021. 151 RCT (25.5%) were conducted in gastro-intestinal cancers, 138 (23.3%) in thoracic cancers, 71 (12%) in breast cancer, 79 (13.3%) in genito-urinary cancers. Experimental treatment was chemotherapy in 322 studies (54.4%), targeted therapies in 331 (55.9%), immunotherapy in 94 (15.9%) and hormone therapy in 52 (8.8%). OS was the EP1 in 298 clinical trials (50.3%) and PFS in 304 clinical trials (51.4%), with an overlap for 79 studies (13.3%) with multiple primary endpoints. 124 RCT (41.6%) with EP1 OS reported a positive result in EP1. Among these, QoL analysis was positive for experimental treatment in 62 studies (50%), without statistically significant difference or unfavourable in 30 (24.2%) and not available in 32 (25.8%). In the 182 studies (59.5%) with EP1 PFS and a positive result in EP1, QoL analysis was positive for experimental arm in 77 studies (42.3%), without statistically significant difference or unfavourable in 49 (26.9%) and not available in 56 (30.8%). FDA drug approvals were reported for 143 studies (24.2%). Among them, QoL results were positive for experimental arm in 101 studies (70.6%), negative in 19 (13.3%), absent in 23 (16.1%). Similarly, 142 studies (24%) were associated to EMA approval: positive QoL in 101 studies (71.1%), negative in 21 (14.8%) and absent in 20 (14.1%). The percentage of FDA and EMA approvals associated with the availability of positive QoL data increased from 2012-2016 to 2017-2021. Namely, the proportion of approvals with available QoL positive results increased from 56.5% to 81.5% ($p<0.001$) among FDA approvals, and from 55.4% to 84.4% ($p<0.001$) among EMA approvals. **Conclusions:** in many cases, a positivity in OS or PFS is not accompanied by the demonstration of QoL benefit. The temporal trend of positive QoL results among treatments approved by regulatory agencies is encouraging. Research Sponsor: None.

Symptom management through electronic patient-reported outcome (ePRO)-based intervention in patients with breast cancer treated with abemaciclib: Primary results from the LIBRA study, a phase II randomized controlled trial.

Toshimi Takano, Tetsu Hayashida, Aiko Nagayama, Yukinori Ozaki, Maiko Takahashi, Tomoko Seki, Takamichi Yokoe, Yosuke Aoyama, Rika Kizawa, Meiko Nishimura, Mari Hosonaga, Fumikata Hara, Takayuki Kobayashi, Takayuki Ueno, Yuko Kitagawa; Cancer Institute Hospital of the Japanese Foundation for Cancer Research (JFCR), Tokyo, Japan; Keio University School of Medicine, Tokyo, Japan; Keio University School of Medicine General Surgery, Shinjuku-Ku, Japan; The Cancer Institute Hospital, Japanese Foundation for Cancer Research, Koto-Ku, Japan; Department of Breast Medical Oncology, Japanese Foundation for Cancer Research, Cancer Institute Hospital, Tokyo, Japan; Department of Breast Oncology, Cancer Institute Hospital of the Japanese Foundation for Cancer Research (JFCR), Tokyo, Japan; The Cancer Institute Hospital of the Japanese Foundation for Cancer Research, Tokyo, Japan

Background: We have developed a system using LINE, a widely-used social network service in Japan, for rapid collection of ePROs based on the PRO-CTCAE criteria. To evaluate the effectiveness of intervention through this system in reducing diarrhea frequency and enhancing quality of life (QOL) in patients treated with abemaciclib, we conducted a randomized controlled trial. **Methods:** Patients with hormone receptor-positive advanced breast cancer scheduled to begin abemaciclib treatment were randomized to the intervention and control arms with 1:1 ratio. The LINE-ePRO system was used to monitor symptoms daily in both arms. In the intervention arm, expert medical staffs contacted patients via phone when symptoms met certain criteria, whereas patients in the control arm received standard care. The primary endpoint was the increase in the number of defecations from baseline during 28 days. The secondary endpoints included the increase in the number of defecations from baseline during 56 days, other symptoms monitored via the LINE-ePRO system, QOL evaluated by EORTC QLQ C-30 and EQ-5D-5L, relative dose intensity (RDI), treatment interruption rate, progression-free survival (PFS), and overall survival (OS). This study (LIBRA, UMIN000045432) is funded by Eli Lilly. **Results:** Between Jan 2022 and Apr 2023, 60 women were enrolled and 58 (29 in each arm) were analyzed in this study. Median age was 57.5 years (range 43-80), 93% of patients were post-menopausal, 71% received abemaciclib as first-line treatment, and 74% were treated in combination with aromatase inhibitors. The increase in the number of defecations from baseline was significantly lower in the intervention arm compared to the control arm both during 28 days (0.64 vs. 1.21 per day, p=0.003) and during 56 days (0.55 vs. 1.18 per day, p=0.0004). No significant difference was observed in other symptoms between the arms. In the EORTC QLQ C-30 scales, global health status/QOL (mean score change from baseline to after one cycle of abemaciclib treatment: 0 vs. -13.5, p=0.038) and diarrhea (20.7 vs. 32.2, p=0.049) were better in the intervention arm. The treatment interruption and dose reduction rates were 41.4 and 31.0% in the intervention arm, and 31.0 and 27.6% in the control arm, respectively. The mean RDI of abemaciclib was numerically lower in the intervention arm (73.5% vs. 84.8%). **Conclusions:** This study is the first randomized trial to demonstrate that the intervention based on daily ePROs reduces the frequency of diarrhea in patients with advanced breast cancer treated with abemaciclib. Clinical trial information: UMIN000045432. Research Sponsor: Eli Lilly.

11111 Poster Session

Comparative patient-reported tolerability (PRT): A multiplicity-controlled analysis of LIBRETTO-531, a randomized controlled trial (RCT) in medullary thyroid cancer (MTC).

Marcia S. Brose, Bruce Robinson, Lori J. Wirth, Jaume Capdevila, Jonathan Wadsley, Eric Jeffrey Sherman, Makoto Tahara, Ana Hoff, Mimi I-Nan Hu, Ming Gao, Fernanda Vaisman, Collin Churchill, Boris K. Lin, Patricia H Maeda, Adrienne M. Gilligan, Yan Lin, Nalin Payakachat, Julien Hadoux, Rossella Elisei; Sidney Kimmel Cancer Center, Thomas Jefferson University Hospital, Philadelphia, PA; The University of Sydney, Sydney, NSW, Australia; Center for Head and Neck Cancers, Massachusetts General Hospital, Boston, MA; Medical Oncology Department. Vall Hebron University Hospital, Vall Hebron Institute of Oncology (VHIO), Barcelona, Spain; Weston Park Hospital, Sheffield, United Kingdom; Memorial Sloan Kettering Cancer Center, New York, NY; National Cancer Center Hospital East, Kashiwa-Shi, Japan; University of São Paulo/ICESP, São Paulo, Brazil; The University of Texas MD Anderson Cancer Center, Houston, TX; Tianjin Union Medical Center, Tianjin, China; Instituto Nacional de Câncer, Rio De Janeiro, Brazil; Eil Lilly and Co, Indianapolis, IN; Loxo@Lilly, Indianapolis, IN; Eli Lilly and Company, Cedar Knolls, NJ; Eli Lilly and Company, Indianapolis, IN; Gustave Roussy, Villejuif, France; University of Pisa, Pisa, Italy

Background: In cancers with longer natural histories, progression free survival (PFS) alone may not adequately capture the impact of treatment side effects (SE) and may, therefore, be complemented by robust measures of patient-reported tolerability (PRT) to quantify overall SE burden. Here, we pioneer the use of a novel, scalable, quantitative PRT metric as a key secondary endpoint to support the regulatory review and inform clinical decision-making of selpercatinib use in LIBRETTO-531 (NCT04211337), an RCT that demonstrated the PFS benefit (HR=0.28) of selpercatinib over vandetanib/cabozantinib (control) in *RET*-mutant MTC. **Methods:** We first assessed PRT using the single Functional Assessment of Cancer Therapy (FACT) item GP5, asking patients to rate "bothered by treatment side effects" from 0 to 4. Patients who reported "3=quite a bit" or "4=very much" on GP5 were classified as "high SE bother," a validated meaningful cutoff for treatment SE burden. In a second pre-specified step, PRT was defined as the proportion of time on treatment (PTOT) with "high SE bother" and was compared between selpercatinib vs. control arms in the tolerability evaluable population. PRT was tested at a 1-sided significance level of 0.025, conditional on achieving statistical significance for PFS and treatment failure-free survival by BICR. To complement PRT, other patient-reported outcomes including health-related quality of life (HRQoL, using EORTC QLQ-C30) and symptomatic adverse events (AEs; using PRO-CTCAE) were evaluated. We calculated the PTOT that patients reported clinically meaningful impairment of HRQoL (using pre-specified cutoff scores) and highly symptomatic AEs (scores of 3 or 4). **Results:** Patients on selpercatinib (n=161) had a significantly better PRT (lower PTOT with high SE bother) than control (n=81) (8% vs. 24%, $p<.0001$). Sensitivity analyses using different cutoffs for high SE bother showed consistent results ($p<.0001$). On QLQ-C30, patients on selpercatinib reported significantly less PTOT with HRQoL impairment across physical (36% vs. 52%), role (2% vs. 11%), cognitive (4% vs. 8%), emotional (6% vs. 11%), and social (2% vs. 8%) functions (all $p<0.01$) vs. control. On PRO-CTCAE, patients on selpercatinib reported significantly less PTOT with diarrhea (5% vs. 38%), fatigue (6% vs. 21%), taste change (3% vs. 15%), decreased appetite (2% vs. 15%), hand/foot syndrome (2% vs. 9%) (all $p<.001$) vs. control. **Conclusions:** Through the incorporation of a novel, single question and quantifiable metric that measured time on treatment under high SE bother into the LIBRETTO-531 study, we demonstrated superior PRT and improved PFS for selpercatinib in patients with *RET*-mutant MTC versus vandetanib/cabozantinib. This simplified PRT metric deserves further adoption as a quantitative endpoint to complement PFS in future RCTs. Research Sponsor: Eli Lilly and Company.

11112 Poster Session

Reasons for unmet care needs in older adults with cancer: Analyses from the 2015–2019 National Health and Aging Trends Study.

Ying Wang, AnnaLynn Williams, Marielle Jensen-Battaglia, Kah Poh Loh, Sally Norton, Christopher Seplaki; University of Rocheser Medical Center, Rochester, NY; University of Rochester School of Medicine and Dentistry, Rochester, NY; University of Rochester Medical Center, Rochester, NY; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY; University of Rochester, Rochester, NY

Background: Despite extensive research on unmet care needs in older adults (ages ≥65) with cancer, few studies explore the reasons for unmet care needs, knowledge of which can inform future interventions. We aimed to identity reasons for unmet care needs in older adults with cancer and associated factors. **Methods:** Our analyses included community-dwelling older adults with cancer from the 2015–2019 National Health and Aging Trends Study (NHATS). NHATS captures unmet care needs in 12 activities from three domains: activities of daily living (ADL), instrumental ADL (IADL), and mobility. We separately evaluated two categories of reasons for unmet care needs: "difficulty performing activities independently" (for participants without a caregiver), and "caregivers' inability to help" (for those receiving caregiver assistance). Personal characteristics included demographic (gender, age, marital status, race, ethnicity, educational level), clinical (cancer type, years since cancer diagnosis), and health variables (physical function, nutritional status, cognition, psychological status). We built logistic models to assess characteristics associated with unmet care needs, adjusting for NHATS year and cancer type. In exploratory analyses, we further evaluated associations of years since cancer diagnosis with unmet care needs. All models were built separately for participants with and without a caregiver. **Results:** Our analysis included 1829 participants. In 2015, participants had a mean age of 81 years; more than half were female (55%), White (79%), non-Hispanic (96%), had impaired physical function (92%), and received caregiver assistance (51%). From 2015 to 2019, 29% to 32% participants without a caregiver reported any unmet care needs due to difficulty with performing the activity independently, with toileting (45-53%) and managing medications (27-31%) being the most prevalent. Between 18% and 20% participants with a caregiver reported any unmet care needs due to caregivers' inability to help, with toileting (26-44%) and going around inside home (20-29%) being the most prevalent. Hispanic ethnicity, being separated/divorced, living alone or with non-spouses, and worse health status were independently associated with unmet care needs due to either reason. Compared to pre-diagnosis, being 1-2, [odds ratio (OR) 1.7], 3-4 (OR 1.8) and 5+ (OR 2.2) years from cancer diagnosis was significantly associated with higher odds of unmet care needs among those without a caregiver, but not those with a caregiver. **Conclusions:** Unmet care needs due to difficulty performing activities independently are common among older adults with cancer. Caregivers generally meet care recipients' needs in IADLs, but may face challenges in toileting and mobility needs. Tailored interventions addressing specific reasons for unmet needs are needed, particularly for those at greater risk. Research Sponsor: None.

11113 Poster Session

Evaluation of drug tolerability as a function of toxicity and quality of life in patients enrolled on I-SPY2.

Amrita B. Basu, Saumya Umashankar, Denise M. Wolf, Hannah Chay, Abigail Abikoye, Thelma Brown, Diane Heditsian, Susie Brain, Tina J. Hieken, Kathryn Jean Ruddy, Sarah Tevis, Anne Hudson Blaes, Shelly S. Lo, Rita Nanda, Christina Yau, Michelle E. Melisko, David Cella, Laura Esserman, Hope S. Rugo, Dawn L. Hershman; University of California, San Francisco Department of Surgery, San Francisco, CA; University of California, San Francisco, San Francisco, CA; Susan G. Komen, Birmingham, AL; UCSF Breast Science Advocacy Core, Palo Alto, CA; Mayo Clinic - Department of Surgical Oncology, Rochester, MN; Mayo Clinic, Rochester, MN; The University of Texas MD Anderson Cancer Center, Houston, TX; University of Minnesota Masonic Cancer Center, Minneapolis, MN; Loyola University Medical Center, Maywood, IL; University of Chicago Medicine, Chicago, IL; Dept. of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL; Department of Surgery, University of California, San Francisco, San Francisco, CA; University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY

Background: Patient-reported outcomes (PROs) are valuable for understanding treatment tolerability and toxicity. I-SPY2 is a phase-II neoadjuvant clinical trial for breast cancer with electronic PROs and quality of life (QOL) assessments. We sought to understand how well the GP5 self-reported tolerability item reflected toxicity burden and QOL during treatment and follow-up in I-SPY 2 participants. **Methods:** Our study included 306 patients who completed the FACIT Item GP5 and answered PROMIS surveys at two or more timepoints. Analysis timepoints included screening (SC), inter-regimen (IR), pre-surgery (PS), 1-month post-surgery (FU1), and 6-months post-surgery (FU2). Symptoms were assessed weekly using PRO-CTCAE and CTCAEv4.0. QOL was evaluated using PROMIS. The GP5: "I am bothered by side effects of treatment," was used to estimate tolerability, where worse tolerability is a higher score. Odds ratios, Spearman correlation, and regularized multi-variate regression were used to evaluate the associations between individual symptoms and adverse events with GP5 scores. **Results:** Demographic information was available for 243 of the 306 (70.2%) participants (median age=47,73.7% white). In the 306, tolerability scores worsened over study treatment, with a maximum mean score of 1.71 at Cycle 11. Tolerability improved after treatment cessation at FU1(1.09). Mean tolerability at week 6 was 1.53. The only clinical factor that was associated with early change in tolerability (week 6 to PS) was age >50 (mean score ranged from 1.55-1.70 vs 1.29-1.45 (age<50), $p<0.05$). PRO-CTCAE and GP5 correlative analysis suggested that higher grade abdominal pain, decreased appetite, dizziness and blurry vision significantly associated with higher GP5 scores at multiple timepoints ($p<0.05$). Symptoms not associated with tolerability were nail loss, acne, hair loss, and rash ($p>0.05$). Additionally, the total number of low-grade (mild to moderate) symptoms a patient experienced during study treatment was significantly correlated to poor tolerability ($p<0.00001$). Among patients with CTCAE data, 9% had adrenal insufficiency, and higher GP5 was found across all study timepoints in those with (compared to without) adrenal insufficiency (mean GP5 = [1.7-1.9] vs [1.3-1.5] respectively). Similarly, among patients with neuropathy (14%), higher GP5 scores were reported across all study timepoints (mean GP5 = [1.8-2.3] vs [1.3-1.5] respectively). Higher GP5 scores during treatment were correlated with higher fatigue scores at PS and FU1 ($p<0.02$ and $p<0.001$) and lower physical functioning at PS ($p<0.01$). **Conclusions:** TheGP5 measure is associated with self-reported symptoms, higher grade adverse events and quality of life scores. Furthermore, greater accumulation of lower grade symptoms can lead to poor tolerability. The single measure GP5 composite score reflects multiple components of treatment toxicity. Research Sponsor: None.

Neuropathy trajectory informed by algorithm-based alerts from remote symptom monitoring (RSM) tool in breast cancer practice.

Joel N. Saltzman, Emelly Rusli, Aaron Galaznik, Debra Wujcik; Cleveland Clinic, Mayfield Heights, OH; Carevive Systems Inc., North Miami, FL; Carevive Systems Inc., Miami, FL; Carevive Systems, Inc, Franklin, TN

Background: The prevalence of chemotherapy-induced peripheral neuropathy (CIPN) ranges from 19% to over 85%[1]. In breast cancer (BC) adjuvant treatment, 40% of women report numbness and tingling after two years with 10% stating the symptoms are severe[2]. Risk factors include age, pre-existing neuropathy (PN), and treatment with taxanes and platinum-based drugs. This study explored the trajectory of neuropathy in data from remote symptom monitoring (RSM) in breast cancer practice. **Methods:** Women undergoing BC treatment who enrolled in Carevive PROmPT, an RSM tool, between 9/1/2020 and 11/29/2023 were included. A composite score (derived from PRO-CTCAE) using presence, severity, and interference reports symptoms as mild, moderate or severe. Mild symptoms are discussed at the next clinical visit while moderate/severe symptoms trigger an alert to the care team for immediate evaluation and mitigation. Analysis of neuropathy trajectory was conducted in patients who did not have PN at baseline, examining time to first neuropathy report and time to alert trigger due to severity. Age at first neuropathy, duration of therapy, cancer stage, race, CIPN drugs use, and the level of neuropathy interference was explored. **Results:** A total of 519 BC patients with one or more alerts were included, of whom 177 (34.1%) reported moderate/severe neuropathy at least once. Of 7,641 total alerts generated, 10.5% were associated with neuropathy. Nearly 40% (n=74) of patients had PN, with median age was 58.5, 31% late stage, 32% Black/African American, and 61% having prior CIPN treatment. About 58.2% of patients (n=103) did not have PN at baseline; of whom neuropathy was first reported over a median of 42 days (IQR: 17.5, 70.5) from baseline and 53.4% of patients (n=55) had mild neuropathy at first report, which then progressed to moderate/severe at a median of 28 days (IQR: 14, 79). About half of patients (52%) described the first neuropathy interference to be a little bit or somewhat. Patients with mild first occurrence of neuropathy (n=55) were then stratified by time to first neuropathy alert (moderate/severe) from first report: 0-28 days (n=28) and >28 days (n=27). For the two groups, median age at first neuropathy was 51 and 49, duration of treatment was 2.4 and 4.4 months, late stage was 18% and 15%, Black/African American 32% and 22%, and receiving CIPN drugs at alert was 24% and 29%, respectively. The most prevalent level of interference upon alert was described as somewhat (32% vs. 28%, respectively). **Conclusions:** Breast cancer patients are at risk for developing severe and sustained neuropathy. Patients without PN whose first report of neuropathy was mild, quickly progressed to moderate/severe neuropathy. Physician notification at first report of neuropathy rather than with an alert of moderate/severe neuropathy provides opportunity for earlier intervention and better outcomes. Research Sponsor: None.

11115 Poster Session

The pre-operative window of endocrine therapy to inform radiation therapy decisions (POWER) trial: Baseline patient beliefs about breast cancer and endocrine therapy.

Lena Turkheimer, Jenna Schlefman, Trish Ann Millard, Gina Petroni, David Brighton, Shayna Lefrak Showalter; University of Virginia, Charlottesville, VA

Background: The POWER Trial (NCT04272801) aims to determine whether pre-operative endocrine therapy (pre-ET) impacts physician recommendations and patient preferences for adjuvant radiation (RT) and endocrine therapy (AET) among women who qualify for RT omission. While physicians characterize this population as low-risk, they often still recommend RT. The POWER trial captures baseline patient perspectives regarding recurrence and medication tolerance using patient-reported outcome surveys and examines how these influence treatment choices. **Methods:** POWER Trial participants received 90 days of pre-ET before surgery and treatment decisions regarding RT. Women $\geq$ 65 years old with ER+ tumors $\leq$ 2 cm, node negative were eligible. Patient beliefs about their cancer and medications were assessed at baseline using the Beliefs About Illness Questionnaire (BIP-Q), Beliefs About Medicine Questionnaire-ET (BMQ-ET), and Perceived Sensitivity to Medicines (PSM) scale. An additional novel, non-validated questionnaire was created to further evaluate patients' beliefs. **Results:** The study cohort included 48 women with mean age of 73.7. Few patients (14.6%) viewed their breast cancer as having a high threat to their health. While half (50.0%) of the participants worried a lot about the return of their breast cancer, only 35.4% thought that a cancer recurrence would be devastating. Participants who worried more about their breast cancer returning were more likely to feel a recurrence would be devastating (Pearson Correlation Coefficient = .67). There was no association between baseline beliefs and RT omission. Most patients (81.3%) did not consider themselves sensitive to medications. Although 81.3% reported side effects as important when deciding to continue or stop medications, almost all participants (95.8%) stated they would continue medications, despite side effects, if it would help lower their risk of recurrence. When specifically asked about AET, 70.8% reported a low level of concern about taking the therapy and 72.9% felt it was necessary. Of study participants, 27 (56.3%) omitted RT and initiated AET, 10 (20.8%) had RT and declined AET, 10 (20.8%) completed RT and initiated AET, and 1 (2.1%) declined RT and AET. **Conclusions:** This analysis shows that many early-stage ER+ breast cancer patients have a low level of worry about breast cancer recurrence, which may support treatment de-escalation such as RT omission. Most participants are open to taking AET despite the potential for side effects, yet historical data demonstrate low rates of adherence to AET. This discrepancy highlights that patients' baseline beliefs about themselves and their medications may not align with their actual adherence. Future analysis from the POWER trial will examine how long-term AET adherence relates to baseline patient beliefs. Clinical trial information: NCT04272801. Research Sponsor: U.S. National Institutes of Health.

11116 Poster Session

A descriptive patient-reported outcomes (PROs) analysis of KEYNOTE-412 to understand head and neck symptom burden.

Lillian L. Siu, Kelly McQuarrie, Behzad Bidadi, Chih-Chin Liu, Christopher M. Black, Anran Wang, Yungan Tao, Lisa F. Licitra, Barbara Burtness, Makoto Tahara, Danny Rischin, Kevin Joseph Harrington, Jean-Pascal Machiels; Princess Margaret Cancer Centre, University of Toronto, Toronto, ON, Canada; Merck & Co., Inc., Rahway, NJ; Gustave Roussy, Villejuif, France; Fondazione IRCCS Istituto Nazionale dei Tumori and University of Milan, Milan, Italy; Yale University School of Medicine and Yale Cancer Center, New Haven, CT; National Cancer Center Hospital East, Kashiwa-Shi, Japan; Peter MacCallum Cancer Center and the University of Melbourne, Melbourne, VIC, Australia; The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust, National Institute of Health Research Biomedical Research Centre, London, United Kingdom; Cliniques Universitaires Saint-Luc and Institut de Recherche Expérimentale et Clinique (Pole MIRO), Uclouvain, Brussels, Belgium

Background: The randomized, double-blind, phase 3 KEYNOTE-412 study (NCT03040999) investigated pembrolizumab (pembro) + chemoradiation therapy (CRT) versus placebo + CRT for locally advanced head and neck squamous cell carcinoma (LA HNSCC). Descriptive PRO analysis may provide important insight to better understand patient (pt) experiences. This analysis evaluated pt experience by examining item-level PRO scores. **Methods:** Adults with LA HNSCC were randomly assigned 1:1 to pembro 200 mg IV Q3W or placebo + CRT. PROs included the EORTC QLQ-C30 and EORTC QLQ-H&N35. Responses to each item of the QLQ-C30 and H&N35 were analyzed descriptively based on treatment group combined data. Each item was evaluated overall, and then for the H&N35 by tumor location and by clinical event (death, distant progressive disease [PD], local regional PD, local PD, and distant metastasis or histologically persistent/residual disease). Symptom burden was defined as responses of "a little," "quite a bit," "very much," or "yes." Items associated with high symptom burden (≥30% of responses "quite a bit," "very much," or "yes") at baseline were analyzed over time. **Results:** Of 756 pts with PRO data, highly endorsed items (≥50% experiencing the symptom) on the QLQ-C30 at baseline were pain, trouble sleeping, needing rest, tiredness, and worry; highly endorsed (≥50%) items from the H&N35 were pain in mouth, painful throat, problems swallowing solid food, coughing, hoarseness, and use of pain killers. Pts with an event, compared to pts who were event-free at the time of data cut-off, experienced greater symptom burden at baseline; for example, pain in mouth (56% vs 50%), pain in jaw (47% vs 37%), use of pain killers (71% vs 58%), weight loss (53% vs 30%), trouble eating (63% vs 46%), and problems swallowing solid food (69% vs 56%). Symptoms at baseline also differed by primary tumor location, demonstrating the heterogeneity of symptom burden across this population. Based on the threshold of ≥30% reporting worse responses at baseline, 20 items on the H&N35 were analyzed over time. Of pts who experienced an event (n = 345, 46%), 6 items met this threshold: pain in mouth (32%), problems swallowing solid food (41%), trouble eating (32%), use of pain killers (71%), use of nutritional supplements (34%), and weight loss (53%). For these items, a similar or greater percentage of pts with symptoms were observed over time in those who had events compared to those with no events. **Conclusions:** Observations of pts enrolled in KEYNOTE-412 study who had events, appearing to have greater symptom burden at baseline, suggests there may be a relationship between baseline item scores and clinical outcomes. Heterogeneity of populations may lead to variability of baseline PRO scores and should be considered in PRO analysis. Further research is needed to explore the relationship between baseline PROs and event outcomes as well as additional subgroup analysis. Clinical trial information: NCT03040999. Research Sponsor: None.

Association of patient-reported experience of care with cancer clinical trial participation.

Michelle Mollica, Timothy S. McNeel, David T Eton, Michael T. Halpern; National Cancer Institute, Bethesda, MD; IMS, Rockville, MD

Background: Few individuals diagnosed with cancer participate in clinical trials. Patient-reported experience of care (PEC), assessing patients' perspectives on interactions with health-care providers and systems, is important in evaluating quality of care. To help identify patient-centered strategies that may enhance trial enrollment, we examined whether PEC may predict enrollment in clinical trials. **Methods:** This study utilized Surveillance, Epidemiology, and End Results-Consumer Assessment of Healthcare Providers and Systems (SEER-CAHPS) linked data, including SEER registry data, CAHPS PEC surveys, and Medicare claims. Individuals in SEER-CAHPS who were diagnosed with lung cancer 2000-2018 and completed a CAHPS survey ≥6 months following diagnosis were included. The study outcome, clinical trial enrollment after cancer diagnosis, was determined using Medicare claims; among individuals who enrolled in clinical trials, only those completing a CAHPS survey before trial enrollment were included. PEC was assessed using 5 global ratings (Overall Care, Personal Doctor, Specialist, Health Plan, and Prescription Drug Plan) and 6 composite measures (Doctor Communications, Getting Needed Care, Getting Care Quickly, Getting Needed Drugs, Care Coordination, and Customer Service); all were scored 0 (worse PEC) to 10 (best PEC). Associations of trial participation and PEC were assessed using multivariable logistic regression, controlling for age, race/ethnicity, dual Medicaid status, fee-for-service vs Medicare Advantage plan at diagnosis, and physical problems limiting activities, and were weighted to correspond to the overall SEER population. **Results:** The study included 5,361 individuals diagnosed with lung cancer; 4.8% of the weighted population enrolled in a clinical trial. Patients with higher PEC ratings for their Specialist (odds ratio [OR] for a 1-point higher PEC score 0.86, 95% CI 0.76, 0.98); for their Health Plan (OR 0.87, 95% CI 0.80, 0.96); and for Getting Needed Care (OR 0.89, 95% CI 0.81, 0.98) had significantly ($p<0.05$) *lower odds*of having enrolled in a clinical trial. Among individuals without physical limitations, association of PEC and trial enrollment were similar. Among individuals with physical limitations, higher PEC ratings for Getting Care Quickly were associated with *higher odds* (OR 1.20, 95% CI 1.03, 1.39) of having enrolled in a trial. **Conclusions:** In this population, reporting worse PEC in certain domains was significantly associated with increased clinical trial enrollment. This suggests patients less happy with their clinical care may be more likely to enroll in trials, perhaps to receive different types of care and/or from different providers. PEC associations with trial enrollment differ between patients with vs without physical limitations, suggesting different strategies may be effective for increasing trial enrollment among these two sub-groups. Research Sponsor: None.

11118 Poster Session

Social determinants of health and patient reported outcomes in lung cancer survivors.

