

National implementation of an AI-based virtual dietitian for patients with cancer.

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Background: Nutritional status is an established key driver of cancer outcomes and patient experience. However, the workforce of oncology dietitians is unable to meet the needs of the population, and 80% of patients seek but do not receive nutrition support. Advances in artificial intelligence (AI) and machine learning (ML) capabilities afford the opportunity to expand reach and rapidly hone in on clinical and contextual needs to deliver evidence-based nutritional guidance. **Methods:** To address this unmet need, an AI-based nutrition expert-platform was developed. Interventions were curated by oncology-nutrition experts based on peer-reviewed literature and clinical guidelines to facilitate self-management of cancer side effects and optimize nutrition. A growing database of over 114,000 evidence-based interventions powers *Ina*, a text-message based virtual nutrition assistant. Interventions are continually enhanced and refined using AI and ML applied to an extensive learning dataset. The tool was implemented nationally in partnership with 25 cancer advocacy organizations. Data on demographics, patient-reported outcomes, and utilization were systematically collected. **Results:** Between July 2019 and August 2023, 3,310 users from all 50 states registered for the virtual nutrition platform. Based on self-report, users were 73% female; mean age 57 years (18–91); most common cancer types were GU (22%), Breast (21%), Gyn (19%), GI (14%), and Lung (12%), representing nearly 90% of users. Users were medically complex, with 50% reporting Stage 3–4 disease, 64% with metastases, and 50% with 2+ chronic conditions. Nutritional challenges were highly prevalent: 58% were overweight/obese by BMI, 83% reported barriers to good nutrition, and 42% had food allergies/intolerances. Levels of engagement were high: 68% of users texted queries to *Ina*, 79% completed surveys, and median user retention duration was 8.8 months. Overall, 94% of users reported being satisfied with the platform and 98% found the guidance to be helpful. In an evaluation of outcomes, 84% reported actively using the nutrition advice to guide their diets, 47% used the recommended recipes, and 82% felt the program improved their quality of life. In this cohort with high symptom burden, 88% reported *Ina* helped them manage their symptoms and 34% noted improved symptom control during participation. **Conclusions:** Implementation of an evidence-based AI virtual dietitian is feasible, and is reported by patients to be beneficial on diet, quality of life, and symptom control. Ongoing evaluations are assessing impact on other outcomes. Research Sponsor: None.

Ensuring precision medicine for veterans with lung cancer: A randomized clinical trial.

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Background: National guidelines recommend molecular testing for patients with non-small cell lung cancer, yet this is not routinely completed in practice. In prior work, we identified barriers to testing in the Veterans Affairs. First, physicians are unaware if and when testing has occurred. Second, patients are unaware of testing and the implications on treatment and clinical outcomes. In response, in collaboration with a Veteran and Caregiver Advisory Board, we created a multilevel intervention led by a peer volunteer who: 1) provides tailored education of molecular testing for 1 month for Veterans newly diagnosed with lung cancer and, 2) alerts clinicians via secure messaging if tumor samples have not been tested. We conducted this randomized clinical trial to assess whether the intervention improves patient knowledge of molecular testing and patient activation and increases receipt of molecular genomic testing compared with usual care. **Methods:** All veterans >18 years old with a new diagnosis of any stage non-small cell lung cancer were eligible. Exclusions included inability to consent. All participants completed baseline assessments at randomization and at 1-month follow-up comprised of a 3-question validated precision medicine knowledge questionnaire and a 13-question validated patient activation measure. Genomic testing was assessed by chart review at 6-months followup. We used regression models to assess differences in mean knowledge and activation scores over time between groups and compared rates of genomic testing. **Results:** 75 Veterans were screened with 46 eligible. All 46 consented to participate, with 23 in each group. All were male (100%), had mean age of 76.3+/-5.54 years; 31 (67.4%) were Latinx; 2 (4.4%) Asian; 11 (23.9%) Black; 1 (2.2%) Native Hawaiian; 32 (69.6%) White; 32 (69.6%) had Stage 4 disease. At 1 month follow-up mean knowledge scores increased over time in the intervention group and remained stable in the control group (mean score 2.30 +/- 0.97 versus 1.16 +/- 1.15, p=0.014). At 1-month follow-up, patient activation increased for the intervention group more than the control group (46.7 +/- 11.3 versus 37.6 +/- 9.26, p=0.002). There were no significant differences in tumor testing between groups (intervention: 95.6% versus control: 86.9%, p=0.62). **Conclusions:** A volunteer led effort improved patient education regarding precision medicine and patient activation among Veterans as compared with usual care alone. Interventions that include volunteers and other support can enhance care and clinical outcomes among veterans with lung cancer. Clinical trial information: NCT05795959. Research Sponsor: LUNGeVity.

Geriatric assessment in older patients with non-small cell lung cancer: Insights from a cluster-randomized, phase III trial—ENSURE-GA study (NEJ041/CS-Lung001).

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Background: To determine optimal treatment in older cancer patients, it is recommended to conduct a geriatric assessment (GA) before chemotherapy. The ENSURE-GA study, which focused on patients aged 75 and older with non-small cell lung cancer (NSCLC), reported that the implementation of GA not only enhanced patient satisfaction with regards to communication with their physicians, but also improve the patients' quality of life. Additionally, we assessed whether GA could improve overall survival and serve as a predictor for severe adverse events. **Methods:** Patients aged ≥ 75 with NSCLC who were unable undergo radical treatment were enrolled. All patients underwent a standardized GA before treatment. The participating institutions were cluster-randomized into either intervention group or control group. For the intervention group, GA summaries and recommendations for GA-guided interventions were provided to guide physicians in selecting treatments and interventions. The control group did not provide physicians with GA summaries. Geriatric 8 (G8) and CARG scores were calculated at enrollment, and we investigated whether adverse events during a 3-month follow-up could be predicted. **Results:** Between 2019 and 2022, 1,021 patients were enrolled from 78 institutions in Japan. No significant differences were observed in patient characteristics or for GA domains between intervention and control groups. Additionally, there were no significant differences seen in 1-year overall survival (20.7m vs 18.8m, $p = 0.414$), or the incidence of grade 3 or higher adverse events in patients treated with medical treatment (36.8% vs 38.1%, $p = 0.732$). The ROC curve for G8 regarding the occurrence of grade 3 or higher adverse events in cases receiving cytotoxic chemotherapy yielded an AUC of 0.525, indicating no discriminatory ability. Furthermore, there was no difference in the incidence of adverse events between low-risk and high-risk patients based on the CARG score. **Conclusions:** The implementation of GA and interventions based on its results enhances patient satisfaction. However, additional studies are needed before incorporating GA into an adverse event prediction system. Developing risk scoring tools specific to cancer types and races may prove useful. Clinical trial information: UMIN0000037590. Research Sponsor: Japan Agency for Medical Research and Development.

Acute care and overall survival results of a randomized trial of a virtual health intervention during routine cancer treatment.

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Background: Despite rapid development of virtual health interventions, little is known of their impact on acute healthcare utilization and survival outcomes. This study aimed to evaluate the effectiveness of Integrative Medicine at Home (IM@Home), a virtual mind-body fitness program, on unplanned hospital admission and overall survival among patients undergoing systemic cancer treatment. **Methods:** We conducted a randomized clinical trial of IM@Home (choice of 23 weekly virtual live mind-body and fitness classes) compared with an enhanced usual care (EUC) control intervention consisting of asynchronous recordings (standard of care plus access to 17 pre-recorded online meditation resources) for patients with melanoma, thoracic, gynecological, or head/neck cancers on systemic treatment who reported moderate or greater fatigue. The study intervention lasted up to 12 weeks, and patients were followed thereafter for clinical events. Admission to a hospital over the study period was collected from patient-reported-outcomes and the electronic medical records and compared between arms. Overall survival was estimated using the Kaplan-Meier method. **Results:** Between October 2021 and March 2023, 128 patients were randomized: (mean age 64 years) 109 (85.2%) were female, 106 (82.8%) white, 10 (7.8%) Black, 7 (5.5%) Asian, and 118 (92.2%) non-Hispanic. 49 (38.3%) patients had thoracic, 44 (34.4%) gynecological, 25 (19.5%) head/neck, and 10 (7.8%) melanoma cancer. 58 (45.3%) were receiving chemotherapy, 45 (35.2%) immunotherapies, and 29 (22.7%) targeted therapies. Compared to EUC, patients in the IM@Home group were less likely to be hospitalized (4/64 [6.3%] vs. 12/63 [19.1%], $p=0.038$) and spent fewer days in the hospital (4.3 vs. 10.5 mean days per patient, $p<0.001$) during the 12-week study period. Overall survival results were assessed in Feb 2024 after a median follow up of 20.3 months. Median overall survival was 24.3 months in the EUC arm and was not reached in the IM@Home intervention arm ($p=0.06$). **Conclusions:** Participation in the virtual IM@Home program reduced unplanned hospitalizations and number of hospitalization days among patients with cancer receiving systemic treatment. Larger studies with longer follow-up are needed to confirm the effect of virtual supportive care on improving overall survival and reducing acute healthcare utilization. Clinical trial information: NCT05053230. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health.

A randomized study comparing electronic patient-reported outcome (ePRO) monitoring with routine follow-up during trastuzumab deruxtecan treatment in patients with metastatic breast cancer (PRO-DUCE study).

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Background: Trastuzumab deruxtecan (T-DXd) is a highly effective agent for HER2-positive metastatic breast cancer (MBC), but is associated with adverse events such as nausea, fatigue, and interstitial lung disease. Based on recent studies showing that symptom monitoring and alert notifications via ePROs could improve patient quality of life (QoL) and prognosis, we hypothesized that employing this method may diminish the treatment burden for patients receiving T-DXd. **Methods:** In this multicenter, randomized controlled exploratory study (jRCTs031200387), we randomized patients with HER2-positive MBC eligible for T-DXd to either the ePRO monitoring (ePROm) group or the usual care (UC) group. ePROm involved weekly symptom and daily body temperature/SpO₂ reports via a smartphone or computer at home. If any symptoms exceeded the predetermined thresholds, an email alert was sent to the medical staff, the ePRO was evaluated, and, if necessary, a phone consultation was provided. The primary endpoint was the change in the Global QoL score of EORTC QLQ-C30 from baseline at week 24. Secondary endpoints included score changes in the functional and symptom scales of EORTC QLQ-C30, and the time to deterioration of Global QoL (defined as a 10-point decrease from baseline). For a score difference between groups of 10 points and a standard deviation of 24, the required number of patients was 55 in each group, with a two-sided alpha error of 10% and a power of 87%. We analyzed the primary endpoint using a mixed-effects model for repeated measures. **Results:** Between March 2021 and January 2023, 111 patients were enrolled at 38 hospitals in Japan, with 56 assigned to ePROm and 55 to UC; the full-analysis set for QoL assessment included 54 and 52 patients, respectively. During the 24-week period, there were 1223 ePRO reports (95% compliance rate) in the ePROm group, including 427 alert notifications (7.9 per patient) to healthcare providers. Overall compliance with the questionnaire for QoL was 97%. Mean changes from baseline scores in Global QoL at week 24 showed that ePROm was significantly better than UC (mean difference 8.0 [90% CI 0.2, 15.8]; p=0.091). Role, cognitive, and social functioning were better in ePROm, with mean differences of 10.0 (95% CI 1.1, 18.9; p=0.028), 6.3 (1.1, 11.5; p=0.017), and 10.9 (3.9, 18.0; p=0.003), respectively. There was no difference in nausea/vomiting (0.5 [- 6.2, 7.1]; p=0.889), while fatigue was significantly better in ePROm (-8.4 [-16.1, -0.6]; p=0.034). Median time to first deterioration in Global QoL score was 3.9 months (95% CI 2.5, 13.9) in ePROm and 3.0 months (95% CI 1.6, 6.7) in UC (hazard ratio 0.73 [95% CI 0.45, 1.17]; p=0.159). **Conclusions:** ePROm systems, especially for symptom and SpO₂ tracking in HER2-positive MBC patients treated with T-DXd, are promising to enhance patient QoL. Clinical trial information: jRCTs031200387. Research Sponsor: Daiichi Sankyo.

Evaluation of a complex survivorship intervention incorporating electronic patient-reported outcomes in early stage breast and gynecologic cancer: Results from the Linking You to Support and Advice (LYSA) randomized controlled trial.

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Background: Expert consensus supports a multidisciplinary strategy in cancer survivorship care to enhance patient outcomes and quality of life. We hypothesized that introducing a women's survivorship clinic into routine follow up care would be feasible, and associated with improved symptom management and quality of life (QOL). **Methods:** LYSA was a multisite randomized controlled trial with parallel arms (experimental and active comparator), co-designed with public and patient involvement. Eligibility: early-stage hormone receptor-positive breast or gynaecologic cancer (GYN) within 12 months of completing primary therapy, and internet access (NCT05035173). Experimental arm attended a nurse-led clinic targeting symptom management, and dietetic consultation. Electronic patient-reported outcome (ePRO) assessments were undertaken at baseline, and bimonthly to 12 months. An online trigger alert system facilitated symptom management. Active comparator arm attended the nurse-led clinic at baseline and end of study. Primary endpoint (feasibility): Proportions of participants completing baseline and follow up ePRO surveys, and engaging in healthcare consultations after ePRO triggers. Pilot efficacy endpoints: changes in cancer-related symptom (PROMIS, PRO-CTCAE, Fear of Cancer Recurrence), health-related QOL Questionnaires (EORTC-QOL, EQ5D5L). Sample size target (n=200) facilitated feasibility outcomes. Between arm differences were estimated using generalized linear model, adjusted for baseline outcome. **Results:** 200 women were randomized, March 2021–August 2022 across two sites; 84% breast and 16% GYN. Consent was obtained in clinic (51%), video call (33%) or phone (16%). Median age was 54 (range 23–78). Of the 173 participants completing the study (n = 90 experimental, 83 comparator), all completed both baseline and end of study surveys. Following symptom triggers (experimental arm), there were 322 study nurse visits across 86 participants, and 243 dietician visits across 73 participants. Engagement with healthcare and other supportive resources was approximately twice more than comparator arm, due to referral. There were no notable between-arm differences with respect to EQ5D5L items at study end. However, experimental arm participants had better EORTC Total scores at study end relative to comparator (difference in means -3.87 95%CI -6.58 to -1.16, p=0.005). There were also significant (p < 0.05) differences observed between the arms for 8/12 symptom items reflecting less fatigue, anxiety and depression in experimental arm at study end. **Conclusions:** The LYSA trial met its primary feasibility endpoint, with high rates of ePRO completion. Secondary endpoint analysis is ongoing including an economic analysis and future studies. Clinical trial information: NCT05035173. Research Sponsor: Irish Cancer Society and Breakthrough Cancer Research.

The impact of self-reported social determinants of health (SDOH) on patient engagement and symptom burden across a remote patient monitoring (RPM) pathway in 42 European hospitals.

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Background: SDOH are a significant driver of cancer care disparities impacting access to care, adherence to treatment plans, treatment-related toxicities and quality of life (QoL) across the cancer care continuum. RPM based on electronic patient-reported outcomes (ePROs) is a powerful tool to facilitate communication between pts and providers, thereby improving symptom management, QoL and disease outcomes. Equitable participation in RPM pathways must be ensured to avoid increase existing disparities. In this study we report the prevalence of unfavorable SDOH and their impact on engagement with RPM and symptom burden in an RPM pathway deployed in routine care across 42 hospitals in FR and BE. **Methods:** Patient-level SDOH data provided by consented pts enrolled in the RPM pathway between 08-2023 and 12-2023 was used. Single-item questions were dichotomized from validated ePROs covering educational level, health literacy (3 subdomains health status, treatment and disease understanding), digital literacy, employment status, financial and food security, caregiver support, and access to care. SDOH profiles were defined as unfavorable (impairment at moderate/elevated level) vs. favorable (absence or impairment at a low level). RPM engagement and symptom burden were defined respectively as weekly ePRO reporting and number of alerts due to severe or worsening symptoms. Multivariable backward stepwise regression models (including age, gender, stage, health behaviors) assessed associations between SDOH profile and RPM engagement and symptom burden. **Results:** 896 (40%) pts provided SDOH data, of which 622 (69%) females with median age of 60 (P25-75 50-70). Most common primary tumor were breast (436, 49%) and gastrointestinal (171, 19%), 488 (55%) were non-metastatic. 653 (73%) pts reported at least 1 unfavorable SDOH, specifically: 199 (22.2%) on educational level, 134 (15.0%) on health status understanding, 27 (3.0%) on treatment understanding, 84 (9.4%) on disease understanding, 218 (24.3%) on digital literacy, 63 (7.0%) on employment status, 104 (11.6%) on financial security, 89 (9.9%) on food security, 348 (38.8%) on caregiver support and 56 (6.3%) on access to care. Lower RPM engagement was associated with unfavorable digital literacy ($\beta -0.05$, $p<0.001$) and treatment understanding ($\beta -0.1$, $p=0.004$). Higher symptom burden was associated with unfavorable financial security ($\beta 0.066$, $p=0.020$) and disease understanding ($\beta -0.1077$, $p=0.001$), but favorable employment status ($\beta 0.0497$, $p=0.025$). **Conclusions:** RPM with ePROs offers an opportunity to screen for SDOH in routine care. The vast majority of pts enrolled had at least 1 unfavorable SDOH. Specific actionable unfavorable SDOH were associated with lower engagement and higher symptom burden. Personalizing RPM pathways according to SDOH may foster equitable care. Research Sponsor: Conquer Cancer and Breast Cancer Research Foundation.

Associations of social determinants of health with avoidance of information, treatment receipt, and physician mistrust for women with breast cancer.

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Background: Social determinants of health (SDoH) are key factors contributing to breast cancer disparities but are difficult to measure. We surveyed a diverse population of women with breast cancer to identify SDoH and demographic measures associated with avoiding information, treatment receipt, and physician mistrust. **Methods:** During 2018–2020, we interviewed 297 women (60% White, 25% Black, 15% Hispanic) with a history of breast cancer treated at three academic institutions. We used multivariable regression to assess the associations of SDoH, demographics, and related factors (social support, discrimination in daily life and within healthcare, education, financial strain, faith, age, birth country, race and ethnicity, marital status) with three outcomes: (1) avoiding information about cancer, (2) lack of initiation of recommended treatments, and (3) physician mistrust. For each model, we included factors statistically significant ($p < 0.05$) in unadjusted analyses. **Results:** Overall, 79 participants (26.6%) reported avoiding information about cancer. Age < 40 , discrimination (treated with less courtesy or as if dishonest), and financial strain (worry about medical bills, uninsured status) were all significantly associated with avoiding information ($p < 0.05$ for all). In multivariable analyses, discrimination in daily life (OR 3.37, 95% CI 1.40–8.10 for being treated as if dishonest) and age (OR 3.36 for age < 40 compared to > 60) were associated with avoiding information. Twenty-two participants (7.4%) reported not initiating at least one recommended treatment. Discrimination in daily life and in healthcare were both significantly associated with treatment receipt, as was financial strain (all $p < 0.01$). In multivariable analyses, discrimination (OR 3.51, 95% CI 1.05–11.76 for being treated as if dishonest) and worrying about medical bills (OR 3.53, 95% CI 1.40–8.93) were associated with lack of treatment initiation. Twelve participants (4.0%) reported not trusting physician's judgements about medical care. Discrimination in daily life and in health care and insurance status were significantly associated with physician mistrust (both $p < 0.05$). Multivariable analysis found that discrimination in both daily life and in health care (OR 5.95, 95% CI 1.40–25.3 for being treated with less courtesy in daily life, and OR 12.79, 95% CI 2.49–65.6 for reporting being treated as dishonest in health care setting) were associated with mistrust. Race and ethnicity were not significantly associated with any of the outcome measures in unadjusted or adjusted analyses (all $p > 0.05$). **Conclusions:** SDoH measures and not race were associated with lack of engagement and trust within the health care system, with experiences of discrimination and financial strain associated with avoiding information, not initiating treatments, and physician mistrust. Research Sponsor: American Cancer Society.

Social vulnerability and clinical trial enrollment: The next frontier of health equity.

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Background: Clinical trials are the basis for novel therapies but may not be representative of disadvantaged groups, particularly low-income individuals. This study assesses how social vulnerability impacts enrollment and explores the interaction between race and social vulnerability among patients with the top five leading causes of cancer death. **Methods:** The national Vizient Clinical Database was queried for outpatients with lung, breast, prostate, colorectal or pancreas cancer from 2022–2023. This includes data from 98% of academic medical centers and more than 110 cancer hospitals. The exposures of interest were Medicaid insurance and social vulnerability as measured by the Vizient Vulnerability Index (VVI), a novel marker of social drivers of health at the census tract level. Participation in a clinical trial was the primary outcome. A multivariable analysis was performed evaluating the association of social vulnerability quartiles with clinical trial participation. Interaction tests were performed for race and VVI. **Results:** 2,660,566 patients were identified. Of these, 36,456 (1.4%) enrolled in a clinical trial: 28.6% with breast cancer, 26.3% prostate, 22.8% lung, 12.8% colorectal and 9.5% pancreas. Trial participants were more likely to be young, White, privately insured, have metastatic disease, and live in a less vulnerable census tract. 5.3% of trial participants were insured by Medicaid (12.2% of Black participants, 8.5% of Asian participants, and 3.5% of White participants), compared to 6.2% of non-participants ($p<0.0001$). 22.6% of participants lived in highly vulnerable neighborhoods (53.5% of Black participants, 19.7% of White participants, and 5.6% of Asian participants), compared to 25.0% of non-participants ($p<0.0001$). Living in the most vulnerable VVI quartile was associated with decreased odds of clinical trial enrollment (OR 0.86; 95% CI 0.82–0.91, $p=0.0442$), as was having Medicaid insurance vs. private insurance (OR 0.76; 95% CI 0.73–0.80, $p<0.0001$). The highest social vulnerability quartiles in the VVI domains for education, neighborhood resources and transportation were associated with decreased enrollment (Table). High social vulnerability decreased the odds of enrollment for Black patients (OR 0.80; 95% CI 0.68–0.88, $p<0.0001$) more than White patients (OR 0.88; 95% CI 0.89–0.96, $p=0.0028$); $p=0.0054$ for interaction. **Conclusions:** 1.4% of patients in this contemporary, cross-sectional cohort enrolled in a clinical trial. Patients with Medicaid have a 24% lower odds of enrollment than privately insured patients. Neighborhood social vulnerability is also barrier to enrollment, even more so among Black patients. Interventions to address social determinants of health may increase racial diversity in clinical trials. Research Sponsor: None.

	aOR	95% CI	p-Value
Education	0.82	0.78-0.86	<0.0001
Neighborhood Resources	0.87	0.83-0.91	<0.0001
Transportation	0.89	0.85-0.94	<0.0001

Cost-utility of geriatric assessment (GA) in older adults with cancer: A model-based economic evaluation of four randomized controlled trials (RCTs).

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Background: Geriatric assessment (GA) is a guideline-recommended approach to optimize cancer management in older adults undergoing chemotherapy. Our recent cost-utility analysis of the published 5C (Clinical and Cost-effectiveness of a Comprehensive geriatric assessment and management for Canadian elders with Cancer) RCT comparing GA and management (GAM) with usual care in older adults with cancer did not demonstrate cost-effectiveness overall. However, the trial was limited by <5% of study participants receiving GA prior to starting treatment. Three other GAM RCTs (GAIN, GAP-70, and INTEGERATE) have recently been published with evidence of efficacy on clinically relevant endpoints. Whether these are more cost effective than 5C is unclear. We evaluated the cost-effectiveness of GAM versus usual care in older adults with cancer using a decision model under a range of plausible scenarios representing the 4 trials. **Methods:** We performed cost-effectiveness analyses using the healthcare payer perspective and a 12-month time horizon. We incorporated Canadian costs and utility data from 5C, and used intervention details and effectiveness data from the three RCTs. We reported healthcare costs per quality-adjusted life year (QALY) and the incremental net monetary benefit (INMB) using a \$50,000 per QALY threshold. In scenario analyses we examined the main cost drivers. **Results:** Across trials, the average QALY per patient ranged 0.577–0.662 for GA and 0.606–0.665 for UC, and the average total costs \$31,234–\$39,432 for GA and \$29,261–\$41,756 for UC. Chemotherapy expenses accounted for 46%–66% of total costs across trials. The INTEGERATE trial had a positive INMB of \$6,074. The GAIN and GAP-70 trials had negative INMB value of -\$2,123 and -\$1,172, respectively. In comparison, in 5C, the total costs were \$39,812 and \$37,450 for GAM and UC, respectively, and QALYs were 0.728 and 0.751, respectively; the INMB was -\$2,713. **Conclusions:** Trial results and the associated model of care from INTEGERATE suggested a positive net monetary benefit, primarily driven by reduced hospitalization. Evaluation of cost-effectiveness under a range of plausible scenarios from RCTs can provide important insights about GAM. Our results add to the growing data supporting the need to implement GAM in older adults with cancer starting chemotherapy and argue for its cost effectiveness under specific scenarios. Future trials should include hospitalization outcomes. Future economic analyses need to accurately capture chemotherapy costs. Research Sponsor: Canadian Cancer Society.

Geriatric assessment-directed supportive care intervention (GAIN-S)-implementation via telehealth in a lower-resourced community.

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Background: Based on randomized controlled trials, ASCO guidelines recommend use of geriatric assessment (GA)-directed interventions for older adults with cancer. The translation of these models to lower resourced settings has been limited. We assessed the feasibility of implementing GA-directed supportive care (GAIN-S) via telehealth in a lower resourced community setting. **Methods:** A quality improvement study was conducted in a high poverty, limited access, and low resourced community oncology practice (City of Hope - Antelope Valley [COH-AV]). Eligible participants were 65+ years with a new diagnosis of a malignant neoplasm under evaluation for cancer therapy. Before starting therapy, patients completed: baseline GA, SupportScreen, and the Fulmer SPICES assessment. A geriatric nurse practitioner (GNP) reviewed GA results and implemented multidisciplinary supportive care interventions (GAIN-S) via telehealth between April 2020 and January 2023. Key evaluation measures included: number of patients who completed GAIN-S; number of referrals to multidisciplinary supportive care services and completion rate; advance directives (ADs); and patient satisfaction with telehealth visits. Participants' demographics, including distance traveled for care, type of cancer, stage, treatment, and telehealth satisfaction items, were summarized using descriptive statistics. To analyze and visualize the implementation process, run charts were utilized. **Results:** 251 patients (mean age 74, 62% Non-Hispanic White, 22% live 60+ miles from COH-AV, 56% stage II or less, 30% received chemotherapy) completed baseline assessments. 242 had initial visits with GNP, 197 via televideo and 45 via telephone. GNP reviewed vulnerabilities with 209 patients and generated 460 referrals for supportive care services, with 85% of services implemented. Highest numbers of referrals were to pharmacy (177), social work (142), occupational therapy (76), and physical therapy (48). GNP discussed GA-guided care plans with all patients and 43 patients completed AD after discussion with GNP. Over 92% of patients were satisfied with telehealth-based GAIN-S in terms of both ease of visit and access to care with their provider and with telehealth. **Conclusions:** Telehealth-based GAIN-S has proven to be feasible in providing accessible healthcare to older patients with cancer in a lower resourced community setting. This approach, well-received by most patients, highlights the potential of telehealth in delivering GAIN-S effectively in such settings. Research Sponsor: UniHealth Foundation.

Geriatric assessment and management with question prompt list using a web-based application for elderly patients with cancer to communicate aging-related concerns: A randomized clinical trial (J-SUPPORT 2101 study).

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Background: Older adults with cancer have aging-related physical and psychosocial problems that should be fully shared with their oncologists. Geriatric assessment (GA) can assess these aging-related problems and guide management. Communication support might also facilitate implementation of GA-guided management (GAM). We conducted this single-blind, parallel-group, multicenter, randomized controlled trial to evaluate the efficacy of a program providing GAM recommendation and communication support between older Japanese patients with cancer and their oncologists. **Methods:** Eligibility criteria were age ≥ 70 years, advanced or recurrent cancers of gastrointestinal origin, referral to one of the two institutions for first- or second-line systemic therapy, and impairment in at least one GA domain as assessed using a web-based application at baseline. In the intervention group, GAM recommendations and question prompt list (QPL) were provided to patients by trained intervention providers to be shared with their oncologists at the first outpatient visit after randomization. Over 5 months after the initial intervention, implementation of GAM recommendations was reviewed monthly by the intervention providers with the patients and their oncologists. Patients in the control group received usual care. The primary endpoint was the number of conversations about aging-related concerns at the first visit. The quality of conversations was assessed in terms of the number of conversations in which stated concerns were acknowledged and considered further by the oncologist and the number of conversations in which acknowledged concerns motivated implementation of GAM recommendations. **Results:** A total of 215 patients (99 women, 116 men; median age 75 [range 70–88] years) were randomized ($n=108/107$ in the intervention/control group) between September 2021 and September 2023. There were no differences between two groups in patient background characteristics including the prevalence of GA impairments. The number of conversations about aging-related concerns was significantly higher in the intervention group than in the control group (mean [SD] 2.95 [1.53] vs. 1.90 [1.49], $p<0.0001$). The number of high-quality conversations and number of conversations about GAM recommendations were also significantly higher in the intervention group than in the control group (1.73 [1.40] vs. 1.12 [1.16], $p=0.001$; 0.57 [0.74] vs. 0.28 [0.47], $p=0.001$, respectively). **Conclusions:** Our program providing GAM recommendations and communication support successfully facilitated aging-related communications between patients and their oncologists. We will further examine whether facilitated communication leads to actual implementation of GAM and improved patient health outcomes in a follow-up study. Clinical trial information: UMIN000045428. Research Sponsor: Japan Agency for Medical Research and Development.

Primary treatment modification strategies among older adults with advanced cancer.

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Background: Primary treatment modification (PTM; any change in dose or agents of the planned chemotherapy regimen from the standard guidelines) is a common therapeutic approach among older adults with advanced cancer due to their geriatric vulnerabilities. However, strategies to employ these modifications are understudied. This study compares a PTM strategy based on Geriatric Assessment (PTM-GA) intervention vs. usual care strategy based on oncologist's impression (PTM-UC) on treatment tolerability in older adults with advanced cancer starting new chemotherapy regimens. **Methods:** In this subgroup analysis of the GAP 70+ study (NCT02054741; PI: Mohile), we included patients aged ≥ 70 with incurable solid tumors who initiated a chemotherapy course with PTM (n=298). For the first (PTM-GA) group, PTM was guided by GA results and recommendations while for the second (PTM-UC) group, PTM was guided by the treating oncologist's estimate only. Tolerability outcomes were assessed within 3 months of treatment and included: 1) any grade 3-5 clinician-rated toxicity according to National Cancer Institute Common Toxicity Criteria; 2) subsequent dose reduction; 3) Activity of Daily Living (ADL) decline; 4) unplanned hospitalization. We used multivariable, cluster-weighted generalized estimating equations models to examine the association of PTM-GA vs. PTM-UC and outcomes adjusting for confounders. **Results:** Mean age was 77 years. The most common cancer types were gastrointestinal (37%) followed by lung cancer (26%). PTM-GA versus PTM-UC was associated with reduced risk of grade 3-5 toxicity (relative risk (RR)= 0.77, 95% CI, 0.61- 0.90) and subsequent dose reduction (RR, 0.46; 95% CI, 0.29-0.73). Point estimates suggest that patients with PTM-GA may have a lower risk of unplanned hospitalization but results did not reach statistical significance (RR, 0.69; 95% CI, 0.46-1.02). PTM-GA vs. PTM-UC was not associated with ADL decline (RR, 1.05; 95% CI, 0.74-1.49). **Conclusions:** Older patients with advanced cancer who had PTM guided by GA recommendations had improved treatment tolerability compared to those who PTM based on oncologist's estimate only. Integrating GA into treatment dosing decisions may lead to improved outcomes in this vulnerable population. Research Sponsor: None.

Effect of war on radiotherapy in Ukraine and how to help.

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Background: The full-scale Russian invasion of Ukraine on February 24th, 2022 brought the largest humanitarian disaster to the heart of Europe since the World War II. In this work, we describe the impact of the full-scale Russian invasion on the radiation therapy (RT) services in Ukraine and suggest how to help. **Methods:** We collected the information on operation of RT centers in Ukraine during the war. In addition, in 2023 an annual survey was conducted by Grigoriev Institute for Medical Radiology in Kharkiv for the IAEA DIRAC database. The survey was sent to 41 RT centers in Ukraine requesting information on equipment, staffing, and patient volume. Due to the war conditions the data provided in the survey is limited to the un-occupied territories. **Results:** After the initial Russian invasion of Ukraine in 2014 and occupation of Crimea and parts of Donbas, Ukraine lost access to 7 RT centers with 18 external beam radiotherapy (EBRT) machines (17% of total). Just before the full-scale invasion in 2022, there were a total of 44 Co-60 machines (57%) and 33 linear accelerators (43%) in the unoccupied territories. As a result of the full-scale invasion of Ukraine in 2022, almost all RT centers suspended operation in the first weeks of war. The most challenging period for RT in Ukraine was in March when Kyiv (where 20 EBRT machines are located) was partially surrounded by the occupiers. Based on the DIRAC survey, compared to 2021 data, in 2022 the number of radiation oncologists decreased on average by 2.9%, medical physicists by 6.7%, and therapists by 6.5% but there was a large variation in staffing levels depending on the region and its proximity to war. The workload in the RT centers close to the combat zone almost halved, while increasing by 10 - 60% in the western and central Ukraine. The total number of patients treated with EBRT decreased by 11% and brachytherapy by 21%. Brachytherapy services sustained the most interruption (47% decrease in LDR and 18% decrease in HDR patient volume) due to inability to perform source exchanges. Overall, approximately 5,500 less patients were treated in 2022 compared to 2021. Despite the ongoing war, Ukrainian cancer centers installed 8 new linear accelerators, with 5 linear accelerators pending installation. In addition, the Ministry of Health of Ukraine has recently purchased 15 linear accelerators to replace the aging Co-60 machine fleet as the future source exchanges might not be possible. There is an acute need in helping Ukraine transition from Co-60 to modern IMRT/VMAT linear accelerators. **Conclusions:** Radiotherapy in Ukraine sustained significant damages since the 2014 Russian invasion, which was exacerbated further by the full-scale invasion in 2022. To support the vitality and absorptive capacity of RT services in Ukraine, the democratic world can help by donating equipment, hardware, software, and participating in training of Ukrainian RT professionals as they transition to modern and high-quality RT care for Ukrainian cancer patients. Research Sponsor: None.

Quality of life for older patients with metastatic cancer in Brazil: A telehealth-based geriatric assessment and supportive care intervention (GAIN-S).

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Background: Older adults with cancer often present unique geriatric and supportive care needs. We sought to evaluate the impact of a telehealth-based multimodal geriatric assessment (GA)-guided supportive care interventions (GAIN-S) program among older patients with metastatic cancer in a Brazilian cancer center. **Methods:** This is a randomized trial. Patients aged 65+ years with metastatic cancer, undergoing treatment, regardless of ECOG status, were enrolled. Following the baseline assessment, patients were randomized 1:1 to receive usual care or GAIN-S. The GAIN-S intervention provided remote, telehealth-based consultations with a nutritionist, psychologist, psychiatrist, and certified fitness trainer. At baseline and 3-months, patients were assessed for emotional symptoms (Geriatric Depression Scale), functional status (Instrumental Activities of Daily Living), coping (BriefCope), and quality of life (Functional Assessment of Cancer Therapy-General). Independent t-tests and linear mixed model were used. **Results:** Out of 86 approached patients, 80 were enrolled (40 per arm), with 3 deceased during treatment (usual care: 2, GAIN-S: 1). Most patients were female (56%), with a median age of 73 years (range, 65-68). Most common cancers were genitourinary (28%) and breast (23%). At baseline, there were no differences in the outcome measures between arms. However, from baseline to 3-months, patients assigned to GAIN-S had improvements in emotional symptoms, functional status, and quality of life compared to usual care (Table). Additionally, those assigned to GAIN-S reported increased utilization of active coping, acceptance, and positive reframing at 3-months. **Conclusions:** GAIN-S demonstrated significant improvements in emotional well-being, functional status, and quality of life among older patients with metastatic cancer. These findings underscore the potential of such telehealth-driven approaches to enhance the supportive care experience in diverse healthcare settings. Research Sponsor: None.

Variable	Time 1			Time 2			T2T1 Difference			P*
	Arm1 Mean (SD)	Arm2 Mean (SD)	P (t-test)	Arm1 Mean (SD)	Arm2 Mean (SD)	P (t-test)	Arm1 Mean (SD)	Arm2 Mean (SD)	Mean Difference (SE)	
GDS	3.3 (3.3)	4.1 (3.3)	0.278	4.2 (3.5)	2.3 (2.4)	0.010	0.8 (1.6)	-1.7 (3.1)	-2.6(0.5)	<0.001
FACTG	85.7 (12.2)	82.9 (13.3)	0.338	83.0 (13.4)	93.4 (10.2)	<0.001	-2.6 (4.3)	10.5 (9.7)	13.2 (1.7)	<0.001
IADL ratio	0.6 (0.3)	0.6 (0.2)	0.868	0.6 (0.3)	0.8 (0.2)	<0.001	-0.1 (0.1)	0.1 (0.2)	0.21 (0.0)	<0.001
IADL total score	4.8 (2.3)	4.8 (2.1)	0.994	4.3 (2.3)	6.2 (1.5)	<0.001	-0.4 (0.8)	1.3 (1.6)	1.8 (0.2)	<0.001
Active coping	5.6 (1.5)	5.4 (1.7)	0.553	5.5 (1.6)	6.0 (1.2)	0.177	-0.1 (0.7)	0.5 (1.4)	0.6 (0.2)	0.0145
Acceptance	6.3 (1.4)	6.5 (1.7)	0.599	6.2 (1.5)	6.8 (1.4)	0.071	-0.1 (0.6)	0.2 (0.6)	0.4 (0.1)	0.009
Positive Reframing	5.7 (1.7)	5.6 (1.9)	0.821	5.6 (1.7)	5.9 (1.6)	0.407	-0.1 (0.6)	0.3 (1.0)	0.4 (0.1)	0.035

Accuracy of a mobile sensor-based system for the detection of chemotherapy toxicity in older adults with cancer.

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Background: Older adults receiving chemotherapy (CT) are at a high risk of toxicity (Tox) and of functional decline. Promptly acting upon CT Tox in older adults is difficult, particularly in developing countries where triage systems and personnel are limited. We previously showed that monitoring older patients using an accelerometer-equipped smartphone is feasible, and that a decline in the number of steps/day may represent a marker of Tox. We aimed to evaluate the diagnostic accuracy of an objective patient-centered measure of physical function (steps/day) for the remote detection of Tox in older adults receiving CT. **Methods:** We included consecutive patients aged ≥ 65 years starting first line CT for solid tumors at a single center in Mexico City. Patients underwent a geriatric assessment and were provided with an accelerometer-equipped smartphone. Daily steps were recorded for ≥ 7 days pre-CT initiation, and median number of pre-CT steps/day was calculated. Patients with ≤ 600 median pre-CT steps/day, and those using walking aids, were excluded (16% of recruited patients). Steps were monitored daily, compared with median pre-CT steps/day, and % decline was calculated. Patients were called daily, and Tox was assessed using PRO-CTCAE questionnaires. The % decline in steps/day from pre-CT was considered as the index test for Tox, while patient report was considered the reference standard. The association between % step decline and moderate/severe Tox was examined using generalized linear-mixed models. AUC was calculated and Youden's index used to choose cutoff points for Tox detection. **Results:** 116 patients were included (96 development cohort, 20 validation cohort). Median age was 73y (range 65–91), 55% were female, and 65% had \leq high school education. The most common tumors were colon (21.5%), pancreas (17.5%), and gastric (12%). 28% of participants had never used a smartphone. The median number of pre-CT steps/day was 2979. Patients were followed for 6764 days, with Tox detected on 64.4% of days. Moderate/severe self-reported toxicity was detected on 1245 days (22.1%), while mild/no toxicity was detected on 4378 days (77.9%). AUC analysis for the development cohort demonstrated that a 32% decrease in steps/day from pre-CT median showed a sensitivity of 77.6% and a specificity of 67.3% for detecting moderate/severe Tox. Sensitivity and specificity of the cutoff in the validation cohort were 75.8% and 69.6%, respectively. Tox associated with a decline in steps/day included fatigue, pain, and nausea. **Conclusions:** A decline in the number of steps/day measured using an accelerometer-equipped smartphone was useful for the remote detection of moderate/severe Tox in older adults with cancer receiving CT, with a high sensitivity and specificity. This patient-centric measure could be used in clinical practice and research to detect and act promptly on Tox and, potentially, improve outcomes. Research Sponsor: Conquer Cancer, the ASCO Foundation.

Disparities uncovered: LGBTQ+ patients report on their cancer care journey.

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Background: In the U.S, LGBTQ+ people face higher cancer rates and worse outcomes than the general population. Few studies have described the experiences of LGBTQ+ people and their caregivers during treatment. As part of an implementation science initiative aimed at improving care for LGBTQ+ patients, we conducted a large survey (n=817) to understand treatment experiences of this population. Here we report our findings which provide insight into how stigma and incorrect assumptions may contribute to medical mistrust and worse experiences.

Methods: In 2023, 817 diverse LGBTQ+ cancer patients from academic and community-based settings, as well as patient advocacy groups, completed web-based surveys evaluating their care experiences during cancer treatment. Participants included patients with gastric (n=165), breast (n=238), ovarian (n=218), prostate (n=56), and colorectal cancers (n=140), including 83 gender non-conforming patients. **Results:** Most LGBTQ+ patients (80%) reported not receiving appropriate preventative cancer screening, with top barriers including *provider did not mention cancer screening tests* (40%) and *did not have a healthcare provider* (28%). Additionally, only 24% felt at least moderately comfortable disclosing their LGBTQ+ status. Inclusive measures that helped patients feel most comfortable included care teams sharing/displaying their own pronouns (39%), making public statements of support (43%), or wearing personal items indicating acceptance (39%). Of those who did disclose their identity, only 50% of gender-expansive patients reported consistently being referred to by the correct names and pronouns. Importantly, patients reported that only 34% of their partners/caregivers felt welcome at appointments, and only 4% felt respected by the care team. Few patients reported receiving key supportive care services, including counseling/support groups (23%), quality-of-life related care, such as sexual function counseling (23%), and LGBTQ-specific resources/education (19%). Furthermore, less than half of LGBTQ+ patients discussed with HCPs how cancer treatment affects fertility (41%), fertility preferences (26%), or fertility preservation (14%), even though only 22% of patients reported not being eligible for fertility services. Interestingly, many of these gaps in care differed based on cancer type. For example, prostate, colorectal, and gastric patients were more likely to report not feeling safe disclosing their LGBTQ+ status (80%, 69%, and 54% respectively), while breast cancer patients were more likely to report having discussed fertility prior to starting treatment (64%). **Conclusions:** This study offers insights into experiences of LGBTQ+ patients and confirms disparities in care are real and pervasive. Ongoing education and inclusion efforts can help create a safe and welcoming environment, enabling equitable care and improved outcomes. Research Sponsor: Bristol Myers Squibb; Gilead Sciences, Inc; Lilly USA LLC; Merck Sharp & Dohme LLC; Pfizer Inc; Eisai Inc.; Novartis Pharmaceuticals Corporation.

Discrimination and disparities experienced among LGBTQ+ young adult cancer survivors (22-39) and adult cancer survivors (40+): A mixed-method study.

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Background: Americans who identify as lesbian, gay, bisexual, transgender, or other sexual and/or gender expansive identities (LGBTQ+) represent approximately 24.2 million (7.2%) people, living in the United States. Those who identify as LGBTQ+ face distinct barriers to preventing and treating cancer. In a recently convened ASCO steering committee meeting, reducing LGBTQ+ discrimination both within and outside the healthcare setting was discussed as a high priority area. Across generations, adults who openly identify as LGBTQ+ has increased, with nearly 20% of younger generations identifying as LGBTQ+. This shift in willingness to openly identify as LGBTQ+ may result from decreased discrimination felt by younger generations. Decreasing discrimination may ultimately help improve cancer-care engagement among people who identify as LGBTQ+. **Methods:** Utilizing a mixed method sequential approach, we examined a national sample of 60 LGBTQ+ cancer survivors' online quantitative survey data including experiences of discrimination. We performed a *t-test* to compare young adults (22-39 years old) to adults (40+ years old). Next, we conducted in-depth interviews with ten individuals from as a subset of the 60 cancer survivors. The transcribed data was analyzed using constant comparative methods and sorted into themes. **Results:** Among the 60 survey respondents, 31 (51.7%) were 40+ years old. Majority of the survey respondents were White (n = 55, 88.3%), ciswomen (n = 40, 66.7%), and identified as bisexual (n = 20, 33.3%). The subset of in-depth interview participants shared similar demographics. Quantitative: The adult cancer survivors reported experiencing higher levels of discrimination than younger adult cancer survivors (Mean Difference = 5.82, 95% CI [1.11, 10.54]). Qualitative: Among the adult cancer survivors (k = 8), three endorsed the theme of "discrimination". While one of the young adult cancer survivors (k = 2), endorsed the theme of "identity pride" defined as satisfaction from and immersion within their LGBTQ+ identity. Mixed Methods: Both quantitative and qualitative data confirmed that adult cancer survivors experienced significant differences in discrimination compared to the younger adult cancer survivors. Within the adult cancer survivor interviews, historical experiences such as the AIDS epidemic led to discriminatory experiences and ongoing medical mistrust. Among younger adult cancer survivors, openly embracing their identities and engaging with the healthcare system was described. These disparities may explain the variation in levels of reported discrimination. **Conclusions:** Research shows discrimination has a profound impact on whether a person identifying as LGBTQ+ will seek out cancer-related care. Therefore, reducing discrimination for people who identify as LGBTQ+ is crucial to reducing cancer disparities. Research Sponsor: Crowd Funding.

Fertility among young breast cancer survivors attempting pregnancy: A prospective, multicentre cohort study.

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Background: Despite high interest among young women diagnosed with breast cancer (BC) in future fertility, prior research has been hampered by short follow-up and lack of prospective assessment of pregnancy attempts. We sought to describe fertility outcomes among young women participating in a prospective cohort who reported pregnancy attempt post-BC diagnosis. **Methods:** Women with stage 0-III BC in the Young Women's Breast Cancer Study (YWS, NCT01468246), a multicenter, prospective cohort of women diagnosed at age ≤ 40 from 2006-2016 who reported attempting pregnancy post-diagnosis were included. Those with prior hysterectomy, bilateral oophorectomy, or metastatic disease at diagnosis were excluded. Data on attempting pregnancy and fertility outcomes were obtained from serial surveys. Multivariable logistic regression with stepwise model selection was used to identify factors associated with pregnancy and live birth. **Results:** Among 1213 eligible participants, 197 reported any attempt of pregnancy (16%) over a median follow-up of 11 years (range: 3-17). Among attempters, median age at diagnosis was 32 years (range: 17-40); 74% were non-Hispanic White; 41% had stage I, 35% stage II, 10% stage III, and 14% stage 0 BC; 76% had HR+ disease; 68% received chemotherapy; 57% received endocrine therapy within one year post-diagnosis; 13% were *BRCA1/2* pathogenic variant (PV) carriers; 51% reported financial comfort at baseline; 51% were nulligravida and 72% nulliparous at diagnosis; 28% had undergone fertility preservation consisting of egg/embryo freezing at diagnosis; 15% reported a history of infertility before BC diagnosis. Most (73%) reported ≥ 1 pregnancy after diagnosis and 65% reported ≥ 1 live birth. Median time from diagnosis to first pregnancy was 48 months (range: 6-125). In the multivariable model, greater age at diagnosis (odds ratio [OR] 0.82 per year increase, 95% CI 0.74-0.90, $P < 0.0001$) was negatively associated with pregnancy, while financial comfort at baseline (OR 2.04, 95% CI 1.01-4.12, $P = 0.047$) was predictive of pregnancy. For live births, greater age at diagnosis was negatively associated (OR 0.82 per year increase, CI 95% 0.76-0.90, $P < 0.0001$) while having undergone fertility preservation at diagnosis was predictive (OR 2.78, 95% CI 1.29-6.00, $P = 0.009$). History of infertility, nulliparity at diagnosis, tumor characteristics, cancer treatment, race, ethnicity, and *BRCA1/2* PV status were not associated with either outcome. **Conclusions:** This is the first prospective study with greater than 10 years of follow-up to report fertility outcomes in young BC survivors accounting for attempting pregnancy. The majority achieved a pregnancy and most reported a live birth. Our findings can be incorporated into the counseling of young BC patients and survivors, and highlight the need for accessibility of fertility preservation services for this population. Clinical trial information: NCT01468246. Research Sponsor: Breast Cancer Research Foundation; BCRF-21-124; Susan G. Komen; SAC100008.

