

1500

Oral Abstract Session

Changes in cancer mortality by race and ethnicity following the Affordable Care Act implementation in California.

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Background: Implementation of the Affordable Care Act (ACA) has resulted in improvements in cancer outcomes but the extent to which these apply to specific racial and ethnic populations is unknown. We examined changes in health insurance distributions pre- and post-ACA and assessed cancer-specific mortality rates by race and ethnicity. **Methods:** The population included 167,181 newly diagnosed breast (n = 117,738), colorectal (n = 38,334), and cervix cancer (n = 11,109) patients younger than 65 years and 141,026 patients 65 years or older in the California Cancer Registry. Hazard rate ratios (HRRs) and 95% confidence intervals (CIs) were calculated using multivariable Cox regression to estimate associations with risk of 5-year cancer-specific death for each cancer site pre- (2007-2010) and post-ACA (2014-2017), and by race and ethnicity (American Indian/Alaska Natives, AIAN; Asian Americans; Hispanics; Native Hawaiian/Pacific Islanders, NHPI; non-Hispanic Blacks, NHB; and non-Hispanic whites, NHW). Difference-in-difference analysis was conducted to compare changes over time between younger (< 65 years) and older (65 years and older) patients. **Results:** Cancer-specific mortality for patients age < 65 was significantly lower post- vs. pre-ACA for colorectal cancer among Hispanic (HRR = 0.83; 95% CI: 0.74-0.93), NHB (HRR = 0.69; 95% CI: 0.58-0.81), and NHW (HRR = 0.90 95% CI: 0.84-0.97) but not Asian American (HRR = 0.95; 95% CI: 0.82-1.10) patients. The HRR for younger NHB colorectal cancer patients was significantly lower than that for patients 65 years of and older (HRR = 1.09; 95% CI, 0.95-1.25, p-interaction < 0.0001). A significantly lower risk of dying from cervix cancer was observed in the post- vs. pre-ACA period among younger NHB women (HRR = 0.68; 95% CI: 0.47-0.99), but this was not significantly different than that for older women (HRR = 0.41; 95% CI, 0.16-1.01, p-interaction = 0.30). No significant differences in breast cancer-specific mortality were observed for any racial or ethnic group. **Conclusions:** Findings show decreases in cancer-specific mortality for colorectal and cervix cancers for some racial and ethnic groups following ACA implementation in California. These results shed light on ongoing discussions as additional states consider Medicaid expansion. Future studies should assess shifts between health insurance plans resulting from the economic impact of the 2019 novel coronavirus (COVID-19) pandemic. Research Sponsor: U.S. National Institutes of Health.

1501

Oral Abstract Session

Association between state Medicaid policies and accrual of Black participants to cancer clinical trials.

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Background: Black individuals remain underrepresented in U.S. cancer clinical trials, partly due to financial barriers to participation. While coverage of the routine costs of trial participation has long been mandatory for Medicare and the commercially insured, only 16 states have enacted similar mandates for Medicaid enrollees. Given the disproportionate representation of Black individuals in state Medicaid programs, we hypothesized that such mandates may have led to improved accrual of Black participants to cancer clinical trials. **Methods:** We conducted a retrospective, quasi-experimental study using de-identified data from the ECOG-ACRIN Cancer Research Group to evaluate changes in the accrual of Black participants to cancer clinical trials associated with state-mandated Medicaid coverage of routine trial costs. The study population included non-elderly adults enrolled in therapeutic clinical trials for breast, colorectal, lung, or prostate cancer from 2000-2019. We employed a difference-in-differences approach with event-study specification to compare outcomes in states that mandated Medicaid coverage of routine trial costs relative to states that did not, before and after mandates were enacted. Outcomes included the proportion of trial participants who had Medicaid insurance (vs. non-Medicaid) and the proportion who were Black (vs. non-Black). Models adjusted for age, sex, cancer type, cancer stage, study phase, and study site (community vs. academic). **Results:** Among 24,321 trial participants (mean age 52.0 [SD 8.2] years, 82.8% female), 7.2% had Medicaid coverage and 10.5% were Black. Compared to states without Medicaid coverage mandates, states with mandates had a statistically significant increase in the proportion of Black trial participants in the first year following the mandate (+6.4 percentage points [95%CI 1.8% to 11.0%]) but not in subsequent years. There was no association between state mandates and the proportion of trial participants enrolled in Medicaid (effects ranged from -0.7 percentage points [95%CI -4.6% to 3.3%] in the first year after mandates to -3.9% [95%CI -8.6% to 0.8%] in the third year). **Conclusions:** State-mandated Medicaid coverage of the routine costs of trial participation was associated with a short-term increase in the proportion of Black trial participants. These findings suggest that Medicaid policies have the potential to improve representation of racial minority groups in cancer clinical trials, and support recent federal legislation mandating state Medicaid programs to cover trial participation costs as of January 2022. Our study was limited by use of data from only one large cancer research group, focus on only four common cancers, and limited power to analyze the policy impact for other racial and ethnic minority groups. Additional work is needed to replicate these findings in larger cohorts of trial participants. Research Sponsor: Leonard Davis Institute of Health Economics Pilot Award, Weill Cornell Ritu Banga Healthcare Disparities Research Award.

Association between the Affordable Care Act Medicaid expansion and survival in young adults newly diagnosed with cancer.

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Background: Medicaid expansion through the Affordable Care Act (ACA), implemented by 26 states in January 2014 and 13 more states in later years, has been shown to improve insurance coverage and early diagnosis of cancer in young adults (YAs). Little is known about whether these improvements translate to a survival benefit in this population. We evaluated the association between the ACA Medicaid expansion and 2-year overall survival among YAs newly diagnosed with cancer. **Methods:** Using the National Cancer Database, we identified 345,414 YAs aged 18-39 years diagnosed with cancer between 2010 and 2017. YAs diagnosed pre-expansion were followed through September 30, 2013 or three months before Medicaid expansion implementation for late-expansion states, and YAs diagnosed post-expansion were followed through December 31, 2019. We applied the difference-in-difference (DD) method to estimate changes in 2-year overall survival before and after Medicaid expansion, in expansion- versus non-expansion states, controlling for key sociodemographic factors. DD analyses were performed for YAs overall, and stratified by cancer type, stage at diagnosis, race/ethnicity, comorbidity, and facility type. **Results:** Among all YAs, 2-year overall survival increased more in expansion states (90.39% pre-expansion to 91.87% post-expansion) than in non-expansion states (88.98% pre-expansion to 90.05% post-expansion), resulting in a net increase of 0.53 percentage points (ppt; 95% confidence interval [CI] = 0.11 to 0.95 ppt). The increase in 2-year overall survival in expansion states versus non-expansion states was greatest among subgroups of patients with female breast cancer (DD = 1.20 ppt; 95% CI = 0.28 to 2.13 ppt) and patients with stage IV disease at diagnosis (DD = 2.51 ppt; 95% CI = 0.28 to 4.74 ppt). Additionally, greater improvement in 2-year overall survival associated with the expansion was seen among racial/ethnic minority YAs (including Hispanic, non-Hispanic Black, and non-Hispanic others; DD = 0.98 ppt; 95% CI = 0.10 to 1.86 ppt) than their non-Hispanic White peers (DD = 0.41 ppt; 95% CI = -0.06 to 0.89 ppt), among patients treated in community cancer programs (DD = 1.10 ppt; 95% CI = 0.32 to 1.88 ppt) than academic comprehensive cancer programs (DD = 0.12 ppt; 95% CI = -0.52 to 0.77 ppt), and among patients with two or more comorbidities (DD = 6.37 ppt; 95% CI = 0.68 to 12.06 ppt) than patients with no comorbidity (DD = 0.48 ppt; 95% CI = 0.04 to 0.91 ppt). **Conclusions:** We provide the first evidence on the association between ACA Medicaid expansion and improved overall survival among YAs newly diagnosed with cancer. Survival benefits are notable among racial/ethnic minority patients and patients with high health-care needs, and by patients' treatment facility type. Research Sponsor: U.S. National Institutes of Health.

Impact of oncology clinical pharmacist intervention on clinical trial enrollment in The U.S. Oncology Network's MYLUNG Consortium.

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Background: The Molecularly Informed Lung Cancer Treatment in a Community Cancer Network: A Pragmatic Consortium (MYLUNG) clinical trial platform aims to advance the use of precision medicine in non-small cell lung cancer patients through a series of prospective and iterative clinic trials. "Protocol 2" is evaluating the patient and tissue journey of newly diagnosed lung cancer patients presenting for care. Timely patient accrual to oncology clinical trials is a known practice challenge. The US Oncology Network recently implemented a clinical pharmacist (ClinReview) to provide remote clinical services to support Protocol 2 enrollment. **Methods:** An oncology-trained clinical pharmacist remotely reviewed chemotherapy regimen orders and a weekly custom recruitment report within six community network practices (n = 149 physicians). The ClinReview pharmacist identified, screened, and assisted with recruitment of eligible patients for enrollment in the MYLUNG study. Relevant and concise patient data were provided to the on-site research team to facilitate ease of enrollment. Enrollments and intervention data were tracked to monitor the impact of the pharmacist intervention. The primary outcome of monthly enrollment was evaluated using a paired t-test. **Results:** Over a 6-month period, the ClinReview pharmacist screened 367 potentially eligible patients, 325 patients were recommended for enrollment, and 103 patients (32%) were consented and enrolled. Enrollment due to this ClinReview intervention increased monthly and ranged from 5 in first month to 33 enrollments in month 6. Average monthly enrollment was significantly greater after ClinReview intervention (3.4 patients/month vs. 6.8 patients/month; p = 0.008). Of the 154 patients recommended for enrollment that were not enrolled, 104 (68%) exceeded their eligibility window allowed by the trial, 15 (10%) were deceased or enrolled into hospice care, 10 (6%) declined trial participation, and 25 (16%) transferred care or were treated at outside facilities. **Conclusions:** We demonstrate that incorporation of an oncology clinical pharmacist in clinical research teams significantly enhanced clinical trial enrollment. The remote pharmacist easily adapted into clinic workflows in community practices. Validation across a broader spectrum of differentially resourced oncology practices will be conducted as the MYLUNG clinical trials platform is executed. Research Sponsor: Amgen, AstraZeneca, Eli Lilly, Genentech, Mirati.

Average monthly patient enrollment by practice, before and with ClinReview intervention.			
	Average enrollment before ClinReview intervention	Average monthly enrollment with ClinReview	Change after intervention (%)
Practice 1	2.2	6.0	177%
Practice 2	3.4	6.8	101%
Practice 3	0.7	1.7	150%
Practice 4	3.4	10.0	194%
Practice 5	5.8	7.5	30%
Practice 6	4.8	8.5	78%
Total	3.4	6.8*	101%

* (p = 0.008).

Operational metrics for the ELAINE II study combining a traditional approach with a just-in-time model.

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Background: Trial recruitment that requires specific actionable mutations based on next-generation sequencing (NGS) is challenging. Barriers can include competing studies, physician study awareness, site proximity, mutation incidence, among other concerns. **Methods:** This study (NCT04432454) opened clinical sites using two methods during the COVID-19 pandemic. The “Traditional” approach included site selection, IRB and contract approval, and trial activation prior to a patient being identified for enrollment. The second approach used the Tempus “TIME” Trials network that would only open a site after identifying a patient with a mutation of interest and eligible for the trial. **Results:** The first patient enrolled was on 10/12/20 and the last patient was on 6/24/21. A total of 16 sites (6 Traditional and 10 TIME) participated. All Traditional sites, and none of the TIME sites, were affiliated with major academic institutions. Duration for full CTA execution for Traditional sites averaged 200.5 days (range 142 to 257) and for TIME sites averaged 7.6 days (range 2 to 14). IRB approval time average for Traditional sites was 27.5 days (range 12 to 71) and TIME sites was 3.0 days (range 1 to 12 days). Days from site selection to activation letter for Traditional sites was on average 250.0 days (range 187 to 281) and for TIME sites was 131.6 days (range 22 to 248). Time from study activation to first consent was 33.3 days (range 18 to 58) for Traditional sites and 8.8 days (range 1 to 35) for TIME sites. The first patient on-study was at a TIME site 115 days prior to a Traditional site and the first 7 patients enrolled were at TIME sites. Traditional sites consented 23 and enrolled 16 patients while the TIME sites consented 16 and enrolled 13. The trial enrolled all 29 patients in 8 months with the anticipated enrollment duration being 12 to 18 months. **Conclusions:** Although the Traditional and TIME programs had different operational models, they both contributed a significant number of patients and reduced the projected enrollment timeline. TIME sites enrolled the initial patients. These results demonstrate that the “Just-in-Time model,” in conjunction with a Traditional model, can reduce projected overall time to enrollment in biomarker-driven studies. Research Sponsor: Sermonix Pharmaceuticals.

Number of patients enrolled at clinical sites by month.

	TIME	Traditional	Total
October 2020	2	0	2
November 2020	3	0	5
December 2020	0	0	5
January 2021	2	0	7
February 2021	1	2	10
March 2021	1	4	15
April 2021	0	4	19
May 2021	0	3	22
June 2021	4	3	29

1505

Oral Abstract Session

Impact of broadening trial eligibility criteria on the inclusion of patients with brain metastases in cancer clinical trials.

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Background: On October 2, 2017, the American Society of Clinical Oncology, Friends of Cancer Research, and the U.S. Food and Drug Administration (ASCO/FoCR/FDA) issued a joint research statement recommending that certain eligibility criteria in cancer clinical trials, including those related to brain metastases, be broadened to make trials more inclusive. We examined whether patterns of exclusions regarding patients with brain metastases changed over time in relation to these recommendations. **Methods:** We used data from ClinicalTrials.gov to evaluate patterns of trial eligibility criteria in phase I-III U.S.-based interventional clinical trials for patients with advanced breast, colorectal, or lung cancers from January 2013 through October 2021. Trial inclusion and exclusion criteria were abstracted; to enhance validity, reviewers were blinded to the year of trial activation. For each trial, we determined whether patients with brain metastases were not excluded, conditionally excluded (i.e., excluded in some circumstances), or wholly excluded. Trial registrations between October 2, 2017-December 31, 2018 were excluded to allow 1 year for newly conceived trials to adopt the recommendations, plus 3 months to account for the lag time between loading trial records and trial activation dates; thus, the independent exposure variable was January 1, 2019. An interrupted time series analysis with multinomial logistic regression was used to assess whether the ASCO/FoCR/FDA recommendations were associated with changes in brain metastases eligibility criteria. **Results:** We evaluated N = 1998 trials. Patients with brain metastases were not excluded in 307 trials (15.4%); conditionally excluded in 1459 trials (74.8%); and wholly excluded in 196 trials (9.8%). In the post-recommendation period, we found a 92% increase in the odds of trials with brain metastases not excluded compared to conditionally excluded (OR = 1.92, 95% CI, 1.08-3.45, p = .03). The estimated proportion of trials in which patients with brain metastases were not excluded increased from 9.2% had the recommendations not been made to 15.6% (p = .04). Conversely, the proportion of trials in which patients with brain metastases were conditionally excluded (76.9%) was lower than expected (85.3%, p = .02). We found no difference in the proportion of trials in which patients with brain metastases were wholly excluded (7.5% vs. 5.4%, p = .28). **Conclusions:** The ASCO/FoCR/FDA recommendations were associated with a shift in patterns of brain metastases exclusion criteria from conditionally excluded to not excluded. To our knowledge, this is the first evidence that cancer clinical trials have become more inclusive of a broader set of patients in response to the ASCO/FoCR/FDA recommendations. More inclusive eligibility improves trial access and representativeness, increasing trial validity and the pace at which trials enroll. Research Sponsor: Public Health Sciences Division of the Fred Hutchinson Cancer Research Center.

1506

Oral Abstract Session

Remote patient-reported symptoms and passive activity monitoring to improve patient-clinician communication regarding symptoms and functional status: A randomized controlled trial (PROStep).

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Background: Oncologists suboptimally assess patient symptoms and functional status, possibly leading to poor symptom management or over-treatment. Remote patient-reported symptoms and passive activity monitoring may provide objective measures of symptoms and functional status to improve patient-clinician communication and symptom understanding. We assessed the impact of a clinician-centered dashboard of longitudinal patient-reported symptoms and step counts on patient-clinician communication regarding symptoms and functional status. **Methods:** This randomized trial enrolled 108 patients with incurable GI or lung cancers treated with chemotherapy at a large academic health center. Patients were randomized to either of Arms A) control, B) weekly patient-reported symptoms via text message + step tracking from a wearable activity monitor, with summary dashboards given to clinicians at each visit, or C) arm B plus text message-based prompts to patients encouraging discussion of symptoms and functional status prior to each visit. We used Kruskal Wallis tests to compare co-primary outcomes (patient-reported perceptions of clinician symptom and functional status understanding at 6 months after enrollment) between control (A) and intervention (B+C) arms on a 5-point scale (1 = Not at all; 2 = Slightly; 3 = Moderately; 4 = Considerably; 5 = Completely). **Results:** 33, 37, and 38 patients were enrolled in arms A, B, and C, respectively. Patients were 54.6% male, mean age was 58.9 years, 77% had GI cancer, and 23% had lung cancer. At six months, there was no difference between control and intervention arms in patient perception of clinician understanding of symptoms (Arm A: 4.5, Arm B/C: 4.5, $p = 0.85$) or functional status (Arm A: 4.5, Arm B/C: 4.3, $p = 0.59$). Patients reported that their oncology team seldom discussed PROStep data during appointments (mean 2.3 on 5-point scale where 2 = seldom). Hospitalization rates were 42% and 45% for Arms A and B/C ($p = 0.8$), respectively, and new palliative care referrals were 9% and 10% ($p = 0.8$), respectively. Mean adherence to weekly patient reports and Fitbit data (at least 4 of 7 days in a week) was 64% and 53%, respectively. Net promoter score was 8.3 on a 10-point scale. **Conclusions:** Clinician and patient-directed dashboards based on patient-generated health data did not lead to higher patient-perceived clinician understanding of symptoms and functional status, although this was limited by moderate adherence to remote symptom and step count collection and low frequency of clinician discussion of PROStep data with patients, highlighting challenges to clinical application of these data sources. Further efforts are needed to improve patient-clinician communication about symptoms and functional status. Clinical trial information: NCT04616768. Research Sponsor: Penn Institute of Translational Medicine and Therapeutics.

1507

Oral Abstract Session

Evaluating mass implementation of digital health solutions to improve quality and reduce disparities in a large multisite community oncology practice.

Amila Meera Patel, Arun Bhardwaj, Ethan Basch, Kathryn Elizabeth Hudson, Susan Marie Escudier, Holly Books, Bhanu Kaushik, Ben Pearson, Christopher Bays, Sydney Townsend, Debra A. Patt; Navigating Cancer, Seattle, WA; UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC; Duke University Medical Center, Durham, NC; Texas Onc PA, Houston, TX; Texas Oncology, Dallas, TX; Texas Oncology, Austin, TX

Background: There is a priority to accelerate the delivery of digital health solutions (DHS) to provide patients with enhanced means for accessing care, but lack of understanding of their utility in certain populations. There are concerns that equitable adoption translate into disparities. We sought to implement a portfolio of DHS across a large practice and characterize engagement across populations to enhance clinical informatics solutions that support care delivery. **Methods:** This is a retrospective evaluation of cancer patients who engaged with a portfolio of DHS between March 1, 2019 and January 15, 2022. We included four tools with opt-in and opt-out functionality: (1) a care management (CM) platform utilized by clinical staff to manage patient activities, (2) an electronic patient-reported outcomes (ePRO) remote monitoring program for tracking symptoms and oral adherence, (3) a patient portal (PP) for securely accessing patient health records, and (4) digital education (DE) for patients regarding disease and treatments. The engaged population was defined as the number of enrolled patients with at least one (1) record of triage activity, (2) completed ePRO assessment, (3) PP login, and (4) DE read activity, for each tool, respectively. The start of the index period was adjusted based on the first go-live date of each tool. We evaluated factors (age, gender, race/ethnicity, preferred-language, marital status, and distance from clinic) associated with patient engagement using Chi-Square test and multivariate logistic regression. **Results:** This analysis included a total of 267,375 unique patients. Of the enrolled population per tool, 172,840 (73.6%), 9,938 (67.7 %), 49,771 (79.2%), and 12,044 (56.9%) patients were engaged in CM, ePRO, PP and DE, respectively. The majority (>50%) of engaged patients were female, White and non-Hispanic/Latino, English-language, and aged 61-80 yrs. After adjusting for covariates, we observed that White and non-Hispanic/Latino [(CM: OR 1.15, ePRO OR 1.46, PP: OR 1.48, and DE: OR 1.36) and English-language (CM: OR 1.2, ePRO OR 1.67, PP: OR 1.8 and DE: OR 1.89) patients were significantly (p-value <0.001) more engaged compared to their counterparts. Male patients were less likely to be engaged in CM (OR: 0.79) and ePRO (OR: 0.65) but more engaged in PP (OR: 1.1) compared to females. No significant difference was observed in engagement between non-rural (<20 mile) vs. rural (≥ 20 miles) and in all age groups 21-40, 41-60, 61-80 and >80 years as compared to reference age of 0-20 years for any digital tools except CM. **Conclusions:** DHS can be used to support the cancer patient journey and we demonstrated high utilization in an array of sociodemographic variables in our population. However, tools designed and implemented with different populations in mind to reduce staff burden and lessen the digital divide should be further explored. Research Sponsor: None.

ePRO-based digital symptom monitoring in a community oncology practice to reduce emergency room and inpatient utilization.

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Background: We have previously reported on the successful implementation of an electronic patient-reported outcomes (ePRO)-based symptom monitoring tool in a community oncology practice. Basch et al reported that use of such a tool in the academic trial setting reduced ER visits and hospitalizations. We have examined the impact of the tool on ER and inpatient utilization in this real world patient population. **Methods:** Highlands Oncology Group (HOG) is a 21 physician oncology group located in Northwest Arkansas. Beginning in June 2020, HOG offered patients receiving parenteral cancer therapy enrollment onto Expain, an EMR-integrated ePRO system which enables remote symptom monitoring during therapy. EMR data were linked with the Arkansas State Health Alliance for Records Exchange (SHARE), the state's Health Information Exchange (HIE), to obtain ER visits/hospitalization data. All patients at HOG treated between September 30, 2020 and November 30, 2021 were included in this analysis. Clinical and demographic characteristics were compared in patients who enrolled on Expain versus those who did not, and corresponding p-values were calculated using Mann-Whitney and Chi-square tests. Crude rates for ER visits / hospitalizations were calculated as the total number of events per total person-time. **Results:** There were 855 patients enrolled on the ePRO system. Concurrently, in the same practice, 1773 patients were treated but not enrolled. Reasons for non-enrollment included patient's choice to not participate and patient not yet offered enrollment due to rolling enrollment. The non-ePRO cohort was slightly older (66.7 vs 63.3 yrs, $p < .001$), more commonly male (47.3% vs 39.3%, $p < .001$) and less likely to be White (85.3% vs 89.4%, $p = 0.003$). The cohorts were comparable with respect to cancer site distribution and included a diverse and representative distribution of common malignancies receiving systemic therapy in a community practice. The proportion of patients with metastatic disease was comparable (ePRO 52.9% vs non-ePRO 51.6%, $p = 0.55$). Health resource utilization rates were lower for patients in the ePRO cohort: ER visits: 1.72 vs 2.34 per 100 patient-months, rate ratio and 95% CI = 0.74 (0.60, 0.92), p -value = 0.005; hospitalizations: 4.76 vs 5.41 per 100 patient-months, rate ratio and 95% CI = 0.87 (0.77, 0.99), p -value = 0.04. **Conclusions:** Our findings confirm the substantial benefits of using an ePRO tool in reducing health care resource utilization, and extend the initial findings of previous publications in the academic, clinical trial setting to the real world setting. This observational data is subject to confounding factors and we are evaluating the robustness using various methods to address non-comparability of the cohorts. We are further examining the benefits in specific patient subsets and attempting to correlate these benefits with improved survival. Research Sponsor: None.

1509

Poster Discussion Session

Disparities in NCI and nonprofit organization funding and effect on cancers with high incidence rates among Black patients and mortality rates.

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Background: National Cancer Institute (NCI) and nonprofit organization (NPO) funding is critical for research and advocacy, but may not be equitable across cancers or racial and ethnic groups. **Methods:** This study evaluated funding from the NCI and NPOs supporting lung, breast, colorectal, pancreatic, hepatobiliary, prostate, ovarian, cervical and endometrial cancers, leukemia, lymphoma and melanoma from 2015-2018. The primary objectives were to assess for disparities in NCI and NPO funding across different cancers compared to their incidence and mortality and their incidence rates across age, racial and ethnic groups. We also investigated if underfunding correlates with fewer clinical trials. Correlations between NCI and NPO funding for each cancer and its incidence, mortality and number of clinical trials were analyzed using scatter plots and Pearson correlation coefficients (PCCs). **Results:** Diseases with the largest combined NCI and NPO funding were breast cancer (\$3.75 billion) and leukemia (\$1.99 billion). Those with the least funding were endometrial (\$94 million), cervical (\$292 million), and hepatobiliary cancers (\$348 million). Disease-specific funding correlated well with incidence, but correlated poorly with mortality (PCCs: 0.74, $p = 0.006$ and 0.30, $p = 0.346$, respectively). Breast cancer, leukemia and lymphoma were consistently well-funded, while colorectal, lung, hepatobiliary and uterine cancers were consistently underfunded. These data are summarized in the Table. NCI and NPO funding increased proportionately as incidence increased for White patients (PCC: 0.73, $p = 0.007$), Hispanic patients (PCC: 0.66, $p = 0.02$), Asian/Pacific Islanders (PCC: 0.77, $p = 0.003$) and Native Americans and Alaskans (PCC: 0.72, $p = 0.008$) while cancers with higher incidence in the Black population were underfunded (PCC: 0.52, $p = 0.08$). The amount of combined NCI and NPO funding for a particular cancer correlated strongly with the number of clinical trials for that disease (PCC: 0.91, $p < 0.0001$). **Conclusions:** Many cancers with high incidence and mortality are underfunded, including those with higher incidence among Black patients. Underfunding strongly correlates with fewer clinical trials, which could impede future advances in underfunded cancers. Research Sponsor: None.

	Leukemia	Lymphoma	Breast	Lung	Colon	Pancreas	Liver	Melanoma	Uterine	Cervix	Ovary	Prostate
NCI+NPO Funding (millions)	\$1,997	\$1,299	\$3,746	\$1,995	\$971	\$942	\$348	\$660	\$94	\$292	\$505	\$1,215
Funding/Incidence	\$33,162	\$16,041	\$14,852	\$7,140	\$7,191	\$17,645	\$6,757	\$8,072	\$1,555	\$22,529	\$22,669	\$7,030
Funding/Deaths	\$81,762	\$61,616	\$91,411	\$10,165	\$19,418	\$22,191	\$10,948	\$67,089	\$8,825	\$70,359	\$35,713	\$44,765

Impact of a shared-care model between community and academic centers for facilitating access to allogeneic and autologous stem cell transplantation.

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Background: Despite curative or disease-controlling roles in AML/MDS and MM, access to allogeneic (allo) and autologous (auto) hematopoietic stem cell transplantation (SCT) remains far from universal. Socioeconomic status (SES) and geographic distance from SCT centers have been shown to be barriers to SCT access. In 2016, Hartford HealthCare (HHC) and the Memorial Sloan Kettering Cancer Center (MSK) pioneered a Shared-Care Model (SCM) to streamline access to allo and auto SCT at MSK, featuring a dedicated nurse SCT coordinator, shared hematology tumor boards, MSK-led didactics for HHC providers, and an electronic health record sharing pipeline. We sought to determine if this has improved access to SCT for HHC patients. **Methods:** A retrospective chart review was conducted of HHC patients aged 18-70 with new diagnoses of AML, MDS, and MM between 2016 and 2020. Socioeconomic status (SES) was estimated by 9-digit zip-code using the Area Deprivation Index (ADI), shown to be a surrogate for healthcare access. Referral or not to a SCT center, referral to MSK through the SCM, and reasons for non-referral were abstracted from the medical record. For patients referred for SCT at MSK, we also captured the number of peri-SCT days in New York City (NYC) and number of subsequent MSK and HHC clinic visits/hospitalizations within 1-year post-SCT. **Results:** A total of 126 patients was included, with 81 (64%) treated for AML/MDS and 45 (36%) for MM. The median age was 60 years (interquartile range [IQR]: 53-66). The majority were white (n = 101, 80%) followed by 10% (n = 13) Black/African American; 10% (n = 12) were of Hispanic ethnicity. The median ADI percentile was 38 (IQR: 20-51; higher percentiles reflect decreased SES). The median ADI for MSK SCT referrals from New York, New Jersey, and Connecticut 2016-2020 for the same indications was 19 (IQR: 10-30, p < 0.001). A total of 90 patients (71%) were referred to SCT centers. Leading reasons for no referral were favorable-risk disease (n = 10), goals of care (n = 9), and death prior to referral (n = 5); 3 patients were not referred due to comorbidities/performance status. No differences were found between patients referred to MSK vs. other centers. Thirty-four HHC patients were referred to MSK (21 AML/MDS, 13 MM), vs. 3 between 2010 and 2015. Twelve patients underwent allo SCT, with median 97 days in NYC (range: 68-247); 8 underwent auto SCT, with median 21 days in NYC (range: 15-48). **Conclusions:** Our findings show the feasibility of a shared-care model between a non-SCT-providing large regional hospital system and a major academic transplantation center. Close collaboration between institutions may minimize time patients spend away from home. The SES of HHC referrals was lower than the general MSK population, suggesting that a shared-care model may facilitate access to SCT for patients with previous barriers for this potentially curative therapy. Research Sponsor: None.

Time to biopsy of screening mammography-detected abnormalities: Evaluating the impact of same-day services implemented during the COVID-19 pandemic.

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Background: Screening mammography programs often require patients undergo multiple visits (screening exam, diagnostic exam, and biopsy) before tissue diagnosis of screen-detected abnormalities. During the COVID-19 pandemic, same-day breast imaging services were leveraged to decrease the number of visits following abnormal screening exams. Specifically, in May 2020, we implemented an immediate-read screening mammography program to synergize with our pre-existing same-day breast biopsy program, such that every effort was made to perform diagnostic imaging during the same visit after an abnormal screening mammogram. This study aims to evaluate the impact of these same-day breast imaging services on time and number of patient visits to undergo breast biopsy after an abnormal screening mammogram. **Methods:** Consecutive screening mammograms performed during normal business hours pre- (6/1/16 to 5/30/17) and post-implementation (6/1/20 to 5/30/21) of same-day services were identified. Patient demographics, imaging and biopsy results, and visit dates were extracted from the medical record. Multivariable logistic, linear, and ordinal regression models estimated with generalized estimating equations were fit to assess the association of period (pre- versus post-implementation), patient age, and race and ethnicity (White versus races other than White) with having a same-day biopsy (biopsy on the same day as the abnormal screening exam), number of days to biopsy, and number of visits. Adjusted odds ratios (aOR) and beta estimates (aBeta) of each covariate and corresponding 95% confidence intervals (CI) were estimated. **Results:** A total of 409/25,922 (1.6%) of patients (median age 61, IQR 50-70) pre-implementation and 221/20,452 (1.1%) patients (median age 62, IQR 49-71) post-implementation had screen-detected abnormalities leading to diagnostic breast imaging and biopsy. Median number of days from screening to biopsy decreased from 16 days pre-implementation to 5 days post-implementation ($p < 0.001$). Pre-implementation, 86.8% of patients required 3 visits between screening and biopsy, while post-implementation only 23.1% required 3 visits ($p < 0.001$). Compared to pre-implementation, the post-implementation period was associated with increased odds of undergoing same-day biopsy (aOR 20.7, 95% CI 8.3-51.7), $p < 0.001$, fewer days from abnormal screening mammogram to biopsy (aBeta -13.3, 95% CI -15.7 to -10.9, $p < 0.001$), and fewer visits (aOR 0.05, 95% CI 0.02-0.09), $p < 0.001$, controlling for age and race and ethnicity. **Conclusions:** Same-day breast imaging services decreased time and patient visits between abnormal screening mammogram and breast biopsy. Same-day services implemented out of necessity during the COVID-19 pandemic should be continued after the pandemic has subsided to improve timeliness of care. Research Sponsor: The 2021 Ralph Schlaeger Fellowship Award.

1512

Poster Discussion Session

Patient- and provider-level factors associated with telehealth utilization across a multisite, multiregional cancer practice.