Yanmei Peng, Andrea L. Cheville, Jennifer Ridgeway, Roberto P. Benzo, Jason A. Wampfler, Claire I. Yee, Matthew Buras, Nathan Y Yu, Vinicius Ernani, Pedro A Reck dos Santos, Karen L. Swanson, Jonathan D'Cunha, Aminah Jatoi, Ping Yang; Mayo Clinic, Scottsdale, AZ; Mayo Clinic Department of Pediatric and Adolescent Medicine, Rochester, MN; Mayo Clinic, Rochester, MN; Department of Internal Medicine, Rochester, MN; Department of Quantitative Health Sciences, Mayo Clinic Arizona, Phoenix, AZ; Mayo Clinic Arizona Department of Statistics, Scottsdale, AZ; Mayo Clinic, Phoenix, AZ

Background: Lung cancer survivors experience more physical and mental challenges, heavier symptom burden, and poorer quality of life than survivors of other cancers. Many symptoms persist or worsen for survivors beyond 5 years of cancer diagnosis, referred as long-term lung cancer survivors (LTLCS). Social determinants of health (SDoH) factors negatively impact patient reported outcomes (PROs) among cancer survivors, but their role in outcomes is under reported in lung cancer survivors and unknown in LTLCS. We investigated the impact of SDoH on PROs in a 20-year prospective lung cancer cohort. **Methods:** Our cohort includes 19,251 lung cancer patients (cases) diagnosed from 1997 through 2016 and followed up to 27 years, of whom 4799 (25%) became LTLCS. SDoH information was obtained by a lung cancer study PRO questionnaire or an institution SDoH questionnaire. Analyzed in this report are 2982 cases and 480 controls who had a low-dose chest CT scan and were ruled out for cancer, all answered at least one PRO questionnaire (first response); and 1366 LTLCS answered 5 years after diagnosis (long-term response). Along with fatigue and dyspnea, 5 SDoH variables, i.e., financial concerns, legal concerns, family and friends support, spiritual well-being, and social activity were scored on a 0 (worst) - 10 (best) scale and dichotomized as 0-5 (deficit/worse/lower) or 6-10 (no deficit/better/higher). We also assessed employment and health-related work experience. A difference of 1.0 unit or more in score was considered clinically meaningful along with a 2-sided test P-value less than 0.05; Chi-square or Fisher's Exact Test and Kruskal-Wallis test were used accordingly. **Results:** Compared to controls, cases were younger (mean age: 62 vs. 65 years, $P<0.05$); more women than men reported worse financial concerns (56% vs. 38%, $P<0.01$) and lower spiritual well-being (43% vs. 26%, $P=0.04$) at first response; this sex disparity reduced but remained significant at long-term. Worse dyspnea (4.4-4.8 vs. 5.6) and fatigue (4.7-4.8 vs. 5.8-5.9) were seen in cases with more financial and legal concerns compared to those with fewer concerns ($Ps<0.01$). Cases with higher family and friends support, spiritual well-being and social activity had less dyspnea (5.7-6.0 vs. 4.2-4.5) and fatigue (5.5-5.9 vs. 3.9-4.4) than those with lower scores ($Ps<0.04$). Employment and health-related work experience data were provided by 2213 responders: Comparing 1735 cases to 478 controls, a lower proportion of cases was employed (28% vs. 39%), more cases "often felt tired after work" (49% vs. 28%), and more cases had "quite a lot" of difficulty in daily work or could not work at all" (26% vs. 9%, $Ps<0.01$). **Conclusions:** We found that in lung cancer survivors, more women than men reported worse financial concerns, and lower SDoH status was correlated with worse dyspnea and fatigue, indicating SDoH-driven interventions are important to improve lung cancer survivors' PROs. Research Sponsor: None.

11119 Poster Session

Change in financial toxicity during early-phase cancer clinical trial (EP-CT) participation.

Sienna Durbin, Debra Lundquist, Andrea Pelletier, Laura A Petrillo, Anh B. Lam, Rachel Jimenez, Victoria Turbini, Viola Bame, Kaitlyn Lynch, Vaishnavi Reddy Yalala, Nicholas Ollila, Benjamin Malowitz, Casandra McIntyre, Dejan Juric, Ryan David Nipp; Massachusetts General Hospital, Boston, MA; Brigham and Women's Hospital, Boston, MA; University of Oklahoma Health Sciences Center, Oklahoma City, OK; Henri and Belinda Termeer Center for Targeted Therapies, Massachusetts General Hospital, Boston, MA; The University of Oklahoma Stephenson Cancer Center, Oklahoma City, OK

Background: The high costs of care (financial toxicity) represent a pressing concern in oncology. Little is known about the financial toxicity experienced by EP-CT participants. We sought to describe changes in financial toxicity during EP-CTs and assess associations of change in toxicity with patient characteristics, additional patient-reported outcomes (PROs), and trial reimbursement structure. **Methods:** We prospectively enrolled adults participating in EP-CTs from 4/2021 – 1/2023. We administered surveys at baseline (between enrollment and Day 1 of trial) and monthly during trial participation. We assessed financial toxicity using the COST tool, graded as low (≥26) and high (0–25) toxicity. We also surveyed baseline hope (Hope Herth Index), quality of life (QOL; FACT-G) and symptom burden (psychological: PHQ-4; physical: ESAS). We calculated within-patient changes in COST score and conducted linear mixed models, controlling for baseline COST score, to determine associations of change in financial toxicity with patient characteristics, baseline PROs, and trial reimbursement structure (using a factor x time interaction term). **Results:** Of 221 eligible patients, we enrolled 205 (median age = 63.3 years [range 32.8-88.6], 57.1% female). Most common tumors were GI (34.6%) and breast (20.0%). At trial start, 35.0% of patients reported high financial toxicity, 40.5% at 1 month, 33.6% at 2 months, 25.5% at 6 months, and 40.0% at 1 year. Within-patient COST score worsened over time (B=-0.20, p=0.059), although this change did not reach significance. We found no patient characteristics that significantly correlated with change in COST score, including age (B=-0.005, p=0.602), sex (B=-0.097, p=0.667), GI cancer (B=-0.11, p=0.118), annual income >$60,000 (B=-0.10, p=0.306), and current employment (B=-0.34, p=0.121). Higher baseline QOL was associated with increased COST score (financial wellbeing, while on trial (B=0.012, p=0.011); there was no significant association with other baseline PROs. Most patients (64.4%) enrolled on trials that offered reimbursement for study costs. Of those offering reimbursement, 40.1% had all research-specific costs reimbursed. There was no significant association between change in COST score and presence of any reimbursement (B=0.12, p=0.614) or presence of full reimbursement (B=-0.072, p=0.784). **Conclusions:** In this cohort of EP-CT participants, over one-third reported high rates of financial toxicity, which appeared relatively stable over time on trial. We did not identify any demographic factors associated with risk of worsening toxicity but did find that high baseline QOL may be protective. Trial reimbursement did not lead to improvement in financial wellbeing. Findings demonstrate that EP-CT participation may not place excess financial burden on at-risk patients and highlight the need to monitor for financial toxicity across all trial participants. Research Sponsor: The ESSCO-MGH Breast Cancer Research Fund.

Evaluating the feasibility of a Mobile Audio Companion (Elly) to reduce anxiety and to improve patient-reported outcomes among patients with cancer.

Tyra Nguyen, Nima Nikravesh, Tailyr Monette, Bianca Luna-Lupercio, Sarah-Jeanne Salvy, Stephen J. Freedland, Arash Asher, Scott A. Irwin, Celina H. Shirazipour, Gillian Gresham; Cedars-Sinai Medical Center, Los Angeles, CA

Background: Anxiety is one of the most commonly reported symptoms among cancer patients, and is a known risk factor for reduced health-related quality of life and other negative patient-reported outcomes (PROs). Mobile health applications (apps) are tools that can be used flexibly in patients' preferred environments with the potential to reduce anxiety and improve quality of life. The current study sought to examine the feasibility and preliminary efficacy of a mobile audio companion app, Elly, to improve anxiety and other critical PROs among cancer patients. **Methods:** This was a single-site, single-arm pilot study conducted over 6-months. Adults 18 years or older with a diagnosis of cancer of any type, received treatment within 6 months of consent, and had access to an iPhone were eligible. The primary outcome was change in mean anxiety t-scores (NIH PROMIS anxiety short form (8a)) administered electronically via REDCap at baseline, 1 (primary timepoint), 3, and 6 months. Secondary outcomes included changes in NIH PROMIS depression, loneliness, social support, and perceived stress scores from baseline to 6 months. Changes in NIH PROMIS T-scores at each time point were calculated and analyzed using paired t-tests. **Results:** Of 53 patients who consented for the study, 38 patients (72%) were included in the analysis (M_{age}: 52.8 years, SD: 11.7, 84.2% female). Most participants reported a history of breast cancer (50%), followed by ovarian (16%), hematologic (11%), and other cancer types (24%) Phone incompatibility and technological challenges were the most common reasons for screen-fails (n=15). All participants downloaded and used the app at least once, with an average of 154 app usage events across participants recorded over the study period (median: 64, range 11-1186 times). The mean baseline anxiety T-score was 63.5 (SD: 2.1). Anxiety levels decreased among participants over time, with a mean difference in anxiety T-scores of -1.9 at 30 days, -3.3 at 90 days, and -3.0 at 6 months from baseline, which was statistically ($p<0.05$) and clinically significant. Participants also reported improvements in perceived stress, depression symptomatology, social support, and loneliness, although statistical significance was not reached. **Conclusions:** Mobile apps, such as Elly, may feasibly be used to support patient-reported anxiety as well as other PROs, especially among those who present with high levels of anxiety at baseline. Efforts to increase access to mobile health apps and provide technical support for patients should be made increase equity across the cancer survivor population. Larger, multi-center randomized controlled trials are needed to build on these findings. Research Sponsor: Cedars-Sinai; Elly Health.

Cost-utility analysis of a supervised exercise program for patients with metastatic breast cancer in the PREFERABLE-EFFECT randomized controlled trial (RCT).

Anouk E. Hiensch, Aniek Schouten, Evelyn M. Monninkhof, Martina Schmidt, Dorothea Clauss, Mark Trevaskis, Helene Rundqvist, Joachim Wiskemann, Jana Mueller, Elsken Van Der Wall, Neil K Aaronson, Elzbieta Senkus-Konefka, Ander Urruticoechea, Wilhelm Bloch, Eva Zopf, Martijn M. Stuiver, Yvonne Wengstrom, Karen Steindorf, Miriam van der Meulen, Anne Maria May, on behalf of the PREFERABLE Consortium; University Medical Center Utrecht, Utrecht, Netherlands; Julius Center for Health Sciences and Primary Care, University Medical Center, Utrecht University, Utrecht, Netherlands; German Cancer Research Center (DKFZ) and National Center for Tumor Diseases (NCT) Heidelberg, a partnership between DKFZ and University Medical Center Heidelberg, Heidelberg, Germany; German Sport University Cologne, Cologne, Germany; Mary MacKillop Institute for Health Research, Australian Catholic University, Melbourne, Australia; Dep of Laboratory Medicine, Karolinska Institutet and Unit of Clinical Physiology, Karolinska University Hospital, Stockholm, Sweden; Heidelberg University Hospital and NCT Heidelberg, a partnership between DKFZ and University Medical Center Heidelberg, Heidelberg, Germany; University Medical Center of Utrecht, Utrecht, Netherlands; The Netherlands Cancer Institute, Amsterdam, Netherlands; Medical University of Gdańsk, Gdańsk, Poland; Gipuzkoa Cancer Unit- OSID/Onkologikoa-Osakidetza, San Sebastian, Spain; Mary MacKillop Institute for Health Research, Australian Catholic University, Melbourne, Australia AND Cabrini Cancer Institute, Cabrini Health, Melbourne, Australia; Dep of Neurobiology Care Science and Society, Nursing, Karolinska Institutet and Karolinska Comprehensive Cancer Center, Karolinska University Hospital, Stockholm, Sweden; Julius Center for Health Sciences and Primary Care, Department of Epidemiology, Utrecht, Netherlands

Background: Exercise for patients with metastatic breast cancer (mBC) significantly reduced fatigue and improved quality of life (QoL) in the multinational PREFERABLE-EFFECT RCT (NCT04120298). Evidence on the cost-effectiveness of exercise for patients with mBC is lacking, albeit essential for implementation in clinical practice. In this study, we evaluated the cost-utility of an exercise program for patients with mBC in the EFFECT RCT. **Methods:** We conducted a cost-utility analysis using data from the 357 EFFECT trial participants (mean age 55 ± 11 yrs, 75% on $1^{st}/2^{nd}$ line treatment). These participants, from centers in NL, DE, SE, PL, ES, AU, were randomized to either a 9-month supervised exercise intervention (n=178) or a usual care control group (n=179). We used a societal perspective with a time-horizon of 9 months. Two different scenario analyses (SA) were used to determine intervention costs using a bottom-up micro-costing method: SA-1) 1-on-1 supervision; SA-2) 4-on-1 supervision. Data on healthcare resource use, productivity loss and QoL (converted to QALYs) were collected with country-adapted, self-report questionnaires, including the iMCQ, iPCQ and EQ-5D-5L, at 3-, 6- and 9-months post-baseline. Multiple imputation was performed, and bootstrapping was used to study uncertainty. **Results:** Compared to usual care, supervised exercise led to a QALY gain of 0.015 (95% CI: -0.02; 0.05) over a 9-month period, corresponding to an increase of 5.3 days in perfect health. The mean intervention costs were €1,696 in SA-1 and €609 in SA-2. The mean total cost differences (adjusted for center and line of treatment) were -€27 (SA-1), and -€1,112 (SA-2), in favor of the exercise group (*Table*). The greatest cost-savings occurred in hospital costs, meaning that the exercise group had lower hospital costs compared to the control group (€4,430 vs €5,211). The probability of supervised exercise being cost effective at a willingness-to-pay threshold of €20.000 or €80.000 per QALY gained was 62% or 76% in SA-1, and 91% or 92% in SA-2, respectively. **Conclusions:** Exercise for patients with mBC is likely to be cost-effective when individually supervised and even dominant (greater cost-savings and more effective) when group-based. Based on our positive findings for both effectiveness and cost-effectiveness, we recommend supervised exercise to be reimbursed as supportive care during treatment for mBC. Clinical trial information: NCT04120298. Research Sponsor: European Union's Horizon 2020 research and innovation program; No 825677; National Health and Medical Research Council of Australia; 2018/GNT1170698.

9-month costs (€, 2021, pooled results after multiple imputation).

	Exercise Group	Control Group
	Mean(€)	*Mean*(€)
Total costs		
SA-1	9342	9334
SA-2	8255	9334
Intervention costs		
SA-1	1696	-
SA-2	609	-
GP	182	191
Paramedic[1]	657	660
Hospital[2]	4430	5211
Home care	94	423
Informal care	729	956
Productivity[3]	1554	1893

[1]E.g., Physiotherapy, psychologist, acupuncture.
[2]Outpatient clinic, hospitalizations, day treatments, emergency care.
[3]Absenteeism, presenteeism.

Age-normed patient-reported outcome measures among cancer survivors.

Samantha Tam, Eric Adjei Boakye, Kylie Springer, Laila Poisson, Nada Al-Antary, Farah Elsiss, Mrudula Nair, Theresa Zatirka, Michael Ryan, Steven S. Chang, Benjamin Movsas; Henry Ford Health, Detroit, MI; Henry Ford Health System, Detroit, MI; Henry Ford Hospital, Detroit, MI

Background: Patient-reported outcome measures (PROMs) are instruments used to collect health-related outcomes that are derived completely from the patient without interpretation from healthcare providers. Monitoring and subsequent intervention based on PROMs collection has demonstrated efficacy in clinical trial settings. This has resulted in implementation of PROMs in routine clinical cancer practices throughout the nation. PROMs have been normed to the general population, but establishing the norms among cancer patients is essential to understanding how PROMs can be evaluated on an individual basis in routine clinical cancer care. This study aims to characterize age-normed PROMs scores among survivors of cancer using the National Institute of Health's Patient-Reported Outcome Measures Information System (PROMIS) depression, fatigue, pain interference, and physical function domains. **Methods:** Routine collection of PROMs using 4 domains (depression, fatigue, pain interference, and physical function) of PROMIS were offered to all patients with a diagnosis of cancer of any disease site at visits with an oncologic provider using computer adaptive testing. All patients ≥18 years old with a completed PROM at least 2 years since their diagnosis of cancer were eligible for inclusion in the analysis. Only completed PROMs were included in the final analysis. Generalized estimating equation models were used to assess the relationship between age and the estimated mean T-score for each PROMs domain, considering repeat measures within a single patient. **Results:** A total of 3,636 patients were included in this retrospective cohort study with a total of 26,173 completed PROMs among all 4 domains. Mean age at diagnosis was 61.2 years (SD=12.44), 64% (n=2324) were female, 68% (n=2,461) identified as White, and 25% (n=893) identified as Black. For fatigue, mean T-score ranged from 48.4 points (SD=9.6) among 18-29 years olds to 56.5 points (SD=10.1) among 90-99 years olds, with no significant change with age (p=0.27). For depression, mean T-score ranged from 48.9 points (SD=9.0) among 60-69 year olds to 51.1 points (SD=8.8) among 80-89 year olds with a 0.3 point/decade decrease in T-score (p=0.01). Pain interference T-scores ranged from 48.6 points (SD=10.5) among 18-29 year olds to 55.0 points (SD=9.4) among 80-89 year olds with a 0.4 point/decade average increase ($p<0.001$). The largest differences were observed in physical function, where scores ranged from 53.5 points (SD=11.0) among 18-29 year olds to 34.3 points (SD=9.2) among 90-99 year olds. There was a 2.1 point/decade decrease in T-score ($p<0.001$). **Conclusions:** Among survivors of cancer, mean PROMIS scores differed by age in the depression, pain interference, and physical function domains but not fatigue. These age-normed PROMIS T-scores, which are required to understand individualized assessments of PROMs, are essential as PROMs are integrated into routine cancer care. Research Sponsor: None.

11123 Poster Session

EROS: Engendering reproductive health within oncologic survivorship—ECOG-ACRIN E1Q11 paradoxical provision of reproductive health.

Ashlesha Patel, Ju-Whei Lee, Howard A. Zaren, Erika K Radeke, Rachel E. Lerner, Jami Aya Fukui, Della F. Makower, Deimante Tamkus, Kendrith M. Rowland, William M. Adler, Alyssa Throckmorton, sharad A. ghamande, Jessica Jones Croley, Andrew William Pippas, Rubina Qamar, Michael Jordan Fisch, David Cella, Lynne I. Wagner, Mary Helen Helen Hackney; Cook County Hospital, Chicago, IL; Dana-Farber Cancer Institute, ECOG-ACRIN Biostatistics Center, Boston, MA; Lewis Cancer & Research Pavilion, Savannah, GA; SHCC MU-NCORP, Chicago, IL; Park Nicollet, Minneapolis, MN; University of Hawaii Cancer Center, Honolulu, HI; Montefiore Medical Center-Weiler Hospital, New York, NY; John H. Stroger, Jr. Hospital of Cook County, Chicago, IL; Carle Clinic, Champaign, IL; Memorial Medical Center, Las Cruces, NM; Baptist Memorial Healthcare System, Memphis, TN; Medical College of Georgia at Augusta University, Augusta, GA; Saint Joseph Hematology Oncology, Lexington, KY; John B Amos Cancer Center, Columbus, GA; Advocate Aurora Health, Milwaukee, WI; The University of Texas MD Anderson Cancer Center; Carelon Medical Benefits Management, Houston, TX; Dept. of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL; Wake Forest University School of Medicine, Winston-Salem, NC; Virginia Commonwealth University, Richmond, VA

Background: For the 10% of women diagnosed with cancer in the reproductive age, reproductive health (RH) is a critical component of oncologic survivorship. RH includes oncocontraception (OC), oncofertility (OF) and sexuality. Guidelines segregate these components resulting in fragmented reproductive health care management. **Methods:** The EROS trial is a clustered randomized trial performed at 17 NCI Community Oncology Research Program (NCORP) sites (including 8 NCORP sites and 9 Minority/Underserved NCORP sites) from 2016-2023. Eligible subjects included reproductively capable women aged 15-55 with new cancer diagnosis. Intervention included RH didactics and decision aids. Childbearing interest was dichotomous, not completed childbearing (including either pregnant or future childbearing interest) or completed childbearing. The objective of this study is to determine provision of OC and OF referral by providers at the baseline visit based on patient's self-reported childbearing interest at study entry. Chi-square tests were used to compare distribution differences in the referral status (receipt: yes vs. no) between treatment arms. **Results:** The EROS study enrolled 420 subjects. Of the 63.6% (267/420) completed childbearing, 62.4% (58/93) in the intervention arm and 40.2% (70/174) in the non-intervention arm received an OC referral (p=0.0006), whereas 98.9% (92/93) in the intervention arm and 93.7% (163/174) in the non-intervention arm received an OF referral (p=0.0487). Of the 36.4% (153/420) not completed childbearing, 48.3% (28/58) in the intervention arm and 33.72% (32/95) in the non-intervention arm received an OC referral (p=0.0729), while 77.6% (45/58) in the intervention arm and 70.5% (67/95) in the non-intervention arm received an OF referral (p=0.3388). **Conclusions:** While the intervention increased the rates of provision of oncocontraception and oncofertility for patients with completed childbearing, our study shows provision of oncofertility referrals at a markedly higher rate than oncontraception. Referral patterns were inconsistent with patient need particularly in completed (receiving OF referral) or delayed childbearing (not receiving OC referral) interest of the patient. The bias favoring oncofertility referral may reflect oncology guidelines emphasizing this aspect of reproductive health despite comprehensive needs of patient. Research Sponsor: None.

11124 Poster Session

If you build it, they will come: Success of the EROS (Engendering Reproductive Health Within Oncologic Survivorship)—ECOG-ACRIN E1Q11 in recruitment of minority patients.

Ashlesha Patel, Ju-Whei Lee, Howard A. Zaren, Erika K Radeke, Rachel E. Lerner, Jami Aya Fukui, Della F. Makower, Deimante Tamkus, Kendrith M. Rowland, William M. Adler, Alyssa Throckmorton, sharad A. ghamande, Jessica Jones Croley, Mary Helen Helen Hackney, Andrew William Pippas, Rubina Qamar, David Cella, Michael Jordan Fisch, Lynne I. Wagner; Cook County Hospital, Chicago, IL; Dana-Farber Cancer Institute, ECOG-ACRIN Biostatistics Center, Boston, MA; Lewis Cancer & Research Pavilion, Savannah, GA; SHCC MU-NCORP, Chicago, IL; Park Nicollet, Minneapolis, MN; University of Hawaii Cancer Center, Honolulu, HI; Montefiore Medical Center-Weiler Hospital, New York, NY; John H. Stroger, Jr. Hospital of Cook County, Chicago, IL; Carle Clinic, Champaign, IL; Memorial Medical Center, Las Cruces, NM; Baptist Memorial Healthcare System, Memphis, TN; Medical College of Georgia at Augusta University, Augusta, GA; Saint Joseph Hematology Oncology, Lexington, KY; Virginia Commonwealth University, Richmond, VA; John B Amos Cancer Center, Columbus, GA; Advocate Aurora Health, Milwaukee, WI; Dept. of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL; The University of Texas MD Anderson Cancer Center; Carelon Medical Benefits Management, Houston, TX; Wake Forest University School of Medicine, Winston-Salem, NC

Background: The average recruitment of minority subjects in oncology trials is 4%. The ECOG-ACRIN EROS trial was designed to be inclusive of minority subjects by inviting Minority/Underserved NCI Community Oncology Research Program (MU-NCORP) sites first, with remaining sites fulfilled by inviting NCORP sites. Our objective is to examine if the EROS study recruited more than 4% minority patients, and if MU-NCORP sites provided higher rates of minority recruitment than NCORP sites. **Methods:** The EROS trial is a clustered randomized trial performed at 17 NCI Community Oncology Research Program (NCORP) sites (including 8 NCORP sites and 9 Minority/Underserved NCORP sites) from 2016-2023. Eligible subjects included reproductively capable women aged 15-55 with new cancer diagnosis. Intervention included RH didactics and decision aids. With respect to self-reported minority status, patients were classified into one of two categories, White and non-Hispanic/Latino or minority (non-White or Hispanic/Latino). Chi-square tests were used to evaluate distribution difference between groups and binomial tests were used for testing proportions against reference points. **Results:** Of the 434 patients enrolled to the trial, MU-NCORP sites recruited 266/434 (61.3%) and NCORP sites 168/434 (38.7%) patients. Among all enrolled patients, 422 patients' race/ethnicity status could be classified. 202/422 (47.9%) self-reported as Hispanic/Latino or non-White ($p<.0001$ 0.48 against 0.04). In MU-NCORP (174/258) 67.4% and NCORP sites (28/164) 17.1% were of minority status. ($p < .0001$). **Conclusions:** The EROS trial was designed with minority inclusion for generalizability of results. Prioritization to include MU-NCORP sites in the EROS trial did result in substantially increased minority recruitment, with the overall minority recruitment rate above usual cancer trials. Such strategy may be followed to increase minority recruitment to oncology trials. Research Sponsor: None.

11125 Poster Session

Viral hepatitis screening in patients with early breast cancer receiving cancer therapy: A quality improvement initiative.

Katherine Klein, Jessica Park Hwang, Vicente Valero, David Luis Ramirez, Jaime Kaushik; The University of Texas Health Science Center at Houston, Houston, TX; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: ASCO guidelines recommend screening all patients for hepatitis B virus (HBV) before initiation of cancer therapy. Comprehensive screening for HBV includes measuring HBV surface antigen (HBsAg), HBV core antibody (anti-HBc), and antibody to HBV surface antigen (anti-HBs). ASCO also recommends hepatitis C virus (HCV) screening in patients with cancer. Cancer patients receiving cancer therapy represent a vulnerable population and reactivation of undetected hepatitis virus can lead to devastating consequences such as liver failure and death. At MD Anderson Cancer Center, rates of hepatitis screening for all cancer patients has been historically low. For example, rates are around 29% for HBV screening in patients receiving cancer therapy in 2019-2021. The aim of this quality improvement study is to increase rates of HBV and HCV screening in early breast cancer patients in the Breast Medical Oncology clinic at MD Anderson before undergoing cancer therapy to at least 50%. **Methods:** Quality improvement measures were implemented by 1) creation of an order panel in the electronic medical record (EMR) which contains all tests needed for comprehensive HBV and HCV screening (HBsAg, anti-HBc, HBsAb, and anti-HCV), and 2) an educational session to providers in the Breast Medical Oncology clinics. Data was collected for patients seen at MD Anderson initiating cancer therapy (start of cycle 1) between April 1, 2023 until September 30th, 2023. Inclusion criteria were early breast cancer patients (Stage I-III) and receiving chemotherapy at MD Anderson. Exclusion criteria were Stage IV disease, or those receiving chemotherapy at an outside institution. **Results:** A total of 340 patients were screened, and 219 were determined to meet inclusion criteria for data extraction. In total, 105 patients (48%) received comprehensive HBV screening, with 137 (63%) receiving at least one HBV test. A total of 122 (56%) patients were screened for HCV. Combining data for both HBV and HCV, 88 (40%) received both comprehensive HBV and HCV screening (HBsAg, anti-HBc, anti-HBs, anti-HCV). A majority of patients (91% for HBV and 93% for HCV) were screened prior to cycle 1 of cancer therapy. The EMR order panel was utilized in 51 (23%) of patients. Anti-HBc was positive in 8 of those tested, and HBsAg was positive in 1 patient. No patients tested positive for HCV. **Conclusions:** Screening rates for HBV and HCV individually were near or exceeded our goal, however rates of combined HBV and HCV screening were lower. Going forward, additional education to providers as well as increased awareness of the available order panel will be needed to ensure we are comprehensively screening for both HBV and HCV in our patients. Research Sponsor: None.

Test	N (%) out of 219
HBsAg	129 (59%)
Anti-HBc	115 (53%)
Anti-HBs	128 (58%)
HBsAg + anti-HBc	108 (49%)
All HBV tests	105 (48%)
Anti-HCV	112 (56%)
All HBV + HCV tests	88 (40%)

11126 Poster Session

Impact of transitions of care nurse navigation on post-discharge follow-up.

Celina Lo, Jackie Miller, Valerie Pracilio Csik; Sidney Kimmel Cancer Center, Jefferson Health, Philadelpha, PA; Jefferson Kimmel Cancer Center, Philadelphia, PA; Sidney Kimmel Cancer Center - Jefferson Health, Philadelphia, PA

Background: Poor discharge communication is among the primary causes of readmissions and many patients are lost to follow-up (F/U) post-discharge (PD). For newly diagnosed (DX) cancer patients, the coordination of care from inpatient (IP) to outpatient (OP) follow-up is critical. At the Sidney Kimmel Cancer Center in Philadelphia, we saw a no show (NS) rate of 6.6% for PD F/U appointments (Oct-Dec 2022) resulting from deficient communication. To improve the IP to OP transition for cancer patients, a Transition of Care Nurse Navigator (ToC NN) pilot was initiated to support patients discharged from Thomas Jefferson University Hospital (TJUH). The goal was to complete 80% of PD visits and reduce the NS rate by 20% by 12/31/23. **Methods:** The target population are patients that are newly DX solid tumor patients that will be discharged to home/rehab and need an OP Medical Oncology appointment. Through communication with hospitalists, IP Fellows/Residents, and/or Attendings, the ToC NN is referred eligible patients. The ToC NN visits patients during hospitalization or follows-up post-discharge to assess Health Related Social Needs and distress. PD F/U appointments are communicated during the initial contact along with information about the OP resources available and referrals are made based on patient interest/needs to social work, nutrition, or supportive medicine. All communication is documented by the EMR and the oncology care team is notified. The ToC NN follows up with the patient/patient's family member 48-72 hours after hospital discharge to check in and do a symptom management call. Additional F/U calls are made as needed. The ToC NN serves as the patient's point of contact (POC) from discharge to OP new patient visit (NPV) appointment. **Results:** The pilot exceeded the 80% goal of completion of PD visits. It revealed a 41.4% increase of PD NPV completion and a 21.9% decrease of NS rate from the 2022 to 2023 data. **Conclusions:** The ToC NN services showed significant impact in supporting patients transition from IP to OP. Our findings confirm having a contact after hospital discharge increases the completion of PD visits due to effective communication and support. Research Sponsor: Internal Departmental Funds.

	Discharged Patients	PD Coordinated	PD NPV Completed	NS Rate
Oct-Dec 2022	41	29 (70.7%)	20 (48.8%)	6.6%
Oct-Dec 2023	37	37 (100%)	36 (97.3%)	5.2%

11127 Poster Session

Implementation of standardized electronic documentation of goals of care discussions to improve cancer care.

Katarina Vasiljevic, Shelly Kane, Brooks Tuyn, Jennifer Schoenecke, Kyle P Edmonds, Kathryn A. Gold; Division of Hematology-Oncology, Department of Medicine, University of California, San Diego, La Jolla, CA; Moores Cancer Center at UC San Diego Health, La Jolla, CA; Cleveland Clinic, Endocrinology and Metabolism Institute, Cleveland, OH; Doris A. Howell Palliative Care Service, University of California, San Diego, La Jolla, CA

Background: Early documentation of physician-led goals of care (GOC) discussions is important to providing comprehensive and individualized quality care to cancer patients as it can provide all members of the patient care team with a context for the type of care each patient wishes to receive prior to and at end of life. The electronic medical record (EMR) should provide easy access to these conversations to seamlessly integrate outpatient, emergency room and inpatient care of cancer patients. **Methods:** The institution-wide initiative was introduced via presentations and emails between 8/2021 and 11/2021 to all Moores Cancer Center faculty at UC San Diego Health. A SmartPhrase was created in our EMR Epic as the intervention, including critical components of a GOC discussion: people present during discussion, goal of cancer-directed treatment, anticipated cancer trajectory shared with the patient, and patient's health care agent. The SmartPhrase was radiolabeled to be easily searchable for any clinician accessing the patient's chart. Physician documentation was tracked for the purposes of achieving a group goal with a target of greater than 50% documentation of GOC discussions within 30 days of the first day of the first cycle of chemotherapy. Prior to physician education, 4% of patients had a GOC note using a searchable SmartPhrase. In 12/2021, we began sending individual emails to physicians to remind them of eligible patients. **Results:** By 1/2022, after education, 50% of physicians ordering chemotherapy had used the GOC SmartPhrase and 29% of patients initiating chemotherapy had a GOC note using the SmartPhrase. After initiation of monthly reminder emails, documentation increased to 51% by 10/2022. An increased use of Advanced Care Planning billing codes was also noted. **Conclusions:** Implementation of an initiative to standardize electronic documentation of GOC conversations improved early documentation of these vital conversations. Radiolabeling of the SmartPhrase made it easily accessible to all members of a patient's care team. Research Sponsor: None.