SNF-CLIMEDIN: A prospective randomized trial of digital intervention in patients with advanced NSCLC—A HeCOG study.

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Background: The purpose of this trial is to investigate the effectiveness of online digital intervention to NSCLC patients in terms of quality of life (QoL), cost and the interrelation with clinical and molecular characteristics. **Methods:** This prospective randomized trial recruited 200 advanced NSCLC patients (3/22–10/23). All had NGS tissue analysis for 161 genes and received standard treatment (predominantly immuno-chemotherapy). Through the CareAcross online platform they received information about their disease and treatment, and periodically reported any of 22 preplanned adverse events (AEs). Patients were randomized 1:1 in the intervention (A) and control (B) arm; patients in arm A received digitally, additionally, evidence-based guidance for the reported AEs. The study was designed to assess QoL improvement (measured per patient as reduction of the number of AEs reported at last contact, compared to those previously reported). EQ5D-5L scores were collected. Patient-case level hospitalizations data were collected and costs were estimated based on reimbursed costs as defined by the Ministry of Health. Results were correlated with patients' clinical and molecular characteristics. **Results:** Clinical and molecular characteristics will be presented during ASCO Congress. For all patients, responses were: CR: 2%, PR: 35.5%, SD: 35%, PD: 10.5%. Median PFS was 7.0 months (95%CI: 5–8), 1-year 18% (38%–55%). Median OS: 12 months (11–14), 1-year 47% (38%–55%). No difference was found between the two arms in any of the above, nor in OS in relation to clinical and molecular characteristics. The most common AEs that patients reported were fatigue, cough, anorexia, nausea. More patients submitted AE reports online than their clinicians (89% vs 68% of patients, $p < 0.01$); more AEs were reported per submission, compared to their clinicians. Patients in arm A reported marginally higher improvement compared to B (77.2% vs 75.7%); 15 of 22 AEs were associated with higher (14) or same (1) improvement in arm A vs B (not statistically significant); of the most common: fatigue (61.3% vs 48.6%), anorexia (86.5% vs 70.2%; $p < 0.05$) and nausea (93.0% vs 87.2%). Baseline EQ5D was similar in both arms; comparing post-treatment (6th cycle) results shows higher improvement in all 5 dimensions in arm A vs B, especially in Anxiety/Depression (final values: 1.9 vs 2.2). The mean AE-related costs in Euros in arm A vs B were: hospitalization: 455.4 (95%CI: 91.9–941.5) vs 779.5 (346.6–1328.5) ($p < 0.001$); diagnostics: 20.3 (0.5–50.8) vs 73.3 (1.3–186.1) ($p < 0.001$). Follow up is ongoing. **Conclusions:** Digital oncology is feasible, cost-effective by reducing hospitalizations, improves certain AEs and tends to improve QoL of NSCLC patients regardless of clinical and molecular status. Patients report digitally more informative AEs for clinical and research analysis. Online platforms can complement the Oncology team. Clinical trial information: NCT05372081. Research Sponsor: Stavros Niarchos Foundation.

A United Kingdom prospective, multicentre, observational cohort study investigating tolerance of anti-cancer systemic therapy in the elderly: The TOASTIE study.

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Background: Older adults have a higher risk of developing chemotherapy (CTx) related toxicity. The Cancer Aging Research Group (CARG) score was developed and validated in the USA to predict risk of severe CTx induced toxicity in older adults; subsequent validation studies have had varying results. The TOASTIE study sought to evaluate the CARG score prospectively in a United Kingdom (UK) population. **Methods:** This multicentre, prospective, observational study recruited patients aged ≥ 65 years commencing first-line neo-adjuvant, adjuvant or palliative CTx for any solid organ malignancy. Those receiving non-CTx agents were excluded. Baseline demographics and established frailty measures were recorded, including Eastern Cooperative Oncology Group performance status (ECOG PS), Rockwood Clinical Frailty Scale (CFS), Geriatric-8 (G8) score and Charlson Co-morbidity Index (CCI). CARG score was calculated after initial Oncology consultation. Follow-up data including CTCAEv5 toxicity and hospital admissions were collected retrospectively. **Results:** 19 centres recruited 330 patients between Nov 2019 - Dec 2022. Median age was 73 years (range 65-92) and 51.9% were male. 54.9% had a primary tumour of gastrointestinal origin, 48.7% received CTx with palliative intent and 70.8% received doublet therapy. At baseline, 85% patients had an ECOG PS 0 or 1, with median CFS 3 (range 0-8), G8 score 12 (range 6-16) and CCI 6 (range 2-12). Follow-up data was available for 314 (92.6%) patients; the median CTx cycles received was 4 (range 1-16) with 124 (39%) patients dose reduced at cycle one. Treatment delays occurred in 83 (26.4%) patients and 123 (39.2%) stopped treatment early, with 60 (48.8%) cases due to treatment-related toxicity. 69(22.3%) patients experienced a CTCAE grade ≥ 3 toxicity and 84 (27%) requiring hospital admission. CARG score was available for 313 patients; 107 (34.2%) low risk, 167 (53.4%) medium risk and 39 (12.5%) high risk. Increasing CARG risk groups had increased toxicity rates (low 19.6%, medium 22.2%, high 28.2%) however this was non-significant with no evidence of robust predictive performance (Table). The performance of CFS and ECOG PS was superior to CARG. **Conclusions:** In this UK older patient population, baseline frailty was prevalent. CARG score was unable to robustly discriminate or predict risk of high-grade toxicity. ECOG showed superior, albeit limited, ability to predict and discriminate toxicity risk. This study highlights the need for development of further tools predictive of toxicity in this population. Research Sponsor: None.

	Grade 0-2 (%)	Grade 3+ (%)	p-Value	AUC
CARG (n=312)	80.4	19.6	0.75	0.57
Low (n=107)	77.7	22.3		(0.49-0.65)
Moderate (n=166)	71.8	28.2		
High (n=39)				
ECOG PS (n=306)	84.4	15.6	0.06	0.62
0 (n=109)	75.3	24.7		(0.53-0.70)
1 (n=158)	64.1	35.9		
2+ (n=39)				
CFS (n=293)	80.3	19.7	0.02	0.61
1-3 (n=223)	63.6	36.4		(0.53-0.69)
4+ (n=66)				

Assessing the environmental and downstream human health impacts of decentralizing cancer care.

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Background: Greenhouse gas emissions from healthcare are substantial and harm persons with cancer. Emissions from outpatient cancer care visits are not well described, nor are the downstream reduction in human harms that could be obtained through visit “decentralization” (telemedicine and local care when possible). **Methods:** This life-cycle assessment (LCA)-based study evaluated changes in emissions and downstream health harms associated with (1) telemedicine visits using retrospective observational analysis and (2) fully decentralized visits using counterfactual modeling. The retrospective observational cohort included persons receiving cancer care at Dana-Farber Cancer Institute (DFCI) and 20 affiliated facilities between 5/2015-12/2020. The main outcome was the adjusted per visit-day difference in emissions (in kilograms carbon dioxide equivalents: kgCO₂e) between two periods: an in-person care period (5/2015-2/2020; “Pre”) and a telemedicine period (3/2020-12/2020; “Post”). Mixed effects log-linear model assessed emissions changes adjusted for age, sex, race, ethnicity, and cancer type, with random effects on person. The counterfactual model assessed emissions changes between actual in-person visits during the Pre period and a counterfactual with maximal decentralization. Visit-day eligibility for decentralization was obtained by categorizing appointments (e.g., clinician visit, infusion) as DFCI required, local care possible, or telemedicine possible. This cohort was matched to a national population diagnosed with cancer over the same period (Cancer in North America [CiNA] dataset) using mixed-effects linear modeling, through which annual changes in disability-adjusted life-years (DALY) from clinician visit decentralization were estimated using Eckelman’s mortality cost of carbon conversion. **Results:** There were 123,890 unique patients in the DFCI cohort seen over 1.6 million visit-days (Pre N=110,180, Post N=61,691) at a median of 6 visit-days per patient (IQR 2, 15). An estimated 72,554,006 kgCO₂e were within scope of the LCA emitted during the study period. In mixed-effects log-linear regression, the adjusted mean absolute reduction in per visit-day emissions between Pre and Post periods was 36.4 kgCO₂e (95%CI 36.2,36.6), or a reduction of 81.3% (95%CI 80.8,81.7) compared to the baseline model. In the counterfactual decentralized care model of the Pre period, there was a relative emissions reduction of 33.1% (95%CI 32.9,33.3). When demographically matched to 10.3 million persons in the CiNA dataset, decentralized care would have reduced national emissions by 75.3 million kgCO₂e annually; this corresponds to an estimated annual reduction of 15.0-47.7 DALYs. **Conclusions:** Employing decentralization through telemedicine and local care can substantially reduce emissions during cancer care delivery; this corresponds to a small reduction in human mortality. Research Sponsor: U.S. National Institutes of Health; 3P30CA006516-57S2; Greenwall Foundation.

AI-assisted clinical summary and treatment planning for cancer care: A comparative study of human vs. AI-based approaches.

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Background: Understanding a patient's clinical narrative, timeline, and history is critical for accurate treatment decision-making. However, reviewing and summarizing complex records is time-consuming and error-prone. Recent advancements in artificial intelligence (AI), specifically large language models (LLM), offer paths to improve quality and efficiency. **Methods:** A study was conducted on 50 breast cancer cases from an academic medical institution, utilizing all medical records—clinic, pathology, and radiology reports—up until the point of the initial treatment decision. All cases were processed using three different approaches: AI-assisted; full-AI; and human-only. In the AI-assisted method, two oncology physician assistants (PAs) revised AI-generated summaries to create clinical summaries. The full-AI method had AI independently produce clinical summaries, while the human-only method had the PAs compile summaries without AI. Eight board-certified international oncology specialists blindly evaluated summaries for faithfulness, completeness, and succinctness using a 3-point scale, ranked their preferences, and tried to predict which summaries were full-AI. Rankings were assessed using a Friedman test followed by a Wilcoxon signed-rank test, and full-AI prediction was assessed using a two-sided one-sample binomial test. After summarization, a distinct AI system with access to clinical guidelines provided treatment plans. These plans were then evaluated by a board-certified oncologist with access to the original treatment decision. **Results:** The study found specialists favored AI-assisted, followed by full-AI, and then human-only summaries, with average ranks of 1.73, 1.93, 2.34 respectively (lower is better, $p < 0.001$). The difference between full-AI and AI-assisted was not significant ($p = 0.11$). Evaluation scores (mean \pm 95%CI, higher is better) showed AI-assisted, full-AI, and human-only scored 2.35 ± 0.13 , 2.14 ± 0.14 , 2.17 ± 0.14 for faithfulness; 2.28 ± 0.12 , 2.01 ± 0.12 , 1.93 ± 0.14 for completeness; and 2.33 ± 0.12 , 2.21 ± 0.12 , 1.99 ± 0.13 for succinctness. The average summarization time was 19.71, 1.17, 26.03 minutes. Full-AI identification accuracy was 0.28 (not different from chance 0.33, $p = 0.46$). With AI-assisted summaries, the treatment plans were accurate in 45 cases (90%) and partially accurate in 5 cases (10%). In the 5 partially accurate cases, the system was accurate with the provided input data, but there were inaccuracies with the input data, including incorrect formats or missing data. **Conclusions:** Incorporating LLMs into the creation of medical summaries has shown improvements in both quality and efficiency, achieving up to 22.2x speed up with full-AI, indicating that AI-assisted summarization tools can potentially enhance care quality. AI-assisted summaries yield accurate treatment plans when the input data is accurate. Research Sponsor: None.

Human-AI teams to improve accuracy and timeliness of oncology trial prescreening: Preplanned interim analysis of a randomized trial.

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Background: Identifying eligible patients for oncology clinical trials (“prescreening”) relies on manual chart review by clinical research coordinators (CRCs), which is time-consuming and often inaccurate. Consequently, 70% of patients with cancer who meet trial eligibility criteria are not offered participation. Natural language processing (NLP) may improve the accuracy and timeliness of prescreening. **Methods:** This was a preplanned interim analysis of a paired-design noninferiority trial, powered to assess timeliness. We adapted NLP algorithms to identify 13 common eligibility criteria related to cancer type/stage, prior systemic therapy, actionable biomarkers, and response criteria. NLP systems performed optical character recognition, entity and relationship extraction, and natural language inference through deep learning and symbolic AI techniques. Deidentified unstructured electronic health records (EHRs) from real-world patients with non-small cell lung (NSCLC) or colorectal (CrCa) cancer were presented to CRCs via a secure platform. Two CRCs were randomized 1:1 to view blocks of 20 charts each with (Human+AI) or without (Human-alone) NLP annotations. In pre-trial assessment, the CRCs had 86% inter-rater agreement. The primary outcome was overall chart-level accuracy, defined as percent of the 13 CRC-coded eligibility items matching a gold standard set, determined by 2-3 clinicians blinded to experimental arms. Paired t-tests compared overall accuracy (noninferiority margin 5%) and criteria-specific accuracy. Significant differences were assessed for superiority using two-sided paired t-tests. Mann-Whitney tests compared the secondary outcome of timeliness (time per chart review). **Results:** Among 74 (40 NSCLC; 34 CrCa) of a planned 400 patients, overall accuracy for Human+AI was noninferior to Human-alone (78.7% vs. 76.7%, mean difference 2.0%, $p < 0.001$ rejecting inferiority); both were greater than AI-alone (63.5%). Superiority for Human+AI was demonstrated for RECIST response, but not for overall nor other criteria-specific accuracy (Table). Median time per review was lower for Human+AI than Human-alone (34.1 vs 43.9 min, adjusted $p = 0.05$). **Conclusions:** Human+AI teams can improve timeliness of trial prescreening with noninferior accuracy. This platform is being used for eligibility assessment in an ongoing clinical trial. Research Sponsor: Mendel AI.

Criteria	Accuracy	
	Human-alone	Human+AI
Biomarker data		
Biomarker name	93.8%	94.8%
Result	88.5%	90.6%
Interpretation	89.7%	92.3%
Performance status	82.5%	75.0%
Prior systemic therapy	90.3%	85.8%
Cancer data		
Site	87.5%	90.6%
Type	87.8%	86.5%
Group stage	74.1%	74.1%
M Stage	46.9%	49.0%
N Stage	50.0%	63.2%
T Stage	56.4%	69.2%
Outcome (Death, Progression)	19.5%	29.3%
RECIST response**	45.7%	61.4%

**Significant for superiority of Human+AI over Human-alone after adjustment for multiple comparisons.

Geographic and racial disparities in bi-specific antibodies trials access for diffuse large B-cell lymphoma.

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Background: The trials of bispecific antibodies to treat diffuse large B-cell lymphoma (DLBCL) have increased exponentially. However, there is a geographic limitation to offering these trials and universal access appears to be limited. Here, we investigate the geographical and racial disparities in accessing bispecific antibodies trials for DLBCL. **Methods:** We searched ClinicalTrials.gov using the terms for DLBCL and bispecific antibodies. A total of 13 out of 51 clinical trials with one or more open sites in the United States (US) were included in this systematic review. 2020 US Census Bureau data was used to obtain data on race and ethnicity. Analysis for this study was performed using SPSS version 26. **Results:** The majority of the included trials were Phase I (62%) followed by Phase II (23%), and Phase I/II (15%). A total of 885 participants were either enrolled or expected to enroll in these clinical trials. Nine (69%) clinical trials were only open in the US while 4 (31%) clinical trials were open in the US and other countries. The majority of the trials were funded by the pharmaceutical industry 62%. There were 50 unique study sites distributed over 24 states with a 2.4 (1-10) mean number of trials per state and 9.9 (1-39) mean number of sites per trial. Study sites were distributed in 24 different states. Midwestern states had the highest number of trials 28%, followed by Southern 26%, Northeastern 24%, and Western 22%. The highest number of study locations (10) and the highest number of open studies (10) were in California. Twenty-seven states had no open bispecific antibodies trials including three in the Northeast (Maine, Rhode Island, and Vermont), five in the Midwest (Illinois, Indiana, Nebraska, North and South Dakota), eight in the South (Delaware, Virginia, District of Columbia, West Virginia, Mississippi, Arkansas, Louisiana, and Oklahoma), and eleven in the West (Arizona, Colorado, Idaho, New Mexico, Montana, Nevada, Wyoming, Alaska, Hawaii, Oregon, and Washington). Using US Census Bureau data, only 20% of African Americans (AA) (8 349 699 of 41 104 200) lived in a county with a bispecific antibodies trial. There were only five states (21%) with 50% or more of the AA population living in a county with an open bispecific antibodies trial and seven states (29%) with 30-49.9% of their AA county residents. Five states (21%) had less than 10% of the AA population living in a county with an open bispecific antibodies trial. Nine (90%) out of ten states with the highest proportion of AA residents (18.6%-41.4%) have no (five states) or only one clinical trial site (four states). **Conclusions:** There is significant geographic and racial disparity in accessing bispecific antibodies trials for DLBCL. Strategies should be framed to address the causes of the observed disparities and to improve access to these trials. Research Sponsor: None.

Medicaid expansion and cancer stage at diagnoses during the COVID-19 pandemic in the United States.

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Background: Substantial cancer underdiagnosis, especially for early-stage diseases, occurred during the COVID-19 pandemic in the US in 2020. The Affordable Care Act expanded Medicaid to nonelderly adults with income up to 138% Federal Poverty Level in states that opted in, potentially facilitating residents' access to care during pandemic-related financial and employment instability, thus aiding in timely detection of cancer. This study examines the association of Medicaid expansion with changes in cancer stage at diagnosis during the COVID-19 pandemic. **Methods:** Adults aged 18-64 years newly diagnosed with cancer in 2019 and 2021 were identified from the National Cancer Database. Year 2020 was excluded to avoid confounding from distinct geographic patterns of COVID-19 infections. A difference-in-differences (DD) approach was used to compare the changes in proportions of patients diagnosed at stage I/II in 2021 vs 2019 between Medicaid expansion states and non-expansion states. Adjusted DD estimates were calculated with linear probability models and stratified by key sociodemographic factors and cancer type. **Results:** A total of 427,368 adults newly diagnosed with cancer in 2019 and 393,961 in 2021 were identified. Patients diagnosed with stage I/II decreased nationwide, however, decreases were larger in non-expansion states (from 58.3% in 2019 to 56.9% in 2021) compared to expansion states (61.4% in 2019 to 60.7% in 2021), leading to a DD of 0.92 percentage points in early-stage cancer diagnosis associated with Medicaid expansion (95% CI = 0.46-1.38). The association was strongest among individuals aged 18-44 years (DD=1.46, 95% CI=0.42-2.49), men (DD=1.46, 95% CI=0.73-2.19), those living in most socioeconomically deprived areas (DD=1.40, 95% CI=0.41-2.40) and nonmetropolitan areas (DD=1.82, 95% CI=0.56-3.09). When stratified by cancer type, the largest associations were seen for esophageal cancer (DD=3.86, 95% CI=0.26-7.45) and prostate cancer (DD=2.81, 95% CI=1.43-4.18). **Conclusions:** Substantial cancer underdiagnosis and declines in proportion of early-stage diagnoses continued nationwide in 2021, the second year of the COVID-19 pandemic. However, the pattern was worse in non-expansion states, suggesting a protective effect of Medicaid expansion on cancer early diagnosis during the public health emergency. Findings may inform policy makers and the public in the 10 states that have yet to expand Medicaid eligibility. Research Sponsor: None.

Importance of information-seeking styles among patients with cancer pre- and post-treatment: A URCC NCORP Research Base study.

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Background: Understanding of information needs and information-seeking styles of patients with cancer is critical for shared decision-making and high quality care. Most patients with cancer want to be involved in the decision-making process but have unmet information needs regarding their disease and its treatment. The goal of this study is to 1) identify information needs and 2) investigate factors associated with information-seeking styles pre-and-post treatment among patients with cancer. **Methods:** This is a secondary data analysis of a longitudinal study of 1003 patients from nine community oncology practices across the United States that assessed information needs of patients with cancer. We recruited patients aged ≥ 18 years with a newly diagnosed cancer. Patients supplied demographic and clinical information at enrollment; information needs assessment including concerns (score ranging, 0-100) and anticipated side effects (0-60), questions on information-seeking styles (1-item), decision-making preferences (1-item), and resource usage (5-items) were obtained within two weeks pre-and-post treatment. We performed multinomial logistic regression to evaluate the association of information needs including concerns, anticipated side effects, and decision-making preferences with information-seeking styles (active vs. passive) at pre-and-post treatment. The analysis was adjusted for age, gender, race, marital status, education, overall health, and cancer and treatment types. **Results:** Mean age was 60.5 (SD=13.0) years. Most were White (93.0%), female (64.0%), had some college (54.3%), and were diagnosed with breast cancer (47.0%). The sources of health information included friends (52.7%), pamphlets (60.2%), and experts (75.6%). Of the total, 43.8% reported that they preferred shared decision making but had concerns about understanding the diagnosis (70.2%) and treatment plan (70.7%). On logistic regression, preference for shared decision making (vs. doctor making all decisions; Odds Ratio (OR) $_{\text{pre-treatment}}=1.87$, $p=.01$; OR $_{\text{post-treatment}}=2.3$, $p<.001$), taking notes while meeting with doctor (vs. not taking notes; OR $_{\text{pre-treatment}}=2.2$, $p<0.001$; OR $_{\text{post-treatment}}=1.8$, $p=0.01$), and information sought that could be useful later (vs. not useful; OR $_{\text{pre-treatment}}=1.9$, $p=.03$; OR $_{\text{post-treatment}}=1.3$, $p=0.38$) were associated with greater odds of active information seeking. Education and cancer type (pre-treatment) and age, cancer, and treatment types (post-treatment) were significantly associated with active information seeking. **Conclusions:** Shared decision making and taking notes during doctor visits are crucial factors associated with active information seeking. Interventions tailored to meet information needs of these patients may help increase patient participation in healthcare decision making. Research Sponsor: U.S. National Institutes of Health; T32CA102618.

Identifying states for targeted alloHCT access initiatives using social vulnerability, physician density, and unmet need.

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Background: Access to allogeneic hematopoietic cell transplantation (alloHCT) is limited by many factors, with only 1 in 3 patients who may need a transplant receiving one. This study examined associations between social vulnerability index (SVI), physician density (PD), and alloHCT unmet need across the United States (U.S.) to identify geographic areas that may be most at-risk of access challenges. **Methods:** A retrospective analysis aggregated public data across 3,141 U.S. counties, including: SVI [Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry]; National Provider Identifier [Center for Medicare and Medicaid Services] data for all registered hematology-oncology and HCT physicians; and 2017 – 2021 alloHCT unmet need [Center for International Blood and Marrow Transplant Research (CIBMTR), NMDP]. PD was defined as providers per 10,000 population. All variables were collapsed into ordinal categories (very low, low, moderate, high) based on quartiles. Counties with moderate/high SVI and unmet need and low/very low PD were defined as at-risk. By state, linear regression and mediation analysis assessed exploratory relationships. **Results:** Among 396 counties defined as at-risk, top states are shown (Table). State (n=51) percent unmet need was correlated with SVI ($r=0.494$, $p<0.001$) and PD ($r=-0.295$, $p=0.036$). Univariate analysis revealed SVI ($b=-0.223$, $p<0.001$) and PD ($b=-0.187$, $p=0.036$) as predictors of unmet need. However, multivariate regression showed only SVI as significant when included with PD. Race/ethnicity as 1 of 4 SVI subthemes (socioeconomic status [SES], household characteristics [including age], race/ethnicity, and housing/transportation) was not correlated with PD, but all other themes were. SES and household characteristics were found to fully mediate the relationship between PD and unmet need. **Conclusions:** This study can help prioritize targeted initiatives through a better understanding of how SVI, PD, and unmet need relate to alloHCT access. This study cannot draw causal conclusions and uses multiple population-level data sources. However, data can examine trends on a regional level within at-risk states to allocate resources to overcome barriers to alloHCT, with special attention on SES and household factors like age. Relationships between variables should be further examined. Research Sponsor: None.

State-level statistics for states with the most population in counties identified as at-risk for alloHCT access challenges.

State	Total Population in At-Risk Counties (Million)	Total At-Risk Counties	PD	SVI	% Unmet Need
TX	12.24	55	0.28*	0.71**	63*
NY	7.48	11	0.50	0.46*	51
NC	4.13	38	0.42	0.69**	67*
FL	3.53	17	0.42	0.71**	60*
NV	3.02	7	0.23**	0.59*	73**
GA	2.85	24	0.31*	0.72**	62*
PA	1.94	7	0.48	0.37	55
SC	1.54	18	0.35*	0.78**	68**
LA	1.47	22	0.35*	0.76**	74**

*Defined as at-risk.

**>1 standard deviation from state-level mean.

Cancer clinical trial participation in socioeconomically vulnerable patients: A risk model to aid in targeted interventions.

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Background: In patients with cancer, those with lower income are 30% less likely to participate in clinical trials. Lower income individuals face direct and indirect costs that can make participation in a clinical trial prohibitive. However, a broader evaluation of specific behavioral, information, insurance, and area-level variables that could contribute to this disparity has not been conducted. We aimed to develop and validate a model to identify socioeconomically vulnerable patients at high risk of non-participation in clinical trials. **Methods:** We used data from the Health Information National Trends Survey (HINTS), a national cross-sectional survey about knowledge of, attitudes toward, and use of health-related information. We analyzed HINTS survey databases that included questions about whether patients with cancer participated in a clinical trial (survey years 2014, 2017, and 2020). We examined 21 different demographic, socioeconomic, behavioral, geographic, and health information questions. We derived a risk model to predict clinical trial participation in a random set of 60% of participants using best subset selection with k-fold cross validation. The derived model was validated in the remaining 40% of participants. Logistic regression was used. **Results:** We examined N=1,023 participants with household income <\$75,000, the current median in the U.S. In the training dataset of n=614 participants, a model with 5 variables was identified. Non-Hispanic White patients and patients without a college education, with high levels of distrust, with high levels of anxiety or depression, and from non-urban areas were all at lower risk of trial participation. We summed the adverse risk factors for all individuals; a risk score with 4 levels was constructed based on distribution quartiles. In the independent validation cohort (n=409), each increase in level of adverse risk factors was associated with a 42% reduction in the odds of trial participation (OR=0.58, 95%-CI, 0.40-0.84, p=.004), indicating successful model validation. Among all individuals, trial participation rates decreased from 18.6% to 7.5% to 4.6% to 2.8%, respectively, as the number of adverse risk factors increased (in quartiles) from 0-1 to 2 to 3 to 4-5. Individuals with 4 or 5 risk factors (vs. those with 0-1 factors) were 87% less likely to participate (OR=0.13, 95% CI, 0.05-0.31, p<.0001). **Conclusions:** We developed and validated a 5-variable risk model that identified a large set of lower income individuals at lower risk of trial participation. In a first-time observation, psychosocial variables were shown to be meaningful predictors of lower trial participation. These findings could aid in the early identification of patients who may benefit from additional support to navigate the treatment trial decision making process, in the name of more equitable participation in trials for all patients. Research Sponsor: Arnold Ventures.

Identifying modifiable risk factors to improve immigrant breast cancer screening in the United States.

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Background: Despite marked reductions in breast cancer mortality since 1990, recent data suggest that progress has slowed—owing in part to plateaus in breast cancer screening in underserved populations. Historically low rates of screening coupled with rising breast cancer incidence make immigrants an important population for targeted intervention. Herein, we (1) compare contemporary rates of breast cancer screening among immigrants versus US natives; and (2) identify modifiable risk factors to inform the development of interventions to improve screening among immigrants in the United States. **Methods:** Using data from the 2019 and 2021 National Health Interview Surveys, screening eligible female participants (ages 40–79 years old) were identified, then classified by immigrant status as defined by nativity (US native vs. foreign-born). Primary outcome was receipt of screening mammogram in the last two years. Logistic regression models examined associations between immigrant status and mammography, with and without adjustments for age, metropolitan residence, overall health status, and survey year. Sequential analysis was then used to assess the degree to which modifiable social risk factors influence the magnitude of the association between immigrant status and mammography. **Results:** Of 20,090 female participants included in the study, 20% were immigrants. Compared to US natives, immigrants were less likely to have received a mammogram in the last two years (67% vs. 72%, aOR [95%CI], 0.87 [0.78–0.96], $p=0.006$)—an effect that was most pronounced among immigrant noncitizens (57%; 0.55 [0.47–0.64], $p<0.001$) but reversed among immigrants with US citizenship (74%; 1.14 [1.01–1.29], $p=0.03$). Of the factors assessed, having a usual source of care (5.73 [4.77–6.87]) or insurance (4.60 [3.74–5.67]) was associated with the greatest odds of biennial mammography, followed by educational attainment (1.38 [1.19–1.60]) and employment (1.19 [1.09–1.30]; all $p<0.001$). While having a usual source of care or employment attenuated—but did not eliminate—the association between immigrant status and mammography (0.87 [0.78–0.96], $p=0.01$ and 0.89 [0.80–0.99], $p=0.03$, respectively), this finding was not observed upon inclusion of insurance status or education in sequential models (0.97 [0.87–1.09], $p=0.6$ and 1.09 [0.96–1.21], $p=0.13$, respectively). With respect to insurance type, Medicare Advantage (4.60 [3.74–5.67]) conferred the largest benefit, followed by private insurance (4.54 [4.00–5.26]), Medicaid (2.63 [2.20–3.14]), and Medicare (4.39 [3.53–5.46]; all $p<0.001$). **Conclusions:** Breast cancer screening remains low in noncitizen immigrant populations. Targeted interventions to improve access to health insurance coverage and primary care for noncitizens may be most effective for improving rates of screening mammography among immigrants and thus warrant further investigation. Research Sponsor: Conquer Cancer, the ASCO Foundation; The Commonwealth Fund.

Patterns of screening and access to care in women diagnosed with breast cancer in a safety-net system.

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Background: Screening mammography reduces breast cancer specific mortality by allowing diagnosis at an earlier stage. Inconsistent guidelines and limitations in access to primary care are among factors that affect screening uptake. In this study, we reviewed patient characteristics, access to care, and uptake of screening mammogram (SMMG) prior to a breast cancer diagnosis at a safety-net system. **Methods:** Parkland Health (PH) is the safety-net system for Dallas County and is affiliated with the University of Texas Southwestern Simmons Comprehensive Cancer Center. Electronic medical records of patients with a new invasive breast cancer diagnosis between 2018 and 2019 at PH were reviewed and data on demographics and clinical presentation were collected. Patients were categorized based on SMMG uptake prior to their cancer diagnosis: never-screened, ever-screened (SMMG > 2 years prior to diagnosis) and recent-screened (SMMG within 2 years of diagnosis). **Results:** A total of 468 new breast cancer cases were identified (48.7% Hispanic; 32.9% Black). Of these, 12.2% were younger than 40 and 27.8% were 40-49. Payer mix included 64.7% uninsured and 34.8% Medicare/Medicaid. Half of the patients (50.6%) never had SMMG. Never-screened rate was higher among younger patients (98.2% in < 40; 53.8% in 40-49; and 39.4% in >50; $p < 0.0001$). Only 25.2% (118/468) of the patients had a SMMG within 2 years prior to their diagnosis. Among patients aged >40, 44.0% (181/411) were never-screened and 28.7% (118/411) were recent-screened. Screen-detection rate among patients >40 was 40.1% (165/411), of whom 22 (13.3% of screen-detects) were diagnosed with cancer on their first ever SMMG. Race/ethnicity, insurance status, and positive family history of cancer were not significantly different between never, ever, and recent-screened patients. Screening uptake correlated with nodal status, tumor size and stage at diagnosis. Patients who had a prior encounter at Parkland were more likely to have a SMMG. Patients established with Parkland primary care at diagnosis were more likely to have early-stage disease. In patients < 40, 24.6% presented with stage IV disease at diagnosis and 57.9% did not have a primary care provider. A positive family history of breast/ovarian cancer or any cancer was noted in 38.6% and 57.9% of patients < 40, respectively. **Conclusions:** In the cohort presented here, 27.8% of patients were between age 40-49, reflecting the impact of a gap in the guideline, which is now addressed in the most recent iteration of USPSTF guidelines. Connecting ED users to primary care, identifying higher risk individuals through family history, and increasing SMMG rate in the primary care setting are among strategies to reduce the rate of late-stage diagnosis of breast cancer, particularly among vulnerable patient populations. Research Sponsor: None.

Unveiling the cost-effectiveness of CDK4/6 inhibitors in treating patients with HR+/HER2- metastatic breast cancer: A closer look at nonmedication expenses.

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Background: Cyclin-dependent kinase (CDK)4/6 inhibitors have significantly enhanced survival outcomes in postmenopausal patients diagnosed with HR+ MBC. Their integration with endocrine therapy (ET) has become the standard of care in MBC treatment lines. There are limited economic evaluations of these innovative, yet costly, therapies. This study assesses the cost-effectiveness of these drugs using EHR derived data and administrative claims to estimate cost. **Methods:** We used the nationwide EHR-derived Flatiron Health (FH) de-identified database to identify 3,879 patients receiving 1st line (1L) treatment for HR+ MBC (2,137 received CDK4/6i+ET and 1,742 received ET alone) between Feb 2015 and Nov 2021. SEER-Medicare claims data was used to supplement the missing cost info in the FH database to quantify monthly medication costs, drawing data from Medicare patients continuously enrolled in PARTs A, B, and D between 2015 to 2021 for at least 24 months and specific to therapeutic approaches for MBC and overall healthcare costs. The costs were adjusted by the patient characteristic: age, race, specific ET or CDK4/6i drug, and Medicare dual eligibility. The effectiveness was measured as progression-free duration in months. All costs were adjusted for inflation. The Incremental Cost Effectiveness Ratio (ICER) analysis was conducted to examine the cost-effectiveness of CDK4/6i as compared with ET alone. **Results:** Average estimated monthly medication costs were \$12,524 and \$322 for CDK4/6i+ET and ET alone, respectively. On average, CDK4/6i+ET increased the estimated medication costs by \$235,564 over the time to first progression and was associated with a gain of 3.2 months of progression-free survival as compared to ET alone, resulting in an ICER of \$73,098 per month without progression. At a willingness-to-pay of \$65,000 per month without progression, both groups have 50% probability of being considered cost-effective. Notably, the average estimated monthly non-medication costs (total costs-medication costs) for the CDK4/6i+ET group were \$2,278 compared to \$4,265 for the ET alone group ($p<0.001$). On average, CDK4/6i+ET decreased the estimated non-medication costs by \$ 22,427. For non-medication costs, the ICER drops to \$7,178 per month without progression making the CDK4/6i+ET the dominant cost-effective choice over ET alone. **Conclusions:** Cost-effectiveness of treating HR+ MBC patients is primarily driven by the cost of CDK4/6i drug prices. However, findings highlight significantly lower overall non-medication healthcare costs using CDK4/6i+ET compared to ET alone in 1L treatment. These cost savings, however, are offset by the high medication costs of CDK4/6i. Thus, lowering the market cost of CDK4/6i drugs or targeting those who can benefit the most could shift the balance in favor of a cost-effective benefit from Medicare perspective. Research Sponsor: American Cancer Society; RWIA-21-123-01-RWIA.

The positive impact of Medicaid expansion on melanoma stage at presentation.

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Background: This study aims to evaluate the impact of the Affordable Care Act Medicaid expansion on melanoma stage at presentation. **Methods:** 12,667 non-elderly patients (age 40–64) who were newly diagnosed with melanoma and known Medicaid expansion status were identified from The National Cancer Database. We excluded patients with private insurance, Medicare, or other government or unknown insurance. The time period for the cohort spanned from 2010 to 2020 which includes pre-expansion (2010–2013) and post-expansion periods (2014–2020). Year-to-year trend analysis and difference-in-difference (DID) analysis was performed to analyze tumor staging between states with Medicaid expansion (MES) and without Medicaid expansion (non-MES) before and after the expansion. **Results:** Out of the 12,667 melanoma patients (56% male, 95% white), 41% of patients were uninsured and 59% had Medicaid during 2010 to 2020. The percentage of patients without insurance decreased significantly from 51% in 2010 to 16% in 2020. There were 21% of patients with stage III and 18% with stage IV melanoma. The trend of melanoma stage at presentation over the study period was shown (Table). Notably, the stage IV melanoma at presentation decreased from 21% to 17% from 2010 to 2020 in MES. In contrast, stage IV melanoma at presentation increased from 20% to 23% over the same period of time in non-MES. After adjusting for confounders, DID analysis revealed a statistically significant decrease in stage IV melanoma at presentation (DID -0.04, $p < 0.001$) as well as a statistically significant decrease in 3 year mortality (DID -0.05, $p < 0.001$) between MES and non-MES before and after Medicaid expansion. In addition, the use of immunotherapy in stage IV melanoma in MES was significantly higher than non-MES (47% vs 41%, $p < 0.001$). **Conclusions:** The findings reveal the positive impact of Medicaid expansion on melanoma stage at presentation and suggest that improved access to healthcare services can facilitate diagnosing early-stage melanoma and decreasing mortality rate. Despite these findings, there are still 16% of patients who still do not have insurance in 2020 which indicates that continued effort is needed to improve the outcomes of these uninsured patients. Research Sponsor: None.

Year-to-year trend analysis on stage at presentation (%) stratified by Medicaid access (n=12,667).												
		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Non-MES	Stage I	41	39	38	36	37	39	34	39	34	38	34
	Stage II	20	20	25	23	22	19	22	17	18	19	21
	Stage III	20	24	21	21	19	22	25	21	24	21	22
	Stage IV	20	16	15	20	21	20	19	23	24	22	23
MES	Stage I	39	43	41	41	48	49	50	49	49	44	46
	Stage II	20	19	19	19	17	16	19	18	16	18	17
	Stage III	20	18	21	23	21	21	18	19	21	22	20
	Stage IV	21	20	18	18	14	14	13	14	15	17	17
Difference in stage IV presentation		1	4	3	-2	-7	-6	-6	-9	-9	-5	-6

Impact of age on clinical trial availability for AYAs with cancer: A time-trend analysis.

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Background: Low participation of adolescents and young adults (AYAs, age 15–39 yrs at diagnosis) in cancer clinical trials (CCT) limits their access to novel therapies and hinders the ability to study disease biology and age-specific toxicities. Patient age may be an important barrier as younger and older AYAs may be excluded depending on the trial's focus. In 2017, the American Society of Clinical Oncology and Friends of Cancer Research issued a joint statement encouraging removal of age as a CCT eligibility criterion unless there is specific biological rationale. To evaluate the impact of this statement, we undertook this analysis of CCT availability for AYAs. Our primary objective was to compare the number of CCT available for AYAs, overall and by tumor types, from 2019–2023 vs previously published data from 2007–2018. The availability of early phase trials and study sponsor was also assessed. **Methods:** We identified CCT registered on ClinicalTrials.gov from January 2019 to July 2023 enrolling patients with 10 malignancies relevant for AYAs (Hodgkin lymphoma, anaplastic large cell lymphoma, melanoma, extracranial germ cell tumors [GCT], medulloblastoma, thyroid cancer, Ewing sarcoma, osteosarcoma, rhabdomyosarcoma [RMS], and synovial sarcoma). Trials were categorized as adult (≥ 18 yrs), transitional (patients $<$ or ≥ 18 yrs), or pediatric (< 18 yrs). Transitional trials with an age range 12–18 to < 40 yrs were defined as AYA specific trials. Early phase included phase 1 and 1/2 trials; late phase included phase 2/3 and 3 trials. Trial availability from 2007–2018 was identified from a prior analysis by deRojas et al in 2019 (PMID:32337483). The proportion of trials in each category was compared between 2007–2018 and 2019–2023 using z-tests. **Results:** There were 1071 eligible trials registered on Clinicaltrials.gov: 840 (78%) adult, 226 (21%) transitional, and 5 (0.5%) pediatric. Four trials were AYA-specific. Compared to the prior 10 years, the proportion of transitional trials did not change overall (19% vs 21%, $p=0.24$) or within any disease. Whereas the proportion of trials available at age 17 has not significantly changed overall (20% vs 21%; $p=0.48$) or within any disease, the proportion of trials available at age 18 significantly increased (95% vs 98%; $p<0.001$) in aggregate and specifically for Ewing sarcoma (93% vs 100%; $p=0.003$), GCT (96% vs 99%; $p=0.002$), medulloblastoma (86% vs 98%; $p=0.006$), RMS (87% vs 98%; $p=0.007$) and thyroid cancer (92% vs 98%; $p=0.01$). Time trends for transitional trials by phase and sponsor are summarized (Table). **Conclusions:** Availability of transitional trials for AYAs has not increased, particularly for those < 18 yrs. The 18-yr-old age limit continues to be an obstacle in CCT availability and enrollment. Research Sponsor: None.

Transitional Trials	2007-2018 N (%)	2019-2023 N (%)	p
Early phase	190 (45)	113 (50)	0.24
Phase 2	189 (45)	83 (37)	0.04
Late phase	42 (10)	30 (13)	0.22
Industry sponsor	132 (31)	107 (47)	<0.001

A unique model: Partnership between community oncology and pharma for clinical trial enrichment.

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Background: Clinical trials are the foundation of oncologic drug development. Historically, only 23% of oncology trials are conducted in the community despite >70% of patients being treated this setting, leading to a disconnect between the therapy being tested and target population. Also, patients are hesitant to enroll in trials- in 2020, only 49% were willing, down from 85% in 2019. One way to improve this is participation by community oncologists, allowing patients to stay close to home. Targeted therapies are increasingly being approved by the FDA, with 89 small molecule drugs approved by 2020. Given the above landscape, Precision Health Informatics (PHI) collaborated with Mirati Therapeutics to pilot a clinical trial enrichment program focused on increasing enrollment of patients in the community related to efficacy and outcomes of adagrasib (KRAS G12C inhibitor) for NSCLC and CRC. **Methods:** This pilot was launched in 2021, with a prescreening study (DetECT) to find eligible patients with KRASG12C mutations. The pilot was then expanded across Mirati 'Krystal' studies in 2022 and to "1719" studies in 2023. These studies were available to all investigators throughout Texas Oncology (TxO) via STAR model (clinical trial access to all TxO investigators/sites through a regulated but rapid approval process). Eligible patients were identified from PHI's proprietary molecular data warehouse (that stores molecular results for >400,000 patients treated at TxO). A data analyst identified patients with KRAS G12C mutation from the warehouse, and then cross-referenced patient-centric data in EMR to assess eligibility. The treating physician was then alerted of their patient's eligibility. Patient demographic information was also collected from the EMR. **Results:** This collaboration resulted in accrual of 118 patients, engagement of 40 different PIs, across 8 different trials. 6 studies remain open across the practice. 21 patients were enrolled on Krystal-001, 7 on Krystal-007, 10 on Krystal-010 and 56 on DetECT. Enrollment was inclusive of patients from urban areas of DFW as well as rural populations in NE Texas, South and West Texas. In DetECT, TxO provided 84% of the total US enrollment, with a diverse population - 54% white, 23% Hispanic, 12% black, 9% Asian. Texas Oncology is the 2nd highest screening and enrolling site on Krystal studies. **Conclusions:** This pilot successfully demonstrates that community oncology can lead the way in clinical trial enrollment, even in early phase targeted therapy studies. Community physicians can be engaged so patients can benefit from research participation close to home. This model shows that a diverse population was accrued and may serve as a blueprint to help Pharma satisfy the diversity requirements for clinical trials. PHI, with its molecular database, may partner with Pharma to identify targetable mutations and drive rapid trial enrollment for targeted therapies. Research Sponsor: None.

Unveiling the interplay of social factors in cancer survivorship: A comprehensive social determinants of health (SDOH) profile analysis.

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Background: SDOHs contribute to patients' cancer survivorship outcomes. While studies tend to focus on individual SDOH, understanding the interplay and collective impact of multiple SDOHs is vital for improving patient outcomes and access to care. Our study aims to understand SDOH profiles in cancer survivors and stratify social risks by analyzing relationships between SDOH profiles and health outcomes using a nationally representative dataset. **Methods:** We conducted an unsupervised clustering analysis using 2013–2018 National Health Interview Survey data, linked to NHIS Mortality Files, to examine 12 social determinants of health (SDOHs) in the general population. 12 SDOH included unmarried status, unemployment, less than high school education, material/psychological/behavioral financial hardship, transportation/food/housing insecurity, delayed care due to other reasons, and low income (less than federal poverty line), and low neighborhood cohesion. K-Modes clustering was used to identify optimal number of cluster. We estimated each cluster's prevalence in younger (18–64 years) and older (65–79 years) cancer survivors, then used weighted Cox regression to assess the risk of overall (OS) in both age groups, adjusting for demographics. **Results:** We identified 5 distinct groups based their SDOH profiles, including group A (few SDOH barriers), B (unmarried but no other SDOH barriers), C (unemployed but no other SDOH barriers), D (unmarried, unemployed, occasionally having other SDOH barriers) and E (the highest rate of financial hardship/transportation/food/housing insecurity/low neighborhood cohesion/low income). Notably, group E, compared to all other groups, had the highest rate of racial minorities in both younger and older groups in both younger (71% vs 5–14%) and older populations (74% vs 1–8%). Older survivors in Group C (HR 2.48, 95% CI: 1.02–6.03), Group D (HR 4.09, 95% CI: 1.65–10.14), and Group E (HR 3.88, 95% CI: 1.44–10.46) had significantly lower OS rates compared to those in Group A. For younger survivors, Group D (HR 1.96, 95% CI: 0.97–3.96) and Group E (HR 1.40, 95% CI: 0.67–2.95) were associated with nonsignificant reductions in OS, possibly due to limited sample sizes. **Conclusions:** SDOHs form distinct clusters, each with profound on cancer survivorship especially among older survivors facing complex social challenges. This necessitates customized health interventions focused on these SDOH profiles, crucial for improving patient outcomes and addressing health disparities. Research Sponsor: University of Texas Southwestern Medical Center.

Navigating disparities: Insights from a colorectal cancer screening program in federally qualified community healthcare centers.