Joshua Pritchett, Bijan J. Borah, Ruchita Dholakia, James P. Moriarty, Hannah Ahn, Ming Huang, Nandita Khera, Mohamed Kharfan-Dabaja, Jonathan Ticku, Aaron L. Leppin, Jon Charles Tilburt, Jonas Paludo, Tufia C. Haddad; Mayo Clinic, Rochester, MN; Mayo Clinic, Phoenix, AZ; Mayo Clinic, Jacksonville, FL; Mayo Clinic Health Syst, La Crosse, WI; Division of Hematology, Mayo Clinic, Rochester, MN

Background: In response to the COVID-19 pandemic, many cancer practices adopted telehealth, including telephone and video appointments. Following a period of initial expansion that began in March 2020, sustained telehealth integration has emerged across the Mayo Clinic Cancer Practice (MCCP) in 2021. The primary objective of this study was to identify factors associated with utilization of telehealth appointments. **Methods:** A cross-sectional, multi-site, retrospective analysis was conducted across MCCP – a multisite, multiregional cancer practice with tertiary referral campuses in Minnesota, Florida, and Arizona, as well as rural, community-based hospitals and clinics throughout the Upper Midwest. Multivariable models were used to examine the association of patient- and provider-level variables with telehealth utilization. **Results:** Outpatient appointments conducted in July – August 2019 (n = 32,932) were compared with those from 2020 (n = 33,662) and 2021 (n = 35,486). The rate of telehealth appointment utilization increased from <0.01% in 2019 to 11.0% in 2020 and 14.0% in 2021. The strongest provider-level predictor of telehealth utilization was female physician provider type (OR 1.06, 95% CI 1.01 to 1.11; P = 0.0297), a trend consistently observed across career stages, practice locations and settings in 2020 and 2021. Additionally, while the rate of telehealth utilization was not significantly different at referral and community-based campuses in 2020, providers at referral campuses were significantly more likely to utilize telehealth than community-based campuses in 2021 (OR 1.1, 95% CI 1.01 to 1.12; P = 0.0289). Regarding patient-level factors, rural residence (defined by Rural-Urban Commuting Area codes), which accounted for 44.2% of the patient population, was significantly associated with lower telehealth utilization as compared to patients with urban residences, particularly for video appointments (OR 1.04, 95% CI 1.02 to 1.07; P < 0.0001). Notably, the disparity in telehealth utilization between rural and urban populations was found to be less pronounced in 2021 as compared to 2020. **Conclusions:** Multivariable analysis across a multi-site, multi-regional cancer practice identified several factors associated with increased telehealth utilization. These included female physician provider type, referral-based campuses, and patients residing in urban settings. A detailed understanding of the factors that influence telehealth utilization – a method of care delivery which represents a “new normal” across many cancer practices – will be essential to enable continued equitable access to high-quality, high-impact, patient-centered cancer care. Research Sponsor: Wohlers Family Foundation.

Association between telehealth and adherence with patient-reported outcomes (PRO)-based remote symptom monitoring among adolescent/young adults (AYA), middle age, and older adults with cancer.

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Background: PRO-based remote symptom monitoring favorably impacts quality of life, healthcare utilization, and overall survival in patients (pts) with cancer. However remote PRO completion rates outside of a clinical trial remained widely varied. With the wide adoption of telehealth in cancer care during the pandemic, telehealth's impact on health behaviors such adherence w remote PROs is not fully characterized. To that end, we investigated PRO completion patterns in routine cancer care, pre- and during the pandemic. **Methods:** We queried a prospectively maintained institutional database of all PROs remotely delivered to pts at our institution from 1/1/18 to 12/31/21. Pts were divided into 2 time cohorts ("pre-pandemic" 1/1/18 to 3/31/20, "during pandemic" 4/1/20 to 12/31/21) and 3 age cohorts (AYA 15-39y, midage 40-64y, older adults 65y+). We calculated descriptive statistics and compared (t-test, ANOVA) between time and age cohorts and independent variables. **Results:** Overall 93,875 unique patients over 4 years received 1+ remote PROs as a part of their routine cancer care. PRO response rate increased from 35% pre-pandemic (12011 of 34742 pts responding) to 67% during pandemic ($p < 0.00001$). To understand patient-level response patterns, we selected one representative global health PRO tool used widely across clinics in our institution and analyzed completion in a representative month over 4 years, 2 before (Oct '18, '19) and 2 mid-pandemic (Oct '20, '21). Overall 2738 pts (median age 60y, range 17-94y; 290 AYA 15-39y, 1444 midage 40-64y, 1004 older adults 65y+) were sent 3249 PROs during these 4m, 1378 PROs to 1075 pts in 2 pre-pandemic months & 1871 to 1663 pts in 2 mid-pandemic months. Overall, PRO response rate increased from 52% pre-pandemic to 81% during, non-responders dropping from 48% to 19%, and response rate without any reminder from the team increasing from 13% pre-pandemic to 79% during. Across all 3 age cohorts, overall PRO response rates increased (AYA up 21%, midage up 27%, seniors up 35%, $p 0.012$), PRO non-response rate decreased (AYA by 21%, midage by 27%, seniors by 35%, $p 0.01$), and PRO response rate without reminders from clinic team increased significantly (AYA, by 71%, midage by 78%, senior by 61%, $p < 0.00001$). When further analyzing by visit type during pandemic, the improvements in overall PRO response rates are driven almost exclusively by telehealth where in-person PRO completion decreased by 19% (pre-pandemic 52%, during 33%) while pts who had an upcoming virtual visit had 94% PRO response rate ($p < 0.00001$). **Conclusions:** Substantially higher adherence with PRO-based remote symptom monitoring was seen during the pandemic with virtual visits accounting substantially for this broad adherence and the highest increases seen in older adults, highlighting the implications of telehealth on cancer care. Research Sponsor: American Cancer Society, the Andrew Sabin Family Foundation, Cancer and Aging Research Group (CARG) R21/R33 Infrastructure Grant.

Electronic research consents for complex early-phase I-II clinical trials integrated with telemedicine visits compared with in-person encounters.

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Background: Based on our previous research with patient satisfaction for electronic consenting (95% of 940 respondents would recommend it another patient), we hypothesized that telemedicine (telemed) would be received as well as or better than in-person clinical research (CR) consent encounters for complex early-phase clinical trial (Phase I-II) and clinical genetic consent discussions by patients. Oncologist experiences to date have shown that telemed works well for uncomplicated clinical scenarios, but its performance alongside increased care complexity is less clear from the patient perspective.

Methods: We conducted a one-time survey of adult patients having a telemed consent visit between 8/31/21 and 2/13/22 and an in-person clinic visit. Nine CR specific questions covered visit preference and empowerment across 6 high value consent agency domains. **Results:** 513 patients completed the survey and consented across 96 Clinical trials (CT), including genetic, therapeutic, diagnostic, and quality of life. Consent discussions were performed by 75 clinicians and 41 non-clinicians, with the majority (64%) for clinical genetic and Phase I-II CTs. Most patients (52%) preferred telemed over in-person clinic visits (19%) when all visit related factors (time, cost, convenience, quality of care, healthcare team interaction) were considered ($P<.05$) (Table). Comparing their last in-person visit with telemed, patients reported feeling either less stressed/overwhelmed (16%) for their consent discussion or about the same (39%) using telemed, and 6% were more stressed ($P<.05$). Patients expressed equal comfort taking agency-supported action across 6 domains regardless of consent setting.

Conclusions: Electronic consenting via telemed is the preferred method for consent in complex early-phase clinical trials when all visit factors are considered and performs as well across 6 key agency domains when compared with in-person visits. Telemed does not contribute additional stress to consent appointments for most patients and performs well across complex clinical genetic and Phase I-II clinical trial discussions. Our findings suggest telemed and electronic consent should be offered as an option for patients throughout their treatment continuum. Beyond MSK, our data support a broader call for organizations to offer telemed platforms for CT discussions to increase overall patient satisfaction and potentially increase participation. Research Sponsor: None.

Question	Prefer Telemedicine (%)	No Difference (%)	Prefer in Person (%)
Considering All Factors About Your Visit	52	29	19
Saying a CT is not right for me	9	82	9
Requesting time to decide about CT participation	12	79	9
Looking information up online	14	79	7
Sharing a concern about taking part in a CT	12	79	9
Asking for more information to better understand a CT	13	73	14
Include friends, family, or care givers to join the CT discussion	17	72	11

Preliminary analysis of an expanded access study of the fixed-dose combination of pertuzumab (P) and trastuzumab (H) for subcutaneous injection (PH FDC SC) for at-home administration (admin) in patients (pts) with HER2-positive (HER2+) breast cancer (BC) during the COVID-19 pandemic.

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Background: Standard of care for HER2+ early/first-line metastatic BC (EBC/MBC) is P + H and concurrent chemotherapy (CT); PH FDC SC offers faster, more convenient admin vs intravenous (IV) P + H. COVID-19 has caused unprecedented strain on healthcare systems and disruption to cancer care; hospital (Tx) at home may: enable pts to continue cancer Tx; reduce exposure to COVID-19; free up hospital resources. This study's main objectives: to enable continuity of care during COVID-19; to assess safety of PH FDC SC given at home. **Methods:** This is an ongoing single-arm, hybrid, decentralized clinical trial (NCT04395508). Pts with HER2+ EBC/MBC who completed concurrent CT with P + H IV and are receiving/about to receive maintenance P + H IV, PH FDC SC, or H SC are switched to PH FDC SC given at home by a home health nursing provider (HHNP) until disease progression, unacceptable toxicity, pt withdrawal, or physician recommendation (pts with EBC will complete ≤ 18 cycles). The study endpoint is safety. A subset of pts took part in HARRIET, a substudy of at-home cardiac surveillance with artificial intelligence-guided cardiac ultrasound and optional 6L ECG acquired by an HHNP. **Results:** Data for 114 pts (1 male) were available at cutoff (Jan 19, 2022): 18 (16%) completed Tx; 20 (18%) discontinued; 76 (67%) remain on study; 79 (69%) had a COVID-19 vaccine while on study. Median age was 49 years; pts were balanced between EBC (n = 55, 48%) and MBC (n = 59, 52%); received a median of 6 (EBC) and 8 (MBC) cycles; and were from metropolitan (n = 109), urban (n = 4), and rural (n = 1) areas. 11 pts tested COVID-19-positive during the Tx phase: 8 continued Tx after appropriate COVID-19 Tx and/or quarantine. Safety is summarized in the table. No new adverse events (AEs) emerged due to home admin. AEs of special interest were grade (gr) 1–2: admin-related reactions (n = 76, 67%), hypersensitivity (n = 5, 4%), cardiac dysfunction (n = 4, 4%), except 1 case of gr ≥ 3 diarrhea. AEs leading to study Tx discontinuation or interruption/dose reduction occurred in 3 (3%) and 15 (13%) pts. A subset of 7 pts completed at-home cardiac surveillance testing; quantitative assessment of left ventricular ejection fraction was feasible in 3 (43%); 5 (71%) preferred at-home surveillance to clinic. **Conclusions:** In this preliminary analysis, safety of PH FDC SC at home was consistent with the established P + H safety profile, indicating that PH FDC SC at home is a viable option for continuing BC care during and beyond COVID-19. Clinical trial information: NCT04395508. Research Sponsor: Genentech, Inc.

AEs	Pts. n / %
Most common, any grade	
Injection site reaction	67 / 59
Diarrhea	17 / 15
Fatigue	10 / 9
Nausea	8 / 7
Injection site pain	6 / 5
Gr ≥ 3	4 / 4
Serious*	5 / 4
Fatal	0

*Not Tx-related: COVID-19 pneumonia, cystitis, acute kidney injury, diarrhea, seizure, sepsis, transient ischemic attack (gr 2).

Outcomes following off-site remote chemotherapy administration.

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Background: The Veteran Affairs Nebraska Western Iowa Health Care System (VA-NWIHCS) utilizes teleoncology and remote chemotherapy services to expand care to veterans in rural Nebraska who have difficulty accessing the primary campus in Omaha. Remote sites in Lincoln (60 miles) and Grand Island (GI) (150 miles) facilitate remote chemotherapy administration with oversight from oncologists in Omaha. This study compares clinical outcomes in patients receiving care at these remote sites to those in Omaha. **Methods:** Data were retrospectively reviewed for 151 patients receiving first-line chemotherapy at VA sites in Omaha, Lincoln or GI between 1/1/2018-12/31/2020. Data collected included age, gender, performance status, comorbidities, overall survival (start of treatment to death/last contact), malignancy type and stage, number of delayed or missed treatment cycles, chemotherapy-related toxicities, and emergency room (ER) visits or hospitalizations. SAS version 9.4 was used for analysis. **Results:** The study population included 108 patients who received their chemotherapy infusions in Omaha, while 43 received their infusions at the remote sites. The demographics of the patients at both Omaha and remote sites (Lincoln/GI) was predominantly male, 96% vs 91% respectively; median age was 69 years in each group; 82% vs 93% ($p = 0.24$) had an ECOG PS of 0-1. The two groups were comparable in terms of common comorbidities: chronic obstructive pulmonary disease (36% vs 37% $p = 0.90$); chronic kidney disease (38% vs 28% $p = 0.24$); coronary artery disease (41% vs 19% $p = 0.01$). Groups had a similar proportion of patients with stage IV disease (39% vs 33%; $p = 0.54$), treatment with curative intent (60% vs 51%; $p = 0.32$), and most prevalent cancers: head/neck (14% vs 12% $p = 0.80$), lung (25% in each $p = 0.99$), and gastrointestinal (10% vs 14% $p = 0.57$). There was no difference in median OS between the on-site treatment and remote treatment groups [96.8 ($n = 84$) vs 92.4 ($n = 32$) months ($p = 0.92$) for patients with solid tumors; 67.7 ($n = 24$) vs 94.3 ($n = 11$) months ($p = 0.73$) for hematologic malignancies]. Chemotherapy-related toxicities were noted in 61% vs 53% of patients ($p = 0.39$) in Omaha vs remote sites, including febrile neutropenia (6% vs 2% $p = 0.99$), neutropenia (6% vs 5% $p = 0.67$), other cytopenia (11% vs 14% $p = 0.59$), dehydration (9% vs 2% $p = 0.18$), nausea (5% vs 7% $p = 0.69$), and neuropathy (3% vs 7% $p = 0.35$). At least one hospitalization occurred in 33% vs 21% ($p = 0.13$) of patients and at least one ER visit in 42% vs 26% ($p = 0.07$). A delay in at least one treatment cycle occurred in 29% vs 21% ($p = 0.32$) of cases and at least one cycle of treatment was missed in 15% vs 19% ($p = 0.59$). **Conclusions:** The evaluated outcomes in oncology patients treated in Omaha versus remote sites via telemedicine under the same providers were similar. Effective oncology care, including parenteral chemotherapy administration, can be provided via telemedicine and this model can help mitigate issues with access to care. Research Sponsor: None.

Remote symptom monitoring after hospital discharge.

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Background: Strategies to improve transitions from the hospital to home for patients with cancer are considered an important component of quality, patient-centered care in oncology. CMS evaluates cancer hospital performance based on the 30-day unplanned hospital readmission rate, and this measure has been endorsed by the National Quality Forum. Nationally, the 30-day readmission rate for oncology patients ranges from 19%-27%. These readmissions come at high psychosocial, physical, and financial costs for patients and caregivers. A remote monitoring intervention that includes frequent contacts with the patient is likely to be effective in improving this transition. **Methods:** We evaluated the feasibility, acceptability, and perceived value of a mobile health intervention to monitor and manage symptoms of adult medical and surgical oncology patients discharged from an NCI-designated cancer center to home. Patients were monitored for 10 days, which is the median time to readmission for an oncology patient. The technology supporting the program included: 1) a patient portal enabling daily electronic patient-reported outcomes assessments; 2) a pulse oximeter to provide data on blood oxygen level and heart rate; 3) alerts for concerning symptoms; 4) an application to allow staff to review and trend symptom data; 5) a secure platform to support communications and televisits between staff and patients; 6) an advanced feedback report to provide just-in-time patient symptom education. Feasibility and acceptability were evaluated through engagement (goal: > 50% response rate) and symptom alerts and perceived value was measured through a patient engagement survey that included a net promoter score (how likely the patient is to recommend the program to similar patients; goal > 0.7). **Results:** Between September 27, 2020 to December 31, 2021, the program enrolled 1,091 medical oncology (median age: 63 years, 55% female) and 4,222 surgical oncology patients (median age: 63 years, 55% female). Of those enrolled, 65% of medical and 74% of surgical oncology patients participated in home remote monitoring by self-reporting symptom data. This resulted in 2,869 completed symptom assessment from medical and 16,009 completed assessments from surgical patients. Sixty-three percent of medical oncology assessments resulted in a yellow (moderate) or red (severe) symptom alert compared with 26% for surgical oncology patients. Pain was the predominant symptom generating red alerts for medical oncology patients (17%). Fifty-two percent of patients completed the engagement survey, and the net promoter score was 0.82. **Conclusions:** A remote monitoring program after discharge was feasible, acceptable, and perceived to be of value by oncology patients discharged from a cancer center. Surgical and medical patients have similar response rates but differ in symptom burden. Future work will evaluate the value of a remote symptom monitoring platform in decreasing readmissions. Research Sponsor: U.S. National Institutes of Health, Other Foundation.

A pragmatic cluster-randomized trial of a standing physician order entry intervention for colony stimulating factor use among patients at intermediate risk for febrile neutropenia (SWOG S1415CD).

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Background: Primary prophylactic colony stimulating factors (PP-CSF) are prescribed to patients undergoing chemotherapy to reduce the risk of febrile neutropenia (FN) but their benefit for regimens with intermediate FN risk is uncertain. Within a pragmatic, randomized trial of a standing order entry (SOE) intervention for prescribing PP-CSF, we designed a substudy to evaluate the effectiveness of PP-CSF for patients receiving therapy with intermediate FN risk. **Methods:** TrACER was a cluster randomized trial where NCI community Oncology Research Program practices were randomized to usual care (UC) or a guideline-based SOE intervention. In the primary study, sites were randomized 3:1 to a SOE of automated PP-CSF orders for NCCN-designated high FN risk chemotherapy regimens and alerts against PP-CSF orders for low FN risk regimens (intervention) versus usual care. A secondary randomization assigned intervention sites to a SOE intervention either to prescribe or not prescribe PP-CSF for patients receiving intermediate FN risk regimens. Clinicians were allowed to override the SOE. Patients age ≥ 18 with either breast, colorectal or non-small cell lung cancer were enrolled and followed for 12 mo. PP-CSF was defined as initiation within 24-72 hours after systemic chemotherapy. Sample size calculations were based on an FN risk reduction from 15% to 7.5%, and provided 80% power at a planned enrollment of 90 patients per site. Mixed effect logistic regression models were used to test differences between sites randomized to prescribe or not prescribe PP-CSF. **Results:** Between January 2016 and April 2020, 24 sites (2,287 patients) were randomized to the intervention. Among intervention sites, 12 were randomized to either SOE to prescribe or an alert to not prescribe PP-CSF for the 542 patients receiving intermediate FN risk regimens. Rates of PP-CSF use were higher among sites randomized to prescribe PP-CSF (37.1% vs 9.9%, OR = 5.90 (95% CI 1.72-20.20; $p = 0.0048$)). Overall, the rates of FN were low and identical between PP-CSF and no PP-CSF arms (3.7% vs 3.7%). Among patients who did not receive PP-CSF, rates of FN were also low and similar between arms (3.8% vs 4.1%). **Conclusions:** While implementation of a SOE intervention for PP-CSF significantly increased PP-CSF use among patients receiving intermediate risk regimens, FN rates did not differ between arms. Despite SOE, 63% of patients assigned to receive PP-CSF did not receive it. FN rates overall were lower than expected and did not differ between patients that did or did not receive PP-CSF. Although this guideline-informed SOE influenced prescribing, the results suggest that neither the SOE nor PP-CSF itself provide sufficient benefit to justify their use for persons receiving intermediate FN risk regimens. Clinical trial information: NCT02728596. Research Sponsor: U.S. National Institutes of Health, Other Government Agency.

Cluster-randomized trial to evaluate the implementation of reproductive health care in cancer care delivery in community oncology practices: Results from ECOG-ACRIN E1Q11.

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Background: Reproductive health (RH) needs of women newly diagnosed with cancer have been poorly addressed. RH management must be aligned with cancer treatment to optimize cancer survivorship. The primary objective of the EROS trial is to evaluate the effectiveness of implementing RH programming to improve RH care among reproductive aged women with cancer. **Methods:** E1Q11 used a cluster randomized design with 17 NCI Community Oncology Research Program (NCORP) Sites randomized to intervention (n = 8) or usual care (n = 9). Intervention sites received study-specific training delivered via webinar and tools to support RH care implementation. Pre-menopausal women aged 15-55 years newly diagnosed with cancer and pre-initiation of treatment were eligible. The primary endpoint was defined as the delivery of RH goal-concordant management within the first 3 months since enrollment. Data were obtained through patient completed questionnaires and medical record abstraction forms at baseline and 3 months. The management rate was analyzed using generalized estimating equations (GEEs) method. **Results:** From 7/2016 - 4/2021, 434 women enrolled (156 intervention, 278 usual care) and 392 were analyzable. The median age was 41 years. Patients self-identified as White 67.5%; Black 21.1%; Hispanic 15.9%. Most patients had breast cancer (83.5%) and local/regional disease (69.5%). A higher proportion of patients at intervention sites (77.1%, 108/140, 90% CI: 0.71-0.83) received goal-concordant RH care compared to patients enrolled from usual care sites (61.5%; 155/252, 90% CI: 0.56, 0.67). A total of 263/392 (67.1%) patients received goal-concordant RH care within the first 3 months of enrollment. The GEE analysis demonstrated patients enrolled from intervention sites were approximately twice more likely to receive goal-concordant RH care than patients at usual care sites (odds ratio, OR = 2.11, 95% CI: 1.30, 3.44, p = 0.003). Younger age (< / = 35 years vs. > 35 years) and better ECOG performance status (PS 0 vs. PS 1-3) were statistically associated with the adoption of RH goal-concordant management (OR = 2.85, 95% CI: 1.59, 5.12, p = 0.0004 and OR = 1.94, 95% CI: 1.04, 3.63, p = 0.04, respectively). The intervention effect on the primary endpoint remained after age and PS were adjusted in the model (adjusted OR = 2.23, 95% CI: 1.30, 3.84, p = 0.004). **Conclusions:** The EROS trial demonstrated significant improvement of goal-concordant reproductive health management amongst racially diverse women newly diagnosed with cancer treated in community oncology practices. Sites randomized to intervention more frequently delivered reproductive care compared to usual care sites. Findings support wider implementation of this intervention to improve reproductive health care delivery, improving cancer care quality for premenopausal women diagnosed with cancer. Clinical trial information: NCT01806129. Research Sponsor: This study was conducted by the ECOG-ACRIN Cancer Research Group (Peter J. O'Dwyer, MD and Mitchell D. Schnall, MD, PhD, Group Co-Chairs) and supported by the National Cancer Institute of the National Institutes of Health.

Improving supportive care for patients with thoracic cancer.

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Background: Improving lung cancer care among Veterans is a priority within the Veterans Affairs due to higher rates of lung cancer incidence, morbidity, and mortality among Veterans compared to non-veterans. Unaddressed symptom burden is common due to many factors including complex comorbidities, psychosocial challenges, smoking history and limited social support networks. Additionally, complications from social determinants of health can obstruct successful discussions of symptom-burden between Veterans and their clinical care teams which can limit compliance with recommended symptom management strategies. To overcome these barriers, we conducted a randomized controlled trial to test the effectiveness of a lay volunteer-led proactive symptom assessment and symptom intervention. The objective was to determine if the intervention improved clinician documentation from baseline to 6-months post-enrollment compared to usual care. Secondary outcomes included change in patient activation, health-related quality of life (HrQOL), and symptom-burden. **Methods:** Patients were randomized into the lay volunteer proactive symptom assessment intervention plus usual cancer care (intervention group) or usual cancer care alone (control group). We conducted electronic health record review to assess primary cancer-clinician symptom documentation of Veterans' symptoms identified as moderate-to-severe at baseline and 6-months using the Edmonton Symptom Assessment Scale. Patient surveys with validated assessments were used to assess patient activation, HrQOL and symptom burden at baseline (time of enrollment) and 6-months post-enrollment. We used regression models to evaluate differences in our primary and secondary outcomes. **Results:** 60 Veterans were consented and randomized into the study (29 control; 31 intervention). There were no differences in demographic or clinical factors across groups. The median age was 70 years (range 56-85), 95% were male, 70% identified their race as White, 53% were married and 48% had a 2-year or 4-year college degree. The majority had at least 3 comorbidities (54%), diagnosed with stage 3 or 4 (62%) and received systemic treatment with chemotherapy and/or radiation (77%). At 6-months post-enrollment as compared to baseline, the intervention group had greater improvements in symptom documentation (56% from 12.5% vs. 29% from 43%, $p = 0.01$), greater improvements in patient activation ($p < 0.001$), HrQOL (< 0.001), and lower symptom burden ($p < 0.001$) than the control group. **Conclusions:** Integration of proactive symptom assessment by lay volunteers has a significant and meaningful effect on symptom documentation, patient activation, quality of life, and reducing symptom burden among Veterans with lung cancer. Clinical trial information: NCT03216109. Research Sponsor: Carevive, Inc, U.S. National Institutes of Health.

1521

Poster Session

The initial outcome of deploying a mortality prediction tool at community oncology practices.

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Background: Hospice improves the quality of life and care for cancer patients and reduces the likelihood of unwanted death in the hospital. Advance Care Planning (ACP) allows physicians to proactively initiate hospice and end-of-life discussions with identified patients, promoting timely hospice care enrollment. We developed a machine learning (ML) model to predict 90-day mortality risk for patients with metastatic cancer. The tool was designed to enable earlier ACP discussions leading to increased hospice enrollment. This study assesses the ML tool usage on ACP documentation in a community oncology setting. **Methods:** Twelve practices across the nation were included in the study, all participating in the Oncology Care Model. Five practices implemented the ML tool during 10/26/2020-9/30/2021, with patients scored every two weeks to provide insights on mortality risk. Patients identified as high-risk were evaluated for ACP utilization, obtained from timely EMR data and historical claims. Seven practices did not implement the ML tool and served as the control for the study. **Results:** A total of 1,663 patients were predicted to have a high risk of mortality at the 12 practices during the time-frame. The median age was 74 years. 53% of patients were males, and 47% were females. ACP documentation varied among the practices. The range was 19.4%-55.8% among ML tool participating practices and 7.4%-31.0% among non-participating practices. The weighted mean of ACP utilization was 34.4% for participating practices and 14.0% for non-participating practices. Compared with non-participating practices, the ACP rate increased significantly by 2.5-fold for participating practices (p-value = 0.03, two-sided T-test). **Conclusions:** This initial outcome study showed improved ACP documentation after deploying a mortality prediction tool in a community oncology setting. We are currently working on propensity score matching and regression analysis to reduce the effect of confounding factors such as practices, patient demographics, diagnosis, and treatment. Future studies will evaluate the impact of mortality tool use on other outcomes, including hospice enrollment, emergency department visits, and hospital admission. Implementing the mortality prediction tool is an ongoing effort with more practices planned to adopt. Research Sponsor: None.

Imaging and physician visits at cancer diagnosis: COVID-19 pandemic impact on cancer care.

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Background: Understanding how cancer system responded to the first wave of the COVID-19 pandemic has crucial implications to de-escalation measures in future waves. Here we examined the pandemic impact on the provision of diagnostic imaging (MRI, CT, and ultrasound) and physician visits (virtual and in-person) at cancer diagnosis in Ontario, Canada. **Methods:** For each week of June 26, 2016–September 26, 2020, we identified cancer diagnoses whose time around diagnosis (91 days +/- the date of diagnosis) fell into this week and restricted those diagnoses to be one per person-day and to patients aged 18+ at the beginning of that week. For these cancer patients, we used physician claims database to identify diagnostic imaging and visits received around cancer diagnosis. In separate segmented negative binomial regression procedures, we assessed the trends in weekly volume of these services per thousand cancer patients in pre-pandemic (June 26, 2016 to March 14, 2020), the change in mean volume at the start of the pandemic, and the additional change in weekly volume in the pandemic (March 15, 2020 to September 26, 2020). **Results:** Among 403,561 cancer patients in the cohort, 41,476 (10.3%) were diagnosed in the pandemic. As COVID-19 arrived, mean diagnostic imaging volume decreased by 12.3% (95% CI: 6.4%-17.9%) where ultrasound decreased the most by 31.8% (95% CI: 23.9%-37.0%) and MRI did not change (p-value = 0.27). Afterwards, the volume of all scans increased further by 1.6% per week (95% CI: 1.3%-2.0%), where ultrasound increased the fastest by 2.4% for each week (95% CI: 1.8%-2.9%). Mean in-person visits dropped by 47.4% when COVID-19 started (95% CI: 41.6%-52.6%) while virtual visits rose by 5515% (95% CI: 4927%-6173%). In the pandemic era, in-person visits increased each week by 2.6% (95% CI: 2.0%-3.2%), but no change was observed for virtual visits (p-value = 0.10). **Conclusions:** Provision of diagnostic imaging and virtual visits at cancer diagnosis has been increasing since the start of COVID-19 and already exceeded pre-pandemic utilization levels. These findings imply the feasibility of combining virtual consultations with diagnostic imaging to manage new cancer patients and highlight the need to monitor the quality of these services. Research Sponsor: Sunnybrook Research Institute and Sunnybrook Foundation COVID-19 Response Grant.

The promising use of hospital at home in an oncology setting.

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Background: Hospitalization at Home (HaH) is an emerging clinical model that delivers the essential elements of acute hospital-level care in the home and has demonstrated efficacy largely for inpatient medical conditions. Few programs have implemented HaH for patients with active cancer diagnoses. There is little data evaluating the impact of HaH on cancer outcomes, patient experience or cost effectiveness. In 2019, the Mount Sinai Health System (MSHS) expanded its HaH program to include oncology patients. Here, we describe our institution's experience of HaH in oncology. **Methods:** We performed a retrospective chart review for solid tumor, myeloma and lymphoma patients at MSHS from August 2019 to November 2021 enrolled in HaH. Patient eligibility for HaH required meeting established institutional HaH admission criteria. Demographics, cancer diagnosis, social situation, indication for antecedent ED or inpatient stay, and HaH admission were extracted from the electronic medical record. Our primary endpoint was rate of successful HaH admission, with success defined as discharge from HaH for complete recovery from the acute condition or transition to hospice. We also evaluated patient social support and home resources. **Results:** We enrolled 19 patients with multiple myeloma (n = 7), lymphoma (n = 1), and solid tumor (n = 11). Sixty-three percent (n = 12) were male, 74% (n = 14) were age 65 or older, and 42% (n = 8) were white. Patients were enrolled in HaH either from an inpatient service (n = 15) or from the emergency room (n = 4). While on the inpatient service, 6 of the 15 patients had received chemotherapy. Post-chemotherapy monitoring was the primary reason for HaH admission. Successful HaH admissions occurred for 79% (n = 15) of patients. The mean duration of HaH admission was 4.5 days (range 1-10 days). Three patients opted to re-enroll in HaH planned care at a later point. There were no significant issues with provider home visits, access, medication delivery, lab draws, or social support. **Conclusions:** The MSHS Oncology HaH program successfully cared for 79% of our cohort demonstrating the functionality of expanding the program to patients with cancer. We continue to increase enrollment for oncology patients. Further studies to assess patient outcomes, cost savings, and re-hospitalization rates when compared to the standard in hospital only care for oncology patients will help determine the benefits and preferred population to utilize oncology HaH. Research Sponsor: None.

Reducing inpatient mortality in patients with cancer through multidisciplinary review and targeted interventions.