Improving quality of oncology (onc) documentation and enhancing structured data collection using a standardized onc note template.

Matthew Folstad, Arun Augustine, Fauzia Hollnagel, Cibele Carroll, Ashleigh Saner, Jeff Pier, Michael Lavitschke, Peter Kleinschmidt, Heidi Twedt, Amye Juliet Tevaarwerk, Hamid Emamekhoo; UW Health, Madison, WI; University of Wisconsin Carbone Cancer Center, Madison, WI; University of Wisconsin, Madison, WI; University of Wisconsin School of Medicine and Public Health, Madison, WI; Mayo Clinic Cancer Center, Rochester, MN

Background: To improve documentation quality in Medical Onc outpatient clinics, a standardized template was created. In this template we embedded: 1. An Epic SmartForm to collect structured data (SD) about patient, disease, and response status at each encounter. Minimal Common Oncology Data Elements (mCODE) compatible SD elements were used to enhance interoperability. 2. Several clinically impactful quality metrics (QM) selected based on the Quality Onc Practice Initiative (QOPI) guidelines. In this analysis, we aim to assess how template use impacted documentation quality. **Methods:** 113,376 outpatient encounters occurred between 01/2018 – 12/2022 (41 providers: 35 physicians, 6 APPs). The template go live was 3/19/2019. 2,520 randomly selected encounters were manually reviewed. Distinct documentation of 8 items served as QMs (Table). Of note, using the template was voluntary and data entry in the embedded form is not mandated. Documentation of each QM was compared between notes authored with/without template. For each note, a completeness score was calculated based on total number of QMs present/note. Categorical comparisons were made using chi-squared or Fisher's exact tests. Numerical/continuous values were summarized using means and standard deviations. A template "user" was defined as a provider using the template in >10% of encounters after go live. This QI project was exempted by IRB. **Results:** 154/2520 encounters were excluded after manual review (visits not for solid tumor malignancy). The template was used in 38.7% (917/2366) of the reviewed notes. Cancer diagnosis was documented in >99.8% of notes regardless of template use. Template use was associated with increased documentation of 7 QMs (Table). Documentation overall completeness improved from 62% to 90% with a very large effect size (Table). Template use positively correlated with female gender and fewer years since last training ($p<0.001$). In the subgroup of notes written by "users" (21 physicians, 4 APPs), individual QM and overall completeness scores improved with template use ($p<0.001$). **Conclusions:** Template use profoundly improved QM documentation (statistically significant and clinically meaningful) by Onc clinic providers. This strategy enhances mCODE compatible structured data collection and semantic interoperability between systems, strengthening the available real-world data (RWD) in EHR. Research Sponsor: None.

Quality Measures	Template Not Used N = 1449 %, mean (SD)	Template Used N = 917 %, mean (SD)	P- Value
Cancer Diagnosis	100 (4)	100 (3)	0.571
Cancer Stage	62 (48)	98 (15)	*
Treatment plan	96 (20)	100 (5)	*
Treatment Phase	26 (44)	92 (26)	*
Treatment Intent	41 (49)	95 (22)	*
Response to treatment	75 (43)	88 (33)	*
Presence of metastatic disease	72 (45)	83 (37)	*
Performance Status	62 (48)	90 (30)	*
Overall completeness	62 (17)	90 (16)	*

*<0.001 (Statistically significant at $p \leq 0.05$)

Comprehensive molecular pathology review service to reduce barriers to precision oncology in rural eastern North Carolina.

Sunil Badami, Insha Pun, Daniela Chala Garcia, Dmitry Tumin, Yaolin Zhou; East Carolina University Health, Greenville, NC; Brody School of Medicine at East Carolina University, Greenville, NC

Background: ECU Health system serves a rural 29-county region where cancer mortality rates exceed those of the state's remaining 71 counties combined. Insufficient tissue and lack of local infrastructure contribute to suboptimal precision oncology care. We aimed to enhance the clinical utility of send-out molecular tests for patients with solid cancers through a quality improvement (QI) initiative. **Methods:** We used the EPIDEM model of QI to explore, promote, and implement a molecular review service, which includes intervening on send-out molecular orders that would otherwise have been insufficient for the requested molecular pathology test. The interventions include combining blocks, sending alternative specimens, and/or modifying testing strategy. We documented cases in a molecular send-out database and electronic health records, evaluated the service's impact, and modified it to include an orderable molecular consultation. **Results:** In 2023, We reviewed 699 send-out comprehensive genomic tests on solid tumors (173 cytology, 192 resections, 332 biopsies), including 582 (83.3%) advanced cancers. In total, there were 576 sufficient reports. Actions taken on 185 orders (26.5% of reviewed cases) led to 156 reported results. Of these, 70 showed clinically significant findings, and 31 patients received targeted therapy because of those interventions. In March 2023, we initiated a formal consultation service with in-depth review. From 3/3/2023-1/29/2024, we performed 50 pre-test (e.g., specimen to use, testing strategy, tumor origin testing) and 60 post-test (e.g., result interpretation, treatment based on molecular data) consultations; 10 patients received both pre and post-test support. The molecular pathologist tended to initiate post-test, while clinicians preferentially initiated pre-test consultations ($p<.01$). Clinician-initiated consultations were more frequent in community practices ($p<.01$). **Conclusions:** Even without the resources for in-house testing, our molecular review service provides essential pre- and post-analytic support by successfully rescuing cases that would have otherwise been insufficient molecular tests and by providing comprehensive consultative support. The positive impact and reception among community oncologists suggest that our strategy holds potential to alleviate barriers to precision oncology in underserved areas. Research Sponsor: Eli Lilly and Company; LGO - Grant ID A-34174.

Tumor Type (No)	Number of Interventions	Sent Multiple Blocks (%)	Sent Alternative Specimens	Recommend Alternative Strategy	Combine 2+ strategies	Results reported
Lung (302)	76	34 (45%)	6 (8%)	9 (12%)	27 (36%)	67 (88%)
GYN (87)	21	18 (86%)	0	3 (14%)	0	21 (100%)
GI (146)	37	23 (62%)	2 (5%)	6 (16%)	6 (16%)	37 (100%)
GU (69)	20	16 (80%)	0	2 (10%)	2 (10%)	18 (90%)
Breast (42)	16	6 (38%)	0	6 (38%)	4 (25%)	15 (94%)
Other (53)	15	10 (67%)	3 (20%)	1 (7%)	1 (7%)	13 (87%)
Total (699)	185	107 (58%)	11 (6%)	27 (15%)	40 (22%)	156 (84%)

11130 Poster Session

Enhancing inpatient chemo/immunotherapy stewardship: A novel scoring rubric approach to optimize utilization and reduce costs.

Aarti Sonia Bhardwaj, Jessica Lyublinsky, Tianxiang Sheng, Priya Jain, Robert Thomas, Cardinale B. Smith; Icahn School of Medicine at Mount Sinai, New York, NY; Mount Sinai Health System, New York, NY

Background: Most inpatient chemo/immunotherapy (IC) is not reimbursed because of the diagnosis-related group code structure for reimbursement. We implemented the use of a novel objective scoring rubric to guide and automate IC stewardship at an academic cancer center to decrease the inappropriate use of IC especially at the end of life. **Methods:** We created a scoring rubric for non-formulary IC that includes type and phase of trial, FDA/NCCN approvals, performance status, line, and goal of therapy. Clinicians enter these criteria in a Redcap form which automatically calculates a score which is then verified by 2 disease specific physicians and a clinical pharmacist. If the threshold score is not met, IC is not approved for administration. IC that is on formulary and standard of care is automatically approved. We compared post-implementation year 1 (1/2022-8/2022) to post-implementation year 2 (1/2023-8/2023) on two primary outcomes: drug cost and utilization. Comparisons were assessed using the Wilcoxon Signed-Rank Test. **Results:** There was a total of 74 requests with 12% not approved in 2022 compared to 96 with 14% not approved in 2023. We compared the median values of the number of times each non-formulary IC was dispensed from January to August in both 2022 (median=6) and 2023 (median=2), p= 0.01. In 2022 the median of average monthly IC drug charges was $$840730 compared to $434586 in 2023 (p= 0.02). In 2022 the median of average monthly ICI drugs was($91651) compared to $55368.35 (p= 0.25) for 2023. The total annual charge of IC decreased by 44% from 2022 to 2023 with the total annual charge of immune checkpoint inhibitors decreasing by 26% (Table). **Conclusions:** Implementation of a novel objective scoring rubric for IC stewardship effectively reduced inappropriate administration, as evidenced by a significant decrease in the number of times non-formulary IC was dispensed and a substantial reduction in drug charges. The total annual charge of IC significantly decreased by 44% showing a sustained improvement over a 2 year period. This approach offers a promising strategy to optimize resource utilization and ensure appropriate utilization of IC, particularly in patients nearing the end of life. Further studies are warranted to evaluate the long-term impact of this intervention on patient outcomes and healthcare costs. Research Sponsor: None.

Annual charges of non-formulary inpatient chemo/immunotherapy (IC) and immune checkpoint inhibitors (ICI).

	2022	2023	Difference	Percent Decrease
Total annual charge of IC	$6,644,040	$3,750,657	$2,524,865	44%
Total annual charge of ICI	$839,357	$622,344	$217,013	26%

11131 Poster Session

Examining the relationship between ECOG performance status and immunotherapy outcomes: Insights from real-world data analysis.

Rachel Chernet, Devashish Desai, Rahul Rajendran, Amber Bixby, Susan Faso, Josh Wallace, Michel R Nasr, Tamara Jamaspishvili, Alina Basnet; SUNY Upstate Medical University, Syracuse, NY

Background: The impact of Eastern Cooperative Oncology Group Performance Score (ECOG) on immunotherapy (IO) outcomes is intricate, as historically clinical trials have primarily enrolled patients with ECOG scores of 0 or 1. The National Comprehensive Cancer Network (NCCN) advises against administering IO to patients with ECOG scores of 2 or higher. However, conflicting findings from research studies and variations in real-world clinical practice complicate this relationship. Our study aims to elucidate the association between ECOG status and the outcomes of immunotherapy. **Methods:** Data collected from SUNY Upstate Medical University treated cancer patients who underwent immunotherapy and chemotherapy was used for analysis. The Kaplan-Meier method and Cox regression were used to analyze survival probability based on therapy, age, and ECOG. **Results:** Of 813 patients included in the study, 46.99% (n=382) received immunotherapy. 51.85% (n=421) were females. The mean age was 64.1 years in IO group and 67.7 years in non-IO/chemo group. 52.5% (n=187) of patients who were $\leq$ 64 years received IO compared to only 42.7% (n=195) of patients who were $\geq$ 65 years (p=0.005). 48.6% (n=118) of patients with ECOG score 0 received IO, while only 40.5% (n=72) patients with ECOG score of $\geq$3 received IO (p=0.279). Patients who received IO with ECOG score of $\geq$3 had higher probability of survival compared to other groups ($p<0.0001$). While, in non-IO group, patients with ECOG 0 had higher probability of survival compared to ECOG 3 (HR 1.773, 1.209 – 2.600). There was no difference in overall survival in patients receiving IO based on age categories (p=0.2627, HR 1.148, 0.901 – 1.462). **Conclusions:** Our findings suggest that relying solely on ECOG status to determine eligibility for immunotherapy may be overly restrictive. Patients with significant comorbidities could still derive benefits from immunotherapy. Further investigation is warranted to comprehensively assess the influence of ECOG status on immunotherapy outcomes. Research Sponsor: None.

Association between comorbidity clusters and mortality in patients with cancer: A machine learning analysis of data from the US National Health and Nutrition Examination Survey 1999–2018.

Chun Sing Lam, Rong Hua, Herbert H. Loong, Chun-Kit Ngan, Yin Ting Cheung; School of Pharmacy, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China; Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China; Worcester Polytechnic Institute, Worcester, MA

Background: Multimorbidity is common among patients with cancer; however, research on cancer prognosis has predominantly focused on cancers in isolation. This study identified comorbidity clusters among patients with cancer using machine learning and examine their associations with survival outcomes in a nationally representative sample of the US. **Methods:** This study used 10 survey cycles of the National Health and Nutrition Examination Survey from 1999 to 2018. Participants aged ≥20 years with a self-reported history of cancer were included. Comorbidities were ascertained through self-reports and quantitative measurements. Machine learning techniques, including Bernoulli mixture model and partition-based methods, were used to identify comorbidity clusters. Cox proportional hazards models were used to analyze the associations between comorbidity clusters and mortality outcomes, including all-cause mortality and cause-specific mortality (cancer, cardiovascular disease [CVD], and respiratory diseases), adjusting for relevant covariates. **Results:** The study included 4,390 participants. Four comorbidity clusters were identified: Low Comorbidity, Metabolic, CVD, and Respiratory. After adjusting for confounders, participants in the Respiratory Cluster had the highest risk of all-cause mortality (adjusted hazard ratio[aHR]=1.62, 95% confidence interval [CI]=1.26-2.08, $p<0.001$), followed by the CVD Cluster (aHR=1.50, 95%CI = 1.26-1.80, $p<0.001$) and the Metabolic Cluster (aHR=1.15, 95%CI=1.02-1.29, $p=0.03$) compared to the Low Comorbidity Cluster. The Metabolic, CVD, and Respiratory clusters were associated with higher risks of cardiovascular disease-related mortality (aHR=1.48-3.05, $p<0.003$), but no significant differences in cancer mortality were observed among the clusters. The effects of comorbidity clusters on all-cause mortality were modified by income-to-poverty ratio (p for interaction=0.04), diet quality (p for interaction=0.02), time since cancer diagnosis (p for interaction=0.009), and cancer prognosis (p for interaction=0.005). **Conclusions:** High comorbidity burden clusters showed increased all-cause and CVD-related mortality. Moreover, diet quality and socioeconomic status modified these associations. Machine learning approaches can provide valuable insights into complex multimorbidity profiles in patients with cancer. Further research is needed to deepen understanding of the relationships between multimorbidity, mortality, and cancer-specific outcomes. Research Sponsor: None.

11133 Poster Session

Unstructured EMR data hold the key to oncology studies: Methods for validating NLP-extracted phenotypes from EMR notes.

Elizabeth H. Eldridge, Elizabeth Trowbridge, Mui Van Zandt, Atif Adam, Christina D. Mack; IQVIA, Boston, MA; IQVIA, South Bend, IN; IQVIA, Elk Grove, CA; IQVIA, Durham, NC

Background: Natural language processing (NLP) parsers are advanced algorithms designed to parse values of interest from free-text stored in Electronic Medical Records (EMR). Given the importance of information stored in free-text for use in oncology research, it is crucial to understand how accurately NLP algorithms are extracting oncology-specific measures of interest. We focus on validating NLP-parsers that identify three measures critical to oncology research by evaluating how closely the NLP-parser results match manual chart abstractor review: AJCC summary cancer stage group (cancer stage), AJCC TNM stage (TNM stage), and surgical treatment of cancer (surgery). **Methods:** Following deployment of the parsers on 8,000 non-identifiable free-text notes housed in an aggregated non-identifiable U.S. EMR database, manual chart abstraction was performed on a random selection of notes (n=300) dated between 2008 to 2023 to validate the parsers' accurate capture of cancer stage, TNM stage, and surgical treatment of cancer. We report true positives (TP), false positives (FP) and positive percent value (PPV). **Results:** The PPV of AJCC Cancer Stage was 99.0% (n=297 TP, n=3 FP). The PPV of the TNM stage NLP-parser was 97.3% for tumor stage (n=292 TP, n=8 FP), 99.0% for nodal stage (n=297 TP, n=3 FP), and 96.7% for presence of metastases (n=290 TP, n=10 FP). The PPV of the surgery parser was 87.8% (n=468 TP, n=65 FP). **Conclusions:** These NLP-parsers performed very well identifying the measures of interest, providing confidence in use of these derived measures which are central to oncology research. Validation is a necessary initial step in processing real-world data for use in real-world evidence generation, with unique considerations needed in the oncology research space due to key information being documented in EMR free-text rather than structured data fields. Research Sponsor: IQVIA.

Commercial health plan spending on oncology drugs approved via the accelerated approval pathway and later withdrawn from the market.

Tejas Patel, Eamonn Curran, Sarah S Hellems; UnitedHealthcare, Minnetonka, MN; Optum, Eden Prairie, MN

Background: The U.S. Food and Drug Administration (FDA) introduced the Accelerated Approval Program in 1992 to expedite the approval of drugs that can be used to treat certain conditions and fill an unmet medical need. Clinical trials conducted to achieve accelerated approval status often use surrogate outcomes as primary endpoints to reduce the time it takes to get FDA approval. Drug manufacturers must conduct further research to verify and report the projected clinical benefit and safety. The FDA may issue traditional approval to previously accelerated approved drug or may request the manufacturer to withdraw a drug from the market based on the clinical benefit and/or safety demonstrated in the confirmatory trial(s). We report members impacted, total drug claims, and total drug cost incurred by a commercial health plan associated with the coverage of oncology drugs approved by the FDA and later withdrawn from the market between 2020 to 2023. **Methods:** Fifteen unique indications associated with oncology drugs that received accelerated approval and later withdrawn by the FDA were identified between 2020 to 2023. A cohort of patients enrolled in commercial health plan was further identified using the ICD-10 code related to the drug indication being withdrawn. To calculate total paid amount for drugs, de-identified administrative claims data submitted on behalf of this cohort were sorted and summed in this time period using either J-code for drugs covered under medical benefits or national drug code (NDC) for drugs covered under pharmacy benefits. **Results:** Between 2020 to 2023, 8 oncology drugs were withdrawn because of later failing to demonstrate clinical benefit in the confirmatory trials, 2 drugs were withdrawn due to safety concerns, and 5 drugs were withdrawn due to drug manufacturer unable to complete a confirmatory trial. In this population, we identified 18,430 unique members with 103,743 administrative claims. The total paid amount was $1,392,553,995 in this time period. The average drug cost per administrative claim was $13,423 and the average drug cost per member was $75,559. **Conclusions:** Drug costs established by manufacturers are not differentiated based on the approval status - accelerated or regular. While drugs approved via accelerated approval pathway may provide benefit to certain patient population, the cost associated with accelerated approved drugs needs more attention. Indication-specific pricing model may help alleviate the cost burden associated with drugs approved via accelerated approval pathway. Research Sponsor: None.

Reasons Drug Withdrawn From the Market	Members Impacted	Total Drug Claims	Total Drug Cost
Failed to demonstrate clinical benefit	9,390	55,992	$713,194,307
Safety concerns	21	90	$1,198,697
Manufacturer unable to complete confirmatory trial	9,019	47,661	$678,160,991
Total	18,430	103,743	$1,392,553,995

11135 Poster Session

Time-to-diagnosis and peri-diagnostic healthcare utilization between screen- and non-screen detected cancers: Evidence from SEER-Medicare.

Xiting Cao, Elizabeth DeYoung Brouwer, Yilin Chen, Scott David Ramsey, Chris Tyson, Kevin Li, Seema P Rego, Omair A Choudhry, David L Veenstra, Jon Ebbert, Tomasz M. Beer; Exact Sciences Corporation, Madison, WI; Curta, Inc., Seattle, WA; Curta Inc, Seattle, WA; Exact Sciences Corp., Madison, WI; Mayo Clinic, Rochester, MN

Background: Cancer screening programs can improve outcomes and may reduce treatment cost and utilization by shifting cancers to earlier, more curable stages at diagnosis (Dx). Few studies have evaluated the impact of screening on outcomes prior to diagnosis. Such information is needed to better understand the potential impact of newer blood-based multicancer early detection technologies. **Methods:** We conducted a retrospective cohort study using SEER cancer registry data linked with Medicare claims. Patients with a breast cancer (BC) or colorectal cancer (CRC) Dx between 2010-2019 were included if they were 65-74 years old at Dx, continuously enrolled in Medicare Parts A&B, had a Charlson Comorbidity Index of ≤2, and no cancer for ≥12 months prior to Dx. Those enrolled in an HMO or with high genetic risk for BC (in BC cohort) were excluded. Patients were assigned to screening groups prior to Dx; screening was defined as ≥1 screening procedure in the 6 months prior to Dx using CPT/HCPCS codes. Screening included FIT/FOBT, sigmoidoscopy, colonoscopy, CT colonography, mt-sDNA (CRC), and mammography (BC). Screened and not screened groups were compared for statistical significance using chi-squared for categorical variables, Wilcoxon rank-sum test for continuous variables. **Results:** Screening procedures were more prevalent in the BC cohort (68%) than the CRC cohort (44%) (table). Both screened subgroups (vs non-screened subgroups) had significantly lower proportions of patients diagnosed at stage 4 (2% vs 10% BC, 16% vs 27% CRC) and shorter times from first screening or imaging procedure to confirmed diagnosis (BC: 33 vs 227 days, CRC: 14 vs 29 days). Screened patients in both cancer cohorts had a similar number of average procedures prior to treatment initiation as non-screened (BC: 4.8 vs 4.2, CRC: 3.3 vs 3.3 respectively, including screening procedures). **Conclusions:** Individuals diagnosed with BC and CRC through screening exhibit earlier stage diagnoses and shorter intervals to diagnosis. Novel screening technologies such as MCED tests can potentially improve peri-diagnostic outcomes in cancers lacking existing or widely adopted screening methods. Research Sponsor: Exact Sciences.

	BC: Screening		BC: No Screening		p-value	CRC: Screening		CRC: No Screening		p-value
Patients in cohort – N (%)	74,538	68%	35,400	32%		21,824	44%	28,071	56%	
Stage at diagnosis – N (%)					<0.01					<0.01
In Situ/Localized (Stages 0-1)	60,411	81%	24,184	68%		10,456	48%	10,353	37%	
Regional (Stages 2-3)	12,558	17%	7,836	22%		7,903	36%	10,079	36%	
Distant (Stage 4)	1,569	2%	3,380	10%		3,465	16%	7,639	27%	
Time from first imaging test to Dx – Median (IQR)	33	(15 - 158)	227	(47 - 328)	<0.01	14	(7 - 64)	29	(8 - 181)	<0.01
Patients with > 90 days from first imaging to Dx – N (%)	23,561	32%	5,968	71%	<0.01	4,106	20%	2,763	36%	<0.01
Procedures (imaging and biopsy) from first imaging through Tx initiation – Mean (SD)	4.8	2.2	4.2	2.2	<0.01	3.3	1.8	3.3	1.9	0.04

Analysis of healthcare provider management of immune-related adverse events and concordance with NCCN Guidelines.

Kristen M. Rosenthal, Megan Cartwright, Rachael Andrie, John A. Thompson; Clinical Care Options, LLC, Reston, VA; University of Washington, Fred Hutchinson Cancer Center, Seattle, WA

Background: Immune checkpoint inhibitors (ICIs) are a mainstay of treatment for many cancers but can cause immune-related adverse events (irAEs) that require prompt recognition and management. In 2017, we developed an online interactive decision support tool [www.clinicaloptions.com/immuneAEtool] for healthcare providers (HCPs) with case-specific recommendations for managing irAEs from a medical oncology expert. In 2019 and 2023, we updated the tool to offer recommendations from the latest National Comprehensive Cancer Network (NCCN) Guidelines. Here, we report a comparison of self-reported irAE management from HCPs using the 2023 tool vs NCCN recommendations and a comparison of practice patterns between the 2023 and 2019 tools. **Methods:** To use the online tool, HCPs entered the affected organ system, symptom grade/severity, and their planned management strategy. The tool showed the NCCN management recommendation for that irAE and then asked if the recommendation changed their intended management approach. **Results:** From July to December 2023, 172 HCPs entered 241 case scenarios into the tool; 53% treated <10 patients/month with ICIs, and 38% of HCPs practiced in the United States. The most common irAEs involved the gastrointestinal (GI)/hepatobiliary (hep)/pancreatic (29% of cases) or dermatologic/oral (19%) systems. Overall, the planned irAE management strategy of HCPs matched the NCCN recommendations in 55% of cases, an increase from the 49% concordance rate in our 2019 analysis. In the current analysis, the lowest concordance was observed for infusion-related reactions (20%), musculoskeletal irAEs (46%), and dermatologic/oral mucosa irAEs (46%; Table). Furthermore, US HCPs had a lower overall concordance rate (46%) than non-US HCPs (66%). Approximately one half (56%) of all HCPs indicated that the NCCN recommendations in the tool changed their management plan. **Conclusions:** These data suggest that many HCPs are challenged to optimally manage irAEs and are not managing their patients in concordance with NCCN guidelines. A detailed analysis of HCP irAE management vs NCCN recommendations, including by organ system and severity, along with a comparison of 2023 vs 2019 practice patterns, will be presented. Research Sponsor: AstraZeneca; Eisai; Merck Sharp & Dohme LLC; Regeneron Pharmaceuticals, Inc.

Concordance rates for irAEs with ≥10 cases.

irAE	Cases, n	Concordant, %
Cardiovascular	16	50
Dermatologic/oral mucosa	46	46
Endocrine	33	58
GI/hep/pancreatic	70	57
Musculoskeletal	11	45
Fatigue	10	60
Pneumonitis	35	66

11137 Poster Session

Linking an early access program (EAP) to the National Health Data System (NHDS) in France and assessing its performances and potential biases.

Vinh-Phuc Luu, Icherak Charkaoui, Muriel Licour, Marion Narbeburu, Christine Le Bihan, Nicolas Ozan; Artificial Intelligence And Cancers Association, Paris, France; French National Cancer Institute, Boulogne-Billancourt, France; OncoReal, Fontenay-Sous-Bois, France; AstraZeneca France, Courbevoie, France

Background: Early access programs (EAP) are a unique opportunity to document first use of innovative treatments in real-world settings. The French HTA body requires mandatory patients' clinical data collection for EAP and since July 2021, has recommended anticipating linkage EAP to the National Health Data System (NHDS). Prior to drug initiation, the collected data is almost complete contrary to follow-up data. To the best of our knowledge, no other study has proposed a methodology to link EAP to the French Cancer cohort (FCC), an extract of the NHDS of over 8 million persons diagnosed or at high risk of cancer, and to assess its assets and downsides. **Methods:** This cohort study has reused data of informed French EAP patients treated with durvalumab from October 1st, 2017 to December 31st, 2018 (n=457) in locally advanced unresectable NSCLC and of patients who received durvalumab at the time of the EAP in the FCC (n=666). The linkage methodology consists in harmonizing available data across sources, defining matching, control and study variables, testing several indirect deterministic linkage algorithms and assessing their performances. Consistency and differences between data sources were described for the best performing algorithm. **Results:** Proposed linkage algorithms required matches on a combination of data among sex, birth year and month, treating hospital ID and department. Performance started at 80.9% (370/457) patients from the EAP cohort linked to eligible patients from FCC up to 85.3% (390/457) for the best performing algorithm. The consistency of linkage variables between the two sources was substantial (Cohen's kappa $>$ 0.8) or excellent (intraclass correlation $>$ 0.9). It was the same for control variables. Comparisons between linked patients and unlinked patients from the EAP cohort showed no statistically significant difference on matching and control variables, except for few cases on history of chemotherapy and history of radiation therapy prior to durvalumab. Similarly, no statistically significant difference was found on matching and control variables between linked patients and unlinked patients from FCC, except for history of radiation therapy and treating hospital department. Median of time difference between foreseen date of first durvalumab administration in EAP versus the effective date in FCC was -1 (IQR = [-9 ; 0]) day. Lack of reported diagnosis related to prior radiation therapy administration in out-of-hospital settings refrained from using them as matching or control variables. **Conclusions:** The study illustrates the feasibility of matching EAP patients to the French NDHS with indirect deterministic linkage. Additional EAP linkages will be required to ensure the validation and reproducibility of such methodology. Further works in progress will document the adequacy of French NHDS data to address effectiveness. Research Sponsor: Artificial Intelligence and Cancers association; None.

11138 Poster Session

Inpatient healthcare utilization in the first year following a childhood cancer diagnosis: A population-based analysis.

Timothy James Daeeun Ohlsen, David Doody, David H Noyd, Arti D Desai, Wendy M. Leisenring, Beth A Mueller, Eric Jessen Chow; University of Washington, Seattle, WA; Fred Hutchinson Cancer Center, Seattle, WA

Background: Children with cancer may require substantial healthcare resources during treatment, including inpatient care. Hospital utilization patterns at the population level, and factors associated with higher utilization, are not well-described. **Methods:** We conducted a retrospective cohort analysis of Washington State (WA) cancer registry data (1992-2013) linked to state birth (1974-2013), death (1992-2013), and hospital discharge (1992-2013) records to identify all WA children diagnosed with cancer <20 years. We examined hospitalization frequency and total inpatient bed days in the year after cancer diagnosis. To evaluate factors associated with outcomes of interest, we constructed multivariable negative binomial regression models of children with ≥1 inpatient admission, calculating incidence rate ratios (IRR). Covariates included rural residence (binary; census tract rural-urban commuting area codes), high neighborhood deprivation (binary; state-normative census block group Area Deprivation Index [ADI]), sex, race/ethnicity, diagnosis age, birth year, and cancer type (per International Classification of Childhood Cancer). Due to differences in utilization by cancer type, we also examined children in subanalyses with acute lymphoblastic leukemia (ALL), lymphomas, and solid (including central nervous system [CNS]) tumors. **Results:** 2,231 children (mean diagnosis age 7.2 years; 68% diagnosed since 2000) had 12,833 inpatient encounters. In the year after diagnosis, children had a median of 4 (IQR 2-8) hospitalizations/year at-risk, and 21 (IQR 8-54) inpatient days (median length of stay 4 days [IQR 2-6]). In multivariable analysis, high ADI (IRR 1.11, 95% CI 1.01-1.21), but not rural residence (IRR 0.95, 95% CI 0.85-1.05), was associated with greater hospitalization frequency. Female sex was associated with lower frequency (IRR 0.94, 95% CI 0.88-1.00). In analysis of total inpatient days, high ADI (IRR 1.15, 95% CI 1.02-1.29) and Hispanic ethnicity (IRR 1.31, 95% CI 1.13-1.51) were independently associated with greater inpatient days. In subanalysis of patients with ALL (N=497), associations between inpatient days and ADI (IRR 1.18, 95% CI 0.99-1.40) and Hispanic ethnicity (IRR 1.01, 0.84-1.23) were no longer significant. For lymphoma (N=259), associations were similar but also no longer significant (ADI IRR 1.14, 95% CI 0.78-1.71; Hispanic IRR 1.26, 95% CI 0.79-2.10). Among patients with solid/CNS tumors (N=1,151), associations with Hispanic ethnicity remained significant (IRR 1.46, 95% CI 1.19-1.80), but not ADI (IRR 1.11, 95% CI 0.95-1.30). **Conclusions:** Children with cancer spend considerable time inpatient during the year after diagnosis. Disparities in hospital utilization mirror some known disparities in childhood cancer survival. Initiatives to alleviate systemic disadvantages may reduce inpatient utilization for some groups. Research Sponsor: Alex's Lemonade Stand Foundation.

11139 Poster Session

Racial/ethnic differences in incidence of squamous cell carcinoma in California.