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Background: Colorectal cancer (CRC) is the second leading cause of cancer deaths in Georgia. Despite evidence for the effectiveness of CRC screening, disparities in access are prevalent in underserved populations. Georgia's Federally Qualified Health Centers (FQHCs) struggle with low screening rates (42.8%), partly due to Georgia's lack of Medicaid expansion, poor access to health services in rural areas, and deficiencies in coordinated strategies. The Georgia Colorectal Cancer Control Program (GCRCCP) was funded by the Centers for Disease Control and Prevention to implement evidence-based interventions (EBIs) in qualifying FQHCs across South Georgia. Here, we assess the program's impact on clinic-level screening rates (SR). **Methods:** Fourteen clinics with 12,159 CRC-eligible patients (ages 50–75) were enrolled from East Georgia Healthcare Center (EGHC) and Albany Area Primary Health Center (AAPHC). FQHC clinics had to have a SR below 60% to participate in the program. In addition to the EBIs (provider assessment and feedback, provider reminders, patient reminders, reducing structural barriers), the GCRCCP integrated provider education using the ECHO Model and navigation through a nationally recognized, evidence-based patient navigation program. We compared baseline (2020 and 2021) and follow-up data (2022) to determine the average change in SR over time, overall, and by demographic sub-groups. **Results:** The overall change in SR for the 14 clinics was +6.7%, from a baseline average of 45.3% to 52% in 2022. The average change in SR for EGHC clinics (n=9) was +11.5% (from 32.2 to 43.7%). Women had a higher SR (44.9%) than men (41.8%), but both realized an increase in SR, +10.5% and +9.1%. Non-Hispanic Black Americans (NHBA) experienced a higher increase in SR, +13.7% (from 37.2 to 50.9%) than their Non-Hispanic White (NHW) counterparts (+7.5% (from 29.8 to 37.3%)). The uninsured vs. insured followed a similar pattern (+15.3% (from 17.8 to 33.1%)) vs. +2.1 (from 45.9 to 48%). The average change in SR for AAPHC clinics (n=5) was +1.8% (from 58.4 to 60.2%). There was a decline in SR for men, -8.6% (from 64 to 55.4%), and an increase for women, +3.8% (from 58.2 to 62%). NHBA had a decrease in SR, -0.8% (from 61.2 to 61%), while NHW Americans had an increase in SR, +0.2% (from 53.8 to 54.2%). The uninsured and insured groups realized minimal increases of +0.6% (from 46 to 46.6%) and +0.8% (from 62 to 62.8%), respectively. **Conclusions:** The implementation of EBIs and patient navigation show varied potential to reduce disparities in accessing CRC screening in underserved populations. FQHC clinics that sustain implementation activities and workflow processes can benefit communities long-term and improve health equity. Research Sponsor: The Centers for Disease Control and Prevention.

Trends in the providers' uptake of advance care planning from 2016 to 2021.

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Background: Advance care planning (ACP) facilitates meaningful discussions and preparation for future medical decisions. This person-centered approach has been recognized for its potential to improve care quality and reduce unnecessary aggressive care at the end of life, especially among cancer patients. We examined the trends in ACP visits across specialty groups that may involve cancer care and between rural and urban areas. **Methods:** We used publicly available data from the Centers for Medicare & Medicaid Services, the Provider Utilization and Payment Data Physician and Other Practitioners Dataset – By Provider and Service files (2016–2021). We included providers in 3 specialty groups that may encounter cancer patients needing ACP: Cancer-Related Specialties, Hospice and Palliative Medicine (HPM), and Midlevel Providers. The primary outcome was billing for any ACP services each year, identified through Healthcare Common Procedure Coding System codes (99497 and 99498). Geographical areas were classified using Rural-Urban Commuting Area codes into metropolitan and non-metropolitan areas. Trends in the percent of providers billing any ACP and average ACP service volumes were described, with Wilcoxon tests used for statistical comparisons. **Results:** The primary analytic sample consists of 1,280,656 provider-years from 2016 to 2021 (Cancer-Related Specialties: 113,012, HPM: 7,320, and Midlevel: 1,160,324). The percentage of providers billing ACP visits tripled from 1.0% in 2016 to 3.3% in 2021. The highest uptake was among HPM physicians (12.8% to 36.9%) compared to cancer-related specialists and midlevel providers (Table). Average ACP service volume was higher in non-metropolitan areas among Cancer-Related Specialties (53.6 vs. 142.9). However, the average ACP service volume by metropolitan status was similar among HPM (75.0 vs. 66.7, $P=0.65$) and higher in metropolitan areas among Midlevel providers (70.2 vs. 54.8, $P<.001$). **Conclusions:** The proportion of physicians billing ACP codes increased including those in HPM and cancer-related specialties, but adoption remained low. Rural-urban disparities in average ACP service volume among cancer-related specialties might reflect a shortage of specialty-trained HPM physicians to provide ACP services. Particularly noteworthy is the absence of HPM specialty in non-metropolitan areas. A comprehensive strategy involving education, awareness, enhanced training capacity, innovative care models for advanced practice nurses, and increased resources, is needed to promote APC use and patient-centeredness in cancer care. Research Sponsor: None.

Trends in percentage of advance care planning by specialty, 2016-2021.

	2016	2017	2018	2019	2020	2021
Cancer-Related Specialties	0.6	1.0	0.9	0.9	1.0	1.1
Hospice and Palliative Medicine	12.8	22.2	26.7	33.6	36.2	36.9
Midlevel	1.0	1.6	2.2	2.7	3.1	3.3

The influence of access to care on radiation therapy utilization among older women with breast cancer.

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Background: In 2004, the Cancer and Leukemia Group B (CALGB) C9343 trial compared outcomes among women aged ≥ 70 who had stage I, estrogen-receptor positive (ER+) breast cancer (BC) who received a lumpectomy and hormonal therapy, treated with and without radiation therapy (RT). While the trial found that overall survival was not different between groups, RT use did not significantly decline after its publication. We investigated regional variation in RT utilization in the United States (US) and its association to access to healthcare among women aged ≥ 70 diagnosed with localized ER+ BC after partial mastectomy (PM) between 2004–2020. We hypothesize that women with greater access to health care will more often receive RT. **Methods:** To examine regional variation in the use of RT and its association with access to healthcare, we extracted data from the Surveillance, Epidemiology, and End Results 17 registry. From 2004 – 2020, 105,694 women aged ≥ 70 years who received a PM for localized ER+ BC across 199 US counties with a population $> 50,000$ were identified. Access to healthcare was measured using six socioeconomic (SES) variables: median household income, % with high school education, % of families above poverty line, % with bachelor's degree, % speaking English, and % employed, measured from 2015–2019. A multivariable linear regression model tested for association between each variable and RT use. A composite SES score was calculated as the sum of z-scores across all six variables and we identified the top 20 and bottom 20 scoring counties. SES score was used as a surrogate for access to healthcare and was correlated to RT use using a linear regression model. **Results:** The percentage of women aged ≥ 70 receiving RT after PM for localized ER+ BC varied across counties from 19.0% to 84.6%. In 2004, receipt of RT was similar between the top 20 and bottom 20 counties (67.8% vs 65.2%, respectively). This decreased after publication of CALGB C9343; by 2020 receipt of RT was 58.7% for the top 20 and 49.2% for the bottom 20 SES counties (Table). In linear regression analysis, SES was significantly associated with RT use ($p < 0.0001$). In multivariable linear regression analysis, only % above high school education was significantly associated with RT use ($p = 0.0205$). **Conclusions:** Among women aged ≥ 70 with localized ER+ BC who underwent PM and who were candidates for omission of RT, those who lived in higher SES counties were more likely to receive RT from 2004 – 2020. Since the CALGB C9343 trial in 2004, RT use has declined; however, the decline was less among those with higher SES and therefore likely less among those with greater access to healthcare. These women may experience over treatment, which may result in personal or system wide harms. Research Sponsor: None.

Year of Diagnosis	% Receiving RT in Top 20 Counties	% Receiving RT in Bottom 20 Counties	% Receiving RT in Top 20 – Bottom 20 Counties
2004	67.8	65.2	2.6
2008	66.5	60.8	5.7
2012	65.1	64.6	0.5
2016	63.8	50.7	13.1
2020	58.7	49.2	9.5

Time to treatment initiation of lung cancer and contributing factors from 2015-2020 utilizing Surveillance, Epidemiology and End Results program database.

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Background: Time from diagnosis of cancer to definitive therapy, or time to treatment initiation (TTI), has significant impact on prognosis. Kohorana et al performed an observational study in 2019 that found that TTI has increased in the United States with an absolute increased risk of mortality ranging from 1.2-3.2% per week in early-stage breast, lung, renal and pancreatic cancers. This study aims at identifying contributing factors and trends that can assist in shortening TTI of lung cancer. **Methods:** This is a retrospective cohort study conducted by review of Surveillance, Epidemiology and End Results Program database. Participants included 212,607 adults ages 18 and older diagnosed with lung cancer during 2015-2020. Variables contributing to TTI were studied like age, sex, race, marital status, geographic location, household income, stage and grade. TTI was measured as less than 30 days and greater than 30 days. ANOVA analysis was performed with SPSS and BlueSky Statistics, with p-value of <0.05 as significant. **Results:** TTI was 1.30 months in males and 1.31 months in females ($p=0.038$). In patients less than 65 years, TTI was 1.14 months, while those greater than 65 had a delay of 1.38 months ($p<0.001$). White patients had TTI of 1.26 months versus non-white patients, 1.44 months ($p<0.001$). Married patients had TTI of 1.24 months versus 1.44 months in widowed patients ($P<0.001$). Income less than \$35,000 had less TTI (1.22 months) than income greater than \$75,000 (1.33 months) ($p<0.001$), but the population earning $< \$35,000$ was smaller ($n=3,082$) compared to $> \$75,000$ ($n=209,525$), therefore not representative of the total population. Metropolitan had longer TTI than nonmetropolitan at 1.34 months versus 1.24 months, $p<0.001$. Grade IV had shorter TTI at 0.94 months with grades I and II having TTI of 1.42 and 1.46 months, respectively ($p<0.001$). Localized cancers had the longest TTI at 1.71 months versus distant at 1.01 months ($p<0.001$). More aggressive cancers had shorter TTI such as grade IV + distant at 0.76 months versus grade I + localized at 1.42 months. Association between grade and stage and impact on TTI was significant at $p<0.001$. **Conclusions:** This study revealed significant factors influencing the duration from cancer diagnosis to treatment among adult patients greater than 18 years old diagnosed with lung cancers. Shorter TTI intervals were observed for females, younger individuals (<65 years-old), white patients, married and those with higher tumor grades and distant cancer. Addressing these disparities requires targeted interventions that consider socioeconomic status, geographic location and cancer characteristics to ensure equitable access to timely and high-quality cancer care. Further investigation is warranted to fully understand the impact of factors such as household income and regional variations on treatment delays. Research Sponsor: None.

Remote delivery of cancer genetic testing in veterans with metastatic prostate cancer: A Million Veteran Program study.

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Background: Germline pathogenic alterations are found in approximately 10% of men with metastatic prostate cancer (mPC) and can inform precision therapy, surveillance, and cancer prevention for family. National guidelines recommend germline genetic testing be offered to all men with mPC, yet uptake of testing in the community has been documented to be 10–12% with many barriers to testing. We conducted a study to determine uptake of testing using remote consenting and testing for veterans with mPC who had participated in the Department of Veteran's Affairs (VA) Million Veteran Program (MVP). We wanted to know if remote testing could augment point-of-care counseling and ordering to increase uptake of germline testing.

Methods: This prospective study enrolled veterans who participated in MVP study with a diagnosis of mPC. Veterans were contacted by mail with an option to opt-out of future contact. Those who did not opt-out were mailed information about the study and received a follow-up call to establish interest in germline testing with a CLIA-level germline test. Those expressing interest provided verbal informed consent and were mailed a saliva collection kit for a multi-gene cancer predisposition gene panel test. Results were disclosed by phone and mailed to the patient with genetic counseling support and were sent to the oncology provider by email, phone or both. Two research coordinators and two part-time genetic counselors provided consenting, counseling and return of results. A study evaluating facilitated communication of results to first degree relatives (FDR) and germline testing of FDR was a component of study. **Results:** As of 2/6/2024, 1952 veterans who were alive with an incident diagnosis of mPC were identified through MVP and did not opt out. Informational letters were sent to the home address of all eligible participants. 683 (35%) of veterans completed informed consent and 457 (23% of total original cohort) completed testing. Among the participants, 70% were White, 21% were Black, 0.5% Asian and 8% unknown, 13% had a germline pathogenic variant. Documentation of positive germline results from study in the chart reports was 58%. Of 30 results relevant for targeted therapy, 16 have received that therapy, 11 were not yet appropriate and 3 patients did not receive targeted therapy. Twenty-nine FDR were contacted and tested through the pilot study of facilitated contact and testing. **Conclusions:** We evaluated uptake of germline testing using a remote, VA system-wide approach to identify and offer genetic testing for veterans with mPC with access and cost issues removed. We completed germline testing at rates higher than those reported in the community with modest personnel requirements, in a diverse population of patients. Documentation of results in the electronic medical record can be improved. Remote genetic testing can augment uptake of testing in large integrated health care systems. Research Sponsor: Veterans Affairs; Prostate Cancer Foundation.

Symptoms reported by patients using an ePRO compared with those reported to nurses via telephone triage.

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Background: It is unclear how symptoms reported by an electronic patient-reported outcomes (ePRO) tool compare to symptoms reported to triage nurses by patient-initiated telephone calls. This work describes symptoms reported using each of these methods, and the percent of patients requiring an acute office visit triggered by these symptom reports. **Methods:** Among patients diagnosed with breast, lung, or colon cancer at three community oncology practices from 2020 to 2023, we examined ePRO symptom reports and compared these with symptoms reported via telephone triage to nurses by patients not using the ePRO tool. **Results:** 3,509 patients reported symptoms by ePROs, and 9,071 patients only reported by phone. Among patients reporting by ePRO, 2,162 submitted both ePROs and used telephone triage services. The most common symptoms that patients reported by ePRO reports (47,284 reports) were weakness / fatigue (72.9% of patients), pain (62.0%), nausea (39.2%), and headache (33.1%). The most common symptoms that patients reported by phone reports (19,344 reports) were pain (32.9%), weakness / fatigue (13.4%), swelling (11.1%), cough (10.3%), and diarrhea (9.4%). The median number of reports in the ePRO group was 6.0 (mean 13.5, IQR: 2.0, 15.0) per patient and the median number of reports in the phone triage group was 1.0 (mean 2.1, IQR: 1.0, 2.0) per patient. The most common high-urgency symptoms in the ePRO group (defined by practice defined symptom threshold) were weakness / fatigue (67.2% of patients), pain (55.7%), headache (40.2%), nausea (32.0%), and difficulty breathing (29.2%), while the most common high-urgency symptoms (as determined by the triage nurse) in the phone triage group were pain (32.4%), weakness / fatigue (11.8%), swelling (11.4%), fever/chills (10.1%), and cough (9.7%). More patients reported high-urgency symptoms by ePRO (n = 1,873, 53.4%) compared to those reported by phone triage (n = 2,448, 27.0%). Of patients in the ePRO group with a severe symptom who visited a site with acute care visits data, 330 patients (45.4%) had an acute care visit within 72 hours of a symptom report compared to 745 patients (47.5%) in the telephone triage group. **Conclusions:** Patients using ePROs reported more symptoms than patients reporting by phone, possibly because electronic reporting allows patients to easily communicate symptoms to care providers and receive prompt attention. Pain and weakness/fatigue were the most common urgent symptoms in both groups. The need for an acute care visit was the same in both groups. Further refinement of the ePRO tool including standardization of symptom thresholds, more uniform implementation in practices, and patient education with respect to optimal use of the ePRO may enable practices to replace telephone triage with ePROs. Research Sponsor: None.

Trend and burden of cancer related hospitalizations in the US: Insights from a National Inpatient Sample Database analysis.

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Background: Cancer-related hospitalizations constitute one of the primary drivers of cancer-related healthcare expenses. Understanding the burden and characteristics of these hospitalizations is essential to appropriately direct resources, improve outcomes, and avoid unnecessary hospitalizations. Our study sought to evaluate the national trends, reasons, disposition status, length of stay, and associated costs for cancer-related hospitalizations. **Methods:** We conducted a retrospective analysis of cancer hospitalizations using the 2008-2019 National Inpatient Sample. Cancer-related hospitalizations were identified using validated Clinical Classification Software (CCS) codes 11 to 45. Trends in hospitalization volume, mortality, length of stay, disposition status, and costs were analyzed overall and by cancer type, adjusted according to the US Consumer Price Index. **Results:** There were 371 million weighted hospitalizations from 2008 to 2019, of which 15.1% (56 million) were cancer related. The most reported cancer types were breast cancer (11.9%), secondary malignancies (11.2%), and prostate cancer (10.3%). The most common reasons for cancer-related hospitalizations were septicemia (4.8%), pneumonia (4.7%), and complications of surgical procedures or medical care (3.1%). Trend analysis showed that the total number of cancer-related hospitalizations increased from 12,963 to 16,500 per 100,000 hospitalizations during the study period (relative increase, 27.3%). Mortality rates decreased from 5.1% to 4.0% (relative decrease, 21.6%), while the length of stay decreased from 3.5 to 3.2 days (relative decrease, 8.6%) during the study period. Disposition to home or short-term facilities decreased (relative decrease, 3.1%), while to long-term facilities increased (relative increase, 20.6%) during the same period. Total hospitalization cost increased from \$55.5 billion in 2008 to \$76.4 billion in 2019 (a relative increase of 37.7%). **Conclusions:** Our analysis shows that while cancer-related hospitalizations and associated costs increased substantially, mortality rates, and length of stay decreased. These trends reflect rising cancer burden but improvements in hospital cancer care quality and efficiency. Ongoing efforts to optimize cancer treatment, minimize unnecessary hospitalizations, reduce length of stay, and facilitate safe discharges are needed to improve patient outcomes and control costs further. Continued surveillance and health policies should address the rising demand for high-value cancer care. Research Sponsor: None.

Trends in key cancer hospitalization metrics, 2008-2019.

Metric	2008	2019	% Change
Hospitalizations per 100,000	12,963	16,500	+27.3%
In-hospital mortality	5.1%	4.0%	-21.6%
Length of stay (days)	3.5	3.2	-8.6%
Total hospitalization cost (billions)	\$55.5	\$76.4	+37.7%

Food for cancer health equity: The impact of a culturally tailored food voucher intervention on food insecurity among Latinx patients with cancer.

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Background: Food insecurity disproportionately impacts immigrant, low-income, and racial and ethnic minorities with cancer. In our prior qualitative work, Latinx and multiethnic patients with food insecurity emphasized the importance of culturally tailored food assistance interventions that could minimize stigma and maintain self-efficacy and autonomy. In collaboration with Latinx patients and community partners in Monterey County, California, we co-developed a culturally tailored food voucher intervention. In this study, we conducted a pilot of the intervention among multiethnic and Latinx patients with cancer and tested the impact on food insecurity and health-related quality of life. **Methods:** We recruited low-income, racial and ethnic minority adults >18 years of age who screened positive for food insecurity using the 2-item Hunger Vital Sign while receiving cancer treatment in a clinic in Monterey County, CA between July 2023 until August 2023. All participants who consented to participate received \$40 monthly grocery store gift cards redeemable at a variety of local retailers for 6 months in addition to usual care provided by trained community health workers who assisted with other health-related social needs. We conducted validated surveys at baseline (time of enrollment) and 6-month follow-up (post-intervention) assessing demographics, food behaviors, food insecurity, and health-related quality of life. We compared pre- and post-intervention proportions with food insecurity using McNemar's tests and change in health-related quality of life using paired t-tests. **Results:** Of the 30 study participants enrolled, 27 (90%) were Latinx; 24 (80%) spoke Spanish as their preferred language; 16 (53%) had advanced (stage 3 or 4) cancer; 12 (40%) were retired or unemployed; 10 (33%) were disabled; 20 (67%) reported a household income <\$35,000 USD. Of the 26 (87%) participants who completed post-intervention surveys, the proportion with food insecurity decreased from 100% to 65% (95% CI 0.60-0.77; $p=0.01$); 100% adhered to recommended treatment; and health-related quality of life scores increased by 8 points from 71.9 \pm 16.1 to 79.5 \pm 10.5 ($p=0.02$) from baseline. **Conclusions:** This culturally tailored food voucher intervention was associated with reductions in food insecurity and improvements in health-related quality of life among low-income Latinx patients with cancer. This intervention may represent an effective approach to overcome food insecurity in Latinx and multiethnic patients with cancer. Research Sponsor: None.

Clinical impact and financial feasibility of remote oncology pharmacists' roles in community oncology practices.

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Background: The clinical and financial impact of oncology-trained pharmacists in the community oncology setting has not been well documented. The US Oncology Network has introduced a novel remote oncology pharmacist model which provides clinical services to oncology community practices to alleviate the burden on oncologists, enhance patient care, and improve workflows. **Methods:** Oncology-trained pharmacists remotely reviewed chemotherapy regimens across 12 community oncology practices. Pharmacists identified opportunities to modify therapy based on clinical criteria, waste reduction, and/or financial stewardship. These modifications were discussed with the treatment team or implemented in accordance with practice-approved policies. Clinical and financial metrics were tracked to assess the overall impact of the pharmacist interventions and provider time saved. **Results:** From January 1, 2023, through December 31, 2023, 27,938 reviews were documented for 19,962 patients. Among these reviews, the majority (14,572, 73%) required modification by the pharmacist, and many (3,005, 21%) were deemed clinically significant by the intervening pharmacist. The most common clinically significant interventions included changes to anticancer drug doses (1155, 38%), modifications to supportive care (742, 25%) and recommendations for additional monitoring (426, 14%). Across 12 practices, 63 drug-related workflow policies were implemented allowing pharmacists to autonomously auto-substitute products, order laboratory tests and adjust chemotherapy doses. These policies saved over 600 hours of physician time. Pharmacist involvement resulted in medication-related margin improvements totaling \$9.3M. Practices also experienced a \$4.3M reduction in the total cost of care in medication expenses. The cost of the pharmacists during this period was \$1.4M, equating to a 560% return on investment compared to margin improvement. **Conclusions:** Community oncology practices operate within a resource-constrained model with limited access to oncology pharmacists. As invaluable members of the care team, pharmacists identified opportunities to significantly enhance clinical care by focusing on medication safety, dosing, and regimen optimization, while demonstrating a tremendous financial impact on small-scale budgets. Oncology-trained pharmacists play a vital role in alleviating care burden of the clinical team by collaboratively developing practice-approved policies and reviewing clinical orders in a high-risk patient population. Research Sponsor: None.

The future is now: Implementation of standard of care, preemptive pharmacogenomic testing in patients with gastrointestinal cancers.

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Background: Preemptive germline pharmacogenomic (PGx) testing provides insight into the safety of high-risk chemotherapy and effective use of supportive care medications in gastrointestinal (GI) cancers. Advances in clinical practice guidelines and clinician support have accelerated the appetite for PGx testing, particularly for drugs with severe adverse reactions. The objective of this study was to assess operational outcomes associated with end-to-end electronic health record (EHR) integration of standard of care, preemptive multigene PGx testing in patients with GI cancers. **Methods:** Patients in two UCHealth GI oncology clinics were tested for five PGx genes related to 5-fluorouracil (5-FU, *DPYD*), irinotecan (*UGT1A1*), and supportive care therapies (*CYP2C19*, *CYP2D6*, *CYP2C9*). The PGx test order was embedded in all GI oncology treatment plans. Patient samples were genotyped, and PGx results were returned as discrete data to the EHR. Automated clinical decision support (CDS) tools provided PGx-guided recommendations at the point of prescribing. We leveraged the EPIS process framework and evaluated operational outcomes such as number of patients tested, lab turnaround time, patients with actionable phenotypes, and number of CDS alerts and clinical actions. **Results:** The analysis included 89 patients who received results for *DPYD/UGT1A1* and 83 patients who received results for supportive care genes. Among samples tested, *DPYD/UGT1A1* and supportive care gene results were returned to the EHR in an average of 4.7 ± 2 days (range 1–8) and 17.3 ± 3 days (range 9–24), respectively. The number of patients with abnormal phenotypes, defined as poor metabolizers for *UGT1A1* and any non-normal phenotypes for the other genes, were *UGT1A1*, $n=10$ (11.2%); *DPYD*, $n=4$ (4.5%); *CYP2C19*, $n=43$ (51.8%); *CYP2D6*, $n=31$ (41.3%; 8 uninterpretable results); and *CYP2C9*, $n=19$ (22.9%). This equated to 14/89 (15.7%) and 68/83 (81.9%) patients having an abnormal result for *DPYD/UGT1A1* and at least one supportive care gene, respectively. CDS alerts fired for 32 drug-gene interactions for 25 distinct patients. Of the alerts, 7 (21.9%) were for 5-FU or irinotecan, which showed for 7/89 patients (7.9%); 25 (78.1%) were for supportive care medications, which showed for 23/83 patients (27.7%). There were 9 clinical actions taken in response to the PGx alerts, 7 (77.8%) for 5-FU or irinotecan and 2 (22.2%) for supportive care drugs. Appropriate clinical actions were taken for 100% of patients with 5-FU or irinotecan drug-gene interactions. **Conclusions:** End-to-end EHR integration of PGx testing and prescribing guidance facilitated clinician adoption of preemptive, standard of care multigene PGx testing, with test results driving important medication changes. Future studies will evaluate the impact of PGx testing on clinical outcomes and cost effectiveness metrics in this population. Research Sponsor: None.

Activating HR+/HER2- and triple-negative breast cancer care teams and their patients in shared decision-making.

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Background: In the rapidly evolving treatment landscape of metastatic breast cancer (MBC), shared decision-making (SDM) is critical to individualize care and improve patient outcomes. To help facilitate improved SDM, we developed an educational toolkit for health care providers (HCPs) to use with HR+/HER2- and triple negative breast cancer (TNBC) patients (pts) and evaluated the implementation of this toolkit at 5 community oncology clinics. **Methods:** In May-June 2022, pts (N=94) and HCPs (N=18) completed surveys assessing attitudes, confidence, goals, and barriers to SDM in MBC care. HCPs then led collaborative learning sessions with their pts using the SDM toolkit to provide education regarding treatment options and side effects, and to better align on shared goals and treatment plans. **Results:** In surveys, only 50% of pts reported that they decide on a treatment plan together with their HCPs, 38% reported being asked about treatment preferences, and 34% reported discussing supportive care, such as mental health care or pain relief. Additionally, very few pts reported high knowledge of BC treatments and side effects. HCPs and pts were misaligned on patient goals and barriers to SDM. For example, 56% of HCPs thought pts were too overwhelmed/anxious/fatigued to make treatment decisions, but only 21% of pts agreed that was a top challenge. While pts and HCPs were aligned on top treatment decision factors of effectiveness and quality-of-life, HCPs underestimated the importance of concerns about side effects (HCPs 11% vs pts 32%), and the cost and duration of treatment (17% vs 30%, and 22% vs 30%, respectively). HCPs correctly identified survival (56%) as a top goal for pts but were less likely to identify progression/recurrence as important to pts (39%). Additionally, 28% of pts reported their top challenge was worrying about being unable to work or meet responsibilities at home; however, only 19% of HCPs recognized this as a top challenge. Following pt-HCPs collaborative education sessions, in which HCPs used the SDM toolkit to facilitate pt education and SDM, HCPs and pts reported improved confidence in pt-HCP communication. Additionally, 46% of pts reported discussing treatment goals with their HCPs and 46% reported taking a more active role in their care following the learning session. **Conclusions:** These findings reveal misalignments between HCPs and patients with BC regarding treatment decision-making. The gaps identified are critical to address as they are pre-requisites for SDM. The downloadable shared decision-making toolkit developed as part of this implementation science initiative can be adopted by breast cancer clinical teams to help facilitate patient education and SDM, empowering patients to be active participants in their care. Research Sponsor: Gilead.

The acceptability of hospital-at-home for persons living with cancer and their caregivers.

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Background: Hospital at Home (HaH) is part of a comprehensive patient-centered model that delivers multidisciplinary acute medical care in the home. While HaH has mainly been tested in general medical patients, uncertainties persist regarding the feasibility and acceptability of this model within oncology populations. This study assessed patient and caregiver characteristics associated with acceptability of a hypothetical HaH program in persons hospitalized with cancer and described patient medical needs. **Methods:** A cross-sectional survey assessing acceptability of a hypothetical HaH program, home characteristics, and demographics was completed by 250 patients and 33 caregivers. Eligible patients were English-speaking adults (18+ years) admitted to the medicine service at a cancer hospital. Acceptability was measured on a 5-point Likert scale and defined as responses of “strongly agree” or “agree” to the statement, “I would consent to the use of my home for my hospital care” if such a program were available. Surveys were conducted in person or via telephone during the index hospitalization. Unpaid adult caregivers were surveyed in person and acceptability of the hypothetical HaH program was similarly assessed. Characteristics of the hospitalization were assessed via the electronic health record. Continuous variables were compared between acceptability groups using Wilcoxon rank sum test; categorical variables were compared using Fisher’s exact test and Pearson’s chi-squared test. **Results:** Median patient age was 63, 134 (54%) were female, 38 (16%) identified as Black and 21 (8.8%) as Hispanic, and 171 (72%) completed some college education or more. 208 patients (83%) rated participation in HaH as acceptable, as did 28 (85%) caregivers. Patients living with metastatic disease were more likely to accept HaH ($p < 0.05$). Acceptability differed by race ($p < .05$) and was lowest among Black patients (74%) and those who preferred not to provide their race (70%). Of those who rated HaH acceptable, 137 (66%) had advanced imaging or a surgical procedure after the first day of admission and 21 (10%) had an absolute contraindication to being hospitalized at home such as a home member using illicit drugs at home (15, 7%). **Conclusions:** Over 80% of persons hospitalized with cancer and their caregivers would agree to HaH. Those with advanced disease were more likely to agree to home hospitalization compared to curative-intent patients, but Black patients were less likely to agree to be hospitalized at home compared to white patients. Many patients had hospitalization characteristics (e.g., imaging) that may be challenging to coordinate from home, but few patients had safety-related contraindications to HaH. These findings will inform future efforts to evaluate and target HaH programs in oncology to patients most likely to agree to and benefit from them, and address barriers to uptake in certain racially minoritized populations. Research Sponsor: None.

Feasibility and satisfaction level of caregivers with telemedicine in childhood cancer: A mixed-methods study.

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Background: Telemedicine has emerged as a crucial solution to addressing health care disparities, especially in countries like India where healthcare disparities are pronounced and specialist care is concentrated in urban areas. **Methods:** We conducted a mixed-methods study among caregivers of children with cancer who had utilised telemedicine in the past 6 months. Telephonic quantitative interviews collected information on diagnosis, current treatment status, residence and socio-economic parameters. A logistic regression model was created to assess patient and caregiver related factors associated with satisfaction with telemedicine. In-depths interviews were conducted in a sub-set of participants followed by thematic analysis. **Results:** Caregiver of 465 patients [median (range) age: 8 (0.1-18) years; 70.04% male; 82.54% with haematological malignancy] participated in this study. Patients had a median (range) of 2 (1-30) telemedicine in the past year, with parents being the most common care giver being involved [n=326 (70.10%)]. Telemedicine was reported to be more convenient than in-person visits and helpful in saving time and money by 90.54% (n=421) patients and 88.6% (n=421) patients reported easier follow up and access to care using telemedicine. Difficulty in explaining issues over telephones or emails was the reason for dissatisfaction for 47.53% (n=221) patients, additionally 22.37% (n=104) patients felt they received inadequate attention during telemedicine. Majority of the patients (85.38%, n=397) planned to continue teleconsultation and 88.39% (n=411) would recommend teleconsultation to others. Socioeconomic status of upper and upper-middle class upper and upper-middle socioeconomic status [OR (95%CI): 2.14 (1.38-3.32), p: <0.001; aOR (95%CI): 2.11 (1.35 - 3.31), p: 0.001] was significantly associated with caregiver satisfaction with telemedicine. Qualitative interview showed themes of monetary and time savings with telemedicine, ease of consultations for minor complaints, delay in responsiveness of doctors, language barriers and difficulty in using telemedicine platforms due to low literacy levels. **Conclusions:** Telemedicine has emerged as a valuable tool for paediatric cancer care offering convenience and accessibility. While most caregivers expressed satisfaction, challenges remain in communication and limited access among caregiver of lower socioeconomic strata. Further studies should aim at developing more patient friendly telemedicine platforms. Research Sponsor: None.

The impact of admitting ward on resource utilization and outcomes among hospitalized cancer survivors.

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Background: With improvements in the early detection and treatment of cancer, there is a growing population of cancer survivors; with a corresponding increase in acute care use among cancer survivors. However, models of inpatient care delivery for cancer survivors differ between hospitals and regions, which may impact resource use and outcomes. Understanding how different models influence outcomes may help define optimal models for inpatient care delivery for this population. **Methods:** We created a multicenter cohort of all cancer patients admitted to medical wards across 26 hospitals in Ontario, Canada from 2015 to 2022, and deterministically linked population-level administrative data including ambulatory oncology data, with each hospital's patient-level electronic information (pharmacy, orders, notes, laboratory/imaging and results). Multivariable regression models compared characteristics and outcomes between patients admitted on oncology wards vs non-oncology wards adjusting for age, sex and comorbidity scores. **Results:** In total, there were 370,118 hospitalizations from 191,990 unique patients. Among these hospitalizations, 38,075 episodes (10.3%) were on an oncology ward. The median time from cancer diagnosis to hospitalization was 4 years. The most common disease sites were genitourinary (21%), gastrointestinal (20%), breast (12%), and lung (10%). The most discharge diagnoses from oncology wards were inpatient chemotherapy (9%), febrile neutropenia (7%), non-Hodgkin's lymphoma (4%), acute myeloid leukemia (4%), myeloma (3%); while for non-oncology wards were heart failure (5%), palliative care (4%), UTI (2%), pneumonia (2%), acute renal failure (2%). In general, cancer patients admitted on oncology wards were younger (64 vs 76), had shorter length of stay (LOS; 9.6 vs 10.1 days), less in-hospital mortality (7.5% vs 11.4%), greater 30-day re-admission rates (29% vs 14%) and were also more likely to undergo CTs (28% vs 21%), MRIs (11% vs 9%) and interventional procedures (8% vs 6%) (all comparisons, $p < 0.001$). Subgroup analysis focusing on the top 5 discharge diagnoses from non-oncology wards, showed that despite higher in-hospital mortality rates (aOR 1.27 95% CI [1.15-1.40] $p < 0.001$), admission to a non-oncology ward for those diagnoses was associated with a shorter LOS (aOR 0.96 [0.92-1.00] $p = 0.03$), reduced 30-day re-admission rates (aOR 0.77 [0.69-0.87] $p < 0.001$), and reduced use of CTs (aOR 0.74 [0.68-0.82] $p < 0.001$), MRIs (aOR 0.80 [0.68-0.95] $p = 0.01$), and interventional procedures (aOR 0.84 [0.69-1.01] $p = 0.07$). **Conclusions:** There are differences in both resource use and outcomes for cancer survivors hospitalized on oncology versus non-oncology wards, including for patients with the same discharge diagnosis. To optimize inpatient cancer care delivery for hospitalized cancer survivors, further exploration is needed. Research Sponsor: Conquer Cancer, the ASCO Foundation; Hold'Em For Life; Canadian Institute of Health Research; University of Toronto; Canadian Cancer Society Research Institute; Hold'Em For Life; St Michael's Hospital; University of Toronto; St Michael's Hospital.

Clinical utility and accessibility of functional precision medicine for relapsed/refractory pediatric and adult cancers.

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Background: Pediatric and adult patients with rare, relapsed, or refractory cancers often have few treatment options. Precision medicine approaches are often the first strategy used to identify salvage therapy options when standard treatments fail. Despite the significant clinical benefit to advanced cancer patients, multiple genomics precision medicine trials have revealed important constraints for patients that lack treatments matched to mutations or biomarkers and have highlighted challenges in drug accessibility associated with novel targeted therapies identified through genomics precision medicine. Current clinical findings from large-scale studies demonstrate ~10% of cancer patients receive clinical benefit from genomics-guided therapies - in part due to limited insight into the complex relationship between tumor molecular characteristics and patient response. **Methods:** We implemented a functional precision medicine (FPM) approach combining genomic tumor profiling with high-throughput drug sensitivity testing (DST) of FDA-approved agents on patient-derived tumor cells to identify treatment options when standard-of-care is exhausted. Clinical utility and benefit of this program was investigated via a clinical trial (NCT03860376) at Nicklaus Children's Hospital in Miami, FL. **Results:** We were returned DST data on 21 of 24 patients DST (median = 102 agents per sample) and genomic profiling on 20 of 24 patients. DST turnaround time was significantly below the 14 days required for clinical use (median = 10 days, $p = 0.0012$). FPM recommendations were returned to 19 (76%) patients, of which 14 patients underwent therapeutic intervention. Six patients received FPM-guided treatments, and five (83%) patients experienced a >1.3-fold improved progression-free survival over their previous therapy, significantly above the rate from physician's choice ($p = 0.0104$). We subsequently opened pan-cancer FPM clinical studies for adults ($n = 36$ patients) and children ($n = 65$ patients). A key objective in these trials is optimizing our DST protocol for tissue samples of various sizes. Here, we report preliminary efforts to optimize our DST approach for tissue samples from resections, core biopsies, and fine-needle biopsies from primary and metastatic lesions. **Conclusions:** The findings from our feasibility study illustrate the potential for FPM to positively impact clinical care for pediatric/adolescent patients with relapsed/refractory cancers, and have supported initiation of currently enrolling clinical studies. An NIMHD-funded expansion cohort now enrolling at Nicklaus Children's Hospital (NCT05857969, $n = 65$ patients), and a rare/relapsed/refractory adult patient cohort at Cleveland Clinic Florida (NCT06024603, $n = 36$ patients). These studies aim to further investigate the impact on clinical outcomes through the use of FPM to recommend treatment options. Clinical trial information: NCT06024603, NCT05857969, NCT04956198, NCT03860376. Research Sponsor: None.

Using machine learning for targeted advance care planning (ACP) conversations in patients with cancer: A quality improvement initiative.

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Background: Despite improvements, patients with advanced cancer often do not receive goal-concordant care at the end of life (EOL). Challenges with prognostication contribute to delays ACP conversations and result in more aggressive care, gaps in symptom management, and hospice underuse. Early identification of patients at high risk for mortality provides an avenue to implement targeted ACP conversations. **Methods:** We used a validated machine learning model that integrates demographics, lab values, vital signs, and medications to predict in-hospital, 30-day, and 6-month mortality risk for patients with a solid malignancy admitted from the emergency department (ED) to a dedicated solid malignancy oncology unit at Duke University Hospital. This unit includes one oncology and one palliative care attending physician, advance practice providers, and nurse coordinators. Providers received an email when a patient was identified as high risk for mortality. A pre-post study design compared ACP documentation and other EOL healthcare utilization before and after the notification intervention. The pre-intervention cohort included patients hospitalized from 1/7/2019 to 10/25/2019 and the post-intervention cohort from 9/19/2020 to 8/31/2021. We excluded patients admitted to the intensive care unit in the first 24 hours. We used chi-square or Fisher's exact tests for categorical variables and Kruskal-Wallis tests for continuous variables; we stratified comparisons of categorical variables by physician division using Cochran-Mantel-Haenszel tests. **Results:** The pre-intervention cohort comprised 105 hospitalizations and 88 unique patients. Mean (SD) age was 64.9 (11.4); 60.0% (n=63) were White, 3.8% (4) Hispanic/Latino, and 65.7% (69) married. The post-intervention cohort comprised 84 hospitalizations and 77 patients. Mean (SD) age was 66.0 (12.2); 52.4% (44) were White, 2.4% (2) Hispanic/Latino, and 60.7% (51) married. Considering index hospitalizations, an ACP note was written for 2.3% (2) of hospitalizations pre-intervention vs. 80.5% (62) post-intervention ($p < 0.0001$). This relationship held even if the physician was in palliative care (4.1% [2] vs. 84.6% [33]) or oncology (0% [0] vs. 76.3% [29]) ($p < 0.0001$). Inpatient length of stay (LOS), hospice referral, code status change, ICU admission rate or LOS, 30-day readmissions, 30-day ED visits, and inpatient and 30-day deaths did not differ significantly between groups. **Conclusions:** Identification of hospitalized cancer patients with high mortality risk via machine learning led to a substantial increase in documented ACP conversations but did not impact EOL healthcare utilization. Further integration of the model in clinical practice is ongoing. Our intervention showed promise in changing clinician behavior, and additional work is needed to evaluate downstream impacts. Research Sponsor: None.

TriHealth Cancer Institute's collaboration with the Tempus AI TIME program impact on clinical trial operations and enrollment.

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Background: TriHealth Cancer Institute has the largest personalized medicine program serving Cincinnati. TriHealth's EMR integration with Tempus AI TIME allows for patient screening using an AI powered software TApp that matches to a broad clinical trial portfolio. Each patient is followed using LINK portal and trials can be activated rapidly via TIME's operational model. The goal of this collaboration is to increase TriHealth's patients' access for clinical trials. **Methods:** The TApp is software utilizing subject data, trial eligibility criteria, and NLP models for AI matching to TIME studies. Unique TApp searches occur whenever there is new patient data or changes to eligibility criteria. All TApp matches are reviewed by Tempus AI nurses followed by confirmatory screening by TriHealth's staff. Trials were activated using the TIME program's standardized operational methods including a pre-negotiated rate card, trials agreement, and a central IRB. Data included number of patients screened, unique TApp searches, trial activations, consents, operational metrics, and financial impact. **Results:** From January 2022 – March 2023, TApp performed 8,653,397 unique searches for 135 TIME trials on TriHealth's population of 18,823 patients. During this period, 985 trial eligibility criteria were modified and 200,776 patient clinical updates occurred. There were 2,032 potential matches (1,944 interventional, 88 observational) for 45 different trials. Tempus AI nurses spent 389 hours reviewing all 1,944 interventional matches and of these sent 284 to TriHealth for evaluation. For TIME studies, 28 patients consented (18 interventional, 10 observational) and 7 trials were activated (4 interventional, 3 observational). Total trial billable revenue for TIME studies was approximately \$241,500 (\$34,500 average per trial). Regarding non-TIME trials, 3 patients consented on 3 interventional studies. Activation time for non-TIME trials compared to TIME trials was 186 days versus 37 days. **Conclusions:** TriHealth's partnership with TIME evaluated 18,800+ patients for 135 trials. Over 8.6M unique TApp searches resulted in 2,000+ patients screened by nurses. Operationally, TIME trials resulted in a 2.3X increase in the number of trial activations, an 80% reduction in days to activation, and 9.3 fold increase in enrollment compared to non-TIME studies. The use of AI enabled patient screening, combined with a structured trial activation process, improved patient enrollment at a community health system. Research Sponsor: None.

Quarter	TApp Searches	Tempus RN Review	Passed RN Review	Consents	Trial Activations
Q1 2022	427,381	74	27	0	0
Q2 2022	521,772	144	75	2	4
Q3 2022	1,416,863	200	78	10	1
Q4 2022	2,637,428	249	57	10	1
Q1 2023	3,649,953	1,277	47	6	1
Total	8,653,397	1,944	284	28	7

A machine learning algorithm based on multi-omics biomarkers for the detection of tumor microsatellite instability.

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Background: Microsatellite instability (MSI) occurs via defects in mismatch repair (MMR) and is characterized by high tumor mutational burden (TMB) and a robust inflammatory response. Accurate MSI-high classification of immune-evasive tumors is vital due to the effectiveness of immune checkpoint inhibitor (ICI) therapy, such as pembrolizumab, which is FDA approved for all MSI-high tumors irrespective of anatomic origin. Detection methods of MSI-status vary widely, including immunohistochemistry (IHC), polymerase chain reaction (PCR), and next-generation sequencing (NGS). We developed a machine learning (ML) model to predict MSI status in patients with solid tumors using comprehensive genomic and immune profiling (CGIP), independent of direct sequencing data from microsatellite sites. **Methods:** We analyzed samples from 1,838 patients with colorectal cancer (CRC) by CGIP, which included DNA panel testing (523 genes) for pathogenic single nucleotide variants (pSNV) and determination of TMB (mut/Mb), and RNA sequencing (397 genes) for gene expression (GEX). The Boruta algorithm was used to select key genomic and GEX changes associated with MSI status. A distributed gradient boosting algorithm created a predictive model that was trained on 70% of the cohort. The model was tested on the remaining CRC cohort (Test), and in the PanCancer Atlas CRCs (TCGA), endometrial adenocarcinomas (EMCA), and CRC with indeterminate MSI testing by CGIP. Performance of the trained model was assessed using sensitivity, specificity, and positive (PPV) and negative (NPV) predictive value. **Results:** Feature selection identified 79 genes with pSNVs, 63 GEX changes, and TMB as informative for MSI prediction. The model showed high predictive accuracy in differentiating MSI-H tumors. Of the 39 cases that failed MSI component of CGIP (Indeterminate), 17 had MMR IHC results available, of which 1 demonstrated loss of MLH1/PMS2 and the other 16 showed intact (normal) expression. Testing of this cohort identified 3 cases as MSI-high, at least one of which was confirmed by IHC. No cases with intact MMR protein IHC were identified as MSI-high by the algorithm. **Conclusions:** Our ML-driven approach accurately assessed MSI status of CRC and EMCA using CGIP data. This approach also identified potential cases with MSI-high status where direct sequencing of microsatellites failed. This study highlights a method to identify patients with potential MSI-high status for orthogonal screening with the MSI component of a test fails. Research Sponsor: None.

Cohort	Sample Size	Median Age (y)	% Female	% MSI-High by CGIP	Sensitivity	Specificity	PPV	NPV
Training	1286	65	44%	6.5%	n/a	n/a	n/a	n/a
Test	552	64.9	46%	7.6%	95.2	99.6	95.2	99.6
TCGA	367	68	47%	13.3%	98.1	92	92	98.1
EMCA	394	68.25	100%	15.9%	95.8	93.7	80.8	98.8
Indeterminate	39	65	60%	n/a	n/a	n/a	n/a	n/a

Multimodal fully automated predictive model for therapeutic efficacy of first-line cancer immunotherapy based on clinical information and imaging modalities including brain MRI and chest CT images in advanced non-small cell lung cancer.

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Background: The integration of imaging and clinical data through artificial intelligence (AI) holds promise for more accurately predicting the therapeutic efficacy of immune checkpoint inhibitors (ICI) \pm platinum-based chemotherapy in individual patients with advanced non-small cell lung cancer (NSCLC). However, tumor segmentation still relies entirely on radiologist evaluation and has not yet achieved fully automated tumor evaluation for image analysis. Furthermore, while central nervous system (CNS) metastasis is a critical prognostic factor in patients with advanced NSCLC, radiomics has primarily focused on chest imaging, with few studies incorporating brain MRI analysis. **Methods:** This study included patients with advanced NSCLC treated with ICI \pm platinum-based chemotherapy as first-line therapy from March 2017 to August 2023. We developed an ensemble model combining a logistic regression model that analyzes clinical information with a deep learning model that extracts image features. Each sub-model was independent, allowing for individual adjustments and the ability to be attached or detached. Both models were trained to predict response, 12-month progression-free survival (PFS), and 12-month overall survival (OS) using cross-entropy loss. The dataset was randomly divided into training, validation, and test sets in a 5:3:2 ratio. This random assignment was repeated four times, and the average area under the curve (AUC) was calculated. The test sets were further classified into high- and low-risk groups based on the predicted results, and log-rank tests were performed on their survival curves. **Results:** The study included 232 patients, with 89 (38%) receiving ICI alone and 143 (62%) receiving ICI + platinum-based chemotherapy. In the entire population, the overall response rate (ORR) for ICI \pm platinum-based chemotherapy was 49.5%, with a median PFS of 7.1 months (95% confidence interval [CI]: 5.8-9.1) and a median OS of 24.5 months (95% CI: 21.2-30.3). The model achieved an AUC of 0.70 (95% CI: 0.65-0.76) for predicting response, 0.65 (95% CI: 0.59-0.71) for 12-month PFS, and 0.69 (95% CI: 0.48-0.90) for 12-month OS. Test sets were classified into high-risk (N = 55) and low-risk (N = 60) groups. The median PFS was 6.8 months in the high-risk group and 14.7 months in the low-risk group ($p < 0.05$). The median OS was 21.5 months in the high-risk group and 34.3 months in the low-risk group ($p < 0.05$). **Conclusions:** We have demonstrated that a multimodal, fully automated ensemble model has significant predictive accuracy for the efficacy and survival outcomes of ICI \pm platinum-based chemotherapy in patients with advanced NSCLC. Research Sponsor: None.

Deep learning vs traditional breast cancer risk assessment models: Are we offering supplemental services to those who benefit the most?