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Background: Excess inpatient mortality is a marker of poor quality in cancer care. We developed a multidisciplinary mortality review committee to review each inpatient death to determine key drivers of mortality and develop targeted interventions to reduce our inpatient mortality index. **Methods:** Through retrospective review, inpatient deaths were identified at Stanford Health Care for patients with an ICD10 cancer diagnosis regardless of inpatient service. Details of each hospitalization were reviewed by a quality consultant and subsequently reviewed by a physician quality team member to identify opportunities for improvement. Most cases were then discussed in a monthly multidisciplinary committee meeting. The committee analyzed key drivers of inpatient mortality, communicated suggestions to the patient's outpatient and inpatient attending physicians, and/or identified opportunities for systemic change. The resulting targeted interventions were tracked using the observed versus expected mortality ratio for inpatient deaths over time. **Results:** From May 2017 through August 2021 we reviewed 528 inpatient oncology deaths. Patients' median age was 65 years, and the median length of stay was 8 days. 73% of patients had metastatic cancer, and 28% received chemotherapy within 14 days of death. 25% of patients had a prior ED visit, and 35% had a prior hospitalization within 30 days of admission. Only 26% of patients had an advanced directive on record at time of death. Opportunities for improvement were identified for 60% of cases (Table). Interventions have aimed to increase advance care planning conversations and documentation, develop predictive models for cancer-related readmissions and mortality, expand outpatient services for urgent symptoms, and expedite transitions to hospice. **Conclusions:** Understanding key drivers for preventable inpatient mortality through a multidisciplinary review process identified targeted interventions that have successfully contributed to reduction of the inpatient cancer mortality index. Research Sponsor: None.

Opportunities for improvement identified by physicians through secondary review of inpatient deaths (n = 528).	
Opportunities for improvement identified in mortality review	% of cases
Lack of outpatient advance care planning conversations and documentation	24
Delay in transition to hospice	13
Delayed or inadequate incorporation of palliative care service	9
Medical futility or aggressive treatment with unlikely clinical benefit	9
Goals of care discordance between providers and patient/family	5

A pragmatic cluster-randomized trial of a computerized clinical decision support system to improve colony stimulating factor prescribing for patients with cancer receiving myelosuppressive chemotherapy (SWOG S1415CD).

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Background: Primary prophylactic colony stimulating factors (PP-CSF) are prescribed to patients undergoing chemotherapy to reduce the risk of febrile neutropenia (FN). Prior studies have shown that 55-95% of CSF prescribing is inconsistent with practice guidelines. We conducted a cluster randomized trial to determine if guideline-informed standing orders for PP-CSF improved prescribing and reduced the incidence of FN. **Methods:** Patients age ≥ 18 with breast, colorectal or non-small cell lung cancer initiating first cancer-directed therapy with NCCN-recommended regimens were eligible. The intervention consisted of automated PP-CSF orders for high FN risk chemotherapy regimens and an alert not to use PP-CSF for low FN risk regimens. Regimen FN risk was based on NCCN guidelines. Clinicians could override the orders. Primary and secondary outcomes were PP-CSF use among patients receiving high and low risk regimens FN incidence within 6 months of initial therapy. Sample size estimates assumed an FN risk of 25% for high-risk chemotherapy. 32 NCI Community Oncology Research Program (NCORP) practices randomized 3:1 to the order entry system (intervention) versus usual care (UC) provided 90% power to detect a 50% reduction in FN at a planned enrollment of 90 patients per site. Mixed effect logistic regression models were used to test differences among randomized sites. 13 practices with pre-existing PP-CSF order sets enrolled in a parallel cohort study. Patients and other stakeholder groups informed study design, conduct and reporting. **Results:** Between January 2016 and April 2020, 2,946 patients were randomized (2287 intervention, 659 UC); 718 were enrolled in the cohort. Mean age across arms was 58.1. 77% of patients were female; 61% diagnosed with breast cancer. Among patients receiving high-risk regimens, PP-CSF use did not differ between arms (89.2% intervention; 95.8% UC, adjusted $p = 0.21$) and was similar to the cohort patients (93.0%). The FN rate for high-risk patients was 5.7% in intervention clinics and 4.2% in UC clinics (adjusted $p = 0.26$); FN was 14.9% among high-risk patients who did not receive PP-CSF. Among patients receiving low-risk regimens, PP-CSF use did not differ between arms (intervention 6.3%, UC 5.5%, adjusted $p = 0.74$) and was slightly lower than the cohort (8.3%). FN rates did not differ between low risk groups (intervention 1.5%, UC 0.8%, adjusted $p = 0.51$). **Conclusions:** Guideline-informed standing orders did not increase PP-CSF use in high-risk patients, nor did it decrease use in low-risk patients. Adherence to guidelines in both risk groups exceeded historical reports. FN rates among patients not receiving PP-CSF were substantially below those reported in CSF guidelines. Automated standing orders for PP-CSF do not appear to be helpful or necessary. Clinical trial information: NCT02728596. Research Sponsor: PCORI, U.S. National Institutes of Health.

Breast cancer screening and diagnosis in a community health system during the COVID-19 pandemic.

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Background: Following the onset of the COVID-19 pandemic in March 2020, there was a drastic reduction in elective procedures, including screening mammograms. This was accompanied by a precipitous drop in the number of breast cancer diagnoses in 2020 compared with other years. The first aim of this study was to determine the extent of reduced mammogram screening during the first year of the COVID-19 pandemic. Secondary aims of this study were to determine the effect of reduced screening on breast cancer staging at initial diagnosis and to determine if there was a significant difference in screening patterns between rural and urban settings. **Methods:** This was a retrospective study. Mammogram data and cancer diagnosis data was collected from the time periods of March 2019 - Feb 2020 (Year 1) and March 2020 - Feb 2021 (Year 2). The patient data was selected from the Duluth/Essentia Cancer registry and through the Essentia Breast Imaging registry. Patient records were reviewed for cancer diagnosis and stage. Data on the number of mammograms performed was collected from Essentia sites across northern Minnesota that offer mammography services, including Duluth First Street, West Duluth, Virginia, and International Falls. **Results:** The demographics of patients diagnosed with breast cancer were similar between the two years. The total number of screening mammograms between March – May 2019 was 3,124. The total from March – May 2020 was 1,016, which is a reduction in the number of screenings of 2,108. Comparing June 2019 – Feb 2020, the total was 10,102, as compared to 10,459 in June 2020- Feb 2021, a total of 357 higher. This translates to a reduction of 1,751 screenings in Year 2 compared with Year 1. Between Year 1 and Year 2, we saw an increase in the proportion of stage III/IV breast cancers diagnosed, from 9.6% in Year 1 to 16.9% in Year 2, accompanied by a decrease in stage I/II cancers from 90.4% to 83.1% ($p = 0.06$). The total diagnoses between Year 1 and Year 2 also decreased from 211 to 185. We saw a significant decrease in the proportion and number of residents that were diagnosed via screening mammograms from urban settings during COVID, while rural patients had a significant increase in proportion and number. **Conclusions:** There was a remarkable reduction in the total number of screening mammograms and breast cancers diagnosed during the first year of the COVID-19 pandemic compared with the year prior. Patients were lost to screening, and potential diagnoses were not made. Those that did come in were more likely to present with an advanced stage cancer. Patients from rural settings were more likely than those from urban settings to be diagnosed via screening mammogram during COVID, but more investigation should be done to determine screening patterns among these populations. Providers should emphasize the importance of screening mammograms with patients and should be attentive to higher-staged cancers due to missed screenings. Research Sponsor: University of Minnesota Medical School.

Time on treatment is prolonged in patients utilizing an ePRO based digital symptom monitoring platform in the community setting.

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Background: Earlier and more effective management of cancer-related symptoms and treatment-related toxicities might improve the survival of patients receiving systemic anti-cancer therapy. One potential mechanism for improved outcomes could be prolonging time on therapy. We have previously reported on the successful real-world implementation of an electronic patient-reported outcomes (ePRO) tool in a community oncology practice. We now report on the impact of the tool on time on therapy for common anti-cancer treatments. **Methods:** We evaluated time on treatment across three community oncology practices that have implemented Expain, an EMR-integrated ePRO system which enables remote symptom monitoring during therapy. We compared drug-specific cohorts of patients that had been enrolled on the ePRO tool with a concurrent cohort of patients not enrolled on the ePRO platform. We examined time on treatment using a Kaplan Meier (KM) approach. Analysis was confined to patients with no prior administration of the parenteral therapeutic agent or a 90-day treatment-free washout period; and to patients with at least three months of potential follow-up. Analysis was only conducted for drugs with at least 80 patients in the Expain arm. **Results:** In each drug-specific cohort, the distribution of age, sex, and primary cancer diagnosis was similar in patients enrolled vs not enrolled on the ePRO (Mann-Whitney and Chi-square $p > 0.05$ except for the rituximab cohort which had more males in the ePRO cohort [67 vs 52%]). The impact of the ePRO-based symptom monitoring system on time on therapy was statistically significant for 5 agents. **Conclusions:** We confirm in the community setting the observation that digital symptom monitoring can increase time on therapy. We believe this is due to more effective management of treatment related toxicities, as well as more effective management of malignancy related or comorbid medical emergencies which might interrupt or lead to the discontinuation of therapy. We are evaluating the robustness of these results after using various methods to address any potential non-comparability of the cohorts. We are also examining the impact of prolonging time on treatment on survival. Research Sponsor: None.

Drug	ePRO (n)	Non-ePRO (n)	log-rank p value	% on therapy at 3 months (ePRO vs Non-ePRO)
bevacizumab	80	257	0.06	70.1 vs 57.4
carboplatin	254	616	0.02	49.1 vs 37.8
oxaliplatin	121	305	0.02	66.7 vs 52.1
pembrolizumab	117	357	< 0.01	79.5 vs 65.2
rituximab	112	472	< 0.01	65.9 vs 45.6

FDA analysis of expanded access use in pediatric patients from 2015 to 2020.

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Background: Expanded Access is a regulatory mechanism that enables patients with a life-threatening condition or serious disease to receive treatment with an investigational drug outside of a clinical trial when no comparable or satisfactory alternative options are available. FDA has decades of experience with expanded access, but little has been reported about its use in pediatric cancer patients. **Methods:** FDA's central electronic database was queried for single-patient investigational new drug (spIND) applications submitted to the Office of Oncologic Diseases between January 2015 through December 2020. Data collection included IND receipt date, IND type/status, drug name, and patient demographics. Duplicate or exempt INDs, those cancelled by the physician-sponsor before initiating therapy, and those requested for indications that occur almost exclusively in adults (e.g. lung cancer) or were missing patient age were excluded. **Results:** Of 2,901 unique spINDs granted, 534 (18%) were for patients less than 18 years of age. The pediatric population was 57% male, median age 6.0 years (range 0.1 to 17); race/ethnicity were reported in <1%. Patients were treated in 132 zip codes across 39 states; one-quarter of submissions were from 5 large academic hospitals. Central nervous system tumors were the most common indication (Table). A total of 98 unique drugs were requested, with 1 to 73 spINDs for each drug; approximately 50% were for tyrosine kinase inhibitors, 25% for other small molecules, and the remainder for immunotherapies and other drug types. Median time for FDA to grant was 1 day. Follow-up information was provided for 75% (annual report or withdrawal letter); 1/3 were withdrawn within 1 year. Over the last 2 years, utilization of the program increased by 120%. **Conclusions:** While approximately 1% of all cancers per year are diagnosed in children under 17 years of age, 18% of spINDs over the last five years were for pediatric patients. Although utilization of this program for children is robust, efforts are needed to assess its impact on patient outcomes and ensure its availability to patients, families, and institutions more widely. These data highlight interest within the pediatric oncology community in accessing innovative therapies, which supports early investigation of promising new drugs in children. Research Sponsor: None.

Tumor types for pediatric spINDs (n = 534).

Class	N (%)	Tumor Type (N)
Nervous System	229 (43)	High-Grade Glioma/Diffuse Intrinsic Pontine Glioma (59); Low-Grade Glioma (67); Embryonal/Other brain tumor (68); Plexiform neurofibroma (35)
Hematologic	102 (19)	Acute Lymphoblastic Leukemia (25); Acute Myeloid Leukemia (36); Lymphoma (9); Other (32)
Sarcoma	90 (17)	Osteosarcoma (58); Ewing (6); Rhabdomyosarcoma (7); Other (19)
Neuroendocrine	30 (6)	Neuroblastoma (28); Paraganglioma (1); Neuroendocrine carcinoma (1)
Liver	7 (1)	Hepatoblastoma (5); Hepatocellular carcinoma (1); Wilm's tumor (1)
Other	76 (14)	Multiple

Evaluation of outcomes in patients (pts) with stage 4 non-small cell lung cancer (NSCLC 4) harboring actionable oncogenic drivers (AOD) when treated prior to report of mutation without tyrosine kinase inhibitors (TKI): An Integra Connect Database (ICD) retrospective observational study.

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Background: In a prior analysis, we identified 525 pts with newly diagnosed NSCLC 4 harboring AOD in the ICD. Of these, 141 were treated prior to the reporting of AOD with chemotherapy (C), immune checkpoint inhibitor (ICI), or both. This report details the clinical outcomes of these 141 compared to the 384 treated after AOD reported. **Methods:** Real world data (RWD) were obtained from a curated ICD for pts with NSCLC 4 diagnosed 1/1/2018-12/31/2020 with cutoff of data 3/31/2021. Pts with EGFR, ALK, ROS1, BRAF, MET, RET, HER2, and NTRK were included if their treatment record were captured. Also included were demographics, ECOG score, date of first report of AOD and dates of initiations of first and any second line of therapy and date of apparent death (AD). Outcome measures were time to next treatment or apparent death (TTNT) and apparent survival (AS) (ICD model does not allow date of death per HIPAA de-identified Expert Determination). Descriptive statistics were used with Kaplan-Meier (K-M) estimates and Hazard Ratios (HR) by Cox regression. 3 cohorts were defined: Group (Gr) A with 384 pts treated after AOD reported and used as the comparator; the 141 pts treated before AOD with C, ICI or both were divided into Gr B (n = 51) who subsequently switched to TKI within 35 days and Gr C (n = 90) who did not switch. **Results:** As shown in data table, AS was significantly worse in Gr B and Gr C, TTNT was significantly worse in Gr C and with worsening trend in Gr B. Two potential confounders were identified: higher ECOG scores might indicate more urgency to assign treatment, but pts with ECOG ≥ 2 were similar in all 3 groups; also, difference in proportion of EGFRm by Group (Gr A 62%, Gr B 57%, and Gr C 29%), but separating cohorts by EGFR mutation status did not alter results. **Conclusions:** While subject to the limitations of a retrospective observational RWD study, this study strongly suggests outcomes are significantly compromised in pts harboring AOD but who are treated initially with C, ICI or both, even in pts quickly switched to TKI. Since a prospective clinical trial is not ethically feasible, these findings may stimulate review of current guidelines, fuel optimization of universal testing in NSCLC 4, and encourage utilization of liquid or ultra-fast NGS with their rapid turnaround times in order to improve survival in this setting. Research Sponsor: Thermo Fisher.

Cohort	n	ECOG ≥ 2	Median TTNT (range) in days	TTNT HR (p-value)	Median AS (range) in days	AS HR (p-value)	HR (p-value) adjusted for EGFR %
Group A	384	31%	706 (631-762)	-	Not reached	-	-
Group B	51	50%	656 (433-658)	1.35 (0.08)	672 (433-1010)	1.72 (0.008)	TTNT 1.32 (0.10); AS 1.69 (0.012)
Group C	90	29%	435 (350-560)	1.52 (0.002)	437 (358-580)	2.36 (< 0.0001)	TTNT 1.43 (0.009); AS 2.23 (< 0.0001)

Oncologists' perspectives on individualizing dose selection for patients with metastatic cancer.

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Background: The goal of treatment for patients with metastatic cancer (MC) is to prolong and maintain quality of life. Patients and oncologists have questioned the current paradigm of initial dose selection for systemic therapy and want additional information about the potential trade-offs between efficacy and toxicity. However, empirical data on oncologists' dose selection strategies and beliefs is lacking. **Methods:** ASCO conducted an international survey of medical oncologists who treat patients with metastatic breast or gastrointestinal cancers. Survey questions addressed experience with and attitudes towards reducing the standard dose of the first cycle of systemic therapy to minimize potential toxicity. The survey was open November 14 to December 13, 2021. **Results:** Among 3,099 eligible ASCO members, 367 completed the survey (response rate 12%), including 117 general oncologists (GO), 142 breast specialists (BRS), and 108 GI specialists (GIS). 77% of respondents practice in the US, 94% had experience leading a clinical trial, and 50% had been caregivers or patients themselves. Most respondents (52%) reported reducing the first dose of systemic agents at least 10% of the time in patients with MC to minimize toxicities. GIS were more likely to report reducing the first dose at least 10% of the time (72% vs. 50% of GO and 51% of BRS, $p < .005$). Of those who dose reduce, 89% reported discussing potential tradeoffs between efficacy and toxicity with patients. Among 10 common breast cancer drugs, capecitabine (76%) was the most likely to be dose reduced at initiation while tamoxifen (4%) was the least likely. Among 10 common GI cancer drugs, regorafenib (78%), capecitabine (71%) and sorafenib (66%) were most commonly dose reduced at initiation, while bevacizumab (7%) and panitumumab (8%) were the least likely. Overall, 65% of respondents agreed it is acceptable to lower starting doses to reduce side effects even at the potential expense of efficacy, with younger clinicians more likely to agree vs. older clinicians (72% age < 50 vs. 55% age > 50 , $p < .005$). While the majority (53%) believe that oncologists should start with the recommended dose and lower it in response to side effects, GIS were more likely to disagree with this approach compared to BRS or GO (57% vs. 37% and 36% respectively, $p < .005$). In contrast, 45% of respondents believe that oncologists should start at a lower dose and consider increasing the dose for future cycles if the drug is well tolerated. There was strong support (89%) for future trials that seek to determine the minimal effective dose as opposed to the maximum tolerated dose. **Conclusions:** Oncologists frequently dose reduce to avoid toxicity in patients with MC but practices and attitudes regarding dose reduction vary considerably. Further research is needed to establish optimal dosing during drug development and to support oncologists and patients in selecting the starting dose in clinical practice. Research Sponsor: American Society of Clinical Oncology.

Will COVID-19 directives to reduce regularly scheduled physical examinations affect recurrence detection in patients with early breast cancer?

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Background: The COVID-19 pandemic has significantly reduced routinely scheduled in person assessment and examination of early breast cancer patients (EBC). To assess if this is likely to impact the detection of recurrent disease, we reviewed recurrence patterns of EBC patients enrolled in a survivorship program that adheres to ASCO guidelines. **Methods:** Charts of EBC patients transferred through a single center Wellness Beyond Cancer Program (WBCP) and who subsequently had a breast cancer recurrence between February 1, 2013 and January 1, 2019 were reviewed. Patient, tumor and treatment characteristics were evaluated. **Results:** Of 206 patients eligible for the current study, 41 patients had ipsilateral breast recurrences (19.9%), 135 had distant recurrences (65.5%) and 30 had contralateral new breast cancers (14.6%). Ipsilateral breast recurrences were detected by the patient in 53.7% (22/41) and by routine imaging in 41.5% (17/21). The majority of distant recurrences (125/135, 92.6%) were detected via patient-reported symptoms. Contralateral breast primaries were detected by patients 16.7% (5/30) or by routine imaging (83.3%, 25/30). Only 2/206 (1.14%) recurrences/new primaries were detected by healthcare providers at routinely scheduled follow-up visits. There was a statistical difference in recurrence detection between image detected vs. self-detected in the following factors: grade 3 (26.5% vs 51%, $p < 0.007$), triple negative breast cancer (3.9% vs. 15.1%, $p = 0.03$), HER2 disease (18.4% vs. 9.8%, $p = 0.04$). **Conclusions:** Despite following ASCO follow-up guidelines for routinely scheduled follow-up appointments with physical examination, healthcare providers rarely detect recurrence disease. While reduced in person visits may affect other aspects of follow-up (e.g., toxicity management), it appears unlikely, provided patients attend regular screening tests, that reduced in-person follow-up is associated with worse breast cancer-related outcomes during the COVID-19 pandemic. Research Sponsor: None.

		Local	Distant	Contralateral
N		41	135	30
How was recurrence detected	N (%) Patient	22 (53.7)	125 (92.6)	5 (16.7)
	Imaging	17 (41.5)	9 (6.7)	25 (83.3)
	Health Care Provider	1 (2.4)	1 (0.7)	0
Most common sites of metastases	N (%) Bone	0	78 (57.8)	0
	Lung	0	9 (18.5)	0
	Liver	0	27 (20.0)	0
Most common symptoms	N (%) Bone Pain	0	44 (32.6)	1 (3.3)
	Respiratory Symptoms	0	27 (20)	0
	Abdominal Symptoms	0	22 (16.3)	0

Ancillary treatment referrals and visits after breast cancer surgery in a sociodemographically diverse population.

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Background: Ancillary therapies by rehabilitative, palliative, and survivorship specialists mitigate breast cancer surgery's physical and emotional effects. Existing data suggest that patients from disadvantaged backgrounds may be less likely to receive such care. We investigated provider referrals and patient visits at a high-volume urban cancer center to identify associated sociodemographic factors and characterize which populations may not be maximally benefiting from ancillary services. **Methods:** Data was culled from electronic health records of surgically-treated breast cancer patients at Yale-New Haven Health System between 2010-2017. Post-operative provider referrals to Physical/Occupational Therapy, Palliative Medicine, and Survivorship Program were evaluated for associations with demographic and disease variables in univariable and multivariable logistic regression analyses. Patient utilization of referrals, defined as attending at least one consultation, were analysed similarly. **Results:** Among 5,496 patients identified, 2,288 (41.6%) were referred for ancillary treatments and 1,572 (28.6%) attended at least one consultation. Provider referrals were highest among patients of Hispanic and Black ancestry (57.5% and 54.9%, respectively), no health insurance (57.6%), lowest percentage high school degree for zip code (50.5%), and lowest median income for zip code (50.7%). These associations remained significant in multivariable analysis [all $p < 0.050$]. In contrast, referral utilization was greatest among patients with private insurance (70.7%), highest percentage high school degree (72.8%), and highest median household income (72.2%), in addition to Hispanic ethnicity (73.5%). In multivariable analysis, highest median household income (OR 1.45, $p = 0.019$) and Hispanic ethnicity (OR 1.50, $p = 0.048$) remained associated. **Conclusions:** In a large urban health system serving a diverse population, traditional markers of poor healthcare access were positively associated with provider referral for ancillary services after breast cancer surgery. However, referral did not translate to utilization, suggesting that access remains a critical barrier to therapies that target post-operative morbidity and elevate quality of life. Research Sponsor: None.

Multivariable analysis of demographic factors associated with referrals and visits to ancillary services after breast cancer surgery.

VARIABLE	REFERRAL OR	REFERRAL P-value	VISIT OR	VISIT P-value
RACE	-	*0.001	-	0.167
White	Ref	Ref	Ref	Ref
Black	1.35	*0.011	1.30	0.131
Hispanic	1.53	*0.002	1.50	*0.048
INSURANCE	-	*0.020	-	0.933
None	Ref	Ref	Ref	Ref
Government	0.83	0.649	1.04	0.948
Private	0.65	0.298	0.99	0.978
MEDIAN HOUSEHOLD INCOME (USD)	-	*<0.001	-	0.138
<65,000	Ref	Ref	Ref	Ref
65,000-79,999	0.74	*0.001	1.20	0.205
80,000-99,999	0.65	*<0.001	1.24	0.169
≥100,000	0.80	*0.026	1.45	*0.019

*Indicates statistical significance.

CONTINUUM: A pilot care transition intervention for hospitalized patients with advanced cancer.

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Background: Patients with advanced cancer are frequently hospitalized and experience burdensome transitions of care after discharge. Interventions to address patients' symptoms, support medication management, and ensure continuity of care after discharge are lacking. We sought to demonstrate the feasibility and acceptability of CONTINUUM (CONTINUity of care Under Management by video visits) for this population. **Methods:** We conducted a single-arm pilot trial (n = 54) of CONTINUUM at Massachusetts General Hospital (MGH). The intervention consisted of a video visit with an oncology nurse practitioner (NP) within 3 business days of hospital discharge to address symptoms, medication management, hospitalization-related issues, and care coordination. Prior to discharge, we enrolled English-speaking adults with advanced breast, gastrointestinal, genitourinary, or thoracic cancers experiencing an unplanned hospitalization who were receiving ongoing oncology care at MGH and being discharged home without hospice services. We defined the intervention as feasible if $\geq 70\%$ of approached and eligible patients enrolled and if $\geq 70\%$ of enrolled patients completed the intervention within 3 business days of discharge. At 2 weeks after discharge, patients rated the ease of use of the video technology and stated whether they would recommend the intervention. NPs completed post-intervention surveys to assess fidelity to the intervention protocol. **Results:** From 01/07/21 to 05/28/21, we enrolled 54 patients (77.3% of patients approached). Of the enrolled patients (median age = 65.0 years; 59.3% and 22.2% had advanced gastrointestinal or thoracic cancers, respectively), 83.3% of enrolled patients received the intervention within 3 business days of discharge. Patient rating of the ease of use of video technology was a mean of 7.8 out of 10, with 71.4% stating they "agreed" or "strongly agreed" that they would recommend the intervention. NP post-intervention surveys revealed that visits focused on symptom management (85.7%), followed by addressing post-hospital care issues (69.0%). At 30 day follow up, 38.8% were readmitted within 30 days of discharge, and 12.2% died within 30 days of discharge. **Conclusions:** We found that CONTINUUM, which consists of an NP-delivered video visit soon after hospital discharge addressing patients' symptoms, medications, and care coordination, represents a feasible and acceptable approach to provide post-discharge care for hospitalized patients with advanced cancer. Future studies will test the efficacy of the intervention for reducing hospital readmissions. Clinical trial information: NCT04640714. Research Sponsor: Conquer Cancer Foundation of the American Society of Clinical Oncology.

Oncology hospital at home in rural communities: The Huntsman at Home rural experience.

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Background: Oncology hospital at home programs have shown promise in decreasing unplanned health care utilization while improving quality of life. While most hospital at home programs serve local urban areas, we extended our oncology hospital at home program, Huntsman at Home, to provide equitable distribution of program services for cancer patients living in rural communities at a distance from our cancer center. **Methods:** Utilizing a community engagement approach we redesigned our urban Huntsman at Home program for 3 rural communities in Southeastern Utah, a 2 to 5 hour one-way drive from Huntsman Cancer Institute. We systematically collected patient data and program modifications required for rural community delivery during the program's first 6 months. Care was delivered by on-ground and telehealth nurse practitioner visits and on-ground registered nurse and physical therapy visits. Cardiovascular remote monitoring was utilized during acute care episodes. **Results:** A total of 47 cancer patients (31 men; 16 women; mean age 69 years) were admitted to the rural program during the first 6 months. Seven patients had 9 acute illness episodes of care. The average length of acute episode care was 6.1 days for treatment of infection, respiratory distress/ hypoxia, cardiac instability (hypotension, tachycardia), and dehydration/electrolyte imbalance and uncontrolled vomiting. Forty patients received subacute management aimed to prevent acute episodes and escalation to the emergency department (ED) or hospitalization. Subacute patients were in the program an average of 15.8 days. There were 4 appropriate escalations (2 hospitalizations, 1 ED visit returned to home and 1 ED visit with hospitalization) for symptoms related to disease progression requiring imaging and hospital-based procedures and one for diagnosis of a post-surgical PE. We found geographic and social determinates of health impacted rural patients' cancer burden, most notably transportation barriers (44.7%). Secondly, we found food insecurity impacted nutritional status in 14.9% of patients. A significant number of patients experienced financial toxicity (29.8%) related to lost wages, co-pays and/or out of pocket expenses for care. Lack of health literacy impacted 48.9% of patients effectively navigating their health care and self-management at home. Robust communication and coordination between the hospital at home clinical team, local primary care providers, the rural hospital, community resources and the patients' cancer center oncology team were keys to improving care pathways. **Conclusions:** Rural oncology hospital at home is feasible and addresses geographic disparities in equitable access to acute and subacute cancer care in local communities. It requires adaptation to rural needs and culture, coordinated escalation procedures and a focus on addressing geographic and social determinates of health that impact cancer burden. Research Sponsor: Rita and Alex Hillman Foundation, Huntsman Cancer Foundation, Cambia Health Foundation.

The impact of an oncology-specific shared savings agreement.

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Background: In response to rising healthcare costs, several innovative payment strategies have emerged to improve the value and efficiency of healthcare spending. One of these strategies is a shift from volume-based to value-based care (VBC), resulting in the introduction of alternative payment models, innovative provider contracting and new value frameworks. The purpose of this study is to evaluate the impact of a VBC arrangement on total cost of care for chemotherapy patients, specifically cancer-related drug costs, daily hospital inpatient admissions and emergency room visits. **Methods:** This is a cohort study of chemotherapy patients, in a single state, enrolled in a large national insurer from January 18, 2021, to September 30, 2021. Oncology patients were divided into two groups; the study group consisted of chemotherapy patients receiving care in a VBC arrangement; the control group consisted of chemotherapy patients receiving care at oncology practices not engaged with the insurer in a VBC agreement. The following levers were employed to improve value: digital symptom tracking, biosimilar or lower-cost drug options and NCCN regimen concordance. We defined cancer-related drug costs as the sum of allowed costs paid for medical and pharmacy claims during the study period. Additionally, we averaged the cost per hospital inpatient day and emergency room visit and compared these by group. **Results:** This study included 1,574 patients, 733 patients in the study group and 841 in the control group. A reduction of 5.1% (a difference of \$441) in cancer-related drug costs per member per treatment month (PMPTM) was observed among patients in the study group. Patients in the study group reported 27.8% fewer inpatient days resulting in a savings of \$194 PMPTM. Similarly, patients in the study group reported 70.0% fewer emergency room visits resulting in a savings of \$59 PMPTM. **Conclusions:** In this study, chemotherapy patients participating in a shared savings VBC spent less on cancer-related drug costs, hospital inpatient days and emergency room visits through three value levers. Further studies are needed to assess if these results are similar all types of healthcare coverage and to what degree additional value levers further reduce costs. Additionally, the long-term health outcomes of these patients should be assessed. Research Sponsor: None.

Impact of cancer diagnosis, stage, and systemic therapies on immunogenicity after COVID-19 vaccination in patients with cancer: A systematic review and meta-analysis.

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Background: Patients (pts) with cancer are at increased risk of severe COVID-19. Both underlying malignancy and anti-cancer treatments influence the immune system, potentially impacting the level of vaccine protection achieved. **Methods:** A systematic literature search of PubMed, Embase, CENTRAL and conference proceedings (ASCO annual meetings and ESMO congress) up to 28/09/21, was conducted to identify studies reporting anti-SARS-CoV-2 spike protein immunoglobulin G seroconversion rates (SR) at any time point after complete COVID-19 immunization (mRNA- or adenoviral-based vaccines) in cancer pts. Complete immunization was defined as 1 dose of JNJ-78436735 vaccine or 2 doses of BNT162b2, mRNA-1273 or ChAdOx1 nCoV-19 vaccines. Subgroup analyses were performed to examine the impact of cancer diagnosis, disease stage, and anticancer therapies on the SR. Overall effects were pooled using random-effects models and reported as pooled SR with 95% confidence intervals (CI). **Results:** Of 1,548 identified records, 64 studies were included in this analysis reporting data from 10,511 subjects. The Table shows the SR in the overall population and specific subgroups. In pts with solid malignancies (SM), disease stage and primary site did not significantly impact the SR. In pts with hematologic malignancies (HM), SR were significantly lower in pts with chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphoma (NHL) compared to acute lymphoblastic leukemia (ALL), Hodgkin lymphoma (HL), and multiple myeloma (MM). Concerning the impact of cancer therapies on SR, pts with SM undergoing chemotherapy had numerically lower SR (N = 1,234, SR 87%, CI 81-92) compared to those treated with immune checkpoint inhibitors (N = 574, SR 94%, CI 88-97) or endocrine therapy (N = 326, SR 94%, CI 86-97) with or without another targeted therapy. Pts with HM treated with anti-CD20 therapy (within the last 12 months: N = 360, SR 7%, CI 2-20; or more than 12m: N = 175, SR 59%, CI 35-80), immune-modulating agents (BTK or BCL2 inhibitors) (N = 462, SR 47%, CI 32-64%) or other immunotherapies (anti-CD19/CART or anti-CD38) (N = 293, SR 37%, CI 23-53) had lower SR compared to pts treated with autologous (N = 353, SR 77%, CI 67-85) or allogenic stem cell transplantation (N = 509, SR 77%, CI 68-84). **Conclusions:** SR varies between cancer types and anticancer therapies with some cancer pts having low protection against COVID-19 even after complete vaccination. Research Sponsor: None.