Deepti Behl, Carol Parise; Sutter Sacramento Medical Center, Sacramento, CA; SIMR, Sacramento, CA

Background: Squamous cell lung carcinoma is strongly associated with a history of smoking. Typically, no actionable mutations are found, and treatment options are more limited. It is not known if race has any impact on the incidence of squamous cell cancers, especially for Asian ethnicities since most studies combine multiple Asian populations in an Asian/Pacific Islander (API) category. The purpose of this study was to compare the odds of squamous cell carcinoma versus adenocarcinoma in Hispanic, American Indian, Middle Eastern, and 7 Asian ethnicities when compared with both Black and White men and women. **Methods:** We accessed 211,987 cases of invasive lung cancer with either squamous cell or adenocarcinoma from the California Cancer Registry 2000-2020. Race was categorized as White, African American/Black, Hispanic, American Indian/Alaskan Native, Middle Eastern, Chinese, Japanese, Korean, Filipino, Southeast Asian (SEA), Pacific Islander, or Asian Indian. Separate logistic regression analyses were used to assess the odds of squamous cell versus adenocarcinoma for each race/ethnicity using White and Black as the reference categories. Analyses were conducted separately for males and females and adjusted for age, smoking status, socioeconomic status, marital status, and Charlson Comorbidity Score. Odds Ratios (OR) and 95% confidence intervals (CI) were computed. **Results:** When compared with White men, American Indian men had increased odds (OR: 1.39; 95% CI: 1.03, 1.88) and Black, Hispanic, Chinese, Filipino, SEA men had decreased odds of squamous cell carcinoma. Japanese women had increased odds (OR: 1.54; 95% CI: 1.15, 2.07) while Black, Hispanic, Middle Eastern, Filipino, and SEA women had decreased odds of squamous cell carcinoma when compared with White women. When compared with Black men, White men, (OR: 1.11; 95% CI: 1.01, 1.24) American Indian, (OR: 1.56; 95% CI: 1.13, 2.13) and Korean (OR: 1.35; 95% CI: 1.05, 1.73) men had increased odds and Chinese, Filipino, and SEA men had decreased odds of squamous cell carcinoma. White, (OR: 1.13; 95% CI: 1.01, 1.28) Japanese, (OR: 1.75; 95% CI: 1.28, 2.39) and Korean (OR: 1.63; 95% CI: 1.09, 2.42) women had increased odds and Southeast Asians had decreased odds when compared with Black women. **Conclusions:** Some Asian ethnicities have a higher risk for squamous cell lung cancer than both Black and White men and women even after adjusting for smoking. This is not apparent when the Asian ethnicities are classified as API. Examining individual Asian ethnicities is important since they have little to no shared genetic or cultural variables and are grouped together for convenience rather than any scientifically plausible reason. Research Sponsor: None.

Association of enrollment in Medicare Advantage plans versus fee-for-service in patients with a late-stage diagnosis of gynecologic cancer.

Elyse Xinyue Zhang, Kevin C Ward, Jane Lowe Meisel, Jeffrey M. Switchenko, Joseph Lipscomb; Emory University, Rollins School of Public Health, Atlanta, GA; Georgia Center for Cancer Statistics, Atlanta, GA; Winship Cancer Institute of Emory University, Atlanta, GA

Background: In the United States, uterine cancer is the most common gynecologic (GYN) cancer; and ovarian cancer causes more deaths each year than any other GYN cancer. There are currently no recommended population-wide screening tests for ovarian or uterine cancer, which are heavily concentrated in older women. Medicare is the primary health insurer for 97% of Americans aged 65 years and older. This study is the first to examine the association between Medicare enrollment plan – Medicare Advantage (MA) versus fee-for-service (FFS) – and stage at diagnosis among older women newly diagnosed with ovarian or uterine cancer. **Methods:** Using the linked Surveillance, Epidemiology, and End Results (SEER) registries and Medicare enrollment data, we identified 101,193 women aged 65 years and older with newly diagnosed ovarian or uterine cancer between 2007-2019. We categorized patients into two groups: 1) those continuously enrolled in Medicare MA for six months prior to their diagnosis, through the diagnosis month, and the month following diagnosis; 2) those continuously enrolled in Medicare FFS within the same eight-month window. Late-stage was defined as "Distant" stage (with "Local" and "Regional" stages representing an earlier-stage diagnosis) using the SEER Summary Stage variable. The association between Medicare enrollment plan and stage was examined through multivariable logistic regression modeling that adjusted for socio-demographic characteristics. The influence of each predictor on the difference in the probability of late stage was summarized as an adjusted marginal effect (ME). **Results:** Among uterine cancer patients, 37% had MA insurance. Compared with Medicare FFS enrollees, the adjusted percentage of late-stage diagnosis was 0.6 percentage points (ppt) lower for MA enrollees (95% CI = -1.1-(-0.1); $P<0.05$). Notably, patients were more likely to have a late-stage uterine diagnosis if they were: non-Hispanic Black or Hispanic (vs. non-Hispanic White); age 75 and older (vs. between 65 -74); and residing in a lower SES neighborhood. Among ovarian cancer patients, 34% had MA insurance. We found no significant difference between Medicare MA and FFS enrollees in ovarian cancer stage at diagnosis. Of note, Non-Hispanic Black patients were significantly more likely to be diagnosed with late-stage disease compared to Non-Hispanic White, and likewise for patients aged 75 and older (vs. between 65-74). **Conclusions:** Among Medicare beneficiaries (age 65+) diagnosed with uterine cancer, those enrolled in an MA plan were significantly less likely to be diagnosed at a later stage. In similar analyses for ovarian cancer, there was no such MA - FFS difference in the probability of late-stage. As enrollment in Medicare Advantage plans continues to grow, it becomes increasingly important to identify whether there are significant outcome differences between MA and FFS plans. Research Sponsor: None.

11141 Poster Session

Estimating adult cancer cachexia prevalence and impact on survival in the US: Real-world data analysis.

Eric Roeland, Jeffrey Crawford, Richard Francis Dunne, Ira Allen Jacobs, John Groarke, Michelle I Rossulek, Nilo B. Cater, Philip D. Bonomi; OHSU Knight Cancer Institute, Portland, OR; Duke Cancer Institute, Duke University Medical Center, Durham, NC; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY; Global Product Development, Pfizer Inc., New York, NY; Internal Medicine Research Unit, Pfizer Inc., New York, NY; Internal Medicine Research Unit, Pfizer Inc., Tampa, FL; Global Medical Affairs, Pfizer Inc., New York, NY; Rush University, Chicago, IL

Background: Cancer cachexia is defined by weight loss that nutritional support cannot fully reverse, leading to worse pt outcomes. Cachexia prevalence across cancer types relies on outdated studies. This study assesses the frequency of cachexia diagnosis using ICD9/10 codes or observed weight loss consistent with real-world cachexia diagnosis and its impact on survival. **Methods:** Retrospective, observational, real-world analysis using deidentified adult pt data from Clinformatics Data Mart database (Aug 1, 2016–Jul 31, 2021). Pts with at least 1 of 23 cancer types were identified using diagnostic and procedure codes and classified in 1 of 3 cachexia categories: (1) diagnosed (diagnostic code identified); (2) observed (BMI decrease: >10% within 12 mo, >5% within 6 mo, or >2% with a BMI <20 kg/m^2), (3) none (with no cachexia diagnostic code/observed). For observed, pts required ≥10 BMI records. Summary statistics presented as mean, median, or n (%). Survival rates compared using Cox proportional hazards model. **Results:** 672,665 pts were identified; 278,923 met inclusion criteria. Diagnosed + observed (subgroup) cachexia rates are shown for the 5 most prevalent cancer types (Table). Over 5 y, diagnosed cachexia rates ranged from 0.9–6.3%; observed from 60–83% (in subgroup with ≥10 BMI records). After cancer diagnosis, observed cachexia was identified on average 0–11 mo, while formal diagnosis occurred on average 11–24 mo. At least 16% of diagnosed and 31% observed pts received diagnosis or met observed criteria at or before cancer diagnosis. Average percent BMI decrease over 5 y was 22.0% ± 12.1, 17.8% ± 9.5, and 6.8% ± 5.5 for diagnosed, observed, and none, respectively. Compared with no cachexia, diagnosed and observed showed worse survival (HR 10.72 [95% CI 10.56–10.88]; HR 2.35 [95% CI 2.32–2.38]), respectively. **Conclusions:** Across all cancer subtypes, prevalence of observed cachexia cases documented by weight loss far exceeded cachexia prevalence based on diagnostic coding. After cancer diagnosis, pts met diagnostic criteria of cachexia within 1 y, but formal diagnosis took up to 2 y. The presence of cancer cachexia (diagnosed or observed), with or without metastatic disease, was associated with lower survival. Research Sponsor: Pfizer.

Diagnosed + observed cancer cachexia rates, 5 most prevalent cancers.

				Observed cachexia* n (%)				
Primary Cancer	Total Pts n	Diagnosed Cachexia n (%)	Observed Subgroup* n	Subgroup Total	>2% BMI Drop <20	>5% BMI Drop 6 mo	>10% BMI Drop 12 mo	None* n (%)
Breast	140795	1296 (0.9)	58158	36154 (63)	6074 (10)	34541 (59)	21588 (37)	22004 (38)
Prostate	110985	1309 (1.2)	45447	27215 (60)	3479 (8)	26397 (58)	15669 (34)	18232 (40)
Intestinal	48180	1390 (2.9)	20145	14422 (72)	3337 (17)	13887 (69)	10050 (50)	5723 (28)
Reproductive	44408	689 (1.6)	18184	11923 (66)	1971 (11)	11385 (63)	7671 (42)	6261 (34)
Lung	42222	2643 (6.3)	18918	15640 (83)	5415 (29)	15104 (80)	11857 (63)	3278 (17)

*Pts with ≥10 BMI records.

Demographics and survival outcomes of stage IV male breast cancer: A retrospective analysis of SEER database.

Nishanth Thalambedu, Bradley Fugere, Sindhu Malapati; University of Arkansas for Medical Sciences, Little Rock, AR; University of Arkansas for Medical Sciences, Littlerock, AR; University of Arkansas Medical Sciences, Little Rock, AR

Background: Male Breast Cancer (MBC) is a rare malignancy accounting for <1% of all breast cancer cases in the United States. It is often lately diagnosed due to lack of awareness leading to substantial morbidity and mortality. Previous studies revealed higher risk of death among males compared to females across all stages, but little known about the impact of Hormone Receptor (HR) and Human Epidermal growth factor Receptor 2(HER 2) statuses on prognosis and survival among MBC patients. So, we aim to study the survival outcomes of stage IV MBC patients using SEER (Surveillance, Epidemiology, and End Results) data. **Methods:** A retrospective analysis was conducted using a SEER database and identified stage IV MBC cases (Any T, Any N, M1) diagnosed between 2010-2015. The selection of these years is based on the reporting of HER2 status on SEER database starting from 2010 and to ensure a current period and a minimum of 5 years of follow-up. Patient demographics, tumor HR/HER 2 status and survival data were extracted and analyzed. Subgroup analyses were performed to show the correlation between HR/HER 2 status and survival. **Results:** The study included 144 patients. 59.7%(86/144) were above 60 years of age. Majority were Caucasians up to 68.1%(98/144) followed by African Americans 18.7% (27/144), Hispanics 6.9%(10/144) and Asians/Pacific Islanders 6.2%(9/144). Among the subtypes, the most common was HR+/HER2- consisting of 69.4%(100/144) followed by HR+/HER2+ 19.4%(28/144), HR-/HER2- 9.7%(14/144), HR-/HER2+ 1.4%(2/144). The median overall survival varied among different subtypes of breast cancer and was noted to be 31.5 months, 25 months, 4.5 months and 10 months among HR+/HER2-, HR+/HER2+, HR-/HER2- and HR-/HER2+ respectively (Table). In the comparison between HR+/HER2+ and HR-/HER2-, the risk of death differed significantly, as indicated by a hazard ratio of 0.26 (95% CI 0.12-0.56, p = 0.001), highlighting a poor survival of HR-/HER2-. **Conclusions:** This retrospective analysis provides valuable insights into the demographics and survival outcomes of stage IV MBC patients. Triple negative (HR-/HER2-) subtype continues to have poor outcomes in males as well, emphasizing the need to explore novel treatment strategies to improve outcomes for this unique patient population. Although, treatment regimens for MBC are extrapolated from women, the disparity in survival across all subtypes requires the need to get more men on breast cancer clinical trials when feasible. Research Sponsor: None.

Demographics and survival outcomes among stage IV male breast cancer from 2010-2015.

Age	
>60	59.7% (86/144)
Race	
Caucasians	68.1% (98/144)
African Americans	18.7% (27/144)
Hispanics	6.9% (10/144)
Asians/Pacific Islanders	6.2% (9/144)
Subtypes	
HR+/HER2-	69.4% (100/144)
HR+/HER2+	19.4% (28/144)
HR-/HER2-	9.7% (14/144)
HR-/HER2+	1.4% (2/144)
Median OS	
HR+/HER2-	31.5 months
HR+/HER2+	25 months
HR-/HER2-	4.5 months
HR-/HER2+	10 months

11143 Poster Session

Knowledge, attitudes, and current practices toward lung cancer palliative care management in China: A national survey.

Mengting Chen, Huiqing Yu, Junhui Zhang, Hong Yang, Liejun Yang, Ling Tian, Sixiong Wang; Chongqing University Cancer Hospital, Chongqing, China; Chongqing University Cancer Hospital, Chongqing Cancer Hospital, Chongqing, China

Background: To demonstrate the status and differences in knowledge, attitudes, and practices (KAP) of lung cancer palliative care (LCPC) management, and to measure patient controlled analgesia (PCA) in cancer pain management in of China. **Methods:** A questionnaire on LCPC management was used in this study, which involved a total of 2093 participants from 706 hospitals in China. Seven major components make up the questionnaire, including chi-square tests or Fisher exact probabilities to measure the differences in KAP between hospitals grades. Comparing distributions of ordered data between groups was done using the Kruskal-Wallis H test or the Mann-Whitney U test. Multiple choice questions use multiple response cross analysis. Correlation was evaluated by the Spearman correlation coefficient. **Results:** 84.2% participants believed that anti-tumor therapy is equally important as palliative care. The satisfaction rate of participants from grade 3 hospitals, which was significantly higher than that of grade 2 and grade 1 hospitals (χ^2=27.402, P=0.002). The most common symptoms requiring LCPC was pain. The major barriers toward to LCPC were "Patients and families are concerned about the safety of long-term use of palliative care related drugs". The most common reasons for the use of PCA treatment were 31.1% participants thought "Patients with systemic application of large doses of opioids or adverse reactions to opioids that cannot be tolerated". The top three barriers toward PCA treatment of cancer pain were (i) worry about adverse reactions of drug overdose, (ii) worry about opioid addiction, and (iii) increase of patients' economic burden. In the past 24 months, 33.9% of the participants had not participated in online or offline training related to palliative care of lung cancer. **Conclusions:** Chinese healthcare workers are in need of training for lung cancer palliative care and, in particular, for controlling cancer pain symptoms. Research Sponsor: Natural Science Foundation of Chongqing of China; Chongqing medicinal biotech association of scientific research projects; Chongqing Scientific Research Institutions Performance Incentive and guidance Project; Chongqing Municipal Education Commission of Science and Technology Research Project; Technology innovation and application development projects of Shapingba district, Chongqing, China.

11144 Poster Session

Breaking through barriers: Unraveling challenges in clinical trial participation among oncologic patients in a developing country.

Erika Bushatsky, Andressa Liz Cândido, Daniel Agustin Vasquez Quispe, Rafaela Paiola, Alessandra Cristina Machado Barata Tavares, Felipe Melo Cruz, Lilian Martins Arruda; Instituto Brasileiro de Controle do Câncer, São Paulo, Brazil

Background: Clinical trials are vital for advancing cancer research and treatment development, yet obstacles to participation impede progress, particularly in regions with limited clinical research awareness, such as Brazil. **Methods:** This study was conducted in a single cancer center in São Paulo, Brazil, between 2020 and 2022. A tailored questionnaire comprising demographic (age, gender, income) and barrier-related sections explored patient-related (10 questions), protocol-related (7 questions), and physician-related (5 questions) barriers. **Results:** Among 206 oncologic patients enrolled in the study, 43.7% were from the public healthcare system, and 56.3% had private insurance. Patients who self-declared as white were 59.7%, and those who self-declared as brown/black were 35.9%. Patient-related challenges included unfamiliarity with trial participants (84.6%), concerns about daily life disruptions (75.4%), and transportation difficulties (66.2%). Protocol-related obstacles involved fears of unknown side effects (62.3%), inability to choose treatment (47.6%), and potential assignment to a placebo group (46.8%). Physician-related barriers included communication issues, strained doctor-patient relationships (94.7%), and patient deference to doctors' decisions (55.4%). Higher-income patients and those in the public health system demonstrated greater clinical research awareness. **Conclusions:** The study emphasizes the critical role of patient education in overcoming barriers to clinical trial participation in oncologic patients. Furthermore, it underscores the necessity of addressing disparities among minority populations, such as non-white individuals with lower incomes, to transform clinical research and ensure universal access to newer therapies. Efforts should be directed towards inclusivity, bridging awareness gaps, and fostering a comprehensive understanding of the benefits of clinical trial participation for all cancer patients. Research Sponsor: None.

11145 Poster Session

Pulmonary toxicities in patients (pts) with metastatic breast cancer (mBC) treated with trastuzumab deruxtecan (T-DXd): The Mayo Clinic experience.

Jenna Hoppenworth, Sarah Premji, Deanne R. Smith, Jodi L. Taraba, Timothy J. Hobday, Prema P. Peethambaram, Jamie Carroll, Kathryn Jean Ruddy, Ciara Catherine O'Sullivan, Amye Juliet Tevaarwerk, Grace Mei Yee Choong, Elizabeth Jane Cathcart-Rake, Siddhartha Yadav, Lisa Ellsworth, Rohit Rao, Ashley Egan, Tufia C. Haddad, Matthew P. Goetz, Karthik Giridhar, Roberto Antonio Leon-Ferre; Mayo Clinic, Rochester, MN; Department of Medical Oncology, Mayo Clinic, Rochester, MN; Mayo Clinic, Rochester, NY; Mayo Clinic Florida, Jacksonville, FL

Background: T-DXd is increasingly used in mBC. A T-DXd toxicity of special interest is interstitial lung disease/pneumonitis (ILD), occurring in 10-15% of pts in the DESTINY-Breast trials, and with potential lower incidence/severity in earlier line settings [Krop et al, ASCO 2023]. However, in routine practice, T-DXd may be used in pts with more heavily pre-treated mBC and previously exposed to other antibody-drug conjugates (ADC) [Premji et al SABCS 2023]. We evaluated the incidence/severity of T-DXd related ILD in mBC at Mayo Clinic. **Methods:** We retrospectively identified pts with mBC who received ≥1 dose of T-DXd at Mayo Clinic, Rochester, MN, between July 2022-December 2023. Demographic, mBC, and pulmonary clinical variables were abstracted from the clinical records. Data was summarized using descriptive statistics. Diagnosis of ILD was determined by treating clinicians, and severity to CTCAE V5 based on clinical documentation. **Results:** 77 pts with mBC received T-DXd during the study period. All were female, the majority (70, 91%) were Caucasian, and median age was 58. 53 (69%) had HER2-low mBC (37 HR+, 16 HR-) and 24 (31%) had HER2+ mBC (17 HR+, 7 HR-). 31 (40%) were active or former smokers. 11 (14%) had pulmonary comorbidities, including 6 (7.8%) with asthma, 2 (2.6%) with prior pneumonitis, and 3 (3.9%) with other pulmonary comorbidities. They had previously received a median of 1 line of endocrine therapy, and 4 lines of chemotherapy, with 20 (26%) having received another ADC. 17 (22%) developed any grade ILD [G1: 3 (4%), G2: 7 (9%), G3: 2 (3%), G4: 1 (1%), G5: 4 (5%)]. Among pts with ILD of any grade, 13 (76.5%) presented with at least 1 symptom (cough/SOB). The median number of T-DXd cycles prior to onset of any grade ILD was 6 (range 2-13), or 18 (range 6-39) weeks. 5 (29%) pts with any grade ILD received a prior ADC. Of pts with ≥G3 ILD (n=7), all were Caucasian, 2 (30%) were prior smokers, none had prior lung disease, and had received a median of 5 prior lines of chemo, with 4 (57%) having received a prior ADC. All grade ≥2 ILDs were treated with systemic steroids, and 1 also received IVIG. CT chest was used for diagnosis of all ILD. 7 pts (41%) required hospitalization, all of whom had bronchoscopy, with 5 (29%) requiring intubation. All pts with G1 ILD (3, 18%) restarted T-DXd without ILD recurrence. **Conclusions:** In this case series,22% of ps treated with T-DXd experienced ILD (5% G5), higher than the rate observed in the pivotal DESTINY-Breast trials, possibly due to real-world use of T-DXd in more heavily pre-treated pts and in pts with pulmonary comorbidities. Research Sponsor: None.

11146 Poster Session

Ambulatory teclistamab administration in patients with relapsed/refractory multiple myeloma.

Nadeem Tabbara, Michael Singel, Natalie Allen, Kathy Mooney, Audra Shedeck, Amber Zukas, Kate Campion, Callan Sollenberger, Christian Burris Gocke, Syed Abbas Ali, Carol Ann Huff, Philip H. Imus, Sarah Waheed; Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD; Johns Hopkins University, Baltimore, MD; Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Washington, DC

Background: Teclistamab (Tec) is the first B-Cell Maturation antigen (BCMA)xCD3 bispecific antibody FDA approved for the treatment of relapsed or refractory multiple myeloma (RRMM) in patients who have received ≥4 prior lines of therapy. The phase 1-2 MajesTec-1 study raised concerns for cytokine release syndrome (CRS)/immune effector cell-associated neurotoxicity syndrome (ICANS). 48-hour inpatient observation is recommended for step-up dosing, which imposes financial and logistical burdens. We report our institutional experience with ambulatory Tec administration. **Methods:** Our inpatient/outpatient (IPOP) hybrid nursing unit is staffed with specialized nurses, advanced practice providers, and attending physicians. Our patients treated in IPOP must live within 1 hour of the hospital and have a 24-hour caregiver. Patients were treated with the recommended step-up dosing schedule. CRS grading and ICE scoring were performed daily. Both CRS and ICANS were graded according to the ASTCT grading systems. We collected toxicities until the second full treatment dose, at which point hospitalization is no longer recommended. **Results:** In total, 25 patients were treated with Tec between January 2023 to December 2023. The median age was 70 years old (range 59-89), with a median of 6 prior lines of therapy. One patient was dialysis dependent prior to starting Tec. All patients were triple class refractory. Thirteen patients (52%) received prior bone marrow transplant. One (4%) patient received prior anti-BCMA CAR-T therapy. Seventeen patients (68%) required admission during the Tec ramp-up period. CRS was observed in 15 (60 %) patients, all of which were grade I/II events. Fourteen of these patients were hospitalized for CRS. They were admitted for median number of 2 hospital days (range 1-6). Tocilizumab was administered for Grade 2 CRS in 3 patients (12%). ICANS was reported in 4 (16%) patients. Two of those patients developed Grade 2 ICANS which completely resolved with dexamethasone. The median number of admitted hospital days for these patients was 3 days (range 2-49). Neutropenia with ANC $<$ 500 was seen in only 1 (4%) patient. Grade 3/4 infections were seen in 3 (12%) patients during the ramp-up period. **Conclusions:** Tec administration through an inpatient/outpatient hybrid model is safe and feasible. CRS was common but low grade and short lived. ICANS was observed, but remained low grade and may be attributable to our older patient population. As our center gained experience with the Tec management, we noticed lower rates of admission for low grade CRS. Lower incidences of infections and neutropenia demonstrate that these complications emerge in the months after starting therapy. Future studies will help identify patients who are higher risk for CRS and ICANS during ramp-up treatment and may pave the way for prophylactic interventions and outpatient administration.
Research Sponsor: None.

End of life (EOL) care in head and neck squamous cell carcinoma (HNSCC) compared to other solid tumors (OST) in Washington (WA) State.

Lauren Shih, Qin Sun, Catherine R. Fedorenko, Neal D. Futran, Brittany Barber, Emily Marchiano, Upendra Parvathaneni, Jay Justin Liao, Cristina P. Rodriguez, Scott David Ramsey, Veena Shankaran; Fred Hutchinson Cancer Center, Seattle, WA; Department of Otolaryngology, Head and Neck Surgery, University of Washington, Seattle, WA; University of Washington, Seattle, WA; University of Washington Medical Center, Seattle, WA; Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA

Background: Real world data describing EOL care in HNSCC is limited. We performed a retrospective study evaluating EOL in HNSCC vs OST in a population-based sample of patients in WA. **Methods:** We used a database linking WA state cancer registry records with claims records from Medicare, Medicaid, and two large commercial insurers. Patients with HNSCC (oral cavity, oropharynx, hypopharynx, or larynx) were compared to OST (any solid tumor diagnosis). Adults with AJCC stage II-IV or SEER stage Regional/Distant who died in 2011-2021 with continuous insurance enrollment 6 months before death were included. We compared proportions of patients with >1 ED visits in the last 30 days of life, ICU admission in the last 30 days of life, chemotherapy in the last 14 days of life, and hospice enrollment at least 3 days prior to death. We performed multivariate regression analysis to determine factors associated with hospice enrollment. **Results:** 1,389 patients with HNSCC and 41,412 patients with OST were identified. Demographics for HNSCC vs OST included median age 68 vs 73, white race 91.5% vs 90.1%, stage IV 57.5% vs 45.3%. Insurance types for HNSCC vs OST were commercial 8.4% vs 9.8%, Medicaid 16.6% vs 8.8%, Medicare 59.1% vs 65.5%, multiple 15.8% vs 15.9% ($p<0.0001$). HNSCC patients had lower rates of >1 ED visits compared to OST (14.1% vs 16.4%, $p=0.02$); there was no significant difference in ICU admission (25.1% vs 24.0%, $p=0.3$) or chemotherapy receipt (6.3% vs 5.1%, $p=0.056$). Hospice enrollment was significantly lower in HNSCC patients (49.0% vs 56.4%, $p<0.0001$). A stratified analysis limited to stage IV patients yielded consistent findings in all categories. HNSCC patients died more at home and less in hospice (20.2% vs 12.7% and 41.5% vs 52.0%, $p<0.0001$). In a multivariate regression analysis (Table) HNSCC, black race, living with a partner, or living in neighborhoods with higher area deprivation index (ADI) was associated with lower hospice enrollment. Patients with Medicare or multiple insurance types were more likely to enroll in hospice; AJCC stage was not significant. **Conclusions:** In this population-based sample, compared to OST, a greater proportion of HNSCC patients were insured by Medicaid at EOL and were less likely to enroll in hospice prior to death. The reasons driving these observed disparities in hospice enrollment warrant further study to optimize EOL care among patients with HNSCC. Research Sponsor: U.S. National Institutes of Health; T32CA009515; Bayer Healthcare.

Multivariate analysis for hospice enrollment.

	OR Point Estimate	95% CI
HNSCC (ref=OST)	0.76	0.68, 0.85
Black (ref=white)	0.80	0.71, 0.91
Living with partner (ref=unpartnered)	0.94	0.90, 0.98
Unknown living status (ref=unpartnered)	0.91	0.85, 0.97
Medicaid (ref=commercial)	1.03	0.94, 1.13
Medicare (ref=Commercial)	1.99	1.86, 2.12
Multiple (ref=Commercial)	2.09	1.94, 2.27
ADI 4-7 (ref=1-3)	0.89	0.84, 0.93
ADI 8-10 (ref=1-3)	0.79	0.75, 0.84

Not shown (not significant): AJCC Stage.

Timing of EGFR or ALK inhibitor initiation and survival among patients with advanced NSCLC.

Tawee Tanvetyanon, Dung-Tsa Chen, Jhanelle E. Gray; Department of Thoracic Oncology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL

Background: ALK or EGFR inhibitor is an ideal frontline treatment for patients with advanced non-small cell lung cancer (NSCLC) harboring targetable alteration in *ALK* or *EGFR*. However, in the real-world setting, frontline treatment may be delayed or unideal. For such patients, the magnitude of survival benefit when initiating ALK or EGFR inhibitor at a much later timepoint remains unclear. **Methods:** We utilized a nationwide electronic health record-derived, deidentified database collected from diverse oncology practices across the United States to investigate the timeliness of preferred targeted therapy (PTT), defined as osimertinib, lorlatinib, alectinib or brigatinib. Individualized data obtained from patients with stage IV NSCLC at diagnosis treated with PTT during 2018 to 2023 were analyzed. Timing of PTT initiation was modeled as time-varying covariate. **Results:** Data from 3250 patients were analyzed: 2640 patients (81%) with *EGFR* mutation and 610 patients (19%) with *ALK* rearrangement. The median time to PTT was 7 weeks from diagnosis with 26.4% of patients started PTT within 1 month. Landmark analyses using timepoints ranging from 1 to 12 months after diagnosis showed that at all timepoints, patients who had started on PTT had a significantly better survival than those who had not (Table). In a multivariable analysis, time to PTT $\leq$ 1 month from diagnosis was an independent predictor of survival: HR 0.74 (95% CI: 0.62-0.89), p=0.002. Prolonged time to PTT was significantly associated with advanced age, positive smoking status and genomic class being *ALK* as compared to *EGFR*. **Conclusions:** In this population-based analysis, an initiation of PTT occurring as late as at least 1 year from diagnosis still resulted in a significant survival benefit, though the magnitude of benefit appeared decreased as time passed. Research Sponsor: None.

Timepoint since diagnosis	Number of patients at risk	Number of patients who had not started PTT vs. had started PTT at that landmark timepoint (%)	Median overall survival from landmark timepoint	Hazard ratio (95% CIs)	*p*-value
By 1 month	3029	2230 (74)	26.8 months	0.85 (0.75-0.97)	0.01
		799 (26)	31.3 months	Reference	
By 2 months	2888	1232 (43)	24.4 months	0.80 (0.72-0.89)	<0.001
		1656 (57)	30.2 months	Reference	
By 3 months	2732	939 (34)	23.9 months	0.78 (0.69-0.87)	<0.001
		1793 (66)	29.9 months	Reference	
By 6 months	2401	671 (28)	22.7 months	0.80 (0.70-0.91)	<0.001
		1730 (72)	27.9 months	Reference	
By 12 months	1883	453 (24)	24.1 months	0.85 (0.73-0.99)	0.04
		1430 (76)	25.3 months	Reference	
By 18 months	1396	286 (20)	23.5 months	0.92 (0.76-1.12)	0.41
		1110 (80)	23.9 months	Reference	

Impact of carboplatin and cisplatin shortages on treatment patterns in patients with metastatic solid tumors.