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Background: Mammography-based deep learning (DL) risk stratification models improve discriminatory accuracy in predicting future breast cancer compared to traditional risk models; however, decisions for and insurance payment of supplemental services such as MRI are driven by traditional scores. The purpose of this study was to compare risk scores and cancer detection rates in patients identified as increased risk by DL vs traditional models in a large screening mammography cohort. **Methods:** This multisite study included consecutive patients ≥ 40 y undergoing routine bilateral screening mammography from 9/2017 to 1/2022 at five facilities. Tyrer-Cuzick version 8 (TC) and National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT) 5-year and lifetime models and a DL 5-year model were used to assess risk. The following thresholds were used to define intermediate risk: $\geq 1.67\%$ for TC and BCRAT 5-year, 2.2 for DL model and high risk: $\geq 20\%$ for TC and BCRAT lifetime, ≥ 6.0 for DL model. Patients were included if all risk scores were available. Patient demographics were retrieved from electronic medical records and cancer outcomes through regional tumor registry linkage. The proportion of increased-risk patients and cancer detection rates (CDR [cancers per 1000 women screened]) across models were compared using Pearson's Chi-square test. **Results:** 148476 exams in 69464 patients (mean age 58.0y [IQR: 50.0-67.0]) were performed. 81.7% (119386/146075) of exams were in White patients and 18.3% (26689/146075) in races other than White. CDR of those classified as intermediate risk by DL was 7.1 (450/63109) vs 4.7 (320/68545; $P < 0.001$) by TC and 4.2 (300/70831; $P < 0.001$) by BCRAT, and as high risk was 20.6 (305/14772) by DL vs 3.9 (64/16442; $P < 0.001$) by TC and 5.0 (29/5782; $P < 0.001$) by BCRAT. 13.0% (19248/148476) were classified as intermediate risk by DL but not by TC or BCRAT, with a CDR of 6.0 in this cohort. 32.0% (47435/148476) were classified as intermediate risk by TC or BCRAT but not by DL with a CDR of 1.1. 8.5% (12577/148476) were classified as high risk by DL but not by TC or BCRAT with a CDR of 20.8. 11.1% (16451/148476) were classified as high risk by TC or BCRAT but not by DL with a CDR of 1.9. **Conclusions:** A significant proportion of patients identified as increased risk by DL model are not assessed as increased risk by commonly used risk models, effectively excluding them from accessing potentially life-saving supplemental services. DL scores met the American College of Radiology's acceptable CDR on screening mammography (≥ 2.5) regardless of traditional scores, however, elevated traditional scores in the absence of elevated DL scores did not meet acceptable standards. Risk assessment guidelines incorporating DL models are necessary to capture patients who benefit the most. Research Sponsor: Radiological Society of North America.

Impact of artificial intelligence (AI) decision support on clinical trial participation: A before-after implementation study on a nationwide molecular tumor board.

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Background: Molecular Tumor Boards (MTB) have become the standard for deriving consensus therapy (Rx) recommendations (rec) for patients (pts) with advanced cancer undergoing comprehensive genomic profiling (CGP). However, finding matched Rx and trial options remains laborious, needing informatics strategies. **Methods:** We examined the outcomes before and after implementation of a decision support system (DSS) at the MTB of the Australian Molecular Screening & Therapeutics program (MoST, ACTRN12616000908437), enrolling pts with refractory solid tumors and linking CGP results to Rx and trials through rec on clinical reports. The DSS comprises a variant interpretation pipeline, a symbolic AI system integrating the TOPOGRAPH database and an annotated trials registry, and a web platform used by the MTB for producing reports shortlisting matching Rx and therapeutic trials. The primary endpoint is the cumulative participation rate (CPR) in genomic matched trials (excluding MoST-related trials) in pts who received Rx after CGP. The secondary endpoints are the CPR in any trial, and overall survival (OS) from MTB. The Fine-Gray model was used to estimate the subdistribution hazard ratios (sHR) for between-group differences in participation. Kaplan-Meier and Cox regression were used for OS analysis. The time-to-event analyses were adjusted for age, ECOG, cancer type, lines of prior rx, and lead-time bias (OS only). **Results:** In 2203 of 5186 pts (42.5%) received ≥ 1 Rx after CGP, 971 pts were reviewed at MTB before and 1272 after DSS implementation in Sep 2020. At 3, 6 and 12 months (m) after enrolment, CPR in matched trials were 3.2%, 5.0%, and 6.8% before implementation and 3.6%, 5.8%, and 8.9% afterwards (sHR 1.19, 95% CI 0.90–1.57, $p=0.23$). Pts who received an MTB rec were more likely to participate in a matched trial (sHR 4.75, 3.13–7.23, $p<0.001$). Notably, DSS specifically increased the likelihood of trial participation following MTB rec (interaction sHR 2.69, 1.02–7.07, $p=0.045$), with 12m CPR increasing from 10.0% to 12.2% after implementation of the DSS in pts with a MTB rec, whilst for pts without a MTB rec, the CPR fell from 3.1% to 1.6% after implementation. No association was seen between participation in any trials and MTB recs (sHR 1.12, 0.95–1.32) or implementation (sHR 0.95, 0.81–1.11; CPR pre 21.6% v post 23.7% at 12m). No OS difference was seen comparing before with after implementation of the DSS (median 16.7 v 15.3m, adjusted HR 0.97, 0.87–1.08). However, pts receiving genomic matched Rx had a longer OS (median 20.1 v 15.0m unmatched, HR 0.76, $p=0.002$). **Conclusions:** The observed interaction between the implementation of DSS and MTB rec suggests there is effect modification in participation rates of pts in genomic matched trials, warranting exploration into how AI might enhance trial participation among pts with incurable cancers undergoing CGP. Research Sponsor: None.

Efficient site selection for clinical trials using simulated annealing.

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Background: Identifying sites with eligible patients for multi-site oncology clinical trials is challenging given increasingly complex inclusion/exclusion criteria, limited site resources, and the need to ensure diversity in trials. This is a complex systems problem with many factors that present nonlinear behaviors. Given manifold combinations of sites, research capabilities, and study characteristics, artificial intelligence solutions may help research sites and sponsors optimize site selection to achieve enrollment, speed, and diversity of goals. We report on one of the first deployments of a multi-AI model solution to optimize site selection for an ongoing clinical trial. **Methods:** The clinical trials were translated into a standardized digital form expressed as rules fully encompassing the inclusion and exclusion criteria. A patient cohort was created from the criteria using the ConcertAI oncology research database, including site affiliations. The sites had numerical features specific to the protocol indication, such as physician count and projected patient count. Each site was scored by its features with the Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) to create higher alignment to the best matched sites. Feature weights allowed TOPSIS to emphasize desirable attributes in an interpretable way. A simulated annealing algorithm, adept with nonlinear objectives, explored site combinations, yielding a high-scoring, constraint satisfying solution. Independent simulations measured convergence and provided a distribution of solutions. Shapley analysis clarified site contributions to score and constraints. The implementation was compiled and parallelized. **Results:** Utilizing a Multiple Myeloma clinical trial protocol with 7 criteria, we formed a cohort of 15,881 patients across 1,246 US clinical trial sites. Each site had 12 features. The weights optimized patient diversity while enrolling at least 10 patients per month across all sites to achieve the targeted study accrual timeline. The result was a set of 3 sites enrolling 12 patients per month with 51% diversity, in agreement with the optimal solution obtained through detailed, multi-week, manual analysis. As constraints increased, and exact verification became impractical, convergence was gauged by decreasing variance in independent solutions. **Conclusions:** Our study introduced a robust, efficient, and interpretable approach to clinical trial site selection. It addressed the challenges posed by increasingly complicated protocols, requirements for study participant diversity, and heterogeneous site features. The multi-AI model scalability underscored its practical utility in streamlining the site selection process for clinical research networks, academic centers, industry sponsored trials, cooperative group studies, and investigator-initiated studies. Research Sponsor: ConcertAI.

Performance of an artificial intelligence/machine learning model designed to identify hospitalized patients with cancer who could benefit from timely specialized palliative care delivery.

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Background: Timely access to specialty Palliative Care (SPC) services provides significant benefits to hospitalized patients with cancer, including improvements in quality of life. However, many patients with cancer who could benefit from SPC suffer from lack of timely referral or do not receive SPC services. A previously published trial of an artificial intelligence/machine learning (AI/ML) model to predict need for SPC at Mayo Clinic increased timely SPC consultation of hospitalized patients overall. We sought to review the performance of this algorithm in patients with cancer across an expanded hospitalized population. **Methods:** The study population consisted of all patients admitted into a Mayo Clinic hospital in Minnesota, Wisconsin, Arizona and Florida between January 2020 and September 2023. Due to the size of the cohort a case-control sample of three controls for every case was created. Patients were considered to be a patient with cancer if they had at least one billing diagnosis up to 1 year prior to their index hospitalization from any of the 5 HCC categories denoting cancer: Metastatic Cancer and Acute Leukemia (HCC 8); Lung and Other Severe Cancers (HCC 9); Lymphoma and Other Cancers (HCC 10); Colorectal, Bladder, and Other Cancers (HCC 11); and Breast, Prostate, and Other Cancers and Tumors (HCC 12). The training data set consisted of 107,076 patient encounters with a total of 8,355,090 time periods of constant risk. An AI/ML model using gradient boosting methods which contained 269 variables (both static and time-varying) of various classes with SPC consultation treated as a time-to-event outcome was trained. **Results:** Due to the longitudinal nature of the prediction, performance was assessed using the max score AUC (using the max score a patient received during a given encounter prior to an event or discharge) to produce the AUC. The model had an overall AUC of 0.932 (0.929, 0.935 – 95% CI). We saw a decrease in performance of the AI/ML model in the Oncology population with an overall performance of 0.818 (0.806, 0.83). Some of the most influential variables were previous SPC visit, age, metastatic disease, acute leukemia diagnosis, and pain scores. **Conclusions:** An AI/ML model can effectively predict the need for an inpatient PC consult in a population of hospitalized patients with cancer. Research Sponsor: None.

Performance for All Hospitalized Patients by Site (AUC 95% CI)		Performance for Hospitalized "Oncology" Patients by Site (AUC 95% CI)	
Overall	0.932 (0.929, 0.935)	Overall	0.818 (0.806, 0.830)
ARZ	0.925 (0.915, 0.935)	ARZ	0.829 (0.801, 0.857)
FLA	0.899 (0.887, 0.911)	FLA	0.835 (0.806, 0.863)
MCHS	0.950 (0.946, 0.954)	MCHS	0.817 (0.794, 0.839)
RST	0.919 (0.913, 0.926)	RST	0.816 (0.795, 0.834)

Using an artificial intelligence platform to enhance cancer detection rates in primary care.

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Background: Patients with cancer who are diagnosed in a primary care setting have the best survival outcomes compared to any other route (e.g. Emergency department, routine referrals, incidental findings etc). This is primarily attributed to detection of cancer at an early stage. In the UK, the Cancer Detection Rate (CDR) metric serves as a measure of this, representing the percentage of cancer diagnoses originating from primary care referral routes. However, detecting cancer presents significant challenges, primarily due to the non-specific nature of cancer presentations, their tendency to overlap with symptoms of other conditions, and their relatively low prevalence. Artificial intelligence (AI) platforms may be able to support this endeavor but are yet to be established. C the Signs is an AI-enabled clinical decision support tool integrated into primary care practices to help clinicians stratify the risk of cancer and advise on which cancer pathway is most appropriate (if at all) for the patient's presentation and history.

Methods: An observational cohort study was undertaken between 1st May 2021 and 31st March 2022 where 35 practices (covering a population of almost 420,000) within the same geographic region in the East of England were offered the use of C the Signs, with the practices opting out as controls. All practices had the same access to referral and cancer diagnostic pathways within the region. The primary end point was to identify if C the Signs had a statistical impact on cancer detection rates in primary care through nationally linked data via Public Health England.

Results: In practices utilizing C the Signs the CDR significantly increased from 58.7% in 2020-21 (prior to the implementation of C the Signs) to 66.0% in 2021-22, reflecting a significant increase of 12.3% ($p < 0.05$). In contrast, practices not using C the Signs maintained a stable CDR of 58.4% in both years. There was no statistically significant variance observed in the referral rate between the two groups, indicating no notable increase in diagnostic or referral activities. **Conclusions:** These findings underscore the importance of integrating cutting-edge technologies into primary care to improve cancer detection rates and facilitate early-stage diagnosis. Implementation of such advancements holds promise for reducing cancer-related mortality rates and enhancing overall patient outcomes. Research Sponsor: None.

Large language models to evaluate racial discrepancies in performance status assignment.

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Background: Oncologic treatment eligibility relies heavily on “Performance Status” (PS), a subjective gauge of a patient’s overall health. Despite frameworks aimed at quantifying PS, these assessments remain prone to potential bias. A systematic evaluation of discrepancies in language between ECOG PS and race has yet to be conducted. Large language models (LLMs) have the ability to synthesize text and may enable an assessment of the relationship between race, note text, and physician-documented PS. We hypothesize that LLMs can quantify these relationships to understand potential inconsistencies in ECOG PS. **Methods:** In our single-institution cohort study, we examined patients from medical or radiation oncology clinics between January 2012 to December 2023 with documented ECOG PS. PS was extracted from clinical notes and redacted from downstream analyses. Notes were categorized by patient-reported race (Asian, Black, White, Other). 1,500 matched subjective assessments (from oncologist clinical notes) and PS were randomly sampled for each race, except for Black patients, where only 640 entries were available. We divided training and test sets using an 80-20 ratio across each race. Using the training cohort, we trained race-specific models to assign ECOG PS based on subjective assessment, using two LLMs: UCSFBERT (BERT pretrained on UCSF data) and RoBERTa. In the hold-out test sets, we applied each model across all races to assign ECOG PS based on subjective assessments. These were evaluated by micro-F1 (model accuracy) and Multiway ANOVA to compute model-specific p-values. **Results:** 13.6% of patients had a documented ECOG 2+, with variation across races (Asian: 16.1%, Black: 17.7%, White: 7.7%, Other: 15.3%). Models tended to assign Black patients with ECOG 0-1 with worse performance status (ECOG 2+). Other than RoBERTa models trained on Asian and White cohorts, all models trained on a specific race showed disparate classification results when applied to other races (out-of-domain), highlighting potential biases in LLM models trained where a specific race predominates (Table; ANOVA). **Conclusions:** This study demonstrates a novel way to use LLM to assess discordance within physician documentation and performance status assignment. It underscores the need for incorporating diverse demographic data when using LLM in medical contexts. This research has potential to dissect how bias may be propagated within physician practice and provide insight into known disparities in clinical trial enrollment and standard of care implementation. Research Sponsor: UCSF; Conquer Cancer, the ASCO Foundation.

Micro F1 scores.						
		Test Race	Asian	White	Black	Other
Model	Train Race					ANOVA p-Value
UCSFBERT	Asian		0.427	0.465	0.360	0.405
	Black		0.376	0.368	0.258	0.377
	White		0.419	0.500	0.380	0.390
	Other		0.406	0.469	0.388	0.383
RoBERTa	Asian		0.443	0.461	0.414	0.402
	Black		0.429	0.487	0.375	0.458
	White		0.413	0.483	0.398	0.424
	Other		0.436	0.505	0.392	0.433

Clinical and sociodemographic factors associated with digital health literacy in patients with non-Hodgkin lymphoma or colorectal carcinoma.

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Background: Digital health literacy (DHL), the capacity to find and understand health information using electronic media, is an emerging social determinant of health. Because DHL may impact patients' ability to benefit from digital health tools and technology-based models of care, it is important to understand how DHL varies in people with cancer. **Methods:** Patients (N=105) who received systemic treatment for non-Hodgkin lymphoma (NHL) or colorectal carcinoma (CRC) in the past year were recruited from 3 cancer clinics. Participants self-reported DHL (on the electronic Health Literacy Scale, eHEALS), general health literacy (3-item Health Literacy Screening questionnaire), sociodemographic characteristics, and clinical trial enrollment. Independent-samples t-tests (two-tailed; α level of 0.05) and correlations were used to test binary associations between sociodemographic and clinical factors with DHL. Linear regression models were used to test whether associations between clinical factors and DHL remained when adjusting for covariates (based on potential relationships with DHL, $p < 0.25$). **Results:** Of the 105 participants, 50 (48%) had NHL and 55 (52%) had CRC. Participants were primarily middle-aged to older adults (median age 63, IQR 53–69.5), male (54%), and white/Caucasian (62%), with a college-level education or higher (54%). The mean eHEALS score was 26.9 (SD=8.24, range: 8–40). Higher DHL was related to higher education level ($r_s = 0.29$, $p = 0.004$) and better general health literacy ($r = 0.25$, $p = 0.009$). Older participants tended to have lower DHL, though this pattern was not statistically significant ($r = -0.12$, $p = 0.21$). DHL did not vary significantly by gender, race/ethnicity, or household income in this sample (all p s > 0.46). Patients with NHL (mean=24.6, SD=8.10) reported lower DHL than patients with CRC (mean=28.9, SD=7.91; $t(103) = 2.72$, $p = 0.008$); this pattern was similar when controlling for age, education, and general health literacy (unstandardized $b = 3.07$, SE=1.65, $p = 0.07$). Interestingly, the small subset of patients who reported participating in a clinical trial (N=10) reported lower DHL than patients who had not ($t(100) = 3.08$, $p = 0.003$). In the adjusted model, patients reporting trial enrollment still showed lower DHL above and beyond the effects of age, education, general health literacy, and disease type ($b = -10.45$, SE=3.20, $p = 0.002$). **Conclusions:** In this convenience sample, DHL varied by cancer type, general health literacy, and education level, suggesting interventions to increase DHL may be well-suited for those with NHL and/or lower education level. Further, these factors may affect technology-based care, an important consideration in eHealth intervention development. This study also indicated a possible link between clinical trial enrollment and lower DHL that should be explored in future studies with larger samples. Research Sponsor: None.

Adaptively learning visual model of surgical resection images via coarse-to-fine-grained strategy for pathological invasiveness prediction in indeterminate stage IA lung adenocarcinoma.

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Background: Indeterminate nodules with high risk of malignancy are suggested to receive video-assisted thoracoscopy biopsy. Frozen section assists surgeons to decide surgical strategies for stage IA lung adenocarcinoma (LUAD) intraoperatively, which is time-consuming and may misdiagnosis due to limited sampling and poor tissue quality. **Methods:** We prospectively enrolled stage IA LUAD patients underwent complete resection between June 2020 and September 2023 in Guangdong Provincial People's Hospital (GDPH), Affiliated Hospital of Guangdong Medical University, Meizhou People's Hospital. All the resected lung nodules were finally diagnosed as pre-invasive lesion (PIL), minimally invasive adenocarcinoma (MIA) or invasive lung adenocarcinoma (IAC) by FFPE pathological diagnosis. Images of the whole section of the lung nodules were taken by smartphones under natural lighting condition in operating theaters without shadowless surgical lights. Patients received preoperative anti-cancer therapy and with low-quality tumor section images were excluded. Images of nodules section, FS reports, FFPE diagnosis and clinical information were prospectively collected. Predictive artificial intelligence (AI) model was developed by a three-step process, which first predict the IAC and non-IAC region at coarse level, and identify fine level features through the high-risk region. The coarse and fine labels were then coordinated through risk ranking loss to reach a final predictive result. **Results:** We prospectively enrolled 1516 patients with 1638 indetermined lung nodules from preoperative chest CT following the inclusion and exclusion criteria, with 2438 images acquired from intraoperative nodule sections. The included patients have median age of 57 years old and 38.6% male patients. The pathological diagnosis for included lung nodules are 122 PIL nodules, 502 MIA nodules and 1014 stage IA LUAD. A multi-task artificial intelligence based on Coarse-to-Fine-Grained Strategy has been established to classify the indetermined lung nodules during the surgery. For binary classification, AI model reach an AUC of 0.86 in differentiation between IAC or non-IAC. For 3-classification level, AI model reach an AUC of 0.87 in differentiation between PIL, MIA or IAC. We further defined the IAC nodules into G1, G2 and G3 according to IASLC lung adenocarcinoma grading system. For 5-classification level, AI model reach an AUC of 0.86 in differentiation between PIL, MIA, IAC-G1, IAC-G2 and IAC-G3. **Conclusions:** Our AI models based on images of intraoperative surgical resection could effectively classify indetermined lung nodules, which can assist thoracic surgeons diagnose the nodules rapidly during the surging and decide the following surgical strategies. Clinical trial information: ChiCTR2300075999. Research Sponsor: None.

Integrating 4 Methods (In4M) to evaluate physical function in patients with cancer: Results of a comprehensive digital health study.

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Background: Physical function (PF) is a core outcome in cancer trials that can inform treatment tolerability. PF can be assessed across modalities including by patient (pt) report, clinician (clin) report, performance tests and digital sensors. The optimal approach for PF measurement has not been defined. **Methods:** In4M is a prospective observational study evaluating PF in pts initiating chemotherapy for breast cancer or lymphoma followed over 9 months. We used an electronic platform (Hugo) to aggregate serially assessed pt-reported PF, clin- and pt-reported ECOG performance status (PS), 6-minute walk test (6MWT) and wearable (Fitbit) data. We evaluated feasibility in all pts; associations among PF measures and the ability of PF measures to detect change were evaluated in pts with both baseline (BL) and 3-month (3M) data. We used Pearson correlations to assess the relationship of average daily steps with measures of PF. To assess change, we compared each PF measure from BL to 3M using a 2-sided $\alpha=.05$ paired t-test. **Results:** Of the 208 pts enrolled, 193 (93%) and 159 (76%) completed surveys, and 121 (58%) and 124 (60%) provided wearable data (evaluable: ≥ 1 day data) at BL and 3M, respectively. When requiring a stringent BL with 4+ days of data with ≥ 1 weekend day to be evaluable, 88 (42%) and 120 (58%) provided wearable data at BL and 3M. At both BL and 3M, pt-reported PF was generally more highly correlated with wearable-derived daily steps than clin-reported PF and 6MWT were (Table). Significant declines in PF were observed for pt- and clin-reported PF (all $p<0.05$), but not other modalities. **Conclusions:** Longitudinal assessment of multi-modal PF data including pragmatic wearable data collection was feasible in pts receiving chemotherapy. Pt-reported PF was the only modality that was both correlated with step count and able to detect change. Additional wearable metrics, correlations among PF measurements and outcomes, and clinically meaningful change scores will be reported. Optimal PF measurement may improve future reporting of treatment tolerability. Clinical trial information: NCT05214144. Research Sponsor: FD005938 Yale University-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI).

Modality	Measure	Scale Range	N	BL Mean (SD)	BL Corr (P) w/Steps	3M Mean (SD)	3M Corr (P) w/Steps	Change Mean (SD, P)
Pt-report	PROMIS Short Form v2.0 PF 8c	T-score (mean 0, SD 50), higher better	149	53 (9)	0.17 (0.09)	46 (8)	0.34 (<0.001)	-7.1 (8.5, <0.001)
Pt-report	EORTC QLQ-F17 PF Scale	0-100, higher better	148	91 (14)	0.19 (0.05)	76 (20)	0.48 (<0.001)	-15 (16, <0.001)
Pt-report	Pt-reported ECOG PS	0-4, higher worse	148	0.57 (0.74)	-0.07 (0.49)	1.24 (0.83)	-0.40 (<0.001)	0.68 (0.83, <0.001)
Clin-report	Clin-reported ECOG PS	0-5, higher worse	145	0.12 (0.32)	0.00 (0.97)	0.28 (0.50)	-0.06 (0.50)	0.17 (0.51, <0.001)
Performance test	6-minute Walk Test	Distance in meters, higher better	113	1461 (243)	0.18 (0.08)	1445 (217)	0.20 (0.06)	-16 (148, 0.25)
Sensor	Fitbit	Average daily steps, higher better	103	6570 (3441)	-	6013 (3081)	-	-557 (2976, 0.06)

Artificial intelligence (AI) content detection in ASCO scientific abstracts from 2021 to 2023.

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Background: Generative AI models such as OpenAI's ChatGPT have been broadly utilized throughout the medical literature. Previous studies have found that AI can generate scientific abstracts which can be difficult to distinguish from the work of human authors. There is a pressing need to characterize utilization of AI in scientific writing to guide policy. **Methods:** In collaboration with ASCO's Center for Research and Analytics, we extracted text from all scientific abstracts submitted to ASCO 2021 – 2023 Annual Meetings. Likelihood of AI content was evaluated by four AI detectors: GPTZero, Originality.ai (OGAI), Sapling, and Kashyap's AI Content Detector (AICD). Each detector produces a numeric likelihood of AI content. Predictions were dichotomized for uniform analysis across detectors: those in the top 5% for a given detector were considered as having high likelihood of AI content. Logistic regression was used to compute odds ratio (OR) for AI-generated content with respect to submission year and abstract characteristics. Predictions were also assessed for 10 human-written abstracts as negative controls, and 10 produced by OpenAI's GPT-3 and GPT-4 models as positive controls. **Results:** 15,553 abstracts met inclusion criteria. 5,179 (33%) were published online only, and 5,327 (34%) referenced registered clinical trials. Across all detectors, abstracts submitted in 2023 were significantly more likely to contain AI content than those in 2021 (OR range 1.3 – 1.7). In abstracts from 2023, AI content score was associated with online only publication, lack of clinical trial number, and abstract track (Table). None of the 10 negative control human written abstracts were identified as AI generated, whereas 100%, 95%, 90%, and 30% of the GPT-3/4 generated abstracts were classified as AI generated by Sapling, GPTZero, OGAI, and AICD respectively using the 5% threshold. Additional results will be presented. **Conclusions:** AI content detectors uniformly suggest a higher likelihood of AI content generation for abstracts submitted in 2023. Predicted AI content is associated with triage of abstracts to online only presentation, suggesting predicted AI content is associated with lower perceived abstract quality. Further work is needed to understand the accuracy of AI detectors and utility in the abstract review process. Research Sponsor: National Cancer Institute; K08CA283261.

Variable	Sapling OR (95% CI)	AICD OR (95% CI)	GPTZero OR (95% CI)	OGAI OR (95% CI)
Track (Ref – Cancer Specific Track)				
Care Delivery, Quality, and Health Services	2.3 (1.7, 2.9)**	1.2 (0.8, 1.6)	1.4 (1.0, 1.9)*	0.9 (0.6, 1.2)
Medical Education and Professional Development	3.8 (1.7, 7.6)**	1.3 (0.4, 3.3)	1.9 (0.7, 4.5)	0.3 (0, 1.2)
Prevention, Risk Reduction, and Genetics	1.9 (1.1, 3.1)*	2.2 (1.3, 3.4)*	2.9 (1.8, 4.4)**	1.6 (1.0, 2.6)
Clinical Trial ID Present	0.3 (0.2, 0.4)**	0.5 (0.4, 0.7)**	0.1 (<0.1, 0.2)**	0.4 (0.3, 0.5)**
Online Only	1.6 (1.3, 2.0)**	2.1 (1.7, 2.7)**	3.0 (2.3, 3.8)**	3.9 (3.1, 5.0)**

*p < .05.

**p < .001.

Effect of a learning-based approach using the echo-signals obtained by a single-unit transducer on detection of breast tumors.

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Background: Breast cancer mortalities in the less developed countries are predicted to increase over the next decades mainly due to the low utilization rates of breast cancer screening programs. Additionally, studies have shown that the sensitivity and accuracy of breast self-examination in women are suboptimal. Therefore, it is important to develop a novel and affordable technology that can accurately detect small breast tumors in women. We have developed a deep learning-based echo-signal processing system that can detect breast tumors with high sensitivity and accuracy by merely obtaining ego-motion estimated echo-signals generated by a single-unit piezoelectric transducer system. **Methods:** We have prospectively collected echo-signals using a single-unit piezoelectric transducer system in 200 patients with breast tumors who underwent curative surgery at the Seoul National University Hospital and SMG-SNU Boramae Medical Center between Oct 2022 and Feb 2024. The data from the first 131 cases was used for the training and testing of the deep learning model with the ratio of 8:2, and the subsequent data from 69 cases was used for the external validation. We used ImageNet pre-trained ResNet50 model to train the deep learning model and adopted various data augmentation methods for model robustness. Five nested cross-validation was used to ensure the generalization performance. **Results:** The median age of the enrolled patients was 55 (IOR, 47-63) and 65 patients (32.5%) had non-palpable breast tumors. Nearly half of the patients (n=93, 46.5%) had tumors smaller than 2.0 cm in the largest dimension. Our deep learning algorithm showed outstanding performance with the area under the curve (AUC) of 0.914 ± 0.022 and 0.964 ± 0.011 for the image- and region-level, respectively, in the training and testing set (n=131). In the external validation set (n=69), the model demonstrated an AUC of 0.846 ± 0.012 and 0.932 ± 0.009 for the image- and region-level, respectively. As shown (Table), the accuracy, sensitivity, and specificity were substantially improved for the region-level analysis when compared with those of the image-level analysis. **Conclusions:** Using a prospectively collected data from 200 patients, we developed a highly accurate and robust deep learning model to detect breast tumors in women by processing echo-signals obtained by a single-unit piezoelectric transducer system. Our data indicate that deep learning approach based on low-volume echo signal can lead to a novel and affordable breast tumor screening strategy that can improve early breast cancer detection. Research Sponsor: L'imagin Inc.

Overall performance of the deep learning model.

	Training and Test Set		External Validation Set	
	Image-level	Region-level	Image-level	Region-level
Accuracy	82.9 %	89.7 %	76.4 %	86.7 %
Sensitivity	84.7 %	90.8 %	80.1 %	89.3 %
Specificity	81.1 %	88.5 %	73.1 %	84.1 %

Association of symptom severity, anxiety, and health literacy with portal usage among patients with cancer.

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Background: Patient portals within electronic health records (EHR) have become increasingly essential in promoting patient-centered oncology care. They offer opportunities for completing symptom surveys that can aid in symptom management, facilitate patient-clinician communication, and enable health monitoring. As part of the Northwestern University Improving the Management of Symptoms During and Following Cancer Treatment (NU IMPACT) study, we examined the relationship between symptom severity, anxiety, health literacy, and shared decision-making with usage of three common features in the patient portal (portal). **Methods:** This study included adults diagnosed with cancer in the NU IMPACT study. Participants completed baseline surveys on socio-demographics, health literacy (Single Item Literacy Screener), anxiety (Patient-Reported Outcomes Measurement Information System; PROMIS), with high anxiety scored as ≥ 60 vs < 60 , shared decision-making (CollaboRATE), and symptom severity (Patient-Reported Outcome version of the Common Terminology Criteria for Adverse Events; PRO-CTCAE). Portal activities one year following enrollment were extracted from EHRs. Portal usage patterns of patient-initiated messages, portal lab and clinical note views were counted as number of days the activity was used over the year and categorized as tertiles. Multivariable ordinal logistic regression models were used to examine associations between survey measures and ordered tertiles of patient portal activities. **Results:** Participants (N=3,464) were mostly female (66%), White (85%), with a mean (SD) age of 61(13) years old. The frequency ranges of patient-initiated messages over a year were 0-163 days, labs viewed were 0-350 days, and clinical notes viewed were 0-103 days. Participants with at least one severe or very severe symptom on the PRO-CTCAE were more likely to be in higher tertiles of patient-initiated portal messages (OR: 1.37, 95% CI: 1.17-1.61), lab views (OR: 1.48, 95% CI: 1.26-1.74), and clinical note views (OR: 1.19, 95% CI: 1.01-1.40). Participants with higher levels of anxiety were more likely to be in higher tertiles of patient-initiated portal messages (OR: 1.54, 95% CI: 1.28-1.85), lab views (OR: 1.22, 95% CI: 1.01-1.46), and clinical note views (OR: 1.42, 95% CI: 1.18-1.71). Participants with higher health literacy were more likely to be in higher tertiles of patient-initiated portal messages (OR: 1.38, 95% CI: 1.09-1.74) and lab views (OR: 1.34, 95% CI: 1.06-1.69), but not note views (OR: 1.03, 95% CI: 0.82-1.30). Shared decision making was not associated with portal usage. **Conclusions:** Patients with greater symptom severity and anxiety may turn to the portal for symptom management. Certain features within the portal may demand a higher level of health literacy for engagement. Understanding the factors that promote and impede portal usage can help optimize cancer care delivery. Research Sponsor: National Cancer Institute.

Continuous remote monitoring of performance status in patients with NSCLC through fitness tracker–derived life-log data.

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Background: Traditional methods for assessing the performance status of cancer patients often rely on clinical evaluations and patient-reported histories. This study utilizes life-log data derived from fitness trackers (FTs) in patients with non-small cell lung cancer (NSCLC) to offer a comprehensive and dynamic perspective on performance status throughout their treatment. **Methods:** Patients with NSCLC scheduled for a minimum of 12 weeks of treatment were enrolled. Custom software facilitated the remote collection of life-log data from participants' FTs (Fitbit Inspire 3), encompassing step count, calories burned, heart rate, sleep patterns, etc. Quality of life surveys assessing patient-reported outcomes (PROs) were completed during regular visits (every 3 weeks) and unscheduled visits (USV), in addition to collecting clinical data such as laboratory parameters and body composition metrics. An end-of-monitoring survey assessed participants' familiarity with this monitoring approach. The study aimed to correlate FT data with clinical parameters and identify patterns predictive of treatment related USVs. **Results:** Of the 98 enrolled patients, 69 patients (70.4%) completed the 12-week follow-up. The cohort predominantly consisted of older adults (≥ 65 years) (55.1%) and patients in palliative care (75.5%), with most undergoing cytotoxic chemotherapy (66.3%) and some receiving oral agents (20%). FT-based remote monitoring revealed that older patients had a comparable 12-week completion rate to younger patients. (69.2% vs. 76.2%, $P=0.604$). Analysis of life-log data from three days before a visit (D-3) to the visit day (D0) showed significant reductions in average step counts ($P=0.022$) and walking distance ($P=0.021$) for USVs compared to regular visits, while resting heart rate (HR) showed a significant increase for USVs ($P=0.049$). PRO-based PROMIS physical function scores and EQ-5D-3L scores showed a significant correlation with both D-3 to D0 acquired resting HR ($P<0.001$, $P=0.002$) and average step counts ($P=0.011$, $P=0.013$), respectively. End of monitoring survey was done from 72 participants indicating high satisfaction and familiarity with the FT-based remote monitoring system, median score of 90 out of 100. **Conclusions:** FT-derived life-log data effectively captured dynamic performance status in NSCLC patients, correlating with clinical outcomes and PRO. These findings support further research into FT data's predictive value for clinical interventions, underscoring its potential in personalized remote patient management. Research Sponsor: None.

AI-enabled digital test to predict disease recurrence for patients with early-stage invasive breast cancer and performance in a MammaPrint low-risk cohort from the Netherlands with a median 6-year follow-up.

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Background: Traditional invasive breast cancer (IBC) grading, although useful, remains limited due to diagnostic subjectivity and absence of phenotypic diversity including the recently observed importance of tumor epithelial – stromal interactions and lymphocyte content-distribution. We developed and validated a clinical grade digital test (PreciseDx Breast, PDxBr) which combines image-derived Artificial Intelligent (AI)-grading features and clinical data (i.e. age, stage, tumor size, LN status) to predict recurrence in early-stage IBC and sought to understand performance in a MammaPrint cohort with outcome data. **Methods:** A MammaPrint cohort with median 6-year follow-up was identified at the Laboratory of Pathology, Dordrecht, the Netherlands (NTH). H&E stained images (digitized at Philips, Eindhoven, NTH) with clinical data (from the pathology and Dutch cancer registries) including demographics, pathology results, MammaPrint risk classification, treatment type and recurrence events were obtained. Performance of the PDxBr validated model (AI-grade + clinical) on the MammaPrint cohort was evaluated using the AUC/concordance index, along with NPV, PPV, Hazards ratio (HR), sensitivity, and specificity. **Results:** 250 patients, median age 57 years, majority stage 1-IIIa, 100% HR+ve, Her2-ve, 84% LN-ve, 67% grade 2 and 66% MammaPrint low risk. There were 15 events (6%: 7 deaths, 3 second primaries, 4 metastases and 1 local regional). PDxBR model classified 134 patients as high risk and 116 as low with 10 of 15 (67%) events identified as high risk. The NPV for PDxBr was 96% with a HR 1.63, Se 70%, Sp 46% vs. MammaPrint with an NPV of 94%, HR of 0.96, Se 40%, Sp 66%; identifying only 5 of the 15 events (33%) as high risk while missing 10. Of note, the AI- grade/imaging model (without clinical features) yielded an NPV of 95% with a HR of 1.46, Se 70%, Sp 42% and correctly identified 10 of 15 events. **Conclusions:** The results from this observational study suggest that triaging patients with the PDxBr test could potentially be adjunctive to the management decision process of patients with early-stage IBC including the use and subsequent interpretation of genomic tests such as MammaPrint. Additional studies are underway to confirm these initial findings. Research Sponsor: None.

Digital health program for patients with cancer to support self-management: A retrospective real-world analysis.

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Background: Sidekick Health's 13-week digital health program was built to support cancer self-management. It was available free of charge to US-based cancer patients through commercial health insurance. The program includes disease education, mindfulness, medication adherence support, and asynchronous messaging with a care manager. We hypothesized that highly engaged users had reduced symptom frequency and severity, and improved quality of life (QoL) outcomes. **Methods:** In-app data were analyzed for registrations Aug 2021-Jan 2024: n(registered)=1286; n(retained ≥ 7 days)=795; n(QoL/symptoms)=284. QoL was defined as self-reported sleep quality, energy and stress (10-point scale, ≤ 4 x/week). Symptoms were also self-reported (10-point scale, ≤ 7 x/week). Generalized linear mixed models for repeated measures were used to investigate QoL, symptom frequency and severity changes over the program. Subgroup analysis: weekly iterative k-means clustering into highly- and less-engaged (based on total active days) to mitigate survival bias. **Results:** Diverse patients from 37 states engaged: mean age 58.0 years (SD=10.5), 71% female; 49% diagnosed < 6 months ago, 36% ≥ 12 months ago; 23% early-stage disease, 26% stable disease, 6% in remission and 2% terminal; 60% received chemotherapy, 24% radiation therapy, and 21% immunotherapy. Most (61%) registered users were active after 7 days and 29% after 90 days. Less-engaged users reported higher mean baseline weight (85.3kg (SD=26.7)) vs highly engaged (76.9kg (SD=18.3); $p=0.010$) but were otherwise similar (age, gender, height, time since diagnosis and treatment: $p>0.05$). For QoL, highly engaged users had improved energy ($p=0.013$) and sleep ($p=0.002$), but not stress ($p=0.164$) vs less engaged. A significant time-group interaction for sleep ($p<0.001$) showed highly engaged users had better sleep, and larger improvements over time vs less-engaged. Overall, users reported fewer symptoms over the program (IRR (95% CI)=0.965 (0.953, 0.978), $p<0.001$). Symptom frequency decreased significantly for stress ($p=0.034$) and nausea ($p=0.003$), but not numbness ($p=0.320$) or fatigue ($p=0.530$). Highly engaged users' symptom severity had a downward trajectory, compared with less-engaged, for fatigue ($p=0.044$) and nausea ($p=0.001$), but not stress ($p=0.234$) or numbness ($p=0.680$). **Conclusions:** The program was accessed by a broad patient group and retention was high. Highly engaged users reported improved QoL (energy, sleep) and reduced symptom severity (fatigue, nausea). Total symptom frequency was reduced over the program, as well as for stress and nausea specifically. These findings indicate digital self-management is not only achievable for patients with cancer, but that higher engagement may improve patient-reported outcomes. Research Sponsor: Sidekick Health.

Outcomes of very young women and adolescent (VYWAA) with breast cancer (BC) in rural and urban Saskatchewan: A population-based cohort study.

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Background: BC is uncommon in VYWAA (≤ 35 years) and accounts for about 1.8% of all BC. As BC screening is typically recommended for women aged 50–74 years there is a risk of delayed diagnosis of BC in VYWAA especially those with rural residence. The current study aims to assess outcomes of a cohort of VYWAA with BC in relation to their place of residence in the province of Saskatchewan over a period of 20 years. **Methods:** In this population-based retrospective cohort study all women ≤ 35 years with histologically documented epithelial BC during 2000–2019 were evaluated. Survival of the entire cohort and its subgroups was estimated using the Kaplan–Meier method, and the survival distribution of different groups was compared by the log rank test. A multivariate Cox proportional hazard model was performed. Various clinical and demographic variables were examined for their prognostic importance of overall survival (OS) for all stages and disease-free survival (DFS) for early-stage BC. **Results:** 248 eligible women with a median age of 32 years were identified, 24% were <30 years of age. Of all patients, 51% had node positive disease, 7% had DCIS, 15% stage I, 42% stage II, 22% stage III and 11% had stage IV disease at initial presentation. Among them 42% had hormone receptor +, 28% had HER2 + and 23% had triple negative BC (TNBC). 16% developed BC within 1-year of pregnancy. 53% were rural resident and 47% were urban resident. Significant differences were noted between the two groups regarding smoking history (42 vs. 25%), HER2+BC (35% vs. 20%) and mean platelet count (285 vs. 258). Median follow up for all women was 91 months with a total follow up period of 294 months. Median DFS of VYWAA with stage I to III disease has not reached. 10-year estimated DFS of all women was 66%. 10-year DFS for stage I and II was 73% and 75%, respectively, vs. 43% for stage III ($p<0.001$). Median OS of entire cohort with stage 0–IV BC has not reached. 10-year OS of all VYWAA was 69%. 10 years OS of urban women was 79% compared to 65% for rural resident ($p=0.041$). 10-year OS of women age >30 years was 74% compared to 62% for age 26–30 years and 55% for age <26 ($p=0.35$). 10 years OS of VYWAA with non-TNBC was 73% compared to 63% for with TNBC ($p=0.028$). On multivariate analysis for women with early-stage disease, stage III BC, HR, 3.0 (1.80–4.92) and grade III BC were significantly correlated with inferior DFS. On a multivariate analysis for OS of all VYWAA with stage 0 to IV disease, rural residence, HR, 1.75 (1.08–2.81); TNBC, HR, 2.25 (1.34–3.80), and stage IV disease, HR, 8.1 (4.72–13.94) were correlated with inferior OS. **Conclusions:** Very young women and adolescent with BC have a high incidence of node-positive disease and HER2+ and TNBC subtypes. TNBC and grade III disease were associated with inferior DFS in stage I–III disease whereas stage IV BC, TNBC and rural residence were correlated with inferior survival in women with stage 0–IV disease. Research Sponsor: The Mach-Gaensslen Foundation of Canada.

Real world study of racial disparities associated with toxicities of sacituzumab govitecan.

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Background: Sacituzumab govitecan (SG) is approved in the treatment of metastatic hormone receptor positive and triple negative breast cancer (BC). The efficacy of SG across racial subgroups is known but no real-world data compares the racial differences in toxicities. We aim to expand knowledge about racial disparities regarding SG toxicities and any ineffective treatment or drug failure. **Methods:** We utilized TriNetX, a multi-health care organization electronic health record database, to identify African American (AA) and Caucasian (C) cohort for outcome comparison. Inclusion criteria required a C50 ICD-10-CM diagnosis code and at least one SG treatment. Age, gender, and race-controlled Cox proportional-hazard (CPH) model was used to analyze the time until the first pause or cessation of SG (defined as first deviation from the approved 21-day SG cycle). Several measures of deviation were noted 0, ± 1 and ± 3 days. Association between race and toxicity outcomes (controlled for age and gender) for anemia, neutropenia, thrombocytopenia, nausea and inpatient encounters were evaluated using multiple logistic regression (MLR). The odds (OR) and hazard (HR) ratios with corrected p-values are reported as an effect size and significance estimation. **Results:** 823 patients met the inclusion criteria (545 C, 116 AA & 162 unknown). The mean age (in years) at the initiation of 1st SG treatment was 58.22 ± 12.7 for C and 58.19 ± 12.18 for AA. AA had a 1.26 times higher hazard of SG treatment pause/cessation as compared to C. Blacks experienced an 88% increase in the odds of having a delay longer than 7-days between 2 doses of 1st cycle SG. Males were found to have an 80% increase in the pause/cessation rate as compared to females. The median number of SG treatments was 6 (3 cycles) for both AA and C. SG was noted as 4th chemo line (median) among all races. When compared to C, AA had decreased odds for neutropenia, increased odds for anemia and increased odds for hospitalization. Hazard Ratio and corrected p-values for outcomes comparing the AA and C cohorts. **Conclusions:** Survival analysis indicates that AA and male patients have an increased SG treatment pause/cessation rate. While the result is sensitive to specific conditions used to calculate the deviation, an increased odds of delay in treatment is also found using logistic regression modeling. Additionally, AA experience increased odds for anemia and late-stage hospitalization. These findings highlight the impact of race on BC outcomes, treatment toxicities and the need for further research to enhance treatment outcomes in diverse populations. Research Sponsor: None.

Model and Time Window	Treatment Cessation	Anemia	Neutropenia	Hospitalization
CPH:	Race - 1.26 (0.025)	-	-	-
Strict (± 0 Days)	Gender - 0.55 (0.044)	-	-	-
MLR: Last and Missed SG	-	1.14 (0.592)	0.51 (0.025)	1.14 (0.592)
MLR: Within 10 days of 1st SG	1.88 (0.003)	2.25 (0.032)	0.64 (0.139)	1.23 (0.453)
MLR: SG Cycle 10 & 11	-	2.03 (0.315)	0.22 (0.046)	2.58 (0.035)

National and state models for relationships between social vulnerability and mammography rates.

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Background: Health disparities arise from the confluence of medical and non-medical factors that affect measures of prevention, treatment, and outcomes. One crucial preventative measure is mammography rate. Neighborhood-level analysis using tools such as the CDC's Social Vulnerability Index (SVI) may identify correlates of disparity in mammography access and utilization. Such investigation may reveal drivers of disparity in communities with lower screening. **Methods:** Self-reported mammography rates among women aged 50-74 were obtained from the CDC's 2018 PLACES dataset at the Census Tract level and merged with the CDC's 2018 SVI release. Data were available for 72,075 Census Tracts across all states and Washington, D.C. National univariate and multivariate regressions were performed between mammography rates and percentiles for SVI percentiles. State-specific multivariate regressions were performed for each state's Census Tracts. **Results:** In the national analysis, significant correlations with non-negligible effect size (correlation coefficient > 0.20 or < -0.20) were found between mammography rate and the following: Theme 2 - Household Composition & Disability ($R = -0.22$, $p < 0.0001$), Mobile Homes ($R = -0.36$, $p < 0.0001$), Civilians with a Disability ($R = -0.24$, $p < 0.0001$), and Minority Status ($R = 0.25$, $p < 0.0001$). The national multivariate model achieved Multiple R of 0.54 and Significance $F < 0.001$. The variables with the most negative associations (lower mammography rates with increased vulnerability) were Income (coefficient = -4.05 , $p < 0.001$) and Speaks English Less than Well (coefficient = -2.33 , $p < 0.001$). Across the state multivariate models, mean Multiple R was 0.70 (95% CI 0.67-0.73), with Significance $F < 0.05$ in all states (Table). The variables with the most negative mean coefficients across models were Income (-3.20) and No High School Diploma (-2.98); the most positive was Minority status (6.11). **Conclusions:** Neighborhood-level social determinants correlate meaningfully with mammography rates. Although lower income, limited English proficiency, and lower educational attainment are most strongly associated with lower mammography, the effect sizes vary across geographies, and additional factors have meaningful influence in certain states. The stronger performance of most state-specific models than the national model reinforces this finding. It demonstrates the need for further analysis at the level of state and within narrower geographies. Ultimately, targeted interventions should address those disparities that are most relevant to specific neighborhoods. Research Sponsor: Wayne State University School of Medicine.

Performance of state multivariate regressions of svi correlation with mammography rates.

# Of Regression Models (n)	51
Mean multiple R (95% CI)	0.70 (0.67 to 0.73)
# of states with strong correlation ($R > 0.6$) (%)	44 (86%)
Mean adjusted R^2 (95% CI)	0.48 (0.44 to 0.52)
States with significance of $F < 0.05$	51 (100%)

Inequities in timely treatment (Tx) initiation for patients (pts) with acute myeloid leukemia (AML) treated in a predominantly community setting in the United States (US).