Variable	Category	N of pts (N of studies)	Overall SR % (95% CI)	Hematologic SR % (95% CI)	Solid SR % (95% CI)
Overall		10,511 (64)	78 (73-82)	74 (68-80)	93 (91-95)
Stage	Non-metastatic	368 (7)			85 (77-91)
	Metastatic	1,084 (8)			88 (82-92)
Primary site (SM)	Non-lung	833 (7)			87 (84-89)
	Lung	180 (6)			88 (82-92)
Type of HM	ALL	37 (4)		67 (28-91)	
	CLL	1,462 (12)		45 (37-54)	
	HL	126 (6)		83 (31-98)	
	NHL	912 (9)		44 (30-58)	
	MM	1,235 (14)		80 (72-86)	

Characteristics associated with functional resilience versus functional decline among adult patients with advanced non–small cell lung cancer.

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Background: As more treatment options become available for advanced non-small cell lung cancer (NSCLC), oncologists still have difficulty predicting functional resiliency versus functional disability throughout treatment. Functional resiliency refers to the ability to recover baseline functional status in the face of an intervening health care event. This study aims to identify characteristics associated with resilience among adults with advanced NSCLC. **Methods:** In a prospective cohort of participants with newly diagnosed stage IV NSCLC, resilience was evaluated based on three functional disability items in the EQ-5D-5L (modified: mEQ-5D-5L) through 12 months of follow-up compared to baseline scores. This included patients treated with chemotherapy, immunotherapy, targeted agents and no treatment. Participants were classified into four groups: functional decline, maintenance, resilient, or variable. Resilience was determined based on improvement in disability scores, with a 1-point increase in functional status score representing a 0.5 standard deviation change on the mEQ-5D-5L. Patient characteristics included demographics, comorbidities, ECOG performance status, presence of brain or bone metastases, mood (GAD-7, PHQ-9), and lung cancer-specific symptoms (QLQ-LC13). Treatment toxicity and toxicity grades were also recorded. Differences between groups were determined through Fisher's exact test or ANOVA. **Results:** Among 207 participants, 87 (42.0%) maintained functional status, 78 (37.7%) experienced functional decline, 22 (10.6%) were classified as resilient and 20 (9.7%) were variable. Characteristics associated with higher resilience ($p < 0.1$) included being employed ($p = 0.02$) and living in a metro setting ($p = 0.10$). Characteristics not associated with resilience included age, education level, smoking status, presence of brain metastases, ECOG performance status, or psychological symptoms. Approximately half the participants ($n = 105$, 50.7%) who received treatment experienced toxicities. One third (33.8%) experienced \geq grade 3 toxicities. There was no significant association between toxicity grade and resilience grouping. **Conclusions:** Characteristics associated with functional resilience included employment status and living setting. At least half of adults with advanced NSCLC experience treatment-related toxicities. It is important to determine characteristics of resilience to better understand which patients will tolerate cancer treatments. Research Sponsor: None.

Impact of provider education on hepatitis B screening practices prior to patients receiving cancer treatment.

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Background: Hepatitis B virus (HBV) reactivation is a known side effect of CD20 targeted therapies with complications ranging from transient hepatitis to fulminant hepatic failure and death. In 2020 the American Society of Clinical Oncology (ASCO) expanded its provisional clinical opinion (PCO) to recommend HBV screening for all patients prior to receiving non-hormonal systemic anti-cancer therapies and if positive, offer viral prophylaxis or treatment. We assessed in a single-institution prospective study if a provider-led educational session on the 2020 ASCO PCO was effective in increasing HBV screening among patients receiving systemic non-hormonal anti-cancer therapies. **Methods:** An educational session for 30 minutes on the benefits outlined in the ASCO 2020 PCO discussing hepatitis B screening was held at a community-based hematology/oncology practice in Michigan. HBV screening panel was added to pre-chemotherapy lab order sets. Provider compliance with HBV screening recommendations was assessed monthly. Patients with positive HBV serology were identified and referred to Hepatology for monitoring and anti-viral treatment/prophylaxis as indicated. Data from 1,984 patient encounters for cancer treatment utilizing either chemotherapy or rituximab among 12 providers from March of 2020 to December 2021. Multivariate and logistic regression analysis was performed. **Results:** The educational intervention on the best practices of screening for Hepatitis B was effective in raising screening. Prior to intervention, 79.3% of all patients receiving rituximab (N = 140) and 15.7% of all patients receiving chemotherapy (N = 1277) had documentation for Hepatitis B before cancer treatment. Post-intervention hepatitis B testing increased both among patients receiving rituximab to 95.8% (N = 48) and chemotherapy to 29.9% (N = 519). In summary, prior to intervention, just 22.0% of 1,417 patient encounters had documentation for Hepatitis B screening before undergoing a treatment regimen. Post-intervention this level was raised to 35.45% (= 37.41,). In this study, 3 cases (0.5%) of acute and 12 cases (2.0%) of chronic HBV were identified from the 603 tested patients. A mixed effects logistic regression model controlling for treatment type and provider found patient encounters occurring post-intervention were 2.30 times more likely to be screened (OR = 2.30, 95% CI = [1.81, 2.93], $p < 0.001$). **Conclusions:** Our single educational session discussing the 2020 ASCO PCO and testing techniques for HBV was effective at increasing the odds of screening 2.3 times among patients receiving non-hormonal systemic anticancer therapies adjusting for therapy and provider. This may serve as a model for other implementations of PCOs. Further research will assess long-term oncologic outcomes of those identified with HBV and effects of anti-viral interventions. Research Sponsor: None.

Long COVID-19 in patients with cancer: Report from the National COVID Cohort Collaborative (N3C).

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Background: Post-acute sequelae of SARS-CoV-2 or long COVID, is characterized by persistence of symptoms and/or emergence of new symptoms post COVID-19 infection. As evidence accumulates and national initiatives arise to address this increasingly prevalent syndrome, characterization of specific patient groups is still lacking including patients with cancer. Using a nationally representative sample of over 4.3M COVID-19 patients from the National COVID Cohort Collaborative (N3C), we aim to describe characteristics of patients with cancer and long COVID. **Methods:** We employed two approaches to identify long COVID patients within N3C: i) patients presenting to a long COVID clinic at four N3C sites and ii) patients diagnosed using the recently introduced ICD-10 code: U09.9 Post COVID-19 condition, unspecified. We included patients with at least one positive COVID-19 diagnosis between 1/1/2020 and 2/3/2022. Patients had to survive at least 90 days from the date of their COVID-19 diagnosis. Analyses were performed in the N3C Data Enclave on the Palantir platform. **Results:** A total of 1700 adult patients with long COVID were identified from the N3C cohort; 634 (37.3%) were cancer patients and 1066 were non-cancer controls. The most common represented cancers were skin (21.9%), breast (17.7%), prostate (8.3%), lymphoma (8.0%) and leukemia (5.7%). Median age of long-COVID cancer patients was 64 years (Interquartile Range: 54-72), 48.6% were 65 years or older, 60.4% females, 76.8% non-Hispanic White, 12.3% were Black, and 3% Hispanic. A total of 41.1% were current or former smokers, 27.7% had an adjusted Charlson Comorbidity Index score of 0, 18.6% score of 1 and 11.2% score of 2. A total of 57.2% were hospitalized for their initial COVID-19 infection, the average length of stay in the hospital was 9.6 days (SD: 16.7 days), 9.1% required invasive ventilation, and 13% had acute kidney injury during hospitalization. The most common diagnosis among the non-cancer long COVID patients was asthma (26%), diabetes (17%), chronic kidney disease (12%), heart failure (9.4%), and chronic obstructive pulmonary disease (7.8%). Among long COVID patients, compared to non-cancer controls, cancer patients were more likely to be older (OR = 2.4, 95%CI: 1.1-5.4, $p = 0.03$), have comorbidities (OR = 4.3, 95%CI: 2.9-6.2, $p < 0.0001$), and to be hospitalized for COVID-19 (OR = 1.3, 95%CI: 1.0-1.7, $p = 0.05$), adjusting for sex, race/ethnicity, body mass index and smoking history. **Conclusions:** In a nationally representative sample of long COVID patients, there was a relative overrepresentation of patients with cancer. Compared to non-cancer controls, cancer patients were older, more likely to have more comorbidities and to be hospitalized for COVID-19 warranting further investigation to identify risk factors for long COVID in patients with cancer. Research Sponsor: U.S. National Institutes of Health.

1541

Poster Session

Enabling community-led integrated women health care models for women cancers screening and early detection through EMPOWER (Enabling and Motivating Partnerships Owned by Women who Engage and Reclaim their lives) project.

Dorothy Ogada Nyongo, Jacqueline Wambua; County first ladies association, Nairobi, Kenya; PO BOX 44212, Nairobi, Kenya

Background: With the growing burden of Women cancers in East Africa, integrating cancer screening and prevention to optimize horizontal care delivery models is a paramount approach to strengthening women-centered and cost-effective primary healthcare. EMPOWER is a unique partnership with the government of Kenya, County referral hospitals, County First Ladies Association, International Cancer Institute, Patient organizations and Roche Kenya to demonstrate integrated cancer prevention and treatment within primary healthcare shared across the Kenyan Health system. **Methods:** EMPOWER clinics were launched with over 300 community health workers (including women living with disabilities) and HCPs were identified and trained to provide facility and community-based screening and early detection for breast cancer, cervical cancer, hypertension and diabetes through an integrated health systems strengthening approach. Mentorship was provided to HCPs through routinely held joint screenings and clinics, weekly Tumor Boards, Teleclinics, Telemedicine and Digital Pathology platforms. In addition, training support was provided through virtual preceptorships, skills-training workshops, hub-and-spoke oncological services provision and robust patient navigation. **Results:** 14 EMPOWER clinics have been launched across Kenya to increase community awareness of breast, cervical, and NCDs, strengthen capacity to deliver integrated Women cancer management services in County health clinics. In Kenya out of 25,502 people screened, 13,192 were screened for breast cancer with 97 abnormal findings identified; 10,349 screened for cervical cancer with 200 abnormal cervical screenings identified and 1,664 screened for prostate cancer with 32 abnormal findings. In addition, an integrated approach in Non Communicable Disease (NCD) care, diabetes and hypertension screening; 4,298 screened for diabetes and 6,116 screened for hypertension. All those diagnosed with cancers were linked to existing cancer care delivery systems and continuous support offered through the strengthened health care systems. Prostate cancer was added as more men turned up for screening events. **Conclusions:** This model is replicable and scalable across LMIC and recently the model inspired health providers' from Tanzania and Nigeria to adopt the same for women's cancers. EMPOWER has demonstrated a scalable care model in Kenya contributing to investments in pathology training and clinical treatment to improve challenges in referrals and updating guidelines to enable multi-disease tissue testing and handling and treatment with Standard of Care. Research Sponsor: Public Private Partnership.

Does the 4R oncology model improve clinicians' effectiveness in patient-facing planning of complex cancer care?

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Background: The 4R Oncology model was proposed within the NCI ASCO Teams Project as an approach to facilitate patient-facing care planning, team-based delivery and patient self-management. 4R (Right Info/Care/Patient/Time) enables care teams and patients to manage complex care with a novel 4R Care Sequence plan. We previously reported that 4R significantly improved patient self-management, namely patients' ability to organize and manage their care (Trosman JCO OP 2021). Here we report the impact of 4R on effectiveness of clinicians to plan and deliver complex multidisciplinary care.

Methods: We surveyed clinicians (physicians and nurses) from 8 cancer centers (4 academic, 4 community) participating in a 4R adoption program. The survey was conducted Mar 2019 to Sep 2019 prior to 4R launch (Baseline cohort), and Nov 2021 to Jan 2022 post-4R launch (4R cohort). Baseline cohort included clinicians conducting care planning with patients. 4R cohort included clinicians who used 4R in care planning with new patients. The survey focused on clinicians' self-reported effectiveness in planning and management of guideline-based care. Descriptive statistics and Fisher's 2-sided test were used in analyses. **Results:** Baseline cohort's response rate was 79% (66/83); 4R cohort's response rate was 86% (62/72). 4R implementation was associated with significant improvement in all 5 metrics of effective care planning between the baseline and 4R cohorts (Table). Within the 4R cohort, 87% (54/62) clinicians found 4R Care Sequences useful or very useful for care planning and management. The majority, 79% (49/62), spent 10 minutes or less on average developing and administering 4R Care Sequence to a new patient, and 58% (36/62) reported decreased overall volume of post-visit inquiries about care plan from patients who received 4R. When asked about 4R delivery format, 65% (40/62) preferred paper, 23% (14/62) electronic delivery and 12% (8/62) had no preference. **Conclusions:** The 4R Oncology model is a promising approach to improving clinicians' effectiveness in patient-facing care planning and reducing the workload associated with patient inquiries. An ongoing 4R research and implementation program continues efforts to identify optimal implementation methods and integrate 4R into clinical practice across the U.S. Research Sponsor: The Coleman Foundation.

	Baseline cohort, n = 66 %	4R cohort, n = 62, %	P value
I am satisfied with ability to create and provide patients with individualized cancer care plans	50%	90%	< 0.0001
I am able to include multiple aspects of comprehensive care in a care plan (surgery, systemic therapy, radiation, supportive care, health maintenance, etc.)	41%	66%	0.005
I am able to effectively discuss a comprehensive care plan with new patients	22%	77%	< 0.0001
My patients can effectively manage their care across specialties	32%	61%	0.001
My practice effectively enables patients to manage their care across specialties	49%	88%	< 0.0001

Demographic and laboratory determinants of humoral immune responses and impact of different anti-SARS-CoV-2 vaccine platforms in patients with cancer: A systematic review and meta-analysis.

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Background: Patients (pts) with cancer have increased mortality from COVID-19 and their vaccination is crucial to prevent severe infection. We aimed to identify demographic and laboratory determinants of humoral immune responses to COVID-19 vaccination in pts with cancer and investigate differences in responses based on the vaccine platform. **Methods:** We searched for records in PubMed, Embase, and CENTRAL up to 28/09/21, as well as conference proceedings from ASCO and ESMO 2021. We included studies of pts ≥ 16 yr with a cancer diagnosis, who were vaccinated against SARS-CoV-2. Studies were excluded if $\geq 10\%$ of the participants had other causes of immunosuppression or baseline anti-SARS-CoV-2 spike protein antibodies (Ab)/previous COVID-19 (PROSPERO ID: CRD42021282338). For this subgroup analysis of studies that reported a proportion of pts with cancer and positive Ab titers at any timepoint following complete vaccination, a random-effects model was used to estimate the humoral response rate (HRR) with 95% confidence intervals (CI). **Results:** We included 64 records, reporting data from 10,511 cancer pts. The HRR in the overall population and by subgroup are shown in Table. Elder patients with hematologic cancers (59%, CI 47-70%, N = 667) and patients with lymphopenia (50%, CI 25-75%, N = 111) or hypogammaglobulinemia (36%, CI 19-57%, N=226) were the subgroups with lower HRR. Male (77%, CI 69-84%, N = 2,659) and Asian (84%, CI 54-96%, N = 37) pts showed a trend to lower HRR when compared with females and other races, respectively. Pts vaccinated with mRNA vaccine platforms (79%, CI 74-83%, N = 9,404) had numerically higher HRR than those receiving the adenovirus vaccines (28%, CI 19-40%, N = 74). **Conclusions:** This study highlights demographic and laboratory determinants of weaker immune responses to SARS-CoV-2 vaccination, permitting better identification of more vulnerable pts. Despite the small number of pts included receiving adenovirus vaccines, these data also suggest prioritizing mRNA platform vaccination in pts with cancer. Research Sponsor: None.

Proportion of pts with anti-SARS-CoV-2 spike protein Ab.				
Determinant	Subgroups (N of studies; pts)	Overall % (95% CI)	Solid cancers % (95% CI)	Hematologic cancers % (95% CI)
Overall	(64; 10,511)	78 (73-82)	95 (89-95)	64 (58-69)
Age	Younger (13; 1,240) vs Elder (13; 1,127)	79 (67-88) vs 71 (57-82)	93 (85-97) vs 93 (85-97)	71 (58-80) vs 59 (47-70)
Sex	Female (26; 2,840) vs Male (25; 2,659)	81 (73-87) vs 77 (69-84)	89 (84-93) vs 89 (84-93)	66 (55-75) vs 61 (51-69)
Race	White (4; 1,675) vs Black (4; 83) vs Asian (3; 37) vs 84 (54-96)	91 (81-96) vs 91 (75-97) vs 84 (54-96)		
Lymphocytes	Lymphopenia (3; 111) vs No lymphopenia (3; 369)	50 (25-75) vs 81 (60-93)		
Gammaglobulins	Hypogamma (4; 262) vs Non-hypogamma (4; 520)	36 (19-57) vs 66 (46-81)		
Vaccine platform	mRNA (59; 9,404) vs Adenovirus (4; 74)	79 (74-83) vs 28 (19-40)		

Analysis of the likelihood of depression versus distress screening to identify need for intervention.

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Background: Psychosocial assessments are increasingly used to evaluate a patient-centered approach to quality cancer care delivery. Value-based oncology programs endorse screening metrics at every encounter. To comply with expectations of these programs, our cancer center utilizes two standardized tools: Patient Health Questionnaire (PHQ) to screen for depression at every encounter; National Comprehensive Cancer Network Distress Thermometer (NCCNDT) to screen for acute distress at clinically meaningful intervals. In 2021, oncology patients completed, on average, 5 annual appointments at Sidney Kimmel Cancer Center (SKCC), with a median appointment frequency of once every 19 days. Given the high encounter-per-patient ratio, we aimed to assess utility of frequent screening leading to supportive intervention. **Methods:** A retrospective analysis was conducted of medical oncology patients seeking care at SKCC with a completed depression and/or distress screening, as recorded in the patient's electronic health record, between 1/1/2021 and 12/31/2021. This analysis intended to evaluate the percentage of patients whose scores indicate need for intervention. Patients who received more than one screening were attributed the highest score recorded during the measurement period. **Results:** A total 13,342 patients were screened at least once for either depression (n = 7,433), distress (n = 1,325), or both (n = 4,584). 3% of all patients screened ever met the intervention threshold (IT) for depression; 33% met the IT for distress. Of the patients who received both types of screenings, 31% met the IT for distress without meeting the threshold for depression. Those 1,418 patients would not have been referred for intervention through depression screening alone. **Conclusions:** This analysis highlights routine depression screening among a cancer population with a high encounter-per-patient ratio may not be sensitive in identifying need for supportive intervention. It also suggests that distress screening is more likely to lead to a supportive intervention than depression screening alone. This analysis combined with the anecdotal assessment by social workers supports the value of distress at clinically meaningful intervals over depression screening at each encounter. Research Sponsor: None.

Depression versus distress screening results.		Depression	
		Below IT (<10)	Meets IT (>=10)
Distress	Meets IT (>=4)	1418 (31%)	145 (3%)
	Below IT (<4)	2964 (65%)	57 (1%)

Impact of proactive symptom monitoring on quality of life (QoL) and treatment toxicity in patients with cancer receiving chemotherapy: A meta-analysis of randomized clinical trials.

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Background: Early recognition and management of symptoms can improve outcomes in cancer patients receiving treatment. A number of randomized trials have investigated the effects of adding proactive symptom monitoring to usual care (UC). These include web-based, application-based, or telephone-based assessments. Results have been variable, and the impact of proactive symptom monitoring on QoL, treatment toxicity and utilization of unscheduled acute care remains unclear. **Methods:** A systematic search of MEDLINE identified prospective, randomized trials that studied the effect of proactive monitoring and intervention versus UC in cancer patients receiving chemotherapy. The difference between proactive symptom monitoring and UC on the mean and SD for QoL using validated scales was collected for each study and pooled in a meta-analysis. Analysis was performed using the standardized mean difference (SMD) using random-effects modeling. The effect size was reported as the Hedges' adjusted g. We also calculated the odds ratios (OR) for the occurrence of several common symptoms of any grade in the individual trials and pooled them in a meta-analysis. Statistical significance was defined as $P < 0.05$. Quantitative significance was defined as a difference in QoL score exceeding the minimal clinically important difference (MCID) based on previous studies for each QoL framework. **Results:** Of the 17 trials which met eligibility criteria, FACT-G and EORTC QLQ C30 were the most consistently utilized QoL tools. The mean difference in score between intervention and control at the last evaluation visits was 2.82 (95% CI -0.57 to 6.21; $P = 0.10$) in FACT-G and 2.33 (95% CI -0.29 to 4.96; $P = 0.08$) in EORTC QLQ C30, neither of which met quantitative or statistical significance. There was a statistically significant reduction in fatigue (OR 0.67, 95% CI 0.46 to 0.97; $P = 0.04$), but no difference in constipation (OR 0.63, 95% CI 0.34 to 1.17; $P = 0.15$), nausea (OR 1.03, 95% CI 0.72 to 1.47; $P = 0.89$), pain (OR 0.83, 95% CI 0.62 to 1.10; $P = 0.19$), or diarrhea (OR 1.41, 95% CI 0.40 to 5.01; $P = 0.60$). SMD for symptom severity was calculated for fatigue, diarrhea, and nausea. Severity of fatigue was statistically lower with proactive symptom monitoring (SMD -0.45, 95% CI -0.69 to -0.22; $I^2 = 0\%$, $P < 0.001$), however, magnitude of effect was modest. **Conclusions:** Proactive symptom monitoring in cancer patients receiving treatment is not associated with significant or meaningful QoL improvement. Similarly, there is limited impact on individual toxicity. Research Sponsor: None.

Cancer health disparities in the state of Georgia: African American oncology care.

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Background: Approximately 58,970 new cancer diagnoses are projected for 2022 in Georgia (GA), contributing to 18,750 deaths. African Americans (AA) make up about one-third of Georgia's population compared to 14% of the national population. Cancer survival rates are lower for AA than non-AA for almost all cancer types. Biological factors do not account for all these differences. We explore the impact of racial disparities on cancer care in Georgia. **Methods:** We used 2020 behavioral risk factor surveillance system (BRFSS) data to capture patient-reported data on various demographic and health coverage variables. Oncology patients in the state of Georgia were selected for our analysis. We evaluated the effect of racial disparities on clinical services received. **Results:** In the state of GA, 9,090 participants responded to the 2020-BRFSS, of which 400 participants had a history of cancer diagnosis other than skin cancer. Males and females comprised 37% and 63%, respectively. AA represented 15.8% of the respondents. The majority of the oncology respondents reported having health care coverage (96%) and having insurance coverage for all cancer treatments (96.8%) despite having 81.9% of the participants unemployed. Compared to non-AA, AA participants reported lower rates of health insurance payment for cancer treatment (84% v 99.3%, $P = 0.0022$) and lower levels of annual incomes (percentage of annual income <50,000\$/year was 72.3% vs 51.5%, $P = 0.0151$). AA participants were four times less likely to have full coverage for cancer-related treatment than non-AA (odds ratio=4.31). There was no statistically significant difference in secondary education rates, health care coverage, the inability to see a physician due to cost, receipt of summary of treatment or written instructions, denial of insurance coverage due to cancer, and clinical trial participation. Participants with at least secondary education were more likely to have full insurance coverage for all cancer treatment expenses ($P = 0.0206$). **Conclusions:** Among cancer patients in Georgia, income rates were lower in AA than in non-AA. They were also less likely to have full coverage for cancer-related treatment. Analysis suggests secondary education increases the likelihood of having full insurance coverage. Education and income disparity may have a bearing on the accessibility and quality of cancer care. Addressing these inequities on a societal level will be key in ensuring high-quality oncology care for all. Research Sponsor: None.

Differences in socioeconomic and health coverage for AA and non-AA respondents to the 2020 BRFSS survey: State of Georgia.				
	Factor	African American (%)	Non-African American (%)	P-value
Health care coverage	Yes	95.2	96.1	0.7012
	No	4.8	3.2	
Participated in cancer clinical trial	Yes	0	6.1	0.2411
	No	100	93.9	
Health insurance paid for all cancer treatment	Yes	84	99.3	0.0022
	No	16	0.7	
Annual income	Less than 25k	40.4	23.3	0.0151
	25 – 50 k	31.9	28.5	
	More than 50 k	27.7	48.1	

Machine learning (ML)-enabled, circulating tumor cell-based classification of patients for non-prerequisite adjuvant therapy.

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Background: Oncology implicates highest precision using next generation diagnostics and progressive therapies assisted by predictive tools. If validated clinically, machine learning (ML) can provide better insights in precision oncology. Furthermore, it longitudinally may stratify the progression of cancer disease burden in a real time. We have developed, Circulating Tumor Cells (CTCs) driven ML model as a predictor for the treatment decision strategy for both surgery and adjuvant therapy in head and neck squamous cell carcinoma (HNSCC) patients. **Methods:** In this study, a total of 380 HNSCC patients who underwent either surgery alone or surgery plus adjuvant therapy were accounted for. CTCs in patients were stratified based on clinicopathological parameters and using OncoDiscover platform having anti EpCAM antibody system regulated by the Drug Controller of India. Following this, we explored the predictive performance of the ML model on the usefulness of adjuvant therapy in HNSCC patients after the surgery. The available data was randomly divided into two subsets. First, 75%, of the original data was applied for Training the ML, and rest 25% of the data was used as a Test set. Survival curves were generated by Kaplan–Meier method and calculated through the Log rank test. **Results:** XGBoost machine learning classifier was superior to Random Forest and SVM-based analyses in predicting the usefulness of adjuvant therapy post-surgery using CTC alone or in combination with other clinical parameters in HNSCC patients. Machine learning algorithms were compared for predicting the accuracy of patients stratification. The results for each model were: XGBoost model (Accuracy = 0.84, ROC value = 0.73, Kappa = 0.43); Random Forest model (Accuracy = 0.81 ROC value = 0.70, Kappa = 0.41); SVM model (Accuracy = 0.76, ROC value = 0.69, Kappa = 0.40). The ROC value of the XGBoost model was highest (0.73) while the ROC value for the SVM model was lower (0.69). We observed that when CTCs were combined with clinicopathological parameters, the accuracy, kappa values and AUC-ROC drastically improved in predicting the usefulness of adjuvant therapy post-surgery. A similar trend was observed when CTCs were combined with clinicopathological parameters in predicting the line of chemotherapy, post-surgery. **Conclusions:** ML-enabled, CTCs driven predictions can be highly accurate and ascertain the patient treatments. CTCs can be a positive predictor for selecting patient's treatment regimen in both surgery as well in type of treatment (e.g. surgery alone or surgery + adjuvant therapy). It can also implicate to classify the patients and determine who necessitates an additional adjuvant therapy. Further investigations in this direction are necessary to predict the treatment options based on ML that may improve the overall survival of cancer patients. Research Sponsor: iNDX.Ai.

Applicability of a web app for lung cancer risk calculation and personalized recommendations for screening in Mexico.

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Background: Lung cancer screening continues to be an area of great opportunity in public health, especially in developing countries. In Mexico, about 10,000 new cases of lung cancer are detected annually, of which less than 5% are diagnosed in early stages. There are no national programs for timely detection of lung cancer in our country, so it is essential to seek accessible measures to prioritize resources for high-risk people. **Methods:** We developed a web app that consisted of a short survey to stratify patients according to their risk of lung cancer (https://cuccuanl.com/tamiz_pulmon/). The questions were based on Nelson's criteria to categorize high-risk subjects who are deemed candidates for screening. The program contained automated logic programmed using JavaScript to guide people to the low or high-risk page if they met standard risk criteria in those age 50 and older. The high-risk page alerted people of their risk, displaying general information about lung cancer as well as contact information to make an appointment at our cancer center. An appointment could be also scheduled within the app if the person so wished. The web app was launched and distributed through social media. **Results:** After a period of 2 months, 939 people completed the survey. The median age of the responders was 40 years, and 61% were men. Of the total, 185 participants were 50 years of age or older. 268 people (29% of the total) were sent to the high-risk page, including persons under 50 years of age with symptoms highly suggestive of lung cancer. According to their smoking status, 80% of the subjects reported active smoking, while 9% reported heavy smoking, considered as more than 20 pack-years. Among all the people evaluated, 44 high-risk subjects scheduled a specialized medical appointment within the web app. **Conclusions:** This pilot study showed a high response of Mexican population seeking lung cancer risk evaluation, especially among the persons who smoke regularly. The use of web apps can result in mass diffusion which will help reach people with less medical access, a common scenario in many developing countries. Further analysis should be made to measure the real impact on lung cancer diagnosis and oncological outcomes. Our study shows how effective social media is as a means of diffusion on health topics. Research Sponsor: None.

Patients with high-risk features (n = 268)		Percent	Absolute #
Suggestive symptoms (all ages)		81%	218
Suggestive symptoms (≥50 years)		15%	41
≥20 pack years + ≥50 years		13%	35
Presence of EPOC		1%	2
Radon Exposure		0%	0
Laboral exposure to contaminated air		9%	25
≥100 wood smoke years		0%	0
Tobacco smoking status		Absolute #	Percent
<50 years old n = 754	Have never smoked	148	20%
	<20 pack-years	555	74%
	≥20 pack-years	51	7%
≥50 years old n = 185	Have never smoked	40	22%
	<20 pack-years	110	59%
	≥20 pack-years	35	19%

*None of the surveyed with ≥20 pack years had abandoned smoking for ≥20 years.

Development of an electronic health record registry to facilitate collection of Commission on Cancer (CoC) metrics for patients undergoing surgery for breast cancer.

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Background: Accurate and efficient data collection is a challenge for quality improvement initiatives and clinical research. We describe the development of a custom electronic health record (EHR) based registry to automatically extract structured Commission on Cancer (CoC) axillary surgery specific metrics from a custom synoptic note template included in the operative reports for breast cancer patients undergoing surgery. **Methods:** The "Smart" functionality of our enterprise-based EHR system was leveraged to create a custom Smart phrase to capture axillary surgery specific variables. A multidisciplinary team developed structured data elements correlating to each axillary surgery-specific variable. These data elements were then included in a note template for the operative report. Each variable could be aggregated and converted into a single flat database through the EHR's reporting workbench and serve as a live, prospective registry for all users within the EHR. **Results:** The final axillary surgery-specific note template in a synoptic format allowed for efficient and easy entry and automatic collection of breast cancer specific metrics. From initial adoption in February 2021 through December 2021, there were 1,254 patients who underwent breast surgery with axillary surgery. The operative notes allowed for automatic capture of metrics from 60.5% (n = 759) of patients. Data capture improved from 37.6% in the initial adoption period of six months to 86.2% in the last five months. Capture rate in December 2021 was 98%. **Conclusions:** We were able to demonstrate successful implementation of provider driven structured data entry into EHR systems that permits automatic data capture. The end result is a custom synoptic note template and a real-time, prospective registry of breast cancer-specific CoC metrics that are robust enough to use for quality improvement initiatives and clinical research. Research Sponsor: None.

Using machine learning on real-world data to predict metastatic status.

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Background: Real world data (RWD) is increasingly used to inform research, patient care, and population health in oncology; however, using RWD at scale requires accurate methods to identify clinically-relevant attributes. Metastatic status is a highly relevant clinical attribute in cancer patients but it is not routinely captured in structured formats and its determination conventionally requires review and interpretation by certified tumor registrars (CTRs). Clinical diagnoses, treatments, imaging procedures and other clinical variables documented in electronic health records (EHRs) can be used to differentiate metastatic from non-metastatic patients. This study describes an effective machine learning approach in utilizing prevalent and standardized data elements from EHRs across multiple health systems. **Methods:** 28,043 lung cancer and breast cancer patients from two large health systems within the Syapse Learning Health Network with data sources from CTR abstraction and EHRs were analyzed. Patients were labeled for reference metastatic status by CTRs and split into training (n = 22,434) and testing (n = 5,609) cohorts, with proportionate distribution of cancer type and metastatic status between cohorts. A regularized gradient boosting algorithm, XGBoost, was trained using over 750 variables from the patient records collected at the time of or after the initial cancer diagnosis. **Results:** Integration of ICD-10-CM codes with antineoplastic treatment history and radiologic imaging procedure orders achieved metastatic status prediction with increases to precision and recall in lung cancer (21% and 32% respectively) and breast cancer (39% and 9% respectively), when compared to the use of only ICD-10-CM diagnosis codes for secondary malignant neoplasms (Table). The addition of treatment and procedure data from different cancer types improved the model classification within individual cancer types. **Conclusions:** One of the biggest challenges in using RWD for precision oncology is identification of clinically-relevant phenotypes at scale. Here we demonstrate a scalable evidence-based method utilizing structured data for imputing metastatic status with high predictive power from two separate health systems. With further validation, this approach may be generalized to other cancer types, applied to temporal slices of data to identify changes in metastatic status, as well as provide a high-confidence designation of metastatic status for other use cases such as staging. Research Sponsor: None.

Model performance metrics.		
	Precision	Recall
Lung and bronchus (ICD-10-CM only)	0.67	0.50
Lung and bronchus (Predictive model)	0.88	0.82
Breast (ICD-10-CM only)	0.56	0.82
Breast (Predictive model)	0.95	0.91

Performance of an artificial intelligence-based annotation algorithm for reporting cancer genomic profiling tests.