Emily Castellanos, Qianyu Yuan, Niquelle Wadé, Khilna Patel, Catherine Rinaldi, Samantha Reiss, Eunice Hankinson, Aaron B. Cohen, Melissa Estevez; Flatiron Health, New York, NY

Background: The United States experienced cisplatin (CP) and carboplatin (CB) shortages in 2023, leading to potential rationing or switching to alternative therapies in multiple cancers. Using a US nationwide, real-world oncology dataset, we assessed changes in the use of CP and CB in 7 cancers during the shortage period. **Methods:** All patients (pts) from the Flatiron Health electronic health record-derived de-identified database (~280 cancer clinics, ~800 sites of care) with a machine learning-extracted metastatic (met) diagnosis of a cancer of interest between March 2022 and June 2023 and evidence of first-line (1L) therapy, were selected. Pts with multiple primaries were excluded. Platinum of interest was identified based on frequency of pre-period 1L use for a given cancer. The pre-period was June 2022 through first month of reported shortage (February 2023 for CP; April 2023 for CB); data cutoff was June 2023. Clinical characteristics of platinum-treated pts stratified by pre- vs post-period by disease were assessed. 1L platinum utilization rates (UR), calculated as the proportion of 1L-treated pts initiating CB/CP within 30 days of met diagnosis, were plotted by month. Cohort-level impact was evaluated with an interrupted time series analysis—overall and stratified by practice type, practice size, and socioeconomic status (SES). Multiple testing was controlled using the Benjamini-Hochberg procedure. **Results:** 10,983 pts received 1L therapy in the study period. Monthly platinum UR were stable across diseases in the pre-period. However, there was a significant post-period decrease in CB usage for non-small cell lung (NSCLC) and endometrial cancers (EC), and a decreasing trend in UR for CB in bladder (BC), ovarian (OC), and small cell lung cancers (SCLC). We also observed a decreasing trend in CP usage for cholangiocarcinoma (CC). Post-period monthly UR were stable for CB and CP in head and neck cancer (HNC), and for CP in BC. Odds ratios (OR) representing the month-over-month change in the odds of receiving platinum therapy during both pre- and post-periods are shown (table). OR trends varied by practice type and disease; no notable trends were seen by practice size or SES. UR with additional follow-up times will be presented. **Conclusions:** We observed decreased platinum use across multiple cancers during the shortage period, most notably for met NSCLC and EC, suggesting shortages led oncologists to seek alternatives to standard 1L platinum-based regimens. Further study of how treatment changes due to platinum shortages impacted pt outcomes is warranted. Research Sponsor: Flatiron Health.

	Platinum	N (pre)	N (post)	OR (pre)	OR (post)	P value
BC	CP	277	217	1.13	0.97	0.32
BC	CB	360	134	0.99	1.04	0.90
HNC	CP	426	306	1.01	0.96	0.56
HNC	CB	533	199	0.99	0.74	0.17
OC	CB	657	194	1.01	0.73	0.08
EC	CB	495	164	1.06	0.58	0.004*
NSCLC	CB	5272	1560	1.00	0.71	<0.001*
SCLC	CB	699	183	1.02	0.80	0.20
CC	CP	310	223	0.98	0.83	0.16

*significant after multiple testing adjustment.

11150 Poster Session

Mutated *KRAS*as a promising target in pancreas cancer: PURPLE registry data to inform real-world incidence and prognostic significance and to aid trial recruitment.

Belinda Lee, Eric Tian, Daniel Croagh, Marion Harris, Benjamin Thomson, Michael Michael, Benjamin Loveday, Sue-Anne McLachlan, Brett Knowles, Jeremy David Shapiro, Rachel Wong, Adrian Fox, Ross Jennens, Tuck Yong, Russell Hodgson, Nezor Houli, Sumitra Ananda, Larissa Rachel Lipton, Shehara Ramyalini Mendis, Peter Gibbs; Northern Health, Peter MacCallum Cancer Centre, Walter and Eliza Hall Institute of Medical Research, University of Melbourne, Melbourne, VIC, Australia; Walter and Eliza Hall Institute of Medical Research, University of Melbourne, St Vincent's Hospital, Melbourne, VIC, Australia; Monash University, Melbourne, VIC, Australia; Monash Health, Bentleigh East, VIC, Australia; Melbourne Health, Parkville, Australia; Peter MacCallum Cancer Centre, Melbourne, VIC, Australia; Peter MacCallum Cancer Centre, Melbourne, Australia; St. Vincent's Hospital, Fitzroy, Australia; Peter MacCallum Cancer Centre, Parkville, VIC, Australia; Cabrini Hospital, Malvern, VIC, Australia; Eastern Health & Epworth Healthcare & Eastern Health Clinical School, Monash University, Melbourne, Australia; St. Vincent Hospital, Melbourne, Australia; Epworth Healthcare, Richmond, VIC, Australia; Northern Hospital, Vic, Australia; Northern Hospital, Western Hospital, Vic, Australia; Peter MacCallum Cancer Centre, Epworth Healthcare, Western Health, Walter and Eliza Hall Institute, University of Melbourne, Melbourne, VIC, Australia; Western Health, Melbourne, Australia; Walter & Eliza Hall Institute of Medical Research, Melbourne, Australia; Walter & Eliza Hall Institute of Medical Research and Western Health, Melbourne, Australia

Background: With around 90% *KRAS*mutation (mt) frequency, pancreatic ductal adenocarcinoma (PDAC) is considered the most *RAS*-addicted cancer. Despite guideline recommendations, genomic testing is not routine in all PDAC patients (pts) in Australia, due to unproven clinical impact. As more novel *KRAS*-direct therapeutics enter clinical trials, understanding the real-world frequency of individual mutations and prognostic significance, and facilitating trial recruitment are important goals, all of which can be supported by registry data. **Methods:** Data extracted from the PURPLE pancreatic cancer registry from 9 participating Australian cancer centres, between 2016-2022, was analysed to compare clinicopathological features, survival based on *KRAS*mt status, and assess feasibility of the platform to identify and molecularly stratify patients for future clinical trials. Survival estimates were calculated using Kaplan-Meier curves and log-rank testing on SPSS (Macintosh v.29). **Results:** Of 721 PDAC routine care pts identified, next generation sequencing (NGS) was undertaken in 378/721 (52%). Median patient age was 68 years (range 52-83); 152 (40%) had resectable, 111 (29%) locally advanced and 115 (30%) metastatic disease. 57/378 (15%) were *KRAS* wildtype. Of 321 pts with a *KRAS* mt, codons 12,13, and 61 were the most common sites of mt, including G12D (45%), and G12V (30%), with lower frequencies of G12R (13%), Q61H (6%), G12A (3%), G12C (1%), and G13D (1%). Comparing *KRAS* wildtype to *KRAS*mt pts, there was no difference in median age (68 vs 67, p=0.63), gender (male: 49% vs 60%, p=0.23), Charlson comorbidity index (p=0.30), or stage at first presentation (p=0.99). Overall *KRAS* wildtype pts were more likely to be ECOG PS 0 at diagnosis (p=0.01) and to receive at least 1 modality of treatment (p=0.004). For all pts, median overall survival (OS) in *KRAS*wildtype versus *KRAS* mt pts was 29.0 months versus 19.7 months (p=0.007), and for the 115 metastatic pts 15.1 versus 10.4 months (p=0.28). Further analysis of the impact by disease stage and by individual RAS mt is underway. **Conclusions:** Registry based analysis informs understanding of *KRAS* mt status of PDAC in a community setting. Here, *KRAS* mt status was associated with worse OS outcomes, likely in part due to the association with ECOG PS and receiving less active treatment. With newer promising *KRAS*-targeted therapies becoming available in clinical trials, known RAS status will aid identification of trial candidates. The clinical utility of NGS and rationale for reflex testing in PDAC is increasing. Clinical Registry information (ACTRN12617001474347). Research Sponsor: Hemstritch Foundation.

11151 Poster Session

Incorporating precision oncology in everyday clinical practice: First two years of comprehensive genomic profiling (CGP) testing experience in Croatia.

Dora Čerina, Jelena Šuto Pavičić, Antonela Njavro, Niksa Librenjak, Ilijan Tomaš, Robert Šeparović, Stjepko Plestina, Žarko Bajić, Natalija Dedic Plavetic, Eduard Vrdoljak; Department of Oncology, University Hospital Center Split, School of Medicine, University of Split, Split, Croatia; Department of Oncology, University Hospital Center Split, Split, Croatia; Department of Oncology and Nuclear Medicine, Sestre Milosrdnice University Hospital Center, Zagreb, Croatia; Department of Oncology, University Hospital Center Zagreb, Zagreb, Croatia; Department of Radiotherapy and Oncology, University Hospital Center Osijek, School of Medicine, Josip Juraj Strossmayer University of Osijek, Osijek, Croatia; Department of Medical Oncology, Division of Medical Oncology, University Hospital for Tumors, Sestre Milosrdnice University Hospital Center, Zagreb, Croatia; Department of Oncology, University Hospital Center Zagreb, School of Medicine, University of Zagreb, Zagreb, Croatia; Research Unit "Dr. Mirko Grmek," Psychiatric Clinic "Sveti Ivan", Zagreb, Croatia

Background: Despite increased availability of modern technologies and evolution of tailored treatment, which has already significantly changed the outcomes in some cancer types, applicability of precision medicine in everyday clinical practice is still emerging and is one of the hot topics. Croatia is among first ones in the World to have entered into force a country-level based project of precision oncology throughout the CGP analysis in everyday clinical work, fully covered by Croatian health insurance. Hence, here we would like to present our data from everyday clinical practice and analyze the penetration of CGP given the opportunity and challenges we had. **Methods:** The study was observational and retrospective in nature, conducted on a country level among all patients on whose tumor specimens CGP was performed between January 1, 2020 and December 31, 2021. Eligible patients for the CGP analysis were those with metastatic disease, with at least 6-12 months of life-expectancy, with ECOG performance status $\leq$ 2, and after the recommendation from the multidisciplinary team. The analysis was performed in accredited laboratory (Foundation Medicine Inc., Cambridge, MA, USA), through FoundationOneCDx for solid tumors, FoundationOne Liquid in case of insufficient tissue or FoundationOneHeme for sarcomas. **Results:** There was total of 481 patients with CGP results. Median age was 61 years (IQR 49-69) and 58% of patients were women, while 42% were men. Most commonly tested were gastrointestinal (29.1%) and reproductive tumors (28.9%) with colorectal (19.1%) and uterine cancer (11.2%) as the most prevalent. At least one clinically relevant genomic alteration was found in 48.7% of patients. The most frequent mutations were those of KRAS (27.2%), PIK3CA (12.9%), AR (10.6%), NRAS (10.4%) and PTEN (9.1%) genes. Currently clinically not relevant mutations were found in 51.8% of patients with TP53 gene mutation as the most common (42.8%). According to the Croatian cancer registry, there was around 26 000 cancer related deaths during the investigated period defining population of at least more than 10 000 potentially eligible patients for the CGP analysis. **Conclusions:** Our results have shown that almost 50% of tested patients could have potential treatment benefit based on the detection of clinically relevant genomic alteration. Unfortunately, taking into consideration country level insurance eligibility criteria for CGP testing and number of potentially eligible cancer patients, we could say that only less than 5% of patients with metastatic disease were tested within first two years and that penetration of CGP is rather low, resulting with a significant number of patients underserved. Research Sponsor: None.

11152 Poster Session

Developing a deep learning algorithm to support decision making for the classification of microsatellite instability (MSI) in cancer, using artificial intelligence(AI).

Maria Teresa Pombo, Julieta Chirkes, Andrea Erbetti, Olivia Sanguinetti, Adrian Perez, Federico Paschetta, Juan Manuel O'Connor, Ana Gorodisch; Alexander Fleming Institute, Colegiales, Argentina; Instituto Tecnológico Universitario Buenos Aires, Argentina (ITBA), Buenos Aires, Argentina; Instituto Tecnologico Buenos Aires (ITBA), Buenos Aires, Argentina; Instituto Privado de Oncología Alexander Fleming Buenos Aires, Argentina (IAF), Buenos Aires, Argentina

Background: Digital pathology (DP) is an image-based environment, which allows the acquisition, and interpretation of pathological information from a digitized slide. The objective of this work was to build an AI model for predicting MSI in endometrial, colorectal, and gastric carcinomas, to simplify laboratory processes, in a developing country. Nowadays, it is crucial to recognize patients who will respond to treatments such as immunotherapy. **Methods:** The computational tool utilized was CLAM (clustering-constrained-attention multiple instance learning). This architecture developed by Lu et al. is a deep learning method that utilizes weak supervision and attention based learning, to identify the most relevant regions for tumor classification, in whole slide images (WSI). CLAM was designed to excel in tumor subtyping tasks which are discernible to human visual perception. We are challenging this architecture by employing it in the detection of a molecular phenomenon. For training and internal evaluation, images from TCGA and CPTAC were obtained for endometrial cancer (EC). For colorectal (CCR) and gastric cancer (GC), only images from TCGA. Archived histological samples with MSI/MMR status from a donor lab , were used for external validation. **Results:** Tests conducted on an *internal* cohort of 58 samples for CCR and GC revealed a sensitivity of 76.9%, a specificity of 78.1%, and an AUC-ROC of 76.3%. In the case of EC, where 38 cases were evaluated, the sensitivity was 100%, specificity was 68%, and AUC-ROC reached 92%. Notably, regarding the *external*cohort consisting of 109 samples, both models demonstrated a high sensitivity of up to 90% in recognizing positive cases. Due to the models' specificity (approximately 45%), it was not possible to accurately predict MSS samples in all three types of tumors. **Conclusions:** Promising results were obtained for the first approach in detecting molecular biology events, such as MSI, using AI. CLAM is a useful platform for digital pathology, but new validations are needed to enhance our work and strengthen the model. It is hypothesized that CLAM may not be the best tool for AI in identifying molecular biology events, so other directions are being explored. For external cohorts, preanalytical changes play an important role in obtaining accurate results with scanners and digitalization. It is crucial to teach healthcare professionals about AI in order to ensure its availability, in every diagnostic laboratory. Research Sponsor: None.

Differences in baseline characteristics and healthcare costs among insured patients with advanced cancer with vs without clinical trial participation.

Karen M Stockl, Pamela Morin, Carolina Reyes, Brock Schroeder, Julia M Certa, Jamie Tucker, Damon Hostin, John Leonard Fox; Optum, Eden Prairie, MN; Illumina, Inc., San Diego, CA

Background: Despite concerted efforts to improve clinical trial participation (CTP), enrollment remains low. Perceived additional costs to the patient or health plan may be barriers to CTP; low biomarker testing rates may be another. This study assessed differences in characteristics of patients with CTP versus patients without CTP in an insured population with advanced cancer. **Methods:** A retrospective analysis was conducted using de-identified administrative claims data from commercially insured and Medicare Advantage (MA) enrollees in the Optum Labs Data Warehouse. Patients ≥18y with claims evidence of advanced cancer and systemic therapy between 01/01/2018 and 02/28/2022 were stratified into 2 groups: 1) with CTP: ≥1 claim with a CTP diagnosis (ICD10 Z00.6) and ≥1 claim with a Q modifier on or within 90 days after index date; and 2) without CTP: no claims with a CTP diagnosis or Q modifier. Patients with >1 primary cancer, T-cell therapy, or <360 days baseline or follow-up (unless death) enrollment were excluded. Biomarker testing, targeted therapy use, and healthcare costs per patient per month (PPPM) were assessed in the baseline period. **Results:** Of 61,490 patients identified, 1753 (3%) had CTP and 59,737 (97%) did not have CTP; 4% of commercial and 3% of MA patients had CTP. Most common tumor types were breast (27%; 2% had CTP), lung (16%; 3% had CTP), digestive tract (15%; 2% had CTP), and prostate (15%; 3% had CTP). Patients with CTP were younger and more frequently had documented biomarker test use in the baseline period than patients without CTP (Table). In unadjusted analyses, the CTP group had higher healthcare costs in the baseline period prior to CTP regardless of insurance type, driven by 51% higher systemic cancer therapy costs and 35% higher ambulatory visit costs. An ongoing propensity score matched analysis will evaluate the impact of CTP on cost of care in the follow-up period. **Conclusions:** Consistent with prior studies, the overall CTP rate among patients with advanced cancers was low (3%). Baseline costs (prior to CTP) were higher for patients that later enrolled in clinical trials than for patients without CTP. Further research is ongoing to assess differences in follow-up healthcare costs for patients with vs without CTP adjusting for baseline characteristics. Research Sponsor: Illumina, Inc.

Baseline characteristics with CTP vs without CTP.

	Overall			Commercial			MA		
	With CTP N=1753	Without CTP N=59,737	P	With CTP N=572	Without CTP N=15,738	P	With CTP N=1181	Without CTP N=43,999	P
Age, y, mean (SD)	67.9 (11.7)	69.5 (11.4)	**<0.001**	56.2 (10.8)	56.6 (10.7)	0.39	73.6 (7.0)	74.0 (7.4)	**0.02**
Female	53%	56%	**0.01**	63%	62%	0.93	49%	54%	**<0.001**
Biomarker test use	32%	19%	**<0.001**	33%	22%	**<0.001**	32%	18%	**<0.001**
Targeted therapy use	9%	8%	**0.048**	13%	12%	0.33	7%	7%	0.27
Baseline healthcare cost, $PPPM, mean (SD)	9213 (10,349)	7049 (8141)	**<0.001**	13,261 (14,245)	10,817 (11,726)	**<0.001**	7253 (7003)	5702 (5823)	**<0.001**

11155 Poster Session

Medicare reimbursement trends of biological reference agents and their biosimilars.

John Albaugh, Puneeth Indurlal; US Oncology, The Woodlands, TX; McKesson, The US Oncology Network, The Woodlands, TX

Background: Biosimilars have the potential to reduce healthcare costs for payers and provide savings to patients by introducing competition and driving down prices. Centers for Medicare and Medicaid Services' (CMS) Average Sales Price (ASP) is used as an index price to determine Medicare drug reimbursement (MCR) in the United States and is published on a quarterly basis. We studied the trends of ASP and MCR reimbursement rates for reference and biosimilar agents. **Methods:** Using publicly available quarterly CMS data, we evaluated and compared the trends of MCR for 7 reference and 25 biosimilar agents for a period of 2 years before and 5 years after launch. We evaluated the MCR for filgrastim, pegfilgrastim, bevacizumab, trastuzumab, rituximab, infliximab, epoetin-alfa, and their respective biosimilars. **Results:** On average, the published MCR for all reference agents increased by 9.2% (range: 0.6% to 16.8%) over the 2-year period prior to the biosimilar launch. Over the 5-year period following the launch of the first biosimilar, reference agents' MCR fell 32.7% (range: -8.0% to -78.0%) while biosimilar agents' MCR fell 50.3% (range: -3.7% to -90.5%) over the same period, with a median follow-up period of 16 quarters. Biosimilar MCR rates fell at an accelerated rate compared to reference agents. 76% (19 of 25) of the biosimilars that entered the market had an initial MCR below, and 20% (5 of 25) above, that of the reference agent. 16 of 18 successive biosimilars for reference agents launched with a MCR above that of the first biosimilar. Despite the fall in MCR, reference agents' rates in the most recent quarter were 2x higher than their corresponding biosimilar agents, except for pegfilgrastim, which had a precipitous fall in MCR (87%) after biosimilar launch to a price lower than 5 of its 6 biosimilars. **Conclusions:** Biosimilars, with lower Medicare reimbursement at launch, and an accelerated decline in ASP post-launch, deliver on the goal of driving lower healthcare costs and increased savings. Biosimilar competition breaks the price increase trends with reference agents and contributes to a decrease in reference agent drug reimbursement. The effects of manufacturer rebates, payer policies, 340b programs, and discounts on ASP and Medicare reimbursement are also areas of active investigation. Research Sponsor: None.

Real-world outcomes in patients with biomarker-selected early-stage non-small cell lung cancer.

Fawzi Abu Rous, Jesse Sussell, Celina Ngiam, Qing Zhang, Thomas Majda, Daniel Sheinson, Sarika Ogale, Ilze Bara, Katja Schulze, Shirish M. Gadgeel; Henry Ford Health System, Detroit, MI; Genentech, Inc., South San Francisco, CA

Background: Extensive literature has assessed the prognostic value of Lung driver mutations (LDMs) in advanced non-small cell lung cancer (aNSCLC). However, their role in predicting outcomes in early-stage cases (eNSCLC) is less defined due to limited data on biomarker-selected eNSCLC. Study variations have led to diverse findings on the prognostic value of individual LDMs in eNSCLC. **Methods:** We retrospectively analyzed patients with resected stage I-IIIa NSCLC diagnosed between 2011-2023 using the nationwide (US-based) de-identified Flatiron Health-Foundation Medicine lung clinico-genomic database, which consolidates data from approximately 280 US cancer clinics (~800 sites of care). We allocated patients to five cohorts classified by early-stage LDM status: ALK+, EGFR+, KRAS G12C+, KRAS non-G12C+ and wild-type (WT - negative for the listed biomarkers). The clinical attributes and treatment patterns for this cohort were described by our group in a previous abstract; here we analyze recurrence-free and overall survival (RFS and OS) by cohort, using the Kaplan-Meier method. We used Cox regression for multivariate analysis, controlling for demographic and clinical characteristics including age, race, insurance status, stage, histology, and smoking status. **Results:** The sample contained 1,595 stage I-IIIa patients with known LDM status. Of these, 2.8%, 20.4%, 10.7%, 19.3%, and 46.8% were ALK+, EGFR+, KRAS G12C+, KRAS non-G12C+, and WT. Median OS and RFS were shorter in the WT group compared to any LDM group; results can be found in the table. These differences in OS and RFS persisted in multivariate analysis; hazard ratios (HR) were all statistically significant ($p<0.05$) and can be found in the table below. **Conclusions:** In this real-world analysis, patients with eNSCLC LDM-positive tumors had improved OS and RFS relative to WT patients. Differences in OS between WT and LDM+ patients are likely due to frequent receipt of targeted therapy (TT) following progression to advanced disease. However, the small fraction of patients that received adjuvant TT within 6 months of surgery (described in our previous abstract) is not likely to explain observed differences in RFS; thus the differences may be due to innate characteristics of these LDMs. Research Sponsor: F. Hoffmann-La Roche Ltd.

Patient outcomes by LDM status.

	WT (N=747)	ALK (N=45)	EGFR (N=325)	KRAS G12C (N=170)	KRAS non-G12C (N=308)
OS (months)	53	109	98	80	67
adjusted HR	REF	0.48 (0.019)	0.48 (<0.01)	0.71 (0.023)	0.76 (0.014)
RFS (months)	18	38	35	39	37
adjusted HR	REF	0.51 (<.01)	.048 (<0.01)	0.48 (<0.01)	0.48 (<0.01)

Note: Point estimate (p-value).

11157 Poster Session

Real-world duration of interruptions in imaging and endocrine therapy (ET) after pregnancy in early-stage estrogen receptor (ER) positive breast cancer (BC).

Rebecca M. Lewinsohn, James Dickerson, Julia Dory Ransohoff, Ingrid Luo, Mina Satoyoshi, Victor Ritter, Lidia Schapira, Allison W. Kurian; Stanford Health Care, Stanford, CA; Stanford Hospital and Clinics, Stanford, CA; Stanford Health Care, Palo Alto, CA; Stanford University, Stanford, CA; Stanford University School of Medicine, Palo Alto, CA; Stanford Comprehensive Cancer Institute, Palo Alto, CA; Stanford University School of Medicine, Stanford, CA

Background: Pre-menopausal women with early-stage ER-positive BC often desire the option for future fertility. The POSITIVE trial demonstrated that a pause in ET to conceive is safe. However, the real-world durations of these pauses, as well as how many patients resume ET, are unclear. Additionally, there are limited data about when and if women reestablish imaging surveillance after childbirth. **Methods:** We generated a cohort of BC patients with a pregnancy-related ICD diagnosis from the Oncoshare registry. This registry merges EMR and California Cancer Registry data for patients treated in the Stanford Health Care Alliance which includes an academic hospital, a community hospital, and a community practice network. Included patients had ≥1 pregnancy after a diagnosis of stage 0-3 ER-positive BC. Chart review confirmed pregnancy and was used to abstract treatment information. Data are presented as unadjusted percentages or medians with interquartile ranges (IQR). Among patients without bilateral mastectomies, we compared time from delivery to first imaging (MRI or mammogram) for those who breastfed vs not and those who restarted ET vs not using the Wilcoxon rank sum test. **Results:** Of the 317 charts reviewed, 71 were included. Most exclusions were due to no pregnancy (46%) or ER-negative disease (25%). Year of diagnosis ranged from 1994 to 2020, with the majority (79%) from 2010 to 2020. Median age at diagnosis was 33 years (IQR 30-35). The distribution of stages was 18% *in situ* disease, 51% stage 1, 17% stage 2, 14% stage 3. 23% (16/71) of women never started ET, with 14 attributing this decision to desiring pregnancy. Among the 55 women who started ET, 75% received tamoxifen without ovarian suppression (OS). After 2015, use of OS became more prevalent (45% of ET), coinciding with the emergence of the SOFT/TEXT data. The median time from ET onset to a pause for pregnancy was 32 months (IQR 22-53), and the median ET pause to delivery was 23 months (IQR 14-48). We recorded 90 pregnancies resulting in 85 live births. After delivery of their first child, the median follow-up was 3.8 years (IQR 2.0-6.8). 40% of patients never restarted ET. Those who did restart did so at a median of 5 months (IQR 3-11) post-delivery. Imaging surveillance resumed for 42% (27/64) at a median of 6 months post-delivery [IQR 3-11]. Time from delivery to imaging was similar between those who restarted ET and those who did not (p=0.91), and between those who breastfeed and those who did not (p=0.42). **Conclusions:** These data support prior work showing that fertility concerns strongly influence adjuvant therapy choice in ER-positive BC. The ET resumption rate after pregnancy was lower in our analysis compared to the POSITIVE trial (73% vs. 40%). Only 42% of women resumed surveillance imaging. This points to clear gaps between the clinical trial population and the real-world clinical setting. Research Sponsor: AHRQ; 5T32HS026128; Breast Cancer Research Foundation; Susan and Richard Levy Gift Fund; Suzanne Pride Bryan Fund for Breast Cancer Research; Regents of the University of California's California Breast Cancer Research Program; 16OB-0149; BRCA Foundation; G. Willard Miller Foundation.

Real-world treatment patterns and outcomes of zanubrutinib in chronic lymphocytic leukemia and small lymphocytic leukemia (CLL/SLL).

Margaret Krackeler, Bryant Chee, Arthur K Orchanian, Lisa Y. Law, Alfredo R. Lopez, Susan Buchanan, Gregory A. Maglinte, Raymond Liu, Zheng Zhu, Lori C. Sakoda, Jahan Tavakoli; Department of Hematology Oncology, Kaiser Permanente, San Francisco, CA; Department of Internal Medicine, Kaiser Permanente, San Francisco, CA; Department of Hematology Oncology, Kaiser Permanente, Davis, CA; BeiGene, Cambridge, MA; BeiGene, San Mateo, CA; Division of Research, Kaiser Permanente Northern California, Oakland, CA

Background: Zanubrutinib (zanu) is a next-generation selective Bruton's tyrosine kinase inhibitor (BTKi) with superior efficacy over first generation ibrutinib (ibru) in CLL/SLL patients (pts). Herein we present real-world treatment patterns based on a formulary change from ibrutinib to zanubrutinib in pts with CLL/SLL in an integrated community oncology practice. **Methods:** We retrospectively analyzed CLL/SLL pts 18 years and older who received at least 3 months of zanubrutinib from October 1, 2018 to September 15, 2023 at Kaiser Permanente Northern California. Treatment patterns, treatment-emergent adverse events (TEAEs: AEs reported during BTKi use), treatment-limiting adverse events (TLAEs: AEs leading to BTKi discontinuation), and mortality were reported. **Results:** A total of 281 pts received zanu (median age: 71 years; 64% male); 190 pts switched from ibru (ibru-zanu), and 91 pts received zanu only. Most pts were White (75%) followed by Black (10%). Compared with ibru-zanu pts, zanu-only pts were older (median age 74 vs 69 years) and had more comorbidities but were comparable in sex, race, and insurance type. The primary reasons for switching to zanu were formulary change (73%) and progression (15%). Median follow-up time after initiation of first BTKi was longer in the ibru-zanu group (Table). Similar TEAE rates were seen with use of both BTKi therapies, with lower TLAE rates with zanu (Table). Most common TLAE were atrial fibrillation and fatigue for ibru, and cytopenias and rash/bruising for zanu. Cardiac TLAE and non-TLAE rates overall were higher with ibru than zanu, and the rates decreased while on zanu after switching from ibru (Table). Dose modification occurred in 34 pts on ibru and 50 pts on zanu (18 ibru-zanu pts, 32 zanu-only pts), with reductions primarily for grade 1-2 AEs. Of the 281 pts who received zanu, 79% remain on treatment at the end of data collection; 13 pts died (8 from infection, including 5 from COVID), with no reports of treatment-related deaths. **Conclusions:** In the real-world setting post-formulary change, zanu is effective and safe in pts with or without prior ibru use. Zanu use had lower cardiotoxicity and TLAE rates than ibru though data was limited by a difference in follow-up time. Similar results were seen in zanu-only pts despite being older and having more comorbidities, with discontinuation most often due to grade <3 AEs. Research Sponsor: Beigene.

	While on Ibrutinib (n=190)	While on Zanubrutinib (n=281)	After Ibru-Zanu Switch (n=190)	After Initiating Zanu Only (n=91)
Median Follow Up, mos (range)	46 (15,115)	23.7 (3.3,26)	24.4 (5.5,26)	8.2 (3.3,25)
TEAE, n (%)	69 (36.3)	88 (31.3)	56 (29.5)	32 (35.2)
TLAE, n (%)	21 (11.1)	22 (7.8)	14 (7.4)	8 (8.8)
Cardiotoxicity, n (%)				
TLAE	8 (4.2)	2 (0.7)	2 (1.1)	0 (0.0)
Non-TLAE	18 (9.5)	6 (2.1)	5 (2.6)	1 (1.1)
Other TLAE, n (%)	19 (10.0)	23 (8.2)	14 (7.4)	9 (9.9)
CTCAE grade of TLAE <3, n (%)	14 (7.4)	19 (6.8)	11 (5.8)	8 (8.8)

11159 Poster Session

Insights from C-CAT repository: A novel approach to identifying appropriate patient populations for anticancer drug development using the clinicogenomic nationwide database in Japan.