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Background: AML is a highly morbid but treatable cancer with several novel Tx available. This study evaluates associations between race/ethnicity and socioeconomic status (SES) on timely Tx initiation in pts with newly diagnosed (ND) AML in a routine clinical setting. **Methods:** This retrospective cohort study uses the Flatiron Health electronic health record-derived, US nationwide, de-identified database. Pts aged ≥ 18 years, with AML diagnosis (Dx) Jan 2014–Dec 2022, had ≥ 2 visits recorded ≤ 3 months after Dx, and who received first line (1L) active Tx were included. 1L Tx was categorized as intensive chemotherapy (IC) or non-IC. Timely Tx was defined as initiation ≤ 14 days after Dx. Race/ethnicity was defined as White or People of Color (POC; including Black, Latinx, Asian, or Other). Logistic regression assessed associations between race/ethnicity and Yost Index-based SES on timely Tx initiation (adjusted for age at Dx, sex, practice type, hydroxyurea as part of 1L Tx [proxy of disease burden], European LeukemiaNet 2017 risk, and secondary AML), with adjusted odds ratios (aOR) reported. **Results:** Overall, 5981 pts with ND AML were included; 58% received non-IC and 42% received IC. Median ages were 76 and 60 years; 80% and 66% were treated in community settings; and median time from Dx to 1L initiation was 11 and 4 days. In the IC cohort, POC vs White pts had similar delays in Tx initiation (13.3% vs 13.8%, aOR 1.22, $p=.2$); significantly fewer POC vs White pts underwent stem cell transplant (SCT) post-remission (30.8% vs 47.7%, aOR 0.44, $p<.001$). In the non-IC cohort, numerically more POC had delayed Tx initiation vs White pts (40.6% vs 36.2%, aOR 1.19, $p=.074$). This disparity was larger in pts of low SES (POC vs White pts: 42.5% vs 34.4%, aOR 1.35, $p=.077$) vs high SES (38.7% vs 35.6%, aOR 1.16, $p=.4$) (Table). **Conclusions:** In a predominantly US community setting, numerical but non-significant race/ethnic disparities in timely 1L Tx initiation were observed for pts with ND AML. Fewer POC vs White pts receiving IC underwent SCT post-remission. Analyses are ongoing to assess mediators and impact on survival. Research Sponsor: None.

	IC, n	IC, aOR (95% CI) On Delayed [†] Tx Initiation	P-Value	Non-IC, n	Non-IC, aOR (95% CI) On Delayed [†] Tx Initiation	P- Value	IC Achieved Remission, n	IC, aOR (95% CI) Undergo SCT Post- Remission	P- Value
POC vs White	472 vs 1438	1.22 (0.88, 1.67)	.2	579 vs 2071	1.19 (0.98, 1.45)	.074	364 vs 1109	0.44 (0.33, 0.57)	<.001*
Low vs high SES	764 vs 1026	0.93 (0.68, 1.25)	.6	972 vs 1468	1.05 (0.88, 1.25)	.6	591 vs 801	0.45 (0.36, 0.57)	<.001*
Low SES:	199 vs 354	1.30 (0.74, 2.26)	.4	221 vs 532	1.35 (0.97, 1.89)	.077	155 vs 277	0.35 (0.21, 0.56)	<.001*
POC vs White									
High SES:	146 vs 651	1.06 (0.58, 1.83)	.8	177 vs 948	1.16 (0.82, 1.63)	.4	117 vs 506	0.65 (0.42, 1.02)	.064
POC vs White									

*Statistically significant ($p<.05$).

[†]Delayed defined as Tx initiation >14 days after Dx.

CI, confidence interval.

Dissecting racial/ethnic disparities in non-small cell lung cancer staging at diagnosis: Intra-ethnic and geographic differences.

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Background: Lung cancer outcomes significantly rely on accurate and early detection. This population-based study aims to identify factors contributing to disparities in the stage of non-small cell lung cancer (NSCLC) diagnoses, focusing on Hispanic ethnic subgroups. **Methods:** Incident cases diagnosed from 2005–2018 were extracted from the Florida State Cancer Registry. Stage was categorized as resectable (Stage I–IIIA) or nonresectable (Stage IIIB/IIIC/IV) NSCLC. Multivariable logistic regression models were used to assess the association between race/ethnicity and stage at diagnosis, adjusted for socioeconomic, smoking status, and clinical factors. Regional stratification involved separate analyses for heavily Hispanic South Florida and the rest of Florida. **Results:** Among 157,034 NSCLC patients, with a racial distribution of 81.0% White, 8.3% Black, and 9.2% Hispanic, 43.2% were diagnosed at a resectable stage. Age-adjusted models showed Black patients had 22% higher odds (odds ratio [OR]=1.22; 95% CI: 1.21–1.23) and Hispanic patients had 11% higher odds (OR=1.11; 95% CI: 1.10–1.12) of non-resectable stage across all subgroups diagnoses compared to White patients. However, after further adjustment, higher odds were significant only for NHB (OR_{adj}=1.12; 95% CI: 1.11–1.14) and Central American Hispanics (OR_{adj}=1.41; 95% CI: 1.35–1.47). Regional differences were significant, with Hispanic patients in South Florida showing more favorable staging outcomes than Whites (OR_{adj}=0.95; 95% CI: 0.94–0.97), while in the rest of Florida, Hispanic patients were at a disadvantage (OR_{adj}=1.09; 95% CI: 1.07–1.10). **Conclusions:** Pronounced NSCLC staging disparities are manifest in Black and Hispanic populations, coupled with striking regional variations among Florida's Hispanic groups which underscores the necessity for targeted research to dissect and address the underlying causes of these inequities in the cancer care continuum. Research Sponsor: The Bankhead Coley Research Program of the State of Florida

Lessons learned from a genetic counseling randomized clinical trial: Implications for recruiting individuals identifying as Asians in research.

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Background: Despite the clinical importance of genetic testing and counseling for cancer risk reduction and treatment, minority populations are less likely to receive genetic testing and counseling or participate in genetics research, contributing to health disparities. In a randomized study of three modes of genetic counseling (GC3) conducted in three safety net hospitals, we noted a lower accrual of participants identifying as Chinese despite the availability of language-concordant study documents and bilingual staff. To understand barriers to recruitment, we conducted a mixed methods study using responses to the San Francisco Mammography Registry (SFMR) Breast Health History questionnaire (used for recruitment for GC3) and qualitative interviews with seven participants of the genetic counseling study. **Methods:** We extracted data from the SFMR from 2014–2018 for patients self-identifying as Asian and a control group of patients self-identifying as White. The primary outcome was the proportion of patients who agreed to be contacted for future breast health research. Survey data included information for personal history of breast cancer, history of biopsy, first-degree relative with cancer, age, and level of education. Z-tests were conducted for comparisons between groups. For qualitative analysis, seven Chinese-identifying participants were interviewed to understand why they chose to participate in the genetic counseling study and identify potential barriers and facilitators. **Results:** We included 121,415 patients (n=38,483 Asian). Asian patients had significantly lower rates of accepting future contact for breast health research studies (25.4% for Asians vs. 48.3% for White, $p<0.0001$). Lower rates were observed across Chinese (23.3%), Filipina (30.2%), Japanese (27.8%), and Vietnamese (23.3%) subgroups ($p<0.0001$ for all). A history of breast cancer (personal or family) or biopsy was associated with higher rates of acceptance within both Asian and White groups ($p<0.001$ for all comparisons). Education did not change participation rates as much in Asian patients as in White patients. The qualitative study found barriers across three domains: awareness, opportunity, and acceptance, with a referral from the participant's medical team identified as a facilitator. **Conclusions:** Individuals identifying as Asian in the SFMR were less likely to agree to be contacted for future breast health research. We identified multilevel barriers through qualitative interviews. This has important implications for designing recruitment strategies for Asian populations. Research Sponsor: None.

Geographic disparities in brachytherapy accessibility for cervical cancer.

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Background: While brachytherapy stands as a crucial component of the treatment for locally advanced cervical cancer, the issue of geographic disparities in brachytherapy accessibility has become a noteworthy public health concern in South Korea. Moreover, the specific factors contributing to these disparities have not been clearly elucidated. In light of this, we conducted a nationwide ecologic study to comprehensively investigate the socioeconomic factors associated with brachytherapy accessibility. **Methods:** A total of 2,998 patients newly diagnosed with cervical cancer in 2020 were identified through the Korea Central Cancer Registry (KCCR). Across 17 administrative districts in South Korea, 32 brachytherapy facilities were available. To capture unique socioeconomic factors for each region, including the number of Korean Medicaid (K-Medicaid), Medicare (K-Medicare) beneficiaries, marriage immigrants, registered foreigners, and total residents, data were obtained from the Korean Statistical Information Service (KOSIS). Notably, K-Medicaid and K-Medicare represent governmental medical insurance assistance for patients in poverty and those aged over 65, respectively. The brachytherapy accessibility rate (BAR) was defined as the number of brachytherapy procedures divided by new cervical cancer cases. Additionally, each district's socioeconomic factor was normalized by the number of residents. Univariate and multivariate logistic regression analyses were conducted to explore the relationships between BAR and socioeconomic factors. **Results:** The capital city and its adjoining metropolitan area accounted for 46.9% of the total brachytherapy facilities, with Seoul having 25% (8 out of 32) and Gyeonggi having 21.9% (7 out of 32). Conversely, three non-metropolitan regions had no brachytherapy facilities. In the multivariate logistic regression analysis, the brachytherapy accessibility rate (BAR) demonstrated an inverse association with both the number of K-Medicare beneficiaries and the total immigrant population (Odds ratios of 0.66 and -2.85, respectively). **Conclusions:** To the best of our knowledge, this is the inaugural study highlighting the robust associations between older age and foreign residency status with reduced accessibility to brachytherapy. The observed inaccessibility to brachytherapy has the potential to impede the delivery of standard care, consequently leading to a poorer prognosis for vulnerable populations. Future research endeavors and targeted social interventions will be imperative to rectify geographic disparities in brachytherapy accessibility and ensure equitable healthcare outcomes. Research Sponsor: None.

Racial disparities in the immunotherapeutic outcomes of patients with non-small cell lung cancer (NSCLC): An in-depth systematic review and meta-analysis.

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Background: The utilization of immunotherapy has become prevalent in the therapeutic approach to non-small cell lung cancer (NSCLC), owing to its association with enhanced survival outcomes. Nevertheless, a notable gap exists in the available information regarding potential variations in the survival benefits of immunotherapy based on the racial demographics of NSCLC patients. **Methods:** A systematic search for articles published until January 2023 was performed on PubMed, EMBASE, and Google Scholar databases. Articles that aligned with the research objective were included, while non-English articles, case reports, conference abstracts, studies combining immunotherapy with other cancer therapies, and studies on small-cell lung cancer were excluded. Data required for review and analysis was independently abstracted into separate Excel files by two reviewers. Furthermore, Statistical analyses were performed using the Review Manager software, and the methodological quality evaluation was done using the Newcastle Ottawa Scale. **Results:** Seven cohort studies were used for review and analysis. A subgroup analysis of data from these studies showed that Black/African American and Asian NSCLC patients receiving immunotherapy had improved overall survival (OS) than White patients (HR: 0.84; 95% CI: 0.75 – 0.95; $p = 0.006$ and HR: 0.53; 95% CI: 0.30 – 0.93; $p = 0.03$, respectively). However, the difference in OS is statistically insignificant when Hispanic patients are compared with white patients (HR: 0.68; 95% CI: 0.46 – 1.00; $p = 0.05$). On the other hand, the subgroup analyses did not demonstrate any significant difference in progression-free survival (PFS) when comparing Black/African American, Asian or Hispanic patients to White patients (HR: 0.93; 95% CI: 0.79 – 1.09; $p = 0.35$, HR: 0.89; 95% CI: 0.51 – 1.55; $p = 0.69$, and HR: 1.01; 95% CI: 0.82 – 1.23; $p = 0.96$, respectively). **Conclusions:** Among non-small cell lung cancer (NSCLC) patients undergoing immunotherapeutic interventions, it is discerned that Black/African American and Asian individuals exhibit superior overall survival (OS) outcomes compared to their White counterparts. However, it is noteworthy that the observed racial disparity does not appear to exert a discernible influence on the progression-free survival (PFS) of NSCLC patients subjected to immunotherapy. Research Sponsor: None.

Association of immune checkpoint inhibitor introduction and changes in survival disparities by health insurance coverage among individuals newly diagnosed with advanced cancers in the US.

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Background: First approved by the US Food and Drug Administration (FDA) in 2011, immune checkpoint inhibitors (ICIs) have transformed treatment options for many cancers. Unfortunately, due to their high cost, individuals without health insurance coverage may not be able to afford them. Therefore, the introduction of ICIs may lead to greater disparities in cancer survival between patients with and without health insurance. This study examined the association of health insurance with changes in survival disparities associated with the introduction of ICIs. **Methods:** We identified individuals newly diagnosed at age 18–64 years at stage IV with any one of the following cancers with FDA approval for ICI treatment, including melanoma (first approved 03/25/2011, n=9992); HR+ HER- female breast cancer (02/03/2015, n=13632); non-small cell lung cancer (NSCLC; 03/04/2015, n=113866); and renal cell carcinoma (RCC; 11/23/2015, n=15403) from the National Cancer Database. Individuals with private health insurance or who were uninsured at the time of the cancer diagnosis were included. For each cancer, we applied a difference-in-differences (DD) approach to examine the changes in two-year overall survival before and after the ICI FDA approval date among individuals without health insurance compared to those with private health insurance, using flexible parametric survival models and controlling for key sociodemographic factors. **Results:** As shown (Table), among patients diagnosed with melanoma, 2-year survival rate increased from 16.33% pre-ICI approval to 27.04% after ICI approval among patients who were uninsured and increased from 28.22% to 45.45% among patients with private health insurance, with the disparity by health insurance status widened by 4.58 (95% confidence interval [CI] = 0.02 to 9.14) percentage points (ppt) after adjusting for sociodemographic factors. For patients diagnosed with stage IV NSCLC, the disparity by health insurance widened by 1.58 (95% CI = 0.52 to 2.64) ppt. **Conclusions:** The introduction of ICIs increased disparities in survival by health insurance status. Policies to improve health insurance coverage options or make new treatments more affordable to uninsured patients are needed. Research Sponsor: None.

Introduction of FDA approved ICI and disparities in survival by health insurance coverage type following diagnosis with stage IV cancers.

	Uninsured			Private Health Insurance			DD	Adjusted DD
	Pre-ICI	ICI	Difference	Pre-ICI	ICI	Difference		
Melanoma	16.33	27.04	10.7	28.22	45.45	17.23	-6.53 (-11.2 to -1.86)	-4.58 (-9.14 to -0.02)
Breast cancer	57.28	60.22	2.94	74.05	78.34	4.29	-1.35 (-7.21 to 4.5)	-5.28 (-10.9 to 0.35)
NSCLC	10.78	14.29	3.51	19.62	27.00	7.38	-3.87 (-4.98 to -2.75)	-1.58 (-2.64 to -0.52)
RCC	24.13	31.89	7.75	35.45	46.86	11.41	-3.66 (-8.7 to 1.38)	-3.37 (-8.31 to 1.57)

Pharmacokinetics (PK) and pharmacogenomics (PGx) of ribociclib (ribo) in Black patients with metastatic breast cancer (mBC): The LEANORA study.

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Background: Ribo is metabolized by CYP3A and used for the treatment of patients with hormone receptor-positive (HR+)/HER2- mBC. FDA recommends dose reduction if used with CYP3A inhibitors due to a 3.2x increase ribo area-under-the-curve (AUC). It is unknown if modifications are needed in patients who lack enzyme activity (e.g., genetic CYP3A5 poor metabolizers (PM)). CYP3A5 varies by genetic ancestry, is known to affect dosing for other drugs (e.g., tacrolimus). CYP3A5, ~85% of people of European ancestry are PM, ~85% of African ancestry are normal or intermediate metabolizers (NM, IM), which may impact ribo exposure and response. 2 percent (41/2066) enrolled in MONALEESA 2, 3, and 7 were Black. **Methods:** This prospective, multicenter cohort study (NCT04657679) assessed the PK and PGx of ribo (600 mg daily + letrozole/fulvestrant) in self-identified Black women with HR+/HER2- mBC. PK (0.5, 1, 2, 4, and 6 hours after ribo) and PGx studies were performed during cycle 1 via liquid chromatography with tandem mass spectrometry and PharmacoScan (ThermoFisher) microarray, which tests 1,191 genes. Including variants in CYP3A5*3, *6, and *7. Phenotypes assigned: PM (2 variant alleles), intermediate metabolism (IM; 1 variant allele), NM (0 variant alleles). The area under the curve (AUC_{tau}) was compared with the exact Wilcoxon rank-sum test; Fisher's exact test assessed the AEs and grade 3+ AEs to day 28. **Results:** 14 completed the trial. CYP3A5 phenotypes were PM (7), IM (6), and NM (1). The primary endpoint, AUC_{tau}, was similar between CYP3A5 PM (39,230 hr*ng/mL; interquartile range [IQR]: 18,745 to 57,566 hr*ng/mL) vs. IM/NM (43,546 hr*ng/mL; IQR: 35,298 to 46,647 hr*ng/mL; p = 0.38). Other PK properties were similar between groups (table). There was a non-statistically significant higher number of AEs and grade 3+ AEs in PMs, when compared to NM/IMs. Study was not powered to assess differences in AEs. **Conclusions:** This cohort study detected no association between CYP3A5 genotype and ribo exposure. However, PMs may have more AEs relative to IMs/NMs. Future steps include exploring the impact of rare variants, including ~70 variants in CYP3A 4 and 5, on ribo exposure in this population. We will explore the role of clinical and genetic factors on the interindividual variability of ribo. Diverse patient representation in clinical trials is critical to ensure research findings are applicable to all patients. Clinical trial information: NCT04657679. Research Sponsor: Conquer Cancer, the ASCO Foundation; BCRF; BCRF-20-156; Georgetown University; P30CA051008; Government Agency.

	CYP3A5 IM/NM n=7	CYP3A5 PM n=7	P-value
AUC _{tau} (hr*ng/mL)	43546 (35298, 46647)	39230 (18745, 57566)	0.38
AUC _{0-6hr} (hr*ng/mL)	14,907 (8254, 15245)	11,102 (6143, 13651)	0.26
Maximum concentration (ng/mL)	3140 (1980, 3540)	3020 (1300, 3470)	0.46
Time to reach maximum concentration (hr)	2.0 (2.0, 4.0)	3.8 (2.0, 5.9)	0.48
Toxicity (any grade)	2 of 7 [29%]	6 of 7 [86%]	0.10
Toxicity (grade 3+)	0 of 7 [0%]	4 of 7 [57%]	0.07

Median (IQR1, IQR3).

Examining disparities in the receipt of curative treatment for hepatocellular cancer (HCC): A multicenter retrospective study from 2016-2023.

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Background: Prior studies suggested disparities in hepatocellular cancer (HCC) treatment and outcomes based on region, race, and socioeconomic status. After the implementation of the Affordable Care Act, including Michigan's Medicaid Expansion in 2014, there's increased interest in how these changes affect HCC care. The study examines factors influencing curative treatment receipt and existing disparities, as a step toward intervention strategies. **Methods:** This is a retrospective study of HCC patients at 6 community-based (4 university-affiliated) hospitals, in Michigan from Jan 2016-Sep 2023. Patients without imaging or histologic confirmation were excluded. Factors associated with receiving curative treatment were determined using both univariate and multivariable logistic regressions. Analysis was done using SPSS 28, with a p -value <0.05 indicating statistical significance. **Results:** Of 680 HCC patients screened, 347 were analyzed. The mean age was 70 years, and 71% were male. 78.3% were White and 16.9% Black. 53.9% had private insurance and 35% had government insurance. Primary HCC etiologies were alcohol and hepatitis C virus (HCV) infection; 74.4% had cirrhosis. Barcelona Clinic Liver Cancer (BCLC) stages varied: A (10.6%), B (28.2%), C (36.4%), and D (24.8%). 59.4% underwent curative treatment (4.6% resection, 30.3% liver-directed, 13.3% systemic, 10.1% combination), while 38.3% had best supportive care. Univariate analysis identified many factors associated with receipt of curative treatment, including race (White>Black), insurance (private>government), earlier BCLC stages, ECOG 0/1/2, Child-Pugh A, lower MELD-Na score (mean=12), <400 alpha-fetoprotein levels, and better liver function (Bilirubin, INR, albumin). Tumor characteristics, such as smaller size, absence of metastasis, and absence of portal vein thrombosis, were also associated with receipt of curative treatment. Overall, the one-year survival rate was 64% for those who had curative treatment and 35% for best supportive care. All with p -value <0.05 . Multivariable analysis showed Black patients (OR: 0.21, CI: 0.051-0.881) with larger tumors (OR:0.89, CI: 0.783-1.00) and lower albumin levels (OR:3.81, CI: 1.649-8.805) at presentation were less likely to receive curative treatment than White. Black patients were also diagnosed at a younger age (66.7 vs. 71.0 years, $p=0.01$), more advanced BCLC stages C/D (74% vs. 57%, $p=0.04$) on presentation, and HCV coinfection (58% vs. 32%, $p<0.001$) than White. Median survival for Black and White were 757 days and 823 days, respectively ($p=0.89$). **Conclusions:** Black patients with larger tumors and low albumin are less likely to receive curative treatment than White. HCV coinfection in the Black population suggests a focus area for early intervention. Further investigation of HCC disparities across various settings is warranted. Research Sponsor: None.

Association between social determinants of health and time to treatment for newly diagnosed multiple myeloma.

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Background: Delayed access to costly anti-myeloma agents due to insurance precertification process or out-of-pocket costs results in treatment initiation with less-costly corticosteroids in some patients with newly diagnosed multiple myeloma (NDMM). Less is known about the scope of the delay and the factors associated with it. **Methods:** This retrospective cohort study used Taussig Cancer Center's Myeloma Patient Registry to identify adults with NDMM between January 1, 2017 and December 31, 2021. Electronic health records data captured (1) time from initial diagnosis to receipt of FDA-approved anti-myeloma agent including vs. excluding corticosteroids, (2) time to initial prescription fill for FDA-approved anti-myeloma drug excluding corticosteroids, and (3) association of race, sex, primary insurance type, area deprivation index (ADI), urbanicity, and time to initial fill for anti-myeloma drug excluding corticosteroids. The latter was examined via cumulative incidence at 30 days since initial diagnosis using the log-rank test and multivariable Cox regression model. **Results:** We identified 723 patients with a mean age at diagnosis of 67 years ± 11 ; 55% were male, 77% White, 22% Black, and 1% other races, covered by private insurance (36%), traditional Medicare (28%), Medicare Advantage (25%), Medicaid (8.4%), and self-pay/other (1.8%); and median follow-up of 784 days (interquartile range [IQR], 415, 1313). Over a third of patients (37%) resided in an area in the most disadvantaged quartile of the ADI; 83% resided in a metropolitan area. Median time to receipt of anti-myeloma treatment was 10 days (IQR, 2, 24) including corticosteroids vs. 18 days (IQR, 8, 37) excluding corticosteroids. Median time to initial prescription fill for an anti-myeloma drug excluding corticosteroids was 31 days (IQR, 16, 75). The cumulative incidence of prescription fill for anti-myeloma drug excluding corticosteroids at 30 days was 40% (95% CI, 36%, 44%) in White individuals, 28% (95% CI, 21%, 36%) in Black patients, and 17% (95% CI, 0.42%, 64%) in other races ($P=.009$) [adjusted HR for Black patients (v. White), 0.63, 95% CI, 0.44, 0.90]; 31% (95% CI, 25%, 38%) in patients with traditional Medicare, 37% (95% CI, 30%, 44%) with Medicare Advantage, 44% (95% CI, 38%, 50%) with Private Insurance, 34% (95% CI, 23%, 48%) with Medicaid, and 31% (95% CI, 9.1%, 61%) self-paying/with other insurance ($P=.07$) [adjusted HR for private insurance (v. traditional Medicare), 1.41, 95% CI, 1.04, 1.93]; 40% (95% CI, 36%, 44%) treated in Taussig Cancer Center and 25% (95% CI, 17%, 34%) in regional hospitals ($P=.003$) [adjusted HR for regional hospitals, 0.59, 95% CI, 0.40, 0.89]. **Conclusions:** Disparities in time to prescription fill for anti-myeloma drugs exist based on socio-demographic factors. Future research should examine the role of precertification criteria and out-of-pocket costs in delays with recommended care. Research Sponsor: National Cancer Institute.

Improving lung cancer health equity by applying deep learning to low dose CT screening of minority and disadvantaged patients.

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Background: In the US, disparities in lung cancer mortality exist for African American, Hispanic, and other minorities. Standard of care low dose CT screening (LDCT) detects early-stage disease and improves mortality, yet disparities are perpetuated in screening by eligibility criteria derived from cohorts underrepresenting these minorities. One such cohort is the National Lung Screening Trial (NLST) cohort which is 92% White. Consequently, guidelines for lung cancer screening may be insufficient to address the unique needs of diverse populations. We hypothesize that Artificial Intelligence prediction of future lung cancer risk from an individual's LDCT can partially mitigate racial and ethnic disparities and improve health system practice guidelines by individualizing screening risk as compared to current general guidelines. Here, we benchmark a Resnet18 3D neural network trained on NLST LDCT images, Sybil, on the diverse patient population of the University of Illinois Health system (UIH) which is 20% White and 60% African American. **Methods:** A real-world cohort from UIH consisting of 1,450 CT studies was evaluated alongside 60,378 CT studies from the NLST cohort. All CT studies evaluated by the model were not used in model training. Using Youden's J index as a probability cutoff, sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were evaluated. Receiver operating characteristic (ROC) and precision-recall (PR) curves were generated to assess model performance between cohorts. NLST data were truncated to achieve equivalent incidence of lung cancer with UIH when generated PR curves. **Results:** Multi-year prediction performance (ROC-AUC and PR-AUC) between cohorts are summarized (Table). For prediction of lung cancer within 1-year of LDCT in the UIH cohort, the model respectively demonstrated sensitivity, specificity, positive predictive value, and negative predictive value among White (0.80, 0.77, 0.54, 0.92), African American (0.84, 0.78, 0.39, 0.97) races and Hispanic (0.75, 0.73, 0.60, 0.84) and non-Hispanic (0.87, 0.77, 0.42, 0.97) ethnicities. **Conclusions:** Model performance was similar between the NLST (92% White) and a diverse, real-world cohort at UIH (20% White) though decreases in ROC-AUC performance in year 1 predictions and may be due to insufficient representation of minority populations during model training. Prospective studies involving larger and more representative patient populations should be conducted to further optimize the model and evaluate its clinical utility to improve lung cancer health equity in minority populations. Research Sponsor: None.

Model performance in NLST versus UIH cohorts.

Year diagnosed	NLST ROC-AUC	UIH ROC-AUC	NLST PR-AUC	UIH PR-AUC
Year 1	0.94	0.87	0.59	0.62
Year 2	0.86	0.85	0.53	0.68
Year 3	0.82	0.85	0.54	0.69
Year 4	0.79	0.84	0.57	0.70
Year 5	0.78	0.84	0.61	0.70
Year 6	0.77	0.83	0.63	0.70

Demographics of cancer screening in Providence's homeless population.

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Background: Adults experiencing homelessness have a higher incidence and mortality from cancer. It is estimated that almost 60% of homeless people in the US are from racial and ethnic minorities. Therefore, cancer mortality among the homeless may be an important disparity. In recent years homelessness has increased in Providence RI due to high rents and end of covid subsidies. The objective of this project was to learn about the demographics of the homeless population in Providence, focusing on risk factors for cancer and barriers to screening, to acquire the necessary information to develop interventions to improve cancer screening in the unhoused population. **Methods:** We conducted a cross-sectional survey of homeless individuals in Providence, RI. Survey data was obtained at homeless shelters, on the street, at soup kitchens and at other community events supporting the homeless. The largest single source of participants was those attending the Mathewson Street Church Friendship Breakfast on Sunday mornings. **Results:** Data was obtained from 278 homeless individuals from September 2023 to December 2023. 70% were male, 30% female. Age ranges included 28 (10%) < 40 years, 78 (28%) 40-49 years, 88 (32%) 50-59 years, 74 (27%) 60-69 years and 10 (4%) > 70 years. Race/ethnicity included 56% White, 18% Black, 13% Hispanic/Latino, 2% Native American, 9% multiracial and 2% other. 51% were sleeping in a shelter, 29% were unsheltered (including outside, car or tent), 12% "couch surfing", and 7% were recently housed. Most participants (92%) had health insurance, the majority being state Medicaid, and had PCP visits (59%), mostly to community health centers, within the last 12 months. 72% of individuals were current cigarette smokers and 45% currently used alcohol. Among women, only 32% were on schedule for mammogram and 61% were on schedule for cervical cancer screening. Colon cancer screening rate for individuals > 45 years was 32%. Only 32% of males over 50 had prostate cancer screening. Barriers identified included needing to have other needs met such as food and housing, lack of transportation to healthcare facilities, and lack of awareness about the need to undergo screening. **Conclusions:** The most common age range of homelessness in Providence, ages 50-59, is when cancer screening should be ongoing. There is a higher incidence of homelessness among minorities. The homeless population have high risk factors for cancer but screening rates for breast, cervical, lung, prostate and colon cancer are well below national guidelines. This represents a health disparity. Given the proportion of participants with a PCP and health insurance, interventions to improve cancer screening in this population may be feasible. We plan to develop educational partnerships with community health centers during the next phase of this initiative to increase awareness and uptake of screening recommendations. Research Sponsor: Genentech.

Post mastectomy reconstruction choice: Do race and ethnicity play a role?

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Background: The choice regarding reconstruction after mastectomy is based on multiple factors. We hypothesized that race and ethnicity are associated with decision making regarding reconstruction and choice for bilateral mastectomy among a diverse patient population with equal access to reconstructive options. **Methods:** A retrospective cohort study was performed of patients who underwent mastectomy with or without reconstruction for cancer or prophylaxis from 1/1/2019–12/31/2020 within a single health care system. Clinical and demographic features were recorded. Study endpoints included reconstruction and contralateral prophylactic mastectomy (CPM) choice. Chi square and logistic regression analyses were performed with hypotheses tested at 5% significance level. **Results:** A total of 663 patients underwent mastectomy for cancer or prevention. Mean age was 54 (range: 24–93) and median BMI 25 (15–58). The majority of women included identified as Non-Hispanic White (NHW) (52%), with other women identifying as Hispanic, Asian, Non-Hispanic Black (NHB), or Other (Table). Of the total cohort, 647 (98%) patients had surgery for cancer, while 16 (2%) had surgery for prophylaxis. Among those with unilateral cancer (N=602, 91%), NHW women were more likely to get CPM (OR 2.12, $p < .001$), while NHB (OR 0.58, $p = .02$) and Asian women (OR 0.47, $p = .01$) were less likely to choose CPM. Asian women were less likely to undergo reconstruction compared to non-Asian women (OR=0.42, $p = .01$), while Hispanic women were almost twice as likely to undergo reconstruction compared to non-Hispanic women (OR 1.93, $p = .016$). Hispanic women were more likely to undergo a DIEP flap (OR 2.77, $p < .001$), while NHW women were more likely to choose implant reconstruction (OR 2.35, $p < .001$). **Conclusions:** In our hospital system, choice for reconstruction or CPM was found to differ based on race and ethnicity. NHW women were more likely to choose CPM and undergo implant-based reconstruction, Asian women were more likely to forgo reconstruction, and Hispanics were more likely to undergo DIEP flaps. Future analysis in this cohort will include other factors such as BMI, insurance status, religion, marital status, and employment status. Research Sponsor: None.

Reconstruction choice by race and ethnicity.

	Asian (N=76, 12%)		Hispanic (N=110, 17%)		NH White (N=340, 52%)		NH Black (N=98, 15%)		NH Other (N=35, 5%)	
	N (%)	OR	n (%)	OR	N (%)	OR	N (%)	OR	N (%)	OR
Implant	20 (26.3)	0.42* (0.24,0.70)	37 (33.6)	0.59* (0.38,0.91)	184 (54.1)	2.35* (1.72,3.24)	33 (33.7)	0.60* (0.38,0.94)	16 (47.1)	1.14 (0.56,2.28)
DIEP	24 (31.6)	1.03 (0.60,1.70)	56 (50.9)	2.77* (1.82,4.22)	78 (22.9)	0.45* (0.32,0.63)	37 (37.8)	1.42 (0.90,2.21)	10 (29.4)	0.93 (0.41,1.93)
No reconstruction	31 (40.8)	2.39* (1.44,3.93)	17 (15.5)	0.52* (0.29,0.88)	77 (22.6)	0.82 (0.57,1.17)	28 (28.6)	1.29 (0.79,2.06)	8 (23.5)	0.96 (0.40,2.09)

NH=Non-Hispanic; OR=odds ratio
(with 95% C.I.); *=statistically significant.

Rapid survey assessment: Barriers and facilitators to mammogram completion in English and Spanish-speaking patients in a federally qualified health center (FQHC) setting.

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Background: Mammography has decreased breast cancer mortality in the US by 40% since the 1980s; yet disparities in screening and outcomes persist in underserved populations. Many studies note language as a barrier to screening with lower mammogram completion amongst Spanish-speaking patients versus those with English language proficiency. At our health center, Spanish-speaking patients were more likely to complete screening mammography compared to patients with English proficiency (53% vs 31% in 2022). To understand this pattern and barriers and facilitators to breast cancer screening, we conducted a mixed methods rapid assessment survey as part of a quality improvement initiative. **Methods:** We developed a patient bilingual survey measuring knowledge, attitudes, and behaviors about breast cancer prevention and screening. We identified consecutive female patients (age 40-75 years) and extracted baseline demographic data from the electronic medical record. Surveys were distributed via our health center's patient messaging service and responses stored on a secure platform. Data analysis included descriptive statistics, chi-squared testing between groups and qualitative analysis to identify common themes from free-text answers. **Results:** The overall response rate was 14% (N=732/5,332) in 30 days. Of the surveys completed, 37% were in Spanish. Spanish-speaking patients more strongly regarded mammography as safe and effective compared to English-speaking patients ($p<0.001$). Spanish-speaking patients were more likely to view getting a mammogram as a priority (79% vs 65% $p<0.001$) and noted speaking about breast cancer prevention in their communities more often ($p<0.006$) as an important factor. Spanish-speaking patients primarily cited cost, scheduling, and language ($p<0.05$) as barriers to mammogram completion, while English-speaking patients cited time constraints, transportation, and discomfort ($p<0.05$) more frequently. Spanish-speaking patients were more likely to prefer speaking with a trusted community member or attending health fairs than English-speaking patients ($P<0.05$). **Conclusions:** Our study demonstrates differences in attitudes, behaviors, and perceived barriers to mammography in English vs Spanish-speaking patients. The increased mammogram completion rate in Spanish-speaking patients may reflect more positive attitudes about screening and more discussion in the community amongst Spanish-speaking patients queried. Reported barriers to screening differed and will guide targeted QI interventions. We demonstrated feasibility and patient engagement in a diverse population using a message system built into our EHR in an FQHC setting. This survey study allows us to elevate patient voices, better understand gaps and preferences, and better tailor future interventions for cancer screening. Research Sponsor: HRSA.

Identifying eligibility criteria that perpetuate race/ethnic disparities in acute myeloid leukemia (AML) clinical trial participation.

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Background: The extent to which eligibility criteria perpetuate race/ethnic disparities in adult AML clinical trial participation is unknown. **Methods:** This multicenter cohort study counterfactually assessed race/ethnic disparities in trial eligibility between Non-Hispanic Whites (NHW) and Minoritized Individuals (MI: Hispanic, Black, Asian, and/or Other) diagnosed with AML between 2010–2022 at six hospitals in Chicago, IL and one in Boston, MA. All newly diagnosed patients were catalogued; those with complete data were analyzed. Eligibility criteria were obtained from 190 front-line phase II/III therapeutic studies active during the same period (1). Common sets of criteria for intensive and non-intensive trials were generated based on prevalent criteria and medians of any associated limits (e.g., QTc \leq 480 ms). Proportions of MI and NHW that would have been eligible based on these common criteria sets were assessed using X^2 tests with odds ratios (OR). Mann-Whitney U tests assessed differences in the median number of trials for which each MI and NHW patient would have been eligible. Analyses with MI groups disaggregated were also performed. **Results:** There were 1283 patients (405 MI, 878 NHW) with a median age of 60 years (57 MI, 61 NHW; $p < 0.001$); 44% were female. According to the common set of 23 intensive trial criteria that was generated, similar proportions of MI and NHW were eligible (24.7% and 24.5%, OR 1.01, 95% CI [0.77,1.33]). With the age limit criterion removed, fewer MI than NHW were eligible (42.7% and 36.0%, OR 0.76, 95% CI [0.59,0.96]). In this set of criteria, prior malignancy (excluding 22.5% and 17.5%, $p = 0.04$), prolonged QTc (17.0% and 8.7%, $p < 0.001$), and coronary artery disease (CAD; 8.6% and 4.1%, $p = 0.002$) generated the largest disparity individually. According to the non-intensive set (14 criteria), fewer MI were eligible than NHW (42.2% and 54.4%, OR 0.61, 95% CI [0.48,0.78]); there was no age criterion in this set. Prior malignancy (22.5% and 17.5%, $p = 0.04$), prolonged QTc (20.5% and 12.8%, $p < 0.001$), and hepatitis B infection (4.0% and 1.0%, $p = 0.001$) generated the largest disparities in this set. Overall, individuals were eligible for a mean of 51.6% of the 190 trials (median: 98 trials, IQR [59,115]). MI were eligible for 6.8% fewer trials than NHW (median difference: 13 trials [88 and 101], $p < 0.001$). Asian, Black, and Other were eligible for 7.7%, 4.8%, and 16.9% less trials than NHW, respectively (all $p < 0.05$). Criteria with the largest individual disparities in median eligibility were lower age limits, hepatitis B, and CAD (all $p < 0.01$). **Conclusions:** Eligibility criteria disparately exclude minoritized individuals from AML clinical trial participation. Based on ASCO recommendations (2), several of the criteria driving disparate eligibility (hepatitis, prior malignancy) are modifiable or removable. 1. Hantel, *Haematologica*, 2023. 2. ASCO, *Clin Cancer Res*, 2021. Research Sponsor: U.S. National Institutes of Health; K08 CA273043; Conquer Cancer, the ASCO Foundation.

Use of surgery for de novo metastatic breast cancer (mBC).

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Background: In the U.S., locoregional surgery for *de novo* mBC was common in the 1990s and 2000s, but subsequent prospective data did not show a survival advantage. Current guidelines recommend surgery only for symptom control. We investigated trends in the use of surgery (lumpectomy or mastectomy) for mBC from 2010 to 2019 using SEER and institutional data, aiming to identify factors that correlate with variability in surgery use. **Methods:** We included all *de novo* mBC diagnoses from SEER-17 from 2010–2019. The primary outcome was receipt of surgery, and we included year of diagnosis, demographic (race/ethnicity, age, marital status, median household income in the patient's county, and urban/rural residence), and disease factors (estrogen receptor (ER) and HER2 status, tumor size, and presence of visceral metastases) in the multivariable logistic regression. We similarly identified all *de novo* mBC diagnoses from Oncoshare, which merges EMR and California Cancer Registry (CCR) data for patients treated in the Stanford Health Care Alliance. For Oncoshare inclusion a patient must have an encounter with Stanford and be in CCR; however, a patient does not have to receive all cancer care at Stanford. In this analysis, we included distance to the cancer center and insurance status. Results are presented as unadjusted percentages or odds ratios with 95% confidence intervals. **Results:** In SEER (n = 24,146), the use of surgery for mBC declined from 41% in 2010 to 22% in 2019, a trend also observed in the institutional data (n = 785). Surgery rates were highest in younger patients and declined with each decade of life (44% for those in their 30s vs 19% for those > 80). Surgery was more common in tumors > 2 cm, ER-negative disease, and in patients without visceral metastases. In SEER, patients from counties with median incomes < \$50,000 were more likely to have surgery than those from counties with incomes > \$75,000 (36% vs 27%; OR: 1.3 [1.2–1.5]). Rural patients were more likely to have surgery than urban patients (34% vs 30%; OR: 1.1 [1.0–1.3]). Unmarried persons had lower odds of surgery than married persons (OR: 0.8 [0.7–0.9]). The institutional data reproduced the findings of the SEER analysis, except that a relationship between surgery and marital status and income was not observed. In the institutional data, patients living farther from the Stanford Cancer Center (> 100 km) were more likely to have surgery (40% vs 32%; OR 2.1 [1.2–3.8]). **Conclusions:** The use of surgery for *de novo* mBC decreased dramatically in the 2010s from 41% to 22%. All demographics saw a reduction; however, younger, and married patients underwent surgery at higher rates. Patients from lower-income and rural counties—areas typically with less access to care—were also more likely to have surgery. The institutional analysis showed that a greater distance from an urban hospital network correlated with increased odds of surgery. These patterns suggest differential care provision in rural areas for patients with mBC. Research Sponsor: AHRQ; 5T32HS026128; Mikitani Cancer Research Fund; Breast Cancer Research Foundation; Susan and Richard Levy Gift Fund; Suzanne Pride Bryan Fund for Breast Cancer Research; Regents of the University of California's California Breast Cancer Research Program; 16OB-0149; BRCA Foundation; G. Willard Miller Foundation.

Trends in location of death for individuals with pediatric cancer in the United States.

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Background: Children and adolescents with cancer face unique symptomatic, psychosocial, and existential challenges at the end of life (EOL). Premature death alongside severe pain and complex symptoms is distressing for the patients and families. Location of death is an important clinical and psychosocial decision for many patients. Therefore, we explored differences in location of death amongst pediatric patients with cancer using a large, national US database. **Methods:** We performed multinomial logistic regressions and analyzed trends in place of death for children and adolescents (ages 0 to 19) diagnosed with cancer from 2003–2019 using the Centers for Disease Control and Prevention Wide-Range Online Data for Epidemiologic Research database (CDC WONDER). We studied associations in place of death with essential decedent characteristics (age, sex, and race) for ICD10 codes C00–C96 and D00–D49, which encompass the most common causes of cancer death in children and adolescents. **Results:** Of 1,910 pediatric oncology decedents, 910 died in a hospital, 794 died at home, 12 died in nursing facilities, 59 in hospice, and 135 in outpatient facilities. Over time, death at home decreased by 50%. Death in the hospital increased by 64% and death in hospice increased by 200%. Children 10–19 years-of-age were more likely to die in hospice than children younger than 4 and children between 5–9 years-of-age. Additionally, they were less likely to die in outpatient medical facilities and ED. 1,388 decedents were White, 411 were Black, 18 were American Indian, and 93 were Asian. Children of racial and ethnic minorities were significantly more likely to die in hospitals than White children with cancer (Black: 1.81 [1.44–2.28], Asian: 1.57 [1.03–2.41], and Hispanic: 1.60 [1.26–2.04]). Black children with cancer were also more likely (1.67 [1.11–2.53]) to die in outpatient facilities compared to White children. Asian children & Black children were less likely to die at home (0.48[0.38–0.61] and 0.55 [0.35–0.86] respectively). **Conclusions:** In contrast to the adult population that has demonstrated steady increases in deaths at home, for children with cancer, relative rates of death at home decreased while death in the hospital increased, with distinct differences among race/ethnic groups. Adequate education and support are needed to facilitate both autonomy and symptom palliation at EOL. Future work must explore underlying reasons for differences in place of death across time and demographic groups, so as to identify and alleviate any potential barriers, and to promote equitable access to a good death for each individual. Research Sponsor: None.

Association of food insecurity with reduced cancer screening rates.

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Background: Social determinants of health, including access to adequate food and nutrition, influence many aspects of health, including cancer screening. This study explored the associations between food insecurity and cancer screening. **Methods:** A retrospective analysis was conducted using the National Health Interview Series from 2018–2022 to capture contemporary screening events. Based on scaled questionnaires, food security was stratified into either food secure or insecure, and then subgrouped into high, marginal, or low security. Associations were made with rates of undergoing at least one screening test. Relationships between variables were evaluated using Chi-Square and Cochran-Armitage trend tests. Logistic regression models were applied to find factors associated with cancer screening. **Results:** Patients included in analyses included: 51,957 for colon, 40,103 for breast, 45,983 for cervical, and 25,781 for prostate cancer screening. Between 2018–2022, those with food insecurity had significantly lower rates of cancer screening than those with food security across all four cancer screens, including colon (68.1% vs. 76.1%, $p < 0.0001$), cervical (83.3% vs. 87.5%, $p < 0.0001$), breast (73.3% vs. 79.5%, $p < 0.0001$) and prostate (41.3% vs. 54.0%, $p < 0.0001$) (Table). This was similar when comparing low, marginal, and high food security, respectively, for colon (68.1% vs. 68.2% vs. 76.1%, $p < 0.0001$), cervical (82.8% vs. 84.1% vs. 87.5%; $p < 0.0001$), breast (72.7% vs. 74.1% vs. 79.5%, $p < 0.0001$), and PSA screening (40.7% vs. 42.2% vs. 54.0%; $p < 0.0001$). Other variables were also analyzed, including insurance type, age, race, BMI, and health status. Those with public health insurance had lower screening rates for cervical cancer compared to those with private insurance ($p < 0.0001$). Individuals with food insecurity reported worse health than those who were food secure ($p < 0.0001$). Lower food security disproportionately affected Black patients ($p < 0.001$), and was associated with younger age ($p < 0.0001$) and higher rates of obesity ($p < 0.0001$). **Conclusions:** Individuals with self-reported food insecurity were found to have lower cancer screening rates than those who were food secure. Further analyses revealed associations between low food security status and obesity, public health insurance, younger age, and Black race. These data suggest that addressing food insecurity should be a priority, as these populations appear most vulnerable to lacking appropriate cancer screening. Research Sponsor: None.

Screening	High Food Security		Marginal Food Security		Low Food Security		P-value
	Total	Screened	Total	Screened	Total	Screened	
Colon cancer	46,263	35,182 (76.1%)	2,339	1,594 (68.2%)	3,355	2,283 (68.1%)	< 0.001
Cervical cancer	39,478	34,554 (87.5%)	2,758	2,318 (84.1%)	3,747	3,101 (82.8%)	< 0.001
Prostate cancer	23,273	12,566 (54.0%)	1,018	430 (42.2%)	1,490	606 (40.7%)	< 0.001
Breast cancer	34,672	27,554 (79.5%)	2,258	1,672 (74.1%)	3,173	2,306 (72.7%)	< 0.001

Disparities in the initial presentation of melanoma across two socioeconomically diverse New York City neighborhoods.

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Background: Disparities in stage at diagnosis among melanoma patients are often seen between urban and rural communities, with patients in rural areas being diagnosed with more advanced tumors. Factors contributing to the disparities include decreased access to dermatologists in rural areas, and lower socioeconomic status (SES). We investigated urban disparities in melanoma T stage at diagnosis among patients residing in 2 New York City (NYC) neighborhoods of differing SES and receiving care within the NYU Langone Health System. The neighborhoods were: Upper East Side (UES) and Brighton Beach/Coney Island (BB/CI).

Methods: We conducted a retrospective chart review (NYU IRB 23-01020) of melanoma patients (N=243) diagnosed from 2018-2022 using ICD-10-CM codes: C43 (malignant melanoma of skin); D03 (melanoma in situ); and Z85.820 (personal history of malignant melanoma of skin). For community-level data we used the American Academy of Dermatology's "Find a Dermatologist" search function to locate member-dermatologists; New York State Cancer Registry data (2016-2020) to determine annual melanoma incidence; and the United States Census Bureau Public Use Microdata Areas to determine the proportion of Non-Hispanic Whites (NHW), income levels, and educational attainment. The distribution of T stages was compared using a chi-square test. A two-sample test was used to assess equality of proportions. **Results:** In UES, the annual melanoma incidence was 30.2/100,000 (95% CI: 27.4-33.2); NHW comprised 74.6% of the population; the median household income was \$135,820; 78% attained education higher than high school; and there are 190 dermatologists within a 0.5-mile radius. In BB/CI the annual melanoma incidence was 14/100,000 (95% CI: 11.6-16.9); NHW comprised 55.1% of the population; the median household income was \$43,118; 46% attained education higher than high school; and there is 1 dermatologist within a 0.5-mile radius. There are 15 dermatologists within a 3.0-mile radius. 155 and 88 patients met inclusion criteria in UES and BB/CI respectively. The distribution of T stages (i.e. T1s to T4) was significantly different between UES and BB/CI with higher proportions of advanced stage tumors in BB/CI ($p=0.0002$). Specifically, the proportion of (T2+T3+T4) tumors/total melanomas was 35/155 (23%) in UES; and 41/88(47%) in BB/CI ($p<0.0001$). For reference, the proportion of T2+T3+T4 melanomas in the United States is 30%. **Conclusions:** We identified substantial disparities in the initial presentation of melanoma in 2 NYC neighborhoods, with proportionately more advanced stage tumors in the community of low educational attainment, less access to dermatologic services, and lesser household income. Neighborhood-based approaches to uncover melanoma disparities can identify areas for community outreach and engagement efforts to improve melanoma awareness and access to dermatologic care. Research Sponsor: None.