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Background: Cancer genomic profiling (CGP) tests have been approved in Japan since June 2019, with the requisite that all test results be discussed by molecular tumor boards (MTBs). More than 20,000 patients in over 200 designated hospitals have taken CGP tests by December 2021. As CGP tests have entered clinical practice, streamlining decision making by MTBs and standardizing interpretation of test results and treatment recommendations have become urgent issues. Here, we evaluated the utility of Chrovis, an annotation algorithm for reporting CGP tests to support MTBs make their recommendations. **Methods:** We retrospectively reviewed the reporting process of all approved CGP tests done at The University of Tokyo Hospital between December 2019 and November 2021. Chrovis provided annotation for each genetic variant by incorporating biologic, clinical, and therapeutic information by referencing several public knowledge databases and using natural language processing, and generated reports using the automated program. The MTB reviewed and made any necessary changes before finalizing the report. Changes in disclosure of germline findings were made according to the recommendations of a national guideline with consideration of past and family history. **Results:** Of the 243 tests, 91 changes in 81 Chrovis reports (33% of all reports) were made by the MTB. The most common type of change was germline disclosure with 26 changes (29%), followed by clinical trial information in Japan (18 changes, 20%) and recommendation of the patient-proposed national basket trial with multiple targeted agents (17 changes, 19%). Changes in germline disclosure increased from June 2021, when an update to a national guideline was released, while the proportion of changes in the latter two types remained unchanged. Gene alterations that led to the highest number of changes was *TP53*, with 13 changes. Changes in therapeutic recommendations were frequently observed in the RAS/MAPK pathway (*BRAF*, *KRAS*, *NF1*, *NRAS*) with 12 changes. More changes were required with a tumor-only tissue CGP panel (57 of 149) compared with a matched tumor/normal tissue CGP panel (24 of 94, $p = 0.04$), mostly due to germline disclosure (24 vs. 2 changes). **Conclusions:** We observed that automated algorithm-based reporting was sufficient in 67% of reports. Recommendation for germline disclosure still requires manual supervision, particularly with tumor-only tissue CGP panels if algorithms do not incorporate medical history. The process of recommending clinical trials needs improvement, e.g., standardizing database formats for inclusion and exclusion criteria. Research Sponsor: Xcoo, Inc.

Can an artificial intelligence-based platform reduce physician burden and increase access to clinical trials?

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Background: Clinical trials for cancer patients are an important treatment option and a resource for drug development. Although patients are more actively searching for treatment options through various approaches, the national average of cancer patients accrued to clinical trials remains static at only 2-4%. The most widely recognized resource is clinicaltrials.gov, which does not offer direct trial matching, is geared toward healthcare professionals and uses complex medical terms that are challenging for many patients. For clinicians, the absence of real-time access and insight into all relevant oncology trials, forms a burden on their already-limited time. Alleviating this burden could reduce barriers to clinical trial accrual. **Methods:** Using AI and an unsupervised natural language process approach, the Trialjectory platform monitors, analyzes and matches patients to clinical trials. Matching is achieved by patient response to a dynamic set of questions curated based on the eligibility criteria of available trials. The online questionnaire (www.trialjectory.com) collects detailed clinical data that include disease characteristics (histological, molecular and mutational status), treatment history, general health and comorbidities. All collected data points are incorporated into the matching process, yielding a high-quality actionable matched-trial list. A skilled support team is available to answer questions and concerns via email, text or phone calls. The platform enables patients to share the matched trial list with their oncologist for discussion. **Results:** from July 2019 - December 2021, 49,906 cancer patients completed Trialjectory's questionnaire. Patient accrual grew rapidly since the second half of 2019 with 1462, 2201, 9364, 12685, and 24194 new questionnaire completions in each consecutive 6-month period from the 2nd half of 2019 through December 2021. 49,199 (98.6%) of registered patients were found eligible for available trials. Of the matched patients, 4428 patients (9%) applied to a clinical trial. Our matching engine identifies each specific trial match to each patient profile with a sensitivity of 90% and a specificity of 95%. When aggregated to a patient level, the chance that a patient will be matched for at least one trial from those that he is eligible to is 99.9%. Metrics are validated by automatically matching multiple artificially-created patient profiles and manually verifying the quality of the match. **Conclusions:** Trialjectory is an effective AI-based tool that offers cancer patients and their oncologists direct, precise and quick access to relevant clinical trials. Our data show a high adoption and growing registration rates and well-above average clinical trial application rate. By democratizing the access to clinical trials, increased opportunities are noted that might lead to increased trial participation. Research Sponsor: Trialjectory.

Machine learning models for accurate pretreatment prediction of chemotherapy associated LV dysfunction in patients with breast cancer and lymphoma receiving chemotherapy (WF-98213 PREVENT and CCCWFU9912 DETECT IV).

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Background: Cancer survivors receiving potentially cardiotoxic chemotherapy are at increased risk for developing left ventricular (LV) dysfunction. We implemented machine learning (ML) models to predict future LV dysfunction in patients with breast cancer or lymphoma scheduled to receive potentially cardiotoxic chemotherapy. **Methods:** We utilized prospectively collected data from NIH studies R01HL118740 (supported by the Wake Forest NCORP Research Base (UG1CA189824)) and R01CA167821. Data included measurements of LV function and demographic factors before, during, and 24 months after initiating potentially cardiotoxic chemotherapy. The two datasets were used both separately and collectively in the development of multiple ML models including penalized linear regression, support vector machine, and random forest (RF). A data preprocessing step properly handled missing information, data imbalance, and encoding. Hyperparameter tuning was performed using cross validation of training data. The final models were assessed with a 20% hold-out test dataset. Cardiotoxicity was defined as a pre- to 24-month post cancer treatment decline in LV ejection fraction (LVEF) of > 10% or to an absolute value of < 50%. **Results:** 276 patients were included in ML models (7% men, 93% women; age 52±13 years). The RF model based on the combined dataset had the best performance with a prediction accuracy, sensitivity, and specificity of 0.94, 0.81, and 0.98, respectively. The most important variables assessed pre-treatment as measured by the Gini impurity factor were in descending order, LVEF, global LV circumferential strain, LV end-systolic volume, body mass index, LV stroke volume, LV end-diastolic volume, and LV mass. **Conclusions:** Prior to cancer treatment, supervised ML methods such as RF models predicted declines in LVEF of > 10% and/or to absolute values below 50% would occur 24 months after initiating chemotherapy for breast cancer or lymphoma. With further improvement and validation using larger datasets, these models may play an important role in cardio-oncology care during and following cancer treatment. Research Sponsor: U.S. National Institutes of Health.

Feasibility of an explainable AI-based therapeutic recommendation-tool utilizing tumor gene expression profiles in advanced and refractory solid tumors.

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Background: Precision oncology aims to guide patient (pts) treatment decisions by matching biological features with available drugs. Extensive genomic analysis allows to identify an actionable alteration in 40-60% of patients. In a recent study of 50 pts with advanced refractory diseases included in PROFILER (NCT01774409), whole exome and fusion transcripts had a limited value over a 90-tumor gene panel (TGP) to increase molecular-based treatment recommendations (MBTR). Herein, we evaluated the feasibility, in the same cohort of pts, of the AI-transcriptional-based therapeutic recommendation-tool OncoKEM to guide treatment recommendations. **Methods:** 77 fresh frozen (FF) and/or FFPE samples including paired specimens for 53 pts with available RNA-Seq gene expression profiles were included. For each pts, a tumor transcriptional profile (TTP) was generated by identifying differentially expressed genes between the pts tumor and a cohort of matched healthy tissue. A large database of drug transcriptional signatures (DTS) was queried in order to identify a “reversal relationship” between the TTP and a DTS. A total of 205 drugs were ranked, including a subset of 61 FDA and/or EMA approved targeted therapies (aTT). **Results:** Most common diagnoses were breast cancers (21% of which 63% were TNBC), followed by ovarian cancers (OC, 18%) and soft-tissue sarcomas (STS, 13%). The median number of previous treatment lines was 4 (range: 1 - 10). Among the 77 tumor samples analyzed, 54 (70%) specimens led to the generation of an OncoKEM report, with no differences between FF and FFPE samples ($p = 0.85$). The overlap between the top 10 proposed drugs between paired FF and FFPE samples was 56% on average. All patients had at least 2 propositions (range: 2-9) of aTT among the top 10 ranked drugs in the Onco KEM reports. Most frequently proposed drugs among the top 10 were palbociclib, talazoparib, infigratinib in TNBC; bosutinib, sapanisertib, SAR125844 in OC; ipilimumab, cabozantinib, sapanisertib in STS. Among the 30 pts (79%) without any MBTR based on TGP/WES/fusion transcript analysis, all had at least 2 proposed aTT in the Onco KEM report (median: 4, range: 2-9). Top ranked drugs were MET (18%), VEGFR (12%), Abl (12%), FGFR (11%), PI3K/AKT/mTOR (11%), PARP (10%) and CDK4/6 inhibitors (7%). **Conclusions:** AI-transcriptional-based therapeutic recommendation-tool OncoKEM is feasible and has the potential to expand personalized cancer treatment in pts with advanced & refractory diseases without tractable genomic alterations. The clinical relevance assessment is planned in an upcoming clinical trial. Research Sponsor: OmiCure.

Machine learning application to find patients with lower-risk myelodysplastic syndrome from real-world data.

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Background: It is a challenge to identify patients with myelodysplastic syndrome (MDS) using structured data from electronic health records (EHRs). Current claims-based algorithms incorporating diagnosis codes, clinical labs, and procedures have not been validated against an expert reference standard. A machine learning-based approach was investigated to identify erythropoietin-stimulating agent (ESA)-treated, lower-risk (LR)-MDS patients from structured EHR data. **Methods:** A sample of 1,549 patients from the Syapse Learning Health Network (SLHN) was identified as potential ESA-treated LR-MDS patients by a team of clinicians and epidemiologists based on diagnosis and medication data from multiple health systems' EHRs and cancer registries. Of these, 404 (25%) were confirmed as ESA-treated LR-MDS patients through a review of patient records by certified cancer registrars (CTRs). The sample was divided into training and validation sets at a ratio of 80/20, stratified by the outcome. Age, sex, diagnosis codes corresponding to MDS and chronic kidney disease, medication (ESA, luspatercept, lenalidomide), clinical lab tests (hemoglobin, absolute neutrophils, platelet, blast percentage), and evidence of bone marrow biopsy were included as the predictive variables for the models. Gradient boosting machines with a nested cross-validation scheme were adopted to build the optimal model on the training set. Model acceptance was evaluated based on precision and recall on the validation set. The optimal model was then applied to the remaining unscreened SLHN patient population. **Results:** The optimal model identified an additional cohort of 157 patients based on the predicted likelihood. Among these, 69 (44%) were CTR-confirmed ESA-treated LR-MDS patients, all of whom were previously missed by the initial expert-determined selection criteria, as shown in the table. **Conclusions:** The application of machine learning methods increased the rate of ESA-treated MDS patient identification even after the expertly-determined population was depleted. This suggests the application of machine learning models using EHR data may improve the efficiency of MDS patient identification and screening efforts for research, quality improvement, and clinical care. Research Sponsor: Bristol Meyers Squibb.

Criteria	SLHN patients screened	ESA-treated MDS
Expert-determined selection criteria		
Two MDS diagnosis* dates ≥ 90 days apart + evidence of ESA treatment [†]	239	122 (51%)
MDS Registry evidence by ICD-O-3 Histology [‡]	1,229	270 (22%)
Patients with suspected MDS based on manual review of clinician notes	41	1 (2%)
Other small sample attempts	40	6 (15%)
Total	1,549	404 (25%)
Machine learning model		
	157	69 (44%)

*MDS ICD-10 codes: C94.6 and D46. †MDS ICD-O-3 Histology: 9980, 9981, 9982, 9983, 9984, 9985, 9986, 9987, 9988, 9989, 9993. ‡ESA treatment: darbepoetin alfa or epoetin alfa. †The first code fell within the study window of 2016-01-01 to 2019-06-30.

Natural language processing-optimized case selection for real-world evidence studies.

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Background: Much information describing a patient's cancer treatment remains in unstructured text in electronic health records and is not recorded in discrete data fields. Accurate data completeness is essential for quality care improvement and research studies on de-identified patient records. Accessing this high-value content often requires manual and extensive curation review. **Methods:** AstraZeneca, CancerLinQ, ConcertAI, and Tempus have developed a natural language processing (NLP)-assisted process to improve clinical cohort selection for targeted curation efforts. Hybrid, machine-learning model development included text classification, named entity recognition, relation extraction and false positive removal. A subset of nearly 60,000 lung cancer cases were included from the CancerLinQ database, comprised of multiple source EHR systems. NLP models extracted EGFR status, stage, histology, radiation therapy, surgical resection and oral medications. Based on the results, cases were selected for additional manual curation, where curators confirmed findings of the NLP-processed data. **Results:** NLP methods improved cohort identification. Successfully returned cases using the NLP method ranged from 75.2% to 96.5% over more general case selection criteria based on limited structured data. For all cohorts combined, 84.2% of the cases sent out for NLP curation were returned with curated content (Table). Each cohort contained a range of NLP-derived elements for curators to further review. In comparison, more general case selection criteria yielded a total of 3,878 cases returned out of 41,186 lung cancer cases sent for curation, for a success rate of only 9.6%. **Conclusions:** NLP-driven case selection of six distinct, complex lung cohorts resulted in an order of magnitude improvement in eligibility over candidate selection using structured EHR data alone. This study demonstrates NLP-assisted approaches can significantly improve efficiency in curating unstructured health data. Research Sponsor: AstraZeneca.

NLP-assisted cohort selection for the six pre-specified lung cancer cohorts.					
Cohort	Cohort Description	Number of cases available from NLP-assisted identification methods	Number of cases sent to Tempus and ConcertAI for curation	Number of cases returned to CancerLinQ with curated content	Percent of successfully curated cases
1A	NSCLC, stage I, II, III, EGFR+, complete resection	408	408	341	83.6%
1B	NSCLC, non-squamous, stage I, II, III, EGFR wild type/unknown, complete resection	4313	1500	1285	85.7%
2A	NSCLC, stage III, unresectable, curative radiation to the chest total dose >= 50 Gy, did receive Imfinzi	852	620	466	75.2%
2B	NSCLC, stage III, unresectable, curative radiation to the chest total dose >= 50 Gy, did not receive Imfinzi	3050	750	724	96.5%
3	SCLC, received Imfinzi or Tecentriq	559	500	402	80.4%
4	NSCLC, received Tagrisso as first line treatment	971	812	647	79.7%
Total:		10153	4590	3865	

Natural language processing of Veterans' electronic health records to confirm diagnoses of monoclonal gammopathy of undetermined significance.

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Background: The Veterans Health Administration (VHA) provides extensive electronic health records (EHRs) on Veterans nationwide. Our prior studies utilized VHA data to study the risk of progression from monoclonal gammopathy of undetermined significance (MGUS) to multiple myeloma. These studies relied on International Classification of Disease (ICD) codes and manual abstraction on clinical notes to both identify and verify MGUS patients. Diagnosis confirmation is necessary because many providers place a diagnosis on the clinical notes to order lab tests, which is often left in the EHR despite a negative test result. However, manual abstraction is labor intensive and time consuming. With the advancement in natural language processing (NLP), we developed a model to make MGUS confirmation more efficient. **Methods:** We randomly selected 700 patients within patients diagnosed with MGUS from 1999-2021 in the VHA identified via ICD codes. A random sample of 500 patients were selected and split into the training (80%) and the testing (20%) sets. The remainder (n = 200) served as the validation set. There were 32,708 unstructured hematology/oncology Text Integration Utility reports and 9,237 lab reports (including 2,322 discrete results and 6,915 unstructured comments). All reports were manually reviewed to confirm MGUS diagnoses and served as the reference standard. We compiled three lists of keywords suggestive of MGUS diagnosis, subtypes of immunoglobulins, and negation modifiers. We trained a symbolic NLP model to identify diagnoses using combinations of the lists along with M-protein levels from lab reports. The optimized combination that gave the highest recall and precision from the training set was used and evaluated on the testing and validation sets. **Results:** Among patients with ICD codes for MGUS, manual abstraction confirmed 84% MGUS diagnoses in the testing set and 80% in the validation set. Our NLP model in the training set confirmed 75% and achieved recall, precision, accuracy, and F1 score of 88.1, 98.7, 89.0, and 93.1%, respectively; in the validation set, our rule confirmed 76% patients and the recall, precision, accuracy, and F1 score were 89.4, 94.7, 87.5, and 92.0%, respectively. On average data abstraction took five minutes per patient (excluding data loading time), whereas NLP model completed 13 patients per minute. **Conclusions:** The developed NLP model to confirm MGUS diagnosis improves accuracy in diagnosis, compared to ICD codes alone. While the performance is similar to that of manual abstraction, our NLP model is an efficient and viable method in MGUS diagnosis confirmation. Research Sponsor: U.S. National Institutes of Health.

	Recall (%)	Precision (%)	Accuracy (%)	F1 score (%)
Dataset (patients/clinical reports/lab reports)				
Training (400/19,309/5,112)	86.52	94.85	85.50	90.49
Testing (100/4,907/1,437)	88.10	98.67	89.00	93.08
Validation (200/8,492/2,688)	89.38	94.70	87.50	91.96

Impact of trial site selection on minority patient recruitment in prostate cancer trials.

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Background: Historically, minority patients have been underrepresented in clinical cancer trials. Despite recognition of this problem, trials in the early 2000's showed a decrease from 10.5% to 6.2% in African American trial participation when compared to trials from the early 1990's. The drop in trial participation is also reflected in prostate cancer trials, although Black men have a 1.76 higher prostate cancer incidence rate than White men. Using prostate cancer as an example, we investigated the impact of trial site selection on potential minority patient recruitment; thus, overcoming a major system-level barrier to trial access. **Methods:** We created a prostate cancer cohort by filtering our real-world data sources (CancerLinQ, Electronic Medical Office Logistics) for adult male patients with ICD10 CM code C61* or ICD9 CM code 185 on 1/1/2015 or later (cohort #1). As a pre-requisite for computing site level prostate cancer patient counts, we used claims data to attribute missing site information. Finally, to identify the most promising sites for minority trial recruitment, we ranked sites by the proportion of Black patients and the overall cohort patient count. We repeated the above steps for a subset of cohort #1, which was based on the criteria for trial NCT00887198 investigating the prostate cancer drug abiraterone (cohort #2). **Results:** The prostate cancer cohort (#1) had 151,261 patients, of which 99,152 (65.6%) were attributed to sites. The percentage of Black patients being treated at the top ten sites ranged from 33.0% to 66.4%, with a median of 45.2% (see table). All ten sites had participated in an interventional cancer trial, and eight had participated in prostate cancer trials. Half of them were community, and half were academic sites. The abiraterone cohort (#2) had 1,267 patients, of which 1,174 (92.7%) were attributed to sites. Among the top ten sites the Black patient percentages ranged from 23.8% to 85.7%, with a median of 39.3%. **Conclusions:** In an analysis of 17 recent FDA drug registration trials for prostate cancer, Black trial participation ranged from only 1.4% to 6.2%, with a median of 3.0%. In contrast, Black patients being treated at the top sites in our data ranged from 33.0% to 66.4%, with a median of 45.2% (cohort #1). The percentages for the abiraterone cohort (#2) were similar, suggesting that even after applying trial criteria the Black patient percentages remain in the double-digits at top sites. Our results demonstrate that informed trial site selection could have a substantial positive impact on minority patient recruitment. Research Sponsor: None.

Top ten sites.				
Site	Black Patients (n, %)	Total (n)	PCa Trial Hist	Type
A	172 (66.4%)	259	Y	Ac
B	227 (57.8%)	393	Y	Co
C	836 (54.2%)	1542	Y	Co
D	438 (47.8%)	916	N	Co
E	329 (46.8%)	703	Y	Co
F	342 (43.5%)	786	Y	Ac
G	1013 (41.1%)	2462	Y	Ac
H	1053 (37.6%)	2798	N	Ac
I	318 (35.9%)	887	Y	Co
J	596 (33.0%)	1804	Y	Ac

PCa Trial Hist, Prostate Cancer Trial History; Y, Yes; N, No; Ac, Academic; Co, Community.

A novel support vector machine to predict sentinel lymph node status in elderly patients with breast cancer.

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Background: Routine sentinel lymph node biopsy in older breast cancer patients with favorable tumor biology is not recommended. However, cases must be evaluated on an individual basis to avoid under or over-treatment. Many nomograms have been developed to calculate the risk of nodal positivity, but machine learning (ML) is a novel tool that may improve the accuracy of nodal prediction. In this study, we developed a support vector machine (SVM) model to delineate factors indicative of sentinel lymph node positivity and refine individualized nodal risk assessment for this heterogeneous patient population. **Methods:** We conducted a single-institution comprehensive retrospective review of patients 70 years or older diagnosed with unilateral stage I-III primary breast cancer from January 2005 to January 2016. Patient data was partitioned into training and testing sets. A SVM model was developed to predict lymph node status using patients' demographics, tumor stage, genetic profile, and imaging data. Primary outcome was model performance determined by area under the curve (AUC). Secondary outcomes were accuracy, sensitivity and specificity. Permutation feature importance (PFI) analysis and accumulated local effect (ALE) plots were used to evaluate significant predictors identified by the SVM. **Results:** We identified 1706 consecutive patients who met the study criteria with a mean age of 76±4.5 years. The plurality of patients were Caucasian (82%), had ER+ (86%), PR+ (70%), HER2- (87%) stage I (72%) breast cancer. Sixteen percent of patients (n = 271) had a positive sentinel lymph node biopsy. The SVM model demonstrated good discriminatory performance for predicting sentinel lymph node positivity with mean AUC of 0.70 (95%CI, 0.62-0.77), mean accuracy of 84% (95%CI, 80-88%), mean sensitivity of 61% (95%CI, 57-66%), and mean specificity of 62% (95%CI, 52-73%). PFI and ALE identified higher disease stage, younger age, family history of breast cancer, margin status, estrogen and progesterone receptor positivity as independently associated with high risk of sentinel lymph node positivity. **Conclusions:** The proposed ML model accurately identified sentinel lymph node status in older patients with breast cancer. This model holds promise for counselling patients as to the potential risk for node positive disease which may impact surgical and adjuvant therapy recommendations. Research Sponsor: None.

Incidence and impact of proportional hazards violations in phase 3 cancer clinical trials.

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Background: Hazard ratio (HR)-based analyses used in oncology trials rely on the assumption of proportional hazards, i.e. a HR that is constant over time. Proportional hazards violations (PHVs) may lead to misinterpretation of trial results. Restricted mean survival time (RMST) is valid with non-proportional hazards and has received recent attention specifically for immunotherapy (IO) trials but has not been routinely adopted in oncology trial design as a whole. We aimed to comprehensively characterize the incidence and factors associated with PHVs among phase 3 oncology trials and assess RMST as an alternate measure of treatment effect in survival analysis. **Methods:** We used Clinicaltrials.gov to identify all superiority-design, 2-arm phase 3 cancer trials with time-dependent endpoints with published results through February 2020. We manually reconstructed patient-level data from published Kaplan-Meier (KM) curves, assessed PHVs with the Schoenfeld residual test ($p < .05$) and analyzed the RMST. To assess reconstruction accuracy, reported and reconstructed HRs were compared. Univariable logistic regression was used to assess the likelihood of PHVs by trial characteristic, with statistically significant factors ($p < .05$) included in a multivariable analysis. Concordance of RMST-based and HR-based analysis was established when both tests agreed as to the statistical significance of the comparison. **Results:** Of 342 KM comparisons eligible for reconstruction, 318 comparisons across 315 trials, enrolling 347,538 patients from 1989-2017, were accurately reconstructed and analyzed. PHVs were identified in 76/318 (23.9%) trials. There was no difference in likelihood of PHVs among IO vs non-IO trials (LR 2.31, 95% CI 0.30 - 17.85, $P = .37$), nor by disease site, year of trial initiation, or sample size. Few trials with PHVs (16/76) pre-specified a plan to account for non-proportional hazards in statistical design. Trials with an overall survival (OS) primary endpoint (PEP) were less likely to have PHVs than trials with a non-OS PEP (LR: 0.50, 95% CI 0.28 - 0.90, $P = .02$). Trials whose PEP was non-significant were more likely to have PHVs (LR 1.73, 95% CI 1.01 - 2.97, $P = .047$). No factor remained significantly associated with PHV in multivariable analysis. Overall, 291/318 (91.5%) KM comparisons were concordant. Among trials with PHVs, 5/76 were significant by RMST but not HR, and 5/76 were significant by HR but not RMST. Of these, 1 led to FDA drug approval, and 2 others are cited in NCCN guidelines. **Conclusions:** PHVs are common across all phase 3 cancer clinical trials. Attempts to account for PHVs in trial design are lacking despite the potential for trial misinterpretation in the event of non-proportional hazards. RMST-based analysis is broadly concordant with HR-based analysis and may aid in interpretation of trials with PHVs. Hence, we recommend that prospective trials include *a priori* a statistical plan to account for PHVs. Research Sponsor: Sabin Family Fellowship Foundation, Fund for Innovation in Cancer Informatics.

Improving first-in-human and window-of-opportunity informed consent forms through participant feedback.

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Background: Although patient advocates have created templates for standard consent forms, assessing patient preferences for First in Human (FIH) and Window of Opportunity (WO) trials consents is important given their unique risks. FIH trials are the first time a drug is tested in humans. In WO trials, treatment naïve patients receive a therapeutic agent in the window of time between diagnosis and standard of care (SOC) surgery. Our goal was to determine patient-preferred presentation of important information in FIH and WO consent forms. **Methods:** The study consisted of two phases: (1) analysis of consents for FIH and WO oncology trials open at a cancer center between 2019 and 2022; (2) interview patients who had reviewed consents for FIH or WO trials during the consent process. FIH consents were analyzed for the location(s) of information stating that the study drug has not been tested in humans (FIH info). The WO consents were analyzed for the location(s) of information stating the risk that trial may delay SOC surgery (WO info). Participants were asked about their preferred placement of the information in their own trial's consent form and whether the consent was clear. Interviews were audio-recorded and double coded. Consent form analysis was compared to patients' preferences. **Results:** 25 consents [20 FIH; 5 WO] were analyzed. 19/20 FIH consent forms included FIH info, and 4/5 WO consent forms included WO info. 42 patients were approached [19 FIH; 23 WO]; 34 [17 FIH; 17 WO] participated. 12/17 (71%) WO participants thought that the trial explanation in the consent form was clear. Conversely, only 9/17 (53%) FIH participants found it clear. **Conclusions:** Patients preferred that the important FIH and WO information be placed early in the consent, though exactly where varied. 82% of FIH participants wanted FIH information in the purpose, while only 19% of WO participants clearly preferred that WO information be in the purpose, and 41% preferred WO information to remain in the risks section. Using consent templates that reflect patient preferences accurately is essential for ethical informed consent; however, a one-size fits all approach may not accurately capture patient preferences, so multiple templates may be necessary. Research Sponsor: U.S. National Institutes of Health, U.S. National Institutes of Health, The Winship and Davidson Impact Fellowship and Winship Cancer Institute of Emory University.

Location of FIH and WO info in consent forms compared to patient preference.

Title	Purpose / Introduction	Title & Purpose	Purpose & Risks	Title, Purpose, & Risks	Title & Risks	Risks	
Location of FIH Info in consent forms (n = 20)	0	0	0	20% (5)	10% (2)	5% (1)	20% (4)
Patient preference for location of FIH info (n = 17)	0	18% (3)	6% (1)	29% (5)	29% (5)	6% (1)	6% (1)
	Introduction	Purpose	End of risks section	Beginning of risks section	Treatment Schedule	"Early on" in consent form	Key Concepts
Location of WO info in consent forms (n = 5)	0	40% (2)	40% (2)	0	0	0	20% (1)
Patient preferences for location of WO info (n = 17)	0	12.5% (2)	25% (4)	18.75% (3)	6.25% (1)	18.75% (3)	12.5% (2)

One FIH and one WO patient had no preference.

Clinical development of new drugs for adults and children with cancer in 2010-2020: Longitudinal study of investigational drugs.

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Background: Many investigational drugs start clinical testing to evaluate potential therapeutic benefits for oncology patients, but few eventually receive FDA approval. Moreover, only a small number is evaluated in pediatric populations, potentially contributing to the paucity of new approved drugs for young patients with cancer. Limited information is available on the development pipeline of investigational drugs, including the range of drug types entering clinical trials, trial phases at which development stalls, or rate of regulatory approval. To inform current clinical development efforts, we characterized the development and outcomes for a comprehensive sample of New Molecular Entities (NMEs) that started clinical testing worldwide in 2010-2015. **Methods:** We performed a longitudinal study using AdisInsight, a commercial database of global pharmaceutical research and development. This is a comprehensive database of drug development activity, which collects and curates data from trial registries, conference proceedings, journal publications, and press releases. Using these data, we identified all NMEs starting their first clinical trial for an oncology indication in 2010-2015. We followed each NME from the start of its first phase I trial to the end of 2020, and identified all associated trials, final development status, and FDA deliberations. We classified trials as pediatric-eligible if patients aged < 18 years were eligible for participation. We used the Drugs@FDA website to identify all FDA actions, including marketing approvals and requests for pediatric trials under pediatric programs (i.e. BPCA requests or PREA requirements). **Results:** A total of 572 NMEs started initial phase I clinical trials in 2010-2015. Among these, the most studied classes were small molecules (N, %: 316, 55%), antibodies (148, 26%), and antibody-drug conjugates (44, 8%). Overall, the NMEs were studied in 6,141 clinical trials by the end of 2020, with a median of 3 trials per NME. The highest pre-approval development phase reached by an NME was phase I for 325 (57%), phase II for 153 (27%), and phase III for 94 (16%). Only 39 NMEs (7%) were approved by the FDA by the end of 2020. Among approved NMEs, the median time (range) from start of first phase I trial to date of first approval was 6 (3-10) years. Among all NMEs, only 67 (12%) were tested in pediatric-eligible trials by the end of 2020, and 5 (< 1%) were approved for use in selected pediatric populations. Three of these had been subject to BPCA requests, and all had PREA requirements waived. **Conclusions:** More efficient clinical development strategies are needed to accelerate the production of new cancer therapies, especially for children. Analyses such as this one should be conducted regularly to help identify areas in need of innovation and to assess the potential impact of regulatory initiatives (e.g. the RACE act, effective since August 2020). Research Sponsor: None.

TBCRC 057: An online survey about anxiety and willingness to participate in breast cancer clinical trials during the COVID-19 pandemic.

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Background: Enrollment in clinical trials has declined during the COVID-19 pandemic. Simultaneously, breast cancer patients have reported heightened anxiety. We assessed whether breast cancer patients' anxiety about the pandemic affects their willingness to participate in trials. **Methods:** English or Spanish-speaking US residents with breast cancer were eligible to complete the online REDCap survey 8/6/21 – 9/30/21. Respondents rated their anxiety about the pandemic on an 11-point scale from 0 (no anxiety) to 10 (worst anxiety possible). Anxiety scores were categorized as no/mild (0-3), moderate (4-6) or severe (7-10). Knowledge about trials was assessed with 11 true/false items and attitudes toward trials with the Attitudes Toward Cancer Trials Scales - Cancer Treatment Subscale (ATCTS-CTS). Respondents rated their willingness to participate in a breast cancer clinical trial before and during the pandemic on 5-point scales from 0 (not at all willing) to 4 (definitely willing). Trial participants were considered "definitely willing." Change in willingness to participate in trials during the pandemic compared to prior was defined as a binary outcome, "less willing" vs "no less willing." Means were compared via t-test and mean difference was tested via paired t-test. Multivariable logistic regression was used to model the association of anxiety and other factors with being less willing to participate in trials during compared to prior to the pandemic. **Results:** Among 385 respondents, median age was 52 (range 25-85), 271 (70%) were non-Hispanic White and 202 (53%) had metastatic disease. 154 (40%) received care at academic centers and 37 (10%) were current trial participants. Most rated their anxiety as moderate (43%) or severe (38%). Mean willingness to participate in a trial was lower during compared to prior to the pandemic (2.97 vs 3.10; $p < 0.0001$). Fifty (13%) respondents were less willing to participate in a trial during the pandemic compared to prior. After controlling for covariates, those with severe anxiety had 5.07 times odds of being less willing to participate during the pandemic compared to prior than those with no/mild anxiety ($p = 0.01$). For every 1-point increase in ATCTS-CTS score (indicating better attitude toward trials) there was a 3% decrease in the odds of being less willing to participate during the pandemic ($p = 0.006$). For every 1-point increase in the clinical trials knowledge score (indicating more knowledge) there was a 15% decrease in the odds of being less willing to participate during the pandemic ($p = 0.02$). **Conclusions:** Pandemic-related anxiety is common in breast cancer patients and is associated with being less willing to participate in trials during the pandemic compared to prior. Education about trials, including safety modifications implemented during the pandemic, may mitigate anxiety and improve willingness to participate. Research Sponsor: Metastatic Breast Cancer Network.