Rui Kitadai, Takafumi Koyama, Yusuke Okuma, Taro Shibata, Takashi Kohno; Division of Genome Biology, National Cancer Center Research Institute/Department of Medical Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan; Department of Thoracic Oncology, National Cancer Center Hospital, Tokyo, Japan; Clinical Research Support Office, National Cancer Center Hospital, Tokyo, Japan; Division of Genome Biology, National Cancer Center Research Institute, Tokyo, Japan

Background: The integration of Comprehensive Genomic Profiling (CGP) with real-world data (RWD) provides crucial insights for anticancer drug development to achieve precision oncology, therefore, the current global trend to construct as the national projects, yet its clinical impact remains underexplored. The therapeutic efficacy of each line of anti-cancer drug in various cancer types and the relationship between genetic alterations and the effect of anticancer drugs is needed to guide the direction of future drug development promptly and precisely. **Methods:** A comprehensive analysis was conducted on data from Japan's Center for Cancer Genomics and Advanced Therapeutics (C-CAT) repository between June 2019 and December 2023. Five genomic profiling assays for CGP testing were reimbursed by nation-wide insurance in Japan. Utilizing the clinicogenomic repository of C-CAT, registered data of therapeutic efficacy of anticancer drug including cytotoxic agents, molecular-targeted agents, and immune checkpoint inhibitors were evaluated in association with genetic alterations. Data on anticancer drug of patients (pts) with recurrent or metastatic disease were included in the analysis. **Results:** The C-CAT registry data encompassed 60,256 pts across 32 tumor organ sites, classified ontology by the OncoTree over 4.5 years. Of these patients, 30,234 were male, and 30,017 were female, with 5 classified as unknown. In terms of age, 31,919 pts were < 65. The most registered origins were colorectal (n=10,110), pancreas (n=8,069), biliary tract (n=5,030), breast (n=3,744), esophagus/stomach (n=3,734), prostate (n=3,701), ovarian/fallopian tube (n=3,521), lung (n=3,427), and soft tissue (n=2,568). *TP53*mutations (58.3%, n=35,102) were most prevalent, followed by *KRAS* (25.8%, n=15,521), *APC* (19.9%, n=11,919), *NOTCH3* (14.1%, n=8,502), and *PIK3CA* (13.0%, n=7,861). The frequency of *BRCA1/2*mutationwas 4.1% (n=2,479). Overall response rate (ORR) for the first-, second-, third-, and fourth-lines treatment were 35.7%, 23.3%, 19.4%, and 19.2%, respectively. Pts treated with cisplatin or carboplatin in the first-line treatment, who had *TP53* mutations, showed a better ORR than those without (44.0% vs. 38.9%, $p < 0.001$). Similarly, pts with *BRCA1/2*mutation showed a better ORR than those without (53.9% vs. 41.4%, $p < 0.001$) in the first-line treatment. **Conclusions:** This study was the first to report the relationship between genetic alterations and the therapeutic effect of anticancer drugs in each line. This approach based on big data analysis potentially accelerates drug development in the appropriate patient population by identifying significant associations between specific genetic mutations and improved outcomes with certain chemotherapy regimens in various cancers. Research Sponsor: None.

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

Yajur Arya, Arshi Syal, Phuuwadith Wattanachayakul, Elvis Obomanu, Joao Manoel da Silveira Lara, Bruce Adrian Casipit, John Charles Leighton, Claudia M. Dourado; Department of Internal Medicine, Jefferson-Einstein Hospital, Philadelphia, PA; Department of Internal Medicine,Jefferson-Einstein Hospital, Philadelphia, PA; Department of Medicine, Albert Einstein Healthcare Network, Philadelphia, PA; Department of Internal Medicine, Philadelphia, PA; Jefferson Einstein Medical Center, Philadelphia, PA; Einstein Medical Center, Philadelphia, PA

Background: Lung cancer is the leading cause of cancer related deaths in the United States. Patients with advanced lung cancer tend to have varying degrees of protein energy malnutrition (PEM), due to multiple reasons including cancer related cachexia, sarcopenia, and adverse effect of chemotherapy. However, the impact of PEM on clinical outcomes in this subgroup needs further exploration. **Methods:** We utilized the 2020 National Inpatient Sample (NIS) Database in conducting this retrospective cohort study. We identified patients with lung cancer and PEM using appropriate ICD-10 diagnostic codes. We stratified patients with lung cancer based on the presence or absence of PEM. A survey multivariable logistic and linear regression analysis was used to calculate adjusted odds ratios (ORs) for the primary and secondary outcomes. A p value of <0.05 was considered statistically significant. The aim of this study was to investigate the impact of PEM on in-hospital mortality, hospital length of stay (LOS), and total hospitalization charge among hospitalized patients with lung cancer. **Results:** We identified a total of 92425 hospitalized patients with lung cancer, of which 10.53% (9739/92425) had comorbid PEM. The overall in-hospital mortality among patients with lung cancer was 5.79% (5360/92425). Among those with concomitant PEM, the mortality rate was significantly higher at 13.13% (1279/9739, $p<0.001$). Utilizing a stepwise survey multivariable logistic regression model that adjusted for patient and hospital level confounders, PEM was found to be an independent predictor of increased in-hospital mortality (adjusted OR 2.11; 95% (confidence interval [CI] 1.77-2.51; $p<0.001$), longer LOS (coefficient 3.02; CI 2.62-3.42; $p<0.001$), and higher total hospitalization charge (coefficient $22105; CI $13423- $30786; $p<0.001$). **Conclusions:** Our analysis demonstrated that PEM was widely prevalent in hospitalized patients with lung cancer and associated with worse outcomes. Efforts should be made to promote nutritional assessment and screening mechanisms with the aim to initiate early nutritional support as indicated. Further prospective studies are warranted to better understand these associations and guide management. Research Sponsor: None.

11161 Poster Session

Genomic landscape and therapeutic implications in advanced solid cancers: KOSMOS-II (KOrean Precision Medicine Networking Group Study of MOlecular profiling guided therapy based on genomic alterations in advanced Solid tumors, KCSG AL-22-09).

Heejung Chae, Harim Koo, Sun Young Kim, Sook Ryun Park, Shinkyo Yoon, Min-Hee Ryu, Soohyeon Lee, Tae-Yong Kim, Tae Min Kim, Sae-Won Han, Se-Hoon Lee, Hyun Ae Jung, Hye Ryun Kim, Minkyu Jung, Gyeong-Won Lee, Mi Sun Ahn, Hongseok Yun, Yoon-La Choi, Sejoon Lee, Jee Hyun Kim; Department of Internal Medicine, National Cancer Center, Goyang, South Korea; Department of Cancer Biomedical Science, Graduate School of Cancer Science and Policy, Goyang, South Korea; Department of Oncology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Department of Internal Medicine, Korea University College of Medicine, Korea University Anam Hospital, Seoul, Korea, Republic of (South); Department of Internal Medicine, Seoul National University Hospital, Seoul National University College of Medicine, Seoul, South Korea; Division of Hematology-Oncology, Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; Division of Medical Oncology, Department of Internal Medicine, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Korea, Republic of (South); Division of Medical Oncology, Department of Internal Medicine, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, South Korea; Department of Internal Medicine, Gyeongsang National University College of Medicine, Jinju, South Korea; Department of Hematology-Oncology, Ajou University School of Medicine, Suwon, South Korea; Department of Genomic Medicine, Seoul National University Hospital, Seoul, South Korea; Department of Pathology and Translational genomics, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; Center for Precision Medicine, Seoul National University Bundang Hospital, Seongnam, South Korea; Department of Internal Medicine, Seoul National University College of Medicine, Seoul National University Bundang Hospital, Seongnam, Korea, Republic of (South)

Background: Despite advances in genomic diagnosis and therapeutics, providing precision medicine remains a challenge in the real-world practical application, especially in nations with diverse next-generation sequencing (NGS) cancer panels and a shortage of available targeted agents due to lack of approval or reimbursement. **Methods:** The KOSMOS-II is an ongoing prospective, nationwide, master observational study with multiple cohorts undergoing molecular-guided treatment (MGT) recommended by a central molecular tumor board based on local NGS cancer panel results for advanced cancer patients (pts) (J Clin Oncol 2023;41:16 suppl TPS 1608). Key genomic features were integrated with clinical data to construct a Clinico-Genomic Database (CGDB). To minimize inter-panel variations, all variant calling format (VCF) data on single nucleotide variants, insertions, and deletions were normalized by lifting over to the same reference genome (hg19). Re-annotation was performed using a consistent pipeline incorporating public databases. This preliminary analysis outlines the genomic landscapes and therapeutic implications in the first half of enrolled patients out of a targeted accrual of 1,000. **Results:** From September 2022 to December 2023, 489 pts were enrolled with a median age of 60 years (19 - 87), male 56.9%, and a median of 4 lines (1-15) of prior systemic therapy. The most common primary cancer sites were colorectum (n = 96, 19.6%), biliary tract (n = 63, 12.9%), and breast (n=40, 8.2%). CGDB was constructed for 360 pts, employing 20 different panels from 31 participating centers. The most common genomic alterations were *TP53* mutation (Mut) (n=183, 50.8%), *APC* Mut (n=124, 34.4%), and *ERBB2* amplification (AMP) (n=90, 25%). MGT was assigned to 59.5% of pts, 45.2% were allocated to investigational drugs targeting genetic alterations approved for other indications (Tier 1), and 12.6 % to clinical trials matching their genetic alterations (Tier 3). The concordance rate between pre-submitted physician choices and the MTB recommendation was 54.6% (Tier 1, 55%; Tier 2 (alternative treatments including palliative care), 46%; Tier 3, 86%). *ERBB2* alterations were most frequently led to MGT; trastuzumab emtansine (n = 75, 20.8%; *ERBB2* AMP n=36; *ERBB2* Mut n=20; *ERBB2* AMP & Mut n=17; NA n=2), or trastuzumab plus pertuzumab (n = 17, 7.5%), followed by *EGFR* gain to bevacizumab plus erlotinib (n = 18, 5%) and high TMB (≥20 mut/Mb) to atezolizumab (n= 46, 12.8%). Response evaluation of Tier 1 treatment was available in 158 patients, with a 16-week clinical benefit rate of 34.8%. **Conclusions:** The KOSMOS-II study demonstrated the feasibility of a pragmatic, nationwide precision medicine approach using diverse real-world NGS panels and favorable clinical outcomes. Research Sponsor: Ministry of Health and Welfare, Republic of Korea; HA22C0052; KOSMOS - Industry Consortium: Roche (Basel, Switzerland) and Lunit (Seoul, Republic of Korea).

11162 Poster Session

Understanding trends of US breast cancer hospitalization, mortality and costs using the National Inpatient Sample database.

Arun Kumar, Zeeshan Solangi, Emeka Agudile, Oday Elmanaseer, Ghulam Shah, Amirta Devi, Kristen Danielle Whitaker; MedStar Georgetown Cancer Institute, Washington, DC; Yale University, New Haven, CT; Harvard T.H. Chan School of Public Health, Boston, MA; NYU Langone Health, Brooklyn, NY; Dow University of Health Sciences, Karachi, Pakistan

Background: Studies have shown a rising breast cancer incidence in the US. However, its impact on healthcare utilization is unclear. Our study delves into the previously unexplored territory of hospitalization and cost trends among breast cancer patients, aiming to shed light on resource allocation and potential areas for improvement. **Methods:** To investigate trends in breast cancer admissions and costs, we queried the National Inpatient Sample database. Patients admitted between January 2011 and December 2019 with following criteria were included in the analysis: female gender, age $\geq$ 18, and ICD diagnosis code corresponding to unspecified malignant neoplasm of the breast as their primary reason for admission. Our primary outcome was defined as the temporal trends in the number of admissions, discharge rates, length of stay, and cost of hospitalization and mortality rates. Analyses were performed using Stata version 15.1 College station TX: StataCorp LP 2017. Appropriate discharge weights were applied to the dataset during the analyses to account for critical elements of sampling design. A p-value of <0.05 was considered statistically significant. **Results:** Between 2011 and 2019, hospital admissions for breast cancer as the primary diagnosis declined significantly, from 32,126 to 12,742 ($P < 0.001$). However, while average length of stay increased slightly from 4.3 to 4.9 days ($P < 0.01$), hospital charges for breast cancer rose dramatically. Adjusted for inflation, mean charges per patient rose 38.8%, from $50,663.86 in 2011 to $70,334.11 in 2019 ($P < 0.001$). Despite this surge, the total aggregate cost ("national burden") of hospitalizations with breast cancer as main discharge diagnosis decreased, falling from $1.63 billion in 2011 to $896 million in 2019 (inflation adjusted) ($P < 0.001$). Discharges for breast cancer peaked in women between 45 and 64, followed by the 65-84 demographic. Compared to the overall decrease in hospitalization rates, the declines in the above age groups were notably steeper with declines of 62% for 45-64 and 48% for 65-84 ($p<0.001$). Although absolute number of breast cancer deaths decreased from 2011 to 2019, the mortality rate paradoxically increased from 4.3% to 5.8% over the same period ($P < 0.001$). This seemingly contradictory trend warrants further investigation to better understand contributing factors. **Conclusions:** While breast cancer diagnoses are on the rise in women, our study reveals a fascinating paradox: significant declines in hospitalization, associated costs, and overall mortality. This encouraging trend likely stems from widespread surveillance mammography with increases in early stage, curable disease diagnosis, and the flourishing landscape of outpatient therapies, including targeted treatments, with more tolerable toxicity profiles allowing for majority of breast cancer care to be completed in the outpatient setting. Research Sponsor: None.

11163 Poster Session

Integration of a machine learning model-generated surgical risk score into the EHR and preoperative workflow.

Kelly Mahuron, Chen Chen, Cameron S Carlin, Naini S. Seth, Rebecca A. Nelson, Carolina Uranga, Lily L. Lai; City of Hope, Duarte, CA; City of Hope National Medical Center, Duarte, CA; City of Hope National Comprehensive Cancer Center, Duarte, CA

Background: We previously developed a machine learning model (MLM) that accurately predicts postoperative complications (POC) for cancer inpatients. As laborious manual entry of patient data is a barrier for risk calculator use, and risk constantly changes depending on clinical status, we sought to integrate our MLM into the electronic health record (EHR) and preoperative workflow as a readily available surgical risk score (SRS) that is generated using real-time data. Here, we report on the integration process and survey results regarding its functionality and impact on patient care. **Methods:** A MLM that predicts severe POC (CD Grade $\geq$3) for cancer inpatients undergoing same-hospitalization operations was previously developed using EHR data. To integrate our MLM into the Epic EHR, we developed a real-time infrastructure (RTI) using the cloud-based platform Azure. EHR data is inputted to RTI and processed in real-time to generate model outputs. These outputs are then sent back to the EHR through the Epic Cognitive Computing Platform to generate each patient's specific SRS. The SRS is dichotomized as "high" or "low" risk based upon a previously determined threshold and is displayed as a "Best Practice Advisory (BPA)" when a surgical case request is entered. In addition to the automated BPA, the SRS is sent to the primary surgeon as an InBasket Case Message. To elicit feedback of our EHR-integrated SRS, a survey was distributed to surgical providers at our institution. **Results:** After integration of our MLM into the EHR preoperative workflow, 185 surgeries were completed between November 16, 2021 to July 31, 2023. The 30-day severe POC rate was 27.6%, and our MLM had precision of 44.7% and recall of 74.5%, resulting in AUROC of 0.78 and AUPRC of 0.53. 35 surgical providers (40% primary surgeons, 34% surgical fellows, 26% advanced practice providers) from the divisions of surgical oncology, colorectal surgery, and gynecologic oncology completed our survey in July 2022 and July 2023. 28 (80%) of providers stated that they have interacted with the SRS through either BPA or InBasket Case Messages. Of these providers, 21 (75%) strongly agreed or agreed that the SRS was visible at appropriate times, and 18 (64%) strongly agreed or agreed that the SRS contains relevant information to assess surgical risk. 8 (29%) strongly agreed or agreed that the SRS was used to facilitate preoperative discussion. The 2023 survey additionally asked whether the SRS impacted the decision to operate; among providers who had interacted with the SRS, 4 (36%) strongly agreed or agreed with this statement. **Conclusions:** Integration of a real-time, MLM-generated SRS into the EHR and preoperative workflow can be successfully performed. While our integrated SRS is visible to surgeons and contains risk assessment felt relevant to the operation, the impact of the SRS on clinical care and decision making remains unclear. Research Sponsor: None.

Therapy-related myeloid neoplasm risk score (TMNRS): A convenient clinical score for TMN risk assessment at presentation in adult patients (pts) with cancer.

Abhay Singh, Megan Herr, Rahul Mishra, Rusina Karia, Theresa Hahn, Swapna Thota; Department of Hematology and Medical Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Department of Internal Medicine, Anne Arundel Medical Center, Annapolis, MD; University Hospitals Geauga Medical Center, Chardon, OH; UTHSC Memphis, Memphis, TN

Background: tMNs are rare, albeit serious complication in cancer survivors. A tMN risk prediction model is currently not available, therefore we leveraged clinical information and history in a large population-claims database to devise the first tMN risk prediction model in adult cancer survivors. **Methods:** SEER-Medicare was used to analyze 970,390 adults aged 66-84 diagnosed with first primary cancer (FPC) from 2000-2011 (with follow-up through 2015), who survived ≥1 year. Medicare claims data classified individuals with *a priori* identified conditions. We focused on prostate, GI, breast, lung, and bladder (n=830,468) FPCs to develop a tMN risk prediction model. The population was divided into training and validation cohorts. X^2 test identified risk factors associated with tMN. The tMN risk score (TMNRS) was created as a simple arithmetic sum of independent predictors of tMN weighted according to the adjusted odds ratio from logistic regression analysis. Pts were categorized into risk groups (Table) based on their TMNRS, which were tested in the validation cohort. Model performance was evaluated using ROC and c-statistics. **Results:** 87-96% of tMN developed within the first 10 years of FPC. Predictors of tMN included history of autoimmunity, infections, cardiovascular disease, granulocyte-colony stimulating factor, FPC stage, chemoradiotherapy exposure, age at FPC diagnosis, and sex. Training analysis distinguished survivors into distinct risk groups (table) with 10-year incidence of tMN ranging from 0.3% to 1.5% (prostate), 0.04% to 1.1% (GI), 0.2% to 1.4% (breast), 0.1% to 1.2% (lung) and 0.1% to 1.4% (bladder). The table summarizes the incidence of tMN and by risk category for each of the FPCs. After validation, the c-statistic ranged from 0.62-0.68. **Conclusions:** We utilized the largest SEER-Medicare cohort to date to develop a tMN risk model. The TMNRS captures several novel predictors and can be readily used in the clinic. This easy-to-use tool distinguishes cancer survivors into clinically relevant groups at risk of tMN development. This study lays the framework for screening and monitoring of pts at high risk of tMN. In future, we will leverage increasingly available molecular data to improve prediction performance of the model. Web-based calculator to be published with the manuscript/available at time of presentation. Research Sponsor: Institutional KL2 award from the University of Buffalo's CTSI (S.T.).

Incidence of tMN overall and by risk group by FPC.

		Prostate	GI	Breast	Lung	Bladder
		n=298,934 %	n=184,811 %	n=173,754 %	n=100,636 %	n=72,333 %
# tMN cases		1685	601	694	300	322
Overall proportion of tMN		0.6	0.3	0.4	0.3	0.4
Training	very low	-	0.04	-	-	0.1
	low	0.3	0.2	0.2	0.1	0.3
	intermediate	0.7	0.4	0.4	0.4	0.5
	high	1.1	1.1	1.4	1.2	1.4
	very high	1.5	-	-	-	-
	c-statistic	.67	.66	.63	.70	.66
Validation	very low		0.05			0.2
	low	0.3	0.2	0.3	0.2	0.3
	intermediate	0.7	0.5	0.5	0.3	0.5
	high	1.1	1.2	1.5	1	1.4
	very high	1.8	-	-	-	-
	c-statistic	.68	.64	.62	.66	.67

11165 Poster Session

The benefit of chart curation of electronic health record (EHR) data: Comparing data completeness between curated and structured data.

Simon Blanc, Anna Rui, Anupama Vasudevan, Mike Gart, Teena Sura, Erin Morgan, Prateesh Varughese, Mercedes Mena-Allauca, Jeffrey A. Scott; Integra Connect PrecisionQ, West Palm Beach, FL; Integra Connect, Daphne, AL

Background: The main objective of an EHR is to effectively standardize clinical workflow. However, EHR data is also utilized extensively as secondary data for clinical research and quality improvement. Healthcare data exists in different forms such as paper, digital images, and notes, only some of which are recorded as structured data in the EHR. It is therefore essential to curate detailed information from unstructured data so that the patient's journey can be understood in depth for research and quality studies. **Methods:** Patients diagnosed with metastatic breast cancer (mBC) between 01-Jan-2020 and 31-Dec-2022 were identified from the Integra Connect PrecisionQ de-identified database of 3 million cancer patients across 500 sites of care across ~80% community oncology and ~20% academic practices. Manual curation was conducted for a sample of these patients and the fill rates of crucial elements were captured as part of this study. **Results:** A total of 13,763 mBC patients were identified during this study period. The availability of data for the different variables was assessed from structured data in 13,120 patients. Additional information was obtained by manual curation for 643 patients. Information on staging and grade were available for 62.8% in the structured data, while curation increased the availability of these details to 99.5% among those 643 patients. The fill rates for patients' tumor size and nodal status, as defined by the T and N values, were found to be 99% in the curated data compared to 60% in the structured data. Similarly, the fill rates were more than 98% for estrogen, progesterone, and HER2 receptor by curation, while they were only approximately 65% in the structured data. HER2 low, HER2-ve, and HER2+ve status was identified in 8%, 45.2%, and 10.1% by structured data and in 57.1%, 84.1%, and 14.0%, respectively, by curated data. Furthermore, the fill rates via curation were 97.1% for HER2 immunohistochemistry tests compared to 49.0% for structured data, while the fill rates for in-situ hybridization (ISH) or fluorescent in-situ hybridization (FISH) tests were 61.3% for curated data compared to 28.4% for structured data. This discrepancy is caused by the fact that IHC and FISH/ISH tests are primarily found only in PDF format. **Conclusions:** This study highlights the need for curation in order to maximize the utilization of EHR data for secondary research purposes and quality studies. Natural language processing and augmented curation methods can further enhance the quality of EHR data for secondary research. Research Sponsor: None.

11166 Poster Session

Trends in mortality from secondary malignancy in the United States, 1999-2019.

Syed Ali Farhan, Syed Husain Farhan, Muhammad Moiz Nasir, Umar Mahmood, Muhammad Haris, Fatima Laique, Sameen Mukhtar, Jawad Ahmed, Rabbia Siddiqi, Abdul Ghani Iqbal, Roha Saeed Memon, Syed Hamza Bin Waqar; The Ohio State University, Columbus, OH; Dow University of Health Sciences, Karachi, Pakistan; University of Toledo, Toledo, OH; UNC Nash General Hospital, Rocky Mount, NC; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL

Background: Recent advancements in cancer diagnosis, treatment, and supportive care increased the survivorship of cancer patients. However, the risk of secondary malignancy (SM), associated most commonly with side effects of radiation and chemotherapies, has emerged as a looming threat to childhood and adult-onset cancer survivors. Recognizing the recent trends in malignancy-related deaths and the risk factors associated could assist healthcare professionals and policymakers in constructing appropriate guidelines for timely diagnosis and individual patient-dependent treatment regimens. Hence, our CDC analysis focuses on highlighting trends in mortality from SM from "1999 to 2019". **Methods:** Using the deidentified death certificate data from the CDC WONDER database, we analyzed mortality trends from 1999 to 2019 for SM. Age-adjusted mortality rates (AAMRs) per 100,000 people were calculated for the total population, stratified by gender, race, age, and site of SM. Annual percent change (APC) was calculated using the Joinpoint regression software. **Results:** A total of 1,499,108 deaths occurred from 1999 to 2019 in the US. The overall AAMR showed a decrease from 27.5 in 1999 to 18.83 in 2007 (APC: -4.71), remained at a relatively constant level of 19.11 till 2013 (APC: 0.48), followed by a rapid rise to 23.29 in 2017 (APC: 5.37), and finally a gradual rise to 24.29 in 2019 (APC: 1.97). Men showed consistently higher AAMR than women throughout the study period between 1999 (AAMR Men: 33.31 vs Women: 23.78) and 2019 (AAMR Men: 28.03 vs Women: 21.51). Moreover, Black (AAMR: 23.89) showed the highest mortality rate, followed by Whites (AAMR: 21.46). American Indian (AAMR: 13.93), Asian (AAMR: 13.89), and Hispanic (AAMR: 15.9) showing similar mortality trends. Furthermore, AAMR increased with age, showing the highest mortality rates in patients 75+ yrs (148.3), followed by 55-74 yrs (61.6), 35-54 yrs (9.23), 15-34 yrs (0.7), and ≤ 14 yrs (0.19). More recently the greatest rise in SM from 2013-2019 was observed in adrenal glands (APC: 11.8), bone and bone marrow (APC: 8.7), kidney and renal pelvis (APC: 7.6), and small intestine (APC: 6.9). Less prominent rise was seen in all other types of SM. **Conclusions:** Despite recent advances in cancer treatments, SM remains one of the most common causes of death in cancer survivors. Our analysis shows that age, gender, race, and site are important factors influencing the risk of SM-related mortality. Although the risk of SM varies across the spectrum of age, findings from one age group could be translated into preventive and screening strategies across other age groups. Guidelines for survivors should be taken into account based on prior treated malignancy and the risk of future ones. Large population based studies are imperative to understand factors behind the recent rise in SM-related mortalities from 2013 onwards. Research Sponsor: None.

11167 Poster Session

Surgical outcomes for non-small cell lung carcinoma by race and surgical facility types in the United States.

Aditi Singh, Cindy Nelson, Ahmed Abdalla; Mayo Clinic, Rochester, MN; Mitchell Cancer Institute, Mobile, AL; University of South Alabama, Mobile, AL

Background: Successful outcomes of surgical treatment of cancer requires expertise and high-quality supportive services for surgical care. Previous studies have shown that case volume and availability of other in-house supportive services affect surgical outcomes. Latest studies have shown that this gap has now significantly reduced. Issues related to access, availability of funding for latest technologies and continuous medical education still exist and likely still impact the surgical outcomes. The objective of the study is to understand the impact of surgical center related factors on survival outcomes for cancer patients based on race and other demographic features. **Methods:** We conducted a retrospective analysis of patients diagnosed with Stage I-III Non-small cell lung cancer (NSCLC) between 2004 to 2020 using the National Cancer Database (NCDB). Patients were divided into 4 cohorts of NCDB assigned facility type (Community Cancer Program, Comprehensive Community Cancer Program, Academic/Research Program, Integrated Network Cancer Program). Racial and other demographic data was analyzed for each of the facility types. Differences in categorical variables were evaluated using a *Chi*-square test. **Results:** 298,393 adenocarcinoma and 129,144 squamous cell carcinoma patients underwent surgery for NSCLC between 2004-2020. 326,798 patients with clinical stages I-III were selected for the analysis. Most surgeries were performed at the academic/research programs and comprehensive community programs. Utilization of each facility type was uniform across all races. The 30-day mortality rate was lowest for the academic/research programs (Community Cancer Program 3.1%, Comprehensive Community Cancer Program 2.6%, Academic/Research Program 1.8%, Integrated Network Cancer Program 2.3%; p=0.000). 30-day mortality rate was higher for American Indian, Aleutian, or Eskimo racial subgroups amongst all age-groups at all the surgical facility types especially for Stage IIIB NSCLC (White: 6%, Black: 3.4%, American Indian, Aleutian, or Eskimo: 14.3%, p=0.006). For each race, the 30-day mortality rate was better at the academic/research programs. Females had lower 30-day mortality for all racial subgroups. Having private insurance was associated with the lowest 30-day mortality rate. This was noted for all races across all the facility types. Lower income status was associated with higher mortality rates across all facility types. This difference was statistically significant for white patients. Majority of patients had less than 10 days of length of stay at all the surgical facility types. **Conclusions:** Outcomes of NSCLC surgery are significantly better at academic/research programs where a higher number of procedures are performed and access to latest surgical technologies is available. Short-term mortality rates are higher for American Indian, Aleutian, or Eskimo racial subgroup. Research Sponsor: None.

11168 Poster Session

Effect of real-time data-driven physician engagement on appropriate precision oncology testing.

Ying Liu, Howard L. McLeod, Jeff Schreier, Nirmala Bhogal, Jordan Clark, Eve Thompson, Arun Rompicherla, Gemma Little, Joshua McKenna, Anjum Ismail, Sarah Varghese, Bethany Michelle Slifko; Diaceutics, Parsippany, NJ; Utah Tech University, St. George, UT; Diaceutics Plc, Belfast, United Kingdom; Diaceutics PLC, Belfast, United Kingdom; Diaceutics, Belfast, United Kingdom

Background: Precision medicine is a paradigm shift in healthcare: 24% of all FDA approvals are precision medicines, with 67% of new approvals relying on companion or complementary testing or on diagnostics prior to clinical use. Yet a recent publication indicates that approximately 64% of potentially eligible patients could be lost due to various clinical practice gaps along patient journey (Sadik et al JCO 2022). Low prevalence biomarker testing is proven to be one of the critical determinants of missed therapy, potentially due to poor physician awareness. The increasingly advanced machine learning (ML) and natural language processing (NLP)-based ability to label, analyze, and segment data can be utilized to monitor and influence testing behavior in real-time. We hypothesize that a real-time data-driven physician-targeted digital engagement can increase biomarker testing rate and in turn enhance patient identification for precision therapies. **Methods:** Unstructured real-world, real-time biomarker testing reports were collected from 494 laboratories across the US. These testing reports were first curated, labeled and extracted via ML and NLP-based technologies to allow data analysis and reveal testing behavior. Suboptimal testing behavior was defined as no requisition of the selected novel biomarker as part of the diagnostic workups. Physicians who identified as having suboptimal testing behavior were selected as candidates to receive a personalized digital engagement over a 4-week period. The digital engagement's purpose was to raise clinical awareness towards the novel biomarker testing. The follow-up testing behavior was analyzed again over laboratory reports collected from 26-weeks' time after the initial engagement. **Results:** 822 physicians were identified with suboptimal testing behavior and selected to receive 4 weeks' follow-up digital engagement. 271 out of 822 (33%) recipients were successfully engaged shown as open and read the digital communication. 42 (~15%) physicians reacted to the communications and ordered the new test at least once during this period. The initial 4 weeks' engagement was observed to be the most impactful, when 23 out of the 42 (~55%) physicians ordered the novel biomarker test for the first time.71 new therapy-eligible patients were identified via data-driven targeted physician digital engagement during the 26 weeks' follow-up period. **Conclusions:** This study illustrates the value of data in influencing or reinforcing testing behaviors and emphasizes the value of data-driven physician-targeted digital engagement in addressing clinical practice gaps which in turn, drive patient identification to match potential eligible precision therapies. Research Sponsor: None.

Geographic and sociodemographic variations in disease burden, epidemiological trends, and risk factors of early-onset lung cancer: A global analysis.