Racial disparities and survival outcome of patients with locally advanced cervix cancer in the international randomised phase 3 OUTBACK trial (ANZGOG 0902, RTOG 1174, NRG 0274).

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Background: OUTBACK was an international multi-center phase 3 trial investigating adjuvant chemotherapy following definitive chemoradiation in locally advanced cervix cancer. We analysed if baseline characteristics were associated with survival outcome. More specifically, we determined whether race held prognostic significance relative to established clinical factors. **Methods:** We compared baseline characteristics (encompassing demographics, biomarkers and participants' self-ratings of EORTC QLQ-C30 scores) between racial groups using chi-squared tests. We then explored relationships between baseline characteristics and survival outcomes using univariable and multivariable Cox proportional hazards regression models with stepwise selection. **Results:** Black or African American participants accounted for 13% (n=121/919) of the OUTBACK study population. There were no evident differences in the proportion of Black or African American participants, as compared to other racial groups, across most baseline characteristics, except for country of residence (USA vs non-USA, $p < 0.01$). When examining the impact of race (Black or African American vs other racial groups) on survival outcomes in locally advanced cervix cancer, we found no evident associations with overall survival (HR 1.2; 95%CI, 0.84 – 1.72; $p = 0.32$) or progression free survival (HR 1.29; 95%CI, 0.95 – 1.75; $p = 0.10$). Multivariable analysis identified several independent prognostic factors for overall survival, including performance status (HR 1.43; 95%CI, 1.04–1.95; $p = 0.03$), FIGO stage (HR 2.02; 95%CI, 1.48–2.75; $p < 0.01$), nodal involvement (HR 1.59; 95%CI, 1.18–2.14; $p < 0.01$), and elevated white cell count (HR 1.68; 95%CI, 1.21–2.33; $p < 0.01$). Role function, social function, financial difficulties and eGFR showed significance in univariable analysis for overall survival but did not retain significance in multivariable analysis. These findings were consistent when examining progression-free survival. **Conclusions:** No discernible disparities in survival outcomes were observed between Black or African American participants and other racial groups undergoing primary treatment for locally advanced cervix cancer. The primary prognostic determinants for this disease continue to be cancer staging and clinical performance status. Enrolment into a clinical trial may have abrogated the historical disparities seen among ethnic and racial groups. Clinical trial information: 12610000732088. Research Sponsor: None.

Occurrence of cancer in people with intellectual disabilities in Germany.

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Background: Intellectual disability (ID) affects about 1% of the general population, involving approximately 1 million people in Germany. People with ID experience shorter life expectancies and one of the most common causes of death include malignancies (20%). In addition to life-style factors, possibly genetic mutations causing ID may contribute to oncogenesis. Whether individuals with ID have a higher-than-expected risk of cancer in Germany remains unknown.

Methods: A cross-sectional study was conducted using nationwide outpatient health insurance data in Germany from 2019. The data set included 438 028 people with ID and 65 762 146 people without ID (0-107 years, male/female). After matching for age, sex, and district code, data from 437 802 people with ID (4.23 % with cancer) and 4 378 020 without ID (5.06 % with cancer) aged 0-95 years were analyzed. Univariate odds ratios estimated the association between ID and cancer occurrence for various cancer diagnoses (ICD-10: C00-C97). The study was approved by the ethics committee of the Berlin Medical Association (Eth-11/23). **Results:** Across all cancer types, people with ID showed lower risks for a cancer diagnosis than those without ID (Odds Ratio [OR] 0.83; 95% Confidence Interval [95% CI] 0.82-0.84); $p < .0001$ for all data. Certain cancer types occurred more often, such as malignant neoplasms of the brain (C71; OR 2.80; 95% CI 2.58-3.03), other parts of the central nervous system (C72; OR 2.45; 95% CI 1.76-3.34), the testicles (C62; OR 1.80; 95% CI 1.68-1.93), the ovary (C56; OR 1.26; 95% CI 1.13-1.4), the corpus uteri (C54; OR 2.02; 95% CI 1.86-2.19), leukemia of unspecified cell type (C95; OR 1.86; 95% CI 1.67-2.06) and other leukemia of specified cell type (C94; OR 1.81; 95% CI 1.43-2.25). However, other entities such as malignant melanomas (C43; OR 0.55; 95% CI 0.51-0.59), prostate cancer (C61; OR 0.59; 95% CI 0.56-0.62), tumors in the respiratory system (C30-39; OR 0.69; 95% CI 0.64-0.74) and the breast (C50; OR 0.82; 95% CI 0.79-0.85) occurred less often. **Conclusions:** People with ID showed a decreased risk for being diagnosed with cancer. This may be caused by lower exposition to certain risk factors in some cancer types such as skin or lung cancers. Difficulties in accessing the health care system and lower cancer screening rates leading to fewer diagnoses may partly explain the results. Later recognition of cancer in a more advanced stage of the disease may be associated with premature deaths and lead to lower prevalence rates. Certain oncological diseases such as malignant neoplasms of the central nervous system, urogenital tumors and hematological neoplasms require a special focus in prevention and therapy. Medical services, screening programs and patient education for people with ID need to be established, adapted and expanded to meet the needs of people with ID and to reach this highly vulnerable population group for guideline-based oncological screening and treatment. Research Sponsor: None.

Racial disparities in presentation and survival for lobular breast cancer.

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Background: We characterized differences in presentation and survival, and identified predictors of survival, among women of varying race with lobular breast cancer. We also assessed if these trends were unique to ILC by comparing with invasive ductal carcinoma (IDC) and mixed invasive ductal-lobular carcinoma (IDLC). **Methods:** Using the SEER database, we performed a population-based retrospective cohort study of women diagnosed with ILC, IDC, and IDLC between 1998 and 2019. We collected race, age, marital status, and income. Clinical data included grade, size, laterality, clinical stage, receptor status, surgery type, chemotherapy, radiation, and breast-cancer-specific survival (BCSS). Differences between racial groups were assessed using Chi-square tests or one-way ANOVA. To identify predictors of survival, Cox-proportional hazard models were constructed. Statistical analyses were performed using SAS and P values < 0.05 were considered significant. **Results:** 38,769 women with ILC were identified, including 32,857 White, 2398 Black, 2352 Asian, and 1162 women of other race. Black women presented with higher-grade, advanced clinical stage, ER+ disease, N2-3 stage, and lower rates of unilateral/bilateral mastectomy than White women. Black women were more likely to not undergo surgery (7.13%), compared with White (4.25%) and Asian (4.04%) women ($P = .0001$). Asian women were younger, had more ER-/PR- ILC, and received more chemotherapy. The five-year BCSS rates in Black, White, Asian, and women of other race were 91.5%, 94.2%, 93.7%, and 95.7%, respectively ($P < .0001$). Predictors of worse survival include Black race (HR 1.32, $P < .0001$), ER-/PR- (HR 2.18, $P < .0001$), ER+/PR- (HR 1.52, $P < .0001$), and no surgery (HR 4.19, $P < .0001$). Radiotherapy was associated with improved survival (HR 0.82, $P < .0001$), while chemotherapy did not affect survival (HR 1.1, $P = 0.0504$). In comparing across breast cancer subtypes, Black women similarly present with higher grade tumors, advanced clinical stage, ER+ disease, and had higher rates of surgery omission in IDC and IDLC. However, ER-/PR- subtype was notably higher in ILC among Asian women compared with IDC, whereas Black women have higher rates of ER+/PR+ and ER-/PR- ILC. Black women had the lowest five-year BCSS rates across all breast cancer subtypes. Predictors of worse survival in IDC and IDLC include Black race and negative hormone receptor status, while radiation therapy was associated with improved survival. **Conclusions:** There are differences in clinical presentation of invasive lobular breast cancer according to race. Black women had more advanced disease, while Asian women were younger. Across all subtypes, overall survival for Black women at 5 years was worse compared to other racial groups. Our data provides insight into the complex interactions of race, clinical characteristics, and survival outcomes in lobular breast cancer, with implications for screening considerations. Research Sponsor: None.

Long term impact of COVID-19 pandemic on mammographic breast cancer screening.

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Background: The impact of COVID19 pandemic on patient health beliefs and healthcare systems has adversely affected mammographic breast cancer screening (MBCS) during the initial stages of the pandemic. The aims of our study were to determine whether the initial decrease in MBCS rates persisted or if there was a rebound in later stages and to quantify the impact on urban and rural populations. **Methods:** This retrospective observational study analyzed data from March 2017 to March 2023 to assess whether eligible women received annual MBCS during this timeframe. We included women aged 40–75 years, drawn from the integrated Mayo Clinic system, encompassing nearly 60 primary care practices in Arizona, Florida, Iowa, Minnesota, and Wisconsin, representing a broad cross-section of the United States (US) population. US census data was utilized to classify a county as urban or rural. We divided the study period into 4 categories: 1) pre-COVID-19 pandemic (March 1, 2017–March 10, 2020), 2) early pandemic (March 11, 2020–March 10, 2021; pre-vaccination period), 3) mid-pandemic (March 11, 2021–March 10, 2022; delta and omicron variant dominant period), and 4) late pandemic (March 11, 2022–March 1, 2023; recovery period). Utilizing the Poisson regression model, we compared the incidence rate ratio (IRR) for rates of MBCS across the 4 predefined time periods. Multivariable modeling was performed to assess the significance of MBCS rates with urbanicity while controlling for the year (2017–2022) and age. **Results:** By race and ethnicity, the women in this cohort were White (92%), Black (3.1%), Asian (3%) and other (1.9%). The median age was 57 years and the cohort included 239,804 women aged 40–75 years. MBCS rates were 49.2% in 2017, 47.1% in 2018, 46.4% in 2019, and decreased to 42.1% in 2020 and improved to 44.7% in 2021 and 43.8% in 2022. Compared with the pre-COVID-19 pandemic period, there was a significant decrease in MBCS rate in the early pandemic (IRR= 0.886, 95% CI 0.879, 0.892, $p<0.001$). Though the MBCS rate improved in the mid-pandemic period, it remained below the pre-pandemic level (IRR=0.941, 95% CI 0.934, 0.948, $p<0.001$). Similarly, during the late stage of the pandemic, the MBCS rate remained lower than the pre-pandemic level (IRR=0.922, 95% CI 0.915, 0.928, $p<0.001$). Rural counties had a lower MBCS rate compared with urban counties (IRR = 0.936, 95% CI 0.931, 0.941, $p<0.001$). **Conclusions:** This study confirms the negative impact of the early COVID-19 pandemic on MBCS, and it revealed its persistent effect, as the current MBCS rate remains below the pre-pandemic rate. These findings were more evident in rural counties. Factors contributing to the long-lasting impact are being analyzed with the intent to develop and implement targeted solutions to improve the MBCS rate. Research Sponsor: Mayo Clinic Health System.

Persistent poverty impacts survival and National Comprehensive Cancer Network guideline-concordant care for patients with melanoma.

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Background: Based on guidelines from the National Comprehensive Cancer Network (NCCN), sentinel lymph node biopsy (SLNB) should be offered to patients with high-risk stage IB or stage II melanoma and adjuvant systemic therapy is recommended for patients with stage III disease. Persistent poverty census tracts are defined as areas where at least 20% of residents were poor as measured by each of the 1980, 1990, 2000 censuses and 2007 American Community Survey 5-year average. The aim of this study was to describe the association between persistent poverty and adherence to NCCN guidelines and cancer-specific survival in patients with cutaneous melanoma. **Methods:** Patients diagnosed with melanoma from 2006–2018 were identified in Survival, Epidemiology, and End Results (SEER) Program registries. The analytic cohort was restricted to patients with superficial spreading melanoma, nodular melanoma, malignant melanoma with regression, lentigo malignant melanoma, and acral lentiginous melanoma. Patient demographics such as age, race, and ethnicity and tumor characteristics associated with stage at diagnosis were analyzed using adjusted regression analyses for patients of all melanoma stages. Demographics and tumor characteristics associated with receipt of SLNB were analyzed amongst pathologic stage IB and II cases, and demographics and tumor characteristics associated with receipt of adjuvant systemic therapy were analyzed amongst stage III cases. Kaplan–Meier curves and adjusted accelerated failure time models were used to examine disparities in cancer-specific survival. **Results:** Of 127,308 total patients, 3.13% (n=3994) lived in census tracts with persistent poverty. In adjusted analyses, persistent poverty was an independent predictor of later pathologic stage at diagnosis (OR 1.32 [95% CI 1.21–1.44] $p<0.001$). Persistent poverty was also associated with lower likelihood of receiving SLNB according to NCCN guidelines (OR 0.717 [SE 0.072] $p<0.01$) and with worse cancer-specific survival (HR 1.25 [1.06–1.47], $p=0.008$) when controlling for age, race, ethnicity, pathologic stage at diagnosis, and histology. In univariable models persistent poverty was associated with increased odds of receiving systemic therapy, but this relationship was not significant on multivariable analysis. **Conclusions:** Patients from areas with persistent poverty had a later pathologic stage at diagnosis, were less likely to receive a SLNB according to NCCN guidelines, and had worse cancer-specific survival. Efforts to better define and resolve disparities in the treatment and survival of patients with melanoma are warranted. Research Sponsor: None.

Disparity in oncology therapy access and differences in clinical pathological features and outcomes in indigenous population lung cancer (LC): A retrospective study from Martinique.

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Background: The epidemiology of cancers in terms of incidence and mortality are different in the French overseas compared to mainland France (FRANCIM 2019 data). Indigenous population are under-represented in clinical trials. Little is known about clinic-pathological features and outcomes from Caribbean islands. We report clinico-pathological features and survival in populations of patients with lung cancer (LC) and delays in access to therapy in Martinique. **Methods:** We conducted an academic retrospective study on patients with lung cancer (LC), treated at the University Hospital in Martinique between 2020–2022. The hospital in Martinique centralized all cancer patients in the territory for treatment. Demographic, risk factors, disease features, and treatment outcomes were collected from medical records. The molecular profile was determined using next-generation sequencing with the Archer FUSION-Plex Lung v2 panel, evaluating at least *EGFR*, *ALK*, *KRAS*, *ERBB2*, *MET*, *ROS1*, *BRAF*, *RET*, *NUTM1*, *PIK3CA*, *FGFR1*, *FGFR2*, *FGFR3*, *NRG1*, *NTRK1*, *NTRK2*, *NTRK3*. We assessed time from symptoms to diagnosis and treatment, and overall survival (OS). **Results:** Overall, 268 patients (pts) were included. Pts were male in 51% cases (N=136), had a smoking history in 57% (N=139/243), with a median pack-years of 40 [IQR 22–50]. Median age was 67 years-old [IQR 58–78]. Histology was adenocarcinoma in 78% (N = 208), squamous cell in 13% (N=34), neuroendocrine tumors in 8% (N=21), and others in 2% (N=5). No small cell carcinoma diagnosed. Tumors had high PD-L1 expression ($\geq 50\%$) in 18% (N=41/227) of cases. An oncogenic addiction was reported in 58% (N =105/181) of non-small cell and non-squamous lung carcinoma: *EGFR*36% (N=65), *ALK*3.3% (N=6), *BRAF*1.1% (N=2), *KRAS*13.3% (N=24). Pts had an ECOG performance status of 0–1 at diagnosis in 66% (N =162/244). LC was metastatic from diagnosis in 65% cases (N=175), with 18% having brain metastases (N=48). Median time between symptom occurrence and diagnosis was 66 days [IQR 21–171] and time between biopsy and treatment start was 56 days [IQR 31–77]. In pts with stage IV disease, 33% (N=59/175) never received a systemic treatment. In patients with at least 6 months of follow-up in the absence of death, median OS was 12.4 months (95% CI 8.6 – 17.1) overall and 8.6 months (95% CI 5.3 – 13.3) in patients with initial metastases. **Conclusions:** The lower overall survival rate than expected in this cancer context address the question of disparity population. One-third of LC metastatic patients did not receive systemic therapy. The local inadequacy of care pathways, leading to disparities in access to imaging, may explain the delays and poorer prognosis. A new initiative from a collaborative group with health authorities, caregivers, politicians and patient's advocacy is actively working to improve cancer patient's outcomes. Research Sponsor: None.

Racial, ethnic, and regional influences on national patterns of mammographic screening for breast cancer.

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Background: Racial, ethnic, and geographic factors can affect disparities in medical care. Mammographic screening has been demonstrated to reduce the risk of breast cancer death for appropriate subsets of women and accordingly is an accepted standard recommendation. Herein, we studied the utilization in screening mammography in patients who have access to primary care physicians according to race, ethnicity, and United States geographic region.

Methods: We queried the Cosmos Epic national database to ascertain mammographic screening rates for women aged 50 to 65 who had 1 or more encounters with a primary care physician. Patients with a previous breast cancer and/or ductal carcinoma in situ history and those with missing race or ethnicity data were excluded. **Results:** The COSMOS database was queried for the period of 11/9/2020 – 11/8/2023. A total of 7,837,164 individuals met our study criteria. The overall rate of positive mammographic screening was 63.8%. Because of the large sample size, small differences in screening rates according to analyzed variables reached statistically significant differences. Accordingly, we defined a clinically relevant low rate of mammography screening for a specific variable as a utilization rate of less than 60%. Using this methodology, there were no differences noted according to race. Both Black/African American and Asian groups had a slightly higher screening rates than Whites. However, the data indicate that rates varied according to ethnicity. Mammographic screening was less frequent in Hispanic/Latino versus not Hispanic (58.9% vs. 64.3%). In addition, rates varied according to census US regions with the lowest rates in the West region (55.5%). Rates of mammographic screening for Blacks/African American and Whites were within 5% of one another in all four of the geographic regions. With respect to ethnicity, the South region had the only difference exceeding 5%, with respective rates of 61.8% for Not Hispanic/Latino versus 55.7% for Hispanic Latino.

Conclusions: Many patients receiving health care in the United States do not undergo recommended mammogram screening. We found no clinically significant difference in screening rates according to race but identified a lower rate in Hispanic/Latino populations, particularly in the South. Targeted educational efforts and community outreach efforts in this region are warranted. Research Sponsor: Kreuger vs. Wyeth settlement.

Racial/ethnic representation and disparities in preclinical cancer models.

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Background: Patient-derived xenograft models (PDXs) recapitulate tumor characteristics credibly and have become a standard for preclinical inquiries that form the basis of clinical trials of novel therapies in oncology. While ample evidence reveals racial/ethnic disparities in cancer care delivery and clinical research, limited data exists regarding racial composition of available PDXs. We sought to define the extent of racial/ethnic representation and disparities among existing PDXs. **Methods:** Data regarding available PDXs was gathered from the publicly accessible CancerModels.org website (<https://www.cancermodels.org/overview>). Seven members of the research team were involved in data extraction. Information on race/ethnicity (White, Black, Hispanic, Asian), sex, age, and cancer type were recorded. The primary objective was to determine the racial/ethnic composition of PDX models and compare this to racial/ethnic demographics of cancer patients, for which we used US population-based cancer estimates calculated using National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER Incidence Data, 11/2022 Submission (1975 - 2020), SEER 22 registries). Descriptive statistics were used. Proportions were compared using Fischer's exact test or Chi-squared tests with Yates' correction (odds-ratio [OR] and 95% confidence intervals [95%CI] or Woolf logit interval) were reported. **Results:** We reviewed 4597 unique PDXs across 33 SEER cancer sites spanning 11 oncology sub-specialties. Of these, 55% models were derived from males and age groups were (years): < 20: 6%; 20-70: 69% and ≥ 70: 25%. Most common cancer sites represented were colorectal (26%), lung (12%), breast (9%), melanoma (9%) and leukemia (7%). Race/ethnicity was not reported in 3395 (73.9%) cases. Racial/ethnic composition of the remaining models was Whites (80.9%), Blacks (7.3%), Hispanics (6.4%) and Asians (5.4%). Compared with their respective proportion of US cancer incidence (69.9%, 10.9%, 13.2% and 5.9%, respectively), these models were over-representative for Whites (OR: 1.82, 95%CI: 1.6-2.1, $P < 0.001$) and under-represented Blacks (OR: 0.64, 95%CI: 0.5-0.8, $P < 0.001$) and Hispanics (OR: 0.45, 95%CI: 0.4-0.6, $P < 0.001$) but not Asians (OR: 0.89, 95%CI: 0.7-1.2, $P = 0.43$). Similar trends were seen in subgroups focused by cancer site. Among colorectal (N = 1201) models, race/ethnicity was reported for 17.2% of cases and Blacks (OR: 0.52; 55.7% of expected; $P = 0.014$) and Hispanics (OR: 0.57; 60.8% of expected; $P = 0.015$) were underrepresented compared to Whites (OR: 1.82; 116% of expected; $P < 0.001$). **Conclusions:** Race/ethnicity are infrequently reported for PDX models. Minority races/ethnicities (Blacks and Hispanics) are underrepresented in preclinical models compared to their burden of cancer incidence. There is a need to develop a diverse repertoire of preclinical models to ensure inclusivity and guide equitable research. Research Sponsor: None.

Racial/ethnic inequities in care for patients with advanced endometrial cancer: What's structural racism and social determinants of health got to do with it?

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Background: Structural racism and social determinants of health (SDOH) have been linked to inequities in cancer care and outcomes. However, little is known about the contribution of such factors to care inequities among patients with endometrial cancer, where Black women experience a nearly two-fold increased risk of death relative to their White counterparts. We examined the role of structural racism and SDOH in explaining racial/ethnic inequities in care for patients with advanced endometrial cancer (aEC). **Methods:** This retrospective study used the nationwide Flatiron Health electronic health record (EHR)-derived de-identified database, focusing on patients diagnosed with aEC from January 2013 to September 2023 (follow-up through December 2023). Outcomes included time-to-treatment initiation, use of immunotherapy or targeted therapy, biomarker testing, and clinical trial participation. We estimated a series of multivariable Cox proportional hazards models assessing racial/ethnic inequities in outcomes, sequentially adjusting for clinical factors (e.g., age, stage at diagnosis) followed by structural racism (residential segregation) and SDOH factors (e.g., insurance, practice setting, area-level vehicle ownership). **Results:** The cohort included 5,496 patients (2.2% Asian, 14.8% Black, 5.2% Latinx, 61.4% White, and 16.0% Other/Unknown). Although diagnosed with more aggressive disease (37% vs. 21% serous carcinoma), Black patients were less likely than White patients to initiate treatment during follow-up (hazard ratio [HR]=0.91 [95% CI: 0.83-0.99]), participate in a clinical trial (HR=0.56 [95% CI: 0.38-0.84]), and receive biomarker testing (HR=0.88 [95% CI: 0.81-0.97]). Compared with their White counterparts, Latinx patients were less likely to participate in a clinical trial (HR=0.41 [95% CI: 0.19-0.87]). Black-White (HR=0.80 [95% CI: 0.47-1.38]) and Latinx-White (HR=0.71 [95% CI: 0.31-1.60]) inequities in clinical trial participation were partly explained by structural racism and SDOH factors, while Black-White inequities in treatment and biomarker testing remained largely unchanged following structural and social determinants adjustment. We saw no racial/ethnic differences in use of immunotherapy or targeted therapy. **Conclusions:** We observed racial/ethnic inequities in treatment initiation, biomarker testing, and clinical trial participation among patients with aEC, with structural racism and SDOH substantially accounting for inequities in trial participation. Thus, findings from this study suggest that efforts aimed at improving diversity in endometrial cancer trials, and overall equity in endometrial cancer outcomes, should prioritize mitigating the structural and social barriers to clinical trial participation. Research Sponsor: Flatiron Health.

Exploring health disparities in prostate cancer through circulating tumor DNA analysis.

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Background: African American men (AAM) suffer from the highest rates of prostate cancer in the world. In addition, AAM experience the highest rates of aggressive prostate cancer and prostate cancer-specific mortality of any ethnic group in the United States [1, 2]. The reasons behind the increased burden of prostate cancer poor outcomes in AAM remain unresolved. A large proportion of variation in prostate cancer mortality remains unexplained solely by epidemiologic risk factors. We investigated genomic differences between AAM and Caucasian men with metastatic castration resistant prostate cancer (mCRPC) utilizing circulating tumor DNA (ctDNA) analysis. **Methods:** AAM and Caucasian men with mCRPC were enrolled in this study. We collected and analyzed 88 plasma samples, including 66 from Caucasian and 22 from African American patients, with no significant age difference between the groups. The targeted sequencing libraries were prepared following the Agilent SureSelect XT HS2 target enrichment workflow coupled with the SureSelect custom prostate cancer panel (Agilent, Inc.). The final libraries were sequenced on an Illumina NextSeq 2000 to generate 150 bp paired-end reads.

Results: A total of 88 men with mCRPC were enrolled. About 60% of African American patients exhibited organ metastasis at the time of diagnosis, while this proportion was 36% for Caucasian patients and they primarily reported metastasis during relapse. Analyzing 1824 variants in 138 genes meeting inclusion criteria, 281 significant mutations across 88 genes revealed racial differences. Notably, 29% of these variants were somatic. Approximately 60 cancer-related pathways, tissues, and diseases were identified from these datasets, encompassing 59 of our significant genes. Among these associated genes, the prevalence of significant variants, higher in AAM, exceeds that in Caucasians in 76% of cases. The top genes that have more contribution in considering pathways are shown (Table). **Conclusions:** Genomic variations were observed in ctDNA analysis between African American and Caucasian patients diagnosed with metastatic castration-resistant prostate cancer. Our findings highlight the potential inclusion of ctDNA analysis in the clinical assessment of these patients, offering valuable insights for informed therapeutic decision-making. The top genes with the most contribution to prostate-related pathways. Research Sponsor: The 100 Voices of Hope; Showalter Trust; Indiana University Melvin and Bren Simon Comprehensive Cancer Center; Brown Center for Immunotherapy; Heroes Foundation.

No.	Gene	Frequency In Prostate-Related Pathways	Number Of Significant Variants Which are Higher In AAM	Number Of Significant Variants Which are Higher In Caucasian
1	AR	49	1	0
2	KLK3	35	1	0
3	TP53	31	0	2
4	PTEN	30	1	0
5	AKT1	27	5	0
6	CCND1	22	2	0
7	TMPRSS2	22	7	1
8	CTNNB1	21	1	0
9	ERG	20	0	2

Improving ethnic and racial diversity in biomarker-driven clinical trials: A proof of concept with the BASECAMP-1 master prescreening study of patients with high-risk solid tumors with human leukocyte antigen-A*02 (HLA-A*02) loss of heterozygosity (LOH).

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Background: Diversity in clinical studies is essential to address health disparities, but racial and ethnic minorities are often underrepresented in clinical studies, especially in precision medicine studies using genetic data (1). BASECAMP-1 (NCT04981119) is an ongoing prescreening study to identify patients with unresectable advanced or metastatic solid tumors and tumor-associated HLA-A*02 LOH for the EVEREST-1 and -2 Tmod chimeric antigen receptor T-cell therapy trials. When enrollment began in 2021, eligibility for Part 1 was restricted to patients with germline HLA-A*02:01 based on preclinical data. Additional analysis revealed the blocker in the Tmod construct had activity across HLA-A*02 subtypes (Mock, et al. *Mol Ther Oncolytics*.2022). Eligibility for Part 1 was then expanded to all HLA-A*02 subtypes, allowing enrollment of more diverse patient populations. HLA-A*02 allele subtypes vary by ethnicity and race; the frequency of HLA-A*02:01 is 96% in non-Hispanic Whites, but ranges from 53% to 73% in other ethnicities and races. The frequency of all other HLA-A*02 allele subtypes (HLA-A*02:XX) is <5% in non-Hispanic Whites but up to 66% in other ethnicities and races (2,3). **Methods:** Patients eligible for BASECAMP-1 were identified at United States study sites. All patients screened before January 16, 2024, for Part 1 were included for demographic and central lab HLA-A typing. The % increase in eligibility and % of heterozygous HLA-A*02 patients with HLA-A*02:XX were calculated by ethnicity and race. **Results:** A total of 1124 patients were screened for germline HLA-A*02 typing; 431 patients were HLA-A*02:01 heterozygous, of whom 37 (9%) were Hispanic, 14 (3%) African American (AA), 2 (<1%) American Indian or Alaska Native, 17 (4%) Asian or Pacific Islander (API), and 324 (75%) non-Hispanic White (Table). The eligibility expansion identified 62 patients with HLA-A*02:XX heterozygosity, of whom 6 (10%) were Hispanic, 6 (10%) AA, 19 (31%) API, and 25 (40%) non-Hispanic White. **Conclusions:** By expanding enrollment to include HLA-A*02:XX, 16% more Hispanic, 43% more AA, and 112% more API patients were identified, improving the diversity in this trial compared with that of initial enrollment. 1. Aldrighetti, et al. *JAMA Netw Open* 2021. 2. Ellis, et al. *Human Immunol*. 2000. 3. Gragert, et al. *Human Immunol*.2013. Clinical trial information: NCT04981119. Research Sponsor: A2 Biotherapeutics, Inc.

BASECAMP-1 Patients screened by ethnicity, race, and heterozygous HLA-A*02 subtype.						
	Race					
	Hispanic/ Latino	African American	American Indian/ Alaska Native	Asian/ Pacific Islander	Non- Hispanic White	Unknown/ Other/Not Specified
Total patients screened, n	96	51	3	85	724	98
HLA-A*02 Type, n	43	20	2	36	349	45
A*02:01	37	14	2	17	324	36
A*02:XX	6	6	0	19	25	9
No HLA-A*02 Type, n	53	31	1	49	375	53
Eligibility increase, %	16	43	0	112	8	25
A*02:XX of total A*02, %	14	30	0	53	7	20

Unveiling inequities in representation: Racial disparities in supportive care breast cancer clinical trial enrollment.

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Background: Supportive care is an integral part of breast cancer survivorship care. However, not much is known if there is adequate representation of racial minorities in supportive care breast cancer (BC) clinical trials (CTs). **Methods:** We conducted a systematic review of supportive care CTs for patients with BC using Covidence. A search of clinicaltrials.gov identified 2695 CTs, of which 173 met inclusion criteria. The SEER database was used as a racial distribution data reference for patients with BC. One-sample proportion tests were performed to assess adequacy in racial representation among supportive care CTs and by intervention type. **Results:** Of 173 supportive care CTs, 133 (77%) trials reported race-specific data. Characteristics of supportive care CTs based on intervention type and race are shown (Table). Although no statistically significant differences in frequencies of Black participants in supportive BC CTs overall were observed compared to the US population (11% vs 12%, $p = 0.40$), they were underrepresented in symptom management CTs specifically (8% vs 12%, $p = 0.004$). When stratified based on diet/physical activity CTs, Black participants were overrepresented in the study population (18% vs 11%, $p = <0.001$). Asian participants were underrepresented in the overall study population compared to the US population (5% vs 7%, $p = 0.01$). However, within psycho-oncology CTs, there was an overrepresentation of Asian participants in the study population (21% vs 7%, $p = <0.001$). No significant differences in enrollment frequencies of Black and Asian participants were found in cognitive health, complementary and alternative medicine, education/communication, and sexual health interventional CTs. **Conclusions:** Our findings highlight inadequate representation of Asian participants in supportive care BC CTs and Black participants in symptom management CTs. This study is limited in that ethnicity was not included in this analysis. Strategies are needed to promote recruitment of diverse individuals in these settings so that we can more accurately generalize findings from supportive care BC CTs. Research Sponsor: None.

	All Participants	Black Participants N(%)	P-Value (95% C.I.)	Asian Participants N(%)	P-Value (95% C.I.)
Overall	17,496	1,929 (11%)	0.40 (0.10, 0.12)	960 (5%)	0.01 (0.04, 0.06)
Diet/physical activity	3,590	635 (18%)	<0.001 (0.15, 0.21)	41 (1%)	0.13 (-0.02, 0.04)
Cognitive health	165	17 (10%)	0.84 (-0.04, 0.24)	9 (5%)	0.80 (-0.09, 0.19)
Symptom management	7,730	649 (8%)	0.004 (0.06, 0.10)	527 (7%)	0.90 (0.05, 0.09)
Psycho-oncology	1,105	65 (6%)	0.16 (0.002, 0.12)	231 (21%)	<0.001 (0.16, 0.26)
Complementary and alternative medicine	1,147	137 (12%)	0.89 (0.07, 0.17)	46 (4%)	0.41 (-0.02, 0.10)
Education / Communication	3,174	373 (12%)	0.82 (0.09, 0.15)	79 (2%)	0.07 (-0.01, 0.05)
Sexual Health	585	53 (9%)	0.55 (0.01, 0.17)	27 (5%)	0.67 (-0.03, 0.13)
SEER	NA	(12%)	NA	(7%)	NA

Global disparities in immunotherapy clinical trials: A comprehensive analysis of low- and middle-income countries over the past decade.

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Background: Immunotherapy (IO) has largely impacted cancer treatment over the last decade, yet its accessibility and representation in clinical trials remain severely limited in low- and middle- income countries. We investigated the involvement of these countries in IO cancer trials, analyzing country-specific rates and influencing factors. **Methods:** Data was obtained from clinicaltrials.gov. Advanced search focused on cancer interventional studies from 12/31/2013 to 01/01/2024 with specific IO treatments. Only completed trials were included. Studies unrelated to immunotherapy or cancer were excluded. Country trial rates were calculated per 100k population. Statistical analysis used Chi-square test for nominal data. **Results:** Of 1593 trials, 1282 were included in the final analysis. Of world's 217 countries and regions (World Bank) 72 (33.2%) participated in IO cancer trials in the last decade. Zero country from low-income group was involved in the trials. Only 2.4% (31) of all trials, included lower-middle-income countries (LMICs). Out of 54 LMICs, only 8 were represented: Ukraine, Philippines, India, Guatemala, Egypt, Vietnam, Morocco, and Eswatini (Swaziland). Ukraine led this group with 16 trials, while the remaining 7 were included in less than 10 trials each. Upper-middle-income countries (UMICs) were included in 21.3% (273) of trials. Out of 54 UMICs, 22 were involved in the trials; China led this group (174), followed by Russia (69), Brazil (52), Mexico and Turkey (41 each). Among the top 30 countries with the highest trial participation, none included LMICs, and only 5 were UMICs. Of 81 high-income countries (HICs) 42 participated in IO trials. USA was involved in over 65% of all trials (840), followed by Spain (222), France (193), and Canada (180). However, population-adjusted rates varied, with European HICs like Latvia (2.16), Belgium (1.09), Norway (0.87) among 25 other countries, showing higher rates than USA (0.25). Majority of trials done solely in one country were also from USA (65%), and China (79%). A significant link was found between the economic status of participating countries and the funding source of trials ($p < 0.00001$). Industry funded 28 of 31 (90%) trials in LMICs, indicating a reliance on industry funding in these regions. Industry favored adult-only over pediatric-inclusive trials ($p < 0.0001$). Out of 80 trials (6.24%) including children, 22 were industry-funded. Exclusively pediatric IO trials were only 4 (0.3%) of all IO trials. LMICs participated in 3.75% (3) of all pediatric-inclusive trials. **Conclusions:** Countries with low economic status and children with cancer from both low- and high-income areas are largely underrepresented in IO cancer trials globally. More inclusive IO trials across age groups and LMICs are vital to implement trial results in real-world settings and close the care gap. Research Sponsor: None.

Decentralized trial recruitment methods to facilitate broad coverage across urban and rural counties for a blood-based test in early colorectal cancer detection.

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Background: Based on the 2022 census, 20% of the U.S. population lives in rural areas. Recent literature suggests that individuals in these areas may encounter health disparities, potentially leading to higher mortality from colorectal cancer (CRC) when compared to their urban counterparts. The PREEMPT CRC is a prospective, multicenter clinical study designed to validate an investigational blood test (MyTectCRC) intended to provide a convenient and accessible option for CRC screening. PREEMPT CRC included a decentralized clinical trial (DCT) site to broaden enrollment from a wider range of geographical areas, including traditionally underrepresented rural regions. This analysis evaluates demographic characteristics of participants from rural and urban areas enrolled in two distinct strategies within the DCT sites.

Methods: Eligibility criteria for PREEMPT CRC have been previously described (NCT04369053). All DCT activities occurred under one clinical study 'Metasite', enabled by a multichannel recruitment strategy that included 1) Direct-to-Participant (DTP) via digital enrollment and 2) Site-Based (SB) partners who supported the principal investigator by identifying participants scheduled to receive a screening colonoscopy. Participant zip codes were mapped to local counties and aligned with either 1) Metropolitan (Urban) or 2) non-Metropolitan (Rural) counties. Enrolled participants were analyzed for demographics and lifestyle behaviors such as tobacco, alcohol, and drug use. **Results:** The DCT site enrolled 12,137 participants, where 7,634 used DTP and 4,503 used SB. Of all DCT participants, 24.4% resided in rural areas. DTP's rural population recruitment (27.8%) was double that of the SB (13.5%). The female and male distribution was similar across the groups. A larger percentage of participants from underrepresented races overall were enrolled from urban areas; however, there were some noticeable trends in the rural population. For participants who resided in rural areas and reported their race, 12.5% of DTP participants were Black and 1.2% were Asian, compared to 9.6% and 1.2%, respectively, in SB. For participants in rural areas who reported ethnicity, within DTP, 5.1% identified as Hispanic/Latinx, compared to 14.3% Hispanic/Latinx in SB. Lifestyle behavior factors were similar between DTP and SB participants who resided in rural and urban areas.

Conclusions: Through the use of a DCT, the PREEMPT CRC study reached rural areas especially through DTP methodology. Furthermore, the use of SB versus DTP showed certain shifts in demographics, these differences highlight the effectiveness of targeted outreach strategies and reflect the importance for integration of multiple methods and tools to enhance essential population characteristics across geographical locations. Clinical trial information: NCT04369053. Research Sponsor: Freenome.

Assessing survival effects of persistent poverty and payer status in non-elderly adults with lung or breast cancer.

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Background: Persistent poverty (PP), defined as area poverty $\geq 20\%$ over 30 years has been associated with increased cancer incidence and worse survival. We examined 1) whether re-siding in a PP area has larger survival effects than areas with similar contemporary poverty rates; 2) whether adjusting for sociodemographics and payer status reduces PP effects; and 3) whether effects differ for relatively poor (lung and bronchus, LCa) vs good prognosis (female breast; BrCa) cancers. **Methods:** We used Surveillance, Epidemiology, and End Results (SEER) data linked to Medicaid and Medicare enrollment records (2007–2013), with census-tract level indicators for PP and current poverty (CP) as of 2010. We selected adults aged 19–64, diagnosed with LCa or BrCa. We created a hierarchical poverty status measure (PP, CP $> 20\%$, CP 10–20%, CP $< 10\%$). Primary payer at diagnosis (SEER) was edited using Medicaid and Medicare enrollment records. Covariates include patient sociodemographics (including age, race, sex (LCa only), marital status), rurality, and region. We used Cox proportional hazard models to estimate effects of poverty status and payer on survival, starting with a limited Model I (poverty status, rurality, and cancer stage), adding sociodemographics, region, and diagnosis year (Model II), plus primary payer (Model III). **Results:** Among LCa (BrCa) 8.8% (5.3%) of 70,964 (246,405) patients lived in PP areas, with 19.1% (13.7%) in areas with CP $> 20\%$; primary payers included 51.9% (75.0%) private, 28.7% (16.9%) Medicaid, and 3.1% (1.1%) uninsured. For both cancers, adjusted hazard of death increased with increasing poverty levels; PP areas showed the highest risk (table). The magnitude of the poverty gradient was smaller for LCa vs BrCa. Adjusting for sociodemographic measures and primary payer reduced the magnitude of poverty status effects, particularly for BrCa. **Conclusions:** We observed significant but distinct associations of poverty status, including PP, with survival for non-elderly adults with LCa and BrCa. With better prognosis, BrCa patients have longer exposure to PP, which may increase the impact on outcomes. Person-level characteristics and health insurance are also key factors affecting care access and survival. These results highlight the need to consider both area context and personal socioeconomic characteristics when targeting and evaluating interventions to enhance survival outcomes. Research Sponsor: None.

Adjusted HR, cancer-related deaths, cancers of lung and bronchus, female breast.

	LCa Model I	LCa Model II	LCa Model III	BrCa Model I	BrCa Model II	BrCa Model III
Poverty, CP $< 10\%$ (ref)	-	-	-	-	-	-
CP 10–20%	1.16*	1.12*	1.09*	1.28*	1.19*	1.12*
CP $> 20\%$	1.26*	1.22*	1.16*	1.57*	1.34*	1.19*
PP	1.29*	1.25*	1.18*	1.73*	1.44*	1.25*
Private Payer, Private (ref)			-			-
Medicaid			0.99			1.44*
Medicare-Dual			1.06 [#]			2.13*
Uninsured			0.91			0.84 [^]

*p < 0.001 [#]p < 0.01 [^]p < 0.05 .

The effect of a multilevel community health worker-led intervention on patient knowledge and receipt of precision medicine: Updated findings from a randomized clinical trial.

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Background: Inequitable access to precision medicine limits its impact. To address disparities, we co-developed a 2-part multi-level intervention with community stakeholders, called the Addressing Latinx CANcer Care Equity Study (NCT04843332). The intervention was designed for low-income and Latinx adults with cancer in rural Monterey County, California. We provided annual training for clinicians about testing guidelines and precision medicine disparities. Trained community health workers educated patients about precision medicine and encouraged them to raise the topic with their oncologist. We tested whether the intervention improved patient knowledge and receipt of precision medicine. **Methods:** Patients with newly diagnosed or recurrent cancer, age ≥ 18 years, able to consent in English or Spanish, and who self-identified as a racial and ethnic minority OR low-income status OR were insured by public or agricultural company insurance OR uninsured and receiving cancer care at Pacific Cancer Care, a rural community oncology practice in Monterey County, were randomized 1:1 to usual care (control group) or usual care augmented with the multi-level intervention for 12 months (intervention group). The primary outcome was whether the multilevel intervention could increase patient knowledge of precision medicine using a validated 6-question survey from the time of enrollment (baseline) to 6 months post-enrollment between groups. A secondary outcome was the receipt of precision medicine. Patients were followed for 12 months. **Results:** 110 participants were randomized; 70% (n = 67) reported Spanish as their primary language; 81% (n = 89) identified as Hispanic. The median age was 55 years (55.4 ± 14.3 , mean \pm SD); the majority had annual household incomes (USD) \leq \$34,999 (59.0%, n = 46); the majority obtained a high school diploma/GED or less (67.3%, n = 74). Most had gastrointestinal (35.5%, n = 39) and breast (24.5%, n = 27) cancers and were diagnosed with stage 3 or 4 (64.5%, n = 71) disease. Precision medicine knowledge was low at baseline across both the control and intervention groups (23.5 ± 19.3 versus 23.0 ± 17.7 , respectively). Intervention group participants had greater precision medicine knowledge at 6 months (39.2 ± 23.0) than control group participants (24.2 ± 20.0) with a greater increase in knowledge over time than control group participants (p < 0.001). More intervention group participants (n=46, 79.3%) received precision medicine testing than control (n=34, 60.7%). Across both groups, 26 of those tested had an actionable mutation. Of those 26, 66.7% (n=6 of 9) in the control group and 94.1% (n=16 of 17) in the intervention group received targeted therapy (p=0.065). **Conclusions:** CHW-facilitated interventions may reduce disparities in precision medicine cancer care. Clinical trial information: NCT04843332. Research Sponsor: None.

Role of social determinants burden on outcomes and survival for AYAs with cancer.

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Background: Health care utilization and survival are correlated with social determinants of health (SDoH). Minimal data exists on the impact of SDoH within AYA Oncology. **Methods:** TriNetX, a de-identified healthcare research database retrospectively examined presence of SDoH billing codes among AYA cancer patients at various time points. Three cohorts were evaluated: ages <15, 15-39, >39. Cox proportional hazards regression was used to assess predictors of SDoH burden and survival in AYAs. **Results:** Baseline demographics were similar across cohorts. AYAs had higher baseline SDoH (25811, 5.2%) compared to <15 (3913, 2.9%) and >39 (58237, 1.8%). After diagnosis, AYAs had greater incidence of SDoH burden at 1y (OR 1.86 vs <15, 2.71 vs >39), 3y (OR 1.79 vs <15, 2.63 vs >39), and 5y (OR 1.8 vs <15, 2.5 vs >39). AYAs with any SDoH had higher occurrences of ED (OR 2.51) and ICU visits (OR 1.94). Within AYAs, baseline SDoH code was most prevalent in 30-39 age group, males, Hawaiian/Pacific Islanders, and lung cancers. The most common SDoH code in AYAs at diagnosis was homelessness at 57.8%. In a multivariate analysis examining incidence of SDoH in AYAs, positive associations were age 30-39; 1.95 (1.61-2.37), males; 1.49 (1.36-1.63), American Indian/Alaska Native; 4.44 (3.12-6.31), and presence of SDoH at diagnosis; 83.0 (71.6-96.3). Mortality in AYAs was associated with age 30-39; 1.81 (1.72-1.91), males; 1.58 (1.54-1.63), unknown race; 1.53 (1.48-1.58), and CNS tumors; 1.15 (1.06-1.25). **Conclusions:** AYAs with cancer have a high prevalence of SDoH burden at diagnosis and acquired. Within AYAs, age 30-39, males, and minority populations were most likely to acquire a SDoH code and have worse survival. The strongest association with both incidence of SDoH burden and mortality was a SDoH code at diagnosis. Research Sponsor: None.

Characteristic	SDoH Outcome			Mortality Outcome		
	HR	95% CI	p-value	HR	95% CI	p-value
Age						
15-19	—	—	—	—	—	—
20-29	1.81	1.48, 2.21	<0.001	1.24	1.17, 1.31	<0.001
30-39	1.95	1.61, 2.37	<0.001	1.81	1.72, 1.91	<0.001
Sex						
F	—	—	—	—	—	—
M	1.49	1.36, 1.63	<0.001	1.58	1.54, 1.63	<0.001
Race						
White	—	—	—	—	—	—
American Indian or Alaska Native	4.44	3.12, 6.31	<0.001	1.33	1.07, 1.66	0.011
Asian	0.54	0.40, 0.72	<0.001	0.53	0.48, 0.58	<0.001
Black or African American	2.31	2.08, 2.58	<0.001	1.41	1.35, 1.47	<0.001
Native Hawaiian or Other Pacific Islander	2.49	1.71, 3.63	<0.001	0.9	0.71, 1.14	0.365
Unknown	0.69	0.61, 0.79	<0.001	1.53	1.48, 1.58	<0.001
Cancer type						
Respiratory	—	—	—	—	—	—
Bone and Tissue	1.01	0.75, 1.38	0.929	0.93	0.85, 1.02	0.12
Breast	0.77	0.57, 1.04	0.088	0.5	0.45, 0.55	<0.001
CNS	0.85	0.63, 1.13	0.262	1.15	1.06, 1.25	<0.001
GI	1.28	0.97, 1.68	0.083	1.08	0.99, 1.17	0.068
GU	0.83	0.64, 1.09	0.181	0.37	0.34, 0.40	<0.001
Head and Neck	0.51	0.38, 0.68	<0.001	0.16	0.14, 0.18	<0.001
Lymphoid	1.04	0.80, 1.35	0.795	1.03	0.96, 1.12	0.388
Skin	0.45	0.34, 0.61	<0.001	0.16	0.14, 0.18	<0.001
Undefined	1.02	0.76, 1.39	0.875	0.73	0.67, 0.81	<0.001
Prior SDoH	83.0	71.6, 96.3	<0.001	1.91	1.51, 2.43	<0.001

Colorectal cancer and the heart: Uncovering the beat of racial disparities in MACCE.