Participation in cancer research in BNSSG, England: A Health Equity Audit 2021.

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Background: Cancer is a cause of health inequalities, and nationally, patients from deprived communities have lower participation rates in cancer research. Equitable access to research benefits patients, healthcare organisations and improves applicability of research. **Methods:** We undertook a health equity audit of participation in cancer research (trials and non-trials based) in Bristol, North Somerset and South Gloucestershire (BNSSG), England from 1.4.2019-30.3.2020 using data from the Acute Trust patient datasets. Comparison cohorts were extracted from a regional primary care dataset (the system wide dataset). Firstly, an incident cancer cohort: diagnosed from 1.11.2019-1.10.2020. Secondly a “living with cancer” cohort: cancer flag in the 5 years prior to 1.7.2021. Deprivation is measured by IMD of home postcode small area (LSOA). **Results:** Results are presented for the audit in the table below, with 95% confidence intervals where appropriate. Compared to people newly diagnosed with cancer, adults aged 70 or older were 56% less likely to take part in research (OR 0.44, 95% CI 0.39-0.51), and adults aged 80 or older were 77% less likely to take part in research (OR 0.23, 95% CI 0.18-0.29). Compared to people newly diagnosed with cancer, people from the most deprived 20% of the population were 27% less likely to take part in research (OR 0.73, 95% CI 0.88-0.92). The most deprived research participants were more likely to be younger, have one or more comorbidities and a recent emergency admission. Patients from outside BNSSG (18%) appear similar in profile to those from within BNSSG, including for deprivation. Better data are needed for other factors relevant to equity, including ethnicity and Inclusion Health. **Conclusions:** This health equity audit confirms and quantifies inequities in access to cancer research in our region. Under-representation of deprived and older patients appeared multifactorial in this audit, but further work to understand facilitators and barriers to recruitment is needed. These results are a call to action. Research Sponsor: None.

Patient Group	Patients	Mean Age (95% CI)	Younger Patients (<18 years) N (%)	Teenagers and young adults (16-24 years) N (%)	Older patients (>70 years) N (%)	Older patients (>80 years) N (%)	Gender (% female)	Patients from Out of Area N (%)	Most deprived 20% population
BNSSG cancer research				participants	1,052	62y (61.0-63.0)*	36 (3.4%)*	12 (1.1%)	365 (34.7%)*
74 (7.0%)*			52.9%**	189 (18.0%)	11.4%*** (9.5-13.3)				
New Cancer diagnosis in BNSSG	5,193	69y (68.1-69.0)	46 (0.9%)	NA	2,827 (54.4%)	1,299 (25.0%)	55.7%	NA	15.0% (14.0-15.9)
Living with Cancer in BNSSG	14,214	67y (66.6-67.1)	107 (0.8%)	NA	7,036 (49.5%)	2,765 (19.5%)	48.1%	NA	12.9% (12.0-13.8)

*Significant difference to the New Cancer diagnosis and the Living with Cancer patient groups, $p < 0.0001$. **Significant difference to the Living with Cancer cohort, $p = 0.0026$. ***Significant difference to the New Cancer diagnosis cohort, $p = 0.0027$.

A retrospective cohort analysis of return-to-work outcomes for cancer survivors using a digital coaching intervention.

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Background: Return-to-work (RTW) is a key unmet need for working age cancer survivors, with up to 40% failing to RTW 1 to 2 years post-diagnosis. This study sought to evaluate RTW outcomes of a multidisciplinary digital coaching intervention provided as routine employee support. **Methods:** A retrospective cohort analysis was conducted from October 2018 to February 2020 where cancer patients with more than 3 months absent from work were provided by their insurance carriers with a multidisciplinary intervention comprising digital resources and telephone calls with a health coach. A logit regression model was used to calculate a propensity score using covariates of age, gender, insurance benefit type, cancer diagnosis date and time from diagnosis. Participants were then matched on a 1:1 basis using the nearest-neighbour method without replacement to create a matched control group out of 1,856 participants who did not receive the intervention. Primary outcomes, derived from insurance-claims data as standard business practice, included rate and time to RTW, along with death and other reasons for claim closure. **Results:** 220 participants enrolled in the intervention, of which 125 met the criteria for analysis (median age 53, IQR 45-58, 91% female). These participants were matched with 125 controls (median age 53, IQR 47-59, 94% female). Median follow-up from cancer diagnosis was 79 weeks (IQR 60-106). Of the matched controls, 22 returned to work (17.6%) compared with 38 (30.4%) in the intervention group ($P = .02$). 19 matched controls died prior to claim closure (15.2%) compared with 13 in the intervention group (10.4%; $P = .26$). Finally, Kaplan-Meier method estimated median time for the first 15% of participants to RTW was 87.1 weeks for controls (CI 60.0-109.1 weeks) compared with 70.6 weeks for the intervention group (CI 52.6-79.6 weeks; $P = .08$). **Conclusions:** This study evaluated the impact of a digitally delivered coaching program in a real-world setting for cancer patients, demonstrating a 12.8% increase in RTW rate over 18 months compared to matched controls. These findings corroborate and add to the literature on cancer as a chronic and manageable disease in the workplace. Research Sponsor: CancerAid.

Applicability of a web app for breast cancer risk calculation and personalized recommendations for screening in Mexico.

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Background: A minority of women with breast cancer in Mexico are being diagnosed through a screening program, which translates into late diagnosis and a worse prognosis. It is imperative to develop easy access and low-cost interventions to increase the screening rate. **Methods:** We developed a web app tailored to guide patients to seek medical consultation if they were at high risk for breast cancer or standard screening recommendations based on the predicted risk for age (<https://cuccuanl.com/calcula-tu-riesgo-de-cancer-de-mama/>). The web app consisted of an 8-question survey designed using object-based programming with HTML5, the additional logic was programmed on JavaScript. The program logic automatically guided patients to medical consultation if they were at high risk for breast cancer, or standard screening recommendations based on their predicted risk for age. On each confirmation page, the contact information of the hospital appeared, also, consultation at the clinic could be scheduled within the web app. The web app was distributed via social media on International Breast Cancer Awareness Day. **Results:** A total of 1,012 persons answered the survey after a follow-up period of two weeks. The median age of respondents was 34 years. Among participants, 10.8% were considered at very high risk for breast cancer due to symptoms, 22% were classified as high risk based on family history or more than 5 years of contraceptive use, and 19% were considered as average-risk population for whom age-based screening tests were recommended. The remaining 48% of participants were considered at low risk for breast cancer development and were directed to educational information about breast cancer awareness. Among all persons that answered our survey, 21 requested a specialized medical appointment within the web app. **Conclusions:** This pilot study showed a high response of Mexican population seeking breast cancer risk evaluation, 11% of women that responded to our survey had symptoms highly suggestive of breast cancer. The use of web apps can result in mass diffusion which will help reach people with less medical access, a common scenario in many developing countries. Further analysis should be made to measure the real impact on breast cancer diagnosis and oncological outcomes. This study shows how effective social media is as a means of diffusion on health topics. Research Sponsor: None.

Risk Category	% of Respondents (n = 1,012)
Low Risk (< 40 Years, No Risk Factors)	48%
Screening Recommendation (≥ 40 Years, No Other Risk Factors)	19%
High Risk (Oral Contraceptive Use for > 5 Years or Family History)	22%
Very-High Risk (Symptom Suggestive of Breast Cancer)	11%

Assessing health electronically for adolescent and young adult oncology patients (AHEAD Study).

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Background: Screening and counseling for health risk behaviors (RB) are recommended but infrequently performed, particularly in individuals undergoing cancer therapy. Unmet needs among adolescents and young adults (AYAs) with cancer translate to poor physical and psychosocial outcomes. The authors aimed to 1) modify an existing RB electronic health assessment (eHA) and intervention tool and 2) determine the feasibility and acceptability of the RB eHA and intervention tool among AYAs with cancer and their oncology providers. **Methods:** The internally developed HRB eHA and intervention tool Check Yourself was adapted by a multidisciplinary healthcare professional panel for an AYA oncology population and informed by literature review and AYA stakeholder feedback. "Check Yourself Oncology" assesses risk and health domains including home, education, sexual health, safety, alcohol/drugs, mental health and medication adherence. Optional feedback is provided for sexual health, safety, alcohol/drugs and mental health domains. Eligible AYAs were 13 to 29 years old, diagnosed with cancer, receiving cancer directed therapy, follow-up scheduled with a Seattle Children's Hospital oncology physician or nurse practitioner, and fluent in English. 72 hours prior to their next oncology clinic visit, participants were text messaged or emailed a personalized link to the Check Yourself Oncology tool to be completed prior to their next visit. Upon completion, a detailed report was sent to the primary clinical oncology team prior to the patient's visit. Feasibility was defined as 1) $\geq 70\%$ completion of the RB eHA and 2) a Feasibility of Intervention Measure (FIM) mean score >4 . Acceptability was defined as an Acceptability of Intervention Measure (AIM) mean score >4 and qualitatively. The FIM and AIM were sent by REDCap survey following the clinical visit; verbal feedback from AYAs and clinicians was analyzed with qualitative content analysis. **Results:** Of 30 eligible, approached AYAs, 25 (83%) enrolled in the study and 23 (76%) completed the Check Yourself Oncology tool and follow-up assessments. The AYAs had a mean age of 17 years (SD = 2.9 years) and 50% identified as female. Four AYAs declined participation due to lack of interest, 1 due to declined parental consent, 1 passively declined after enrollment, and 1 declined further participation following the confidentiality terms. The mean FIM and AIM scores were 4.1 (SD=0.6) and 4.0 (SD =0.7) respectively. Seventeen AYAs (74%) felt that the feedback provided was relevant and useful. 74% of visits providers reported that they incorporated the results in the care of the patient and 87% reported the results positively impacted care. **Conclusions:** Risk behavior screening with motivational feedback through the modified eHA tool Check Yourself Oncology is feasible and acceptable in AYAs undergoing cancer directed therapy. Clinical trial information: NCT04484194. Research Sponsor: Seattle Children's Research Institute.

Evaluating an AI-based nutrition expert platform delivered via SMS-text to support patients with cancer.

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Background: Interventions incorporating nutritional strategies can prevent and manage nutrition-related symptoms, however, due to a shortage of oncology dietitians (RD CSO) combined with healthcare access disparities, many patients do not receive the support they need, resulting in poor outcomes and quality of life (QoL). High rates of cell phone utilization among all demographics offers a unique opportunity to provide interventions using mobile technology. **Methods:** Launched to select groups in 2019, Ina (trademarked by Savor Health LLC) is a virtual nutrition assistant powered by an artificial intelligence (AI)-enabled expert platform, to facilitate self-management of cancer treatment side effects. The platform combines evidence, expertise, and unique patient data to deliver the personalized guidance patients would receive from an RD CSO, “on-demand” via text. This study applied the RE-AIM framework to evaluate the intervention from five dimensions. **Results:** Reach: The program reached 1,706 users as of 2021. Based on self-report among 1209 users, 78% are patients, 18% are caregivers, and 5% are healthcare professionals with 66% female and 34% male. Ina supports all cancer types, and top diagnoses among users are genitourinary (28%), lung (20%), gynecologic (16%), gastrointestinal (15%), and breast (11%). Disease burden is high, with 62% of users reporting they are experiencing nutrition-addressable symptoms at any given time. Effectiveness: Based on weekly patient reported outcome (PRO) surveys, 87% of respondents report Ina helps them manage symptoms, and 80% report that using Ina has improved their QoL. The cumulative likelihood to recommend is 4.1 on a 5-point scale. Adoption: Users are from over 18 cancer organizations, proving the feasibility and accessibility of this intervention. Implementation: Ina is accessible 24/7 via text, and is offered to patients in a B2B2C model. Users typically receive responses to nutrition-related questions within seconds from the AI platform (or 1-3 minutes with live RD oversight). Each active user (one that engages at least once in a given month) asks an average of 2.8 questions per month. Maintenance: The median time users remain on the platform is 156 days (range 0-884) and 57% of evaluable users stayed on the platform 6 months or longer. The platform’s database, which includes over 54,000 referenced interventions, grows daily via supervised machine learning supported by RD CSOs. When surveyed on future feature development, respondents are most interested in tele-nutrition (57%), mental health (65%), and stress management (62%). **Conclusions:** Initial data suggests this is a feasible and accessible tool to support cancer patients’ unique nutrition and symptom-management needs. Clinical trials are needed to validate feasibility and assess impact on clinical and QoL outcomes. Product development to integrate language and cultural preferences is ongoing. Research Sponsor: None.

Impact of the COVID-19 pandemic on oral oncolytic adherence.

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Background: COVID-19 has substantially decreased cancer screening, management visits and surgeries. CVS Health recently developed a best-in-class mobile app and website that enables oncology patients to start and stay on therapy. This study examined the impact of COVID-19 on adherence to oral oncolytic agents in a large health plan with a significant digital health platform. **Methods:** This retrospective cohort study included adult patients with chronic myelogenous leukemia (CML), ovarian cancer or prostate cancer initiating oral oncolytics between 3/1/19 and 3/1/2021. Patients were divided into two groups: pre-COVID oral oncolytic initiators before 3/1/20 and COVID initiators after 3/1/20 and were followed for 1 year after therapy initiation. The primary outcome was optimal adherence to oral oncolytic agents as defined by a medication possession ratio (MPR) ≥ 0.8 . Percent of digital engagement, defined as the number of times a patient interacted with the CVS digital platform, was examined as a secondary endpoint and was considered as a binary and categorical endpoint (none, low (< 28), moderate (28-105) and high (> 105)). Descriptive statistics and logistic regression modeling were performed; p-values < 0.05 were significant. **Results:** In total, 15,494 patients were included in the study, with 8,067 (52.07%) in the pre-COVID initiator group. Patient demographics were similar across study groups, with the exception of pre-COVID initiators who were less likely to be male (75.32% vs. 77.34%; $p < 0.01$) and receive copay assistance (38.37% vs. 41.70%; $p < 0.01$). No difference in digital engagement pre and during COVID was noted (74.55% vs. 73.60%; $p = 0.18$). Pre-COVID initiators were less likely to be optimally adherent than COVID initiators (84.75% vs. 85.96%; $p = 0.04$). Therapy persistence was more common among COVID initiators, with greater number of fills (Median [quartile (Q) Q1-Q3]: 10 [4-12] vs. 9[4-12]; $p < 0.01$) and less changes to therapy (8.87% vs. 9.95%; $p = 0.02$). After regression, COVID initiation of oral oncolytics was not associated with optimal adherence (odds ratio (OR) = 1.06 [95% (confidence interval (CI) 0.96-1.16]). Adherence increased as digital engagement increased (low: OR 0.64 [95% CI 0.56-0.72]; moderate: OR 0.67 [95% CI 0.56-0.76]; high: OR 1.71 [95% CI 1.48-1.99]). Other factors associated with increased adherence were copay assistance, male gender and age between 65 and 84 (all $p < 0.05$). Factors associated with decreased adherence were therapy change, CML and age < 50 years (all $p < 0.05$). **Conclusions:** The onset of the COVID-19 pandemic did not significantly impact optimal adherence for new-to-therapy oral oncology patients. Patients with high digital engagement during the pandemic experienced significantly improved adherence than those not engaged. Additionally, persistence and number of fills were slightly improved in COVID initiators, suggesting that the current pandemic may have influenced adherence behaviors. Research Sponsor: None.

Mobile app in oncology: A pilot survey on Latina patients with gynecological cancers and their perception on utilizing a mobile app.

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Background: Mobile applications have changed the way that users access information and revolutionized healthcare by allowing patients to educate themselves regarding their diagnosis and treatment. Challenges in developing a mobile health application include patient satisfaction and usage over time. Barriers to usage include trust, personalization, and accessibility. Investigating the patient population's preferences on app content and ease of use is imperative. The use of mobile applications specifically for Latina Gynecologic Oncology patients undergoing treatment has yet to be investigated. **Methods:** Fifty-six patients were recruited from the Gynecologic Oncology clinic at an urban academic health sciences center located on the Texas-Mexico border. Cross-sectional analyses were performed. Subjects were asked a series of 10-point Likert scale questions including how comfortable they would feel using medical applications on their smartphones. Linear regression models were fit with this scale score as the outcome. **Results:** The age of the 56 patients ranged from 28 to 77 years with a mean of 53.9 years (SD: 11.1). Spanish was the preferred language of 53.8% of the patients (28/52). Forty-four subjects were available for the regression analyses. Subjects were asked, "Would you feel comfortable using medical applications on your smartphone," where 1 represented "not at all comfortable" and 10 represented "very comfortable". The mean comfort scale score was 7.39 (SD: 2.85). Thirty of the 44 subjects (68.2%) replied "Multiple times per day" to the question about how frequently they use mobile apps on their phone. After controlling for the patient's age in a regression model, patients who used mobile apps multiple times per day had an average comfort scale score that was 1.75 points higher than that of women who did not use mobile apps on their phone multiple times per day ($p = 0.03$). After adjusting for the frequency of mobile app use, there was a reduction of 0.11 points ($p = 0.002$) in the comfort scale score for every one year increase in the patient's age. **Conclusions:** Our unique pilot study found a positive association between the frequency of current app use and anticipated comfort in using smartphone medical applications. Overall, patients demonstrated a considerable amount of comfort with the prospect of using a mobile app. These findings support the idea of creating a mobile app designed to monitor Latina Gynecologic Oncology patients in efforts to lessen patients' postoperative burden, improve mortality and morbidity outcomes, and decrease health care system costs. Research Sponsor: None.

Parameter estimates from the linear regression analyses in 44 patients.

Model	Frequency of mobile app usage:	Age: 1 year increase	Education: College vs. Less education	Adjusted R-squared
1	2.35 ($p = 0.01$)	-	-	0.13
2	1.68 ($p = 0.046$)	-0.10 ($p = 0.003$)	0.33 ($p = 0.66$)	0.28
3 (Final)	1.75 ($p = 0.03$)	-0.11 ($p = 0.002$)	-	0.30

Association between remotely-monitored activity, patient-reported outcomes, and physical function in patients with advanced pancreatic cancer.

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Background: Patients with pancreatic ductal adenocarcinoma (PDAC) experience significant functional decline over the course of their treatment, which can negatively impact their quality of life (QOL) and clinical outcomes. There are currently no standardized methods to monitor physical function (PF) in PDAC patients outside the clinic setting. The use of wearable technology to obtain continuous and objective activity data combined with routine collection of patient-reported outcomes (PROs) provides an opportunity to monitor PF and intervene in a timely matter. **Methods:** We conducted a single-site, single-arm prospective study in advanced stage 3 and 4 PDAC patients between 2019 and 2/2022. Patients used a wrist-worn wearable activity monitor (Fitbit) continuously for 8 weeks and completed NIH PROMIS surveys (PF, pain, fatigue, sleep disturbance, and emotional distress) at baseline, week 4 and week 8. ECOG performance status (PS), hand grip strength, and timed 15-foot walk test were also assessed at each timepoint. Pearson correlation coefficients were calculated for activity data (step counts, distance, stairs, time spent sedentary and in light, moderate, or vigorous activity, sleep), PROs, and functional outcomes. Multivariable regression models, adjusted for age, sex, and cancer stage, were fit to evaluate associations between activity metrics, PROs, and functional outcomes. Multivariable cox proportional hazard models were fit to evaluate the impact of activity levels on survival. **Results:** A total of 40 patients consented onto study: 50% female, median age: 67 years (range 47-85), 92% ECOG 1. Baseline activity data are summarized in Table. Statistically significant correlations between step counts and PF T-scores (coeff: 0.6, $p = 0.001$) and lower pain scores (coeff: -0.53, $p = 0.002$) were observed. Increased stairs count and time spent in moderate and high physical activity were also positively correlated with increased PF ($p < 0.001$). No statistically significant correlations were observed between hand grip strength, activity metrics or PROs. Fewer average step counts and worse PF scores were significantly associated with poor survival with hazard ratios (HR) of 1.44 per 1000 steps (95% CI 1.06, 1.97, $p = 0.02$) and 1.69 (95% CI 1.1-2.56, $p = 0.017$), respectively, after adjusting for age, sex, stage, and ECOG PS. **Conclusions:** Findings from this research suggest that the use of wearable technology for remote monitoring of daily activity is feasible and may be used to supplement functional assessment and predict outcomes in PDAC patients. Larger trials are needed to validate findings. Research Sponsor: Pancreatic Cancer Action Network.

Activity metric	Mean (SD)
Steps/Day	4627.7 (3144)
Distance/Day (miles)	2.0 (1.4)
Stair flights/Day	4.3 (6.9)
Sedentary times (Hours)	14.7 (3.76)
Active minutes	
Light	162.6 (79.6)
Moderate	9.9 (12.9)
High intensity	5.9 (9.3)
Sleep (hours)	5.3 (2.8)

1573

Poster Session

Interface software can markedly reduce time and improve accuracy for clinical trial data transfer from EMR to EDC: The results of two measure of work time studies comparing commercially available clinical data transfer software to current practice manual data transfer.

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Background: Clinical studies and new drug approvals are delayed by slow data transfer and transcription errors from site entered data. These delays have been compounded by a shortage of data entry personnel at sites such that data entry approaches 10-30 days post visit. Data transfer is largely performed by manual keyboard entry from electronic medical records (EMR) into electronic case report forms (ECRF). **Methods:** We conducted two separate measure-of-work time studies to compare a commercially available interface software product, ProXimity to the current manual data entry. The clinical trial data from two different EMRs (ARIA and IKM G2) to an EDC (Medidata Rave). The EDC mirrored an IRB approved clinical study. Time to transfer data and error rates were the primary and secondary endpoints, respectively. For study 1 Aria EMR data from 3 subjects and 1497 data fields including demographics, vital signs, ECOG PS, physical findings, adverse events, and lab results including CBC, CMP, urinalysis, coagulation, serology were selected for visits from Screening and C2D1. For Study 2 IKM G2 data from 6 subjects and 834 data fields included demographics, vitals, and lab results. The data entry personnel were aware of the timed nature of the study. **Results:** Study 1 ProXimity took 13.2 min to transfer the data compared to 73.4 min for manual entry, with error rates of 0.8% compared to 3.5%, respectively. In Study 2 Proximity took 6.5 min compared to 29 min for manual entry, with error rates of 1.4% each due to non-conformant data (text). **Conclusions:** Software data transfer interfaces can markedly shorten the time for data entry, reduce error rates and reduce operational costs. Research Sponsor: None.

PRECISE CURATE.AI: A prospective feasibility trial to dynamically modulate personalized chemotherapy dose with artificial intelligence.

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Background: Most treatment guidelines recommend chemotherapy at maximum tolerated doses, which does not always lead to optimal efficacy, but implicitly results in toxicity. To overcome this challenge, we developed CURATE.AI, a small data, AI-derived platform that harnesses only a patient's own prospectively/longitudinally acquired data to dynamically identify their own optimal and personalized doses. We subsequently harnessed CURATE.AI to dynamically modulate individualized chemotherapy doses for patients in a prospective clinical trial. **Methods:** We conducted an open-label, multi-center, single-arm, prospective feasibility trial in patients diagnosed with advanced solid tumors and treated with single-agent capecitabine, XELOX or XELIRI (+/- biologics) (NCT04522284). The standard-of-care (SOC) capecitabine dose was 1000 mg/m², unless adjusted by clinician to account for patient's comorbidities and organ dysfunction. Using an AI-discovered second-order correlation between patient-specific variation of capecitabine doses and corresponding tumor marker (CEA, CA19-9 or CA-125) readouts for each cycle, CURATE.AI generated individualized patient digital avatars and recommended bespoke dose for the subsequent cycle. The clinicians were permitted to accept CURATE.AI dose recommendations, or reject the recommendations and dose based on clinical judgement. **Results:** Since August 2020 we recruited ten patients: single-agent capecitabine (n = 1), XELOX (n = 6), and XELIRI (n = 3). As of 20 Jan 2022, one patient remains on the trial. The prescribed dose was on average reduced by 20 % (\pm 13.8 %) as compared to the projected SOC dose. The nine reported patients completed 3.9 cycles (\pm 2.2 cycles), with the longest participation lasting 8 cycles. CURATE.AI recommendations were considered in 27 out of 40 total dosing decisions and accepted for prescription in 26 of those decisions. The reasons for not considering CURATE.AI included insufficient time from patient recruitment to the first dose administration and complex medical circumstances at the time of the dosing decisions. **Conclusions:** CURATE.AI has been successfully incorporated into the clinical workflow of dynamic dose selection in the treatment of solid tumors under a clinical trial. Prospective validation of CURATE.AI led to a reduction of an average prescribed capecitabine dose, which alongside additional preliminary findings may eventually play an important role in improving patient response rates and durations compared to SOC. Results from the PRECISE CURATE.AI trial support the initiation of a randomized clinical trial and potential expansion towards other oncologic indications. Clinical trial information: NCT04522284. Research Sponsor: Institute for Digital Medicine (WisDM) Translational Research Programme (R-719-000-037-733) at the Yong Loo Lin School of Medicine, National University of Singapore, Other Government Agency.

1575

Poster Session

Analyzing patient engagement with digital health tools to facilitate equity across a large statewide community oncology practice.

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Background: Digital health solutions (DHS) allow for enhanced remote communication between patients and clinical staff and the COVID-19 pandemic has brought these tools to the forefront of care delivery. Once adopted, barriers to adequate utilization still exist. Given the important need to decrease digital divides, and the diversity of patients and care settings across our clinic's 220 sites of service, we sought to understand how utilization of oncology DHS may be limited among certain populations.

Methods: We investigated utilization among cancer patients who enrolled and engaged with a portfolio of DHS between March 1, 2019 and January 15, 2022. This portfolio includes three tools: (1) an electronic patient-reported outcomes (ePRO) remote monitoring program for tracking symptoms and oral adherence, (2) a patient portal (PP) for securely accessing patient health records, and (3) digital education (DE) for patients regarding disease and treatments. ePRO completion rate, average number of PP logins, and DE read rate were used as measures of utilization for each tool, respectively, and compared among patients with different age (< 65 and ≥65 years), language preference [English (EL) or Spanish (SL)], and distance from clinic (non-rural: < 20 miles OR rural: ≥20 miles). Mann-Whitney U and Chi-Square tests were used to compare continuous and categorical variables, respectively.

Results: This study included a total of 77,347 unique patients representing 651,004 digital encounters. 9,938 patients engaged in ePRO, 49,771 patients in PP, and 12,044 patients in DE. Engagement across all DHS was high in patients of age group < 65 (ePRO: 72.7%, PP: 79.67% and PE 54.7%) as compared to ≥65 years, but the ePRO completion rate is high in ≥65 age group (59.0% vs 55.6%), whereas no significant difference was observed in the PP login activity and DE read rate. EL patients were significantly (p-value < 0.01) more engaged (ePRO 68% vs. 54%, PP: 80% vs. 62%, DE: 57% vs. 37%) and had higher digital utilization (ePRO completion rate: 57.31% vs 53.23%, average PP logins: 7.48 vs 7.14 and DE read rate: 96.2% vs 90.8%) than SL patients across the DHS. Patients living in rural areas comprised roughly 25% of the population and participated across tools similarly as patients living in non-rural areas (ePRO 67% vs. 69%, PP: 79% vs. 79%, DE: 56.9% vs. 56.8%). Utilization of the portfolio was variable based on rural vs non-rural status (ePRO completion rate: 56.3% vs. 57.4%, average PP logins: 7.9 vs. 7.3, DE read rate: 96.02.7% vs 96.3%).

Conclusions: Despite variable engagement based on age, language, and rural status across the portfolio, patients within these populations continue to utilize the DHS. How we understand and explore enhancements to DHS remain under investigation for tool optimization for patient-specific barriers to care. Research Sponsor: None.

Comparative effectiveness of different interventions for cancer-related fatigue delivered digitally by online platforms.

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Background: As cancer treatments improve, patients' quality of life becomes even more important. In parallel, supportive care delivery is increasingly challenging, also due to resource pressures and COVID19. The effectiveness of digital and remote patient support tools as a complementary approach to improve patients' quality of life is under evaluation. Fatigue is considered among the most prevalent and persistent side effects regardless of tumour type; also, despite ongoing research, there is no single approach established. We compare the effectiveness of different self-care interventions delivered by online platforms to cancer patients in several countries. **Methods:** Patients report side effects (including Fatigue) on the CareAcross online platforms and receive tailored support to help them improve their quality of life. The supportive material encompasses many topics, and patients may receive several combinations. For Fatigue, different topics (nutrition, hydration, rest etc) were analysed to evaluate effectiveness based on prospectively collected patient reported outcomes. **Results:** 1456 breast, lung, colorectal or prostate cancer patients from 8 countries (mainly UK, Germany, France, Spain, Italy) reported Fatigue at least once. This analysis focuses on persistent fatigue: 1215 patients reported Fatigue more than once, receiving up to 7 permutations of topics (F1-F7; F4-7 consist of F1-3 combinations). All permutations include the "Physical Activity" topic (see Table). Overall, the "Hydration" topic stands out as consistently linked with the most effective material (all except F3). Comparative analysis between similar combinations shows that those with "Anemia warnings" and "Rest" tend to be more effective (F7>F6). Ambiguously, the "Physical activity before & after treatment", "Relaxation exercises" and "Fatigue diary" topics contribute to effectiveness (F5>F1), but do not counterbalance absence of the previous 3 (F1>F3). Food-related topics have unclear impact, too: "Food types" is absent from the top combination (F2) where "Food timing" is used; however, that topic is linked with a slightly inferior combination (F7>F5). **Conclusions:** Fatigue is a complex, multi-factorial challenge; digitally delivered interventions can lower its incidence. Hydration appears effective, but the nature of these interventions complicates their thorough evaluation. Randomised studies may enhance these findings and enable additional personalisation towards further quality of life improvements. Research Sponsor: None.

Material (beyond "Physical Activity")	F1 (N = 65)	F2 (N = 77)	F3 (N = 79)	F4 (N = 213)	F5 (N = 200)	F6 (N = 205)	F7 (N = 376)
Physical activity before & after treatment			Y		Y	Y	Y
Relaxation exercises		Y	Y	Y	Y	Y	Y
Fatigue diary		Y	Y	Y	Y	Y	Y
Food types	Y		Y	Y	Y	Y	Y
Food timing		Y		Y		Y	Y
Hydration	Y	Y		Y	Y	Y	Y
Rest	Y			Y	Y	Y	Y
Anemia warning	Y			Y	Y		Y
Effectiveness—reduced Fatigue Incidence	27.7%	41.6%	21.5%	29.1%	34.0%	29.8%	32.2%

Electronic capture of cancer-related distress in a community oncology program.

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Background: Cancer related distress can be seen in as many as one in two patients. Many organizations such as the Commission on Cancer require distress screening. National Comprehensive Cancer Network (NCCN) distress thermometer is a common tool used for screening. We studied feasibility of embedding the NCCN thermometer into oncology electronic health record (EHR) for routine patient care. We concurrently studied feasibility of using a mobile health tool for serial evaluation of cancer related distress. **Methods:** A flowsheet containing NCCN distress thermometer questions was created in Epic EHR (Epic Systems, Verona, WI). Oncology nurses used the flowsheet for routine patient assessment. Patients with distress level ≥ 4 answered additional questions. Ancillary care providers such as palliative care nurses or social workers addressed the identified needs by providing appropriate 'services'. A field to capture these interventions was created. We also adapted our previously reported web based mobile tool [1] for monitoring cancer distress. Patients rated their distress on a 1-10 scale and highlighted the distress domain (physical, emotional, practical, family). Distress level ≥ 4 generated a color-coded flag for provider review and intervention. Data from both electronic tools was periodically analyzed to inform patient care and quality improvement. **Results:** Between January and December 2021, Epic EHR based distress flowsheet collected 28,594 distinct responses in 911 patients. 57.4%, 14.9%, 14.1%, 9.4% and 2.3% of the responses were in the physical, emotional, practical, familial and spiritual domains respectively. 'Other' responses were 1.4%. Cumulative frequency of non-physical problems was 42.5%. 1819 'services' were provided with 357 emotional, 351 work, 351 housing, 350 transportation and 350 financial need-based interventions. Of 1231 patients who used the distress scale and provided additional comments, 315 (25.5%) had distress levels ≥ 4 . The mobile tool captured 849 unique patient responses to the distress question between April 2020 and February 2022. Distress level ≥ 4 was flagged by 281 unique patients (33.09%). Average distress level was 2.7. Emotional domain problems generated the greatest distress level followed by family, physical and practical problems in decreasing order. **Conclusions:** We demonstrate feasibility of electronic capture of cancer related distress to facilitate holistic patient care in a community-based oncology program. EHR based and mobile tool distress evaluations generated concordant results. Distress caused by emotional, practical and familial domain problems was nearly as frequent and often more severe than distress caused by physical problems, underscoring the need for comprehensive cancer care. References: Sanyal, A. *Mobile health tool for monitoring cancer treatment complications*. 2020 ASCO Quality Care Symposium: American Society of Clinical Oncology. Research Sponsor: None.