Wang-Zhong Li, Xianhua Gui, Hengrui Liang, Wei Wang, Wenhua Liang, Jianxing He; Department of Thoracic Oncology and Surgery, the First Affiliated Hospital of Guangzhou Medical University, State Key Laboratory of Respiratory Disease, National Clinical Research Center for Respiratory Disease, National Center for Respiratory Medicine, Guangzhou, China; Department of Respiratory Medicine, The Affiliated Drum Tower Hospital of Nanjing University Medical School, Nanjing, China

Background: Exploring the emerging trend of early-onset lung cancer (EOLC) burden is pivotal for guiding the implementation of preventive strategies among young adults. We aimed to provide a comprehensive examination of the geographic and sociodemographic variations in the disease burden, along with epidemiological trends and risk factors associated with EOLC over the past three decades. **Methods:** EOLC refers to lung cancer diagnosed in individuals aged 20-49 years. Utilizing the GBD 2019 data, we estimated the age-standardised incidence, mortality, and disability-adjusted life years (DALYs) rates for EOLC by sex, socio-demographic index (SDI) quintiles, and geographical location for the period from 1990 to 2019. We investigated the relationships between concomitant risk factors and EOLC incidence at national level, and calculated the DALYs attributable to risk factors. The relative contribution of population growth, population ageing, and epidemiological changes to the variations in burden of EOLC over study period was measured using the decomposition analysis. Incidence was forecast to 2040 using the Bayesian age-period-cohort model. **Results:** A total of 135,704 EOLC cases, equating to a age-standardised incidence rate of 4.0 (95% UI 3.6 to 4.3) per 100,000, were estimated in 2019 worldwide and was the second leading cause of cancer death among young adults, with higher disease burden occurred in males and those from middle and high-middle SDI regions. An overall decreasing trend in burden of EOLC was observed globally; such trends were more pronounced among males and followed a gradient across SDI levels, with the greater decrease observed in high and high-middle SDI regions. Sex, tobacco smoking prevalence, per capita cigarette-equivalent estimates, average age of smoking initiation, ambient ozone pollution, and GDP per capita were independently and significantly associated with EOLC incidence at the population level. Smoking remained the top contributor to burden of EOLC, with the exception of Andean Latin America, North Africa, and the low SDI regions, where ambient particulate matter pollution and household air pollution from solid fuels ranked as the foremost attributable risk factors. Population growth was the primary driver behind the global increase in EOLC cases in low and low-middle SDI regions, while epidemiological changes accounted for the most substantial reduction in EOLC cases across most regions. The global incidental cases of EOLC was projected to increase by 31.1% in 2040, with a more pronounced increase in females and those from high-middle and middle SDI locations. **Conclusions:** Our findings underscore significant geographic and sociodemographic disparities in the epidemiological burden of EOLC, emphasizing the necessity for policymakers to devise and apply region-specific, evidence-driven preventive strategies. Research Sponsor: National Natural Science Foundation of China; Grant No. 82022048, 82373121, 82303338; National Key R&D Program of China; Grant No. 2022YFC2505100, 2022YFC2505105; Postdoctoral Research Foundation of China; Grant No. 2023T160146, 2023M740835; Postdoctoral Fellowship Program of CPSF; GZB20230179; Grant of State Key Laboratory of Respiratory Disease; Grant No. SKLRD-Z-202401.

11170 Poster Session

Census tract–level social determinants of health and variability in stage at diagnosis of bladder, breast, and non-small cell lung cancers.

henry G Kaplan, Molly Scannell Bryan, Xiaohan Hu, Hina Mohammed, Monika A. Izano, Thomas D. Brown, George R. Simon, Jose A. Karam, Anna B. Berry; Swedish Cancer Institute, Seattle, WA; Syapse, West Chester, PA; Merck & Co., Inc., Kenilworth, NJ; Syapse, San Francisco, CA; H. Lee Moffitt Cancer Center and Research Institute, Celebration, FL; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Social determinants of health (SDOH) can identify underserved populations, inform the patient journey, and identify opportunities to improve outcomes. In cancer, SDOH may influence stage at diagnosis through exposure to risk factors for aggressive cancer and decreased access to care. However, privacy restrictions can limit research with SDOH in real world datasets, which often only know a patient's broad location. **Methods:** Geocoding was undertaken on addresses of patients diagnosed between 1/1/17 and 9/30/22 with bladder (n=6078), breast (n=28,958), and non-small cell lung cancer (NSCLC, n=14,957) in the Syapse Learning Health Network of U.S. community health systems. Location was linked to five indicators of SDOH at the census tract level: the Social Vulnerability Index (SVI); percent (%) of tract spending >30% of income on housing; % of tract with broadband internet; county designation as a primary care shortage area; and rural urban commuting area (RUCA). Nested multivariable ordinal logistic regression models estimated independent associations between demographic, clinical, and SDOH factors with stage at initial cancer diagnosis. The statistical significance of including SDOH variables was assessed using a likelihood ratio test (LRT) comparing the models before and after including SDOH. **Results:** After successful geocoding and linkage to census tracts, there were marginal differences in the distribution of the five SDOH across stages at diagnosis within the three tumor types. In multivariable models adjusted for year of diagnosis, age, sex, race, ethnicity, smoking, and primary payor, among the tested SDOH measures, county designated as primary care shortage (proportional odds ratios (OR): 1.31, 95% confidence interval (95% CI): 1.05-1.64), and non-metropolitan area (0.69, 0.50-0.94) were statistically significantly associated with stage at bladder cancer diagnosis. SVI (1.52, 1.31-1.76) was also statistically significantly associated and directly proportional with stage at breast cancer diagnosis. Among patients with NSCLC, broadband internet access (1.01, 1.00-1.01), primary care shortage (1.15, 1.03-1.27) and non-metropolitan area (0.85, 0.74-0.99) were statistically associated with stage at diagnosis. In all three tumors, LRTs found that models with SDOH were statistically significantly better at predicting stage at diagnosis than those without ($p < 0.001$). **Conclusions:** Using granular, census-tract geospatial resolution for geocoding of SDOH, we find that patients who live in greater vulnerability are diagnosed at later stages than those who live in areas of less vulnerability, suggesting that consideration of SDOH variables is important in assessing stage at diagnosis and identify patients with an unmet need for outreach and screening. Research Sponsor: Merck.

11171 Poster Session

Treatment trends for metastatic urothelial carcinoma across eight Mexican centers: A global oncology perspective.

Evelyn Lilian Beas-Lozano, Yuly Andrea Remolina Bonilla, Rosa Caballero, Nora Sobrevilla-Moreno, Perla Perez Perez, Maria Guadalupe Díaz-Alvarado, Omar Alejandro Alejandro Zayas-Villanueva, Erika Martinez, Saul Campos Gomez, Luis Arturo Cardoso Aparicio, Dolores Mendoza Oliva, Maria T. Bourlon; Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, Mexico; National Institute of Medical Sciences and Nutrition Salvador Zubirán, Mexico City, Mexico; Instituto Nacional de Cancerologia, Mexico City, Mexico; Centro Medico Nacional XX de Noviembre, Mexico City, DF, Mexico; Hospital Universitario "Dr. José Eleuterio González", Monterrey, NL, Mexico; Medica Sur, Mexico City, Mexico City, Mexico; Centro Oncologico Estatal ISSEMYM, Toluca, Mexico; Sedena, Ciudad De México, Mexico; Hospital de Especialidades HGZ 50, IMSS, San Luis Potosi, Mexico; Urologic Oncology Clinic, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, DF, Mexico

Background: Urothelial carcinoma represents 3% of new cancer cases globally. Metastatic urothelial carcinoma (mUC) poses a notable challenge to healthcare systems, given its treatment complexity and high mortality. These challenges are magnified in resource-constrained settings. We aim to describe treatment trends for mUC across public and private Mexican centers. **Methods:** Retrospective study across 8 referral centers. Adults with mUC from 01/2001-12/2021 were included. We assessed clinical records, demographics and comorbidities. We recorded subject eligibility for first line platinum therapy, treatment lines received, and access to novel drugs. Descriptive statistics were used for demographics, treatment details and outcomes. Survival analysis was performed, including Kaplan Meier curves and Cox proportional hazards model. **Results:** We found 342 cases of mUC, 76% were male, with a median age of 67 years. Median follow-up was 8.4 months. Among those that received a first line (n=223, 65%), regimens used were cisplatin-based chemotherapy (n=100, 45%), carboplatin-based chemotherapy (n=87, 39%), gemcitabine (n=5, 2.2%), immunotherapy (n=4, 1.8%) or unspecified (n=27, 12%). Most causes of cisplatin ineligibility were ECOG $\geq$2 (41%) and glomerular filtration rate $<$60 ml/min (33%). Of those who received upfront platinum therapy (n=187), 65% received $>$3 cycles (n=121), 20% received 2 or 3 cycles (n=38) and 15% received 1 cycle (n=28). Progression as best response was found in 47% (n=88). Avelumab maintenance was only used in 14/99 eligible patients (14.1%). The proportion of individuals receiving a second, third or more lines was 24.6%, 8.8% and 3.5%, respectively. The most common second line treatment was chemotherapy (64.4%) followed by immunotherapy (28.6%). Median overall survival (mOS) was 11.8 months. Treatment notably impacted mOS, favoring those who received a first line(16.7 vs. 4.6 months, $p<0.0001$). Stratified analysis showed worse mOS for those with visceral disease (17.1 vs 10.3 months, p=0.0065) and ECOG $\geq$2 (17.6 vs 5.8 months, $p<0.001$).These features correlated with higher mortality, while first line treatment was associated with lower mortality. **Conclusions:** These data represent the first effort to delineate treatment trends of mUC in Mexico. First line treatment rates were higher than those described worldwide (35-60%[1]). Further, cisplatin-eligibility was higher compared to reports of high-income countries. Considerable rates of progression to platinum therapy were found, likely due to aggressive disease. This study highlights the limited access to novel treatments, showed by the infrequent use of avelumab maintenance, immunotherapy or targeted agents. Research Sponsor: None.

Multivariate analysis.

Variable	Hazard Ratio	Confidence Interval (95%)	p
Visceral disease	1.49	1.10-2.02	0.009
ECOG ≥ 2	1.54	1.11-2.14	0.009
First line treatment	0.46	0.32-0.65	<0.001

Retrospective analysis: Does 5-FU dose adjustment per DPYD mutation status affect toxicity?

Deevyashali Parekh, Vanita Noronha, Vijay Maruti Patil, Nandini Sharrel Menon, Minit Jalan Shah, Anuradha Chougule, Kumar Prabhash; SUNY Upstate Medical University, Syracuse, NY; Tata Memorial Centre, Mumbai, India; Hinduja Hospital, Mumbai, India; Tata Memorial Hospital, Mumbai, India; Tata Memorial Hospital, Tata Memorial Centre, Mumbai, India

Background: 5-Fluorouracil (5-FU) forms a cornerstone in neoadjuvant chemotherapy (NACT) regimens for solid tumors including head and neck cancers. The DPYD gene encodes for enzyme dihydropyrimidine dehydrogenase (DPD) which catalyses an essential, rate-limiting step in the metabolism of 5-FU. Heterozygous genomic alteration of DPYD (30-35% of population) result in reduced potency of DPD enzyme, while homozygous DPYD alteration (0.1-0.2% of population) results in no functional DPD. Reduced functioning of DPD leads to slower metabolism of 5-FU causing toxicity such as bone marrow suppression, cytopenias etc. The Clinical Pharmacogenetics Implementation Consortium (CPIC) have released guidelines recommending reducing the dose of 5-FU in patients with these genomic alterations of DPYD from 25% to avoiding its use based on a calculated activity score (DPYD-AS). **Methods:** A phase III randomized study compared a DC vs DCF regimen as NACT in technically unresectable oral cancer was published in March 2024. We utilised data from the 'DCF' arm of this study. Patients underwent DPYD testing and we stratified these patients based on DPYD status. In the study, patients underwent the appropriate dose reductions per the CPIC guidelines based on DPYD-AS scores. We evaluate the frequency and degree of adverse events in these groups to determine whether this dose reduction effectively reduces toxicity from 5-FU in these patients. Adverse events were graded per CTCAE. Analysis by Fishers exact test. **Results:** 247 patients in the DCF arm were included. 85 (34.4%) did not undergo DPYD testing. 118 (47.8%) did not have any DPYD mutation, 44 (17.8%) had heterozygous mutation while 0 had homozygous mutation. The adverse events by DPYD genotypic subgroup are shown in the table. **Conclusions:** There was no statistically significant difference in adverse events between the group with no DPYD mutation who received the full dose of 5-FU and the heterozygous DPYD mutation group receiving a lower 5-FU dose based on DPYD-AS score. Thus, the dose reduction as set out by the CPIC appears to appropriate. Research Sponsor: None.

Frequency of adverse events with 5-FU.

	No DPYD mutation	DPYD heterozygous mutation	P-value
Mucositis n, %	26/118, 22%	12/44, 27.3%	0.688
(Grade 3 or worse n, %)	**(6/118, 5.1%)**	**(2/44, 4.5%)**	**(1.000)**
Nausea n, %	9/118, 7.6%	3/44, 6.8%	1.000
(Grade 3 or worse n, %)	**(1/118, 0.8%)**	**(0/44, 0%)**	**(1.000)**
Vomiting n, %	9/118, 7.6%	3/44, 6.8%	1.000
(Grade 3 or worse n, %)	**(1/118, 0.8%)**	**(0/44, 0%)**	**(1.000)**
Raised Creatinine (over 1.1) n, %	3/118, 2.5%	0/44, 0%	0.565
(Grade 3 or worse n, %)	**(0/118,0%)**	**(0/44, 0%)**	**(1.000)**
Anemia n, %	22/118, 18.6%	8/44, 18.2%	1.000
(Grade 3 or worse n, %)	**(1/118, 0.8%)**	**(1/44, 2.3%)**	**(0.475)**
Neutropenia n, %	8/118, 6.8%	5/44, 11.4%	0.521
(Grade 3 or worse n, %)	**(1/118, 0.8%)**	**(0/44, 0%)**	**(1.000)**
Thrombocytopenia n, %	3/118, 2.5%	2/44, 4.5%	0.616
(Grade 3 or worse n, %)	**(1/118, 0.8%)**	**(0/44, 0%)**	**(1.000)**

Outcomes of liver transplant recipients with pretransplant malignancies: Insights from a single institution's experience.

Nikitha Vobugari, Kirk Heyne, Ashton Connor, Zainub Ajmal, Shubham Adroja, Yuan Gao, Sunil Mathur, Sudha Kodali, Ashish Saharia, Constance M Mobley, Ahmed M Elaileh, Khush Patel, Rafik Mark Ghobrial; University of Minnesota, Minneapolis, MN; Houston Methodist Cancer Center, Houston, TX; Houston Methodist Hospital, Houston, TX; Houston Methodist Neal Cancer Center, Houston, TX; Houston Methodist Neal Cancer Center, Missouri City, TX; Houston Methodist JC Walter Jr Center for Transplantation and Sherrie and Alan Conover Center for Liver Disease and Transplantation, Houston, TX; Houston Methodist Jr Center for Transplantation and Sherrie and Alan Conover Center for Liver Disease and Transplantation, Houston, TX; Sherrie and Alan Conover Center for Liver Disease and Transplantation, JC Walter Jr. Transplant Center, Houston Methodist Hospital, Houston, TX

Background: Increasing liver transplantation (LT) utilization has resulted in more and more patients with a history of a non-hepatobiliary malignancy. Rather than deny such patients a lifesaving therapy the benefits must be weighed against risk of tumor recurrence and de novo malignancies (DNM) post-LT, especially with the immunosuppression required. While data has been presented on outcomes of pre transplant malignancies (PTM) in kidney and heart transplants, LT data is lacking. Our aim is to characterize rates of recurrence, DNM, and overall survival (OS) post-LT at a single, high volume American center. **Methods:** This retrospective study at Houston Methodist Hospital included patients who underwent LT with known history of PTM. Data was extracted from electronic health records, and descriptive statistics performed. Institutional IRB approval is obtained. **Results:** Between 01/1999- 12/2022, 1617 LTs were performed at our institute. We identified 261 LT recipients with 297 PTM, including 91 non- and 206 hepatobiliary cancers (See Table). Follow-up period ranged from 1 to 23 years. Post-LT malignancies were observed in 66 patients, 25% of the study population. Tumor recurrences accounted for 44 (17%) cases, and DNM were seen in 22 (8%). The DNMs included skin non-melanoma (n=8 cases), head & neck (3), PTLD (2), prostate (2), renal (1), lung (1), CRC (1), pancreatic (1), gynecologic (2), and poorly differentiated (1). The OS rate at 1-, 5-years (excluding those less than 5 years follow-up and unknown), and at time of last follow-up were 86.6%, 60-65% and 70%, respectively. Patients with post-LT malignancies had lower OS compared to those without (46% vs. 77.7%). **Conclusions:** To our knowledge, this study is the first to assess post-LT outcomes in patients with PTM. This study of LT recipients with PTM demonstrates post-LT malignancy rates of 25%, including 17% with recurrences and 8% with DNM. The latter is within the previously reported range of 3-14% DNM in the general post-LT population and dominated by skin cancers. Post-LT OS is excellent in these recipients and comparable to all LT patients. However, OS is lower in those with post-LT malignancies, implying a possible role for increased cancer surveillance. Limitations include retrospective design and potential chart bias. Future work in this cohort will focus on immunosuppression effects for this high-risk population. Research Sponsor: None.

Composition of PTM and outcomes.

PTM	Number of LT Recipients	Number of LT Recipients With Cancer Recurrence	Number of LT Recipients Alive at Time of Data Collection/ 5years
Hepatocellular carcinoma (HCC)	167	18	114
Cholangiocarcinoma (CCA)	39	14	20
Anal	1	0	1
Breast	19	3	15
Heme	9	0	9
Skin Melanoma	4	1	3
Skin Non-Melanoma	16	2	14
Renal	2	1	1
Prostate	5	1	4
Other/unknown GU	15	0	13
Colorectal (CRC)	11	2	8
Lung	2	1	2
Thyroid	4	0	4
Head and Neck (H&N)	2	0	1
CNS	1	1	1
Gynecologic	2	0	2
Total N of cancers	297	44	205
Total N of patients	261	42	196

Effect of combination of genomic variation–based machine learning and clinical pathology on accurate diagnosis of tumors: Lung adenocarcinoma and lung squamous cell carcinoma.

Weiguang Gu, Haitao Wang, Mengxia Zhuang, Qing Hao, Zhizheng Wang, Wenjin Liu, Leilei Lu, Xiaowei Dong, Fei Pang, Hongli Qin, Kai Wang; Nanhai People's Hospital, the Second School of Clinical Medicine, Southern Medical University, Foshan, China; The Second Hospital of Tianjin Medical University, Tianjin, China; Nanhai People's Hospital/Department of The Sixth Affiliated Hospital, School of Medicine, South China University of Technology/The Second School of Clinical Medicine, Southern Medical University, Foshan, China; OrigiMed, Shanghai, China

Background: Non-small cell lung cancer (NSCLC) is the most prevalent form of lung cancer, with lung adenocarcinoma (LUAD) and lung squamous cell carcinoma (LUSC) being the predominant subtypes. Given the significant differences in treatment approaches and clinical outcomes between LUAD and LUSC, accurate identification of these pathological subtypes prior to treatment initiation is crucial. **Methods:** This study aimed to enhance the diagnostic accuracy for LUAD and LUSC by integrating a machine learning artificial intelligence (AI) model with the expertise of pathologists. The AI model was trained and validated on a cohort of 10,693 and 5,571 cases from the OrigiMed database, each confirmed by at least three pathologists. Targeted sequencing of 450 cancer-related genes was performed. **Results:** Analysis of the validation set demonstrated an overall accuracy of 89.2% across 28 tumor types, with individual accuracies ranging from 22.2% to 100%. For the top one prediction, the AI model achieved an accuracy of 82.7% for LUAD and 67.9% for LUSC. However, when considering the top three predictions, the accuracy significantly increased to 92.1% for LUAD and 93.0% for LUSC. To further validate the diagnostic capability of the AI model, a large sample of 4,531 LUAD cases and 207 LUSC cases from 4,502 patients was collected for comparative analysis with pathologists' diagnoses. The results indicated that 87.9% of LUAD cases and 83.6% of LUSC cases were consistent with the AI model's diagnosis, while 4.9% of LUAD and 9.7% of LUSC cases showed discrepancies. To investigate these inconsistencies, a subset of 30 LUAD cases and 16 LUSC cases was selected for re-evaluation by independent pathologists. Four poorly differentiated cases from the discrepancy group were ultimately diagnosed as 2 LUADs and 2 LUSCs, supporting the initial AI diagnosis. For instance, Patient 40 was initially diagnosed with LUSC; however, the AI system identified the pathology as LUAD, which may be attributed to the detection of the KIF5B-RET fusion. This diagnosis was subsequently corroborated by an additional pathologist who observed gland-like structures and ambiguous solid mass formations within the tumor tissue, consistent with LUAD histopathology. **Conclusions:** In summary, we have presented a machine learning AI model that leverages next-generation sequencing (NGS) technology for the auxiliary diagnosis of cancer. By applying this AI model to diagnose LUAD and LUSC and comparing it with the diagnoses made by human pathologists, we have demonstrated that the integration of pathological diagnosis and AI machine learning can significantly enhance and even surpass the diagnostic capabilities of human physicians. This advancement holds great potential in improving the accuracy of tumor diagnosis and the precision of treatment. Research Sponsor: None.

11175 Poster Session

Biomarker testing and targeted therapy use among patients with non-small cell lung cancer in the United States: An analysis using a physician notes real-world database.

Vernon Videna, Dave Iwanyckyj, Fernando Otalora, Melanie Jardim; Amplity Health, Langhorne, PA

Background: Biomarker testing informs treatment decisions by identifying patients who would clinically benefit from targeted regimens, leading to improved patient outcomes. However, the use of guideline-recommended biomarker testing in patients with advanced non-small cell lung cancer (NSCLC) is inconsistent. This study investigates the rates of biomarker testing in patients with NSCLC using a qualitative, real-world database. **Methods:** Natural language processing (NLP) was used to search and analyze the Amplity Insights database, consisting of transcribed, de-identified, records of physician-patient interactions obtained from patient medical records across the United States. This was a retrospective analysis of patients with a diagnosis of NSCLC (October 2003 - November 2023). Patient characteristics, biomarker testing, and treatment use were summarized and described. **Results:** 61,018 patients with NSCLC (mean [standard deviation] age of 69.8 [10.5] years) were identified. Among these, 50.6% were female and 87.9% identified as white. Among records with staging information, 26.6% had early-stage disease (stage 0-II) and 73.4% had late stage (stage III-IV) disease. In total, 13.4% (n=8,151) of all patients received biomarker testing. 13.3% (n=879) and 22.4% (n=2,402) of patients with stage III and IV, respectively, had biomarker testing performed; rates were higher in patients who were receiving care from an oncologist (16.8%, 31.0%, respectively). Among patients who had a confirmed actionable mutation (n=6,387), 35.9% received an appropriately matched targeted therapy and 10.1% received a nonindicated targeted therapy without harboring the indicated mutation. Of these, 40.7%, 22.7%, and 37.7% of patients harbored EGFR or ALK mutations, or were PD-L1 positive, respectively, and 35.8%, 17.8%, and 40.2% received the appropriate indicated treatment, respectively, based on testing. ALK-, EGFR-, and PD-L1-targeted therapies were taken by 12.1%, 9.4%, and 1.9% of patients, respectively, without evidence of the indicated biomarkers. **Conclusions:** These findings suggest that biomarker testing may be underutilized and that many patients may not be benefitting from treatment with precision therapies, highlighting the need for additional educational strategies to optimize precision oncology and elevate patient outcomes. Research Sponsor: None.

A deep learning–enabled workflow to estimate real world progression-free survival in patients with metastatic breast cancer.

Gowtham Varma, Rohit Kumar Yenukoti, Praveen Kumar-M, Bandlamudi Sai Ashrit, K Purushotham, Subash C, Sunil Kumar Ravi, Verghese Kurien, Avinash Aman, Mithun Manoharan, Shashank Jaiswal, Akash Anand, Rakesh Barve, Viswanathan Thiagarajan, Patrick Lenehan, Scott A. Soefje, Venky Soundararajan; nference, Cambridge, MA; nference Labs, Bengaluru, India; Mayo Clinic, Rochester, MN

Background: Progression-free survival (PFS) is frequently measured in oncology clinical trials. In analyses outside of the trial setting, various strategies have been utilized to assess real-world PFS (rwPFS), including manual abstraction of clinical records, natural language processing (NLP) of oncology notes and radiology reports, and longitudinal analyses of radiologic images. Here we develop and validate a new semi-automated workflow that combines NLP of clinical notes with structured electronic health record data to facilitate the evaluation of rwPFS in patients with metastatic breast cancer (mBC). **Methods:** This study analyzes de-identified EHR data using nference nSights. The data is extracted following privacy-preserving protocols and is HIPAA compliant. The overall cohort included 316 patients with HR-positive, HER2-negative mBC who initiated Palbociclib and Letrozole combination therapy between January 1, 2015 and December 31, 2021. We developed and implemented an ensemble of deep-learning NLP frameworks to capture progression events from unstructured clinical notes and radiology reports. A change in the line of therapy, as determined by structured drug order/administration records, was also considered a progression event. We used manually curated "ground-truth" datasets to evaluate the performance of the progression-event capture workflow at the levels of both sentences (N = 1000) and patients (N = 100) by calculating sensitivity, specificity, precision, accuracy, and F1 scores. Progression events and censoring events (death, loss to follow-up, end of study period) were considered to compute rwPFS. **Results:** At the sentence level, progression events were captured from clinical notes and radiology reports with a sensitivity of 99.8%, specificity of 96.7%, and accuracy of 98.2% (Table). At the patient level, initial progression was correctly captured within a window of +/-30 days with a sensitivity of 92.5%, specificity of 83.0%, and accuracy of 88.0% (Table). In a sample of 100 patients, the median rwPFS was determined to be 25 months (95% CI; 15-35 months) by manual curation and 22 months (95% CI; 15-35 months) by the semi-automated workflow. In the overall cohort, median rwPFS was 20 months (95% CI; 18-25 months). **Conclusions:** An ensemble of NLP algorithms extracted progression events from clinical notes and radiology reports with high accuracy. A semi-automated workflow enabled rapid and accurate determination of rwPFS in mBC patients receiving a combination chemotherapy regimen. Further evaluation of this workflow to estimate rwPFS in other cancers and therapeutic settings is warranted. Research Sponsor: None.

	Sentence-Level Capture of Progression Events (N = 1000)	Patient-Level Capture of First Progression Event (N = 100)
Sensitivity	99.8%	92.5%
Specificity	96.7%	83.0%
Precision	96.6%	86.0%
Accuracy	98.2%	88.0%
F1 Score	98.2%	89.1%

Workflow validation metrics.

11177 Poster Session

Long-term cardiovascular outcomes in survivors of 20 adult solid tumors: Large population-based matched cohort study.

Arunkumar Krishnan, Kunal C. Kadakia, Declan Walsh, Saleh A Alqahtani; Levine Cancer Institute, Atrium Health, Charlotte, NC; Levine Cancer Institute, Charlotte, NC; Levine Cancer Institute, Department of Supportive Oncology, Charlotte, NC; King Faisal Specialist Hospital & Research Center, Riyadh, Riyadh, Saudi Arabia

Background: The past few decades have seen notable advancements in how cancer is diagnosed and treated, with improvements in cancer survival. Cardiovascular diseases (CVDs) are the major life-limiting comorbidity among cancer survivors. Evidence is scarce on the risks of specific CVDs in survivors of a wide range of solid tumors, hindering informed strategies for prevention and management. Thus, we evaluated a large population-based U.S. electronic health records database. **Methods:** This large retrospective cohort study was conducted by using the TriNetX dataset between January 2008 and December 2022. All adult patients (>18 years) with a diagnosis of 20 most common solid tumors alive 12 months after diagnosis were matched with controls without a cancer history in a 1:1 ratio with these a priori identified potential confounders: demographics, BMI, nicotine dependence, comorbidities, labs, and medications. The primary outcome was the first incidence of CVD like heart failure (HF), major adverse cardiovascular events (MACE; unstable angina, myocardial infarction, or coronary artery intervention), or venous thromboembolism (VT), and cerebrovascular events (CVE; stroke, transient ischemic attack, cerebral infarction, carotid intervention). Hazard ratios (HR) were calculated to assess the outcomes. **Results:** 890126 individuals with a solid tumor of interest followed up at least 1 year later were identified and matched to 1787244 controls. The VT risk was higher among survivors of 18 out of 20 specific solid cancer types than controls. HRs ranged from HR 3.68(95% CI 3.48-3.89) for kidney cancer and HR 1.27 (95% CI 1.21–1.35) in patients after pancreatic cancer. HRs for VT were more prominent without prior CVDs. Higher risks of CVDs were the most common immuno -and chemotherapy. Higher risk of HF was observed in lung (HR 1.46, 95% CI 1.32–1.89), liver (HR 1.22, 95% CI 1.18–1.26), and ovarian (HR 2.01, 95% CI 1.64–2.45) cancers and in patients younger than 55 years. Pericarditis and arrhythmia were common in lung, bile duct, and stomach cancers. A greater risk of arrhythmia was also observed in lung, kidney, and thyroid cancers, whereas CVE was observed in CNS cancers. **Conclusions:** Survivors of site-specific solid tumors are at a higher medium to long-term risk of one or more CVDs than the general population. Notably, substantial variations in risk were observed across different cancer primary sites. The outcomes underscore the importance of heightened monitoring for CVDs after a cancer diagnosis. Research Sponsor: None.

11178 Poster Session

Assessing secular trends in lung cancer stage in the United States community oncology setting from 2013 to 2023.

Lisa Herms, Zhaohui Su, Nicholas J Robert, Amy K. O'Sullivan, Jessica K Paulus; Ontada, Boston, MA

Background: Detecting disease at an early stage is critical to improving lung cancer (LC) survival, as reflected in guidelines recommending screening with low dose computed tomography for individuals at high risk by clinical societies including the NCCN (2011) and US Preventive Services Task Force (2013, updated 2021). Presenting stage distribution may also be impacted by healthcare utilization changes following the COVID-19 pandemic. Real-world data (RWD)-based investigations are important complements to national cancer registries to provide insight into this potentially changing diagnostic landscape, especially given utilization, practice and referral patterns unique to community settings. We thus assessed LC stage from 2013-23 in a large, nationally representative sample of community oncology practices leveraging RWD. **Methods:** This is a retrospective observational cohort study of patients within The US Oncology Network and non-Network practices, which include a nationally representative network of over 3,700 providers and more than 1 million patients seen annually in community-based oncology practices. All adult (≥18 years) patients diagnosed with non-small cell LC (NSCLC) or small-cell LC (SCLC) who had a first observed stage available in the community oncology setting within 2013 to 2023 were included. Demographics and medical history data were sourced from structured data fields in iKnowMed, an oncology-specific electronic health record system. Time trends of patient diagnosis and characteristics were descriptively evaluated. **Results:** The analysis included 98,806 patients with LC (84,023 [85.0%] NSCLC and 14,783 [15.0%] SCLC). Approximately half were female (49.7% and 50.3% in each disease), three-fourths were White (72.7% and 77.0%, respectively), and mean ages at diagnosis were 69.9 and 68.1 years. From 2013 to 2023, there was an increase in the total number of patients observed in the database with a documented stage, from 7,159 to 9,115 (27.3% increase) for NSCLC and from 1,162 to 1,595 (37.3% increase) for SCLC. This was largely driven by an absolute increase in advanced stage diagnoses. The proportion of patients diagnosed with Stage IV NSCLC increased from 43.3% in 2013 to 49.3% in 2023, while the proportions of Stage 0/I and II diagnoses decreased. A similar trend was observed for SCLC, with 60.3% of patients diagnosed with Stage IV in 2013 compared to 68.2% in 2023. The proportion of Stage IV NSCLC cancers increased in the pandemic period, from 48.0% in 2019 to 51.6% in 2020 and 50.6% in 2021. **Conclusions:** Over the last decade, the proportion of advanced stage LC cases has increased, possibly reflecting changes in referral patterns and utilization specific to the community setting, including those related to the COVID-19 pandemic. The burden of advanced disease highlights the need for continuous investment in advanced-stage treatments as well as early detection efforts. Research Sponsor: Ontada.