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Background: Due to its high prevalence, colorectal cancer (CRC) forms a considerable burden on the healthcare system. Advancements in treatment modalities like immunotherapy have led to significant improvement in the 5-year survival. This, along with the cardiotoxic therapy regimens results in a remarkable incidence of major cardiovascular and cerebrovascular events (MACCE). Thus, it becomes imperative to address the intricacies of factors including racial disparities in MACCE, as these aid with facilitating equitable management of all CRC patients.

Methods: Using ICD-10 codes, patients with CRC were identified from National Inpatient Sample 2019 database. We included all-cause in-hospital mortality (ACIHM), acute myocardial infarction (AMI), atrial fibrillation (AF), cerebrovascular accident (CVA), and sudden cardiac death (SCD) as MACCE for the outcomes. Baseline characteristics including demographics, comorbidities; and MACCE outcomes were studied using chi-square for categorical or ANOVA for continuous data (statistical significance determined as p -value < 0.05) and results were stratified based on patient's races. **Results:** A total sample patient population of 171,695 patients with a diagnosis of CRC were identified of which 70.71% (121,410) were White, 13.85% (23,790) were Black, 9.15% (15,720) were Hispanic, 3.23% (5,555) were Asian/Pacific Islander, 0.5% (840) were Native American, and 2.55% (4380) belonged to Other races. Substantial differences in the prevalence of comorbidities were noted with hypertension (46.32%) and renal failure (24.74%) being more common in Black patients, diabetes mellitus (37.5%) in Native American patients, and dyslipidemia (37.89%) in White patients. Upon comparison with White patients, the ACIHM was higher in Black patients with adjusted odds ratio (aOR) of 1.23 (95% CI 1.057-1.432, $p = 0.007$) and Asian/Pacific Islander patients with aOR of 1.359 (1.014-1.823, $p = 0.04$). While AMI was found to be lower in all races, as compared to White patients, AF was remarkably higher in all races. CVA was higher in Black patients as compared to White patients with aOR of 1.626 (95% CI 1.401-1.886, $p < 0.001$). SCD was substantially higher in Black patients with aOR 2.059 (95% CI 1.478-2.869, $p < 0.001$), and in Hispanic patients with aOR 1.743 (95% CI 1.1-2.761, $p = 0.018$), when compared to White patients. **Conclusions:** The study noted higher prevalence of MACCE across the board with poorer outcomes in non-White populations, which highlights the urgent need for resource allocation to improve outcomes. This has to be done in pre and post cancer treatment patients, especially in high risk populations. Additionally, the role of cardio-oncology service at every stage of management of CRC appears to be crucial. Research Sponsor: None.

Association of socioeconomic status with aggressive end-of-life care in patients with cancer before and during the COVID-19 pandemic.

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Background: Aggressive care near the end-of-life (EOL) reflects poor quality of cancer care. We examined the association between trends in aggressive EOL cancer care and socioeconomic status (SES) before and during the COVID-19 pandemic. **Methods:** We conducted a population-based cohort study of adults diagnosed with cancer who died from 03/16/2015 to 03/15/2020 (pre-COVID-19 period) and from 03/16/2020 to 03/15/2021 (COVID-19 period). Aggressive EOL care was defined as a composite outcome of percentage (%) of patients with systemic anti-cancer therapy (SACT) use, >1 ED visit, >1 hospitalization, or ≥ 1 ICU admission in the last 30 days of life. We conducted an interrupted time series analysis using segmented linear regression, estimating monthly trends before, at the start of, and during the first year of the pandemic. Analyses were stratified by SES, based on area-level material deprivation quintiles (Q1, least; Q3, intermediate; Q5, most deprived). **Results:** Of 173,915 decedents with cancer (mean [SD] age 72.1 [12.5] years; females 45.9%), 59,613 (34.3% [95% CI, 34.1-34.5]) had aggressive EOL care; 10.3% (10.2-10.5) received SACT, 14.0% (13.8-14.2) had >1 ED visit, 10.3% (10.2-10.5) >1 hospitalization, and 13.4% (13.2-13.5) ≥ 1 ICU admission within 30 days of death. During the course of the pre-COVID-19 period, patients in Q1 (33.5% [33.0-34.1]) were less likely to receive aggressive care at the EOL than those in Q3 (34.1% [33.5-34.6]) or Q5 (34.8%, 95% CI, 34.3-35.3). Specifically, patients in Q1 were less likely to have ED visits (Q1, 12.9% vs Q3, 14.2% vs Q5, 14.9%), and hospitalizations (9.7% vs 10.3% vs 10.6%) than Q3 and Q5, and less likely to have ICU admissions than Q5 (13.1 vs 13.0% vs 14.4%); however, they were more likely to receive SACT at EOL (11.1% vs 9.9% vs 9.1%). During the pre-COVID-19 period, aggressive care increased by 0.032% (95% CI, 0.026-0.038, $P < 0.0001$) monthly; this increase was significant in Q1 ($P = 0.002$) but not in Q3 ($P = 0.31$) or Q5 ($P = 0.21$). Within Q1, there was a pre-COVID-19 increase in EOL SACT use ($P < 0.0001$) and ED visits ($P = 0.04$) but not in hospitalizations and ICU admissions. In March 2020, aggressiveness of care decreased by 2.37% (95% CI, -2.98 to -1.76, $P = 0.0002$), which was significant in Q5 ($P = 0.04$), but not Q1 ($P = 0.07$) or Q3 ($P = 0.81$). Within Q5, there was a decrease in EOL ED visits ($P = 0.0008$) but not in SACT use, hospitalizations, or ICU admissions. **Conclusions:** More than one third of adults with advanced cancer received aggressive EOL care, which increased in the 5 years prior to COVID-19 pandemic and was attenuated at its onset. Indicators of aggressive care differed by SES, with greatest SACT use in those with highest SES and greatest hospital services use in those with lowest SES. Measures to reduce aggressiveness of care should take into account disparities related to SES. Research Sponsor: Canadian Institutes of Health Research; Canada Graduate Scholarship (Doctoral); Peterborough KM Hunter Charitable Foundation.

The impacts of area-level social deprivation on overall survival in patients receiving immune-checkpoint inhibitors (ICI) treatments: A retrospective cohort study.

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Background: Despite recent advancements in ICI therapy, disparities in treatment outcomes persist, potentially influenced by social factors. We investigated the association between Area-level social deprivation (ALSD) and overall survival in patients treated with ICIs, aiming to uncover the potential socioeconomic barriers to effective cancer care. **Methods:** The study included newly diagnosed solid or liquid tumor patients treated with ICIs between 2012 and 2020 at the Ohio State University Comprehensive Cancer Center. Socioeconomic deprivation was defined using the Social Deprivation Index (SDI), a validated measure of disadvantage across small areas using seven components related to demographic and household characteristics. A high ALS D was defined as an SDI score above the sample's third quartile. Crude and Adjusted Cox proportional models with robust variance to account for group clustering were used to examine the association between overall survival and ALS D. We also examined the relationship between all-cause mortality and each of the seven components of ALS D. **Results:** A total of 3,317 patients were included in the study with a median age of 62 years, 59.1% males and 89% White non-Hispanics. An estimated 30.7% of patients had lung cancer, 16.3% melanoma, and 10.8% head and neck cancer. Type of cancer was significantly associated with deprivation states ($P < 0.001$). The median (interquartile range) survival time for all participants was 10.3 (3.7–22.3) months. The high ALS D group had 440/800 (55.0%) deaths over 10,999.0 person-years reported, while the low ALS D group had 1275/2517 (50.7%) deaths over 40,994.8 person-years reported – risk ratio of 1.29 (95% CI: 1.15–1.43). High ALS D was significantly associated with a higher risk of all-cause: the crude risk of all-cause mortality was 21% higher for patients in the high vs. low ALS D groups [HR: 1.21; 95% CI: 1.08–1.36]. In the fully adjusted models, high ALS D was associated with an 18% higher risk of all-cause mortality [adjusted HR: 1.18; 95% CI: 1.06–1.33] compared to low ALS D. In a sub-analysis, we limited our cohort to patients undergoing immunotherapy as first-line treatment, and low ALS D remained a significant predictor of increased risk of all-cause mortality. Area-level poverty and residing in areas with higher percentages of rented housing were the main drivers of the increased risk of all-cause mortality in patients residing in high ALS D areas. **Conclusions:** Patients from areas with higher levels of social deprivation had a significantly higher risk of all-cause mortality compared with their counterparts in less deprived areas. Addressing adverse social factors could expand the benefits of ICIs for everyone and help reduce disparities in cancer care. Future strategies should consider social interventions to advance equitable healthcare outcomes for all cancer patients. Research Sponsor: None.

Predicting therapeutic clinical trial enrollment for underrepresented patients in neuro-oncology using supervised machine learning.

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Background: Despite the unique ability of machine learning (ML) techniques to uncover complex interactive effects in datasets, studies exploring predictors of clinical trial enrollment have largely used standard statistical methods to discern associations. Furthermore, there have been limited applications of ML to close existing disparities in clinical trial enrollment of underrepresented patients in neuro-oncology. This study aims to use supervised machine learning to define and validate primary contributors of therapeutic clinical trial enrollment for a) all patients, b) women and c) NIH-designated minority patients with low- and high-grade glioma. **Methods:** Adult glioma patients who received care from the UCSF Brain Tumor Center between 1997- 2017 were identified in a prospective registry. Bootstrap forest (BF) and Recursive Partitioning (RP) models were created by randomly dividing patients in a 70/30 split into development (DEV) and validation (VAL) cohorts among all patients, women, and NIH-designated minority patients, separately. Model performance was assessed using the area under the curve (AUC) in the DEV and VAL cohorts. **Results:** Among 1042 patients, 350 patients (33.6%) enrolled in a therapeutic clinical trial. There were 445 women (42.7%), of which 144 (32.4%) enrolled, and 141 minority patients (13.5%), of which 39 (27.7%) enrolled. For all patients, in order of decreasing influence, the BF model selected median neighborhood household income, age, neighborhood poverty level, distance from hospital, tumor location, tumor volume, treatment with chemotherapy, occupation, KPS, insurance status, employment status, seizure at presentation, and volumetric extent of resection (EOR) to predict trial enrollment (DEV AUC: 0.984; VAL AUC: 0.746). For women, the BF model selected distance from hospital, age, household income, neighborhood poverty level, tumor location, treatment with chemotherapy, and KPS for trial prediction (DEV AUC: 0.972; VAL AUC: 0.746), whereas for minority patients, the BF model selected neighborhood poverty level, age, occupation, distance from hospital, tumor volume, insurance status, employment status, and EOR to predict trial enrollment (DEV AUC: 0.9830; VAL AUC: 0.769). The RP model for women designated those with non-White race as less likely to enroll (DEV AUC: 0.735; VAL AUC: 0.665) while the RP model for minority patients characterized those who preferred a non-English language or who were divorced or widowed as less likely to enroll (DEV AUC: 0.775; VAL AUC: 0.601). **Conclusions:** Supervised machine learning models achieved similar predictive performance among patient subgroups, while uncovering interactions between gender identity, minority status, and sociodemographic variables. These findings can guide targeted recruiting efforts to advance equitable trial enrollment for women and minorities. Research Sponsor: None.

Disparities in breast cancer prevention initiatives at a comprehensive cancer center: Who are we serving?

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Background: Despite advances in personalized breast cancer risk assessment and screening, populations at highest risk for cancer-related mortality are often excluded. At the IU Simon Comprehensive Cancer Center, a high-risk screening program (HRSP) identifies and serves women at increased risk of breast cancer. Risk assessment using Tyrer Cuzick v.8 and Gail models is performed in mammography; women at increased risk are navigated to a clinic appointment to discuss individualized screening and prevention services including MRI, chemoprevention, and/or genetic testing. We hypothesize gaps in the demographic and socioeconomic (SES) characteristics of women seen for a HRSP appointment, compared to women receiving a cancer diagnosis at the same mammography sites. **Methods:** Retrospective review was performed of women who met criteria for the HRSP (age ≤ 65 and Gail 5 yr risk $\geq 3\%$ or TC v.8 10-yr risk $\geq 8\%$, or recommended by the radiologist) and subsequently accepted, scheduled, and attended an appointment from 6/2020 to 6/2022 (n=233). This population was compared to women who were diagnosed with breast cancer at the same clinical sites over the same dates, without history of being evaluated in the HRSP. Age was restricted to ≤ 65 to match the HRSP population (n=685). Zip codes were used to calculate area-based SES by median household income and percent poverty. CDC social vulnerability index (SVI) was evaluated using the U.S. Census Bureau and American Community Survey (0=least vulnerable, 1=most vulnerable). Comparisons across groups by age, race, insurance status, area SES and SVI were made using the Wilcoxon or Chi-square test. **Results:** Cancer cases were significantly older than those attending the HRSP (median age 54 vs 49 p < 0.001). Black patients represented 19.4% of participants diagnosed with cancer, versus 10.8% of participants attending the HRSP (p=0.0032). There was also a disparity in insurance coverage, with 83.8% of women seen in the HRSP being privately insured, versus 75.6% of women diagnosed with cancer (p=0.011). There was no statistical difference in SVI (0.64 vs 0.66 p=0.11) or area poverty rate (11.2 vs 12.0 p=0.26) between the groups; cancer cases came from areas with lower household income (69,611 vs 73,165 p=0.04). **Conclusions:** Women seen in the HRSP were more likely to be younger, White, privately insured, and from an area with higher household income, compared to women diagnosed with cancer in the same health system at the same mammography sites. This highlights disparities in access to individualized breast cancer interception such as chemoprevention, high-risk screening, and genetic testing, which may further existing disparities in breast cancer-related mortality based on race and SES. Further studies will investigate barriers and motivators to personalized breast cancer prevention in high-risk groups, and utilize community partnerships to develop equitable interventions. Research Sponsor: Catherine Peachey Fund.

Exploring disparities in palliative care utilization among hospitalized patients with hepatocellular carcinoma: A retrospective cohort study.

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Background: Hepatocellular carcinoma is one of the common gastrointestinal cancers, and its advanced stage requires palliative care due to its inferior prognosis and mortality. Palliative care significantly improves the burden of HCC on patients and the healthcare system. Despite the evidence of its use, reported utilization could have been better. This study aims to investigate the disparities in utilization of palliative care in hospitalized patients with HCC and examine related factors. **Methods:** This retrospective cohort study used data from the 2018–2020 National Inpatient Sample (NIS) database. Patients aged 18 or above with hepatocellular carcinoma were studied to determine how their utilization of palliative care varied based on their race and other identifiable risk factors. Palliative care utilization encompasses palliative care/ comfort care or under the care of a palliative care physician or referral. We examined these patients' demographics, All Patient Refined Diagnosis Related Group (APR-DRG) risk of mortality, and their relationship with palliative care utilization. **Results:** This study identified 128,140 patients with hepatocellular carcinoma (HCC), of whom 26,730 (20.9%) had utilized palliative care. The majority of study participants were White and male. The palliative care utilization (PCU) group comprised mainly White patients, with 50% of the group having extreme APR-DRG risk of mortality. Compared to Whites, Blacks had increased odds of palliative care utilization in both unadjusted (OR=1.08; 95% CI: 0.99–1.18) and adjusted models (aOR=1.11; 95% CI: 1.01–1.22). Hispanics had reduced odds in both unadjusted (OR=0.83; 95% CI: 0.75–0.91) and adjusted models (aOR=0.84; 95% CI: 0.76–0.93). Moreover, over 50% of study participants were in large, bed-sized hospitals and on Medicare insurance. **Conclusions:** Our study showed significant disparities in palliative care utilization among hospitalized patients with hepatocellular carcinoma. While the majority of patients were White and male, Black patients had increased odds of palliative care utilization, and Hispanics had reduced odds. Additionally, patients in large, bed-sized hospitals and on Medicare insurance comprised over 50% of the study population. The racial disparities in utilization might stem from differences in socio-cultural beliefs and practices alongside other factors. Efforts are needed to address these disparities and ensure equitable care for all patients, particularly vulnerable populations. Further research and quality improvement initiatives are essential to explore and address these disparities and contributing factors, enhancing outcomes for patients with HCC. Research Sponsor: None.

Association of single nucleotide polymorphisms (SNPs) in inflammatory pathways with breast cancer (BC) risk: A multi-ethnic scoping review.

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Background: Breast cancer is the most prevalent cancer affecting women of every ethnic group in the United States. This is a scoping review assessing SNPs in inflammatory pathways posited to modify BC risk by ethnicity. **Methods:** We followed PRISMA guidelines for scoping reviews. PubMed, Medline, and OVID databases were interrogated for publications between 1/2000-12/2023 using search terms “breast cancer” AND [BMI OR “body mass index” OR elevated BMI OR obesity] AND [SNP OR “single nucleotide polymorphism” OR polymorphism OR mutation] AND [inflammation OR cytokines OR IL-1 OR IL-2 OR IL-4 OR IL-6 OR IL-8 OR IL-10 OR IL-12 OR TNF- α OR TGFB OR CRP] AND [Asian, Black or Hispanic]. A single reviewer assessed 72 unique publications and determined that 42 met inclusion criteria. Two reviewers extracted the following data: demographics, SNP, number of cases and controls by ethnicity. Disagreements were resolved by consensus with a third reviewer. **Results:** Data were extractable from 42 studies, all case controls. In analyses stratified by ethnicity, we detected effects of SNPs on BC risk (Table). IL-1 β rs1143634 and IL-10 (1082 A/G) had a significantly increased BC risk in Asian populations but insignificant in white populations. There were minimal publications for Black and Hispanic populations. **Conclusions:** The association of inflammatory SNPs and BC risk is complex and can be both protective and predisposing to BC, with ethnicity modifying SNP risk. Future research can be directed at assessment of SNPs and BC risk in diverse populations. Research Sponsor: None.

Author	Year	Country	Ethnicity	Gene	SNP	Normal Allele	Abnormal Allele	Odds Ratio	Confidence Interval	P Value
Lee et al.	2006	Korea	Asian	IL-1 β -31C/T		TC	CC	-0.305	(-0.603-0.006)	
Pooja	2012	India	Asian	IL-1 β	rs1143634	TC	CC	0.901	(0.292-1.509)	
AL-Eitan et al.	2020	Jordan	Asian	IL-1 β	rs1143634	TC	CC	1.531	(0.858-2.203)	0.00001
Hefler et al.	2005	Germany	White	IL-1 β	rs1143634	TC	CC	0.039	(-0.441 - 0.519)	
Kaarvatn et al.	2012	Croatia	White	IL-1 β	rs1143634	TC	CC	-0.363	(-0.733 - 0.007)	0.1938
Scola	2006	Italy	White	IL10	1082 A/G	AC	AA	0.239	(-0.405-0.883)	
Smith et al.	2004	UK	White	IL10	1082 A/G	AC	AA	-0.364	(-0.914-0.185)	
Balasubramanian	2006	UK	White	IL10	1082 A/G	AC	AA	-0.044	(-0.349-0.261)	
Gonullu	2007	Turkey	White	IL10	1082 A/G	AC	AA	1.353	(0.231-2.475)	
Onay et al.	2006	Canada	White	IL10	1082 A/G	AC	AA	0.228	(-0.114-0.570)	
Guzowski	2005	USA	White	IL10	1082 A/G	AC	AA	0.742	(-0.384-1.868)	0.066
Tian	2017	China	Asian	IL10	1082 A/G	AC	AA	-0.079	(-1.311 - 0.269)	
Li et al.	2014	China	Asian	IL10	1082 A/G	AC	AA	1.235	(0.132-2.337)	
Pooja	2012	India	Asian	IL10	1082 A/G	AC	AA	0.276	(-0.167-0.719)	
Kong	2010	China	Asian	IL10	1082 A/G	AC	AA	-0.188	(-0.707-0.331)	
Abdolrahim-Zadeh	2005	Iran	Asian	IL10	1082 A/G	AC	AA	0.13	(-0.220-0.480)	
Atoum	2016	Jordan	Asian	IL10	1082 A/G	AC	AA	-0.409	(-0.933-0.114)	
Vinod et al	2015	India	Asian	IL10	1082 A/G	AC	AA	-1.049	(-1.579 - 0.519)	0.000001

A nationwide analysis of demographic and treatment patterns in admissions for malignant pleural effusions from 2016-2020.

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Background: Malignant pleural effusions are an indicator of metastatic malignancy, with poor survival and need for palliative procedures to alleviate symptoms. Our study aims to identify the disparities in the utilization of these procedures and their effects on hospitalization outcomes.

Methods: The Nationwide Inpatient Sample (NIS) was used to identify all adult hospitalizations with malignant pleural effusion (MPL) between the years 2016-2020. We studied patient demographics and treatment modalities during admission. The study's primary outcome measure was to identify the difference in the total length of stay (LOS) and total healthcare cost (THC) incurred during admission. The secondary outcome was mortality rates among patients undergoing these procedures. Statistical analysis was done using multivariate linear and logistic regression models. **Results:** A total of 439,245 admissions for MPL were identified, constituting 0.2% of all U.S. admissions. Among these, 59.6% were females and mean age was 67.3 years. There were 68% Whites, 15% Blacks, 8% Hispanics, 4% Asians or Pacific Islanders, 0.4% Native Americans, and 2.9% others. About 61% had Medicare, 11.2% Medicaid, 25.7% Private insurance, and 1.9% Self-pay. Most admissions occurred in teaching hospitals (76.3%), urban settings (94.5%), and hospitals with larger bed strength (56.1%). The most common primary admission diagnosis was sepsis (8.3%). The most common primary malignancies were Lung (39.9%), breast (27.9%), gastrointestinal (9%), and hematopoietic malignancies (7.1%). We studied rates of thoracentesis, Pleurodesis, Decortication, and intrapleural chemotherapy. The mean LOS and THC increased in admissions where procedures were performed, highest for decortication (12.1 days, $p < 0.01$). However, the odds of death in hospitals significantly reduced. When compared to primary lung cancer causing malignant effusions, primary G.I., renal, urinary, and upper aerodigestive malignancies with MPL had significantly higher mortality rates ($p < 0.05$). Disparities were observed in procedures performed, with women having 29% lower odds of undergoing decortication ($p < 0.001$). African Americans had lower odds of undergoing any procedures for MPL when adjusted for age, sex insurance status, compared to whites. Teaching hospitals had 10.9 times higher odds of performing thoracentesis but lower odds of performing pleurodesis and decortication ($p < 0.05$). **Conclusions:** This investigation provides insights into the favorable impact of invasive procedures on in-hospital mortality for malignant pleural effusions, suggesting a possibility that patients with better performance status underwent such interventions. We also noted racial and sex-based disparities in the performance of these procedures. Further studies are essential to identify the reasons for this disparity to help promote equitable care. Research Sponsor: None.

Challenges and solutions to recruiting diverse populations to oncology clinical trials: A mixed-methods study of clinical research coordinators.

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Background: Multiple barriers limit the enrollment of diverse populations in oncology clinical trials (CTs). A review of our institutional CTs recruitment dashboard identified underrepresentation of Black and Latinx adults among thoracic and gastrointestinal (GI) oncology CTs participants compared to demographics of our catchment area and patient population. We conducted a mixed-methods study to identify barriers and potential solutions to the enrollment of diverse populations in oncology CTs in our institution. **Methods:** We conducted a mixed methods study enrolling clinical investigators and clinical research coordinators' (CRCs) at an NCI-designated CCC in Northern California. Data from CRCs is presented. All CRCs supporting CTs in the thoracic and GI medical oncology were invited to participate in qualitative, one-on-one, semi-structured interviews. Participants completed 60–90 minutes interview and a short survey. Data were analyzed using a thematic inductive approach. **Results:** Of 14 CRCs, the majority were female (78.6%), with primary focus on thoracic (50.0%) and GI (35.7%) oncology CTs. 64.3% of CRCs reported >80% of their work was dedicated to coordinating and managing therapeutic cancer CTs. In survey responses CRCs identified inability to take time away from work/family (64.3%), inadequate insurance coverage (42.9%), lack of transportation (35.7%), and language barriers (35.7%) as major barriers to enrollment of diverse patients in CTs. In qualitative interviews CRCs expressed the need of culturally and language appropriate materials for CT recruitment, establishing a sense of connection between clinical research staff/PI and patients, accommodating socioeconomic concerns, and resources to respond to potential participants' mistrust of medical research. Main obstacles faced by CRCs during patient enrollment in CTs included lack of time, low patient awareness, resistance from colleagues, lack of multilingual staff, and inadequate logistical support. CRCs identified in-person interpretation as beneficial and identified a strong rapport between the clinical provider and the potential participant as the most important component to boost recruitment of minorities. Lastly, CRCs highlighted that institutional efforts are needed to increase CT participation among all populations. **Conclusions:** Lack of representation of diverse populations in CTs remains a complex challenge. Our study of CRCs' perceptions highlights access to in-person translators, culturally and language concordant materials, education resources, and increased rapport as key areas for intervention to facilitate patient enrollment of diverse populations. Analysis into practice-specific patterns within our cancer centers can help identify areas for interventions to support the recruitment and enrollment of diverse populations in oncology CTs. Research Sponsor: None.

Potentially inappropriate medications and their association with frailty, unplanned hospitalizations, and mortality in patients with cancer treated in the national U.S. Veterans Affairs Healthcare System.

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Background: We previously operationalized the NCCN list of high-risk medications in older adults into a measurable scale—Geriatric Oncology Potentially Inappropriate Medications (GO-PIMs)—to aid oncology teams in identifying PIMs and understand their impact (1). This scale revealed that PIMs were prevalent and associated with frailty in older patients with blood cancers. The current study aims to evaluate the ability of GO-PIMs to identify high-risk medications and their impact in patients with both solid and liquid tumors managed in a large national healthcare system. **Methods:** We performed a retrospective cohort study using data from the national Veterans Affairs (VA) Cancer Registry and electronic health record, including all veterans newly diagnosed with a solid or liquid malignancy in the years 2000–2023. The number of GO-PIMs for each patient were measured among outpatient pharmacy prescriptions in the 90 days preceding the initial diagnosis date (the index date). We evaluated the association of PIMs with baseline frailty (the electronic Veterans Affairs–Frailty Index [VA-FI], categorized as nonfrail [0–0.2], mildly frail [0.2–0.3], and moderate-to-severely frail [0.3–1.0]), time to unplanned hospitalization, and mortality in multivariable models adjusting for age, gender, cancer type and stage, Charlson comorbidity index, and socioeconomic factors (rurality, area deprivation index, and history of homelessness). **Results:** Among 307,487 newly diagnosed patients (median age 68.5, IQR 62.1–75.8; most common cancers: prostate [20.5%], lung [23.1%], GI [21.3%]), GO-PIMs were prevalent (39% patients with ≥ 1 GO-PIM). The most common classes of PIMs were SSRIs (12.4%); opioids (10.7%); benzodiazepines (9.5%), and corticosteroids (9.5%). Each additional PIM increased the odds of being mild or moderate-to-severely frail at diagnosis by 65%, controlling for all covariates (ordinal regression adjusted OR [aOR] 1.65, 95% CI 1.63–1.66). Increasing number of PIMs was also associated with a higher hazard of unplanned hospitalization (Cox regression aHR 1.04, 95% CI 1.04–1.05) and death (Cox regression aHR 1.05, 95% CI 1.05–1.06), controlling for frailty and all covariates. **Conclusions:** Independently of cancer type and stage, comorbidity, and other covariates, increasing PIMs identified by the GO-PIMs scale was associated with an increased risk of frailty at diagnosis, unplanned hospitalization in follow-up, and death. We are implementing the GO-PIMs scale in a clinician-facing application that will automate real-time detection of PIMs and recommendations for oncology teams in routine clinical practice. 1. Hsieh and DuMontier et al., *J Natl Compr Canc Netw*, 2022. Research Sponsor: U.S. Department of Veterans Affairs, Cooperative Studies Program; National Institute on Aging; NIAR33-AG057806; U.S. Department of Veterans Affairs; IK2CX002218; U.S. Department of Veterans Affairs; 1I01BX001584; National Institutes of Health; P01-155258-07; U.S. National Institutes of Health; P50-100707; American Heart Association; 857078.

Current trends of clinical trials for older patients with cancer: A systematic review.

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Background: While accounting for 40% of the cancer population, older adults are underrepresented in clinical trials. Older-age-selected studies are desirable, but their characteristics and overall performance are unknown. This systematic review assessed design and outcomes of trials focused on this patient population. **Methods:** We searched Embase and PubMed with the keywords “older adults”, “cancer” and “clinical trials”, from inception to March 1, 2023. We included phase (Ph) I, II and III trials testing systemic therapies in solid cancer patients (pts) aged ≥ 70 yrs. For each of the selected trials, we carried out an ad-hoc search for age-unselected trials testing the same interventions in the same setting. We followed the PRISMA guidelines for systematic reviews and registered the study on the PROSPERO database (CRD42023465089). **Results:** We screened 25,868 records and included 313 studies. 48 (15.4%) were Ph I-I/II, 232 (74.1%) Ph II, and 33 (10.5%) Ph III. The minimum-age threshold used to define ‘old’ was 70–74 yrs in 79.9%, 75–79 in 19.8%, and 80 in 0.3% of cases. Most trials (76.7%) were run in the palliative setting. Common tumors included lung (60.4%) and colorectal cancer (15%), while chemotherapy (88.5%) and targeted therapy (23.6%) were the most frequently tested treatments. Non-conventional primary endpoints (e.g., toxicity, feasibility, functional status, quality of life [QoL]) were used in 8.3% of Ph II-III trials. 24 studies were published in 1990–2000, 126 in 2001–2011, and 163 in 2012–2023. The median accrual time was 32 (IQR 21.5–44.5), 30 (IQR 20–43) and 43 months (IQR 36–65) for Ph I, I/II–II, and III, respectively. Of 234 trials reporting the pre-planned target accrual, 77.8% enrolled $\geq 90\%$ of the required pts. Premature study discontinuation occurred in 50 studies (5.9% of Ph I, 14.2% of Ph II and 39.4% of Ph III), the major reason being slow accrual, while only 9 and 6 closed due to futility and overt efficacy, respectively. Among the 233 trials with a pre-defined statistical hypothesis, 60% met the primary endpoint, including 63.7% Ph I/II–II and 35.5% Ph III trials. Geriatric assessments (GA) and QoL analyses were carried out in 88 (28.1%) and 72 (23%) trials, respectively. Only 18 (5.8%) studies were dedicated to frail pts. Corresponding age-unselected trials were available for 154 older-patient studies. Compared with those, a higher proportion of age-unselected studies enrolled $\geq 90\%$ of the required pts (95% vs 83.5%, $p=0.03$) and met the primary endpoint (80.3% vs 63.9%, $p=0.03$). **Conclusions:** The interest in clinical trials of solid tumors in older patients has increased over time. While Ph I and II trials are feasible, still a substantial proportion of Ph III trials suffer from slow accrual and premature discontinuation. Interventions to tackle barriers to recruitment should be implemented. Efforts should be made to systematically include GA and QoL analyses, which are key for this patient population. Research Sponsor: None.

Diagnostic test use and time to cancer diagnosis in Medicare recipients.

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Background: In the Medicare-aged population, liver, ovarian and pancreatic cancers have an incidence of 34–73/100,000, are associated with high mortality, can often be associated with no or vague symptoms, and rely on multiple tests for diagnosis (dx). Our objective is to quantitate dx testing and time to a cancer dx in Medicare recipients. **Methods:** Pts with newly dx'd liver, ovarian or pancreatic cancers were identified in 100% fee-for-service (FFS) Medicare enrollment and claims data from 1 Oct 2017 – 31 Dec 2022. Dx test use was tracked for up to 24 months prior to dx; pts had to have ≥ 1 dx test within 60 days before the cancer dx date. Inclusion criteria also included ≥ 24 months of continuous enrollment in FFS Medicare prior to dx and qualification based on age ≥ 65 . Exclusion criteria included prior cancer dx and Medicare Advantage enrollment. The start of dx workup was identified by looking back in time at the sequence of dx tests occurring before the cancer dx date and were separated by ≤ 60 days between consecutive tests. The earliest test in the sequence was deemed the first dx test. Index date was defined as the latest office visit date before the first dx test or date of the first dx test if no office visit met criteria. Dx tests (ie, biopsies, endoscopies, imaging, lab tests) were identified by billing/CPT codes. Dx workup duration from index to dx date and dx test types received were tracked. **Results:** Among 59,490 Medicare beneficiaries analyzed, mean age was 77.0 (SD 7.3), 60% were female, and 80% were non-Hispanic White. Median (25th, 75th percentile) days from index date to cancer dx was 56 (24, 109) for liver, 47 (20, 91) for ovary, and 43 (16, 89) for pancreas. Dx testing modalities utilized for each cancer type (Table) demonstrate high variability. The percentage of pts who underwent both CT and MRI to help establish a liver, ovarian and pancreatic cancer dx was 38.6%, 14.1% and 32.3%, respectively. While overall imaging use prior to dx was high, PET and PET-CT use was low ($<1\%$ PET; 1.7%–2.2% PET-CT). **Conclusions:** Multiple tests are utilized to establish a cancer dx in Medicare beneficiaries, including use of multiple imaging modalities in the same patient. 25% of pts required more than 89–109 days, depending on cancer type, to establish a dx. There may be opportunities to increase diagnostic efficiency and shorten time to cancer diagnosis in older individuals. Research Sponsor: GRAIL, LLC.

Dx Test (%)	Liver (N=16,022)	Ovary (N=10,590)	Pancreas (N=32,878)	Total (N=59,490)
Any biopsy*	48	50	53	51
Any endoscopy (eg, GI endoscopy, bronchoscopy, laparoscopy; all considered endoscopy per CPT codes)	24	20	51	38
Any CT	81	81	91	86
Any MRI	52	18	37	37
Any nuclear medicine imaging	10	7	8	8
Any x-ray	62	67	59	61
Any ultrasound	62	53	44	51
Any general urine and serum lab test	91	91	90	90
Any genetic lab test/non-genetic CA-specific lab test	5 / 54	13 / 53	4 / 39	6 / 46

*Potential explanations for biopsies not being available in all pts include pts being labeled as having CA by radiology findings alone and lag times in claims data.

Effect of a 12-week remote exercising program (ExlOnc) on quality of life and symptoms of older patients with cancer in Brazil.

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Background: Leading organizations, including ASCO, recommend physical activity for patients with cancer. However, numerous barriers hinder patients from maintaining regular physical activity, particularly among older adults, who have lower participation in exercise programs. This study aims to evaluate the effects of a 12-week supervised remote exercise program on the health-related quality of life (HRQOL) of older patients with cancer (aged ≥ 65) undergoing treatment in Brazil. **Methods:** This was a single-arm pilot study evaluating a remote physical activity program which combined supervised and remote exercise. Eligible patients were contacted through WhatsApp for the initial assessment and received guidance on weekly exercises. The Vedium platform was employed to demonstrate proper home exercise techniques. The prescribed regimen consisted of 3-5 hours per week (4-6 days a week), encompassing both resistance and aerobic exercise. Outcome measures included overall HRQOL (FACT-G, scale 0-108) and symptom assessment (ESAS). Assessments were conducted at baseline and after 12 weeks. Descriptive statistics were calculated, and linear mixed models were employed to analyze changes from before to after the intervention. **Results:** Out of 46 approached patients, 41 patients were enrolled, with a median age of 70 years (range 65-88). Of the participants, 56.1% were female, 70.7% were white, and 58.2% were married, with 53.5% holding a college degree. The most common cancer types were breast (26.8%), genitourinary (22.0%), and lung (17.1%), all diagnosed at advanced stages. A significant improvement was observed in overall HRQOL ($M_{T1}=83.2$ to $M_{T2}=94.4$, $P=0.001$). Improvements were also seen in the severity of various symptoms, including pain ($M_{T1}=1.6$ to $M_{T2}=0.7$, $P=0.001$), fatigue ($M_{T1}=3.8$ to $M_{T2}=1.3$, $P=0.001$), nausea ($M_{T1}=0.8$ to $M_{T2}=0.2$, $P=0.01$), depression ($M_{T1}=2.6$ to $M_{T2}=0.8$, $P=0.001$), anxiety ($M_{T1}=3.2$ to $M_{T2}=1.2$, $P=0.001$), drowsiness ($M_{T1}=1.8$ to $M_{T2}=0.4$, $P=0.001$), and appetite ($M_{T1}=2.2$ to $M_{T2}=0.6$, $P=0.001$). **Conclusions:** This study demonstrates a positive impact of a 12-week remote physical activity program on HRQOL and symptom management for older patients with cancer, and set the stage for future randomized trials. Despite the challenges posed by cancer treatment, incorporating such programs into patient care could be an effective strategy to enhance overall well-being and mitigate treatment-related symptoms. Research Sponsor: None.

Accelerated epigenetic aging and risk of chemotoxicity in older adults with early breast cancer.

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Background: Older adults with breast cancer have considerable heterogeneity in their risk of chemotoxicity; two people with the same chronological age have different risks of chemotoxicity. This heterogeneity in chemotoxicity may be due to older adults having variable rates of biological aging. Some older adults age faster biologically compared with their chronological age (i.e., accelerated epigenetic aging [AEA]), while others do not. AEA is a blood biomarker of aging, but its utility as a biomarker of chemotoxicity is unknown. Here, we evaluated the association between AEA and risk of chemotoxicity in older adults with early breast cancer. **Methods:** In a prospective multicenter study of 397 women age >65 with stage I-III breast cancer treated with neo/adjuvant chemo, we extracted genomic DNA from blood to estimate the participant’s rate of biological aging at baseline (prior to chemotherapy). Using two established epigenetic clocks (AgeAccelGrim and DunedinPACE), we classified individuals as either having AEA or not (dichotomized as a yes/no variable) for each clock. Our primary endpoint was grade 3+ chemotoxicity (yes/no, yes defined as any grade 3+ toxicity attributed to chemo). Using multivariable logistic regression, we examined the association between AEA and grade 3+ chemotoxicity, adjusting for sociodemographic, geriatric, and clinical covariates. **Results:** The median (range) pretreatment chronological age was 70 (65-85), AgeAccelGrim was -0.88 (-10.4-15.7), and DunedinPACE was 1.03 (0.69-1.45). Of the 397 women, 31 (8%) had AEA per AgeAccelGrim, 63 (16%) had AEA per DunedinPACE, and 184 (46%) experienced grade 3+ chemotoxicity. Women who had evidence of AEA as measured by AgeAccelGrim (≥ 6.83 years, adjusted OR = 2.73, 95% CI 1.17-6.41, $p = 0.02$) or DunedinPACE (≥ 1.17 biological years per chronological year, adjusted OR = 2.20, 95% CI 1.18-4.10, $p = 0.01$) had greater odds of having grade 3+ chemotoxicity compared to women without AEA (AgeAccelGrim <6.83 or DunedinPACE <1.17, respectively). **Conclusions:** In this cohort of older women with early breast cancer, those with pre-chemo AEA had increased odds of chemotoxicity compared to women without any evidence of AEA. Future research is needed to examine whether measures of biological age can be translated to the clinical care of older patients with breast cancer. Clinical trial information: NCT01472094. Research Sponsor: Conquer Cancer, the ASCO Foundation; 2023YIA-3100001264; National Institute of Aging; AG074918; National Cancer Institute; CA277660.

	Grade 3+ Chemotoxicity			Multivariable Analysis*	
	Yes n=184	No n=213	Total N=397	OR (95% CI)	p-value
AEA by AgeAccelGrim (years)					
<6.83	163 (45%)	203 (56%)	366	1.00	
≥ 6.83	21 (68%)	10 (32%)	31	2.73 (1.17-6.41)	0.021
AEA by DunedinPACE (biological years per chronological year)					
<1.17	145 (43%)	189 (57%)	334	1.00	
≥ 1.17	39 (62%)	24 (38%)	63	2.20 (1.18-4.10)	0.013

*Adjusted for age, BMI, race/ethnicity, education, geriatric assessment, and no. of comorbidities.

Start low, go slow: A systematic review and meta-analysis of upfront tailored treatment dosing in older adults with advanced cancer.

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Background: Older adults aged ≥ 65 with advanced cancer are underrepresented in treatment trials. This gap limits informed decision-making regarding the dose and tolerability of proposed therapies. Standard chemotherapy is associated with $>50\%$ serious adverse event rate among older adults, with frequent dose reduction and early treatment discontinuation. A "start low, go slow" (SLGS) approach begins systemic therapy at lower-than-standard doses and increases the dose if well-tolerated. This alternative dosing strategy has shown value in minimizing adverse events and functional decline without compromising the overall effectiveness of treatments. We conducted the first systematic review and meta-analysis of SLGS effectiveness among older adults across advanced cancers. **Methods:** This review, was registered with PROSPERO and adhered to PRISMA criteria, covering PubMed, Journal of Geriatric Oncology and EMBASE from January 2000 until December 15, 2024. Eligible study designs were randomized controlled trials, retrospective trials, and non-randomized clinical trials with patients with advanced cancers who underwent systemic therapy. We reported all studies that studied the SLGS approach. Our studied outcomes were overall survival (OS), progression-free survival (PFS), treatment discontinuation, and toxicity. Data extraction included author, patient, cancer type, treatment, and survival outcomes. A meta-analysis using fixed effects and risk ratios (RR) was performed when sufficient data was available; significant outcomes had $\alpha < 0.05$. **Results:** Our search identified 13 studies testing SLGS strategies in oncology, including 3,508 patients, with a median age 63-78 years. The -represented cancers included colorectal (6 studies, 3059 patients total), lung (2 studies, 113 pts), chronic myeloid leukemia (2 studies, 127 pts), non-Hodgkin lymphoma (1 study, 45 pts), and prostate (2 studies, 164 pts) cancers. Ten (77%) studies assessed OS and PFS. Five studies (39%) compared SLGS against standard doses, finding no significant differences in PFS and OS across all trials. Dose escalation rates for SLGS ranged from 5% to 60%. The ability to complete planned cycles was higher with SLGS compared to standard dose (1 study, 43% vs 26%, $p=0.04$). Treatment discontinuation was not different for SLGL vs. standard dose (5 studies, meta-analysis RR 1.07, 95% CI 0.90-1.27, $p=0.42$). Toxicity ranged from 5% to 89% across studies; SLGS had lower grade ≥ 3 adverse events compared to standard dose (4 studies, meta-analysis RR 0.88, 95% CI 0.80-0.94, $p < 0.001$). **Conclusions:** This is the first systematic review and meta-analysis analyzing the SLGS approach to systemic therapy dosing in older adults with advanced cancer. Compared to standard-dose systemic therapy, older adults pursuing a SLGS strategy had greater completion of planned cycles, reduced toxicity, and similar survival. Research Sponsor: National Cancer Institute; K08CA263541.

Analyzing correlates for cervical cancer awareness in Mauritania, Madagascar, and Benin from the Demographic Health Survey (DHS): 2017-2022.

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Background: Cervical cancer is the leading cause of cancer-related mortality in low- and middle-income countries (LMICs). Prior studies associate high cervical cancer awareness with reductions in cervical cancer incidence. Herein we utilize nationally representative Demographic and Health Surveys Program (DHS) to analyze correlates of cervical cancer awareness and inform global outreach strategies. **Methods:** All DHS surveys conducted between 2017-2022 were queried for questions on cervical cancer awareness. Socio-demographic (e.g., age, marital status), socioeconomic (e.g., education, wealth, literacy) and variables pertaining to healthcare decision making, intimate partner violence (IPV), and female genital mutilation/circumcision (FGC/M)) were extracted. Sample weights were applied, and bivariate logistic regressions were performed. Variables with $p < 0.20$ were included in multivariate analysis. **Results:** Of the DHS surveys, we analyzed data from 25,239 women aged 15-49 years old living in Mauritania, Madagascar, and Benin - the only three countries which met search criteria. Cervical cancer awareness varied from 41% in Mauritania (3,283/7,290), 32% in Madagascar (3,071/9,597), and 10% in Benin (783/7,712). After multivariate adjustment, age (OR=1.03 [1.02-1.04]; OR=1.04 [1.03-1.05]; OR=1.03 [1.01-1.05]), education (OR=1.21 [1.06-1.38]; OR=1.68 [1.48-1.91]; OR=1.83 [1.51-2.23]), and wealth index (OR=1.18 [1.07-1.30]; OR=1.24 [1.16-1.32]; OR=1.18 [1.07-1.30]) were associated with increased awareness across Mauritania, Madagascar, and Benin, respectively. Mobile telephone ownership was associated with increased awareness in Mauritania (OR=1.87 [1.48-2.36]) and Benin (OR=1.66 [1.27-2.19]), and internet usage was associated with increased awareness in Madagascar (OR=1.75 [1.46-2.10]) and Benin (OR=1.71 [1.33-2.31]). Women who underwent FGC/M (OR=0.81 [0.67-0.98]) were associated with decreased awareness in Mauritania. Women who experienced IPV were associated with increased awareness (OR=1.39 [1.11-1.73]) in Mauritania. Women who independently make healthcare decisions were associated with decreased awareness in Mauritania (OR=0.88 [0.83-0.95]) but increased awareness in Madagascar (OR=1.07 [1-1.15]). Rurality was associated with decreased awareness in Madagascar (OR=0.71 [0.59-0.84]). Last, less than 1% (200/25,239) of all women were screened for cervical cancer. **Conclusions:** Age, education, and wealth were associated with increasing awareness, while rurality and FGM/C were associated with decreased awareness in various settings. Given the known association between awareness and screening, targeted efforts to increase awareness among women with lower socioeconomic status has the potential to reduce global cervical cancer disparities. Research Sponsor: None.

Assessment of endocrine therapy adherence in a nurse-led cancer survivorship clinic: Results from the Linking You to Support and Advice (LYSA) trial.

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Background: The care of those living with and beyond a cancer diagnosis requires dedicated cancer survivorship services to ensure optimal symptom control and quality of life. Supporting adherence to adjuvant endocrine therapy is also an essential component of care. We examined endocrine therapy adherence rates, and factors associated with non-adherence, in patients with early-stage breast cancer enrolling in a survivorship trial (LYSA). **Methods:** Women with early-stage hormone positive breast (n=168) cancers within 12 months of completing primary therapy, were enrolled in a randomized control trial with parallel arms (PMID 36357934). Experimental arm had access to nurse-led symptom management, dietetic consultation, and undertook bimonthly electronic patient reported outcome (ePRO). Active comparator group had access to conventional care and ePRO was completed at beginning and end of study. Endocrine therapy adherence was reported as the ability to take medication as prescribed over prior 4 weeks (Michigan Oncology Quality Consortium Adherence Tool), with response quantified as Excellent (adherence close to 100%), Very Good (80%), Good (60%), Fair (40%) and Poor (20%). Adherence Objective (Secondary) was adherence rate at 12 months after study entry in both arms, and factors associated with non-adherence. **Results:** A total of 148/168 women with breast cancer who completed the LYSA study reported adjuvant endocrine therapy use (74 experimental arm, 74 active comparator) during study conduct. Therapies included aromatase inhibitors (53%), tamoxifen (39%) and ovarian suppression combinations (8%). At study entry $\geq 80\%$ adherence was reported in 74% of overall cohort (75% experimental, 72% comparator, $p=0.7$), with 1.6% reporting not taking any medication. By end of study (12 months), $\geq 80\%$ adherence was reported in 74% overall (77% experimental, 71% comparator, $p=0.4$), while non-adherence rates were 2.9%. Among the pre-specified reasons for non-adherence at study end, "simply missing it" ranked highest (10%), and 5% "experienced side effects". Post-menopausal patients were more likely than pre-menopausal to report excellent (versus sub-excellent) adherence at study end (OR 4.60, 95%CI 1.45 – 16.13, $p = 0.012$, adjusted for arm, age, and ECOG). Additional exploration of reasons for non-adherence will be presented. **Conclusions:** Adjuvant endocrine therapy adherence rates in both arms at 12 months after study entry collected via ePRO were good ($\geq 90\%$ reporting excellent or very good adherence). Additional factors potentially associated with non-adherence are being analyzed including self-care agency, symptom burden and quality of life. Clinical trial information: NCT05035173. Research Sponsor: Irish Cancer Society and Breakthrough Cancer Research.