Association between remote monitoring and acute care visits in high-risk patients initiating intravenous antineoplastic therapy.

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Background: Acute care visits (emergency department [ED] visits or inpatient admissions) for patients with cancer are growing disproportionately. Traditional oncology care models have not effectively identified and managed at-risk patients to prevent acute care. A next step is to harness advances in technology and mobile applications to enable patients to report symptoms any time, enabling “digital hovering” - intensive monitoring and management of high-risk patients. Our objective was to evaluate a digital platform that identifies and remotely monitors high-risk patients initiating intravenous antineoplastic therapy with the goal of preventing unnecessary acute care visits. **Methods:** This was a single-institution matched cohort quality improvement study conducted at an NCI-designated cancer center between January 1, 2019 and March 31, 2020. Eligible patients were those initiating intravenous antineoplastic therapy who were identified as high-risk for seeking acute care. Patients were identified as high-risk for an acute care visit by their oncologist with decision support from a web-based machine learning model. Enrolled patients’ symptoms were monitored using a digital platform. The platform is integrated into the EMR and includes: 1) a secure patient portal enabling communication and daily delivery of electronic patient-reported outcomes symptom assessments; 2) clinical alerts for concerning symptoms; and 3) a symptom trending application. A dedicated team of registered nurses and nurse practitioners managed reported symptoms. These clinicians acted as an extension of the primary oncology team, assisting with patient management exclusively through the platform. The primary outcomes evaluated were incidence of ED visits and inpatient admissions within six months of intravenous antineoplastic initiation. **Results:** Eighty-one high-risk patients from the intervention arm were matched by stage and disease with contemporaneous high-risk control patients. Matched cohorts had similar baseline characteristics, including age, sex, race, and treatment. ED visits and hospitalizations within six months of treatment initiation were analyzed using cumulative incidence analyses with a competing risk of death. The cumulative incidence of an ED visit for the intervention cohort was 0.27 (95% CI: 0.17, 0.37) at six months compared to 0.47 (95% CI: 0.36, 0.58) in the control group ($p = 0.01$). The cumulative incidence of an inpatient admission was 0.23 (95% CI: 0.14, 0.33) in the intervention group versus 0.41 (95% CI: 0.30, 0.51) in the control group ($p = 0.02$). **Conclusions:** The narrow employment of technology solutions to complex care delivery challenges in oncology can improve outcomes and innovate care. This program was a first step in using a digital platform and a remote team to improve symptom care in the home for high-risk patients. Research Sponsor: U.S. National Institutes of Health.

Lack of price transparency for prostate-directed radiation therapy relative to radical prostatectomy.

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Background: For patients with low to favorable-intermediate risk prostate cancer (PC), management with active surveillance, radical prostatectomy (RP), external beam radiation therapy (EBRT), and brachytherapy (BT) are all National Cancer Center Network-supported definitive monotherapy options. Because therapy is non-urgent and choosing therapy can be complex, patients routinely seek second opinions and cost can be an important consideration. Recent federal price transparency (PT) guidance requires hospitals to provide payer-negotiated prices for ≥ 300 common services in a “shoppable,” user-friendly, online format. 70 services, including RP, are specified, while the remainder are left to institutional discretion. Despite equipoise between radiation therapy (RT, inclusive of EBRT and BT) and RP in definitive treatment for PC, inclusion of prices for RT is optional. National Cancer Institute (NCI)-designated cancer centers (NCI-CC) are high volume referral centers who have the option to volunteer prices for RT; the rate at which NCI-CC choose to report payer-negotiated price estimates for prostate-directed RT is unknown. We hypothesize that reporting rates for BT and EBRT are significantly lower than for RP. **Methods:** Through online query, we identified “shoppable” price tools for NCI-CC in December 2021. Using billing codes and keyword searches, we queried these price tools for cost estimates for RP, EBRT (delivered using intensity modulated radiation therapy), and BT. Descriptive statistics, include frequency counts and proportions, were performed. The rate of reporting of “shoppable,” negotiated prices for each therapy was assessed. These rates were compared using the chi-squared test (significance level of $\alpha = 0.05$). **Results:** Of the 63 NCI-CC offering clinical care, 58 (92%) published “shoppable” tools. 6 (10%), 7 (11%), and 51 (81%) published “shoppable” prices for EBRT, BT, and RP, respectively, demonstrating a significantly higher rate of publication of prices for RP than for EBRT or BT ($P < 0.001$). All of the published prices for BT were for high dose rate BT. The 11 Medicare Prospective Payment System–exempt NCI-CC had the highest rates of reporting “shoppable” prices at 91%, with 64%, 27%, and 36% including prices for RP, EBRT, and BT, respectively. **Conclusions:** Under existing regulations, patients with PC can obtain payer-negotiated price estimates for EBRT and BT from just roughly 10% of NCI-CC, while price estimates for RP are offered by $> 80\%$ of these institutions. This represents a potential obstacle to informed decision making, undermines the stated goals of US PT health policy, and the impact on utilization rates (or patient choice of therapy) is unknown. Moving forward, mandating the inclusion of common RT services (EBRT and BT) in “shoppable” price tools is a straightforward intervention that may be highly beneficial in this common cancer population. Research Sponsor: None.

Pharmaceutical industry payments to physicians for the promotion of cancer drugs.

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Background: Personal financial payments from the pharmaceutical industry to oncologists are common and increasing. A prevalent view is that the purpose of industry payments to physicians is to facilitate education on new drugs. However, little is known regarding the distribution and trends in industry payments related to cancer drugs. The goal of this study was to characterize current patterns in industry payments related to cancer drugs, and test whether these patterns are consistent with an educational purpose. **Methods:** We included on-patent cancer drugs without generic/biosimilar competitors, and used publicly-available federal data sources to measure Medicare spending (proxy for overall drug revenue), number of prescribers, and industry payments (Open Payments, which includes data regarding which the drug[s] was the subject of each payment) for each calendar year from 2014-2018. We analyzed General Payments to individual physicians, which encompasses payment types such as meals, travel, consulting, and speaking fees. We tested two hypotheses implied by the claim that industry payments serve educational purposes. First, payment amounts should not be associated with drug revenue. To test this hypothesis, we used generalized estimating equations (GEE) to model the association between mean per-physician industry payments and Medicare spending. Second, payments related to a given drug should decline over time as physicians become educated. To test this hypothesis, we determined the relative year-to-year change in industry payments for all cases wherein consecutive years were observed, and used GEE to estimate the year-to-year change with respect to duration of time since initial FDA approval. **Results:** The sample included 89 drugs and 361 drug-year observations. The total amount of industry payments for oncology drugs increased during the study period, from \$53,333,854 in 2014 to \$90,343,731 in 2018. There was no association between log-transformed mean, per-physician industry payments and per-physician Medicare spending (estimate -0.001, 95%CI: -0.005, 0.004). In aggregate, Industry payments for cancer drugs were greatest immediately after FDA approval and trended downward over time; the estimated industry payments in the subsequent year for a drug with mean payments of \$1,000 per-physician in the index year was: \$681* for drugs 0-4 years since approval, \$825 for drugs 5-9 years, and \$679* for drugs ≥ 10 years (* $p < 0.05$). **Conclusions:** The absence of association between industry payments and Medicare spending and the decline in industry payments for drug subsequent to approval are consistent with claims that these payments function to facilitate physician education. Research Sponsor: U.S. National Institutes of Health.

Exploring country priorities and contextual considerations for implementing national cancer control plans (NCCP) among participants of International Cancer Control Partnership (ICCP) ECHO.

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Background: Promoting NCCP implementation by low- and middle-income countries (LMICs) is key to addressing inequities in cancer outcomes and the global burden of cancer. We explored contextual factors that may influence implementation of NCCP priorities in LMICs. **Methods:** Seven countries participated in the 2021 International Cancer Control Partnership ECHO (R) geared toward creating a community of practice to inform NCCP implementation. Using qualitative methods, we conducted focus group discussions (FGDs) with country teams who were asked to identify NCCP priorities and provide contextual considerations around implementing these in the 12-months program. FGDs were audio-recorded, transcribed, double-coded, and underwent thematic analysis. **Results:** Thirty-three participants from 6 Sub-Saharan African countries and 1 country in Asia took part in 7 FGDs, including 14 physicians, 9 non-governmental organizations, 6 Ministry of Health/NCCP and 4 cancer registry representatives. All seven country teams (100%) prioritized cancer early detection, especially for cervical (71%) and breast (57%) cancer, including by educating primary care clinicians (57%) and general population (43%) about cancer signs and symptoms. Related contextual factors included late-stage diagnosis of cancer (43%) and low knowledge about cancer among primary care clinicians and the general population (29% each), respectively. Finding resources for implementation of NCCP priorities was important given lack of funding (57% each). Harmonizing programs and building partnerships for implementation (57%) was prioritized given perceived fragmentation of efforts and benefit of leveraging limited resources (29% each). Improving access to treatment (43%) was a priority given a lack of oncology specialists (29%) and unaffordable treatment (14%). Improving access to palliative care (43%), including by writing guidelines (29%), was prioritized due to late-stage diagnosis and insufficient access to palliative care (14% each). Improving cancer registry data was essential for NCCP program planning (43% each), while cancer research (43%) was key to answering specific questions related to cancer registry data (14%) and program impact (29%). Additional contextual considerations for making progress on these priorities discussed by country teams included leveraging existing programs (100%) and learning from other countries and ICCP technical experts (57% each). **Conclusions:** There were similarities in country NCCP priorities and contextual factors affecting implementation. These results allow for future exploration of how LMIC country teams implement NCCPs and examine the value of communities of practice promoted by ICCP and facilitated by ECHO, towards improving cancer outcomes. Research Sponsor: None.

Financial payments from the pharmaceutical industry to U.S. cancer centers, 2014-2019.

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Background: Payments from the pharmaceutical industry to US health care providers were made public through Open Payments in 2013. Since then, industry payments to individual physicians have been studied extensively, but payments to hospitals remain uncharacterized. The goal of this study was to examine trends in industry payments to US cancer centers. **Methods:** We identified all US cancer centers that were National Comprehensive Cancer Network (NCCN) members or were National Cancer Institute (NCI) comprehensive cancer center as of 2019. Each institution was manually mapped to Open Payments, which contains industry payment data. Where applicable, subsidiary hospitals were included with the parent center. Among the NCCN centers, we used National Plan and Provider Enumeration System data to identify medical oncologists practicing there. Oncologists were linked to Open Payments by name and address. We analyzed “research payments” (RP), which include payments related to preclinical and clinical research, and “general payments” (GP), which include non-research-related payments in categories such as speaker fees, consulting fees, meals, grants, charitable contributions, and licensing fees. We ascertained public research support from NIH data, and included all research project grants. We used correlation analysis and linear regression models to assess the association between industry payments to a cancer center and to oncologists practicing at that center. All dollar values were inflation-adjusted to 2019 dollars using the Consumer Price Index for medical care from the US Bureau of Labor Statistics. **Results:** Overall industry RP to US cancer centers increased from \$527 million in 2014 to \$653 million in 2019, while GP increased from \$346 million to \$786 million. NCI research funding increased from \$1,397 million in 2014 to \$1,583 million in 2019 (13.3% increase) while overall industry payments (RP+GP) increased from \$873 million to \$1,439 million (64.8% increase). Industry payments were highest as a portion of total income (industry + NCI) at MD Anderson (64.2%) and lowest at St. Jude (0.1%). Among NCCN institutions, industry payments to cancer centers and the oncologists practicing at those centers were correlated (coefficient = 0.382). A \$1,000 increase in GP to a cancer center from a given pharmaceutical company was associated with a \$1.00 (\$0.61 - \$1.30) increase in GP from that company to oncologists at that cancer center. **Conclusions:** From 2014-2019, cancer center funding from industry sources grew quickly, driven by an increase in non-research payments, and now approaches the amount of public research funding cancer centers receive. Cancer center acceptance of industry payments is associated with increased industry payments to its employed physicians, which are known to sway prescribing practices. These trends raise concerns regarding the ability of these institutions to fulfill their public missions. Research Sponsor: U.S. National Institutes of Health.

Disparity in initiation of checkpoint inhibitors among metastatic melanoma and lung cancer.

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Background: Checkpoint inhibitors are transforming cancer care. However, the high prices of these medicines raise concerns over their affordability and disparity in use. The objective of this study is to describe the disparity in initiating checkpoint inhibitors and examine patient- and area-level factors associated with delayed initiation. **Methods:** This study is a retrospective cohort study using Optum data. We identified commercially insured patients newly diagnosed with metastatic lung cancer and melanoma since the introduction of checkpoint inhibitors in these cancers (lung cancer cohort: diagnosed between January 2015 and December 2020; melanoma cohort: diagnosed between January 2011 and December 2020). Time from metastatic cancer diagnosis to initiating checkpoint inhibitors was analyzed using Cox proportional hazard models. Independent variables included county-level measures (percentage of black population, percentage of Hispanic population, percentage of other minority, percentage of population living below poverty line, rurality, number of medical oncologist per population, and having a National Cancer Institute designated cancer center) and patient-level characteristics (age, sex, Charlson comorbidity index, any dual eligibility, Medicare Advantage, and year of diagnosis). We clustered standard errors at the county level. **Results:** The percentage of metastatic lung cancer and metastatic melanoma patients on checkpoint inhibitors increased from 23% to 52% from 2015 to 2020 and from 22% to 58% from 2011 to 2020. Counties with greater percentage of black, Hispanics, and other minorities were high urban with greater density of medical oncologists and NCI-designated cancer centers. However, greater percentage of Hispanic population in a county was associated with significantly slower initiation of checkpoint inhibitors for both the lung cancer and the melanoma cohorts (hazard ratios [HR]: 0.937 and 0.946, respectively; p-values: < 0.001 and 0.014, respectively). Percentage of other minority population in a county was associated with slower initiation for metastatic lung cancer (HR: 0.983; p-value: < 0.001). No other county-level factors had a significant coefficient from the multivariate Cox models. In terms of patient-level characteristics, older age, female, more comorbidities, any dual eligibility, and Medicare Advantage were associated with significantly slower initiation for the lung cancer cohort and older age and female were associated with significantly slower initiation for the melanoma cohort. **Conclusions:** Commercially insured metastatic lung cancer and melanoma patients who lived in counties with greater percentage of Hispanic population had slower initiation of checkpoint inhibitors after their cancer diagnosis, despite the fact that those counties had greater density of medical oncologists and NCI-designated cancer centers. Research Sponsor: None.

The impact of physician-hospital integration on spending and quality of oncology care.

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Background: There has been increasing hospital and health system ownership of physician practices in recent years, particularly in oncology. However, relatively little is known about how this impacts care delivery for patients with cancer, who use many hospital-based services that may be impacted by integration. We evaluated the impact of physician-hospital integration in oncology on spending and quality of care for Medicare beneficiaries with cancer. **Methods:** We used Medicare Fee-for-Service claims from 2005-2019 linked with a unique Health System and Provider Database, developed by National Bureau of Economic Research and Harvard University researchers, to track practice ownership relationships over time. We used a stacked event study to assess outcomes for patients three years before and after oncologists move from independent practices to hospital- or system- owned practices. We compared outcomes to a control group with oncologists who shifted from independent to hospital- or system-owned practices in later years. We focused on two cohorts of patients. The first cohort included cancer patients with presumed incident or recurrent cancer based on ≥ 2 visits to an oncologist and no visit in the past year. For these patients, we evaluated the impact of physician-hospital integration on the likelihood of receiving chemotherapy following the visit. The second cohort included 6-month episodes for patients receiving chemotherapy. For these patients we evaluated the impact of physician-hospital integration on spending, utilization, and quality. Quality measures included receipt of timely chemotherapy (within 60 days) following surgery, inpatient readmissions, non-use of tamoxifen + strong CYP2D6 inhibitors, and end-of-life intensity of care measures. **Results:** There was no change in the likelihood of receiving chemotherapy with an initial oncology consultation following an oncologist's transition to hospital-based employment. Total spending during six-month chemotherapy episodes increased by \$1391 (95%CI: \$465, \$2316). The primary contributors to this growth were increases in spending on inpatient care, chemotherapy administration, and office visits. Spending growth, where observed, was driven primarily by higher Medicare prices for care in hospital outpatient settings. We found no positive impact of physician-hospital integration on timeliness of chemotherapy initiation, readmissions, concurrent use of tamoxifen+strong CYP2D6 inhibitors, or intensity of end-of-life care. **Conclusions:** Physician-hospital integration resulted in higher prices and thus higher spending, but had limited impact on utilization and no detectable impacts on measures of quality. These results suggest that claims of quality improvements and concerns regarding overuse associated with physician-hospital integration may be overstated. Our results also support continued movement towards site-neutral payments. Research Sponsor: U.S. National Institutes of Health.

Market determinants of commercial prices for intravenous chemotherapy infusions.

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Background: Recent price transparency legislation mandated that hospitals across the country report their individually negotiated prices with insurers. Using this data, we sought to characterize the prices paid for standard intravenous (IV) chemotherapy infusions, and determine the hospital, regional, and market factors associated with higher prices. **Methods:** We utilized a database of U.S. hospital-reported price transparency data to characterize prices for the most commonly billed chemotherapy drug administration Common Procedural Terminology (CPT) codes—96413 (initial IV chemotherapy infusion) and 96415 (additional hour of IV chemotherapy). We obtained standard charges and commercial prices negotiated with private payers from hospitals that directly administer chemotherapy. To assess variation in prices, we calculated the ratio of the 90th percentile price to the 10th percentile price among private payers in each hospital and among hospitals in each Hospital Referral Region (HRR). We performed multivariable linear regressions to assess hospital, regional, and market factors associated with higher prices. **Results:** A total of 1,458 hospitals reported at least one price for CPT code 96413 or 96415. Hospitals reported 1 chargemaster and a median of 18 (IQR: 8–35) commercial prices negotiated with different private payers. National median commercial prices for CPT codes 96413 and 96415 were \$536.00 (IQR: \$326.43–\$784.63) and \$175.06 (IQR: \$98.28–\$327.25), respectively. Within each hospital, the 90th percentile commercial price was 2.2 times higher, on average, than the 10th percentile price for CPT code 96413, and 2.8 times higher for 96415. Among different hospitals within each HRR, the median commercial price at the 90th percentile hospital was 1.5 times higher than at the 10th percentile for CPT code 96413, and 2.3 times higher for 96415. On multivariable analysis, higher prices for CPT code 96413 were observed at for-profit hospitals (\$215.12 higher than government not-for-profit hospitals, 95% CI: \$55.22–\$429.61). Higher prices for CPT code 96415 were observed at hospitals with higher predicted practice costs (\$35.79 for every 1% increase in the geographical practice cost index, 95% CI: \$16.69–\$54.87), and a lower disproportionate share percentage (\$0.96 for every 1% decrease in DSH patient percentage, 95% CI: \$0.08–\$19.41). **Conclusions:** Commercial prices for commonly billed IV chemotherapy infusions demonstrate significant variability. Prices for identical infusions vary by a factor of 2 depending on which hospital or private payer a patient selects. While prices for CPT code 96415 are largely explained by the relative cost of care, prices for the more expensive 96413 appear to be driven by the profit-status of the hospital. Further study is required to characterize the implications of such high levels of price variability on access to care and overall healthcare costs. Research Sponsor: None.

Time to access to novel anticancer drugs in Europe, a case study in seven European countries.

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Background: After European Medicines Agency Marketing Authorization (EMA-MA) different national reimbursement processes may contribute to unequal access throughout the EU. The aim of this study is to investigate the access time to new anticancer medicines in seven high-income Northern European countries and factors influencing the reimbursement process. **Methods:** We performed a retrospective database study. New anticancer medicines were included with a positive CHMP advice between January 2016 and January 2020, leading to EMA-MA followed by an application for national reimbursement approval in Germany, UK, France, The Netherlands, Belgium, Norway and Switzerland. The relevant Health Technology Assessment (HTA) - and reimbursement websites for each country were used to identify reimbursement dates. Time to access was defined as the time between EMA-MA and date of inclusion in the relevant reimbursement list. In addition we investigated the differences in national approval process and study-, medication- and patient- related factors which might influence the time to reimbursement. **Results:** We found that for the thirty-six new anticancer medicines, national reimbursement came on average 289 days after EMA-MA, with a variety of -125 in Switzerland (i.e. non EU-member) to 1415 days. Of these EMA-MA new anticancer medicines 42% were reimbursed in all countries. The average number of cancer medicines reimbursed in the examined countries was 27 (75%), with a range of 24 (67%) in Belgium to 36 (100%) in Germany. The shortest average time from EMA-MA to reimbursement were in Germany, 2.33 days, France and Switzerland following with 207 days and 279 days respectively. The median time to reimbursement was 227 days with a range of 3 days in Germany to 553 days in Belgium. In Germany, where there is no pricing and reimbursement approval required when launching a pharmaceutical, 100% of the cancer medicines are reimbursed within five days. After one year, in the UK 56% of the medicines are reimbursed, followed by 53% in the Netherlands, France and Switzerland. Belgium and Norway have a one year reimbursement rate of 14% and 11% respectively. Access to anticancer medicines is dependent on regulatory procedures, HTA and price regulations. Germany has a fast market access for anticancer medicines with a price regulation one year after launching the medicines. In the other countries, price regulation is part of the launching process. Other factors which might accelerate the time to reimbursement we are examining are high clinical benefit score (ESMO-MCBS), (non-)orphan status of the medicines and submission by big pharmaceuticals. **Conclusions:** This study shows that after EMA-MA, except for Germany, on average it takes a long time for anticancer medicines to be reimbursed in Northern European countries. There is a considerably variety both within and among countries. Research Sponsor: None.

Reliability of cancer registry primary payer information and implications for policy research.

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Background: Researchers commonly use “Primary Payer at Diagnosis” measured in cancer registry data to assess the impact of health policy, such as the Affordable Care Act, on insurance, and the impact of insurance on cancer care and outcomes. Measurement error may bias estimated effect size and significance. Little is known about patterns of Medicaid or Medicare misreporting in registry databases commonly used for policy analysis. **Methods:** We used the National Cancer Institute’s Surveillance, Epidemiology and End Results registry data for adults aged 19-64 years at diagnosis with known cancer stage, linked to most recently available (2007-2011) CMS records on Medicaid and Medicare enrollment at diagnosis month. We recoded the registry Primary Payer variable into 6 categories: private/managed care, Medicare, Medicaid, other government, status unknown, uninsured. State-year policy data regarding Medicaid eligibility and managed care enrollment were also linked. We compared the registry data to Medicaid and/or Medicare enrollment data, and calculated underreporting rates by patient characteristics and state policy. **Results:** The linked sample (N = 896,031) was 68% non-Hispanic white, 49% male. Overall, the registry data reported 7.8% Medicare and 10.1% Medicaid, while enrollment was 5.5% Medicare, 10.4% Medicaid, and 3.4% dual Medicare-Medicaid. The registry data concordantly identified 61.4% and 57.7% of persons identified per enrollment data to be Medicaid-only and Medicare-only, respectively (Table). Most Medicaid-only enrollees without concordant registry information were reported to have private insurance or be uninsured. Medicaid underreporting (39% overall), was higher for males (43%) vs females (37%), in low (46%) vs high (38%) poverty areas, for Medicaid poverty expansion or waiver enrolled (50%) vs cash assistance related eligibility (33%), and in states with large managed care enrollment, all at $p < .001$. If Medicaid and Medicare enrollment data were used to edit the registry data, 8% of persons would switch insurance assignment. **Conclusions:** Primary Payer data reported by cancer registries are subject to measurement error and may result in biased estimates of insurance-related policy impacts. Enhancement with objective Medicaid and Medicare enrollment data will reduce measurement error and may result in unbiased estimates necessary to support policy assessment. Research Sponsor: None.

Distribution of CMS Medicaid & Medicare enrollment by registry primary payer (column %).					
Registry Payer Data	Total (100%)	Medicaid only (10.4%)	Medicare only (5.5%)	Dual enrolled (3.4%)	Neither (80.7%)
Private	68.0	19.3	28.2	7.6	79.6
Medicare	7.8	3.7	57.7	80.2	1.9
Medicaid	10.1	61.4	1.4	6.5	4.3
Other government	3.3	1.2	6.1	1.0	3.5
Unknown insurance status	5.6	3.9	5.2	4.0	5.9
Uninsured	5.1	10.6	1.3	0.7	4.9

Effect of immunotherapy and time-of-day infusion chronomodulation on survival in advanced cancers.

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Background: Emerging clinical studies report correlation of time-of-day infusion (TOI) to immunotherapy outcomes and the intricate interplay of the human circadian rhythm and cancer and immunotherapy exposure. Preclinical and clinical studies have shown cancer chronotherapy to play important role in transcriptional rhythmicity of oncogenic process. We evaluated the association of TOI and immunotherapy outcomes in a large cohort to determine impact of TOI on overall survival (OS) and progression free survival (PFS). **Methods:** We reviewed charts of patients with solid tumors who received immunotherapy, specifically anti programmed cell death protein 1 (PD1) and anti-programmed death-ligand 1 (PD-L1) agents at MD Anderson Cancer Center. Infusion times were divided into two hours cohorts from 8am-8pm and one overnight cohort from 8pm-8am. Accelerated failure time models were used to model OS (log-normal distribution) and PFS (Weibull distribution) with relation to TOI after adjusting for factors such as age, gender, tumor type and prednisone > 10mg daily use within 1 month of immunotherapy initiation to minimize confounding factors. **Results:** Of 6151 patients with advanced tumors, 4441 patients received immunotherapy therapy after adjusting for minimum 140 patients in each tumor cohort from 10/15/2016 until 10/15/2021. Tumor types included advanced lung cancer (31.4%), melanoma (28.7%), renal (14.4%), breast (7.6%), colon (6.2%), liver cancer (3.9%) and head and neck (H&N) cancers (2.8%). Median age was 63 (15-99) with 58% males and 42% female. 1894 (43%) patients received investigational agents and 2547 (57%) received standard of care therapies. Mechanism of action of various agents: anti PD1, anti-PDL1, TGF- β RII and anti-PDL1, anti-PD-1 with OX40+ T Cell activation, PD-1 / PD-L1 bispecific antibody, PD-L1 dependent 4-1BB agonist and anti PD-1 and CTLA-4 activity. Among all patients, median OS was 26.4 months while median PFS was 4.8 months. Preponderance of immunotherapy TOI occurred between 12-2pm and 2-4pm in all patients. Patients receiving overnight TOI with lung, renal and breast cancer demonstrated significantly ($p < 0.05$) poorer OS compared to TOI (10am-4pm) whereas in melanoma, significantly lower OS was seen with overnight, 8-10am and 6-8pm compared to 10am-4pm TOIs. Among H&N cancer patients, early TOI (8-10am) was associated with significantly lower OS compared to afternoon TOI (12pm-4pm). PFS trends were less distinct than for OS but showed a slighted inverted tendency towards lower PFS following daytime TOI. **Conclusions:** In this large cohort of patients treated with immunotherapy, clinically significant association of TOI with overall survival is seen. These intriguing findings warrant prospective validation in a future randomized trial to harness the role of chronomodulation of cancer therapies for improving outcomes. Research Sponsor: None.

Novel use of clinical pathways to identify poor prognosis lung cancer patients: Implementation and outcomes.

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Background: Cancer patients in the last year of life have different clinical needs and evolving goals of care. Using our oncology decision-support pathways to help clinicians consistently identify such patients in a systematic and prospective fashion, at a discrete moment in the care trajectory, may be an important step towards matching the care of these patients with their stated goals. **Methods:** Medical oncologists from each disease group at the Dana-Farber Cancer Institute (DFCI) were tasked with identifying clinical settings in each oncology care pathway associated with an expected median survival of < 12 months. This information was embedded into the underlying data model of the pathways platform, allowing us to determine how often clinicians navigated through each poor prognosis node. **Results:** From 3/1/20 – 6/30/21, there were 264 navigations in 205 unique lung cancer patients receiving standard of care (i.e., not on clinical trial) for a clinical condition associated with poor prognosis. Overall, the median overall survival from the time of a patient's first navigation through a poor prognosis node during the defined study period was 6.4 months. Table lists outcomes for each specific setting. Patients with squamous or small cell lung cancer being treated in or beyond the third-line setting had notably poor outcomes, with less than a third of these patients surviving 6 months from the time of navigation. **Conclusions:** A clinical pathways platform can be a key tool in designating clinical scenarios associated with poor prognosis and identifying patients who may be particularly at risk. Pathways analytics provide real-world evidence corroborating the expected poor prognosis based on published studies and can identify specific clinical subsets for whom specific resources are warranted. By embedding this into the pathways data model, we aim to alert physicians to conduct goals of care conversations, offer supportive care resources, and match patients to appropriate treatment options and clinical trials. Research Sponsor: None.

Setting	Navigations	Died/ censored	6-month survival, %	Median overall survival (OS) from date of pathway navigation, months (95% CI)
Metastatic NSCLC, non-squamous, targeted therapies inappropriate or exhausted, 3 rd line and beyond	95	77/18	51%	6.6 (5.0-8.3)
Metastatic NSCLC, squamous, 2 nd line	26	16/10	64%	9.0 (2.6-13.3)
Metastatic NSCLC, squamous, 3 rd line and beyond	23	18/5	33%	3.5 (1.8-5.5)
SCLC, second line	62	47/15	47%	5.7 (3.9 – 7.5)
SCLC, 3 rd line and beyond	58	49/9	32%	4.2 (3.2-5.2)

Patient efficacy in telehealth is moderated by distress among patients with cancer: A cross-sectional survey study.

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Background: The COVID-19 pandemic increased the use of telehealth to reduce exposure, which was critical for patients with cancer. The extent to which patients with cancer view telehealth visits as meeting their medical needs was investigated using a cross-sectional survey. **Methods:** Patients currently receiving cancer treatment at a single cancer institute who had had at least one telehealth visit were emailed an online survey. Response rate was 5% (94/1944). The survey measured patients': 1) Emotional Thermometer (i.e. distress, anger, depression, anxiety, and need for help on a 0-10 scale); 2) Telehealth usability questionnaire (TUQ; 21-items with various subscales, like interaction quality; $\alpha=0.98$); and 3) Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) scale (five items, e.g., "How confident are you in your ability to make the most of your visits with your doctors?"). Respondents completed the PEPPI-5 for in-person visits and for telehealth visits. Descriptive statistics were calculated for all measures. A generalized linear model was estimated predicting PEPPI-5 for telehealth visits from emotional thermometer and TUQ scores. The interaction between emotional thermometer and TUQ scores was estimated to test the hypothesis that emotional distress moderated the relationship between TUQ and efficacy in patient-provider interactions during telehealth visits. **Results:** Across all five thermometers, 30.8% (28/91) reported a high score on at least one metric. The most frequently reported high score was for anxiety, 23.3% (21/90) and least frequently reported high score was for anger, 12.2% (11/90). The mean TUQ score was 5.5 (SD=1.5) and mean PEPPI-5 score for telehealth visits was 8.1 (SD=2.4). As shown in Table, emotional thermometer scores did moderate the relation between TUQ and patient self-efficacy during telehealth visits. For high emotional thermometer scores, self-efficacy decreased as TUQ scores decreased. **Conclusions:** For patients experiencing high emotional distress, low comfort and ability with telehealth usability resulted in low patient self-efficacy in communicating with providers and getting medical needs met. Telehealth is a convenient and effective modality; however, in times of emotional distress for patients who are not familiar with telehealth, in-person clinic visits may result in greater patient self-efficacy. Research Sponsor: None.