11179 Poster Session

Intra-read analysis of radiologists in the setting of blinded independent central review of oncology studies.

Amir Elbahnasawi; Clario, Charlottesville, VA

Background: This study explored the outcome of an analysis completed on the Intra-reader variability of radiologists when assessing the imaging endpoint surrogates of Date of Progression (DOP) and Best Overall Response (BOR) within the context of Blinded Independent Central Review (BICR) in Oncology clinical trials. The analysis encompassed 55,000 test cases derived from 217 clinical trials involving 138 readers. **Methods:** Data collection and parsing were executed through a Python script, enabling a manual analysis of the results. The analysis posited that Intra-read variability serves as a valuable tool when seeking to exclusively observe the consistency of readers in a specific re-read setting. **Results:** The data analysis yielded significant insights, revealing that 89.81% of readers demonstrated substantial and above agreement in DOP determinations, while 72.38% achieved the same in BOR determinations. This suggests a higher level of consistency in DOP compared to BOR determination. Notably, 11 DOP and 20 BOR inconsistencies were observed. This prompted further investigation which led to 5 of the 138 readers being flagged based on discrepancies against their own prior or subsequent reads. The kappa values for these 5 readers ranged from 0.33 to 0.59, consistently indicating fair and moderate agreement. **Conclusions:** This analysis underscored the role of Intra-read variability in identifying inconsistent readers within the landscape of BICR in Oncology clinical trials. The re-read inconsistency is not a universal requirement, and its application is recommended primarily for complex oncology clinical trials or those with indications known to have elevated adjudication metrics. The study emphasized the potential for targeted retraining strategies based on Intra-read analysis outcomes, contributing to the ongoing refinement of reader proficiency. Future directions may involve further exploration of specific retraining strategies or assessing the effectiveness of exclusively using Intra-read variability as a metric for reader performance. Research Sponsor: None.

Rethinking the impact of pretransplant malignancy on eligibility for double lung transplantation (DLT): An analysis of 23,291 recipients.

Wongi Woo, Hye Sung Kim, Ankit Bharat, Young Kwang Chae; Feinberg School of Medicine, Northwestern University, Chicago, IL

Background: The outcomes for double lung transplant recipients with a history of pretransplant malignancy (PreTM) have not been extensively studied in a large, multicenter database. Given the rising need for transplants among older patients with a history of cancer and the improving outcomes of DLT, this study aimed to analyze recipient outcomes in the modern era. **Methods:** This study evaluated the United Network for Organ Sharing (UNOS) registry for adult DLT performed between 2005 and 2023. Patients with a history of previous or multi-organ transplants, and those with donors who had a history of malignancy, were excluded. Propensity-score matching was used to compare patients with or without PreTM. Posttransplant malignancies (PostTM) were classified into cutaneous and non-cutaneous types. The primary outcomes were overall and PostTM-free survival. **Results:** Of the 23,291 DLT recipients, 1,870 recipients (8.0%) had a history of PreTM, which was classified into twelve types. Patients with PreTM experienced worse overall (HR 1.20 [95% CI 1.12-1.29], p<0.001) and PostTM-free survival (HR 1.32 [95% CI 1.24-1.41], p<0.001). After propensity-score matching for age, sex, and race, the differences in overall survival between the two groups were diminished (HR 1.05 [95% CI 0.97-1.13], p=0.229). Although PostTM-free survival was still worse in the PreTM group, this difference was not observed after excluding cutaneous PostTM (HR 1.06 [95% CI 0.99-1.15], p=0.116). The incidence of PostTM of the same PreTM type among patients with PreTM was 13.5% (253/1870), which was not higher than the incidence of de novo PostTM incidence among patients without PreTM (p=0.633). **Conclusions:** Patients with PreTM show similar overall survival rates after DLT as those without PreTM, despite a higher incidence of PostTM, mainly cutaneous. Importantly, there is no increased risk of the original cancer type recurring in PreTM patients compared to the risk of de novo malignancy. These findings highlight the necessity for a more nuanced evaluation of transplant candidacy to prevent premature exclusion of PreTM patients from potentially life-saving surgeries. Research Sponsor: None.

Cox-proportional hazard analysis of clinical outcomes.

	Without PreTM	With PreTM	*p-value*
Entire cohort		**HR (95% CI)**	
Overall Survival	1	1.20 (1.12-1.29)	<0.001
PostTM-free survival	1	1.32 (1.24-1.41)	<0.001
Non-cutaneous PostTM-free survival	1	1.21 (1.13-1.29)	<0.001
Propensity-score matched cohort*		**HR (95% CI)**	
Overall Survival	1	1.05 (0.97-1.13)	0.229
PostTM-free survival	1	1.13 (1.06-1.22)	<0.001
Non-cutaneous PostTM-free survival	1	1.06 (0.99-1.15)	0.116

CI, confidence interval; HR, hazard ratio; PreTM, pre-transplant malignancy; PostTM, post-transplant malignancy *Age, sex, race matched.

11181 Poster Session

Clinical trial participation and end-of-life care among older adults: A multi-center longitudinal observational cohort analysis of 121,717 patients with cancer.

Ishwaria M. Subbiah, Puneeth Indurlal, Divya Deepak, Gunjan Sharma, Jody S. Garey, Lydia Mills, Lalan S. Wilfong; Sarah Cannon Research Institute (SCRI), SCRI Oncology Partners, The US Oncology Network, Nashville, TN; The US Oncology Network, The Woodlands, TX; Texas Oncology, The US Oncology Network, Dallas, TX

Background: Patients' access to clinical trials remains significantly disparate across the US & world. Complex drivers, some rooted in evidence while others in perceptions, impact shared decision making about trial participation esp in older adults (65y+). To that end, we investigated clinical trial participation (CTP) and unplanned healthcare utilization & hospice use in patients w cancer. **Methods:** We queried the prospective longitudinal observational cohort of all patients with cancer receiving care at any of the 323 practice locations of 14 multi-site community cancer centers across 11 US states, all within the US Oncology Network and participating in the Oncology Care Model (OCM), an alternative payment model pilot from CMS to promote quality cancer care while reducing costs. We extracted data from OCM episode claims, medical records from 7/1/17-6/30/22 and used propensity score matching by time period, age, gender, date of death, cancer type to identify matched episodes for further stratification by CTP, to compare hospice care & unplanned ER utilization by non-trial usual care vs CTP. **Results:** Overall, 121,717 pts received cancer care across 282,604 OCM care episodes in the community during this 5-yr period. Most (94%) were older adults aged 65y+ with breast, lung, multiple myeloma being the most common cancers. Of 121,717 pts, 4800 (3.9%) participated in a cancer treatment clinical trial in at least one care episode. Analysis of the 13,260 propensity score-matched episodes (6630 usual care vs 6630 CTP) shows: 1. ER/Observation visits: Patients on clinical trials *did not*have any more ER/Obs visits vs usual care (ER/Obs episodes: CTP 23.4%, usual care 22.3%, p0.11). 2. Hospitalizations: The proportion of care episodes with hospitalization was higher in CTP vs usual care (25.9% vs 21.9%, $p<0.001$). 3. Hospice enrollment: Patients on clinical trials *were no less likely* to enroll in hospice >3 days prior to death, compared to non-trial usual care cohort (CTP 56.8%, usual care 52.6%, OR 1.18, p 0.13). Furthermore, median duration of hospice in patients on trials was not different from usual care (CTP 8 days, usual care 9 days, p 0.16). **Conclusions:** Our findings show that while more hospitalizations were observed, clinical trials participation is not associated with sub-optimal end of life care outcomes pertaining to hospice enrollment & duration as well as unplanned ER/healthcare utilization. Further efforts to integrate access to clinical trials and evidence-based supportive/palliative care in a scalable sustainable model of goal-concordant, patient-center cancer care are ongoing. CMMI Disclaimer: *The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document.* Research Sponsor: None.

Impact on biomarker documentation in community oncology by optimizing clinical decision support.

Daniel Rubin, Victoria Handy, Steven Gilmore, Aimee Ginsburg, Andrea Dickens, Josh Howell, Shannon Hough; McKesson Specialty Health, The US Oncology Network, The Woodlands, TX

Background: Timing of biomarker results is critical to informing the selection of appropriate precision medicine-based treatment options for patients. Prior studies have demonstrated that low rates of biomarker testing may be driven by poor documentation. Our clinical decision support (CDS) tool aims to provide community oncology clinicians with a clear picture of the ever-growing available treatments. Evaluation of CDS data revealed an excess of biomarker results documented as "unknown" thought to be related to results availability. **Methods:** During treatment selection in the CDS tool, providers answer various prompts related to the patient's disease, staging, treatment intent, and biomarker results. Prompts are aligned with NCCN guidelines for the respective cancer type. Changes were implemented to ease providers' documentation of biomarker results. For adjuvant (adjNSCLC) and metastatic NSCLC (mNSCLC), prompts were relocated to align with when biomarker results were likely to be available. For metastatic castrate resistant prostate cancer (mCRPC), some biomarkers are only needed after a patient has received prior docetaxel and hormone therapy, thus prompts were moved to that scenario. Re-prompting of biomarker status for subsequent therapy was also implemented if the initial response was "unknown." We report changes in percentage of known biomarkers specifically in adjNSCLC, mNSCLC, and mCRPC. Descriptive statistics were used to describe the rates of known biomarkers, and a chi-square test was used to analyze differences from pre and post changes. **Results:** In this evaluation, 85,493 biomarkers were documented. In adjNSCLC and mNSCLC, biomarker prompt changes increased documentation of known biomarkers from 69% to 78% and 59% to 79% pre- to post-implementation. In adjNSCLC, *ALK* and *PD-L1* recording increased by ≥10% (P<0.00001). For mNSCLC, documentation increased for all known biomarkers (P<0.00001), including ≥15% increases for 8 of 10 biomarkers. In mCRPC, known biomarker documentation improved from 34% pre-implementation to 61% post-implementation. *BRCA1/2*, *MSI*, *MMR*, *TMB*, and *PSMA* biomarker recording increased by ≥20% (P<0.00001) after prompt changes. Selected biomarkers are shown in the table. **Conclusions:** Adjusting prompts in a CDS tool to align with the availability of biomarkers in clinical practice increased the documentation of known biomarker results for adjNSCLC, mNSCLC, and mCRPC. Based on these findings, similar changes are being implemented for other cancer types in the CDS tool. Research Sponsor: None.

	Pre-Implementation Known Biomarkers, % (n)	Post-Implementation Known Biomarkers, % (n)	p-value
AdjNSCLC	**69% (1,228/1,791)**	**78% (1,751/2,245)**	
mNSCLC	**59% (28,607/48,140)**	**79% (16,938/21,473)**	
ALK	63%	83%	<0.00001
EGFR	70%	85%	<0.00001
mCRPC	**34% (2,945/8,627)**	**61% (1,949/3,217)**	
BRCA1	40%	61%	<0.00001
BRCA2	41%	61%	<0.00001
MSI	32%	72%	<0.00001
MMR	30%	67%	<0.00001

11183 Poster Session

Impact of social determinants of health on health-related quality of life in cancer survivors.

Josephine Peitz, Sally Nneoma Adebamowo; University of Maryland School of Medicine, Baltimore, MD; Department of Epidemiology and Public Health and Greenebaum Comprehensive Cancer Center, University of Maryland School of Medicine, Baltimore, MD

Background: Social determinants of health (SDoH) encompass the various environmental conditions that influence health, well-being, outcomes, and potential risks. Adverse SDoH can exacerbate health disparities and result in a reduced health-related quality of life (HRQoL). We conducted an investigation into the impact of SDoH on the HRQoL of cancer survivors. **Methods:** The study population was a nationally representative cohort of individuals aged 20-80 years who took part in the United States National Health and Nutrition Examination Survey (NHANES) 2001 to 2018 cycles. We evaluated HRQoL by measuring the number of physically unhealthy days, mentally unhealthy days, inactive days, as well as assessing social support and emotional well-being. We used logistic regression models to investigate the impact of each SDoH on the HRQoL of cancer survivors. **Results:** We included 4,780 participants in our analyses, comprising 2,533 women and 2,247 men. The participants mean age was 66 (±14) years at the time of enrollment, and 55 (±17) years at the time of cancer diagnosis. Among the total study population, non-melanoma skin cancer (16%) was the most prevalent cancer type. After adjusting for age, age at cancer diagnosis and gender, people who had the lowest self-reported health were more likely to have completed fewer years of education (OR 0.380 [95% CI: 0.32 - 0.45], $p < 0.0001$), be unemployed (OR 2.30 [1.91 - 2.77], $p < 0.0001$), have lower family income (OR 0.36 [0.28 - 0.45], $p < 0.0001$), be food insecure (OR 3.90 [2.80 - 5.44], $p < 0.0001$), not have private health insurance (OR 1.68 [1.37 - 2.07], $p < 0.0001$), and have been hospitalized overnight in the last year (OR 5.23 [3.49 - 7.83], $p < 0.001$) compared to those with the highest self-reported health. SDoH including employment status, family income, food security status, health insurance type, and overnight hospital patient status, were significantly associated with physical and mental health, and physically active days. Level of education and food security were significantly associated with social support and emotional well-being. **Conclusions:** Adverse SDoH were associated with the reduced HRQoL of cancer survivors in the United States. These findings underscore the importance of addressing and mitigating these social determinants in order to alleviate health disparities and improve the overall well-being and quality of life for cancer survivors. Research Sponsor: American Cancer Society; Research Scholar Grant RSG-22-079-01-CSCT.

11184 Poster Session

New-onset atrial fibrillation, cardiovascular outcomes and all-cause mortality in patients with newly diagnosed cancer: A large population-based matched cohort study.

Diptasree Mukherjee, Declan Walsh, Saleh A Alqahtani, Arunkumar Krishnan; Apex Institute of Medical Science, Kolkata, India; Levine Cancer Institute, Department of Supportive Oncology, Charlotte, NC; King Faisal Specialist Hospital & Research Center, Riyadh, Riyadh, Saudi Arabia; Levine Cancer Institute, Atrium Health, Charlotte, NC

Background: Studies have shown an association between atrial fibrillation (AF) and cancer, but the relationship is incompletely studied. there is also a paucity of data regarding the specific association between cancer type and AF risk . Notably, the longitudinal associations of new-onset AF with adverse cardiovascular (ACV) outcomes in Newly Diagnosed Cancer Patients remain unclear. Thus, through a comprehensive nationwide population-based study, we assessed the associations between new-onset AF and subsequent risks of ACV events and all-cause mortality. **Methods:** This large retrospective cohort study was conducted using the TriNetX database and included adults (>18 years) with any new cancer diagnoses. We performed 1:1 propensity score matching (PSM) for demographics, BMI, nicotine dependence, comorbidities, cancer type, and medications to similar controls as cancer patients without AF. The primary outcome was new ACV events like heart failure (HF), major adverse cardiovascular events (MACE; coronary artery intervention myocardial infarction, or unstable angina), ischemic heart disease (IHD), and cerebrovascular events (CVE; cerebral infarction, carotid intervention, stroke, transient ischemic attack. The secondary outcome was all-cause mortality. Sensitivity analysis assessed statistical robustness. Hazard ratios (HR) were calculated to compare group outcomes. **Results:** Among the new diagnoses, 52,606 developed AF, and 374,959 remained AF free during the follow-up. After PSM, both cohorts (51,567 each) were well-matched. The mean follow-up duration was 4.8 (± 2.7) years. Among newly diagnosed cancer patients, those with incident AF had higher risk of MACE (HR 1.56; 95% CI 1.49–2.16), HF (HR 3.10; 95% CI 2.76–4.36), IHD (HR 1.68; 95% CI 1.41–2.01), CVE (HR 2.93; 95% CI 2.13–4.04), and all-cause mortality (HR 2.56; 95% CI 1.89–3.78) compared with those without incident AF. We noted a higher incidence rate during the initial months after the diagnosis of AF for both sexes. During the first year, the association with any ACV events (men: HR 2.78, 95% CI, 1.85–3.20; women: HR 1.81, 95% CI, 1.31–2.67) was more substantial than that following AF diagnosis for both sexes. New -onset AF was strongly associated with metastatic cancer. In sensitivity analysis, we excluded individuals with <1 year of follow-up results were consistent, and all statistically significant associations remained unchanged. **Conclusions:** cancer patients who developed AF had significantly higher risks of subsequent adverse cardiovascular events and greater all-cause mortality. AF was strongly associated with metastatic disease. Our findings highlight the importance of strategies for AF prevention to mitigate macrovascular complications in all newly diagnosed cancer patients. Research Sponsor: None.

11185 Poster Session

Comparative analysis of actionable gene reporting in targeted panels versus comprehensive NGS testing for solid tumor samples.

Chaugiang Duong, Roisin Puentes, Nathan Montgomery, Derek Lyle, Fernando J. Lopez-Diaz; NeoGenomics Laboratories, Aliso Viejo, CA; Neogenomics Laboratories, Aliso Viejo, CA; Neogenomics Laboratories, Durham, NC; Neogenomics Laboratories, Fort Myers, FL; NeoGenomics Laboratories, San Diego, CA

Background: The landscape of actionable genes significantly influences clinical decisions in cancer diagnosis, prognosis, and treatment planning. In a clinical context, the selection of NGS panels hinges on striking a balance among informative data, insurance coverage, and the preferences of patients and healthcare providers. Molecular pathology reference laboratories commonly employ large-scale next-generation sequencing (NGS) testing, curating smaller, disease-specific targeted panels. This study investigates the prevalence of unreported actionable genes in real-world clinical samples subjected to disease-specific panels. **Methods:** We analyzed SNV/InDel DNA variants in 795 clinical solid tumor samples using the Illumina TSO 500 platform for comprehensive NGS panel testing of 517 genes. Comprehensive NGS panel-tested samples were intersected with disease-specific targeted NGS panels for breast (54 genes), brain (62 genes), colorectal (36 genes), and lung (44 genes). An artificial filter was applied to align targeted panels with patient disease. Variants were classified based on pathogenicity, and benign variants were filtered out. Detected variants were assessed for actionable mutations as defined by the FDA recognized OncoKB actionable gene database criteria. Additionally, 1484 lung patient samples tested with a lung-specific targeted panel were de-identified and unmasked to the comprehensive NGS tumor profiling to investigate the prevalence of actionable alteration beyond those covered by the disease-specific panel. **Results:** The study revealed that 3.2% of breast, 0% of brain, 66.2% of colorectal, and 2.7% of lung samples had additional actionable mutations undisclosed by the targeted panels. The number of actionable genes beyond those included in the targeted panels were 14 for breast, 2 for brain, 25 for lung, and 41 for colorectal cancer. This underscores the importance of comprehensive testing to fully capture each patient tumor's actionable mutation profile. **Conclusions:** Our findings detect masked actionable mutations in down-sampled targeted panels and highlight the need for comprehensive testing to accurately identify actionable mutations in various cancer types. Reporting actionable mutations can significantly influence clinical decision-making, emphasizing the importance of NGS test selection in routine molecular diagnostics as well as the impact of integrating comprehensive NGS testing. Research Sponsor: None.

11186 Poster Session

Time to treatment initiation: An assessment of trends in delays in patients with lung cancer across Missouri.

Lakshmi Ramya Chelapareddy, Mohammad Beheshti, Kushal Naha, Iris Zachary; University of Missouri Hospital, Columbia, MO; Missouri Cancer Registry and Research Center, Department of Public Health, College of Health Sciences University of Missouri, MU Institute for Data Science and Informatics, Columbia, MO; Missouri Cancer Registry and Research Center, Department of Public Health, College of Health Sciences University of Missouri, Columbia, MO

Background: Lung cancer is a major health challenge globally. Missouri's incidence rate of 68.1% exceeds the national rate of 54.0% indicating a significant disease burden. It is the 2nd most common malignancy in men and women in the state. Timely treatment can significantly improve while delays can worsen outcomes. The Institute of Medicine strongly recommends efforts promoting timely care in lung cancer. The RAND Cooperation suggests treatment should begin within 6 weeks after diagnosis. These priorities align with the Healthy People 2030 Initiative which aims to reduce lung cancer incidence and mortality through enhanced screening and early treatment. The U.S. National Committee on Health Care identified a goal of 60% of lung cancer patients receiving treatment within 30-days of diagnosis. Our primary objective was to assess delays in treatment initiation post-diagnosis and to investigate Missouri's adherence to treatment delay guidelines in lung cancer patients. **Methods:** Study population included adults (age>18) with a diagnosis of Lung Cancer, identified using ICD-10 codes C50.0-C50.9. Records were retrieved from the Missouri Cancer Registry and Research Center database for the years 2012-2022. Data for 2022 had a completion rate of 90%, all others had at least 95% completeness. We used the RAND guidelines 42-day treatment delay rule and the Missouri Cancer Action Plan's (MCAP) 30 day treatment delay metric as our benchmarks. Treatment delay was determined by subtracting the Date of Initial Diagnosis from the Date of First Course Treatment. Records with missing or incomplete dates were excluded. Data processing and analyses were performed using Python 3.11. **Results:** Of the 68,293 adult lung cancer patients in the database, 7,882 were excluded due to missing or incomplete data. Among the eligible 60,411 patients, 89.5% were Caucasian, median age was 69 (range 18-105), gender distribution was nearly equal with males accounting for 51.3% of the total. Average time from diagnosis to treatment was 36.8 days, with a median of 27 days. About 31.2% of patients had a gap over 42 days from diagnosis to first treatment. This delay has risen from 26.3% in 2012 to 42.6% in 2022, marking a 16.3% increase. In terms of adherence to the MCAP's 30 day treatment delay metric, 45.6% of patients experienced more than a 30-day gap between diagnosis and treatment. The trend shows an increase in delays, from 40.4% in 2012 to 58.1% in 2022, reflecting a 17.7% rise. **Conclusions:** Despite the declining incidence rate of lung cancer in Missouri over the years, our analysis revealed a surprising increase in treatment initiation delays over the years. The average time from diagnosis to treatment and the percentage of patients experiencing delays exceed the RAND guideline and the MCAP's treatment delay metric and with a rising trend from 2012 to 2022. Further analysis into factors causing delay in treatment initiation is needed and being planned. Research Sponsor: None.

11187 Poster Session

Disparities in frontline treatment and overall survival in the era of targeted tyrosine kinase inhibitor therapy for chronic myeloid leukemia: 2004-2021.

Victoria Vardell, Srinivas Kiran Tantravahi; Department of Hematology and Hematologic Malignancies, University of Utah, Salt Lake City, UT; Division of Hematology and Hematologic Malignancies, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT

Background: The treatment of chronic myeloid leukemia (CML) was revolutionized in 2001 with the introduction of the BCR::ABL tyrosine kinase inhibitor (TKI), imatinib. In 2006, dasatinib was approved, followed by nilotinib in 2007. Two other TKIs, bosutinib & ponatinib were approved in 2012, followed by the allosteric ABL myristoyl inhibitor asciminib in 2021, providing multiple options for patients (pts) who have refractory disease. In this study we examine how survival has improved in CML pts with the availability of multiple TKI's and identify disadvantaged socioeconomic & demographic groups which continue to have disparate survival. **Methods:** The National Cancer Database was used to identify CML pts diagnosed (dx) from 2004-2021. Demographic, treatment, & overall survival (OS) were compared by era of TKI availability, with pts dx from 2004-2005 considered to be treated in the imatinib era, 2006-2011 for dasatinib & nilotinib, 2012-2020 with access to bosutinib & ponatinib, and 2021 for asciminib. **Results:** Of 44,993 CML pts identified, 55.8% were male & 82.5% were White, with median age of 58 years. The portion of pts who were untreated (due to contraindication or early death) decreased by each time period, from 17.8% in the imatinib era to only 7.8% in 2021. The rate of upfront transplant decreased from 2.5% from 2004-2005, to 0.8% in 2021. For dx 2004-2005 median OS was 11.5 yrs (95% CI 10.6-12.5). This increased to 13.6 yrs (CI 13.1-14.1), with age-adjusted hazard ratio (HR) of 0.86 (CI 0.81-0.91) for pts dx 2006-2011, with median OS unreached for 2012-2020, HR 0.67 (CI 0.63-0.71, $p<0.001$); referenced to 2004-2006. Survival at 1-, 5- & 10-yrs was improved for each subsequent time period of dx, with 5-yr OS of 65%, 71%, & 76%, respectively, $p<0.001$. On multivariate cox regression adjusted for yr of dx, features associated with reduced OS included age (HR 1.06 [95% CI 1.05-1.06], $p<0.001$ for each yr), Black race (HR 1.11 [95% CI 1.05-1.18], $p<0.001$), increased comorbidity index (HR 1.94 [95% CI 1.84-2.04], $p<0.001$ for index ≥ 2), uninsured (HR 2.20 [95% CI 2.01-2.41], $p<0.001$), or insured through Medicaid (HR 2.40 [95% CI 2.23-2.58], $p<0.001$). **Conclusions:** Survival for CML pts has significantly improved during the last 20 yrs with the availability of each additional TKI, likely related to increased treatment options for pts with resistance or intolerance. Additional TKI options, particularly approval of ponatinib for patients with T315I mutation, have a secondary benefit of decreasing the utilization of allogenic transplant. Though survival has improved for all pts, pts from traditionally underserved populations, including pts who are underinsured or from racial minority groups, have reduced OS. Continued advances in treatment & efforts to improve access to care for underserved populations is vital to achieve equitable survival outcomes in CML. Research Sponsor: None.

TPS11188 **Poster Session**

Cost-effectiveness of an oral THC: CBD cannabis extract for secondary prevention of refractory, chemotherapy-induced nausea and vomiting.

Mbathio Dieng, Peter S. Grimison, Adrienne Kirby, Antony Mersiades, Izabella Pokorski, Martin R Stockler, Rachael L Morton; The University of Sydney, Camperdown, Australia; Chris O'Brien Lifehouse, Sydney, NSW, Australia; The University of Sydney, Sydney, NSW, Australia; NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; The University of Sydney, Camperdown, NSW, Australia

Background: The CannabisCINV trial showed the incorporation of a THC:CBD (tetrahydrocannabinol:cannabidiol) cannabis extract in addition to usual, guideline-recommended antiemetic prophylaxis, reduced the incidence of refractory chemotherapy-induced nausea and vomiting. The aim of this within-trial cost-effectiveness analysis was toassess the incremental costs and benefits of oral THC: CBD versus placebo, for preventing chemotherapy-induced nausea and vomiting. **Methods:** The analysis was performed from a health system perspective, using prospectively collected data from the CannabisCINV trial and linked Medicare data. The evaluation focused on the costs and benefits associated with oral THC: CBD cannabis extract versus placebo in addition to usual care, on complete response: defined as no emesis and no use of rescue medications during the overall treatment phase (0-120 h, cycle 1). The primary economic outcome was an incremental cost-effectiveness ratio (ICER) of achieving a complete response. One-way sensitivity analyses and non-parametric bootstrapping (with 1,000 replications) were conducted to assess the robustness of results. **Results:** Of 147 participants randomized, 60 of 73 assigned THC:CBD and 66 of 74 assigned placebo consented to Medicare data linkage. The incidence of complete response was higher for THC:CBD than placebo (24% vs 5%, absolute difference 19%, 95%CI 13 to 26%). The mean cost (AUD) of hospitalisation was $580 (SD $7,831) for the intervention group and $1,873 (SD $7,235) for placebo. The mean healthcare costs (AUD) were $1,464 (SD $4,667) for THC:CBD group and $2,725 (SD $9,237) for the placebo. The THC:CBD group had a mean total healthcare cost saving of $1,261 per patient (95% CI -$3,550 to $1029) compared with the placebo group. THC:CBD was less expensive and more effective than placebo (i.e. dominant), in the primary analysis, and over the range of prespecified sensitivity analyses. **Conclusions:** This within-trial analysis indicates oral THC: CBD is cost-effective for the treatment of refractory, chemotherapy-induced nausea and vomiting from a health system perspective and supports reimbursement in this setting. The trial and economic evaluation were prospectively registered in the Australian and New Zealand. Clinical trial information: ACTRN12616001036404. Research Sponsor: None.

TPS11189 **Poster Session**

Implementing fragmentomics into real world screening interventions to evaluate clinical utility among individuals with elevated risk for lung cancer (FIRSTLUNG) L301.

Lindsey Behlen Cotton, Chris Cisar, Peter Brian Bach, Carolina Sheridan, Niti U. Trivedi, James Davis, Demetria Tennefoss; DELFI Diagnostics, Baltimore, MD; Duke University Department of Anesthesiology, Durham, NC; Delfi Diagnostics, Inc., Centerville, TN

Background: To optimize the impact of lung cancer screening at the healthcare system level, additional tools are needed to increase the benefits of screening. While low-dose computed tomography (LDCT) has been shown to improve lung cancer detection and reduce mortality, it is not without its risks, such as radiation exposure, false-positive results, and unnecessary interventions often leading to complications. The additional complexity of lung cancer screening is the subpar adherence to LDCT for eligible individuals, which undermines the benefits of screening. Therefore, there is a need for alternative non-invasive methodologies that exploit our understanding of the biology of cancer pathogenesis. This clinical utility study aims to observe how a non–invasive blood-based test impacts physician behavior and LDCT utilization. **Methods:** FIRSTLUNG 301 (NCT06145750) is a prospective, cluster randomized controlled trial (RCT) to observe the impact of the DELFI Lung cancer screening test on lung cancer screening utilization in primary care practices. Enrolled practices must meet the eligibility criteria of having a minimum of 50 actively engaged individuals in the practice eligible for lung cancer screening per the 2021 USPSTF criteria. These practices will be randomized 1:1:2 to Arm A1 (control), Arm A2 (control), or Arm B (intervention). Arm A practices will be randomized 1:1 into two groups (A1:A2) to observe the standard of care for lung cancer screening. Practices in A1 will be observed; practices in A2 will receive standard education on lung cancer screening for CME credit. Randomizing within Arms A1 and A2 aims to delineate the impact standard lung cancer screening education may have on utilization. Arm B (intervention) practices will receive education and have access to order the blood-based test for screen-eligible individuals that remained unscreened. The primary study endpoint is the proportion of practice-identified lung cancer screen-eligible individuals receiving a screening CT order and scan during the study period in the entirety of Arm A (control) versus Arm B (intervention). This RCT aims to understand the utilization and impact on lung cancer screening uptake after the DELFI blood-based test intended to inform clinical guidelines and policies focused on improving patient care and health outcomes. Progress: The study was initiated on October 31, 2023, with practice randomization. As of February 2024, the study is open for enrollment with an estimated primary study completion date of December 2025. Clinical trial information: NCT06145750. Research Sponsor: None.