Multi-cancer early detection (MCED) test performance in cancer survivors.

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Background: Cancer survivors (CS) are at risk for recurrent or new primary tumors in any organ, but there is lack of clear guidance and options for long-term surveillance. We analyzed the performance of a blood-based MCED test that detects cancer-specific methylation patterns and predicts cancer signal origin (CSO) in CS in the PATHFINDER study (PF; NCT04241796). **Methods:** PF enrolled 6662 participants (pts) ≥ 50 yr without clinical suspicion of cancer; 6578 samples were analyzed with a refined MCED test. Pts were stratified by CS status (treated cancer > 3 yr prior to study vs no prior cancer); in CS, prior cancer type and time from diagnosis were recorded. Cancers diagnosed during PF were classified as recurrent or new primaries. Positive predictive value (PPV), number needed to screen (NNTS), and CSO accuracy were assessed. **Results:** CS comprised 25% (1609/6578) of pts analyzed; 73% were female. Median age was 66 yr; age at prior diagnosis was 8% < 40 , 22% 40–49, 70% ≥ 50 yr. Most common prior cancers were breast (749, 47%), melanoma (163, 10%) and prostate (141, 9%). A higher proportion of pts with cancer diagnosis was observed in CS vs those with no prior cancer (Table). Among 20 CS with cancer signal detected, 10 cancers were diagnosed in 9 pts; 5 recurrent (all metastatic breast) and 5 new primaries (uterine stage 1 [found as incidental lesion on imaging during MCED-triggered workup for recurrent breast cancer], sarcoma stage 2, ovarian stage 3, lymphoma and CRC stage 4). During 1-yr follow-up in those with negative MCED result, new cancer diagnoses in CS included 13 recurrences (all local) and 15 new primaries. Of the 13 new primaries with known stage, 46% were stage 1 (2 breast, 1 melanoma, 1 thyroid, 1 lymphoma, 1 lung), 31% stage 2 (2 lymphomas, 1 melanoma, 1 breast), 15% stage 3 (1 pancreas, 1 pleural mesothelioma), and 7% stage 4 (1 prostate). Yield, PPV, NNTS, and CSO accuracy were similar in CS and no prior cancer group. Years between MCED cancer detection and prior cancer in CS was 4–11 for recurrent and 8–15 for new primaries. Most (4/5) new primaries were cancers with no USPSTF-recommended screenings. **Conclusions:** The MCED test detected both cancer recurrences and new primaries in CS for whom multiple years had elapsed since their original diagnosis, potentially expanding surveillance options for this patient group. Cancers in CS not detected by MCED were predominantly early stage. Test performance was similar in those with and without a cancer history. Clinical trial information: NCT04241796. Research Sponsor: None.

	Prior Cancer N = 1609	No Prior Cancer N = 4969	Total N = 6578
PF pts diagnosed with cancer, n (%)	37 (2.3)	83 (1.7)	120 (1.8)
MCED+, n (%)	20 (1.2)	38 (0.8)	58 (0.9)
NNTS, n (range)	179 (101, 406)	311 (207, 552)	263 (188, 411)
Yield Rate, % (95% CI)	0.56 (0.25, 0.99)	0.32 (0.18, 0.48)	0.38 (0.24, 0.53)
PPV, % (95% CI)	45.0 (25.8, 65.8)	42.1 (27.9, 57.8)	43.1 (31.2, 55.9)
Specificity, % (95% CI)	99.3 (98.7, 99.6)	99.5 (99.3, 99.7)	99.5 (99.3, 99.6)
CSO accuracy, % (95% CI)	88.9 (56.5, 99.4)	81.2 (57.0, 93.4)	84.0 (65.3, 93.6)

Evaluating the utility of routine survivorship exams in breast cancer: Modality of detection of recurrence in a prospective cohort study.

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Background: National Comprehensive Cancer Network surveillance guidelines for invasive breast cancer recommend a history and physical exam every 3–12 months for the first 5 years, followed by annually, and mammography every 12 months. However, frequent in-office visits create time toxicity for breast cancer survivors, may have low utility in recurrence detection, and can create false reassurance. This study evaluates the modality of breast cancer recurrence in an integrated health system with access to primary and specialty care. **Methods:** We investigated mode of detection of recurrent breast cancer in the Pathways Study, a prospective cohort study of adult women diagnosed with and treated for invasive breast cancer in Kaiser Permanente Northern California, with enrollment from 2006 to 2013, and follow-up through December 2021. In this analysis, we included 4,431 women diagnosed at Stages I–III. Cohort members were followed for recurrences, deaths, and other outcomes. Of primary interest was modality of detection of recurrence, categorized as patient-driven symptoms, surveillance mammogram, diagnostic testing (i.e., other surveillance imaging for recurrence such as PET CT or MRI), routine clinical breast exam, or incidental finding. **Results:** A total of 617 (13.9%) women were identified as having breast cancer recurrence. Patients with recurrence shared similar demographic characteristics to those without recurrence. The recurrence population had median age of 59.2 years, BMI of 28.2 kg/m², and racial/ethnic composition of 63% white, 13% Hispanic, 12% Asian, and 10% black. The median time from diagnosis to recurrence was 4 years. Seventy percent of recurrences were found to have distant metastatic disease, of which only 6.7% had concurrent local nodal and/or breast involvement. For those without metastases, 17.7% had recurrence localized in the ipsilateral breast, 2.8% in both the breast and locoregional nodes, and 9.3% only in locoregional nodes. Most recurrences were detected by patient driven symptoms (69.4%). Among the total cases, 8.1% of patients were diagnosed by routine mammogram, 10.9% with diagnostic testing and 4.5% by incidental finding. Recurrences in 6.8% of patients were detected by routine physician exam. Overall survival for those with recurrence was 31.1% and most deaths were attributed to breast cancer (89%). **Conclusions:** Our study, the largest investigation of breast cancer recurrence modality of detection in a US community oncology setting with comprehensive care, revealed the majority of recurrences were identified through patient self-detection with only 6.8% detected by physician exam. Most recurrences were distant, underscoring the need for alternative screening modalities to detect metastatic recurrences earlier, especially in the context of emerging treatments and improved survival rates for oligometastatic disease. Research Sponsor: None.

Facilitating adaptive coping with fear of recurrence among breast cancer survivors: Feasibility and acceptability outcomes from a three-arm randomized controlled trial.

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Background: Fear of cancer recurrence (FCR) is one of the most prevalent and disruptive problems for breast cancer survivors (BCS). Acceptance and commitment therapy (ACT) and cognitive behavioral therapy (CBT) have shown promising effects for FCR in a recent meta-analysis, yet head-to-head comparisons of these interventions are rare. We present feasibility and acceptability outcomes from a randomized controlled trial comparing ACT to CBT and enhanced usual care (EUC) for BCS with clinically significant FCR. **Methods:** Eligible women were ≥ 18 years old, diagnosed with stage I–IIIA breast cancer, within 5 years of completing cancer treatment (ongoing endocrine therapy was allowed), and reported clinical FCR at enrollment. Participants were randomly assigned to group-based ACT, CBT, or EUC, all delivered via videoconference. ACT and CBT consisted of 6 weekly 1.5-hour sessions; EUC was a single 1.5-hour survivorship coaching session. Outcomes included accrual, session attendance and engagement, intervention helpfulness, and retention. Variables were summarized by mean (SD) if numerical or relative frequency if categorical. At significance level $\alpha = 0.05$, the Kruskal–Wallis test was used to compare overall differences between the three groups, and two-sample T-tests with unequal variances were used for pairwise comparisons between the groups with Bonferroni multiple-comparison adjustment. **Results:** Of 446 BCS who screened eligible, 390 (87.4%) enrolled. Most participants were white (81.8%), not Hispanic (98.4%), partnered (68.4%), and college-educated (71.3%). Most were within 2 years of completing cancer treatment (55.7%), and mean age was 55.8 (SD = 12.0) years. Among those assigned to a 6-session intervention, participants attended a mean of 5.0 (ACT) and 5.2 (CBT) sessions; 96.1% of EUC participants attended the single session. Mean session engagement (rated per participant per session by interventionists on a 0–10 scale) was significantly different across the three groups ($p < .0001$), with mean (SD) of 9.3 (0.8) for ACT, 9.5 (1.0) for CBT, and 7.9 (1.3) for EUC. Pairwise comparisons showed higher engagement ratings in ACT ($p < .0001$) and CBT ($p < .0001$) over EUC, with no significant difference between ACT and CBT ($p = .14$). At post-intervention, participants rated mean (SD) helpfulness on a 0–10 scale as 7.2 (2.6) for ACT, 7.9 (2.0) for CBT, and 5.5 (2.7) for EUC. Overall, mean helpfulness was significantly different across the groups ($p < .0001$) and favored CBT over ACT ($p = .0109$) and EUC ($p < .001$) and favored ACT over EUC ($p < 0.001$). Outcome data retention was 93.8% through the 6-month follow-up. **Conclusions:** High accrual and attendance rates suggest that BCS are receptive to FCR interventions and may find ACT or CBT more engaging and helpful than a single session of survivorship coaching. Clinical trial information: NCT05364450. Research Sponsor: National Cancer Institute; 5R01CA255480; Walther Cancer Foundation.

The use of telehealth in a large community oncology practice prior to and during the COVID-19 pandemic.

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Background: The COVID-19 pandemic prompted implementation of telehealth services in oncology following CMS approval for reimbursement. Using data from a single large US-based community oncology practice, we characterized the adoption of telehealth, evaluated telehealth's impact on patient transit to the site of care, and the frequency of ER visits and hospitalizations. **Methods:** A retrospective cohort analysis was conducted using data from January 2019 through June 2022 from the FCS EMR database, IQSS's RefineIQ database, which captures and standardizes patient treatments for consistent analysis, InfoDive, a reimbursement platform with data on clinic visits, and Oncology Care Model data. The target population included all patients with cancer aged 18 or older under active management at FCS during the study window with at least 60 days of follow-up. Patient disease and demographic characteristics and ER/hospital care visits were compared between telehealth groups, as well as impact of telehealth use on transit time and distance traveled for patients was summarized using descriptive statistics. **Results:** 178,531 patients were analyzed. Median age was 68, with 64% female and 47% white. 97% of patients lived in a metropolitan area, 97% in Florida, and 77% in areas with less than \$78,000 median income. Median duration of disease was 41 months, 24% of patients were stage IV and 93% ECOG 0-1. 20% of patients used telehealth, with 81% having only one telehealth use per year. Patients using telehealth, compared to those that did not, were more likely to be white (50% vs 46%), have commercial insurance (30% vs 27%), live in areas where annual median income was > \$78,000 (25% vs 22%) and ≥95% of the population graduated high school (31% vs 26%). Telehealth saved a median of 5 miles driven per user annually. Users tended to have more advanced disease than non-users, with a higher proportion of metastatic disease (27% vs 23%), high CMS risk score (16% vs 15%), and line of therapy 2 or greater (10% vs 7%). Users had higher median annual oncology clinic visits both pre- (5 vs 3) and post-telehealth approval (6 vs 5). Hospital admissions after ER visits were more frequent among users both pre- (14% vs 13%) and post-telehealth approval (29% vs 25%). **Conclusions:** Telehealth was somewhat more likely to be used by patients with cancer in more affluent communities, white patients, patients who had more advanced disease and more frequent clinic and hospital visits. Most patients who used telehealth used it only once, and the low utilization of telehealth had limited impact on patient transit effort to the clinic. This study is limited by its concentration at a single large practice in Florida, the relatively low use of telehealth, retrospective design, and selection bias, as the telehealth population had more advanced disease and likely needed more frequent intervention. Research Sponsor: Seattle Genetics.

Patient satisfaction with cancer care delivery through telemedicine at a comprehensive cancer center across three years during and after the COVID-19 pandemic.

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Background: Telemedicine, once sparingly utilized, surged during the COVID-19 pandemic to enhance care accessibility and safety concerns. Despite initial satisfaction, its usage remains highly variable across institutions. We sought to explore patient satisfaction at a comprehensive cancer center, associations with demographic characteristics, and change over time. **Methods:** A survey was sent to all first-time telemedicine users at Memorial Sloan Kettering Cancer Center from September 2021 to October 2023. Adult patients who had their initial telemedicine visit, regardless of specialty, received the questionnaire. It comprised 10 general questions about the telemedicine experience and 11 questions regarding clinical trial education and informed consent. To analyze the unstructured free text responses, we employed *BERTopic*, a topic modeling algorithm that leverages transformer-based embeddings to facilitate the creation of easily interpretable topics within a collection of text documents. Through topic modeling with *BERT* embeddings, we captured subtle nuances and semantic relationships in language to identify topics more effectively. **Results:** A total of 15,111 patients completed 15,251 questionnaires; 140 patients completing two surveys. Patient demographics are summarized in Table 1; the median age at encounter was 66 years and 98% of patients preferred English. Satisfaction levels were high, with 92% expressing willingness for future telemedicine visits and 90% recommending it to other patients. Notably, 21% found telemedicine superior to in-person visits, while 53% considered them equal. Further, satisfaction remained consistent across six-month intervals from 2021-2023. In 1606 (11%) surveys, patients noted discussing clinical trials; 17% preferred in-person discussions for the informed consent process while most either preferred telemedicine or had no preference. Topic modeling revealed 18 topics within the unstructured dataset; key topics included comments on video & audio quality, connectivity and technology issues, convenience for patients who live outside of the city and those with physical limitations, and long wait time to see a doctor. **Conclusions:** Our analysis confirms high patient satisfaction with telemedicine, including discussions on clinical trial enrollment, that has remained consistent in the years following the COVID-19 pandemic. Given variability in use, it is important to identify how to better deliver telemedicine to those patients who prefer it. Research Sponsor: National Institutes of Health and National Cancer Institute Cancer Center Support Grant P30 CA008748; National Cancer Institute MATCHES P50 CA271357; National Cancer Institute T32 CA275764.

Patient characteristics.

Characteristic	N = 15,111
Age – median (IQR)	66 (57,73)
Female Sex, N (%)	7,953 (53%)
Race, N (%)	
White	12,705 (87%)
Black	656 (4.5%)
Asian	879 (6.0%)
Ethnicity, N (%)	
Hispanic or Latino	744 (5.2%)
Not Hispanic or Latino	13,510 (95%)
Preferred Language, N (%)	
English	14,796 (98%)
Other	315 (2.1%)

Quality of telehealth-provided cancer care in VA.

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Background: As the largest integrated health care system in the United States, the Veterans Health Administration (VA) has extensive experience in utilizing telehealth-(TH) to deliver care to the 10 million enrolled Veterans, including the~50,000 patients newly diagnosed with cancer annually and ~500,000 cancer survivors. The VA National TeleOncology (NTO) service was established in 2020 to provide specialized treatment regardless of geographical location. We sought to compare quality in TH-delivered care compared to traditional (TR) in-person VA care. **Methods:** Using the VA EHR, we identified patients who had an ICD-10 diagnostic code for an incident malignancy from Dec 2016 to March 2021 at three medical centers providing both TR and TH care. We used EHR review to classify patients as TH users, if they received TH services at least once for their cancer care, or TR care if no telehealth was used. Using both structured EHR data and manual review by two trained abstractors, we gathered demographic, clinical, and treatment characteristics to calculate 25 Quality Oncology Practice Initiative (QOPI) measures in the domains of symptoms and toxicity management (2), end of life and palliative care (10), and core measures (13). We report QOPI measures descriptively; and used chi-squared tests with $\alpha = 0.05$ to compare TH and TR. **Results:** We identified 972 patients with lymphoma, prostate, lung or colorectal cancer. 427 (44%) were TH users and 545 (56%) were TR, and they were predominately white (n=819, 84.3%) men (n=930, 95.7%). TH users had better (n=13), worse (n=9), same (n=2) and unevaluable (n=1) descriptive performance on measures. For example, TH and TR were similar in administration of appropriate antiemetic therapy for high and moderate-risk antineoplastic agents (44.8% vs 42.4%). TH performed better than TR for chemotherapy summary being completed within three months of chemotherapy ending (83.4% vs 75.6%) and for emotional well-being being assessed by the second office visit (92.3% vs 89.9%). Appropriate tobacco use cessation administration within the previous year was statistically higher in TH (85.3% vs 76.2% $p=0.0021$). No differences were statistically significant for any other QOPI measures. **Conclusions:** VA is a leader in TH cancer care because of both its volume and quality. VA-provided TH cancer care quality is similar to or better than that of TR in-person care. NTO specifically, and VA teleoncology broadly, provides another option to Veterans for cancer care. Research Sponsor: VA National Medical Oncology Program.

Mobile health–supported comprehensive intervention model (CIMmH) improved physical fitness of patients with esophageal cancer after esophagectomy: Prospective randomized controlled trial.

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Background: Esophageal cancer (EC) significantly impacts patients' quality of life (QOL) post-esophagectomy, with malnutrition, reduced physical activity, and psychological distress being common. Our preliminary study indicated that a Mobile Health-Supported Comprehensive Intervention Model (CIMmH) is safe, feasible, and efficacious in improving QOL and physical fitness for EC patients. This randomized controlled trial (RCT) evaluates the effectiveness of CIMmH in promoting post-surgery recovery for EC patients. **Methods:** EC patients undergoing modified McKeown esophagectomy were randomly allocated to either the intervention group, receiving the CIMmH protocol (nutrition, exercise, psychological support), or the control group, receiving standard postoperative care. Outcomes were assessed at baseline, 1 month, and 3 months post-surgery. Key metrics included sarcopenia (assessed via skeletal muscle index and psoas muscle thickness on CT scans), quality of survival (EORTC-QLQ-C30 and EORTC-QLQ-QES-18), physical fitness (six-minute walk distance, SMWD), and nutritional status (body weight). **Results:** Of 111 screened patients, 80 were enrolled (40 per group). Follow-up assessments were completed by 76 patients at 1 month and 69 at 3 months. At 1 month, the intervention group showed a significant improvement in SMWD compared to the control group ($P=0.020$), though no difference was observed at 3 months ($P=0.835$). The intervention group also demonstrated a significant increase in the skeletal muscle index at 3 months ($P=0.039$), alongside notable improvements in the 30-second arm curl test and cough symptom relief ($P=0.027$ and $P=0.045$, respectively). No significant differences in QOL scores or body weight were observed between groups at any time point. **Conclusions:** CIMmH significantly enhances short-term physical fitness in EC patients post-esophagectomy. These findings suggest the need for further refinement and optimization of the intervention to maximize its long-term effectiveness and impact on QOL. Clinical trial information: ChiCTR2000041007. Research Sponsor: Ethicon Excellence in Surgery Grant.

Telehealth consultations and recruitment trends in clinical trials: A retrospective analysis at investigational cancer therapeutics, a dedicated phase I department at The University of Texas MD Anderson Cancer Center.

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Background: Recruitment to phase I/II clinical trials have been reported to vary between 30% and 55% across centers, primarily relying on in-person visits. However, with the onset of the COVID-19 pandemic, there has been a noticeable surge in telehealth consultations. Consequently, there is currently a dearth of data available regarding this approach within the context of early phase-clinical trials. **Methods:** Data on patient's first visits to the Investigational Cancer Therapeutics (ICT), a dedicated Phase I department at The University of Texas MD Anderson Cancer Center (MDACC), were retrieved from the institution's electronic platform. The ICT department offers phase I-II clinical trials for patients with advanced cancer. We included first visits between January 2020 and December 2023. Initial telehealth visits were conducted via video or telephone, with patients from either Texas or other states in the United States. Visits were classified into two groups: internal referrals, originating from other departments within MDACC, and new patient visits, including patients who had not been seen at MDACC prior to the ICT visit. Recruitment was defined as the percentage of patients who consented to participate in a clinical trial. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS). **Results:** A total of 6,965 patients had a first visit in the Investigational Cancer Therapeutics Department between January 2020 and December 2023. Of these, 4,321 patients (62%) had their initial in-person visit, while 2,644 patients (38%) opted for telehealth consultations. Internal referrals accounted for 6,304 patients (90.5%), while new patient visits comprised 661 patients (9.5%). Among the entire cohort, recruitment rate for phase I-II clinical trials was 53.2% (n= 3,702). Patients with initial telehealth consultations had a recruitment rate of 55.1%, compared to 52.0% among those with in-person consultations ($\chi^2=6.538$, $p<0.011$). Recruitment was higher among internal referrals at 53.7% compared to 47.5% for external referrals ($\chi^2= 9.355$, $p=0.002$). Notably, recruitment was statistically higher in internal consults that underwent telehealth versus in-person visits (55.4% versus 52.6%, $p=0.027$), while there were no statistical differences in new patient visits (47.4% vs. 47.8%, $p=0.939$). **Conclusions:** Telemedicine consultations emerge as a valuable alternative for evaluating and discussing treatment options for patients with advanced solid tumors, thereby enhancing accessibility to early-phase clinical trials. The flexibility of conducting initial visits remotely may mitigate geographical and logistical challenges and allow for a more inclusive and diverse participant pool, fostering broader representation in clinical trial research. Research Sponsor: None.

Chemotherapy Care Companion: Enhancing cancer care through digital remote monitoring.

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Background: Oncology patients often encounter preventable acute issues prompting the need for proactive monitoring and management. To manage disease and therapy complications, Ochsner Health developed Chemotherapy Care Companion (CCC) for remote monitoring of treatment patients. This abstract highlights the feasibility of digital remote monitoring (DRM) in managing oncologic patient care, while increasing patient satisfaction and reducing patient events and healthcare costs. **Methods:** Starting in January 2021, patients initiating an oral or intravenous cancer treatment with an active Ochsner portal account and smartphone became eligible. Providers can manually enroll patients via an order set and receive enrollment reminders within the Epic electronic medical record (EMR). Patients receive a digital WiFi-enabled monitoring scale, blood pressure cuff, and ear thermometer, at no cost. Patients are reminded via phone alerts to take vitals at 9am and 3pm, along with a daily questionnaire. The data is transmitted wirelessly to the EMR, where abnormal vital signs or questionnaire responses trigger escalations sent to an Epic in-basket pool. During clinic hours, advanced practice providers (APPs) review and intervene, utilizing embedded urgent care slots for same-day access. In August 2022, a patient satisfaction survey comprising of nine questions was distributed to all enrolled patients. **Results:** A retrospective analysis was conducted from September 2022 to August 2023 including 722 participants, 7,360 escalations and 668 interventions. Patient compliance reached 62%, defined as submitting at least 50% of daily vitals. The most common interventions were related to hypertension, hypotension, weight changes, and questionnaire responses. Regarding questionnaire responses, diarrhea, pain, fever, and dizziness were the mostly frequently triaged. Data analytics revealed that CCC led to a 5.9% decrease in emergency room visits, a 41.7% decrease in the rate of inpatient hospital admissions, and a 32.3% improvement in the inpatient length of stay compared to non-enrolled patients. Extrapolating this data across 5,500 oncology patients within our hospital system, CCC could prevent 172 ER visits, 914 inpatient hospital admissions and 2,006 hospital days. The survey (131 responses) revealed high satisfaction with CCC: over 80% felt a sense of security, 90% were overall satisfied, and more than 90% would recommend CCC. **Conclusions:** Findings highlight the value of integrating DRM in cancer care, showcasing its ability to reduce healthcare costs and optimize resource utilization while enhancing patient care and satisfaction. Moreover, the study underscores the high patient satisfaction and engagement with DRM, bolstering its feasibility and acceptance in oncology care. Further investigation is warranted to explore the financial benefits for hospitals, insurance companies, and pharmaceutical companies. Research Sponsor: Ochsner Health.

Patient-reported experience with an immunotherapy telehealth platform.

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Background: The Making Telehealth Delivery of Cancer Care at Home Effective and Safe for Immunotherapy (MATCHES-IO) intervention seeks to improve the efficiency and patient experience for those treated with single agent pembrolizumab. Because pembrolizumab is administered as an outpatient infusion every 3-weeks, patients require up to 18 clinic visits per year to receive treatment, which is arduous. During the COVID-19 pandemic, the FDA granted accelerated approval for an extended interval dosing administered every 6 weeks, but despite this approval every 3-week dosing remains the standard (65% of prescriptions) as clinicians perceive this schedule enables them to identify and manage toxicity early. Telehealth may be the impetus to change the standard to the more convenient 6-week in person schedule, but evidence is needed. **Methods:** We conducted a single arm pragmatic trial to evaluate the efficiency and patient experience of a telehealth immunotherapy platform (MATCHES-IO) in patients with non-small cell lung, genitourinary, or melanoma cancers receiving single agent pembrolizumab. MATCHES-IO evaluates whether in-person visits for pembrolizumab therapy q6wk (rather than q3wk), with interim telehealth toxicity checks between in-person treatments, is more efficient and enhances patient experience relative to the standard q3wk infusion visits. The components of the platform include clinician-patient virtual visits, labs at home, biometric devices at home for vital sign monitoring, and electronic patient-reported outcomes to monitor for common IO-related toxicities. Patient experience was assessed after each MATCHES-IO televisit for up to two televisits. We measured experience with a patient experience survey that included the net promoter score, of how likely are they to recommend this intervention to similar patients (scale 0-10, higher score is desirable). A score of 9 or greater is considered excellent. **Results:** Between July 2023 and February 2024, 27 patients were enrolled, median age 68 (range 45-85), 74% white, 11% black, 11% Asian, and 41% female. Cancer types included thoracic (59% of patients), genitourinary (33%), and melanoma (7%). 19 patients (70.4%) have completed a MATCHES-IO televisit and completed the patient experience survey. The median net promoter score was 9 (range 2-10). 94% patients perceived a benefit to the MATCH-IO televisit including saved time (83% of respondents), patient convenience (83%), convenience for caregiver/family (44%), saved money (44%), and better monitoring of cancer and treatment (39%). 78% of patients found the at home visit less stressful than the in-person visit. **Conclusions:** Patients endorsed an enhanced experience with an immunotherapy telehealth platform for extended dosing of pembrolizumab. Further follow-up is needed to confirm these experience findings and determine whether this platform improved efficiency through fewer in-person visits. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health.

Establishing a protocol to increase racial/ethnic minority enrollment on an active radiation oncology randomized clinical trial.

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Background: In the United States (US), underrepresented racial/ethnic groups lack ample enrollment in clinical trials, yielding ungeneralizable trial results. Barriers to increasing minority enrollment include decreased awareness of clinical trials, lack of access, financial burden and toxicity, medical system mistrust, and discordant physician-patient demographics. The ongoing Spine Patient Optimal Radiosurgery Treatment for Symptomatic Metastatic Neoplasms (SPORTSMEN) clinical trial (NCT05617716) has a study design to actively accrue minority patients. We present our protocol addressing key targets to increase minority enrollment on this randomized, phase II clinical trial. **Methods:** Adults with evidence of symptomatic spine metastases are eligible. Baseline demographics (including race/ethnicity) are reported for statistical analysis. Our protocol seeks to minimize barriers to minority enrollment and targets four key areas. Access to care: SPORTSMEN involves institutions located in zip codes with diverse ethnic populations, presently located in regions 46% and 70% African American. Clinical trial design: SPORTSMEN has a prespecified goal of accruing patients to mirror US census representation. The rate of minority enrollment will be reviewed periodically at the discretion of the Data Safety and Monitoring Board. Community outreach and engagement: The trial team will engage with local health care systems to create an alliance within different oncology specialties to provide the basis and benefit for SPORTSMEN and patient-centered education on eligibility criteria, rationale, and intended outcomes. Our principal focus will be providers in prostate, breast, and lung cancers as minorities with these primary site malignancies have a higher propensity to be trial-eligible. Furthermore, we understand the historical mistrust of minorities for the medical community. Therefore, we will engage local grassroots organizations such as churches, community outreach centers, and social clubs to increase awareness of clinical trials and to help foster trust. Financial burden and toxicity: SPORTSMEN does not have direct enrollment costs. A short-course treatment regimen is used to minimize the number of treatment visits required allowing for decreased resources for travel, time lost at work, and additional childcare or eldercare needs. Financial toxicity will be objectively quantified using the validated COST-Functional Assessment of Chronic Illness Therapy survey. Increasing clinical trial diversity is a challenge that must be addressed with meaningful intent to present robust Level 1 data that broadens the understanding of treatment response in all demographics. Our protocol takes a patient-centered approach to achieve the objective of concordant racial/ethnic representation in a randomized clinical trial. Clinical trial information: NCT05617716. Research Sponsor: Bristol Myers Squibb Foundation.

Breaking barriers for cancer clinical trials: A multi-tiered interventional approach to boost racial and ethnic minority participation in early-phase studies.

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Background: Racial and ethnic minority populations are underrepresented in cancer clinical trials. The USC Norris Comprehensive Cancer Center (USC NCCC) has multiple clinical trial recruitment sites, including the Los Angeles General Medical Center (LAG), the largest safety-net hospital in the western USA. LAG partners with USC to provide cancer care to the underserved minority population of LAC, including clinical trials. As a result, between 2015–2022 a total of 120 LAG patients were accrued to phase I clinical trials; enrolled subjects were 66% Hispanic, 21% Asian, 4% Black, and 9% other. An interventional study was designed to further enhance the referral and participation of racial and ethnic minority patients from other Los Angeles County (LAC) safety-net facilities. The study is funded by the Stand up to Cancer Diversity in Early Development Clinical Trials Research Grants Program. **Methods:** This interventional study has 3 specific aims. First, to identify barriers to referral for minority and underserved patients: Qualitative interviews will be conducted with key stakeholders in the LAC safety net system which will uncover barriers to referring minority and underserved patients. A screening tool developed by the NCI to characterize barriers will be used. Second, to implement a multi-component program to enhance the referral of patients to early-phase clinical trials. The intervention addresses system-level, provider-level, and patient-level factors to improve the process, with a demonstration site compared to a non-demonstration site. Key features include a streamlined referral process for healthcare professionals with a singular centrally operated email managed by a specialized facilitator, weekly meetings to assign trials to prospective patients, and facilitation of approval and scheduling for referrals. We will educate providers regarding trials and exchange feedback on the referral process. We will extend resources to patients to assist with financial and transportation limitations. We will compare change in referral and enrollment rates at baseline and after the intervention for both the demonstration site and non-demonstration site. Third, to explore the impact of remotely conducted clinical trials: A clinical trial (NCT05340309) administers study drug subcutaneously and uses telemedicine visits, wearable sensors, and a smartphone app for monitoring. This pilot trial will be analyzed to determine the model's impact on barriers to enrollment. The above interventions may provide a model that can be adapted in other healthcare delivery settings to optimize referral and enrollment of racial and ethnic minorities. Research Sponsor: Stand Up 2 Cancer.

A new model to enhance enrollment of diverse participants to therapeutic clinical trials.

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Background: Disparities in United States clinical trial participation are well described, with the inclusion of only 8% Black, 6% Asian, and 1% Hispanic participants in phase III oncology trials supporting US FDA filings in 2020. The FDA, Cancer Moonshot, and ASCO-ACCC have issued guidance, sponsored initiatives, and developed strategies to raise awareness around the importance of equality, diversity, and inclusion at centers with current clinical research capabilities. Centers with ongoing research capability are typically large academic or private practice sites located in urban areas. There is an urgent need to expand clinical trial offerings to rural communities as geographic constraints disproportionately limit people of color and people of low socioeconomic status from accessing innovative drugs offered only through clinical trials. An additional contributing factor to low enrollment of diverse participants is a lack of racial, ethnic, gender, and geographic diversity amongst clinical trial investigators, who may be more relatable and, thus, effective at recruiting underrepresented patients to clinical trials. Lastly, to provide high quality care for their patients, clinical investigators must have ability to identify and select trials which address the specific needs of the patients within their practice. We hypothesize that a tool which improves identification and inclusion of an expanded investigator pool will result in improved diversity of clinical trial participation. **Methods:** We have developed a bi-directional matching software program that allows healthcare providers to define their areas of interest and match them to available pharmaceutical company clinical trial opportunities. The software, Golgi-CONNECT, will be piloted with up to 500 oncology-focused healthcare providers across a diverse geographic landscape and up to 6 pharmaceutical companies of varying sizes to evaluate the functionality and usability of the application. Additionally, HCP-reported barriers to clinical trial conduct, inclusive of financial, infrastructure, training, mentoring and lack of support staff will be collected. Research Sponsor: Golgi, Inc

Developing behavioral intervention to support molecular testing of patients with biliary tract cancer.

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Background: Biliary tract cancer (BTC) represents 7% of gastrointestinal malignancies in the United States, with an incidence of 0.5 to 2.0 cases per 100,000 individuals. Standard care involves systemic chemotherapy, predominantly gemcitabine and cisplatin. Recent advancements in immunotherapy, as evidenced by the TOPAZ-1 trial and KN966, support the use of durvalumab, and pembrolizumab as treatment options. Genetic tumor testing identifies up to 40% of BTC patients with targetable mutations, leading to recent FDA approvals for FGFR2 inhibitors – pemigatinib, infigratinib, futibatinib, and IDH1 inhibitor ivosidenib. The emerging data on inhibitors targeting the BRAF mutation, together with HER2 amplification, underscore the importance of understanding the tumor's molecular profile. Navigating this evolving treatment landscape emphasizes an unmet need for patients to comprehend the pivotal significance of tumor molecular profiling in formulating effective and personalized treatment plans. Identifying knowledge gaps among BTC patients concerning tumor genetic testing and precision medicine, along with strategies to address these gaps, holds promise for improving the management and the outcome of patients with BTC. **Methods:** This is a behavioral intervention study where participants will undergo two in-person survey interviews before and after an educational intervention. The initial survey aims to establish baseline knowledge about the BTC diagnosis and treatment and ascertain preferences for various educational interventions. Patients' knowledge gap will be determined by comparing their responses to the initial survey and medical history documented by their treating physicians. They will then be provided with a 10-minute educational video. Participants will have the flexibility to access the video multiple times. Within 6 weeks from enrollment, they will have a post-education survey to determine the effectiveness of the education intervention. Following completion of baseline surveys, collaboration with key stakeholders including medical oncology and community perspectives will be initiated to identify knowledge gaps and inform the design of an educational intervention. The study enrollment will be targeted at BTC patients receiving systemic therapy at Georgetown University Hospital, Fox Chase Cancer Center, and Hackensack Meridian Health. Ten participants are enrolled and have completed the first survey and intervention. This study is currently enrolling participants: GUIRB: STUDY00007119. Research Sponsor: The Ruesch Center for the Cure of Gastrointestinal Cancers.

A phase IV study of ApricityCARE program for cancer adverse events rapid evaluation to improve treatment outcomes of ethnic/racial minority patients with non-small cell lung cancer (NSCLC) receiving immune checkpoint inhibitors (ICI).

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Background: ICI have changed the treatment landscape of NSCLC, with many now FDA approved in not just advanced, but even early-stage disease. With the increase in ICI use, the incidence of immune-related adverse effects (irAEs) has also risen, occurring in up to 16% of ICI-treated patients. Prompt recognition and timely management are necessary to avert potential poor outcomes from direct toxicity and/or early treatment discontinuation. However, existing barriers to access care that disproportionately impact racial and ethnic minority patients may amplify challenges in early, effective management of irAEs. Using technology-enabled health interventions in a culturally competent manner can improve access to health care resources and reduce health disparities. These platforms need to be optimized at the technology and health literacy level of underserved minority communities and adapted to meet the community's needs. **Methods:** We have designed a multi-center phase IV clinical trial to 1) assess factors related to suboptimal and optimal use of the ApricityCARE, a virtual first-response clinical support (or coverage) to provide 24/7 symptom monitoring and side effect management and 2) determine the impact of the program on ICI toxicity management for NSCLC patients receiving ICIs in a highly diverse community. Eligible patients are those with a confirmed diagnosis of NSCLC who self-identify as a member of an ethnic minority or underserved population, prescribed for any treatment regimen that includes an ICI. The study entails a 50-patient run-in phase with two focus group discussions, stratified on a Likert-type scale based on the frequency of utilization, to determine factors impacting usability of the ApricityCare program. This data will inform optimal implementation of ApricityCare for the randomized phase of the study, where 230 patients will be assigned 1:1 to use of ApricityCare versus standard of care. The run-in phase of the study is currently accruing at Columbia University, and is planned to open at NYU, Mount Sinai, and Montefiore (NCT05812274). Clinical trial information: NCT05812274. Research Sponsor: Stand Up to Cancer.

GUIAR: Promoting lung cancer screening in Hispanic head and neck cancer survivors.

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Background: Hispanics are the leading racial/ethnic group in Miami Dade. Miami has the highest number of Hispanics diagnosed with lung cancer (LC) in the U.S. Hispanics have worse LC mortality than Non-Hispanic Whites, partly due to lower rates of LC screening (LCS) and exclusionary eligibility leading to advanced LC diagnoses. Even with more liberalized criteria, the rates of LCS uptake in eligible participants was 5.8% in 2022. This number is expected to be even lower for Hispanics, though quantifiable data to assess the trends in this population does not exist. Besides tobacco use, a previous cancer poses a risk for LC. The incidence of LC in head and neck cancer (HNC) survivors is almost double than the average population. However, no prospective studies have been conducted in this space. In this clinical trial, we aim to create the first LCS program tailored to Hispanic HNC survivors. **Methods:** Our study received IRB approval by University of Miami (UM) [NCT06124508]. We will pre-screen all subjects with HNC treated from 2012-2017 to determine their eligibility. We will enroll 125 participants who will complete a survey to assess awareness and disposition to LCS. All will be referred to UM's LCS program. A total of 62 Participants will undergo 1:1 randomization to a tailored educational intervention vs standard of care. The intervention consists of annual 60-minute visits with a nurse navigator with tailored education in the participant's native language about LC risk factors, LCS eligibility, and LCS process. Subjects in the intervention arm will also complete a semi-structured interview to explore cultural beliefs and barriers to LCS. For Hispanic HNC survivors, our primary aim is to assess awareness and disposition to LCS. Secondary aims include: To learn barriers to LCS; To create and test a tailored a LCS program; and to compare the rates of LCS uptake between arms at baseline and year 1. Data analysis for the baseline survey: Descriptive statistics will be used to summarize the demographic, clinical characteristics, and responses. The outcomes of interest are the proportion of patients who are aware of LCS recommendations and willing to pursue LCS and identifying demographic and clinical characteristics that are related to awareness of the recommendations. Data analysis for the qualitative interview: We will use a modified form of grounded theory^{4,6} to analyze the interview transcripts. Qualitative data will be analyzed using a constant comparative method to develop themes from the data by coding and analyzing at the same time using NVivo10 Software. Data analysis for the randomized study: All randomized patients who complete the Year1 survey will be included in the analysis. We will compare the uptake rates of LCS between baseline and year-1 in each arm using McNemar's test. Fisher's exact test will be used for comparing the rates between the arms. The same analyses will be performed for the awareness rate. Clinical trial information: 20220746. Research Sponsor: LUNgevity; U.S. National Institutes of Health; University of Miami.

Serial testing to assess cognitive function in patients with cancer being treated with immunotherapy.

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Background: The advent of immunotherapy (IT) has revolutionized lung cancer treatment, becoming a primary modality from Stages Ib to IV. While the short-term side effects of IT are well documented, its long-term impact on cognitive function are under explored. This is a crucial area of investigation given the significant impact of cognitive health on the quality of life in cancer survivors. Preclinical investigations suggest neurocognitive alterations in IT-treated patients, evidenced by increased microglial activation and cytokine release, contributing to observed cognitive deficits such as impaired cued fear memory and object recognition. This study leverages the Montreal Cognitive Assessment (MoCA) to investigate these potential cognitive changes in a clinical setting, aiming to provide crucial insights into the long-term effects of IT. **Methods:** This single-center, open-label pilot study enrolls patients with various cancer types and stages undergoing IT. Exclusion criteria include prior history of underlying cognitive dysfunction, dementia, depression or psychiatric illness, history of brain metastasis or radiation. The study comprises three cohorts: those receiving IT alone, those undergoing chemo-immunotherapy, and a control group with no active treatment (in remission with prior history of cancer and have received IT in the past). Each of the IT and chemo-immunotherapy groups will include 72 patients, while the control group will consist of 40 participants. Baseline cognitive function is assessed using the MoCA scale, with follow-up assessments at 3 and 6 months from baseline. Patient enrollment commenced in April 2022, with 4 patients enrolled in the IT group, 16 in the chemo-IT group, and 32 in the control group. The primary objective is to assess the Cognitive function change in each individual group of patients. The secondary objective is to assess change of MoCA scores after 3 months and 6 months in patients receiving immunotherapy alone in lung cancer patients. The changes in MoCA scores will be plotted and summarized with mean change, standard deviation of change and standard errors of mean change. MoCA scores at baseline and at 6 months will be compared using paired t-tests. The study will analyze the rate of change in MoCA scores over time, comparing outcomes across the treatment cohorts. Clinical trial information: NCT06160700. Research Sponsor: None.

A phase II randomized double-blind placebo-controlled study of fisetin to improve physical function in frail older breast cancer survivors (TROFFi).

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Background: Among postmenopausal breast cancer survivors treated with chemotherapy, one-third experience a persistent decline in physical function even 12 months after completing treatment. This decline has been associated with loss of independence, disability, and death. One mechanism that is thought to drive chemotherapy-related decline in physical function is cellular senescence, a state of terminal growth arrest. Chemotherapy increases the burden of senescent cells (SnCs), which develop a senescence-associated secretory phenotype (SASP) that over time leads to functional decline. Preclinical mouse studies have demonstrated that eliminating chemotherapy-induced SnCs in mice led to reductions in SASP and improved physical activity. In patients with stage I-III breast cancer treated with chemotherapy, expression of p16^{INK4a} (p16), a known Snc marker, rapidly increased after chemotherapy and persisted over time. Higher levels of pretreatment p16 have also been associated with increased frailty in older breast cancer survivors. Novel senolytic agents have been developed to eliminate SnCs. Among existing senolytics, fisetin is a natural dietary supplement with a favorable safety profile and preclinical efficacy to reduce Snc burden and alleviate frailty in mice. There are multiple ongoing studies of this plant flavonoid in humans, but few are studying the effects of fisetin on chemotherapy-related functional decline in breast cancer survivors. Therefore, we hypothesize that targeting SnCs with fisetin after chemotherapy will improve physical function in frail older breast cancer survivors by reducing systemic Snc burden. **Methods:** This phase II randomized, placebo-controlled study will enroll 88 postmenopausal women with stage I-III breast cancer who experience physical functional decline after completing neo/adjuvant chemotherapy. Key eligibility criteria include being postmenopausal and within 12 months of completing neo/adjuvant chemotherapy at the time of enrollment. All participants must have evidence of physical functional decline, as measured by a 6-minute walk distance (6MWD) <400 meters, prior to enrollment. Participants will be randomized 1:1 to either placebo or oral fisetin (20mg/kg) on days 1-3 of 14-day cycles for a total of 4 cycles. The primary objective is to determine the effect of fisetin on physical function, as assessed by the change in 6MWD from baseline to end of treatment. Secondary objectives include studying the effect of fisetin on quality of life and additional measures of function including fatigue, cognition, and neuropathy. We will also determine the effect of fisetin on biomarkers of aging, including circulating markers of senescence, as well as the safety of and adherence to fisetin. Enrollment on this study began March 2023 and is currently ongoing. Clinical trial information: NCT05595499. Research Sponsor: Conquer Cancer, the ASCO Foundation; 2023YIA-3100001264; National Institute of Aging; AG074918; National Cancer Institute; CA277660.

Linking in with advice and supports for men impacted by metastatic cancer: The LIAM Mc trial (NCT05946993).

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Background: Multidisciplinary supportive care interventions are key to preventing and managing adverse effects of cancer and its treatment for patients, reducing symptom and psychological burdens and enhancing quality of life (QoL). However, the optimal composition of these interventions for men with genitourinary (GU) cancers is poorly understood. The LIAM Mc Trial is an enhanced supportive care programme, funded by the Irish Cancer Society and designed with the input of patient representatives who highlighted the unmet needs of cancer survivors. An important aspect of the trial is to demonstrate how to improve the survivorship supports and services for underserved communities of men who experience disparities in cancer incidence, prognosis, outcome and QoL, and have not traditionally been the focus of such initiatives. **Methods:** Using an embedded mixed-method process evaluation this prospective trial aims to assess the feasibility and impact of a holistic 12-week survivorship programme amongst men with advanced GU cancers at an Irish Cancer Centre. The programme involves twice-weekly sessions with input from a dedicated physiotherapist, dietitian, and nurse specialist, along with education sessions from medical social worker and psycho-oncology specialists, and programme oversight provided by medical oncologists. Outcomes are measured at three timepoints; pre-intervention, immediately post-intervention and at 6 months post intervention, and will include EORTC QoL; muscle strength; body composition through bio-electrical impedance analysis and ultrasound; diet quality; cancer related symptom control; cancer related fatigue scores; feasibility outcomes, qualitative interviews and a process evaluation. Any man with a locally advanced or metastatic GU cancer who has recently completed a course of treatment or is stable on active anti-cancer treatment is eligible for the programme. Over the two-year study period the sample size target is 72 participants. The primary endpoint of the study is to evaluate the feasibility of introducing an enhanced supportive care programme as part of routine management for male cancer patients with metastatic disease. Acceptability, satisfaction with the programme and QoL changes are key secondary endpoints. Barriers to participation are also a key outcome under investigation. The study was activated in May 2023 with the first participants enrolled in June 2023. To date 17 men have enrolled with accrual completion anticipated in June 2025. Clinical trial information: NCT05946993. Research Sponsor: Irish Cancer Society; MHI22BAM.

Neuro-oncology anywhere: A decentralized approach to clinical trials in brain tumors and beyond.

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Background: The majority of patients with primary and secondary central nervous system (CNS) malignancy develop cognitive impairment, fatigue, and mood-related symptoms. Radiotherapy has been shown to contribute to symptom burden often limiting quality of life and functional status. The development of interventions mitigating neurocognitive toxicity requires an accurate assessment of function and symptom burden. Formal neuropsychological evaluation is resource and time intensive, and often challenging to incorporate in routine clinical practice. There is a critical need to accurately assess cognition without causing undue burden to cancer patients while evaluating the efficacy of interventions that can be scaled and implemented at a population level. **Methods:** To adequately assess the neurocognitive function and related symptoms in patients with CNS malignancy we have designed an open-label decentralized clinical trial that will randomize patients who received intracranial radiation for primary or metastatic brain tumors in a 1:1 allocation to a therapy targeting radiation-related toxicity (metformin shipped to patient home) plus health promotion with a wearable device vs. health promotion with a wearable device alone. Participants will be stratified based on tumor type (glioblastoma vs. other glioma vs. brain metastases vs. meningioma) and age (<70 vs. 70+ years). Participants will be provided a wearable device for monitoring health status. Participants will undergo serial remote cognitive assessments with the Mayo Test Development Through Rapid Iteration, Validation and Expansion platform (Mayo Test Drive). Remote reported symptom collection via patient surveys and remote neurologic examination by telehealth will also be incorporated. Cognitive assessments and symptom surveys will be designed for completion on a smartphone, tablet, or computer device. Health data will be collected from the wearable device, including the number of steps per day and sleep quality/duration. Participants receiving metformin will utilize device apps to report medication adherence and adverse events. Study-related laboratory assessments will be completed remotely and transmitted electronically. This decentralized clinical trial will provide real-world cognitive and quality-of-life data for patients with primary and metastatic brain tumors while providing preliminary data on the effectiveness of device-based health promotion with or without metformin for treating radiation-related cognitive decline. Results gained from this study will guide future trials in neuro-oncology and other fields. This study is expected to open in March 2024. Research Sponsor: Mayo Clinic; National Center for Advancing Translational Sciences (NCATS); UL1 TR002377.