Summary results from generalized linear model estimating patient efficacy during telehealth visits.				
Parameter	Estimate	Standard Error	t-Value	P-value
Intercept	0.04	1.41	0.03	.97
TUQ	1.39	0.25	5.58	<.0001
Emotional Thermometer (low)	6.03	1.80	3.35	.001
TUQ X Emotional Thermometer	-1.00	0.32	-3.15	.002

Responses to telehealth expansion for older adults with cancer during the COVID-19 pandemic.

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Background: Synchronous video visits (“telehealth”) were rapidly adopted to facilitate provision of cancer care during the COVID-19 pandemic, with little time to comprehensively assess patient and provider needs. Attitudes toward telehealth use during active treatment (vs. survivorship care) were largely unknown, as were perceptions of, experiences with, and needed support for telehealth use among older adults with cancer. Older adults in particular may face increased vulnerability to inequities in access to care due to limited digital literacy. **Methods:** We conducted surveys and semi-structured interviews with providers, staff, and older patients (age ≥ 60) from a comprehensive cancer center. Data collection occurred between Dec 2020 - Nov 2021. **Results:** We completed a total of 106 provider/staff surveys, 128 patient surveys, 20 provider/staff interviews, and 15 patient interviews. A majority of surveyed providers/staff felt that telehealth should “definitely be offered” during treatment-phase encounters (55.9% treatment follow-up; 69.1% results communication; 70.2% discussing treatment side effects). Similarly, most patients indicated they would be willing to have video visits with a member of their care team for: discussing treatment side-effects (73.5%), results communication (69.6%), and treatment follow-up (65.7%). Patients reported experiencing challenges with joining video visits (29%) and understanding the telehealth process (28%). Similarly, less than a third (30.8%) of providers/staff agreed or strongly agreed that the institution did a good job of preparing patients for their first telehealth encounter. Patients felt the institution should do more to communicate the advantages of telehealth to older adults in handouts and videos, which included: engaging multiple family members in critical appointments (e.g., treatment decisions, end-of-life), seeing their doctor when they were too sick to travel, and reducing potential exposure to infectious disease at the clinic. Participants suggested several strategies to assist patients with limited digital literacy: offering video tutorials of the connection process, creating “fake appointments” to practice online connections, and hiring a digital navigator to assist with technical difficulties and setup of the online portal. Despite challenges, a majority of surveyed patients (65.7%) and providers/staff (76.9%) intend to continue using telehealth after the COVID-19 pandemic passes. **Conclusions:** Use of telehealth for cancer care was received positively by older patients and providers/staff. Taking targeted steps to enhance implementation could reduce barriers to care, including among older adults and other populations with limited digital literacy, thereby promoting greater equity of access to telehealth benefits beyond the pandemic. Research Sponsor: Simmons Comprehensive Cancer Center, Community-Engaged Research Pilot Award.

Evaluation of a pharmacist-led video consultation to identify drug interactions among patients initiating oral anticancer drugs.

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Background: The past decade has seen a dramatic increase in the number of oral anti-cancer drug (OACD) approvals in the United States. Though polypharmacy and drug-drug interactions (DDIs) likely contribute to OACD toxicity, the prevalence of these features in patients on OACDs remains largely unknown. We aimed to evaluate a one-time 30-minute pharmacist-led video consultation among metastatic cancer patients initiating OACDs to identify medication list inaccuracies as well as the prevalence, characteristics, and severity of OACD-related potential DDIs. **Methods:** We conducted a single-arm, prospective telehealth intervention study among 29 patients initiating OACDs to evaluate a one-time 30-minute pharmacist-led video consultation. The video visits focused on identifying and discussing polypharmacy and potential DDIs, and pharmacists then communicated recommendations to each patient's oncologist. We estimated the prevalence, characteristics (QTc prolongation, absorption interactions, etc.), and severity of OACD-related potential DDIs. Lexicomp and Micromedex were used to assess potential DDIs and measure severity on a standardized scale (A – D, X). In addition, we assessed the prevalence of medication list inaccuracies, polypharmacy, and patient satisfaction. **Results:** Twenty-five patients completed the intervention (86% completion rate) of whom 40% were 75 years of age or older and 60% were men. The majority were white (68%) and non-Hispanic (76%). Sixteen patients (68%) had a solid tumor diagnosis. Nearly half (48%) were insured by Medicare. The median number of medications per patient was 9 with a range of 4 – 21, and 96% of patients had at least 5 prescriptions listed. The median number of medication list errors was 2 with a range of 0 – 16, with at least 1 error for 76% and more than 1 error for 52% of patients. Pharmacists identified potential OACD-related interactions in 9 cases (40%). These included change in drug absorption or metabolism (7), QTc prolongation (1), hypotension (1), and bleeding (1). Interactions were classified as either category C (8) or D (2), requiring close monitoring or a change in treatment, respectively. All patients expressed a high level of satisfaction with the video visit. **Conclusions:** Polypharmacy, medication list errors, and potential DDIs are prevalent among patients initiating OACDs despite use of an electronic medical record requiring medication reconciliation. Our study suggests that a one-time remote 30-minute pharmacist-led video consultation can effectively identify and address OACD-related potential DDIs, which may decrease medication complexity and improve adherence in this population. Research Sponsor: American Cancer Society.

Variation in telemedicine usage in gynecologic cancer: Are we widening or narrowing disparities?

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Background: Telemedicine rapidly increased with the COVID-19 pandemic and may be a way to reduce care disparities. Our aim was to evaluate sociodemographic (race, insurance), patient, health system, and cancer factors associated with use of telemedicine in gynecologic cancers. **Methods:** We conducted a retrospective cohort study of patients with documented endometrial or ovarian cancer using the nationwide de-identified electronic health record-derived Flatiron Health data. We used multi-level regression models to analyze the association of telemedicine usage during COVID-19 pandemic (2020-2021) with sociodemographic, patient, health system, and cancer factors overall. **Results:** Of 13,450 patients with endometrial or ovarian cancer, 14.4 % (95%CI 14.0-16.1) used telemedicine during COVID-19 for their cancer care within the Flatiron Health network. Insurance was not associated with likelihood of telemedicine in any model. Region was significantly associated with telemedicine usage across models with patients living in the Northeast more likely to use telemedicine. **Conclusions:** In this large cohort study, we found regional disparities across cancer types and oncology settings. Expanding access to telemedicine may improve racial and geographic disparities in gynecologic cancer. Research Sponsor: American College of Obstetrics and Gynecology, University of Pennsylvania Basser Center for BRCA.

Predictors of telemedicine usage during COVID-19 in gynecologic cancer.		
	Risk ratio	Risk ratio
	Endometrial cancer	Ovarian Cancer
Patient Race		
Black	0.79 (0.62-1.01)	0.83 (0.62-1.12)
Asian	0.94 (0.57-1.57)	1.44 (1.04-1.97)*
Other	0.83 (0.63-1.10)	1.11 (0.93-1.34)
Unknown race	0.95 (0.74-1.22)	1.06 (0.87-1.28)
White	Reference	Reference
Hispanic or Latino	1.39 (1.00-1.94)	0.77 (0.59-1.02)
Patient Insurance		
Medicaid	0.85 (0.61-1.18)	0.82 (0.62-1.08)
Medicare	0.86 (0.68-1.07)	1.02 (0.85-1.22)
Uninsured	0.92 (0.73-1.17)	0.85 (0.70-1.03)
Unknown	0.90 (0.071-1.15)	0.85 (0.68-1.05)
Private insurance	Reference	Reference
Region		
Southeast	0.29 (0.22-0.38)**	0.44 (0.36-0.53)**
Midwest	0.44 (0.33-0.58)**	0.48 (0.38-0.61)**
West	0.56 (0.44-0.72)**	0.67 (0.56-0.79)**
Unknown	1.05 (0.84-1.31)	0.86 (0.70-1.04)
Northeast	Reference	Reference
Recurrent cancer	1.11 (0.89-1.40)	1.70 (1.49-1.93)**

Risk ratios are adjusted for age, BMI, ECOG status, stage, and histology.

*p-value<0.05.

**p-value<0.001 (Bonferroni correction applied).

Hematology/oncology outpatient perspectives on telehealth one year into the COVID-19 pandemic.

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Background: Telehealth use expanded during the COVID-19 pandemic, but few studies have explored patient perspectives on it after the initial months. Using mixed methods, we aimed to understand patient telehealth perspectives and to examine for whom telehealth is less optimal. **Methods:** A modified Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ) for hematology/oncology outpatient care was sent to patients ≥ 18 years old within the M Health Fairview Masonic Cancer Clinic with ≥ 1 prior telehealth visit (phone and/or video). Two focus groups were also conducted. We summarized cohort characteristics and views on telehealth. We dichotomized selected TSUQ items (measured on a 1-5 scale) and evaluated them using logistic regression, adjusted for age (< 65 years, ≥ 65 years), gender, race (White, other), income ($< \$50,000$, $\$50,000-99,000$, $\geq \$100,000$, prefer not to say), education (no college degree, at least college degree), and having cancer (yes, no). Focus group data were analyzed qualitatively. **Results:** Of 7848 invitations, 588 surveys were completed (7.5% response rate). For respondents, 71% were female, 68.7% married/partnered, 90.6% identified as White, and 36.1% had a graduate/professional degree with an annual salary $\geq \$150,000$ (21%). Most had cancer (73.3%) but were not currently receiving treatment (36.5%); 40% each had employer-based insurance or Medicare. Focus group members ($n = 16$) were chosen from a demographic mix of 121 volunteers. Most survey respondents found telehealth satisfactory [mean $3.8 \pm$ standard deviation (SD) 0.9] and easy to use (mean $3.4 \pm$ SD 0.9), 72.2% found it convenient, and 82.2% agreed that it saved time. Most (78.6%) would be happy with a combination of telehealth and in-person care going forward, but those with cancer were less likely to prefer future telehealth care (adjusted odds ratio [OR] 0.52, 95% confidence interval [CI] 0.34 - 0.81). Being male and having lower incomes were associated with greater telehealth satisfaction, (male vs. female, OR 1.68, 95% CI 1.00 - 2.83), income $< \$50,000$ vs. $\geq \$100,000$ (OR 2.47, 95% CI 1.16 - 5.28). Focus group members reported between 1 - 30 telehealth visits (overall care range 8 months - 30 years). Views on telehealth mirrored survey results. Time saved and reduced exposure risk were beneficial, especially for those in rural settings and for those seeing genetic counselors or palliative care. However, concerns were voiced about fewer in-person interactions, communication gaps, and provider style variability. **Conclusions:** Our findings show that oncology patients prefer care in person despite telehealth's benefits. Additional work is needed to ascertain the optimal, and possibly patient subgroup-specific, combination of in-person and telehealth in ambulatory hematology/oncology care to manage the needs of different populations. Research Sponsor: University of Minnesota Department of Medicine, Division of Hematology, Oncology, and Transplantation Grant.

Utilization of telemedicine among patients newly diagnosed with cancer.

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Background: The use of telemedicine among cancer patients remains limited. Because of the COVID-19 pandemic, CMS expansion of telehealth with 1135 waiver was enacted in March 2020, broadening the opportunities to provide patient care using telemedicine. This study examined the impact of the CMS expansion on the use of telemedicine among cancer patients. **Methods:** We identified newly diagnosed patients with 5 common cancers (breast, prostate, lung, colorectal, and lymphoma) between 3/2019 and 12/2020 from Optum's de-identified Clinformatics Data Mart Database. Patients who had 6 months of full enrollment (3 months before and 3 months after the first [index] cancer diagnosis date), had cancer claims on 3 separate dates within 3 months of the index date for the specific cancer diagnosis, and no prior history of cancer were included. We defined telemedicine use as patients who had a telemedicine procedure code within 1 month of their index diagnosis and had the cancer diagnosis on the telemedicine claim. We conducted an interrupted time series analysis to examine the impact of CMS expansion on telemedicine use. A multivariable logistic regression model was used to identify factors associated with telemedicine use during the post-expansion period. **Results:** Of 96,632 patients included, the average crude rate of telemedicine use was 0.12% before and 14.2% after the expansion in March 2020 (see Table). There was a significant impact of expansion on telemedicine use (21% increase; $p < 0.001$). The peak rate (adjusted) was 28% in April 2020, decreasing and plateauing in July/August 2020, with rates staying in the range of 10-12% between August and December 2020. During the post-expansion period, lymphoma, prostate, and lung cancer patients (adjusted rates: 14.6%, 15.7%, and 15.9%, respectively) were more likely to use telemedicine compared to patients who had breast (12.7%) or colorectal (12.3%) cancer. Patients who were older (adjusted rates: ≥ 65 years, 13.8%; 50-64, 14.2%; 20-49, 18.6%), Black (12.4% vs 14.4% for White, 15.5% for Hispanic and 16.6% for Asian), resided in East South Central census division (8.4% vs 23.5% in New England) and had Medicare (12.2% vs 20.3% for commercial insurance) were less likely to use telemedicine (all $p < .001$). **Conclusions:** After the CMS telehealth expansion, the use of telemedicine among newly diagnosed cancer patients increased significantly. Telemedicine use varied by patient age, geographic location, race/ethnicity, and payer. Further research is needed to understand the pattern of telemedicine use. Research Sponsor: U.S. National Institutes of Health.

Unadjusted rates of telemedicine use before/after March 2020 expansion by cancer site.

Cancer site	Before % (N)	After % (N)
Breast	0.15 (18688)	13.3 (13627)
Prostate	0.11 (15916)	15.1 (11609)
Lung	0.08 (9543)	15.0 (6962)
Colorectal	0.13 (6879)	12.3 (5077)
Lymphoma	0.13 (4704)	15.7 (3627)
Overall	0.12 (55730)	14.2 (40902)

Telemedicine adoption and utilization among financially distressed patients with cancer during the COVID-19 pandemic: Insights from a longitudinal nationwide survey.

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Background: Telemedicine use during the COVID-19 pandemic among financially distressed patients with cancer, with respect to the determinants of adoption and patterns of utilization, has yet to be delineated. We sought to systematically characterize telemedicine utilization in financially distressed patients with cancer during the COVID-19 pandemic. **Methods:** We conducted an analysis of survey data assessing the use of telemedicine in patients with cancer during the COVID-19 pandemic collected by Patient Advocate Foundation (PAF) from May 2020 to December 2020. Primary study outcome was telemedicine utilization rate. Secondary outcomes were independent predictors of telemedicine utilization patterns, volume, and utilization preferences. Multivariate and poisson regression analyses were used to identify predictive factors. **Results:** Of the 1,390 respondents, 627 completed two survey waves and were included in this study. Telemedicine adoption during the pandemic was reported by 67% of patients, with most (63%) preferring video visits. Younger age (odds ratio, 6.07; 95% CI, 1.47-25.1), and higher comorbidities (odds ratio, 1.79; 95% CI, 1.13-2.65) were independent predictors associated with telemedicine adoption. Younger age (19-35 yrs.) (incidence rate ratios [IRR], 1.78; 95%CI, 24-115%) and higher comorbidities (≥ 3) (IRR; 1.36; 95%CI, 20-55%) were independent predictors associated with higher utilization volume. As area deprivation index increased by 10 units, the number of visits decreased by 3% (IRR 1.03, 95%CI, 1.03-1.05). **Conclusions:** The rapid adoption of telemedicine may exacerbate existing inequities, particularly among vulnerable financially under-resourced patients with cancer. Policy-level interventions are needed for the equitable and efficient provision of this service. Research Sponsor: None.

The role of telemedicine in care of patients with cancer: A real-world experience from a Peruvian cancer institute during the COVID-19 pandemic.

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Background: For patients with cancer, the COVID-19 pandemic has increased morbidity and mortality due to their bigger susceptibility to infection and to the discontinuity of treatment. In this context, telemedicine has become an invaluable tool for cancer care. The purpose of this study is to describe the impact of telemedicine in the care of cancer patients from a Latin American public institution. **Methods:** Retrospective, descriptive and cross-sectional study of cancer patients who received medical care through telemedicine from the Department of Medical Oncology of the Instituto Nacional de Enfermedades Neoplásicas (INEN) during the COVID-19 pandemic, from March 2020 to February 2021. Data collection was performed in real time by medical oncologists. Impact was measured with a comparison between the amount of cancer care during the COVID 19 pandemic vs the previous year. A modified version of the University of Kansas Cancer Center telephone satisfaction survey was conducted. Variables included the process of requesting an appointment by telemedicine, satisfaction with telemedicine service and distribution of drugs. **Results:** 16 456 telemedicine visits were carried out in one year time, 96.1% were conducted by telephone and only 3.9% used a video communication platform. 73% of patients were female and 62% were in the age group from 31 to 60 years old. 43% corresponded to solid tumors where breast cancer was the most frequent diagnosis. Patients in active treatment represented 70% (n = 11587), with 64% of patients being treated with curative intent and 36% within the palliative setting. Regarding the result of telemedicine visits, 62% (n = 10,281) had a medical prescription (40% corresponded to hormonal therapy; and 19%, to intravenous or subcutaneous systemic treatment). Overall, 8% (n = 56) of cases required an in-person visit. In the annual comparative analysis (against in-person visits during the previous year), the gap was 23% (60%, 20%, 8% and 13% during the first, second, third and fourth quarters, respectively). According to the type of medical care, telemedicine accounted for the 27.6% of the total medical care employed during in the year. The maximum level of usage was in May 2020 with 52% and in February 2021 with 48%, coinciding with the first and second waves of COVID in Peru. The satisfaction survey was applied to 5765 randomly chosen patients from July to October 2020. The mean scores for the 3 variables studied were: 4.6 / 5 points for the process of requesting an appointment, 4.58 / 5 points for telemedicine service and 4.33 / 5 points for the distribution of medicines and orders. **Conclusions:** Telemedicine is key to guarantee the continuity of care for cancer patients with an adequate level of satisfaction. If the Telemedicine service had not been implemented, the number of medical consultations would have dropped to 40% in comparison to the previous year. Research Sponsor: None.

Improving care coordination for adolescents and young adults with cancer.

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Background: In the US, many of the 90,000 adolescents and young adults (AYAs) (i.e., individuals ages 15-39) diagnosed with cancer each year do not receive services to address the range of needs they experience during cancer treatment. AYAs' unmet needs are associated with higher distress, poorer health-related quality of life, and higher physical symptom burden. However, AYAs often do not use services available to them through their cancer programs, even when they face no access issues (e.g., cost, insurance status, local service capacity). AYAs report barriers to service use including lack of awareness, challenges navigating large volumes of information and complex health systems, and hesitance to broach needs with providers without prompting. To facilitate a systematic and patient-centered approach to addressing AYAs' unmet needs, we leveraged user-centered design to develop the AYA Needs Assessment & Service Bridge (NA-SB). NA-SB includes a patient-reported outcome measure assessing AYAs' physical, psychosocial, and practical needs, and a collection of referral pathways for connecting AYAs to services based on the needs they report. In this feasibility pilot study, we are evaluating the implementation of NA-SB in the University of North Carolina Lineberger Comprehensive Cancer Center (UNC) AYA Cancer Program. **Methods:** Eligible participants include AYAs ages 18-39 currently undergoing cancer treatment at UNC (n = 25-50). The needs assessment portion of NA-SB is administered electronically through REDCap during routine clinical encounters with the AYA team. After an AYA completes the needs assessment, an AYA provider (i.e., social worker/nurse practitioner) reviews their responses and initiates referral pathways. Six weeks following their completion of the needs assessment, AYAs complete a survey assessing their perceptions of (1) the usability of the NA-SB needs assessment, (2) the feasibility, acceptability, and appropriateness of implementing NA-SB, and (3) the extent to which their needs have been met. We are also assessing participating providers' perceptions of NA-SB's implementation through periodic check-in calls. **Results:** We will report descriptive statistics on participant demographics, needs reported, and quantitative outcomes. We will analyze data from provider check-in calls inductively to further elaborate on implementation experiences and determinants. **Conclusion:** By harnessing patient-reported data to facilitate care coordination for AYAs, NA-SB has the potential to improve processes of care and subsequent outcomes for AYAs, an underserved and understudied population. This pilot study represents a critical first step towards translating NA-SB into routine cancer care for AYAs. Clinical trial information: NCT04586127. Research Sponsor: U.S. National Institutes of Health.

TPS1599

Poster Session

Evaluating the feasibility of using an electronic patient-reported outcome (ePRO) smartphone application (app) and biosensor by patients with cancer undergoing systemic treatments.

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Background: Almost half of the nearly 370,000 patients with cancer who receive chemotherapy in the United States each year experience Emergency Department (ED) visits and unplanned hospital inpatient (IP) stays during treatment, largely due to poorly controlled symptoms. Recent studies have shown that utilizing PRO information in oncology practice can improve symptom management and patient outcomes. This study aims to examine the feasibility and usability of a PRO app paired with a biosensor to identify patients who are at high risk for ED and IP visits. **Methods:** This prospective, pragmatic, observational study will evaluate the feasibility and usability of a clinic-provided smartphone app and smartwatch biosensor for monitoring patients undergoing systemic cancer treatment. Eligible patients are 18–80 years old, ECOG PS 0–2, have a biopsy-proven solid tumor diagnosis of cancer (excluding non-melanoma skin cancer), and are scheduled to receive the first dose of intravenous (IV) or oral cancer therapy as an initial or new line of treatment. Patients should be able to provide informed consent, wear the biosensor daily, and complete the app ePRO survey and questionnaires in English. Study exclusion criteria include receiving radiation or hormone therapy only, residing in a skilled nursing facility, participating in another clinical trial, current pregnancy, and wearing pacemakers, implantable cardioverter defibrillators, cochlear implants, and/or neurostimulator devices. The app collects PROs (PRO-CTCAE), app usability and satisfaction (modified mHealth App Usability Questionnaire [mMAUQ]) and patient satisfaction with the biosensor (modified Quebec User Evaluation of Satisfaction with Assistive Technology [QUEST 2.0]). The study is divided into two phases: (1) vanguard (N = 30); (2) operational (N = 70). Patients will be asked to wear the biosensor and enter PROs into the app daily for a 2-week (vanguard) or 6-week period (operational). The vanguard sample size allows for the recruitment of ~10 patients at each of the three participating oncology community clinics as is standard for initial device and software testing and development. Study endpoints for feasibility include: (1) vanguard – patient recruitment and protocol adherence, completeness of data capture, app usability, user satisfaction of biosensor; (2) operational – validity of self-reported hospital visits, feasibility of using electronic case report forms. Data collected from the vanguard will inform modifications to the app for the operational phase. The operational phase sample size is sufficient to assess data capture completion and clinical trial recruitment procedures in diverse practice settings (e.g., low volume vs. high volume, rural vs. urban). Clinical trial information: ISRCTN25569053. Research Sponsor: Genentech, Inc.

Natural history study for children and adults with rare solid tumors.

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Background: Rare cancers is defined as fewer than 15 cases per 100,000 people per year and account for 27% cancers diagnosed and lead to 25% of cancer-related deaths. Nearly 13% (1 in 8) of all cancers diagnosed in adults ages 20 and older are rare. All pediatric cancers are rare and approximately 12,600 children under the age of 20 years are diagnosed with cancer each year. Rarity of these diseases has caused a stagnation in understanding the tumor biology and developing newer therapies. Initiatives like Orphan Drug Act (1983) and Rare Disease Act (2002) has led to improvement in funding and research about these rare tumors. The Cancer Moonshot Research Initiative funded My Pediatric and Adult Rare Tumor (MyPART) network (cancer.gov/mypart) in the NCI Pediatric Oncology Branch and launched a longitudinal Natural History Study for Children and Adults with Rare Solid Tumors (NCT03739827). **Methods:** A prospective study to evaluate the natural history of rare pediatric and adult solid tumors comprehensively and longitudinally. Patients of any age with a rare solid tumor (<15 cases per 100,000 people per year) are eligible. Patients with germline mutation who are at risk of developing these tumors or relatives of participants are also eligible. Patients can participate from home or are invited to NIH for annual evaluations. Participants complete individual medical history, family history, patient related-outcomes measurements (PROs) and provide samples (blood, saliva) for DNA analysis. Tumors are analyzed using a 500+ gene panel (TruSight500, Illumina Panel) and undergo a comprehensive genomic and epigenomic analysis. Participants invited to NIH undergo a clinical evaluation, genetic counseling, blood collection (standard clinical labs, germline DNA/RNA, immune phenotypes, cytokines, exosomes), and imaging studies, as indicated. The goals of this study are to 1) Estimate and define the clinical spectrum of rare cancers 2) Evaluate and follow biological relatives of patients with rare tumors or carriers of germline genetic variants that predispose to development of rare tumors 3) Develop a better understanding of these diseases in an effort to develop a) Novel therapeutic interventions, b) Preventive/screening guidelines, c) Endpoints for future clinical trials, and d) Relevant patient reported outcomes that can improve our understanding of patients psychosocial and functional needs. Subprotocols under this protocol for children and adults include adrenocortical cancer (NCT04447014), neuroendocrine neoplasms (NCT04488263) and Chordoma (NCT0391046) to gather tumor specific data. Study accrual is ongoing. Clinical trial information: NCT03739827. Research Sponsor: U.S. National Institutes of Health.

Addressing Latinx CANcer Care Equity (ALCANCE) randomized controlled trial: Precision medicine and community health workers.

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Background: Cancer mortality has declined over the past decade due to clinical advances including precision medicine. Despite these clinical advancements, low-income and racial/ethnic minorities experience worse cancer morbidity and mortality. Specifically, these populations have lower rates of genomic testing and are significantly underrepresented in precision medicine research. Community-based, culturally tailored approaches are needed to address these ongoing disparities. The objective of this randomized controlled trial is to test whether a community health worker (CHW)-led intervention can improve patient understanding of precision medicine topics and delivery of evidence-based cancer care more than usual cancer care alone. **Methods:** We developed a county-wide cancer care initiative and a community advisory board (CAB) comprised of patient, caregiver, payer, clinician, and governmental stakeholders in Monterey County—comprised of 60% Latinx, non-English speaking, immigrant populations. As guided by the CAB, we developed a CHW-model to provide education on precision medicine and screen for complications of social determinants of health in 1:1 discussions with patients. In collaboration with a local community oncology clinic, we plan to randomize 110 patients with cancer who are receiving active treatment into usual care or usual care plus the CHW-led intervention. Inclusion criteria includes patients who are: 1) 18 years of age or older; 2) racial/ethnic minorities; 3) low-income; 4) uninsured or insured by Medicaid and/or local agricultural employers; and 5) speak English or Spanish. Exclusion criteria includes: 1) lack capacity to consent to study procedures; 2) plan to move from the area within a year. We will measure the effect of the intervention on patient knowledge of precision medicine using a survey adapted from Davies et al. Secondary outcomes include effect on health-related quality of life using the Functional Assessment of Cancer Therapy – General, patient activation using the Patient Activation Measure, satisfaction using the Satisfaction with Decision Scale, prognosis and treatment preferences using an adapted survey by Weeks et al., health-care utilization, and receipt of evidence-based cancer care. We will administer surveys at baseline, 3-, 6- and 12-months post-enrollment. To date, 67 participants have been enrolled. This study will show if CHW-models increase knowledge of precision medicine in this population. Clinical trial information: NCT04843332. Research Sponsor: California Initiative to Advance Precision Medicine through grant #OPR18113, This work is also supported, in part, by the Lung Cancer Research Foundation.

Screening for high frequency malignant disease (SHIELD).

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Background: Implementation of asymptomatic cancer screening has yielded positive impacts on global cancer mortality rates. However, significant screening adherence gaps exist. A blood-based multi-cancer screening test with clinically significant performance in cancers where early detection and intervention can save lives, can address adherence gaps, especially by reducing access barriers inherent to current screening options. Effective evaluation of such a test in screen relevant populations requires studies designed to enroll individuals across multiple cancer types, taking into account prevalence rates for the cancers being evaluated, allowing for overlapping screen-eligible populations, and ensuring representation of individuals from diverse ethnicities and geographies. **Methods:** SHIELD (Screening for High Frequency Malignant Disease; NCT# 05117840) is a prospective, observational, multi-center basket study ongoing in the United States and Europe uniquely designed to recruit individuals across multiple cancer types. The study's primary objective is to evaluate the performance of a blood-based multi-cancer screening test (GuardantLUNAR-2, Guardant Health, USA) to detect cancer in screen-relevant individuals as compared to the reference standard cancer screening modality. The study will recruit eligible individuals into multiple separate cohorts with specified pathways for cancer screening. Within each cohort, eligible individuals consent to whole blood collection within 90-days of the standard of care screening method. Clinical diagnoses, including the diagnosis of cancer, are made per standard of care. Primary outcomes are sensitivity, specificity, negative predictive value, and positive predictive value of the test as compared to the standard of care screening modality. Secondary outcome is the number of screen-detected cancers, early- (stage I/II) and late-stage (stage III/IV), per 1000 screened individuals. Follow-up continues for 24 months with outcomes collected at one and two-years to investigate the possibility of incidental non-screen relevant cancer cases and interval screen-relevant cancer cases that had not reached clinical threshold for detection at initial screening. Additional cancer specific follow-up is designed per cohort. The first cohort to enroll screen-eligible individuals, cohort A, is focused on those who meet guideline criteria for lung cancer screening with low dose CT. Additional cancer-risk cohorts will begin enrolling as the study expands and are designated cohort B, C, etc. Cohort A: Eligibility criteria are aligned with lung cancer screening guidelines – age 50-80 years with > 20 pack-year smoking history who are current smokers or have quit < 15 years prior, without a cancer history, preinvasive lung lesions, or current treatment for pneumonia. Cohort A enrollment, targeting 9,000 subjects over 24 months at up to 120 global sites, began in January 2022. Clinical trial information: NCT05117840. Research Sponsor: Guardant Health.

Telehealth weight loss program for breast cancer survivors is feasible and acceptable: Preliminary results of pilot clinical trial.

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Background: Current weight loss programs for breast cancer survivors utilize a hybrid of in-person visits or individualized telephone-based sessions modeled after the Diabetes Prevention Program. Telehealth may be an effective and efficient means of communicating with patients who otherwise cannot participate in in-person visits. To test this concept, we conducted a pilot single-arm study (NCT04855552) to examine the feasibility and acceptability of a weight loss group program via telehealth for breast cancer survivors. **Methods:** Patients ≥ 18 years with ECOG performance 0 or 1, a BMI of ≤ 25 kg/m², and completion of adjuvant radio- and/or chemo-therapy > 6 months were eligible. Patients attended weekly zoom teleconference counseling grouped sessions either at noon or 5 pm led by a licensed clinical psychologist for 20 weeks followed by sessions in weeks 22 and 24. Patients were encouraged to use MyFitnessPal.com, an online tool, to monitor calorie intake and physical activity and digital scales to monitor weight to share with study staff to enhance accountability and provide opportunity for feedback. Feasibility was defined as a ratio of enrolled/eligible patients $\geq 50\%$. Acceptability was assessed from surveys pre- and post-treatment, and qualitatively from exit interviews. Secondary endpoints included changes in Quality of Life-Breast Cancer Patient (QOL-BC), Patient Health Questionnaire (PHQ-9), and percent weight loss from baseline to 24 weeks. **Results:** Clinical characteristics of patients are summarized in Table. The ratio of enrolled (n = 12)/eligible (n = 23) participants was 52% thus confirming study feasibility. One patient dropped out after 2 sessions. Qualitative results from exit interviews showed that 7/9 patients rated the telehealth format as "extremely acceptable". Surveys also indicated that the format and delivery of the program remained acceptable across most domains with no significant changes, except an increase in "approval" from 4.1 to 4.7 ($p = 0.05$). Patients' mood improved on the PHQ-9 from 4.2 to 1.2 ($p = 0.03$), and QOL-Physical Wellbeing improved from 56.9 to 66.3 ($p = 0.004$). Overall, 199 of 236 participant-sessions (84%) were attended. Percent weight loss was 6.5% \pm 2.5%. **Conclusion:** This proof-of-concept weight loss program was feasible and acceptable for our patients yielding improvements in QOL, mood, and a clinically significant weight loss over 6-months. This group-based video approach represents an intervention strategy that could be widely-disseminated and may provide stronger accountability/support than a one-on-one approach in some patients. Future work is aimed at refining strategies to increase patient enrollment/retention. Clinical trial information: NCT04855552. Research Sponsor: intramural institutional funds.

Participants (n = 12)	N or Average (SD)
Age	60 (14)
Race	
White	11
Black	1
Home distance from hospital (miles)	39 (42)
Pre-trial weight (lbs)	192 (40)
Post-trial weight (lbs)	170 (23)